International Standard

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First edition
2024-11

Ophthalmic instruments — Optical coherence tomographs —

Part 1: Optical coherence tomographs for the posterior segment of the human eye

Instruments ophtalmiques — Tomographe à cohérence optique —

Partie 1: Tomographe à cohérence optique du segment postérieur de l'oeil humain

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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 document 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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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

This first edition of ISO 16971-1 cancels and replaces the first edition (ISO 16971:2015), which has been technically revised.

The main changes are as follows:

— revision of the dated references;

— document restructured;

— definitions added with particular emphasis on performance parameters;

— added example performance parameters;

— clarified requirements for presentation of OCT images;

— clarified minimum requirements for data exchange; DICOM required;

— test methods not mandatory anymore; added additional test methods;

— extended requirements for the information to be supplied by the manufacturer;

— deleted annex on *Minimum requirements for a normative database;*

— Annex A *Example for test device* added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Until the early 21st century, it was impossible to obtain clinically relevant depth-resolved information of the inner structures of the human eye, including those of the retina. With optical coherence tomography (OCT), eye care practitioners now have an available non-invasive method that allows the rapid generation of high-resolution three-dimensional in vivo images of the eye. Before the first edition of ISO 16971 was published, there were no well-defined and widely accepted requirements for either OCT instruments or the data collected and displayed with them. Consequently, it was very difficult to compare the instruments, their measurement results, and clinically relevant diagnostic findings based on them.

The first edition of ISO 16971 was an important first step towards defining the necessary terminology and performance requirements for OCT instruments and to establishing standardized framework conditions for the application of OCT technology to ophthalmic imaging.

This edition continues the task by extending the requirements of ISO 16971 and specifying a more comprehensive set of characteristics for OCT instruments. To facilitate this, ISO 16971 has been divided with this document serving as the first part addressing OCT instruments for the posterior segment of the human eye.

Ophthalmic instruments — Optical coherence tomographs —

Part 1:
Optical coherence tomographs for the posterior segment of the human eye

1 Scope

This document is applicable to optical coherence tomography (OCT) instruments, systems, and methods that are intended to image and measure the biological tissue of the posterior segment of the human eye.

This document specifies characteristics and minimum requirements for OCT instruments and systems. It specifies type tests and procedures to verify that a system or instrument qualifies as an OCT instrument or system in accordance with this document.

NOTE In this document the term OCT refers to ophthalmic applications.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

ISO 15004-2, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements*

NEMA PS3/ISO 12052, *Digital Imaging and Communications in Medicine (DICOM) Standard*, National Electric Manufacturers Association, Rosslyn, VA, USA (available free at https://www.dicomstandard.org/).

3 Terms, definitions and symbols

For the purposes of this document, the terms and definitions given in ISO 15004-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
A-scan
one-dimensional axial profile of sample reflectance

Note 1 to entry: axial is the direction of incidence of the measuring beam.

Note 2 to entry: An A-scan is typically depicted either as a plot of reflectance versus depth or as a column in a B-scan image with intensity corresponding to reflectance.

3.1.2
B-scan
two-dimensional cross-sectional measurement of sample reflectance, typically depicted on a display as intensity as a function of depth and transverse position

Note 1 to entry: A B-scan is often constructed by transverse scanning and placing neighbouring A-scans side by side.

3.1.3
en-face OCT image
2D transverse OCT image derived from the OCT signal between transverse surfaces in an OCT volume, where these transverse surfaces are usually derived by image processing that identifies boundaries between layers in the tissue

Note 1 to entry: Typically, an en-face OCT images is associated with a transverse volume slab of a given layer of tissue, e.g. retinal nerve fibre layer (RNFL), retinal pigment epithelium (RPE) or choroid.

3.1.4
manufacturer
natural or legal person with responsibility for design or manufacture of an ophthalmic instrument with the intention of making the ophthalmic instrument available for use, under their name, whether or not such an ophthalmic instrument is designed or manufactured by themselves or on their behalf by another person

[SOURCE: ISO 13485:2016, 3.10, modified — The word "medical device" has been replaced by "ophthalmic instrument" and the original notes to entry have been deleted. Text has been made gender-neutral.]

3.1.5
OCT volume
three-dimensional (spatial) representation of the results of a volume scan

Note 1 to entry: An OCT cube is a subtype of an OCT volume.

3.1.6
ophthalmic instrument
device designed to have an application to the eye, and intended by its *manufacturer* (3.1.4) to be used in the diagnosis, treatment, or monitoring of a patient, or for compensation or alleviation of disease, injury or disability

[SOURCE: ISO 15004-1:2020, 3.1]

3.1.7
optical coherence tomograph
OCT instrument
medical device or system that measures, processes, and displays OCT images of target objects

3.1.8
optical coherence tomography
OCT
optical interferometric measurement technique for obtaining cross-sectional images of a target object, using partially coherent optical radiation to determine the relative depths of backscattering structures within the object

EXAMPLE Biological tissue of the human eye is an example of a target object.

3.1.9
standard eye
emmetropic eye that has a focal length of 17 mm in air and with retinal tissue with an index of refraction of n = 1,33 to n = 1,39

Note 1 to entry: The manufacturer specifies the index of refraction.

3.1.10
structural OCT image
two-dimensional image representing the reflectance of the sample tissue along a surface

Note 1 to entry: Typically, the representation of results of one or multiple B-scans.

3.1.11
volume scan
three-dimensional sampling of the reflectance of the sample tissue

Note 1 to entry: Often realised as a sequence of spatially adjacent B-scans.

3.1.12
volume slab
slab
contiguous region of interest in an OCT volume, roughly in the form of a layer or slice

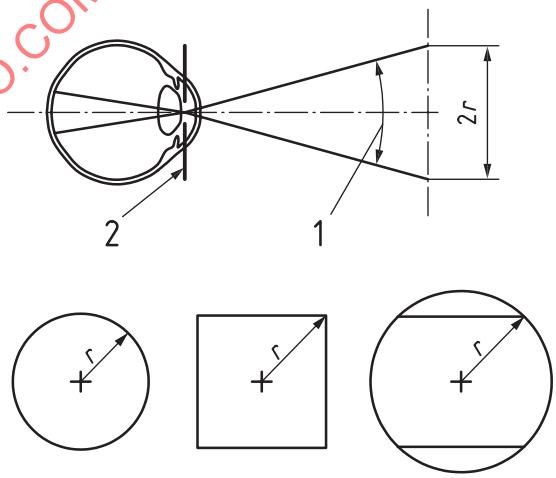
Note 1 to entry: A slab can follow an anatomical structure or can be plane. It can be as thick as the retina or as thin as a single surface.

3.2 Optical properties

3.2.1
angular field of view
FOV
angular extent from which an image can be taken, expressed as the angle subtended at the exit pupil of the eye by the maximum dimension 2r

[SOURCE: ISO 10940:2009, 3.2, modified]

Note 1 to entry: See Figure 1.



Key
1 angular field of view
2 entrance pupil of instrument/exit pupil of eye

Figure 1 — Meaning of dimension r for various formats

3.2.2
axial range
measuring range of the OCT instrument in the axial direction in tissue in a *standard eye* (3.1.9)

Note 1 to entry: This corresponds to the length of an A-scan.

Note 2 to entry: The axial range can be calculated by dividing the optical path length range by the assumed refractive index of the tissue.

3.2.3
axial resolution
full width half maximum of the OCT signal of a single punctiform reflector in axial direction, given in tissue in a standard eye

3.2.4
transverse range
transverse extent of an OCT image at the image plane in a standard eye

3.2.5
transverse optical resolution
full width at half maximum of the OCT signal of a single punctiform reflector in transverse direction, given in tissue in a standard eye

3.3 Signal characteristics

3.3.1
axial sampling density
distance between the corresponding locations in tissue for two adjacent OCT image pixels in axial direction

3.3.2
axial signal roll-off
attenuation in OCT signal with axial depth in tissue, specified by the decrease in sensitivity at a given axial location in the image window relative to the maximum sensitivity

3.3.3
sensitivity
ratio between irradiated optical power and minimum detectable optical power reflected back from the sample to the system

Note 1 to entry: Sensitivity is typically expressed in decibels.

Note 2 to entry: Sensitivity of OCT instruments is not the same as the term sensitivity used to describe clinical accuracy for clinical performance testing.

Note 3 to entry: In the OCT literature, 'sensitivity' is frequently used to denote 'maximum sensitivity.'

3.3.4
maximum sensitivity
sensitivity (3.3.3) measured at the axial depth of the greatest signal

3.3.5
minimum sensitivity
sensitivity (3.3.3) measured at the axial depth of the least signal

3.3.6
transverse sampling density
displacement of the OCT beam between neighbouring A-scans or B-scans

3.4 Optical coherence tomography angiography

3.4.1
optical coherence tomography angiography
OCTA
imaging method for detecting motion contrast by means of *optical coherence tomography* (3.1.8), typically used for visualising blood vessels

Note 1 to entry: OCTA quantifies difference among multiple scans of the same tissue volume.

3.5 Anatomy and physiology

3.5.1
retinal thickness
axial distance between the first inner surface of the retinal nerve fibre layer (inner limiting membrane) and the retinal pigment epithelium (RPE)

3.6 Data processing

3.6.1
lossless compression
technique where the decompressed image is identical to the original uncompressed image

[SOURCE: ISO 12651-1:2012, 4.87]

3.7 Symbols

The symbols used in this document are given in Table 1.

Table 1 — Symbols and quantities

Symbol	Quantity
d_{glass}	Thickness of sample glass
n_{glass}	Index of refraction of sample glass
n_{tissue}	Index of refraction of posterior segment tissue for a standard eye ($1{,}33 \leq n_{tissue} \leq 1{,}39$)
N_{glass}	Thickness of a sample glass piece in axial direction, expressed in pixels
N_{total}	Total image height of an OCT image in axial direction, expressed in pixels
S	Sensitivity of the OCT instrument
R_{sample}	Reflectivity of sample surface
T_{filter}	Transmission of neutral density filter (ND filter)
P	OCT signal height: quantity proportional to the measured radiant power of the optical radiation backscattered at the sample surface[a]
P_{sample}	OCT signal height of sample surface
σ_{bg}	Standard deviation of the OCT signal height of the noise floor
[a] The square root of this quantity is proportional to the amplitude of the interference fringes.	

4 Requirements

4.1 General

The optical coherent tomograph shall conform to the requirements specified in ISO 15004-1, IEC 60601-1, IEC 60825-1, and the requirements described in 4.2 to 4.4.

NOTE The definition of a laser product in IEC 60825-1 applies to an optical coherence tomograph with a superluminescent diode as radiation source.

4.2 Construction and function

4.2.1 Optical properties and specifications

OCT instruments shall provide specifications for transverse optical resolution, axial optical resolution, axial range, maximum sensitivity, minimum sensitivity, angular field of view and axial signal roll-off.

Table 2 provides examples with typical values.

Table 3 lists the tolerance requirements.

Table 2 — Example with typical values

Specification	Typical value
Transverse optical resolution	≤30 µm
Axial optical resolution	≤15 µm
Axial range	≥1,5 mm
Maximum sensitivity	≥95 dB
Minimum sensitivity	≥85 dB
Angular field of view	≥20°
Axial signal roll-off at 1 mm depth in tissue	≤6 dB

4.2.2 Tolerance requirements

OCT instruments shall conform to the requirements in Table 3.

Table 3 — Requirements for tolerances

Specification	Requirement
Tolerance on axial range	±3 %
Tolerance of the angular field of view	±5 %

4.2.3 Co-alignment of fundus image and OCT hardware

If the instrument provides a fundus image and it does not correct the alignment through software, then the co-alignment of any marker on the fundus image and the corresponding OCT scan position shall have a maximum distance of 100 µm over the central field of view (diameter of 20°) in static conditions, for the environmental conditions indicated in the technical description.

NOTE As an example, if the readout is a two-dimensional fundus image, the position/location can be indicated by a line positioned on the two-dimensional fundus image. Similarly, if the readout is a three-dimensional fundus image, the position/location can be indicated by a plane positioned on the three-dimensional fundus image.

4.2.4 Light hazard protection

The OCT shall conform to all requirements specified in ISO 15004-2, with the exception that if the first edition applies, then for ISO 15004-2:2007[1)], Table 2, 5.4.1.4 and Table 4, 5.5.1.3, a 3,5 mm diameter irradiance averaging aperture rather than a 1 mm diameter aperture shall apply.

1) This document is being revised by ISO/FDIS 15004-2:2024.

4.3 Analysis and presentation of results

4.3.1 Presentation of structural OCT images

To facilitate the interpretation and comparison of structural OCT images taken with different OCT instruments, a standardized grey scale display shall be offered.

The standardized grey scale display shall employ a continuous grey scale with values corresponding to the amount of detected light at each pixel (which is proportional to P).

NOTE 1 Typically, a logarithmic characteristic curve is used for the grey scale.

NOTE 2 OCT instruments complying with this document can additionally provide displays using parameters different from these standardized ones, e.g. colour displays.

4.3.2 Retinal thickness measurement

4.3.2.1 General

The calculation of the retinal thickness shall be performed assuming refractive indices within the range from n = 1,33 to n = 1,39[11][12][13][14][15].

4.3.2.2 Presentation of retinal thickness maps

OCT instruments should offer a colour coded retinal thickness map.

4.3.3 Reference database

For OCT instruments, a reference database for measurements can be included. In this case, the OCT instrument should be capable of comparing the result of each tested location for these measurements with the age-specific normal mean value and distribution of normal values.

If multiple reference databases are included, the version of the normal value table used shall be specified on the display by a unique identifier whenever the displayed results depend on it.

Printouts or digital documents presenting results based on the reference database shall contain the unique identifier of the normal value table used.

4.4 Data exchange

All stored OCT images shall be exportable in a digital format. A common raster graphic format shall be supported.

EXAMPLE Possible formats are portable document format (PDF/A-1a version 1.4, see ISO 32000-1, ISO 19005) or standard raster graphic formats like JPEG (see ISO/IEC 10918-1, ISO/IEC 14495 (all parts)) or Portable Network Graphic (PNG, see ISO 15948).

For the export of raster graphics, there shall be no loss of information relative to the images displayed on the instrument. If the displayed images are compressed for export, lossless compression should be used.

OCT images and supported derived data, generated by the OCT instrument, shall be exchangeable via DICOM using SOP classes as specified in DICOM PS3.4: Service Class Specifications, in NEMA PS3/ISO 12052. In doing so, the OCT instrument shall be at least conformant to the Standard SOP Classes of Ophthalmic Photography 8 Bit Image Storage or Ophthalmic Photography 16 Bit Image Storage SOP Class and the DICOM Ophthalmic Tomography Image Storage SOP Class for network exchange.

If the required export functionality is not directly provided by the OCT instrument, it shall include an interface to a specified external system that facilitates this function.

NOTE An example of an external system for this purpose is a PACS (picture archiving and communication system), which supports the storage, archiving, and sharing of medical images.

5 Recommended test methods

5.1 General

All tests described in this document are type tests. The test methods in this chapter are recommendations. Other test procedures are possible if they are scientifically substantiated and measure the corresponding parameters according to their respective definition in Clause 3.

5.2 Measurement setups

The tests specified in this clause should be performed with measuring setups that include a lens with a focal length similar to that of the human eye (17 mm) that focuses the optical OCT radiation. In or near the OCT focal surface, target structures are placed complying with the test conditions specified in the respective subclause.

A neutral density (ND) filter with a known attenuation at the wavelength of the OCT instrument can be added between the lens and the target to prevent detector saturation.

NOTE Uncertainty in the attenuation of the ND filter will affect the sensitivity measurement.

More complex test devices that allow for multiple tests can be used for measurements. An example for such a device is given in Annex A.

The test device should have optical dispersion matching the human eye or dispersion should be accounted for numerically when analysing the measurement data.

5.3 Test methods for optical properties

5.3.1 Transverse optical resolution

For transverse optical resolution, either of the methods given in 5.3.1.1 or in 5.3.1.2 should be used.

5.3.1.1 Sharp edge method

Use a knife edge or another sharply delineated structure in front of a scatterer and perform the following procedure:

a) Take at least one B-scan across the edge;

b) Use the resulting average linear power profile to determine the edge response function;

c) Calculate the derivative of the edge response function to determine the line spread function.

The transverse optical resolution should then be determined by measuring the width (full width at half maximum) of the line spread function.

5.3.1.2 Microbead method

The measurement setup should include a target with nanoparticles (e.g. polystyrene microbeads or FeO particles) of appropriate size and distribution.

NOTE For nanoparticle targets see References [15] and [16].

At least one B-scan should be taken and the reflectance peak of several point scatterers along the lateral dimension should be evaluated. The full width at half maximum should be calculated from the averaged linear power profile to quantify the transverse optical resolution.

5.3.2 Axial optical resolution

At least one A-scan should be taken along the optical axis of the test device. The image depth should be sufficient to capture the reflex of the front plane of a glass plate, allowing for the measurement of the reflex width. The width (full width at half maximum of the averaged linear power profile) of the reflex from the glass plate should be measured to quantify the axial resolution.

5.3.3 Axial range

For axial range, z_{max}, the test device should include a piece of glass on the order of 1 mm thickness whose thickness d_{glass} and refractive index n_{glass} are known. The thickness of the glass slide should be measured in the OCT scan in units of pixels.

The axial range in tissue is determined by Formula (1).

$$z_{max} = N_{total} \cdot [(n_{glass}/n_{tissue}) \cdot d_{glass}]/N_{glass} \quad (1)$$

NOTE An air gap on the order of 1 mm thickness can also be used for the measurement.

5.3.4 Angular field of view

Angular field of view measurement should be conducted using an OCT focal surface that simulates the curvature of the human retina. The focal surface should contain calibrated scale marks (e.g. concentric circles with equal visual angle increments around the optical axis).

A centered B-scan of maximum length setting should be performed and the OCT FOV should be evaluated by counting the scale marks in the OCT image.

5.4 Test methods for signal quality

5.4.1 Sensitivity

For sensitivity, the measurement setup should include a flat glass surface with known reflectivity of the glass R_{sample} and an ND filter with known transmission T_{filter}. The signal height P_{sample} of the specular glass reflex above the noise floor σ_{bg} is measured and the sensitivity S is determined by Formula (2):

$$S = 10 \cdot \log_{10}(P_{sample}/\sigma_{bg}) - 10 \cdot \log_{10}(R_{sample} \cdot T_{filter}^{2}) \quad (2)$$

NOTE Formula 2 gives the sensitivity in decibels.

5.4.2 Axial signal roll-off

For axial signal roll-off, the sensitivity is measured as a function of depth position within the OCT image. To vary the depth position, the reference and/or the sample arm of the OCT interferometer is changed.

NOTE If the sample arm length is changed, then the position of the test device needs to be maintained at a pupil conjugate.

5.5 Co-alignment of fundus image and OCT scan

5.5.1 General

The measurements in this subclause are only required, if

— the OCT instrument provides an independent fundus image that is not calculated from the same OCT data as the corresponding OCT image, and

— the co-location between the fundus image and the OCT scans is not established by a software function after each scan.

NOTE If the fundus image is calculated from the same OCT data as the corresponding OCT image, then the spatial correlation is necessarily perfect, and no measurement is necessary.

If the OCT instrument is capable of performing volume scans and calculating en-face images, the method described in 5.5.2. should be used, otherwise the method described in 5.5.3 should be used.

5.5.2 En-face method

Use a measurement setup with a suitable structured target in the OCT focal plane that covers at least the central 20° field of view and perform the following procedure:

a) Take an OCT volume scan covering at least the central 20° field of view;

b) Calculate a suitable en-face OCT image from the volume scan e.g., an axial projection;

c) Register the en-face image and the corresponding fundus image relative to each other and calculate the average transverse displacement;

d) In the registered images, measure the transverse displacement of a representative number of off-centre features that are clearly discernable in both images and cover the field of view;

NOTE This requirement can be fulfilled by calculating a dense displacement map that includes the test locations.

e) Check the results. The positioning is in tolerance if the displacement values determined in c) and d) are smaller than 100 µm.

5.5.3 Line scan method

Use a measurement setup that has a filament or other suitable linear structure with a width of 200 µm and perform the following procedure:

a) Place the test device in position (equivalent to patient eye);

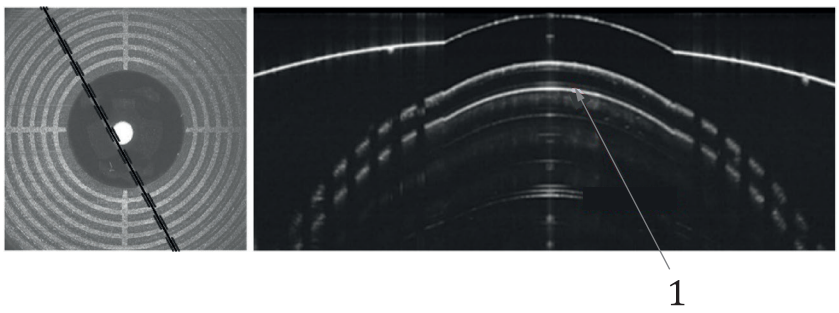
b) Use OCT scan line mode;

c) Position the scan preview line to be congruent with the filament of the test device (including angle, lateral x and y);

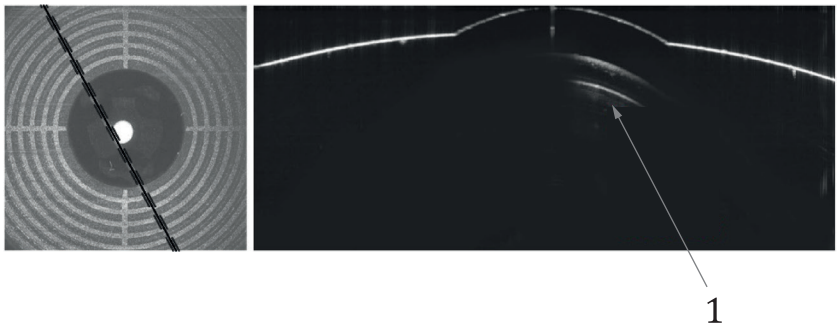
d) Check the resulting OCT scan signal.

— The positioning is in tolerance, if the OCT signal is present on the full scan length, according to the length of filament [see Figure 2 a)];

— The positioning is not in tolerance if the OCT signal is only in part or even not present [see Figure 2 b)].



a) Co-alignment in tolerance[a]



b) Co-alignment not in tolerance[b]

Key

1 filament

[a] Left: preview scan line (dashed) is congruent with filament (black). Right: OCT signal shows filament in full length.

[b] Left: preview scan line (dashed) is congruent with filament (black). Right: OCT signal shows small intersection with filament only or even no signal.

Figure 2 — Illustration of evaluation of OCT scan signal

6 Information to be supplied by the manufacturer

6.1 General

The OCT instrument shall be accompanied by documents containing at least instructions for use and a technical description. In particular, these shall contain the following information:

a) name and full address of the manufacturer;

b) any additional information as specified in IEC 60601-1 and in ISO 15004-1;

c) information about potential optical radiation hazards as specified in ISO 15004-2;

d) a reference to this document, i.e. ISO 16971-1:2024, if the manufacturer or supplier claims compliance with it.

NOTE The technical description can be included in other accompanying documents e.g. the instructions for use

6.1.1 Warnings and safety-related information

6.1.1.1 Artefacts

The accompanying documents shall contain a description of all known clinically relevant imaging artefacts with examples and instructions on how to recognise them.

Instructions to avoid or reduce artefacts shall be included if a clinically relevant reduction is practicably possible for the user.

NOTE 1 This includes possible artefacts in the fundus image or in data analysis modes like optical coherence tomography angiography (OCTA).

NOTE 2 Whether an artefact is clinically relevant is generally determined by the manufacturer by a risk management process according to ISO 14971.