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Ophthalmic optics and instruments — Optical devices for enhancing low vision

Optique et instruments ophtalmiques — Dispositifs optiques pour malvoyants

Reference number
ISO 15253:2000(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15253 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A and B of this International Standard are for information only.

Ophthalmic optics and instruments — Optical devices for enhancing low vision

1 Scope

This International Standard applies to optical devices specified by the manufacturer for use by visually impaired persons as optical low-vision aids. It specifies the optical and mechanical requirements and test methods for such devices, including optical devices with electrical components such as illuminators.

It does not apply to electro-optical devices for enhancing low vision.

NOTE Requirements and test methods for electro-optical devices for enhancing low vision are specified in ISO 15254, *Ophthalmic optics and instruments — Electro-optical devices for low vision*.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 12870, *Ophthalmic optics — Spectacle frames — General requirements and test methods.*

ISO 14889, *Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses.*

ISO 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods.*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply. The symbols for certain of these terms are language-dependent. Equivalent terms in other languages, and the corresponding symbols used in those languages as well as in English, are given in annex B.

3.1
astronomical telescope
Keplerian telescope
compound optical system, afocal in normal adjustment, consisting of a positive objective element or group and a positive ocular element or group forming a magnified, inverted image

3.2
binocular aid
optical device, usually consisting of two separate optical systems mounted in alignment, intended to be used with both eyes simultaneously

3.3
biocular aid
optical device in which both eyes view through a single optical system

3.4
distance cap
negative lens placed in front of a near-vision telescope/telemicroscope objective to adapt the device for viewing a distant object

3.5
equivalent power
reciprocal of the equivalent focal length in air measured in metres

NOTE Equivalent power is expressed in dioptres, or reciprocal metres.

3.6
eyepiece
ocular
optical element or group nearest to the eye in an optical imaging system, used for viewing the image formed by the objective

3.7
focal length
linear distance separating the principal focal point (or focus) of an optical system from a point of reference

See Figure 1.

NOTE The distance needs to be further specified in accordance with the point of reference chosen, e.g. vertex, principal point. See definitions 3.7.1 to 3.7.3.

3.7.1
back vertex focal length
distance in an optical system from the back surface to the back focal point, measured along the optical axis (axis of symmetry)

See Figure 1.

3.7.2
front vertex focal length
distance in an optical system from the front surface to the front focal point, measured along the optical axis (axis of symmetry)

See Figure 1.

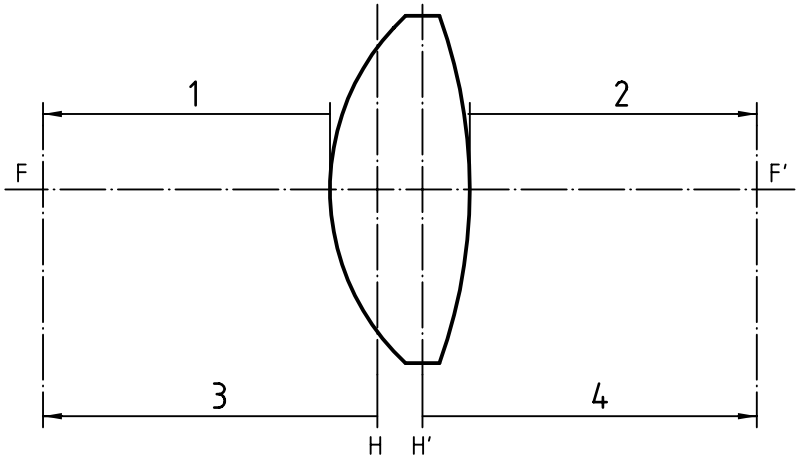
3.7.3
equivalent focal length
distance in an optical system from a focal point to the corresponding principal point, measured along the optical axis (axis of symmetry)

See Figure 1.

NOTE See **equivalent power** (3.5).

3.8
focusing telescopic device
device intended to be adjusted by the user for a range of object distances

3.9
free working distance
⟨optical low vision aid⟩ distance between the most anterior portion of a near-vision telescope/telemicroscope and the object



Key

1 Front vertex focal length
2 Back vertex focal length
3 Focal length
4 Equivalent focal length

Figure 1 — Illustration of focal lengths

3.10
Galilean telescope
compound optical system, afocal in normal adjustment, consisting of a positive objective element or group and a negative ocular element or group forming a magnified, erect image

3.11
hand magnifier
device intended to be positioned and supported by the user's hand and without artificial support

3.12
linear field of view
⟨of a low vision aid⟩ maximum observable extent of the object plane visible through the low vision aid under the conditions of use stated by the manufacturer

3.13
low vision aid
device used by visually impaired persons to enhance vision

3.14
low vision-aid telescope
optical system, Keplerian with inverted image or Galilean, that forms a magnified retinal image of an object

3.14.1
hand telescope
telescope designed to be hand-held

3.14.2
spectacle telescope
telescope mounted in or on a spectacle frame

3.15
magnification
ratio between any linear dimension of the retinal image when the magnifying device is in use and the corresponding dimension when the object is viewed without the magnifying device

3.15.1
angular magnification
ratio of the angle subtended by the image to that subtended by the object at a viewing point of reference such as the entrance pupil of the eye

3.15.2
nominal magnification
M
⟨for magnifiers⟩ magnification calculated from the product of the reference seeing distance (see 3.20), in metres, and the equivalent power F (see 3.5), in dioptres

EXAMPLE With a reference seeing distance of 0,25 m the nominal magnification is calculated from the formula $M = 0{,}25\ F$.

3.15.3
trade magnification (deprecated)
M_{trade}
⟨for magnifiers⟩ magnification calculated from the formula:

$$M_{\text{trade}} = M + 1$$

NOTE This definition is included since some text books on low vision refer to trade magnification. This term should not be used in future.

3.16
magnifier
low vision-aid microscope
lens system designed to produce an enlarged image

NOTE It may be a simple single element or a compound multiple-element system.

3.16.1
spectacle magnifier
spectacle microscope
magnifier in the form of spectacles and intended to be worn as spectacles, mounted or held close to the eye, which includes power in addition to a normal near correction

3.16.2
illuminated magnifier
magnifier incorporating illumination

3.17
monocular aid
optical device to be used before only one eye

3.18
optical dimensions
zone of optical dimensions
optical zone of magnifier
usable linear size of a magnifier when mounted

NOTE It is expressed in millimetres.

3.19
reading cap
positive lens placed in front of a telescopic objective to adapt the device for viewing a near object

3.20
reference seeing distance
least distance of distinct vision (deprecated)
agreed distance of 250 mm between the anterior corneal vertex of the eye and the object observed

NOTE The reference seeing distance is used, above all, as a reference parameter for calculating the magnification of optical instruments used for near vision.

3.21
relative distance magnification
change in the size of the retinal image that is obtained by changing the viewing distance

3.22
resolution
smallest separation between two details, expressed as a linear or angular measurement, at which a pair of points may be recognized as being separate under a given set of conditions

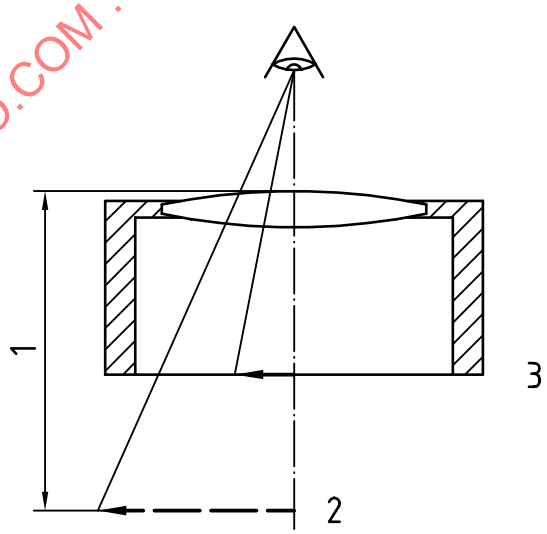
3.23
stand magnifier
magnifier in which the support is designed to position the optical system at a set or adjustable distance from the object to be viewed

3.23.1
vertex image distance
⟨for stand magnifiers⟩ distance from the magnifier surface nearest to the eye to the virtual image when the object is placed at the designated position

See Figure 2.

3.23.2
exit image vergence
⟨for stand magnifiers⟩ reciprocal of the vertex image distance, expressed in metres

NOTE The unit of vergence is the dioptre.



Key
1 Vertex image distance
2 Image plane
3 Object plane

Figure 2 — Illustration of vertex image distance, object plane and image plane

3.24
telemicroscope
near-vision telescope
telescope adapted for viewing near objects

3.25
terrestrial telescope
astronomical telescope to which has been added an erecting system

4 Classification

4.1 Magnifiers

a) Hand-held

b) Stand

c) Head-mounted, including spectacles and spectacle-mounted

4.2 Telescopes — Distance vision

a) Hand-held

b) Head-mounted, including spectacles and spectacle-mounted

4.3 Telescopes — Near-vision/telemicroscopes

a) Hand-held

b) Head-mounted, including spectacles and spectacle-mounted

4.4 Telescopes — Adjustable

a) Hand-held

b) Head-mounted, including spectacles and spectacle-mounted

5 Requirements

5.1 Optical characteristics

5.1.1 Resolution

5.1.1.1 General

The resolution of the optical device shall be measured at an object contrast level of not less than 80 %.

5.1.1.2 Magnifiers and telemicroscopes/near vision telescopes

When tested in accordance with 7.4, the device shall resolve a target which consists of line pairs measuring not more than 0,233 mm per pair (0,116 mm per element) within the central 70 % of the linear field of view, for targets having white light meeting the specifications of CIE standard illuminant D65 within the illuminance range of 750 lx to 1000 lx with the device used as intended by the manufacturer.

5.1.1.3 Telescopes

When tested in accordance with 7.4, the device shall resolve targets consisting of line pairs subtending an angle of 2′ (or less) having elements subtending an angle of 1′ (or less) within the central 70 % of the linear field of view, or the central 10°, whichever is the smaller, unless these requirements exceed the diffraction limits of the device. In that case, the target when specified in cycles per degree shall not be less than 50 % of the diffraction limit for monochromatic light at 555 nm within the above specified area. The telescope shall meet these requirements at the limits of the claimed working range.

5.1.2 Equivalent power — Magnifiers

The equivalent power of the magnifier measured along the optical axis shall not deviate by more than 5 % of the value declared by the manufacturer. The difference in power between the two meridians shall not be more than 2,5 %.

For magnifiers designed with significantly different powers in the two meridians, the deviation of the equivalent power in the two principal meridians shall not total more than ± 2,5 % of the stronger power.

5.1.3 Angular magnification — Telescopes

The angular magnification of the telescope measured along the optical axis shall not deviate by more than 5 % of the value stated by the manufacturer.

5.1.4 Lateral variation of magnification — Magnifiers and telescopes

When the linear field of view of the device is examined as described in 7.5, the variation in magnification over the central 70 % of the linear field shall comply with Table 1 or Table 2.

The manufacturer shall state the method of testing.

Table 1 — Magnifiers/Near telescopes

Equivalent power dioptres	**Lateral variation of magnification** %
up to 12	5
over 12 to 20	10
over 20	15

Table 2 — Distance telescopes

Magnification	**Lateral variation of magnification** %
below 3 ×	2,5
3 × to 5 ×	5
over 5 ×	7,5

5.1.5 Transmittance

If claims about transmittance are made by a manufacturer, the measurements should comply with the relevant International Standard[1)] and the appropriate transmittance curves shall be made available on request.

1) ISO 14490-5, *Optics and optical instruments — Test methods for telescopic systems — Part 5: Test methods for transmittance,* is in course of preparation.

5.2 Materials and construction

5.2.1 Materials

Components designed to come into direct contact with the skin of the patient shall be made from a material which, when used as intended by the manufacturer, shall conform with ISO 15004.

5.2.2 Flammability

When the device is tested as described in ISO 15004, there shall be no continued combustion after withdrawal of the test rod.

5.2.3 Resistance to immersion

For devices that are claimed to withstand immersion in water, the following requirement shall be met:

After the device has been fully immersed for 5,0 min ± 0,5 min in water at 40 °C to 45 °C and allowed to dry in air at 20 °C ± 5 °C, it shall comply with all requirements specified in this International Standard.

5.2.4 Resistance to perspiration

Parts of the device covered by the scope of ISO 12870 (spectacle frames) shall meet the relevant requirements of ISO 12870.

5.2.5 Robustness of head-mounted, including spectacles and spectacle-mounted, devices

Parts of the device covered by the scopes of ISO 12870 (spectacle frames) and of ISO 14889 (spectacle lenses) shall meet the relevant requirements of ISO 12870 and ISO 14889.

5.2.6 Resistance to drop

If claims are made that the device is drop-resistant, the manufacturer shall state the conditions under which this claim is made and the conditions of testing.

6 Environmental conditions of use

Under the environmental conditions of use given in Table 3, all requirements specified in this International Standard shall be met. These requirements take precedence over 5.1 of ISO 15004:1997.

Table 3 — Environmental conditions of use

Criterion	Environmental condition
Temperature	–25 °C to +35 °C
Relative humidity	30 % to 85 %
Atmospheric pressure	800 hPa to 1060 hPa
Shock (without packing) [a]	10 *g* during 6 ms
[a] Applicable to hand-held devices only.	

7 Test methods

7.1 General

All the methods described are type tests. Equivalent alternative methods are acceptable but it is the responsibility of the manufacturer/tester to demonstrate the equivalence of the methods used.

7.2 Equivalent power — Magnifiers

Test methods for the determination of equivalent power shall be used which have, at a confidence level of 95 %, relative uncertainties of less than 0,5 %.

7.3 Angular magnification — Telescopes

Test methods for the determination of angular magnification shall be used which have, at a confidence level of 95 %, relative uncertainties of less than 0,5 %.

7.4 Resolution test

7.4.1 Test principle

The following test set-up is used to test the resolving power of low vision aids. The optotype consists of Ronchi rulings orientated in the directions 90°, 180°, 45° and 135° (see Figure 3 for an example). The criterion for assessing the resolution is the successful recognition of the various directions of the ruling. In the test, the portion of the linear field of view is measured in which the optotype can be resolved.

The visual acuity required of the observer is at least 1,0.

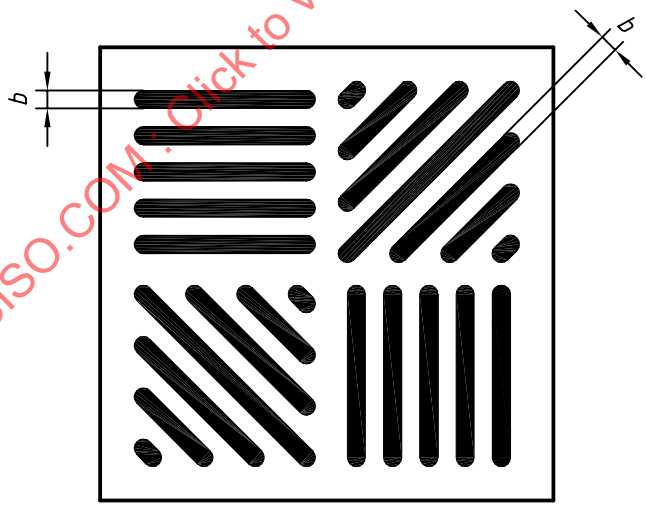


Figure 3 — Example of an optotype with Ronchi rulings

7.4.2 Test set-up

7.4.2.1 General

To perform the test, set up the experiment on the optical bench. Position the optotype on a white screen which can be adjusted at 90° to the optical bench. The range of adjustment corresponds to at least the horizontal extent of the field of view of the low vision aid to be tested.

The illumination of the screen and hence also of the Ronchi ruling is performed using standard illuminant D65 with an illuminance between 750 lx and 1000 lx measured at the plane of the optotype. The optotype consists of a Ronchi ruling with a line width of b = 0,116 mm and a contrast of at least 80 % (see Figure 3).

NOTE The optotype most suitable for this purpose is in the form of deposited metal on glass.

7.4.2.2 For magnifiers and telemicroscopes/near-vision telescopes

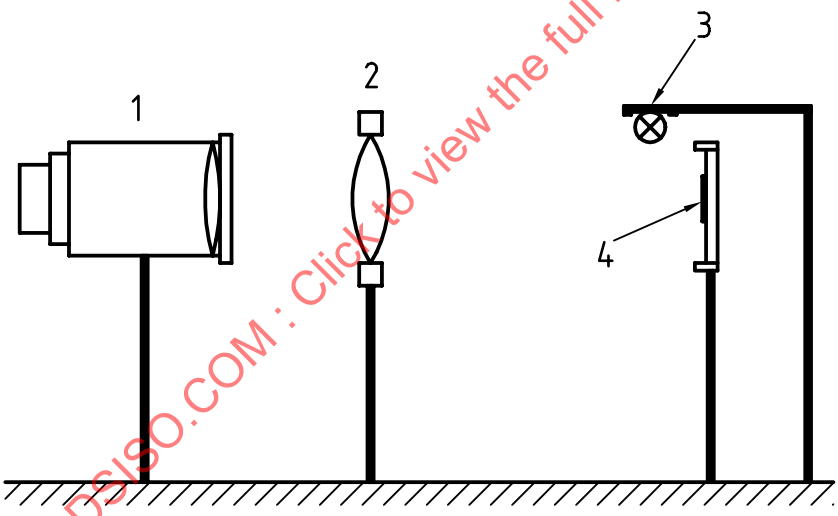
Position a mount to which all of the low vision aids to be tested can be attached in front of the optotype. The distance between the optotype and the low vision aid shall be variable.

Set up an observation telescope with angular magnification between 3 × and 8 × in front of the low vision aid and focus on the image of the optotype. Re-focusing of the observation telescope during the measurement is not allowed.

An example of the set-up is shown in Figure 4. Prior to measurement, align the test set-up so that the x and y directions of the optotype, the low vision aid and the observation telescope correspond.

Set the distance between the low vision aid for near vision and the observation telescope in accordance with the distance between the user's eye and the low vision aid in the manufacturer's instruction for use.

Set the distance between the low vision aid for near vision and the optotype in accordance with the manufacturer's instructions for use.



Key

1 Observation telescope
2 Low vision aid for near vision
3 Illumination of the screen
4 Screen with optotype

Figure 4 — Example of a test set-up for near-vision aids

7.4.2.3 For telescopes

Position a collimator lens which images the optotype at infinity in front of the optotype. For this purpose, bring the optotype into the focus of the collimator.

To ensure that the specified visual angle is not changed, the collimator equivalent focal length shall equal 400 mm for the line width b = 0,116 mm.

Calculation of the collimator equivalent focal length f':

Line width b = 0,116 mm

Visual angle α = 1′ = 0,016 6°

tan $\alpha = b / f'$

therefore f' = b / tan α (where α is in degrees)

therefore f' = 400 mm

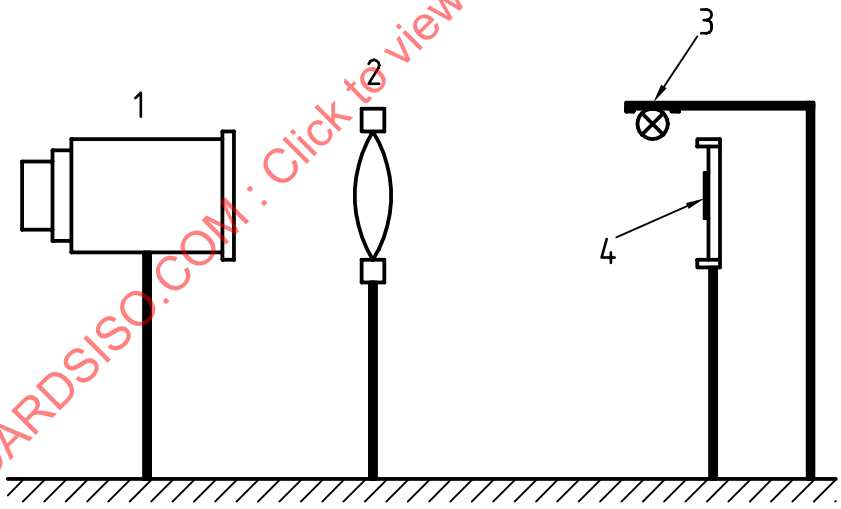
The field of view of the telescope system shall not be limited by the collimator lens. Furthermore, the resolution shall not be influenced by the collimator lens, but only by the system to be tested. To meet this requirement, the diameter of the collimator lens shall be at least 1,2 times the diameter of the entrance pupil of the telescope.

An example of the set-up is shown in Figure 5. Prior to measurement, align the test set-up so that the x and y directions of the optotype correspond with those of the low vision aid and the telescope under test.

The distance between the telescope under test and the collimator shall be as small as possible to ensure that the field of view is not limited by the collimator.

In afocal telescopes, set the distance between the collimator and the optotype to the equivalent focal length of the collimator.

In non-afocal telescopes, adjust the distance between the collimator and the optotype so that the optotype is sharply imaged by the telescope.



Key

1 Low vision aid for distance vision
2 Collimator
3 Illumination of the screen
4 Screen with optotype

Figure 5 — Example of a test set-up for telescopic systems

7.4.3 Test procedure

7.4.3.1 For magnifiers and telemicroscopes/near-vision telescopes

After exact alignment of the test set-up, determine the field of view attainable with the respective low vision aid. Here, move the optotype to the frame edge of the low vision aid in order to establish to what extent the optotype is visible. Perform this action horizontally and vertically. The observation telescope may need to be swung into a new position during this process. Determine the horizontal and vertical extents of the field of view by reading the respective measured values off the scale.

Two values are obtained:

A_{hor} = linear extent of field of view in horizontal direction, measured in millimetres;

A_{vert} = linear extent of field of view in vertical direction, measured in millimetres.

Subsequently repeat the procedure, with the optotype only being moved towards the edge of the low vision aid until one of the directions of the Ronchi ruling cannot be identified. Here once again, the measured values are read off the scale, therefore providing the horizontal and vertical extents of the still-resolvable field of view. The observation telescope shall not be re-focused during this procedure.

The following values are obtained:

A_{hor*} = linear extent of resolvable field of view in horizontal direction (millimetres);

A_{vert*} = linear extent of resolvable field of view in vertical direction (millimetres).

Instead of performing the test in the vertical direction, where the difficulties can be experienced when measuring the extent, it is possible to rotate the low vision aid about 90°.

7.4.3.2 For telescopes

After exact alignment of the test set-up, determine the field of view attainable with the respective low vision aid. Here, move the optotype to the frame edge of the low vision aid in order to establish to what extent the optotype is visible. Perform this horizontally and vertically. Determine the horizontal and vertical extent of the field of view by reading the respective measured values off the scale.

Two values are obtained:

A_{hor} = linear extent of field of view in horizontal direction, measured in millimetres;

A_{vert} = linear extent of field of view in vertical direction, measured in millimetres.

Subsequently repeat this procedure, with the optotype only being moved towards the edge of the low vision aid until one of the directions of the Ronchi ruling cannot be identified. Here once again, the measured values are read off the scale, providing the horizontal and vertical extent of the still-resolvable field of view.

The following values are obtained:

A_{hor*} = linear extent of resolvable field of view in horizontal direction (millimetres);

A_{vert*} = linear extent of resolvable field of view in vertical direction (millimetres).

Instead of performing the test in the vertical direction where the difficulties can be experienced when measuring the extent, it is possible to turn the low vision aid about 90°.

7.4.4 Test evaluation

For the evaluation, use the formula

$(A^* \times 100)/A$

to obtain the percentage of the linear field of view at which the optotype can be resolved.

7.5 Determination of lateral variation of magnification

The determination of lateral variation of magnification shall be performed under the conditions stated in the manufacturer's instruction for use. Measuring devices for the determination of lateral variation of magnification shall be used which have, at a confidence level of 95 %, relative uncertainties of less than 0,5 %.

NOTE An example of a test method is given in annex A.

8 Marking and instructions for use

8.1 Marking

Each device shall be clearly marked with at least the following:

a) identification of the device or the manufacturer;

b) manufacturer's declared value for the equivalent power for magnifiers.

Each device, except those that are custom made, shall additionally clearly be marked with at least the following:

c) manufacturer's declared value for angular magnification for telescopes;

d) manufacturer's declared value for either nominal magnification or equivalent power for telemicroscopes/near-vision telescopes.

8.2 Information to be provided by the manufacturer

The manufacturer shall supply with each device at least the following information, in addition to repeating the items of information specified in 8.1:

a) manufacturer's declared value for the exit image vergence, for stand magnifiers;

b) free working distance, for telemicroscopes;

c) the statement "FIRE RISK — DO NOT LEAVE MAGNIFIER IN DIRECT SUNLIGHT" in upper-case letters, using bold typeface;

d) instructions for the care and cleaning of the device;

e) any characteristic claimed under 5.2.

On request, the manufacturer should make available the following information: the mass of the device, identification of the lens material(s), and the optical dimensions of the magnifier, expressed in millimetres.

Annex A
(informative)

Determination of lateral variation of magnification

A.1 Principle

A series of distortion assessment charts representing barrel distortion at a number of discrete levels are presented in a range of sizes. The grids of the appropriate size are viewed with the magnifier or telescope under defined conditions and the degree of pincushion distortion is estimated from the grid or grids which most nearly compensates for the magnifier's distortion.

NOTE The majority of devices only exhibit pincushion distortion; this test deals with that form of distortion only.

A.2 Apparatus

A.2.1 Hand and stand magnifiers

A.2.1.1 Distortion assessment charts, generated by means of a computer program to represent, respectively, barrel distortions of 0 %, 5 %, 10 %, 15 % and 20 % for hand and stand magnifiers. The charts are presented in six rows in descending order of size.

See Figure A.1.

A.2.1.2 Adjustable brow support, in the form of a stand with a crossbar, in order to standardize the position from which the distortion of the magnifier is assessed.

A.2.2 Distance and afocal telescopes

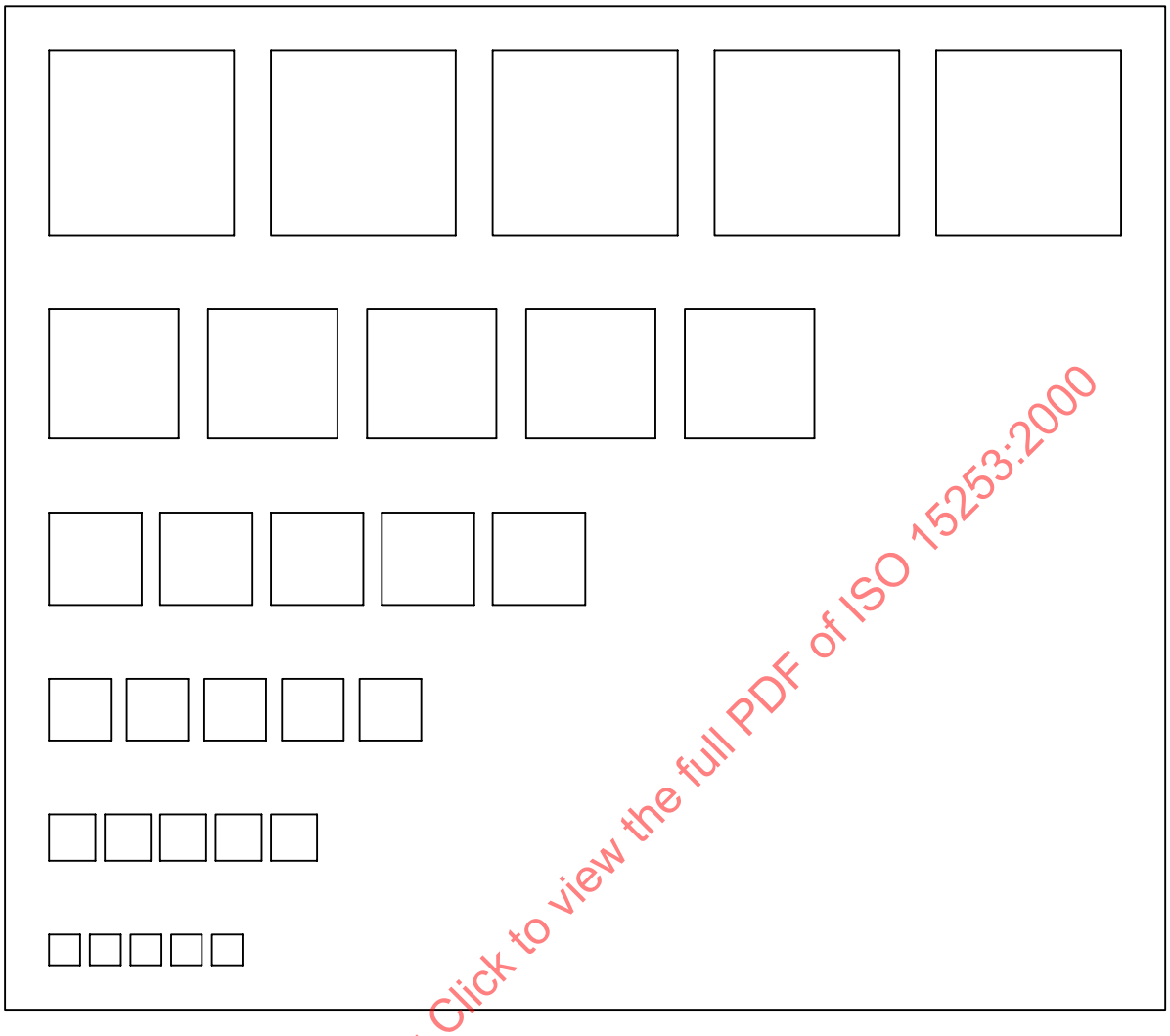
A.2.2.1 Distortion assessment charts, generated by means of a computer program to represent, respectively, barrel distortions of 0 %, 2,5 %, 5 %, 7,5 % and 10 % for, principally, distance telescopes. The charts are presented as 4 × larger versions of those generated for magnifiers. Some near-vision telescopes are found to work better with the magnifier assessment charts, due to their shorter working distances.

A.3 Procedure

A.3.1 Magnifier viewing position

For magnifiers where the object distance is governed by a fixed frame or stand, place the chart flat on a table and mount the magnifier on the chart with the centre spot of a suitable grid on the optical axis of the magnifier. Hand magnifiers shall be attached to an adjustable stand and the distance between the test chart and the magnifier shall be set in accordance with the manufacturer's instructions for use. Move the stand so that the centre spot of a suitable grid is on the optical axis of the magnifier.

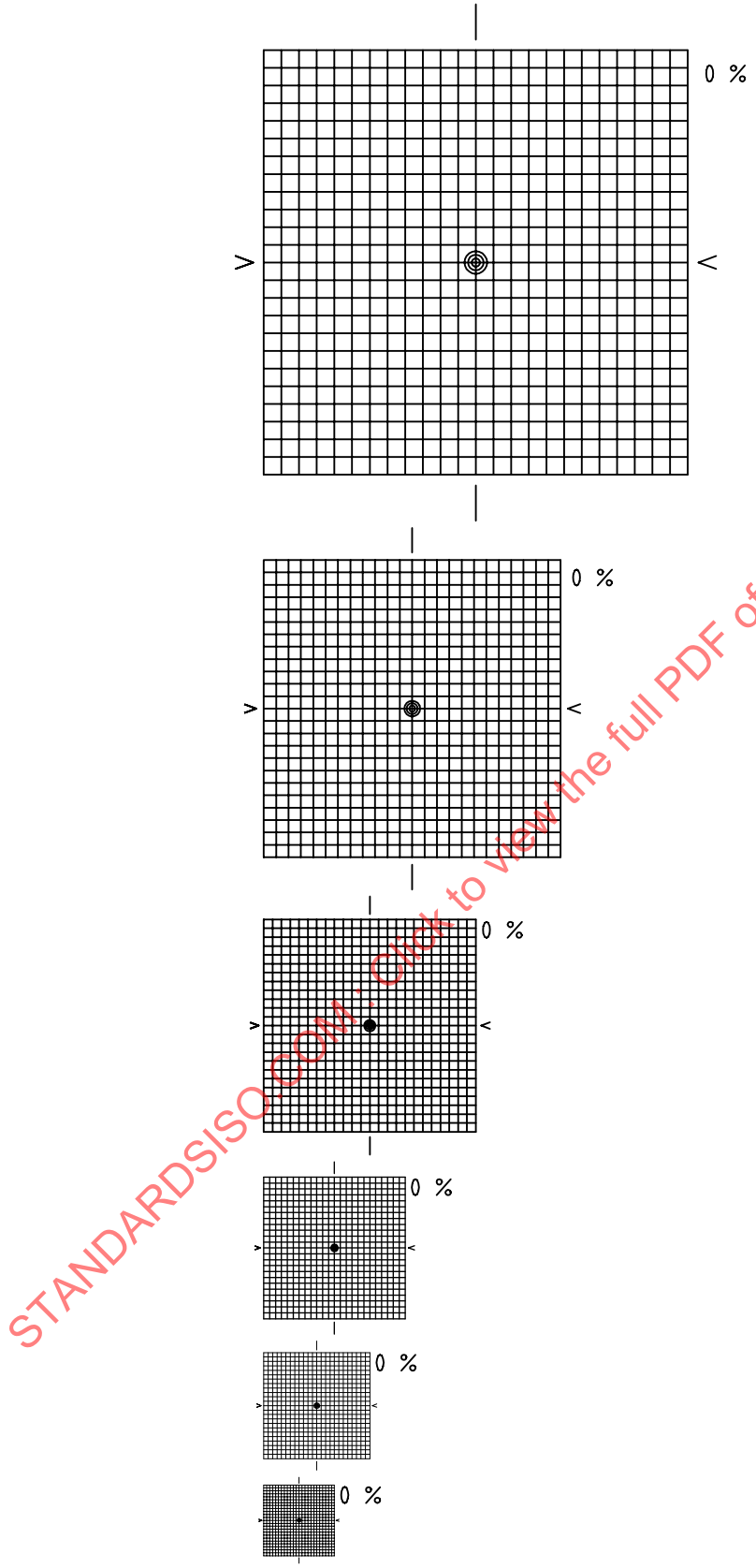
Use the brow support to fix the distance at which the assessment will be done. The distance between the magnifier and the assessor's eye shall be set in accordance with the manufacturer's instructions for use. The assessor's eye shall lie on the optical axis of the magnifier.



NOTE The charts are presented in six rows in descending order of size [see Figure A.1 b) which gives the left-hand column for illustration]. Within each row, the charts give grids in, from left to right, increasing degree of barrel distortion of 0 %, 5 %, 10 %, 15 % and 20 % [see Figure A.1 c) which gives one row for illustration].

a) General layout, with charts/grids shown simplified as blank squares

Figure A.1 — Example of a series of distortion assessment charts



b) Left-hand column of grids, illustrating the sizes of subsequent grids

Figure A.1 — Example of a series of distortion assessment charts *(continued)*