Hangzhou EVERFINE Test and Calibration Technology Co.,Ltd.

Test Report

扫一扫验真伪

Report No. N20260915951003

Applicant:	Chengdu Jasmine Bio Tech INC
Address:	Room 1, 5th Floor, Building 1, Jindiweixin Wenjiang Intelligent Manufacturing Park, No. 88 Haida Road, Jinma Street, Chengdu Cross-Strait Science and Technology Industry Development Park, Wenjiang District, Chengdu, Sichuan Province, China.
Product:	Assistive Assessment System for Brain Physiology and Cognitive Function
Sample Number:	JC20260914-038
Type/Model:	EM-2000C-D01
Manufacturer:	Chengdu Jasmine Bio Tech INC
Standard:	ISO 15004-2:2024 Ophthalmic instruments-Fundamental requirements and test methods-Part 2:Light hazard protection
Receipt Date:	2026 Y 09 M 15 D
Testing Period:	2026 Y 09 M 15 D ~ 2026 Y 09 M 16 D
Issued Date:	2026 Y 10 M 09 D
Approved by:	
Verified by:	
Tested by:	

Effective Stamp

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DECLARATION

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2、 The test report will be deemed invalid without signatures (or stamps) of the test, reviewer and authorized personnel, and the stamp of our organization.

3、 If there is any dissent of the report, the customer shall notify our organization within 15 days after the report issued.

4、 The result is for reference mainly in scientific research, teaching, internal quality control, etc.

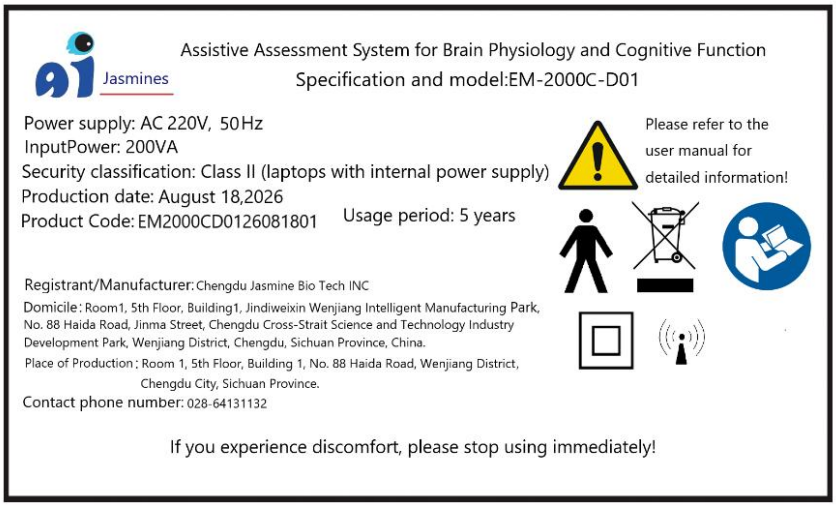
5、 The data of this report originates from the report numbered N20260915951001.This report is the copy of the report numbered N20260915951001.

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7、 All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.

Hangzhou EVERFINE Test and Calibration Technology Co.,Ltd.

Test Report

Sample information	Name of Sample	Assistive Assessment System for Brain Physiology and Cognitive Function
	Type/ Specification	Main Tested Model EM-2000C-D01 Covered Model EM-2000C-D02、EM-2000C-D03
	Ex-Factory No.	EM2000CD0126081801
	Sample No.	JC20260914-038
	Manufacture	Manufacturer: Chengdu Jasmine Bio Tech INC Address：Room 1, 5th Floor, Building 1, No. 88 Haida Road, Wenjiang District,
	Rated Voltage /Frequency	AC220V, 50Hz
	Appearance	Normal
	Sample Picture	 Front side  Nameplate

<table>
<tr><td></td><td colspan="5">The Name of Sample,Type/Model .Rated Voltage/Frequency and Manufacturer are provided by the Applicant.</td></tr>
<tr><td rowspan="10">Test overview</td><td>Test type</td><td colspan="4">Sample commission</td></tr>
<tr><td>Standard methods</td><td colspan="4">ISO 15004-2:2024 Ophthalmic instruments-Fundamental requirements and test methods-Part 2:Light hazard protection</td></tr>
<tr><td>Basis for conformity assessment</td><td colspan="4">ISO 15004-2:2024 Ophthalmic instruments-Fundamental requirements and test methods-Part 2:Light hazard protection</td></tr>
<tr><td>conformity assessment rules</td><td colspan="4">Binary assessment rules that are simply accepted</td></tr>
<tr><td>Test place</td><td colspan="4">Optical Radiation Metrology and Calibration lab of EVERFINE</td></tr>
<tr><td>Test instructions</td><td colspan="4">The result is measured at the distance 15mm from the exit pupil plane.</td></tr>
<tr><td>Environment condition</td><td colspan="4">Temperature：(24.6~25.2)℃ Relative humidity：(45~50)%</td></tr>
<tr><td rowspan="6">Main instruments</td><td>No.</td><td>Name</td><td>Type</td><td>Certification Vertify</td></tr>
<tr><td>1</td><td>High accurary array spectroradiometer</td><td>HAAS-2000-VIS</td><td>2027-07-02</td></tr>
<tr><td>2</td><td>High accurary array spectroradiometer</td><td>HAAS-2000-UV</td><td>2027-07-02</td></tr>
<tr><td>3</td><td>High accurary array spectroradiometer</td><td>HAAS-2000-IR1</td><td>2027-07-02</td></tr>
<tr><td>4</td><td>High accurary array spectroradiometer</td><td>HAAS-2000-IR2</td><td>2027-07-02</td></tr>
<tr><td>5</td><td>Wide-band Imaging Radiance Meter</td><td>CXM-213</td><td>2027-07-16</td></tr>
<tr><td>Model coverage</td><td colspan="5">Main Tested Model EM-2000C-D01 and Covered Model EM-2000C-D02 and EM-2000C-D03 are identical in working principle, structural composition, circuit structure, operation mode and sample placement (desktop or floor-standing type), as well as performance. The differences among different models lie in key components and the installation position of the host with software installed.
The manufacturer and specification model of the camera in key components are consistent between the main model EM-2000C-D01 and the variant model EM-2000C-D03;The manufacturer and specification model of the camera are diffferent for variant model EM-2000C-D02.The host with softwire installed of main model EM-2000C-D01 and variant model EM-2000C-D03 is external, variant model EM-2000C-D02 is embedded inside the plastic part. The rest of the structure remains the same. Differences in camera model and host mounting position do not affect the final compliance of optical radiation safety classification.</td></tr>
</table>

Test conclusion	The Light hazard protection of the tested sample is classified: ☑Group 1 instrument □ Group 2 instrument Effective Stamp
	Remarks:Test case does not apply to the test object :—, Test case dose blank to the test object: /.

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
4	**Classification principles**		
4.1	**General**		
4.2	**Group 1 instruments**	Confirmed	Pass
4.3	**Group 2 instruments**	Group 1 instrument	—
5	**Requirements for classification**		
5.1	**General**		
	The following requirements are intended to ensure that ophthalmic instruments are so designed that the energy in all wavelengths is consistent with the safe use of the instrument.Ophthalmic instruments should be designed to exclude unnecessary radiation exposure to the eye.Therefore, ophthalmic instruments shall comply with the requirements for classification as Group 1 instruments see 5.2) unless higher emissions are necessary to achieve the intended clinical purpose.	Confirmed	Pass
	If one or more additional devices are intended to be used in combination with an ophthalmic instrument as specified by the manufacturer and_in a way that could increase the optical radiation hazard,the combined system shall be tested to determine whether it fulfils the requirements for Group 1or Group 2 limits.	Non-combined use	—
5.2	**Requirements for classification as a Group 1 instrument**		
	An ophthalmic instrument shall be classified as Group 1 if any of the following criteria apply.	Confirmed	Pass
5.2.1	Its components, e.g. lamps, light-emitting diodes, non-removable filters, lenses, fibres, etc., prevent exposures more than the limits specified for instruments in the Group1and manufacturer's test certification or relevant documentation exists. Such instruments shall be classified as Group 1 by the manufacturer's test certification of the components themselves without the need for further measurements on the instrument itself. If such components prevent some, but not all exposures from exceeding the limits specified for Group1, then measurements shall be required only for those parameters in Table 2 where the limits can be exceeded.	Not Applicable	—
	Where more than one certified component is used,the manufacturer shall ensure that the combined radiation does not exceed the Group 1 limit.	Not Applicable	—

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
5.2.2	The emission values from any of the following instrument types are less than or equal to those given for the determination of Group 1 classification (see 5.4):	Confirmed	Pass
	— continuous wave instruments;	Confirmed	Pass
	— pulsed instruments;	Not Applicable	—
	— time-limited instruments;	Not Applicable	—
	— scanning instruments;	Not Applicable	—
	— multiple source instruments;	Not Applicable	—
	— instruments for long-term repetitive daily use.	Not Applicable	—
5.2.3	It is a dose-limited instrument as defined in 3.5, for which the manufacturer shall demonstrate how its construction and design achieve the requirements of a Group 1 instrument.	Not Applicable	—
5.3	**Requirements for classification as a Group 2 instrument**		
5.3.1	The output level exceeds some or all the exposure limits of a Group 1 instrument(see 5.2).	Group 1 instrument	—
5.3.2	Under its intended conditions of use,the output level is consistent with the exposure values in Tables 4 and 5.	Group 1 instrument	—
5.3.3	For each operating mode where Group 1 limits are exceeded, the manufacturer shall document a justification and address the associated risks in the risk management file. A justification is not required if a vertical standard contains requirements for Group 2 instruments.	Group 1 instrument	—
5.3.4	If an instrument has some operating modes that are dose limited (i.e. radiant emissions are prevented from exceeding Group 1 exposure limits) and others in which Group 2 exposures are possible, the requirements of 5.3.1 and 5.3.2 apply only for operating modes that are not dose limited.	Group 1 instrument	—
5.4	**Exposure limits for Group 1 classification**		
5.4.1	**Continuous wave instruments**		
	The criteria for the exposure limits for continuous wave instruments relating to anterior segment and retinal irradiance are specified in Table 2 and Table 3.	Confirmed Details in Table 1	Pass
5.4.2	**Pulsed instruments**		

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	Pulsed instruments shallbe evaluated at theirhighest single - pulse output. For repetitively pulsed instruments, the cumulative effective (weighted) exposure for any given time interval shall not exceed the limit value for that time interval. The ultraviolet, visible, and infrared limits for Group 1 pulsed instruments shall be evaluated for the total cumulative effective exposure using the Group 1 criteria specified in Tables 2 and 3.	Not Applicable	—
5.4.3	**Time-limited instruments**		
	The maximum exposure duration for Group 1 time-limited instruments is determined by the radiant power output of the instrument and the Group 1 limits in Table 2 and Table 3. This time limit applies to any given eye within a 24-hour period. The exposure duration shall be limited by the manufacturer to meet the requirements for each intended use.	Not Applicable	—
5.4.4	**Dose limited instruments**		
	The exposure limits for dose-limited instruments are the Group 1 limits in Table 2 and Table 3, taking into account multiple exposures for any given eye within a 24-hour period.	Not Applicable	—
5.4.5	**Scanning instruments**		
	If the radiant power exceeds the Group 1 limit for a static beam, do the following: The value of pulse width △t to be used as exposure duration in Table 2 and Table 3 shall be found using the scan velocity, v, and the linear dimension of the beam cross-section in the scanning direction at the irradiated tissue surface, d, in Formula 8: $\Delta t = \frac{d_s}{v_s}$ （8）	Not Applicable	—
	When using the requirements for pulsed instruments (see 5.4.2) the value of N, the number of pulses, is the number of times the scan passes over the circular aperture of 0,03 mm on the irradiated tissue surface.	Not Applicable	—
	The exposure over any portion of the scanned area shall not exceed the exposure limits that would apply to a spot size equivalent to that portion.	Not Applicable	—
5.4.6	**Instruments with multiple sources**		
	The optical radiation emissions from instruments that are designed to direct optical radiation on to thesame point(s)in or on the eye from multiple light sources shall be below all applicable limits for each light source alone. For all intended consecutive and/or simultaneous use of the light sources, the limit that is applicable for each surface of the eye (cornea,	Not Applicable	—

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	lens, retina) is given by Formula (9): $\frac{H_1}{\text{Limit}_1}+\frac{H_2}{\text{Limit}_2}+\ldots+\frac{H_i}{\text{Limit}_i}\leq 1$ (9)		
5.4.7	**Instruments for long-term repetitive daily use**		
	Instruments such as head-mounted displays that provide augmented or enhanced vision for low vision patients can be worn for many hours per day on a continuing basis and shall be Group 1. Such long-term repeated exposures will require exposure limits lower than those established for a 5000 s duration. The 5000 s duration has been established as a reasonably foreseeable maximum duration of use for clinical ophthalmic instruments.	Not Applicable	—
	If ultraviolet radiation exposure is possible, the Group 1 limit for an 8-hour daily $H_{S\text{-}CL}$(250 nm to 400 nm)exposure shall be 0,1 μW/cm²(S(λ)weighted).	Not Applicable	—
	Aphakic retinal irradiance, $E_{A\text{-}R}$ for visible light shall be limited to 10 μW/cm²(A(λ)weighted), and infrared retinal exposure, $E_{VIR\text{-}R}$, shall be limited to 10 mW/cm²(R(λ) weighted).	Not Applicable	—
5.5	**Recommended maximum exposure (RME) values for Group 2 instruments**		
5.5.1	**Continuous wave instruments**		
	The criteria for calculating the recommended maximum exposures(RMEs) for continuous wave instruments relating to anterior segment and retinal irradiance are specified in Tables 4 and 5.	Group 1 instrument	—
5.5.2	**Pulsed instruments**		
	Pulsed instruments shallbe evaluated at theirhighest single-pulse output. For repetitively pulsed instruments, the cumulative effective (weighted) exposure for any given time interval shall not exceed the RME value for that time interval. The ultraviolet, visible, and infrared RMEs for Group 2 pulsed instruments shall be evaluated for the total cumulative effective exposure using the Group 2 criteria specified in Tables 4 and 5.	Group 1 instrument	—
5.5.3	**Time-limited instruments**		
	The maximum exposure duration for Group 2 time-limited instruments is determined by the radiant power output of the instrument and the Group 2 exposure values in Tables 4 and 5. This time limit applies to any given eye within a 24-hour period. The time limits shall be determined by the manufacturer for each intended use.	Group 1 instrument	—
5.5.4	**Scanning instruments**		

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	If the radiant power exceeds the Group 2 RME value for a static beam, do the following: The value of pulse width △t to be used in Tables 4 and 5 shall be found using the scan velocity v., and the linear dimension of the beam cross-section in the scanning direction at the retina, ds, in Formula(10): $\Delta t = \frac{d_s}{v_s}$ (10)	Group 1 instrument	—
	When using the requirements for pulsed instruments(see 5.5.2) the number of pulses, N, is the number of times the scan passes over the circular aperture of 0,03mm on the retina.	Group 1 instrument	—
5.5.5	**Instruments with multiple sources**		
	The optical radiation emissions from instruments that are designed to direct optical radiation on to the same point(s) in or on the eye from multiple light sources shall be below all applicable RMEs for each light source alone. For all intended simultaneous use and subsequent use for the ultraviolet radiation, the RME that is applicable for each surface of the eye (cornea, lens, retina) is given by Formula(11): $\frac{(E,H)_1}{\mathrm{RME}_1}+\frac{(E,H)_2}{\mathrm{RME}_2}+\cdots+\frac{(E,H)_i}{\mathrm{RME}_i}\leq 1$ (11)	Group 1 instrument	—
5.5.6	**Instruments for long-term repetitive daily use**		
	Although head-mounted displays for long-term repetitive use would normally be Group 1 instruments, Group 2 exposures can be justified under extenuating conditions (e.g. irradiation of retinal implants in eyes with no photoreceptors).	Group 1 instrument	—
	Long-term repeated exposures higher than the Group 1 limits can be necessary. In such cases, the exposure shall be limited to the minimum effective level.	Group 1 instrument	—
5.6	**Exposure limits and maximum recommended exposure values**		
	Table 2, Table3, Table 4 and Table 5, each on a single page, list the exposure limits for Group 1and maximum recommended exposure values for Group 2.	Confirmed	Pass
6	**Test methods**		
6.1	**General**		
	All tests are type tests. measurements shall be made at the instrument's intended working distance.	15mm	Pass
6.2	**Classification of instruments into Group 1 or Group 2**		
	The first step in determining whether an instrument with broadband radiant output is Group 1 or Group 2 shallbe to measure the maximum radiation output of the instrument. If the	Group 1 instrument Confirmed	Pass

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	maximum total radiant output is below the Group 1 limit specified in Table 2 or 3, the instrument is a Group 1 instrument, and no more measurements are needed.		
	If the radiant output of any wavelength band exceeds the relevant Group 1 limit(s) shown in Tables 2 or 3 the instrument shall fulfil the requirements of a Group 2 instrument. The measurement methods specified in Annex D can be used. Annex E provides guidance.	Group 1 instrument	—
6.3	**Spectral measurements**		
	Spectral irradiance, spectral radiance, spectral radiant exposure, and integrated spectral radiance measurements shall take into account potential errors related to variation in spectral weighting within the selected bandwidth of the monochromator. The appropriate weighting factors tabulated in Annex A [A(λ)] and/or $R_A(\lambda)$] shall be applied.In the exceptional case of an instrument intended for use only on phakic eyes of patients over the age of 2 years, B(λ) replaces A(λ)and Rp(λ) replaces $R_A(\lambda)$.Total irradiance or radiant exposure values over a given spectral range are calculated by summing all the adjusted individual measurements over the range.At all times, measurements shall be performed under the conditions defined in Table 6.	Confirmed	Pass
6.4	**Group 2 instruments: determination of time and number of pulses to reach recommended maximum exposure**		
6.4.1	Determination of time t_{max} to reach the recommended maximum exposure for weighted corneal and lenticular ultraviolet radiation radiant exposure, $H_{S\text{-}CL}$		
	To determine the time to reach a potential optical radiation hazard for weighted corneal and lenticular ultraviolet radiation radiant exposure, Formula(12) shall be used: $t_{max}(H_{S-CL}) = \frac{6 \cdot 10^{-3}\ J/cm^2}{E_{S-CL}}$ (12)	Group 1 instrument	—
	The corneal radiant exposure shall be evaluated by averaging the highest localized radiant power incident upon a circular area with a diameter of 3 mm (0,07cm²)at the corneal plane.	Group 1 instrument	—
6.4.2	Determination of time t_{max} to reach the recommended maximum exposure for photochemical aphakic retinal radiant exposure		
	To determine the time to reach a significant optical radiation hazard for photochemical aphakic retinal exposure, Formula (13) shall be used. $t_{max}(H_{A-R} = 10\ J/cm^2) = \frac{10\ J/cm^2}{E_{A-R}}$ (13)	Group 1 instrument	—

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	Clause 7 requires a report of the time to reach a radiant exposure value of 10J/cm².	Group 1 instrument	—
	The limit for a Group 1 instrument is 2,2 J/cm²and above this value the potential risk increases.To calculate $t_{max}$for 2,2 J/cm² substitute 10 J/cm²by 2,2 J/cm²in Formula(13).For instruments that will be used on phakic eyes of patients over the age of 2 years only, the blue-light hazard function B(λ) can be used, instead of the aphakic photochemical hazard weighting function A(λ) to calculate the time to reach maximum recommended photochemical exposure.	Group 1 instrument	—
6.4.3	Determination of the number of pulses necessary to reach the recommended maximum exposure for photochemical aphakic retinal exposure, n_{max}(for pulsed instruments)		
	To determine the number of pulses necessary to reach a significant optical radiation hazard for aphakic retinal exposure, Formula(14) shall be used: $$n_{\max}(H_{\mathrm{A-R}} = 10\ \mathrm{J/cm^2}) = \frac{10\ \mathrm{J/cm^2}}{H_{\mathrm{A-R}}\ \mathrm{J/cm^2/pulse}} = \frac{10\ \mathrm{J/cm^2}}{\frac{[\sum_{305}^{700} H_\lambda\ \mathrm{J/cm^2} \cdot \Delta\lambda \cdot A(\lambda) \cdot \Delta\lambda]}{\mathrm{pulse}}} \quad (14)$$	Group 1 instrument	—
	Clause 7 requires a report of the number of pulses necessary to reach a radiant exposure value of 10 J/cm² designated n_{max} (H_{A-R}=10 J/cm²).	Group 1 instrument	—
7	**Information supplied by the manufacturer**		
7.1	**Information provided on request**		
	The manufacturer shall, on request, provide the user with a graph showing the relative spectral output of the instrument between 305nm and 1100nm when the instrument is operating at maximum light intensity and maximum aperture or effective aperture. The spectral output shall be shown for the beam after it exits the instrument.	See Figure 1	Pass
	For Group 2 instruments, if the RME values are not directly given in the marking or via an electronic interface, the manufacturer shall provide RME information via an online link (see Z.3.3). The URL shall remain stable for the expected service life of the instrument.	Group 1 instrument	—
7.2	**Accompanying documents**		
7.2.1	General		
	Manufacturers shall provide accompanying documents that contains all relevant optical radiation safety information. It is the responsibility of the manufacturer to provide the safety information indicated below and to decide which additional information is relevant and, therefore, is provided.	Confirmed	Pass

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
7.2.2	Dose-limited instruments		
	For instruments that are in Group 1 by being dose-limited, the manufacturer shallprovide a description of how the design and construction meet the requirements for classification as a Group1 instrument.	Not Applicable	—
7.2.3	Cautionary statements		
	For Group 2 instruments, the following information and cautionary statements shall be provided in a prominent position in the user manual. The cautionary statements below are provided as examples. The manufacturer may use modified wording as long as the same information is conveyed and no signal word of a lower warning level than CAUTION is used. If appropriate, several statements may be combined.	Group 1 instrument	—
7.2.3.1	Continuous wave and time-limited instruments		
	If the instrument does not fulfil the requirements of Table 2, Row 1, the manufacturer shall provide the user with information concerning the time to reach a potential optical radiation hazard as determined in 6.4.1.	Group 1 instrument	—
	If the instrument does not fulfil the requirements of Table 2, Row 3, the manufacturer shall provide the user with information concerning the time to reach a potential optical radiation hazard as determined in 6.4.2. A cautionary statement shallbe included,and the following are examples: CAUTIONARY STATEMENT: "CAUTION — The light emitted from this instrument is potentially hazardous.Exposure to light from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm²after _min. Although the risk of retinal injury just exceeding 2,2 J/cm² is low, caution is advised, as some patients are more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10J/cm² (exposure duration exceeding min) entail a significant risk of injury.	Group 1 instrument	—
7.2.3.2	Pulsed and time-limited pulsed instruments		

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	If the instrument does not fulfil the requirements of Row 7, Table 3-Retinal photochemical aphakic light hazard, the manufacturer shall provide the user with information concerning either the number of pulses or the time to reach a potential optical radiation hazard as determined in 6.4.3, with either cautionary statement A or cautionary statement B: CAUTIONARY STATEMENT: "CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2J/cm²after pulses or min at a pulse rate of oulses/sec. Although the risk of retinalinjury atan exposure just exceeding 2,2J /cm² is low, caution is advised, as some patients may be more susceptible than others. Exposures exceeding the recommended maximum exposure(RME) of 10J/cm² (exceeding pulses or min at a pulse rate of pulses / sec) entail a significant risk of injury.	Group 1 instrument	—
7.2.3.3	Multiple source instruments		
	For multiple source instruments with continuous wave output that can illuminate the same points on the retina: The manufacturer shall provide the user with information on how to determine the time to reach the recommended maximum exposure. This shall apply for the combination of light sources at various intensity settings. A cautionary statement shall be included, and the following are examples: CAUTIONARY STATEMENT: "CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to the summed light of spatially overlapping light sources from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2J/cm² after, e.g. min for source 1, min for source 2, and min for source n,ifall sources are operating concurrently. Although the risk of retinal injury at a cumulative exposure just exceeding 2,2J/cm ² is low, as some patients may be more susceptible than others, caution is advised. Exposures exceeding the recommended maximum exposure (RME) of 10J/cm ² (cumulative exposure duration exceeding4,5 times the Group 1 limits) entail a significant risk of injury.	Group 1 instrument	—

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	For instruments with multiple sources of pulsed light output that can illuminate the same points on the retina, the manufacturer shall provide the user with information on how to determine the number of pulses to reach the recommended maximum exposure. This shall apply for the combination of light sources at various intensity settings. A cautionary statement shall be included, and the following are examples: CAUTIONARY STATEMENT: "CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light of spatially overlapping pulsed light sources from thisinstrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2J/cm²after,e.g. pulses for source 1, pulses for 2, and pulses for source n. Although the risk of retinal injury at an exposure just exceeding 2,2J/cm²is low, caution is advised, as some patients may be more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm ² (cumulative exposures from all sources exceeding 4,5times the Group 1 limit) entail a significant risk of injury.	Group 1 instrument	—
	For multiple source instruments with continuous wave and pulsed light output that canilluminate the same points on the retina, the manufacturer shall provide information on how to determine the combination of the time and number of pulses to reach the maximum recommended exposure. This shall also apply for the combination of light sources at various intensity settings. A cautionary statement shall be included, and the following are examples: CAUTIONARY STATEMENT: "CAUTION—The light emitted from this instrument is potentially hazardous.Exposure to light from this instrument when all sources are operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2J/cm² after min. Although the risk of retinal injury at an exposure just exceeding 2,2J/cm² is low, caution is advised, as some patients may be more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10J/cm² (cumulative exposure duration exceeding min) entail a significant risk of injury.	Group 1 instrument	—
7.2.3.4	Variable brightness		

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	Where provision is made to vary brightness, the manufacturer shall provide the user with information concerning the indication of the maximum intensity and fractions of maximum intensity.	Non-Variable brightness	—
7.2.3.5	Operation microscopes, endoilluminators and slit lamps		
	For operation microscopes and endoilluminators, the accompanying documents shall include the following cautionary statement: CAUTIONARY STATEMENT FOR OPERATION MICROSCOPESAND ENDOILLUMINATORS: "CAUTION — The light emitted from this instrument is potentially hazardous.Exposure to light from this instrument when operated at maximum intensity will potentially exceed the recommended maximum exposure (RME) of 10J/cm ² after min unless additional action is taken by the user to minimize exposure.	Not Applicable	—
	For slit lamps, the accompanying documents shall include the following cautionary statement: CAUTIONARY STATEMENT FOR SLIT LAMPS WHEN IMAGED TO THERETINA: "CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when operated at maximum intensity and focused on the retina at a fixed location will potentially exceed the recommended maximum exposure (RME) of 10J/cm^2 after min unless additional action is taken by the user to minimize exposure.	Not Applicable	—
7.2.3.6	Instruments intended for phakic eyes of patients over the age of 2 years		
	If the instrument is only intended to be used with aphakic eyes and a phakic spectral weighting function is used to show compliance with this document, the manufacturer shall include a cautionary statement in the accompanying documents that warns the user that the use of the instrument on phakic eyes may be hazardous. For instruments intended for the use on phakic eyes only, the accompanying documents shall include the following cautionary statement: CAUTIONARY STATEMENT FOR INSTRUMENTS INTENDED ONLY FOR PHAKICEYES: "CAUTION — Light output hazardous for aphakic or pseudophakic eyes. This instrument is only intended to be used for phakic eyes.	The photochemical retinal hazard(aphakic), visible and IR thermal hazard of the equipment do not exceed the limit values	—

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
	Using it on non-phakic eyes may lead to eye injury. Do not use the instrument for aphakic or pseudophakic eyes."		
7.2.3.7	Cautionary statements regarding risk of thermal injury		
7.2.3.7.1	Continuous wave and time-limited instruments		
	If the instrument does not fulfil the requirements of Table 3, Rows 8 to 10, the manufacturer shallprovide the user with information concerning the time to reach a potential optical radiation hazard at each of the available radiant output settings. A cautionary statement shall be included, and the following is an example: CAUTIONARY STATEMENT: "CAUTION — The light emitted from this instrument is potentially hazardous.Exposure to light from this instrument may cause thermal retinal injury when operated at radiant outputs that produce weighted retinal intensities more than 0,7W/cm². Although the risk of retinal injury decreases with decreasing exposure duration and spot size for a given intensity, caution is advised, as the risk increases rapidly with increasing irradiance, and some patients are more susceptible than others. Exposures exceeding1,0W/cm² for more than 42 minutes entail a significant risk of injury.	Group 1 instrument	—
7.2.3.7.2	Pulsed instruments		
	If the instrument does not fulfil the requirements of Table 3,Rows 8 to 10, Weighted retinal thermal light hazard, the manufacturer shallprovide the user with information concerning the potential optical radiation hazard at each of the available radiant output settings. A cautionary statement shall be included, and the following is an example: CAUTIONARY STATEMENT: "CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument may cause thermal retinal injury when operated at intensities that produce retinal exposures that exceed the Group 1 limit for the exposure duration and spot size in use. Although the risk of retinal injury is low at the Group 1 limit and it decreases with decreasing exposure duration and spot size for a given intensity, caution is advised, as the risk increases rapidly with increasing intensity, and some patients are more susceptible to injury than others. Exposures exceeding the recommended maximum exposure (RME) for the exposure conditions in use entail a significant risk of injury.	Group 1 instrument	—

ISO 15004-2:2024			
Clause	**Requirement +Test**	**Result-Remark**	**Conclusion**
7.3	**Marking**		
7.3.1	Radiation output		
	For all Group 2 instruments, where provision is made to vary the radiation output, the manufacturer shall provide on the instrument an indication of the maximum intensity and available intensity settings below maximum intensity.	Group 1 instrument	—
7.3.2	Consult accompanying documents		
	Group 2 instruments shall be marked with the refer to instruction manual/booklet mandatory action safety sign ISO 7010-M002 (see Annex E symbol 1).	Group 1 instrument	—
7.3.3	Safety information for optical radiation		
	Group 2 instruments shall be marked with a label indicating the time or the number of pulses to reach the Recommended Maximum Exposure for photochemical aphakic retinal radiant exposure (see 6.4.2 and 6.4.3) - depending on what applies-or providing a link with access to this information. In addition, a dated reference to this document shall be given. Instruments with electronic user interfaces may fulfil this requirement by providing the RME information on the interface.	Group 1 instrument	—
	Group 2 instruments shall be marked with safety sign ISO 7010-W027(see Annex E symbol 3).	Group 1 instrument	—
	If the ophthalmicinstrument is a laser device, instead of safety sign ISO 7010-W027, the safety sign ISO 7010- W004 shall be used (see AnnexE symbol 2).	Group 1 instrument	—

Table 1 Test Data of 953.7nm Light Source					
Row	**Location**	**Parameter and type**	**Radiometric formula**	**Group 1（cumulative exposure duration：5000s）**	
				Group 1 Limit	**Measured Value**
1	Cornea/Lens (Photochemica)	Weighted radiant exposure	$H_{S-CL}=\sum_{250}^{400}H_\lambda\cdot S(\lambda)\cdot\Delta\lambda$	0.6 μW/cm²	8.48E-06 μW/cm²
2	Cornea/Lens (Thermal)	Unweighted UV radiant exposure	$H_{UV-CL}=\sum_{250}^{315}H_\lambda\cdot\Delta\lambda$	Not Applicable	Not Applicable
3	Cornea/Lens (Thermal)	Unweighted UV radiant exposure	$H_{UV-CL}=\sum_{315}^{400}H_\lambda\cdot\Delta\lambda$	100 mW/cm²	1.80E-04 mW/cm²
4a	Cornea/Lens (Thermal)	Unweighted VIS and IR radiant exposure	$H_{VIR-CL}=\sum_{400}^{1200}H_\lambda\cdot\Delta\lambda$	1 W/cm²	1.21E-03 W/cm²
4b			$H_{IR-CL}=\sum_{1200}^{2500}H_\lambda\cdot\Delta\lambda$	200 mW/cm²	0.00E+00 mW/cm²
5	Cornea/Lens (Thermal ,small beams)	Unweighted VIS and IR radiant exposure	$H_{VIR-CL}=\sum_{400}^{1200}H_\lambda\cdot\Delta\lambda$	Not Applicable	Not Applicable
6	Iris (averaged over0,2mm d)	VIS/IR Thermal hazard	$H_{VIR-I}=\sum_{320}^{1400}H_\lambda\cdot I(\lambda)\cdot\Delta\lambda$	0.81 W/cm²	1.29E-02 W/cm²
7	Retina	Photochemical hazard for aphakic eyes	$H_{A-R}=\sum_{305}^{700}H_\lambda\cdot A(\lambda)\cdot\Delta\lambda$	0.44 mW/cm²	1.76E-03 mW/cm²
		Photochemical hazard for aphakic eyes for phakich eyes	$H_{B-R}=\sum_{305}^{700}H_\lambda\cdot B(\lambda)\cdot\Delta\lambda$	0.44 mW/cm²	8.26E-04 mW/cm²
8	Retina (large spot d_r> 1,7mm)	VIS/IR Thermal hazarda	$H_{VIR-R}=\sum_{380}^{1400}H_\lambda\cdot R(\lambda)\cdot\Delta\lambda$	Not Applicable	Not Applicable

9	Retina (intermediate spot d_r>0,03mm to 1,7mm)		$H_{VIR-R}=\sum_{380}^{1400}H_\lambda \cdot R(\lambda)\cdot \Delta\lambda$	1.61 W/cm^2	4.93E-02 W/cm^2
10	Retina (large spot d_r≤0.03 mm）		$Q_{VIR-R}=\sum_{380}^{1400}Q_\lambda \cdot R(\lambda)\cdot \Delta\lambda$	Not Applicable	Not Applicable

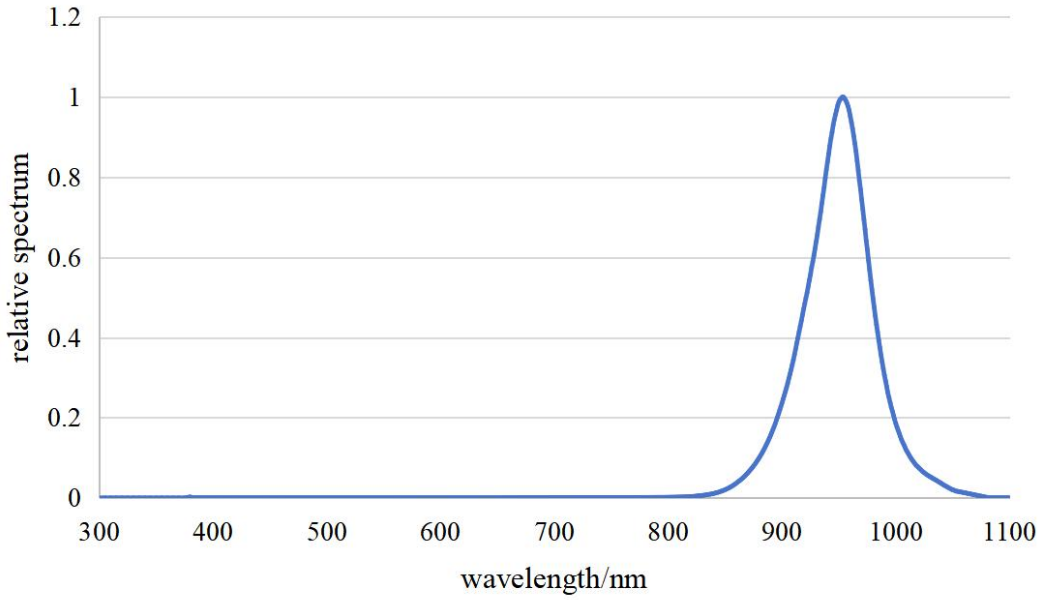


Figure 1 The relative spectrum of 953.7nm light source

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