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Imaging materials — Digital hard copy for medical imaging — Methods of measuring permanence

Matériaux pour l'image — Photocopie numérique pour imagerie médicale — Méthodes de mesure de la permanence

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 42, *Photography*.

Introduction

This International Standard prepared by ISO TC 42, WG 5 provides information for measuring the image stability and other relevant properties of medical dry hard copy films with greyscale images made with photothermographic, thermographic, and microcapsule type materials or with inkjet printing. Medical colour images and prints on reflective material for referral purposes are not covered.

Medical dry hard copy films are employed widely for digitally recording medical images in general radiography and mammography, because of the systems' simplicity, flexibility, ease of use, and attendant environmental advantages. First realizations of medical dry hardcopy systems entered the market together with CR and DR modalities in the 1990s, starting with photothermographic, thermographic, and microcapsule type materials. Recently, also inkjet based systems were also available. Dry hard copy systems gained through its one-step dry processing method which obviates the need for film processing equipment and liquid processing solutions and provides a significant saving in capital and labour costs.

Thermally processed dry hard copy films use osynthetic polymers, e.g. poly (vinylbutyral), poly (vinyl alcohol), and poly (styrene butadiene) as binders for image forming silver clusters, instead of gelatine being used in wet processed AgX films. This renders the binder more inert to moisture and its deleterious effects, including oxidation. The support for thermally processed dry hard copy films is normal, photographic grade PET [poly (ethylene terephthalate) safety film.[1][2][3][4][5][6]

A disadvantage of thermally processed dry hard copy images is their greater potential instability caused by the presence of unused chemicals after image formation; these are not removed by liquid processing solutions as with conventional silver halide films. Consequently, the potential for formation of excessive fog exists throughout the life of the thermally processed dry hard copy film. Such degradation of image quality has occasionally been observed in the course of prolonged exposure to ambient illumination or storage under high temperature or, most frequently, due to unintended over-exposure to light and heat in a reader-printer (view box). Also, in case of a fire in the storage area or near a vault or safe, the temperature sometimes increase sufficiently high to cause image degradation, even though the temperature used for generating thermally processed dry hard copy images range well above 100 °C. These images are considerably stable under normal user and storage conditions as well as on accelerated ageing studies[7][8][9]). Hence, thermally processed dry hard copy films do not fall within the provisions of ISO 18901 that apply to chemical fixation.

Inkjet based dry hard copy images may also be susceptible to temperature, humidity and light depending on the details of the technical details of the inkjet printing system, its type of ink (e.g. aqueous, solvent or wax based), the colorants (dye or pigment) and the type of ink receiver layers (porous, swellable, etc.) of the hard copy film.

General radiographs are normally viewed on light boxes at a luminance level of 2 000 to 4 000 cd/m^2, whereas according to American College of Radiology (ACR) recommended practices,[24][25] mammograms and clinical quality reviews are viewed at a luminance of at least 3 000 cd/m^2 or higher depending on the modality. In addition, all mammograms and mammogram test images are required to be masked completely during diagnostic inspection, so that no light directly emitted by the light box surface can reach the observer's eyes. The recommended level of intensity of surrounding illumination in that viewing situation is below 10 cd/m^2. In practice, light box outputs and surrounding illumination conditions do vary considerably and, therefore, this standard requires use of a light chamber which permits close control of all illumination parameters, temperature, relative humidity and duration of exposure.

Everyone concerned with the preservation of records on radiographic film understands that specifying the chemical and physical characteristics of the material does not, by itself, ensure that the records will not deteriorate. It is also recognized that enclosure materials used to make radiographic envelopes effects the preservation quality of records It is also essential to provide the correct storage temperature and humidity, and protection from the hazards of fire, water, fungus, and certain atmospheric pollutants. These aspects are considered in pertinent International Standards for storage of films, for example, ISO 18902[16] and ISO 18911.[17]

Imaging materials — Digital hard copy for medical imaging — Methods of measuring permanence

1 Scope

This International Standard establishes test methods for measuring the stability of photographic films intended for storage of medical records. It is applicable to greyscale images on films for use in transmission mode that are based on thermally processed materials (photothermography, thermography, microcapsule) or created by inkjet printing. Thermally processed materials have a base of safety polyester [poly (ethylene terephthalate)] and work predominantly with silver behenate salts dispersed in non-gelatinous emulsions or dye-based microcapsule emulsions that are thermally processed to produce a black-and-white image. In inkjet printing ink droplets are jetted onto a film with an ink-receiving layer to produce a greyscale image.

This International Standard does not cover wet-processed black-and-white films or black-and-white paper. It is not applicable to medical colour images or colour prints created by colour inkjet or dye diffusion thermal transfer (D2T2). Neither does it cover medical greyscale images printed on reflective materials for referral purposes or filmless systems such as picture archiving and communication systems (PACS) in medical imaging.

This International Standard requires the arbitrary choice of "illustrative end points" for changes in colour and perceived contrast to depict quantifiable changes due to physical ageing. Extrapolations based on 'illustrative end points' do not have any proven diagnostic or clinical relevance due to the lack of corresponding statistically significant scoring by radiologists.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5-2, *Photography and graphic technology — Density measurements — Part 2: Geometric conditions for transmittance density*

ISO 5-3, *Photography and graphic technology — Density measurements — Part 3: Spectral conditions*

ISO 18907, *Imaging materials — Photographic films and papers — Wedge test for brittleness*

ISO 18924, *Imaging materials — Test method for Arrhenius-type predictions*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
adherography
imaging technology utilizing a high intensity laser beam to form a positive carbon image through differential thermal adhesion

Note 1 to entry: This process involves fusion of a laser sensitive, carbon-containing layer with the final imaging layer in exposed areas, followed by controlled peeling, which removes the unexposed portion. The positive image is then made durable and permanent by the application of a transfer coat.

3.2
microcapsule
imaging technology in which heat-responsive microcapsules containing dye precursors are thermally rendered to develop a dye image

Note 1 to entry: Heat-responsive microcapsules containing dye precursors are dispersed together with a development emulsion on a polyester support. Application of computer-modulated heat that matches the density pattern of a digital image renders the walls of the microcapsules differently permeable. The varying amounts of developer, which penetrate the capsule walls, produce corresponding differences in dye image density. The capsule walls revert to their impermeable state on cooling and provide protection against dye formation and dye degradation under normal storage conditions.

3.3
phase change solid inkjet
imaging technology based on modulated deposition of micro-droplets of non-aqueous, waxy inks on a microcellular surface of a layer coated on a polyester support

Note 1 to entry: Four shades of neutral ink are used to obtain the wide grey scale density range required for medical images. The melting point of the ink is considerably above ambient temperature, ensuring image stability under normal storage conditions.

3.4
photothermography
imaging technology based on thermal development of a light-induced latent image in dispersed silver salts

Note 1 to entry: The process involves a polymeric layer containing light sensitive silver halide crystals, light insensitive silver behenate crystallites, silver soaps and a reducing agent coated on a polyester support. A latent image formed by light exposure of the silver halide crystals catalyses an oxidation-reduction reaction between the silver behenate and the reducing agent upon heating above 120 °C. This yields a metallic silver image by physical development.

3.5
thermography
imaging technology based on image-wise thermal modulation and development of dispersed silver salts

Note 1 to entry: The process utilizes a polymeric layer containing a light-insensitive organic silver salt, a reducing agent and a stabilizer, coated on a polyester support. Reduction of the organic silver salt by the reducing agent accelerated by heat (100 °C–200 °C) yields a metallic silver image whose densities are controlled by the adjustable temperature of print head elements. The integrity of the silver image under normal storage conditions is secured by stabilization of the unused silver salt.

3.6
aqueous inkjet
imaging technology involving image formation with an aqueous ink by a modulated deposition of micro-droplets on the surface of an ink absorbing layer coated on a polyester support

Note 1 to entry: Black-and-white and colour images can be produced by suitable selection of inks.

3.7
just noticeable difference levels
jnd-levels
measure of the non-linear response of the visual system to luminance stimuli defined as a table of ascending photometric luminance levels (between 1 and 10 000 cd/m^2), which are perceived as equidistant with the smallest perceivable difference ("just noticeable difference") between them[20]

3.8
jnd-contrast
Δjnd
numerical difference between the jnd-levels of two neutral patches on a radiographic film for a given viewing situation (intensity of light box and ambient light intensity), which is used as measure of perceived contrast between the two patches

3.9
change in jnd-contrast
(Δ*jnd* (t)/Δ*jnd*(0)) – 1
measure of relative change in perceived contrast between two neutral patches — for example in the course of a stability test: Δ*jnd*(t) / Δ*jnd*(0) – 1, i.e. [(jnd-contrast after treatment)/(jnd-contrast before treatment)] – 1

3.10
colour changes
Δa*, Δb*
differences in the CIE colour coordinates a* and b*, e.g. in the course of incubation of dry hardcopy film

3.11
endpoints
set of numerical values defining those changes in colour (Δa*, Δb*) and jnd-contrast [(Δ*jnd*(t)/Δ*jnd*(0)) – 1], for given reference visual density (D_{vis}) at which time to failure is evaluated in the course of thermal-stability and light-stability tests in order to produce Arrhenius extrapolation plots following the Arrhenius test method described in ISO 18924

3.12
diagnostic endpoint
set of endpoints, for which changes in colour (Δa*, Δb*) and jnd-contrast [(Δ*jnd*(t)/Δ*jnd*(0)) – 1] for given visual density (D_{vis}), have been correlated with loss of the materials' diagnostic function based on statistically validated psychophysical scoring by radiologists

Note 1 to entry: At the time of writing this standard document insufficient data was available to specify diagnostic end points that could be judged as "relevant or prohibitive" from the standpoint of medical diagnostics. Diagnostic end points need a correlation with judgments or scores by radiologists, for which a statistically relevant set of psychometric data for a given medical application or modality is needed. Diagnostic end points depend on a variety of factors, amongst which are — nonexclusively — type of modality, pathology under investigation, method of image processing, printer settings and density range of the medical image.

3.13
illustrative endpoints
set of arbitrarily defined endpoints for changes in colour (Δa*, Δb*), and jnd-contrast Δ*jnd*(t)/Δ*jnd*(0) – 1 for a given reference visual density D_{vis}, at which time to failure is evaluated in the course of thermal stability tests

Note 1 to entry: Arrhenius extrapolations based on illustrative end points do not have any proven diagnostic or clinical relevance due to the lack of corresponding psycho-visual data. For diagnostically relevant Arrhenius extrapolations a set of diagnostic end points would be necessary.

3.14
film base
plastic support for the emulsion and backing layers

3.15
emulsion layer
image or image-forming layer of photographic films, papers and plates

3.16
safety poly (ethylene terephthalate) base
polyester film base composed mainly of a polymer of ethylene glycol and terephthalic acid

3.17
processed dry hard copy film
dry hard copy film on which a (test) image has been written by its corresponding printer (in analogy to the wet processing of conventional AgX based film)

4 Physical test methods

4.1 General

This section describes tests for layer adhesion (4.2), binder stability (4.3) as well as blocking and image interaction (4.4).

4.2 Layer adhesion

4.2.1 General

Layer adhesion failure is tested under two conditions, namely for tape-stripping (4.2.2) and humidity cycling (4.2.3).

4.2.2 Tape-stripping adhesion test

4.2.2.1 General

The results of the tape-stripping test may depend upon the adhesive tape used if the bonding force between the adhesive tape and the particular film surface under test is not sufficiently high. For this reason, a minimum bonding force is specified for this test. This bonding force shall be determined by applying the adhesive tape to the film surface in the same manner as described in the tape-stripping test. The tape shall be rapidly peeled back from the film surface at an angle of approximately 180°. The peel back force required to separate the tape from the film shall be measured by a suitable device such as a strain gauge or spring scale capable of reading the maximum force used. A bonding force of at least 0,9 N per millimetre of tape width is required.

4.2.2.2 Specimen preparation

Although the dimensions of the processed film specimen are not critical, one dimension shall be at least 150 mm to allow proper handling during the test. Four specimens shall be used for the emulsion surface and four specimens for the backing layer, if present.

4.2.2.3 Conditioning

All specimens shall be conditioned at 23 ± 2 °C and at 50 ± 5 % relative humidity for at least 15 h. This can be accomplished by means of an air-conditioned room or an air-conditioned cabinet. The specimens shall be supported in such a way as to permit free circulation of the air around the film and the linear air velocity shall be at least 150 mm/s.

4.2.2.4 Procedure

The film specimens shall not be removed from the conditioning atmosphere for testing. Apply a strip of pressure-sensitive, plastic-base adhesive tape about 150 mm long to the surface of the processed film. Press the tape down with thumb pressure to ensure adequate contact, leaving enough tape at one end to grasp. No portion of the tape shall extend to the edges of the film specimens or extend to film notches. In order to facilitate physical ageing, the adhesive-taped film specimens shall be kept for 16 h prior to stripping. Hold the specimen firmly on a flat surface and remove the tape rapidly from the film surface. This shall be accomplished by peeling the tape back on itself and pulling the end so that it is removed from the film at an angle of approximately 180°.

4.2.2.5 Reporting of results

The processed film shall be examined for any evidence of removal of the emulsion layer or backing layer, when tested.

4.2.3 Humidity-cycling adhesion test

4.2.3.1 General

This test evaluates the sticking, blocking and delaminating of emulsion or backing layers or transference of paper material to the film surface.

4.2.3.2 Specimen preparation

Two specimens of processed film shall be selected from an area of high density. The preferred specimen size is 50 mm × 50 mm, or 50 mm × film width where the size of the film permits. However, dimensions are not critical, provided all specimens are of uniform size and proper handling is possible.

4.2.3.3 Procedure

The procedures can be followed either with two separate humidity-temperature controlled ovens or by using two glass desiccators as described below. The physical test conditions of temperature, relative humidity and duration of the test shall remain the same in both procedures.

NOTE Films occasionally exhibit what appear to be small pinholes in the image after processing. These can be caused by dirt or dust particles on the emulsion surface at the time the raw film is exposed and should not be confused with holes or cracks in the emulsion layer. The existence of such clear spots in the image prior to humidity cycling should be noted so that their presence does not lead to a false interpretation of adhesion weakness.

4.2.3.3.1 Humidity-temperature controlled oven method

Mount the test specimens in a specimen rack and place the rack inside the oven in such a way that the specimens are freely exposed to the required conditioning atmosphere. Place the rack in a forced-air circulating humidity and temperature controlled oven for 8 h at 50 ± 2 °C and 80 ± 5 % relative humidity. After 8 h, place the specimens and specimen rack for 16 h in a second humidity and temperature controlled oven maintained at 50 ± 2 °C and 11 ± 5 % relative humidity.

The sequence of time periods of 8 h at high relative humidity and 16 h at low relative humidity shall constitute one cycle.

NOTE This can be easily accomplished by placing the specimens in the high relative humidity chamber in the morning and in the low humidity chamber in the evening.

Each film specimen shall be subjected to 12 humidity cycles. After this, remove the film specimens from the specimen rack and examine the emulsion and any backing layer for any evidence of peeling, flaking, or cracking produced as a result of the humidity-cycling treatment (see 4.2.3). During an interruption in the cycling procedure, the film specimens shall be kept at 50 ± 2 °C and 11 ± 5 % relative humidity.

4.2.3.3.2 Glass desiccator method

Two glass desiccators with saturated aqueous salt solutions are placed in an oven that is controlled at 50 ± 2 °C: In one dessicator a saturated solution of ammonium sulfate $(NH_4)_2SO_4$ in water is provided at the bottom of the jar and in another dessicator a saturated solution of lithium chloride in water.

Ensure that the saturated solutions contain an excess of undissolved crystals at 50 °C. The undissolved crystals shall be completely covered by a layer of saturated salt solution and the surface area of the solution should be as large as practical. The jars with salt solution shall be kept in the oven at 50 ± 2 °C for at least 20 h prior to use to ensure attainment of equilibrium. At 50°C, the atmosphere in the jar with ammonium sulfate $(NH_4)_2SO_4$ will reach 80 % rV, representing the high relative humidity condition, whereas the atmosphere in the jar with lithium chloride will reach 11 % rH, representing the low relative humidity condition[10][11]

NOTE 1 The relative humidity in the desiccator method is based on the normal vapour pressure of the salt solution, but the relative humidity tolerance cannot be specified.

Mount the test specimens in a specimen rack and place the rack in the first desiccator jar with the saturated ammonium sulfate solution in such a way that the specimens are freely exposed to the required conditioning atmosphere. After 8 h, place the specimens and specimen rack for 16 h in the second desiccator jar with the saturated lithium chloride solution. Maintain both jars in the forced-air circulating oven at 50 ± 2 °C.

The sequence of time periods of 8 h at high relative humidity and 16 h at low relative humidity shall constitute one cycle.

NOTE 2 This can be easily accomplished by placing the specimens in the high relative humidity jar in the morning and in the low humidity jar in the evening.

Each film specimen shall be subjected to 12 humidity cycles. After this, remove the film specimens from the specimen rack and examine the emulsion and any backing layer for any evidence of peeling, flaking, or cracking produced as a result of the humidity-cycling treatment (see 4.2.3). During an interruption in the cycling procedure, the film specimens shall be kept at 50 ± 2 °C in the desiccator with the low relative humidity (saturated Lithium Chloride solution).

4.2.4 Reporting of results

The film shall be examined under the magnification and lighting conditions that are normal for the intended use of the product. The emulsion layer or backing layer of the processed film shall be examined for layer separation, edge peeling and delaminating that can impair its intended use. Other phenomena relating to changes in colour, visual density or surface characteristics, such as gloss, smudge, and defects introduced upon humidity cycling shall not be reported.

4.3 Binder stability test

4.3.1 General

Binder stability is tested by the wedge brittleness test as outlined in ISO 18907. Physical aging can cause differences in the brittleness behaviour (or flexibility) of both emulsion and backing layers and can lead to brittle failure during handling of large-sized radiographic films. The wedge brittleness measurements shall be made on five unheated and five heated specimens of processed film, with the sample heating procedure representing an accelerated simulation of binder ageing. Each specimen shall preferably contain a low-density area. Although the dimensions of the processed film specimen are not critical, one dimension shall preferably be at least 350 mm, but at least 150 mm in length in order to comply with the brittleness test ISO 18907. Five film specimens shall be subjected to accelerated ageing as described in 4.3.2.

4.3.2 Accelerated ageing conditions for “heated film specimens”

Processed film shall be subjected to accelerated ageing conditions to meet the requirements for binder stability. The test specimens shall be conditioned at 23 ± 2 °C and 50 ± 5 % relative humidity for at least 15 h. After conditioning, place the specimens in a moisture-proof envelope and heat-seal the envelope.

NOTE 1 A suitable moisture-proof envelope is a metal foil bag that is coated on the inside with polyethylene for heat sealing.

To prevent sticking between adjacent specimens, it may be necessary to interleave them with aluminium foil. Ensure a high ratio of film to air volume by squeezing out excess air prior to heat-sealing. Use a separate envelope for each film sample. Heat the envelopes in an oven for two weeks at (60 ± 2 °C).

NOTE 2 Incubation is accomplished in a closed environment to prevent escape of any decomposition products that may be produced during incubation. Such products may catalyse further degradation of the film base.

NOTE 3 In the subsequent text, samples subjected to these accelerated ageing conditions are designated “heated film”. Comparison samples kept under room conditions are designated “unheated film”.

NOTE 4 In case of thermally processed radiographic films, significant differences in appearance due to increase in image density will be noticed between unheated film and heated film specimens. This physical change in appearance is not relevant for the measurement of brittleness failure.

An alternative method of incubating the specimens in a closed environment is by placing them in 25 mm borosilicate glass tubes. Each tube shall have two flanged sections separated by a gasket to provide a moisture seal and shall be held together by a metal clamp. A suitable inert gasket may e.g. be made from polytetrafluoroethylene. Sufficient film specimens shall be used to provide a high ratio of film-to-air volume.

4.3.3 Conditioning

Both the heated and unheated specimens (4.3.1) shall be conditioned as described in 4.2.2.3 before conducting the wedge brittleness test (4.3.4).

4.3.4 Procedure

The film specimens shall not be removed from the conditioning atmosphere for testing of wedge brittleness. The wedge brittleness of the unheated and heated specimens shall be measured as specified in ISO 18907.

4.3.5 Reporting of results

Any increase in the wedge brittleness value of the set of heated specimens from that of the set of unheated specimens shall be noted and reported accordingly.

4.4 Blocking test and image interaction test

4.4.1 General

This method is intended to simulate image interactions of dry hardcopy film under confined, mixed storage conditions, namely imaged dry hardcopy film interacting with imaged dry hard copy film of the same kind, with dry hard copy prints from other manufacturer's or wet processed films as well as different enclosure materials. Stacks of such material combinations are incubated with a load exerting homogenous pressure in order to simulate confined storage and to check for blocking and image interaction failure.

4.4.2 Specimen preparation and conditioning

The preferred specimen size is 50 mm square even though the dimensions are not critical, provided all specimens are of uniform size. The size of the specimens shall be smaller than the physical dimensions of the load to create a uniform pressure of 4 kPa [or 0,6 psi] across the sample area. Each specimen shall have half of its area imaged to a diffuse optical density, $D \geq 2{,}0$ (referred to as D_{max}) and the other half processed to D_{min} density as shown in Figure 1.

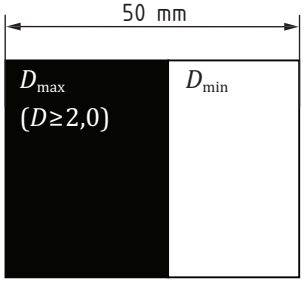


Figure 1 — Blocking specimen

The number of specimens required for this test depends on the number of combinations of materials that shall be tested as a pair for blocking and image interaction. The test of a given film material with itself

requires four samples. The number of specimens required for the test of one kind of film with another type of film is two per pair of film. The specimens of imaged film shall be conditioned at 40 ± 2 °C and 60 ± 5 % RH using a humidity controlled oven. The specimens shall be placed in the humidity oven, so that they are freely exposed to the required conditioning atmosphere for at least 15 h in order to attain moisture equilibration.

4.4.3 Film stacking and test procedure

After moisture equilibration is attained, and without removing from the humidity ovens, the film specimens shall be stacked with 90° turns with respect to D_{max} and D_{min} pattern. The stack shall contain two sheets of the hard copy (HC) film under test and two sheets of the same or a different type of HC film, a wet processed AgX film or an enclosure material. Blocking propensity is evaluated due to the interaction of emulsion (E) to back (B) side of film 1 and film 2, respectively, i.e. E_1 to E_2, E_1 to B_2, B_1 to E_2 and B_1 to B_2 for all combinations of D_{max} to D_{min} as given by the stacking scheme. Two examples of stacking order are shown in Figure 2, keeping in mind that the D_{max} to D_{min} pattern is turned by 90° from layer to layer.

The stack shall be placed under a uniform pressure of 4 kPa (or 0,6 psi). The weighted stack shall remain in the same humidity controlled oven for 3 days at 40 ± 2 °C and 60 ± 5 % rH. After 3 days the film stack shall be removed from the oven and allowed to cool. The film specimens shall then be individually removed from the stack and examined for evidence of film blocking (sticking/delaminating), changes in density and evaluated for ferrotyping, gloss/haze differences and any possible image transfer between adjacent specimens.

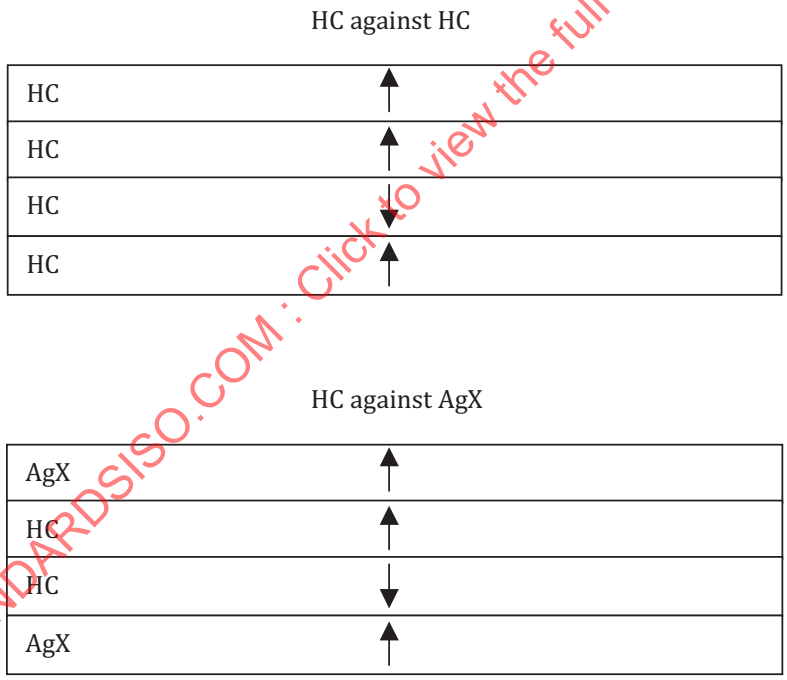


Figure 2 — Stacking diagram — Hard copy HC and AgX film with emulsion side up (↑) and emulsion side down (↓)

A control experiment of similar combinations of the digital film without the AgX film shall be performed if the blocking is due to interaction with AgX film. Additional permutation and combinations between hard copy films and enclosure materials shall be carried out as needed. Interactions between AgX films are not relevant in this test.

4.4.4 Reporting of results

The processed film shall be examined for evidence of blocking (sticking), delaminating or surface damage, changes in haze and gloss, and for any evidence of image interaction or image transfer (density transfer) to adjacent films or enclosure.

5 Test methods for image stability

5.1 General

Test methods for image stability cover thermal ageing test (5.2), light chamber test (5.3) and image spread test (5.4).

International Standard (ISO) visual diffuse transmission density shall be measured with a densitometer that has spectral conformance to ISO 5-3, and geometric conformance to ISO 5-2. Samples of processed film for use in the dark stability (thermal-ageing) tests and light stability (light chamber) tests shall contain a processed step-wedge with at least 11 steps, such as the Society of Motion Picture and Television Engineers (SMPTE) target. The analysis applies the methods of Digital Imaging and Communications in Medicine (DICOM) on perceived contrast (just noticeable differences in perceived contrast) and the methods of CIE on colour difference measurements as outlined in Annexes C, D, and E respectively. The image spread due to thermal aging shall be evaluated by analysis of the Contrast Transfer Function (CTF) at one high image frequency, which is discussed in 5.4. The image spread test target requires a specific periodic square wave bar pattern.

5.2 Thermal-ageing test (dark stability)

5.2.1 Introduction

The thermal ageing test is based on the accelerated test method ISO 18924 (Arrhenius test method). Long-term dark stability of dry hard copy films is evaluated by a series of incubation tests carried out at several elevated temperatures at a particular relative humidity. This standard procedure for accelerated testing of thermal stability is based on stressing material at elevated temperatures, i.e. several specimens are incubated at a number of elevated temperatures T and the time $t_{\text{end point}}$ to reach an illustrative end point (e.g. certain change in jnd contrast or colour) is determined. Then, a specific model for the thermal degradation process is applied to allow extrapolation of the time to reach the end point at lower temperatures which are relevant for the use case or storage conditions, for which real-life testing would take far too long.

If only one single, thermally activated degradation process is predominant in the material, the degradation process can be described by the Arrhenius equation (see Arrhenius Test Practice ISO 18924). In case of ideal Arrhenius behaviour, the data points in a plot of logarithm of time to reach end point over reciprocal temperature, i.e. log ($t_{\text{end point}}$) vs. $1/T$, wherein T is expressed in K, will fall on a straight line. Then, a linear regression of the data is applied to fit a straight line to this logarithmic plot and the resulting model can be used as extrapolation to lower temperatures. Arrhenius Test Practice ISO 18924 summarizes the requirements and prerequisites of a meaningful evaluation: at least four data points should fall on the straight line for a statistically significant evaluation and no phase transition (e.g. glass transition) should be present in the temperature range under investigation.

Two incubation techniques, known as the “sealed-bag” and the “free-hanging” methods, are available for the accelerated dark stability testing. These protocols simulate two different kinds of storage conditions and tend to produce somewhat different results as volatile and sublimable components that are released during accelerated thermal [6][7][8][9] tests due to the presence of unused chemicals left with the dry hard copy film after image formation (refer Annex B).

In one storage condition, the dry hard copy film is stored in a sealed container with very little air. Any substance released by dry hard copy film is trapped inside the container and can interact with the image or support. This situation is best simulated by the “sealed-bag” method, in which preconditioned specimens are sealed in a moisture-proof bag from which most of the air has been expelled. This

method also eliminates any potential contamination with other materials in the oven, and prevents any unintentional light-induced reactions after controlled light exposure of the specimens during the sample conditioning as outlined in 5.2.5. An appropriate number of such bags are placed into ovens maintained at different test temperatures to permit specimen evaluation at periodic intervals.

The second storage condition simulated by the "free-hanging" method is performed inside a constant temperature-relative humidity controlled chamber. The specimens are suspended in this relatively large test chamber at a sufficient distance from each other to ensure free access of the circulating air to all surfaces.

The user of the "free-hanging" protocol should note that any of the volatiles potentially released by the dry hard copy films during incubation might possibly contaminate other films in the chamber and thus introduce additional degradation processes in other film materials being incubated "free hanging" within the same test chamber (potential for cross contamination)..

The user of this International Standard should be aware that the moisture content (by weight) of the specimens would differ somewhat with the two test methods, especially at the higher oven temperatures. With the "sealed-bag" method, the moisture content of the specimens will remain essentially constant, independent of oven temperature (the relative humidity, however, generally will increase with increasing temperature, which will lower the effective glass transition temperature of several polymer binders). With the "free hanging" method, however, the actual moisture content of the specimens will generally decrease somewhat as the temperature of the chamber is increased. The influence of these differences in specimen moisture content, any extraneous light-induced reactions, and the glass transition temperature of the binder on predictions of ageing behaviour may vary depending on the dry hard copy film, the range of oven temperatures employed, and the selected relative humidity value(s).

If it is suspected that differences in specimen moisture content could have a significant impact on fading or fogging behaviour for a particular dry hard copy film, it would be useful to conduct tests with either or both methods at several relative humidity conditions.

The choice of test method should be based on the known properties of the dry hard copy films being evaluated and the expected storage conditions of these materials. The processed dry hard copy films are normally kept in partially opened envelopes during storage. The choice of test method used shall be reported.

5.2.2 Test target

A processed step tablet with at least 11 steps between 0 % and 100 % pixel intensity levels is required. The application of a Kanamori or DICOM calibration is recommended before printing the specimens, as it provides a more equidistant spacing of the perceived density levels across the step tablet, However, the actual printer calibration drops out of the analysis, and calibration serves only to provide an approximately uniform coverage of the relevant density range of the dry hard copy film. An example of a step tablet is the standard SMPTE target as illustrated in Figure 3 that can be conveniently obtained as a tiff file..

NOTE The SMPTE target tiff file can be obtained from The Society of Motion Picture and Television Engineers (SMPTE) in Los Angeles, CA, USA, or SMPTE, 3 Barker Avenue, White Plains, NY 10601.

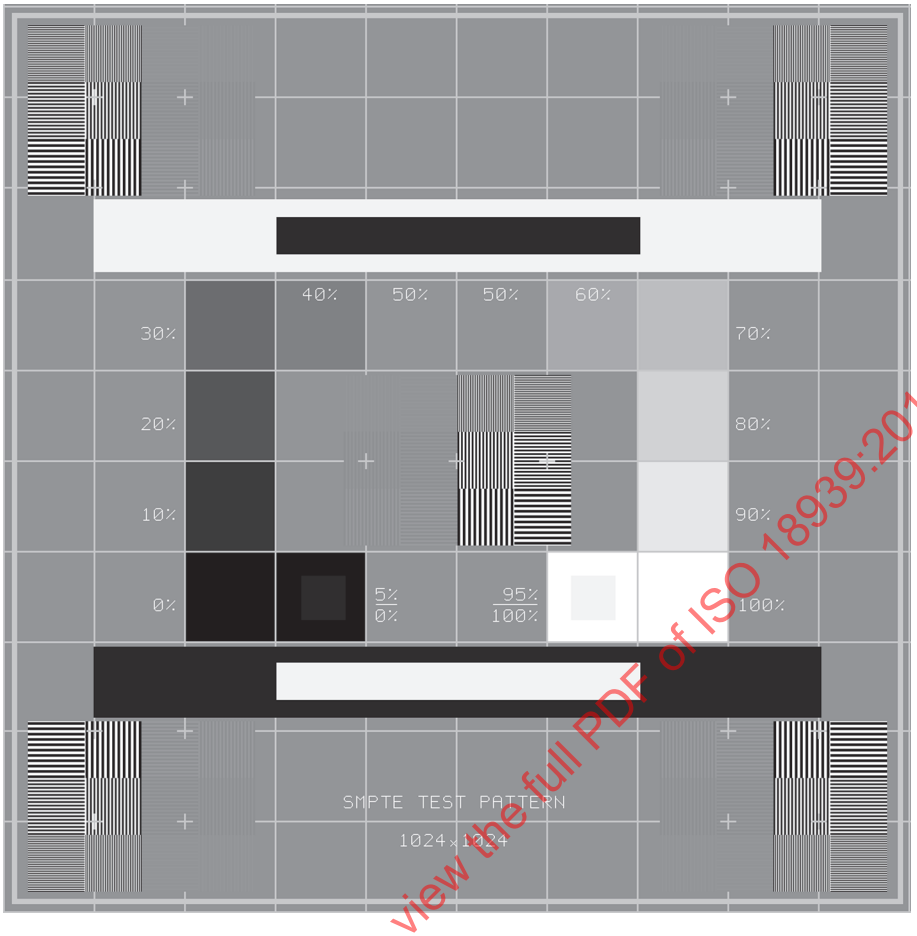


Figure 3 — SMPTE target (reproduced with kind permission of SMPTE)

5.2.3 Specimen conditioning and initial measurements

At least two specimens of dry hard copy film with the 11-step tablet as test target shall be processed for each intended incubation time and temperature condition. In addition five additional D_{min} specimens shall be prepared as fillers materials for each intended time and temperature condition in case of the heat-sealed bag method.

The processed specimen with step tablets shall receive a light exposure of eight hours on a lighted view box with a light level of 3000 cd/m^2 and a surface temperature of 40 ± 2 °C. The lighted view box shall be kept at 23 ± 2 °C and 50 ± 5 % relative humidity. Alternatively, the 8 h exposure episode can be realized with the light chamber described in 5.3.

After light exposure the initial visual density readings and the CIE a* and b* parameter shall be measured for all patches of the step tablet. The density readings are converted into DICOM JND levels as explained in Annex D.

Ranges for suggested visual density D_{vis} analysis are indicated below:

Low density range: $D_{vis} < 1,0$

Mid density range:$1,0 \leq D_{vis} < 2,0$

High density range: $D_{vis} \geq 2,0$

Density readings of the D_{min} specimens for use as fillers material in the heat-sealed bag incubation are not required.

5.2.4 Incubation conditions

5.2.4.1 General

At least two film specimen, either “free-hanging” or in “heat-sealed bag”, shall be incubated at each temperature of the Arrhenius test scheme. Each temperature set point shall be controlled to ± 2 °C.

A typical temperature-and-times scheme is suggested for example in Table 1. The covered temperature range shall be at least 20 K, preferably wider, and temperature intervals shall be approximately equal. However, the lower the test temperature, the more precise the Arrhenius prediction is. Therefore, if the highest test temperature is ≤ 45°C, the required temperature range that has to be covered by the test scheme can be reduced to 15 K: For example, the range of 30°C to 45 °C is acceptable, while the range of 40°C to 55°C is not. The reduced temperature range may be practical to avoid distortion of the Arrhenius analysis due to the presence of a phase transition of the binder at elevated temperature (e.g. 45°C).

A description of how these incubation conditions were chosen and the time-temperature relationship for dark ageing are discussed in the literature.[7][8][9][12][13]

Table 1 — Suggested time-temperature relationship for Arrhenius incubations

Temperature °C	23	32	38	50	60	65
Time t_1	28 d	14 d	7 d	1 d	6 h	2 h
Time t_2	56 d	28 d	14 d	2 d	12 h	6 h
Time t_3	112 d	56 d	28 d	3 d	1 d	12 h
Time t_4	224 d	112 d	56 d	7 d	3 d	1 d
Time t_5	448 d	224 d	112 d	14 d	7 d	2 d
Time t_6	960 d	448 d	224 d	28 d	14 d	3 d
d days h hours						

5.2.4.2 Constant relative humidity testing (free-hanging)

For each temperature condition (see example Table 1) samples of all materials shall be hung by clips or other means, such that they are freely exposed to the atmosphere within a temperature and humidity controlled chamber. Relative humidity shall be controlled to 50 ± 5 %. Other humidity set points can be investigated as option. Weight may be attached by clips to the lower end of the samples, to prevent excessive curl of specimens due to humidity effects or to prevent excess movement of the samples due to the air circulation in the chamber. One temperature/humidity controlled chamber is required for each temperature condition. However, if there is a problem with gas phase cross-contamination of samples, some samples may have to be segregated in their own chamber to prevent any potential contamination with other samples in the chamber.

A single set of targets, two per material, can be run using this method. Then, samples are removed for density and colour reading and replaced after readings have been made.

5.2.4.3 Constant moisture content testing (sealed-bag)

Duplicate dry hard copy film specimens shall be sandwiched in between five sheets of the same film after equilibration at 23 ± 2 °C and 50 ± 5 % relative humidity for at least 15 h. This specimen sandwich shall be wrapped with aluminium foil and placed inside a laminated (aluminium foil-polyethylene lining) heat-sealable envelope to prevent escape of moisture during high temperature incubation. These envelopes are then heat sealed after excess air has been squeezed out. Use of two bags is recommended to reduce any effect of pinholes.

The film samples shall be incubated as suggested in Table 1 and shall be periodically withdrawn for density, and colour measurements.

5.2.5 Measurements before and after incubation

A densitometer and a colorimeter (or spectrophotometer) are used to monitor the changes in visual density and CIE a* and b*, respectively, of the specimens before and after thermal incubation as a function of time. Changes in visual density and colour (a* and b*) may affect retrieval of diagnostic information of the dry hard copy film on view box. Visual density readings shall be collected with a densitometer having spectral conformance to ISO 5-3, and geometric conformance to ISO 5-2. The DICOM JND levels according corresponding to the visual density readings are calculated according to the DICOM standard display function (SDF) as outlined in Annex D, taking the light intensity of the view box and the ambient level into account. The CIE parameters a* and b* shall be evaluated based on a fluorescent illuminant representing "cold daylight" with a colour temperature in the range of 6 000–6 500 K and the CIE (1931) 2 degree observer as outlined in Annex E.

NOTE "Normal" spectrum fluorescent lamps of the CIE type F5 ("cool daylight" with colour code 765) employ halo phosphors, that are no longer available from ca. 2010 on (environmental reasons). Industry recommended replacement type is "cool daylight" with colour code 865, which is based on three band phosphors (CIE type F10–F12).

5.2.6 Reporting of results

For each temperature, the incubation time is determined, at which a certain change in JND contrast or a change in colour (a*, b*) is reached. Due to the lack of diagnostic end point, illustrative end points can be chosen arbitrarily, such as a change in JND-contrast [($\Delta jnd(t)/\Delta jnd(0)$) – 1] of 20 % or a change in colour by 4 Δa* or Δb* units (see Annexes D and E). Based on these time-to-end points the Arrhenius plots are prepared as outlined in 5.2 and test procedure ISO 18924 and the extrapolated lifetimes are reported for the set of illustrative end points.

The set of illustrative end points and the incubation protocol ("sealed-bag" and /or "free-hanging") shall be reported.

5.3 Light chamber test

5.3.1 General

The light chamber test is designed as a simulation of an unintentional light exposure episode of hard copy film on a lighted view box (medical film illuminator). The light output and surface temperature of view boxes for medical radiographs depends on their diagnostic use (e.g. general Radiography, Mammography), their construction (screen materials, in-built ventilation, number of fluorescent bulbs or LED lamp units etc.) and the microenvironment (thermal insulation, ambient temperature and relative etc.) and varies considerably. For better comparison, a light chamber with fluorescent lamps is used for this failsafe test, which enables the user to independently control light exposure and temperature / relative humidity during the light stability test of the medical hard copy film.

5.3.2 Schematics of a light chamber apparatus

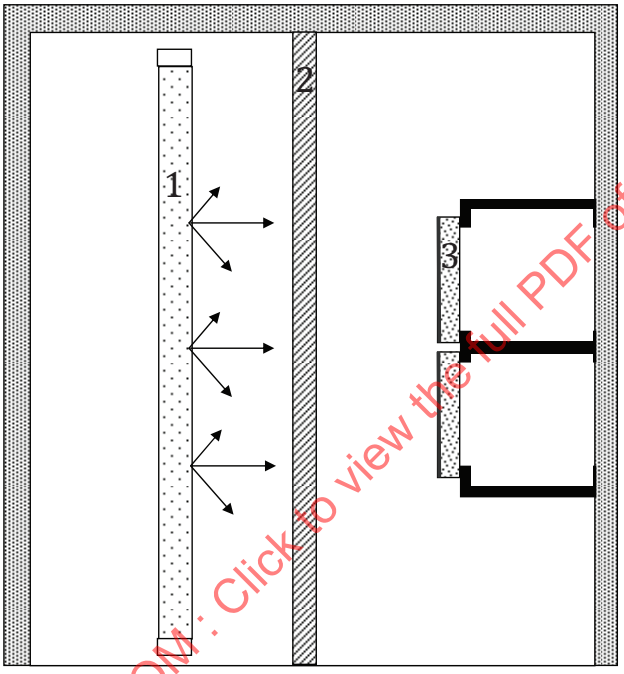
The schematics of the light chamber apparatus used in this test are shown Figure 4. The compartment with the fluorescent lamps is separated by a Polymethylmethacrylate (PMMA) screen from the chamber such that the temperature and humidity of the chamber space can be controlled independently of the heat emission of the fluorescent lamps. Typically, the compartment with the fluorescent lamps requires a heat sink on its own to limit the thermal load of the test chamber space, which otherwise would jeopardize the stability of the test chamber climate.

The PMMA screen shall be made out of a clear (i.e. not opaque) and non UV absorbing grade of Polymethylmethacrylate with a thickness of 3–4 mm, such that the emission lines of the fluorescent

lamps in the UV range of 300–400 nm can pass. The fluorescent lamps shall represent “cool daylight” with a colour temperature of 6000 °K to 6500 °K, when measured through the PMMA filter.

NOTE 1 The “normal” spectrum fluorescent lamps of the CIE type F5 (“cool daylight” with colour code 765), that were historically used in view boxes for medical hardcopy film, are no longer available from ca. 2010 on because of environmental issues with halo phosphor. Industry recommended replacement type is “cool daylight” with colour code 865, which is based on three band phosphor (comparable to CIE type F10–F12). In addition, new illuminators come with a variety of new illumination technologies, such as OLED or LED, which represent a complete different spectral power distribution and which also lack emission of UV lines.

It is recommended to change one half of the fluorescent lamps in the light chamber after 2000 h of operation to maintain a constant flux and spectral power distribution: Beyond 2 000 h of operation, occasional creation of pinholes have been observed in the lamps phosphor coatings, that may introduce an increased emission of the spectral lines in the UV range.



Key

1 fluorescent lamps
2 clear PMMA
3 sample plane with film specimen

Figure 4 — Light chamber apparatus

5.3.3 Sample target and initial measurements

The test target of 5.2.2 is used, i.e. a step wedge with at least 11 steps, such as the SMPTE test target. One specimen shall be required per film type and per incubation time. Separate sets of specimens shall be used for each sampling interval.

No explicit preconditioning shall be necessary, but the printed film shall not be exposed to humidity greater than 65 % RH or temperatures above 25 °C. Also, the printed film shall not be exposed to cumulative light exposure greater than 200 lx h before the test, quantifying the obvious rule that the amount of ambient light that the samples receive prior to such light stability testing shall generally be minimized.

Initial visual density readings and the CIE a* and b* parameter shall be measured for all patches of the step tablet. The density readings are converted into DICOM JND levels as explained in Annex D.

5.3.4 Mounting specimens in the light chamber

The specimens shall be placed in free-hanging mode in the chamber and mounted such that the emulsion side of the specimen shall face the fluorescent lamp.

The light chamber shall be set to the following conditions, which resemble the conditions at the surface of an average viewing box for general radiography.

a) Illuminance on sample shall be 9400 ± 860 lx (560 ± 50 fc), which is equivalent to a uniform flux of 3000 + 275 cd/m^2 (nits) corresponding to the diffuse exposure conditions of a standard view box (see Annex A).

NOTE 1 The measurement of illuminance is performed with a lux-meter, i.e. a calibrated radiometer with photopic response and a diffuse probe. The surface of the sensor probe is mounted in the sample plane facing in direction of the light source. Illuminance readings are collected over sufficient positions within the sample plane in order to identify the sample mounting area that is conform to the required illuminance homogeneity condition: it depends on the construction of the light chamber (e.g. carousel vs. flatbed type, light reflection off the inner walls), how illuminance drops towards the edges of the sample area.

b) Air temperature at sample position is controlled at 40 ± 2 °C;

NOTE 2 Chamber air temperature distribution is assessed by a (set of) calibrated temperature probe(s), which is placed "free hanging" at different positions in the sample plane for collection of temperature readings with the chamber in operation. A representative set of measurement positions is chosen according to chamber geometry. Suitable temperature probes are, for example, PT100 probes and thermocouples. Probes shall be shielded from direct exposure from the lamps in order to avoid distortion of the temperature measurement.

c) Relative Humidity at sample position is controlled at 20 % ± 5 % RH.

NOTE 3 Relative humidity distribution in the chamber is assessed by a (set of) calibrated humidity probe(s), which is placed "free hanging" at different positions in the sample plane for collection of relative humidity readings. A representative set of measurement positions is chosen according to chamber geometry. Suitable humidity probes are e.g. psychrometers or capacitive sensor. Probes shall be shielded from direct exposure from the lamps in order to avoid distortion of the relative humidity measurement.

NOTE 4 The specified relative humidity represents the constant dewpoint approach with respect to the use case: elevated temperature at the surface of the view box, which is suspended in a standard environment with 21°C and 50 %rH.

d) A Polymethylmethacrylate (PMMA) sheet separates the fluorescent lamps from the sample compartment. The sheet shall be made of a clear non-UV absorbing PMMA grade with a thickness of 3–4 mm

Before commencing the test, the light chamber shall be turned on and allowed to warm up until temperature and light levels have stably reached set point conditions.

In addition to the conditions referred to as "average radiography view box conditions" before, other temperature and light levels may be tested to check the fail safe behaviour of film on view boxes at higher flux levels (e.g. 5 000 cd/m^2) or higher surface temperature (e.g. 45 °C). In case of higher temperature, the relative humidity shall be adjusted according to constant dew point.

5.3.5 Measurements after incubation

The individual set of specimens shall be removed from the light chamber periodically after exposures of 8 h, 24 h and 72 h respectively in order to simulate exposures of dry hard copy films left inadvertently on a lighted view box for shorter durations during breaks, overnight and over the weekend. This simulates the effects of simultaneous exposure of dry hard copy images to excessive light and heat. The changes in visual density, a* and b* values shall be measured for each step as outlined in 5.2.5. The density readings are converted into DICOM JND levels as explained in Annex D.

5.3.6 Reporting of results

Plots of changes in colour CIE a* and b* and jnd-levels after exposure to the "average general radiography view box conditions" shall be reported. Unlike the dark stability tests, which are performed at several time–temperature combinations, the light stability exposure is conducted at one temperature and shall provide only a relative comparison under real-life conditions for a particular hard copy film product as function of exposure time, but without additional extrapolation based on any "illustrative" end points.

5.4 Image spread test

5.4.1 General

Image spread due to thermal aging shall be evaluated making use of changes in the contrast transfer function (CTF), which is derived at a given modulation frequency before and after the incubation.

5.4.2 Sample target

The test target is made of a periodic square wave bar pattern with alternating bars of the same width with constant modulation of their density levels. The test target contains said periodic test pattern at two density levels, covering the low density range and the high density range. For each density range, a specific modulation of the square wave pattern is used. The modulation is characterized by the solid density of large patches using the same digital printer control value as in the square wave patterns.

The initial printed density of the darker and lighter solid patch of the bar pattern for the high density range shall be 2,5 ± 0,2 and 1,5 ± 0,2 respectively. The initial printed density of the darker and lighter solid patch of the bar pattern for the low density range shall be 1,2 ± 0,1 and 0,6 ± 0,1 respectively. The tolerance of the difference of the higher and lower density shall be ± 0,1.

The frequency of the bar pattern shall be 7 ± 2 cycles/mm. Other frequency ranges can be also measured, but the CTF values of the range of 7 ± 2 cycles/mm shall be reported. The square wave pattern shall be printed in two orientations, namely horizontal and vertical or main and sub-direction of the printer.

An example of schematics of a CTF test target with a square wave pattern (SWP) is shown in Figure 5: HH and HL are the solid patches that have digital image data corresponding with the darker and lighter bars of the high density ranges of the bar pattern. LH and LL are the solid patches that have the digital image data corresponding with the darker and lighter bar of the low density ranges of the bar pattern. Patches H3, H2 and H1 are the "3 on 3 off", "2 on 2 off" and "1 on 1 off" bar pattern of the high density range respectively, and patches L3, L2 and L1 are the "3 on 3 off", "2 on 2 off" and "1 on 1 off" bar pattern of the low density range respectively. The subscript m means the main direction of the printer and the subscript s means the sub-direction of the printer. Images which contain the above mentioned bar pattern and the solid patches shall be printed for the CTF measurements.

The following example calculation explains the relevance of 7 ± 2 cycles/mm for some typical printer resolutions, which are expressed in lpi [lines per inch]. For a 508 lpi printer, the 2 pixels on / 2 pixels off pattern represents a square wave pattern with 5 cycles/mm. For a 300 lpi and 320 dpi printer, the 1 on/1 off pattern would represent 5,91 and 6,30 cycles/mm, respectively. The user shall be aware, that the conversion from printer resolution [lpi] to period of the bar pattern [cycles / mm] employs a factor 2.

Calculation: cycles / mm = 0,039 37 [inch/mm] x (lpi [lines/inch] / $period_{SWP}$)

wherein $period_{SWP} = 2n$, for a bar pattern with n pixels on/n pixels off.

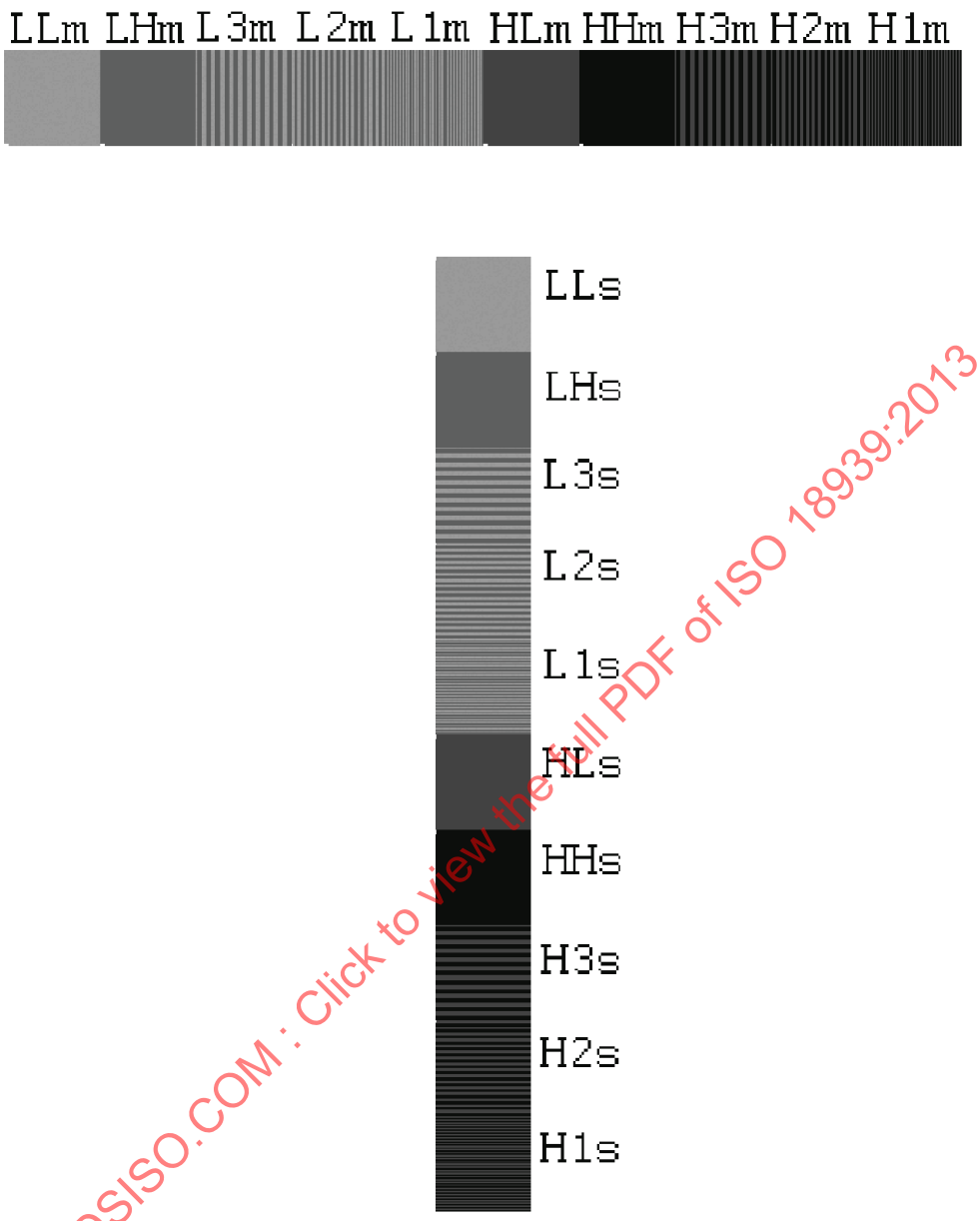


Figure 5 — Schematics of CTF sample test target

5.4.3 Specimen conditioning and incubation conditions

The prepared specimens shall be preconditioned as described in 4.2.2.3. The preconditioned specimens shall be incubated in 40 ± 2 °C and 50 ± 5 % RH for 2 weeks. Other incubation conditions, such as 50°C / 50 % RH for 1 week or 2 weeks, or tests at elevated humidity, such as 40 ± 2 °C and 80 ± 5 % RH for 2 weeks, can be also applied in order to check the extended heat resistance performance of the materials.

5.4.4 Measurement procedure and calculation of CTF parameter

The images shall be measured with microdensitometric scans before and after the incubation. Microdensitometric scans shall be performed with a flatbed scanner with optical resolution over 1600 dpi or alternatively any microdensitometer. Care should be taken that the results are not influenced by flare or adjacency effects, particularly when using flatbed scanners. In order to check that these effects are not influencing the results, scans should be repeated after rotating the sample by 90 and 180 degrees and

checking that the results remain the same. In addition, care should also be taken that the file format in which the scan is saved does not cause unwanted image artefacts, e.g. by interpolation or scaling. More details on the potential issues with these measurements can be found in the literature.[18]

Alignment of the bars with the scan direction should be carefully controlled (within 1 degree), because misalignment is known to introduce blurring. The scanner should be operated as a linear detector in colour-to-luminance mode, delivering 16 bit images representing greyscale values linear in intensity in the range between minimum density of 0,15, to maximum density of 4,00. The scanner greyscale values shall be calibrated by the visual diffuse density reading from a step tablet corresponding to the calibrated printer/dry hard copy material combination.

The dimension of the aperture for the micro-densitometric measurement shall be 10 µm by 100 µm. In case of a low resolution printer where noise caused by pixel pattern is observed, the broader aperture dimension, such as 20 µm to 40 µm by 100 µm, shall be used in order to reduce the noise.

The maximum visual density value of the darker bar, D_{max}(bar), and the minimum visual density value of the lighter bar, D_{min}(bar) shall be measured. At the same time, the average density of the solid patch, D_{max}(solid), which is produced from the same digital image data of the darker bar and the average density of the solid patch, D_{min}(solid), which is produced from the same digital image data of the lighter bar shall be measured.

The CTF value shall be calculated as follows:

$$CTF = \{D_{max}(bar) - D_{min}(bar)\} / \{D_{max}(solid) - D_{min}(solid)\}$$

5.4.5 Reporting of CTF results

The CTF values before incubation, CTF(initial), and after incubation, CTF(incubated), shall be calculated for the each sample. Deterioration of the image due to thermal ageing is reported as the ratio of CTF(incubated)/CTF(initial) × 100 (%). Reporting shall also contain printer resolution and pixel size of the test target (e.g. 1 pixel on/off or 2 pixels on/off.)

Annex A
(informative)

Light stability test conversion of units

The SI unit lux (lx) and the non-SI unit foot-candela (fc) are measures of illuminance, which is the light level incident on the sample.

The SI unit candela/m^2 (cd/m^2) and the non-SI unit foot-lambert (ft-l) are measures of luminance, which is a measure of the light output for a light source. "Nits" is used as non-SI synonym for cd/m^2. Conversion factors for the illuminance units and the luminance units are given below.[19][26]

Illuminance conversion factor: 1 fc = 10,76 lx

Luminance conversion factor: 1 ft-l = 3,426 nits

A view box, which is a light source, have their light output rated in cd/m^2 (or nits), while light meters, which measure the light level at a certain point in space, gives readings in lx (or fc). The determination of illuminance (fc) given the luminance of the light source (nits) depends on the nature of the light source. The view box can be approximated by a Lambertian light source, whose radiance is independent of viewing angle. The illuminance, E [lx], for a point on a surface of a Lambertian light source with luminance, L [cd/m^2], is given by π I [cd / m^2] = * E [lx].

Other illuminance to luminance conversions:

1 lx = 0,318 nits

1 lx = 0,093 ft-l

1 fc = 3,426 nits

1 fc = 1 ft-l

Annex B
(informative)

Effect of residual compounds on thermally processed radiographic images

The thermal processing of dry hard copy films does not include removal of substances that can induce fog or change in colour (non-image silver and residual chemicals) during subsequent use and storage. However, fog formation requires thermal activation. Moreover, the degradation potential of the fog-inducing compounds diminishes slowly under ambient storage conditions, because they sublime and diffuse out of the image layer. Evidence of such diffusion and the influence of storage conditions were provided by the differences in the amount of fog-inducing activators detected by chemical analysis of samples incubated in tightly packed, heat-sealed bags and those incubated in a free-hanging mode.[7] The former contained higher residual amounts of activator compounds than the latter.

The processed dry hard copy films are normally kept in partially opened envelopes during storage, which is simulated by the free-hanging incubation test method. This keeps even relevant for practical files with dry hard copy films that are stored in tight stacks leading to a reduction of the exchange rate of air. The situation is different for storage of dry hard copy film in a sealed container as given by moisture proof metal laminated PE bags. This test method simulates the most severe situation and can be used to additionally accelerate test if results from free hanging are not available within reasonable time.[7][8][9] However, the failure mechanism in heat sealed bags might not be representative of the practical filing situation

Annex C
(informative)

Simulated thermal ageing tests

The experimental method used to derive the predicted lifetimes of dry hard copy films at ambient conditions of storage is based on the data that appear in.[7][8][9] In order to extrapolate the high temperature incubation results to normal keeping conditions, the data was treated by classical chemical kinetics as described in references.[1][2][6] It is recognized that the rate-controlling step in image degradation of photographic films may be much more complex than a first order approximation. Nevertheless, Arrhenius plots provided a reasonable means of extrapolation to predict lifetimes of several kind of imaging media at room temperature conditions.[12][13][14][15]

In round-robin inter-laboratory tests conducted during the preparation of this test method standard, the reproducibility and applicability of accelerated thermal testing on medical dry hard copy materials has been investigated. Arrhenius plots were prepared based on illustrative end points for changes in visual density, DICOM grey-levels (jnd-contrast) or colour (CIE a* and b*). In some cases (i.e. certain material and particular sensitometric property), linear Arrhenius plots were reported, in other cases significant deviations from linear shape were found. In the latter cases, extrapolation errors (typically under-estimations) of the order of at least 2 to 3 times can be expected by the assumption of simple Arrhenius degradation behaviour.

An important prerequisite of the Arrhenius test procedure is the assumption that the predominant degradation processes at elevated temperatures and design-for-use temperatures are the same. Therefore, no phase transitions shall occur in the temperature range under test, which may limit the highest available test temperature considerably, resulting into a limited acceleration of this thermal ageing approach.

Annex D
(informative)

Greyscale evaluation based on just noticeable differences (JNDs) defined DICOM standard display function (SDF)

D.1 Calculating jnd-values from diffuse visual print density[20]

According to DICOM, JND values (just noticeable differences) give a better representation of the greyscale perception than visual density. JND values express the perceived greyscale in terms of just noticeable (distinguishable) luminance levels L. This correlation is described by the DICOM standard display function (SDF).

For the purpose of this standard, we refer to a special application of the DICOM SDF. The transmission medical hard copy print with diffuse visual density D is displayed on a viewing box with luminance level L_0; the print density can be regarded as optical filter modulating the intensity of the light-box. In addition, the ambient luminance L_a, which will be reflected off the print surface, is also taken into account. The luminance L obtained from an optical density D of the print is thus calculated by:

$$L = L_a + L_0 * 10^{-D} \quad \text{(D.1)}$$

where

L_0 is the luminance of the light box with no film present (3 000 cd/m^2 in this example);[[24]][[25]]

L_a is the luminance contribution due to ambient illuminance reflected off the film (10 cd/m^2 in this example;[[24]][[25]]

D is the diffuse visual density (densitometer with photopic response, V_λ).

At density $D = 0$ (no film density) the luminance is given by $L_a + L_0 = 3\,010$ cd/m^2. At high densities ($D > 2$, 0), on the other hand, the luminance value asymptotically drops to the value of L_a, which is 10 cd/m^2 in this example.

For the measurement of luminance, i.e. the emission of light from a light source per solid angle, a radiometer is needed. Nevertheless, in the special situation within an ideal field of diffuse light (i.e. in good approximation directly in front of a viewing box) luminance readings (cd/m^2) can be replaced by technically more simple irradiance measurements (lx), which can be obtained with a lux-meter. In this case, the relation lx = π * cd/m^2 holds, i.e. the readings lx/π can be used as input for cd/m^2 (see Annex A).

The luminance L_0 of the light box switched on and with no film present can thus be measured with a lux-meter that faces towards the light box with the measurement port in contact with the diffusing screen of the view box. The luminance L_a of ambient light being reflected off the surface of the medical film on the view box can approximately be measured as follows by placing a representative number of medical hard copy prints on the view box. The view box shall be switched off and the ambient light switched on. Face the lux-meter towards the view box and measure the irradiance (lx) from the typical viewing distance. Care is exercised such that no shadow scene is present more than necessary with your own body and that do direct reflections of lamps on the view box or medical hard copy film are present.

The jnd values of the DICOM SDF actually represent a table of ascending luminance levels, which an average human observer can distinguish. The DICOM SDF is derived from Barten's model of the contrast sensitivity of the human visual system. The SDF represents luminance contrast sensitivity data for periodic sinusoidal gratings with a frequency of 4 cycles / degree as function of viewing conditions.