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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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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”.

