
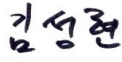
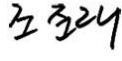




Test Report issued under the responsibility of:



TEST REPORT IEC 62471 Photobiological safety of lamps and lamp systems	
Report Reference No.	CB2023-00139
Date of issue	June 27, 2023
Total number of pages	21 Pages
Name of Testing Laboratory preparing the Report	KTC (Korea Testing Certification)
Applicant's name	iMediSync Inc.
Address	15F, 411, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea
Test specification:	
Standard	IEC 62471:2006 (First Edition) & EN 62471:2008
Test procedure	CB
Non-standard test method	N/A
Test Report Form No.	IEC62471B
TRF Originator	VDE Testing and Certification Institute
Master TRF	Dated 2018-08-16
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Test item description	iSyncWave LED, Physical devices for medical use (Infrared light irradiator)	
Trade Mark		
Manufacturer	Same as applicant	
Model/Type reference	ISW-MKR201L, ISW-MKR201, ISW-MKR202L, ISW-EKR201L, ISW-EKR201, ISW-EKR202L	
Ratings	DC 5 V, 2 A / DC 9 V, 1.5 A / DC 3.7 V, 2 900 mAh	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	KTC (Korea Testing Certification)
Testing location/ address	Heungan-daero 27 beon-gil 22, Gunpo-city, Gyeonggi-do, Korea	
Tested by (name, function, signature)	Sung-Hyun Kim Technical Engineer	
Approved by (name, function, signature) ..	Junrae Cho Technical Manager	
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	
Testing location/ address		
Tested by (name, function, signature)		
Approved by (name, function, signature) ..		
<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address		
Tested by (name + signature)		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
<input type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	Testing procedure: CTF Stage 4:	
Testing location/ address		
Tested by (name, function, signature)		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
Supervised by (name, function, signature) :		

<p>List of Attachments (including a total number of pages in each attachment): Attachment 1 : European group differences and national differences (2 pages) Attachment 2 : Spectral graphs (1 page) Attachment 3 : Pulsed source characteristics (1 page) Attachment 4 : Photographs (1 page)</p>															
<p>Summary of testing:</p>															
<p>Tests performed (name of test and test clause):</p> <p>The LED output power was measured under normal conditions noted it details of measurement procedure and measurement results</p> <p>Measurement results : See table 6.1</p> <p>Summary of result(IEC 62471)</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="padding: 2px;">Hazard</th> <th style="padding: 2px;">Risk Group</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Actinic UV</td> <td style="padding: 2px;">N/A</td> </tr> <tr> <td style="padding: 2px;">Near UV</td> <td style="padding: 2px;">N/A</td> </tr> <tr> <td style="padding: 2px;">Blue Light</td> <td style="padding: 2px;">N/A</td> </tr> <tr> <td style="padding: 2px;">Retinal Thermal Weak Visual</td> <td style="padding: 2px;">Exempt</td> </tr> <tr> <td style="padding: 2px;">Infrared</td> <td style="padding: 2px;">Exempt</td> </tr> <tr> <td style="padding: 2px;">Thermal Skin</td> <td style="padding: 2px;">Pass</td> </tr> </tbody> </table>	Hazard	Risk Group	Actinic UV	N/A	Near UV	N/A	Blue Light	N/A	Retinal Thermal Weak Visual	Exempt	Infrared	Exempt	Thermal Skin	Pass	<p>Testing location: KTC (Korea Testing Certification)</p> <p>Address Heungan-daero 27 beon-gil 22, Gunpo-city, Gyeonggi-do, Korea</p>
Hazard	Risk Group														
Actinic UV	N/A														
Near UV	N/A														
Blue Light	N/A														
Retinal Thermal Weak Visual	Exempt														
Infrared	Exempt														
Thermal Skin	Pass														
<p>Summary of compliance with National Differences (List of countries addressed): The Sample(s) tested complies with the requirements of 62471:2006 Compliance with European Group CENELEC Common Modifications (EN) are verified. Difference and National Differences, ATTACHMENT is recorded at page. 17</p> <p><input type="checkbox"/> The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis, leave it blank or delete the whole sentence, if not applicable)</p>															

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

1st Package Label(Gift Box)

iSyncWave2

REF ISW-MKR201
SN IM23xxxxxxxxBXXXX

Rating: 3.7 V, 2,900 mAh Li-ion (Min.)
 DC 5.0 V / 2.0 A, 9.0 V / 1.5 A

iMediSync Inc.
 15FL, 411, Teheran-ro, Gangnam-gu, Seoul,
 Republic of Korea, (06160)

YYYY-MM-DD

MD

i

A

B

C

D

E

F

Rx Only Caution: United States Federal law restricts medical devices to sale by or on the order of a (licensed healthcare practitioner)

www.imedisync.com **iMediSync**

Made in Korea

2nd Package Label(Carton Box)

iSyncWave2

REF ISW-MKR201
SN IM23xxxxxxxxBXXXX




Rating: 3.7 V, 2,900 mAh Li-ion (Min.)
 DC 5.0 V / 2.0 A, 9.0 V / 1.5 A

iMediSync Inc.
 15FL, 411, Teheran-ro, Gangnam-gu, Seoul,
 Republic of Korea, (06160)

YYYY-MM-DD

FC

FCC ID: N/A

CE

XXXX

K

E

www.imedisync.com **iMediSync**

Made in Korea



LED Label

Exempt group in accordance with IEC 62471:2006

I : < 40 mW/cm², λ : 765 ~ 935 nm

LED Pulse 1~45 Hz, 1~30 min.

Device Label

iMediSync Inc.
 15FL, 411, Teheran-ro,
 Gangnam-gu, Seoul, Republic of Korea

Model : ISW-MKR201L

Rating : 3.7V 2,900 mAh Li-ion (min.)

Serial Number : IM23xxxxxxxxAXXXX

UDI Label

UDI



(01) 08800108500363
 (11) 220726
 (21) IM23xxxxxxxxAXXXX

Test item particulars	
Tested lamp	<input type="checkbox"/> continuous wave lamps <input checked="" type="checkbox"/> pulsed lamps
Tested lamp system	See page 2
Lamp classification group	<input checked="" type="checkbox"/> exempt <input type="checkbox"/> risk 1 <input type="checkbox"/> risk 2 <input type="checkbox"/> risk 3
Lamp cap	N/A
Bulb	LED
Rated of the lamp	See page 2
Furthermore marking on the lamp.....	-
Seasoning of lamps according IEC standard	-
Used measurement instrument.....	IDR-300
Temperature by measurement.....	25 °C
Information for safety use.....	Not required
Possible test case verdicts:	
– test case does not apply to the test object : N/A	
– test object does meet the requirement : P (Pass)	
– test object does not meet the requirement : F (Fail)	
Testing:	
Date of receipt of test item	: 2023-06-14
Date (s) of performance of tests	: 2023-06-14 ~ 2023-06-27
General remarks:	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. Throughout this report a <input checked="" type="checkbox"/> comma / <input type="checkbox"/> point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) : EM-Tech Co., Ltd.	
Address : 9-21, Dongtansandan 9-gil, Hwaseong-si, Gyeonggi-do, Republic of Korea	

General product information and other remarks:

Product Description :

- This product is a medical device equipped with near-infrared LEDs.

Model differences :

- The model has the same hardware structure, but differs in the presence or absence of LED irradiation and EEG measurement modes through the software.
- Models : ISW-MKR201L, ISW-MKR201, ISW-MKR202L, ISW-EKR201L, ISW-EKR201, ISW-EKR202L
 - ***_MKR**** : Medical device
 - ***_EKR**** : Electronic device
 - ***_***201 : EEG measurement
 - ***_***202L : LED irradiation
 - ***_***201L : EEG measurement + LED irradiation
- The test is performed on the ISW-MKR201L model as a representative.

Test Condition :

- The test was performed with end product.
- Tested with a fully charged state
- Tested at 45 Hz setting with all LEDs on
- Tested in full bright condition

Additional Information :

- The information about LED package
 - Manufacturer: EVERLIGHT ELECTRONICS CO., LTD.
 - Model : HIR383C/L289
- Electro-Optical characteristics of LED package

Parameter	Symbol	Min.	Typ.	Max.	Unit	Condition
Radiant Intensity	I_e	11	35	93	mW/sr	$I_F=5mA$
		-----	140	-----		$I_F=20mA$
		-----	700	-----		$I_F=100$ Pulse Width $\leq 100\mu s$ and Duty $\leq 1\%$
Peak Wavelength	λ_p	-----	850	-----	nm	$I_F=20mA$
Spectral Bandwidth	$\Delta\lambda$	-----	45	-----	nm	$I_F=20mA$
Forward Voltage	V_F	-----	1.45	1.65	V	$I_F=20mA$
		-----	1.80	2.40		$I_F=100mA$
		-----	4.10	5.25		$I_F=1A$ Pulse Width $\leq 100\mu s$ and Duty $\leq 1\%$
Reverse Current	I_R	----	----	10	uA	$V_R=5V$
View Angle	$2\theta_{1/2}$	----	18	----	deg	$I_F=20mA$

IEC 62471			
Clause	Requirement + Test	Result – Remark	Verdict
4	EXPOSURE LIMITS		-
4.1	General		-
	The exposure limits in this standard is not less than 0,01 ms and not more than any 8-hour period and should be used as guides in the control of exposure		P
	Detailed spectral data of a light source are generally required only if the luminance of the source exceeds $10^4 \text{ cd}\cdot\text{m}^{-2}$	see clause 4.3	N/A
4.3	Hazard exposure limits		-
4.3.1	Actinic UV hazard exposure limit for the skin and eye	no emission	N/A
	The exposure limit for effective radiant exposure is $30 \text{ J}\cdot\text{m}^{-2}$ within any 8-hour period		N/A
	To protect against injury of the eye or skin from ultraviolet radiation exposure produced by a broad-band source, the effective integrated spectral irradiance, E_s , of the light source shall not exceed the levels defined by:		N/A
	$E_s \cdot t = \sum_{200}^{400} \sum_t E_\lambda(\lambda, t) \cdot S_{UV}(\lambda) \cdot \Delta t \cdot \Delta \lambda \leq 30 \quad \text{J}\cdot\text{m}^{-2}$		N/A
	The permissible time for exposure to ultraviolet radiation incident upon the unprotected eye or skin shall be computed by:		N/A
	$t_{\max} = \frac{30}{E_s} \quad \text{s}$	>30 000 s	N/A
4.3.2	Near-UV hazard exposure limit for eye		-
	For the spectral region 315 nm to 400 nm (UV-A) the total radiant exposure to the eye shall not exceed $10000 \text{ J}\cdot\text{m}^{-2}$ for exposure times less than 1000 s. For exposure times greater than 1000 s (approximately 16 minutes) the UV-A irradiance for the unprotected eye, E_{UVA} , shall not exceed $10 \text{ W}\cdot\text{m}^{-2}$.	no emission	N/A
	The permissible time for exposure to ultraviolet radiation incident upon the unprotected eye for time less than 1000 s, shall be computed by:		N/A
	$t_{\max} \leq \frac{10\,000}{E_{UVA}} \quad \text{s}$	>30 000 s	N/A
4.3.3	Retinal blue light hazard exposure limit		-
	To protect against retinal photochemical injury from chronic blue-light exposure, the integrated spectral radiance of the light source weighted against the blue-light hazard function, $B(\lambda)$, i.e., the blue-light weighted radiance, L_B , shall not exceed the levels defined by:	no emission	N/A
	$L_B \cdot t = \sum_{300}^{700} \sum_t L_\lambda(\lambda, t) \cdot B(\lambda) \cdot \Delta t \cdot \Delta \lambda \leq 10^6 \quad \text{J} \cdot \text{m}^{-2} \cdot \text{sr}^{-1}$	for $t \leq 10^4 \text{ s}$ $t_{\max} = \frac{10^6}{L_B}$	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	$L_B = \sum_{300}^{700} L_\lambda \cdot B(\lambda) \cdot \Delta\lambda \leq 100 \quad W \cdot m^{-2} \cdot sr^{-1}$	for $t > 10^4$ s	N/A
4.3.4	Retinal blue light hazard exposure limit - small source		-
	Thus the spectral irradiance at the eye E_λ , weighted against the blue-light hazard function $B(\lambda)$ shall not exceed the levels defined by:	see table 4.2 no emission	N/A
	$E_B \cdot t = \sum_{300}^{700} \sum_t E_\lambda(\lambda, t) \cdot B(\lambda) \cdot \Delta\lambda \leq 100 \quad J \cdot m^{-2}$	for $t \leq 100$ s	N/A
	$E_B = \sum_{300}^{700} E_\lambda \cdot B(\lambda) \cdot \Delta\lambda \leq 1 \quad W \cdot m^{-2}$	for $t > 100$ s	N/A
4.3.5	Retinal thermal hazard exposure limit		-
	To protect against retinal thermal injury, the integrated spectral radiance of the light source, L_λ , weighted by the burn hazard weighting function $R(\lambda)$ (from Figure 4.2 and Table 4.2), i.e., the burn hazard weighted radiance, shall not exceed the levels defined by:	see table 4.2 evaluated by weak visual stimulus	N/A
	$L_R = \sum_{380}^{1400} L_\lambda \cdot R(\lambda) \cdot \Delta\lambda \leq \frac{50\,000}{\alpha \cdot t^{0,25}} \quad W \cdot m^{-2} \cdot sr^{-1}$	($10 \mu s \leq t \leq 10$ s)	N/A
4.3.6	Retinal thermal hazard exposure limit – weak visual stimulus		-
	For an infrared heat lamp or any near-infrared source where a weak visual stimulus is inadequate to activate the aversion response, the near infrared (780 nm to 1400 nm) radiance, L_{IR} , as viewed by the eye for exposure times greater than 10 s shall be limited to:		P
	$L_{IR} = \sum_{780}^{1400} L_\lambda \cdot R(\lambda) \cdot \Delta\lambda \leq \frac{6\,000}{\alpha} \quad W \cdot m^{-2} \cdot sr^{-1}$	$t > 10$ s EL : 60000 ($W \cdot m^{-2} \cdot sr^{-1}$)	P
4.3.7	Infrared radiation hazard exposure limits for the eye		-
	The avoid thermal injury of the cornea and possible delayed effects upon the lens of the eye (cataractogenesis), ocular exposure to infrared radiation, E_{IR} , over the wavelength range 780 nm to 3000 nm, for times less than 1000 s, shall not exceed:		P
	$E_{IR} = \sum_{780}^{3000} E_\lambda \cdot \Delta\lambda \leq 18\,000 \cdot t^{-0,75} \quad W \cdot m^{-2}$	$t \leq 1000$ s : 17 ms(on time) EL : 382327,74 ($W \cdot m^{-2}$)	P
	For times greater than 1000 s the limit becomes:		-
	$E_{IR} = \sum_{780}^{3000} E_\lambda \cdot \Delta\lambda \leq 100 \quad W \cdot m^{-2}$	$t > 1000$ s	P
4.3.8	Thermal hazard exposure limit for the skin		-
	Visible and infrared radiant exposure (380 nm to 3000 nm) of the skin shall be limited to:		P

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Clause	Requirement + Test	Result – Remark	Verdict
	$E_H \cdot t = \sum_{380}^{3000} \sum_{\lambda} E_{\lambda}(\lambda, t) \cdot \Delta t \cdot \Delta \lambda \leq 20\,000 \cdot t^{0,25} \quad \text{J} \cdot \text{m}^{-2}$	EL : 7221 (J•m ⁻²) Value : 2,05 (J•m ⁻²)	P
5	MEASUREMENT OF LAMPS AND LAMP SYSTEMS		-
5.1	Measurement conditions		-
	Measurement conditions shall be reported as part of the evaluation against the exposure limits and the assignment of risk classification.		P
5.1.1	Lamp ageing (seasoning)		-
	Seasoning of lamps shall be done as stated in the appropriate IEC lamp standard.	No appropriate IEC lamp standard.	P
5.1.2	Test environment		-
	For specific test conditions, see the appropriate IEC lamp standard or in absence of such standards, the appropriate national standards or manufacturer's recommendations.		P
5.1.3	Extraneous radiation		-
	Careful checks should be made to ensure that extraneous sources of radiation and reflections do not add significantly to the measurement results.		P
5.1.4	Lamp operation		-
	Operation of the test lamp shall be provided in accordance with:		-
	– the appropriate IEC lamp standard, or	No appropriate IEC standard.	N/A
	– the manufacturer' s recommendation		P
5.1.5	Lamp system operation		-
	The power source for operation of the test lamp shall be provided in accordance with:		-
	– the appropriate IEC standard, or	No appropriate IEC standard.	N/A
	– the manufacturer' s recommendation		P
5.2	Measurement procedure		-
5.2.1	Irradiance measurements		P
	Minimum aperture diameter 7mm.		N/A
	Maximum aperture diameter 50 mm.		N/A
	The measurement shall be made in that position of the beam giving the maximum reading.		P
	The measurement instrument is adequate calibrated.		P
5.2.2	Radiance measurements		-
5.2.2.1	Standard method		-
	The measurements made with an optical system.		P
	The instrument shall be calibrated to read in absolute radiant power per unit receiving area and per unit solid angle to acceptance averaged over the field of		P

IEC 62471			
Clause	Requirement + Test	Result – Remark	Verdict
	view of the instrument.		
5.2.2.2	Alternative method		-
	Alternatively to an imaging radiance set-up, an irradiance measurement set-up with a circular field stop placed at the source can be used to perform radiance measurements.		P
5.2.3	Measurement of source size		-
	The determination of α , the angle subtended by a source, requires the determination of the 50% emission points of the source.		P
5.2.4	Pulse width measurement for pulsed sources		-
	The determination of Δt , the nominal pulse duration of a source, requires the determination of the time during which the emission is > 50% of its peak value.		P
5.3	Analysis methods		-
5.3.1	Weighting curve interpolations		-
	To standardize interpolated values, use linear interpolation on the log of given values to obtain intermediate points at the wavelength intervals desired.	see table 4.1	P
5.3.2	Calculations		-
	The calculation of source hazard values shall be performed by weighting the spectral scan by the appropriate function and calculating the total weighted energy.		P
5.3.3	Measurement uncertainty		-
	The quality of all measurement results must be quantified by an analysis of the uncertainty.	see Annex C in the norm	P
6	LAMP CLASSIFICATION		-
	For the purposes of this standard it was decided that the values shall be reported as follows:	see table 6.1	-
	– for lamps intended for general lighting service, the hazard values shall be reported as either irradiance or radiance values at a distance which produces an illuminance of 500 lux, but not at a distance less than 200 mm		N/A
	– for all other light sources, including pulsed lamp sources, the hazard values shall be reported at a distance of 200 mm	Non-GLS	P
6.1	Continuous wave lamps		-
6.1.1	Except Group		-
	In the except group are lamps, which does not pose any photobiological hazard. The requirement is met by any lamp that does not pose:		-
	– an actinic ultraviolet hazard (E_s) within 8-hours exposure (30000 s), nor	No emission	N/A

IEC 62471			
Clause	Requirement + Test	Result – Remark	Verdict
	– a near-UV hazard (E_{UVA}) within 1000 s, (about 16 min), nor	No emission	N/A
	– a retinal blue-light hazard (L_B) within 10000 s (about 2,8 h), nor	No emission	N/A
	– a retinal thermal hazard (L_R) within 10 s, nor	1.7 mrad FOV(for pulse source)	P
	– an infrared radiation hazard for the eye (E_{IR}) within 1000 s		P
6.1.2	Risk Group 1 (Low-Risk)		-
	In this group are lamps, which exceeds the limits for the except group but that does not pose:	All risk are in the except group	-
	– an actinic ultraviolet hazard (E_S) within 10000 s, nor		N/A
	– a near ultraviolet hazard (E_{UVA}) within 300 s, nor		N/A
	– a retinal blue-light hazard (L_B) within 100 s, nor		N/A
	– a retinal thermal hazard (L_R) within 10 s, nor		N/A
	– an infrared radiation hazard for the eye (E_{IR}) within 100 s		N/A
	Lamps that emit infrared radiation without a strong visual stimulus and do not pose a near-infrared retinal hazard (L_{IR}), within 100 s are in Risk Group 1.		N/A
6.1.3	Risk Group 2 (Moderate-Risk)		-
	This requirement is met by any lamp that exceeds the limits for Risk Group 1, but that does not pose:	All risk are in the except group	-
	– an actinic ultraviolet hazard (E_S) within 1000 s exposure, nor		N/A
	– a near ultraviolet hazard (E_{UVA}) within 100 s, nor		N/A
	– a retinal blue-light hazard (L_B) within 0,25 s (aversion response), nor		N/A
	– a retinal thermal hazard (L_R) within 0,25 s (aversion response), nor		N/A
	– an infrared radiation hazard for the eye (E_{IR}) within 10 s		N/A
	Lamps that emit infrared radiation without a strong visual stimulus and do not pose a near-infrared retinal hazard (L_{IR}), within 10 s are in Risk Group 2.		N/A
6.1.4	Risk Group 3 (High-Risk)		-
	Lamps which exceed the limits for Risk Group 2 are in Group 3.	All risk are in the except group	N/A
6.2	Pulsed lamps		-
	Pulse lamp criteria shall apply to a single pulse and to any group of pulses within 0,25 s.		P
	A pulsed lamp shall be evaluated at the highest nominal energy loading as specified by the manufacturer.		P

IEC 62471			
Clause	Requirement + Test	Result – Remark	Verdict

	The risk group determination of the lamp being tested shall be made as follows:		P
	– a lamp that exceeds the exposure limit shall be classified as belonging to Risk Group 3 (High-Risk)	Exposure limit not exceeded	P
	– for single pulsed lamps, a lamp whose weighted radiant exposure or weighted radiance does is below the EL shall be classified as belonging to the Exempt Group	repetitively pulsed lamp	N/A
	– for repetitively pulsed lamps, a lamp whose weighted radiant exposure or weighted radiance dose is below the EL, shall be evaluated using the continuous wave risk criteria discussed in clause 6.1, using time averaged values of the pulsed emission		P

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Clause	Requirement + Test	Result – Remark	Verdict

Table 4.1 Spectral weighting function for assessing ultraviolet hazards for skin and eye			-
Wavelength ¹ λ, nm	UV hazard function S _{uv} (λ)	Wavelength λ, nm	UV hazard function S _{uv} (λ)
200	0,030	313*	0,006
205	0,051	315	0,003
210	0,075	316	0,0024
215	0,095	317	0,0020
220	0,120	318	0,0016
225	0,150	319	0,0012
230	0,190	320	0,0010
235	0,240	322	0,00067
240	0,300	323	0,00054
245	0,360	325	0,00050
250	0,430	328	0,00044
254*	0,500	330	0,00041
255	0,520	333*	0,00037
260	0,650	335	0,00034
265	0,810	340	0,00028
270	1,000	345	0,00024
275	0,960	350	0,00020
280*	0,880	355	0,00016
285	0,770	360	0,00013
290	0,640	365*	0,00011
295	0,540	370	0,000093
297*	0,460	375	0,000077
300	0,300	380	0,000064
303*	0,120	385	0,000053
305	0,060	390	0,000044
308	0,026	395	0,000036
310	0,015	400	0,000030

¹ Wavelengths chosen are representative: other values should be obtained by logarithmic interpolation at intermediate wavelengths.
* Emission lines of a mercury discharge spectrum.

IEC 62471			
Clause	Requirement + Test	Result – Remark	Verdict

Table 4.2	Spectral weighting functions for assessing retinal hazards from broadband optical sources	-	
Wavelength nm	Blue-light hazard function B (λ)	Burn hazard function R (λ)	
300	0,01		
305	0,01		
310	0,01		
315	0,01		
320	0,01		
325	0,01		
330	0,01		
335	0,01		
340	0,01		
345	0,01		
350	0,01		
355	0,01		
360	0,01		
365	0,01		
370	0,01		
375	0,01		
380	0,01	0,1	
385	0,013	0,13	
390	0,025	0,25	
395	0,05	0,5	
400	0,10	1,0	
405	0,20	2,0	
410	0,40	4,0	
415	0,80	8,0	
420	0,90	9,0	
425	0,95	9,5	
430	0,98	9,8	
435	1,00	10,0	
440	1,00	10,0	
445	0,97	9,7	
450	0,94	9,4	
455	0,90	9,0	
460	0,80	8,0	
465	0,70	7,0	
470	0,62	6,2	
475	0,55	5,5	
480	0,45	4,5	
485	0,40	4,0	
490	0,22	2,2	
495	0,16	1,6	
500-600	$10^{[(450-\lambda)/50]}$	1,0	
600-700	0,001	1,0	
700-1050		$10^{[(700-\lambda)/500]}$	
1050-1150		0,2	
1150-1200		$0,2 \cdot 10^{0,02(1150-\lambda)}$	
1200-1400		0,02	

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Clause	Requirement + Test	Result – Remark	Verdict

Table 5.4 Summary of the ELs for the surface of the skin or cornea (irradiance based values)					-
Hazard Name	Relevant equation	Wavelength range nm	Exposure duration sec	Limiting aperture rad (deg)	EL in terms of constant irradiance $W \cdot m^{-2}$
Actinic UV skin & eye	$E_S = \sum E_\lambda \cdot S(\lambda) \cdot \Delta\lambda$	200 – 400	< 30000	1,4 (80)	30/t
Eye UV-A	$E_{UVA} = \sum E_\lambda \cdot \Delta\lambda$	315 – 400	≤ 1000 > 1000	1,4 (80)	10000/t 10
Blue-light small source	$E_B = \sum E_\lambda \cdot B(\lambda) \cdot \Delta\lambda$	300 – 700	≤ 100 > 100	< 0,011	100/t 1,0
Eye IR	$E_{IR} = \sum E_\lambda \cdot \Delta\lambda$	780 – 3000	≤ 1000 > 1000	1,4 (80)	18000/t ^{0,75} 100
Skin thermal	$E_H = \sum E_\lambda \cdot \Delta\lambda$	380 – 3000	< 10	2π sr	20000/t ^{0,75}

Table 5.5 Summary of the ELs for the retina (radiance based values)					-
Hazard Name	Relevant equation	Wavelength range nm	Exposure duration sec	Field of view radians	EL in terms of constant radiance $W \cdot m^{-2} \cdot sr^{-1}$
Blue light	$L_B = \sum L_\lambda \cdot B(\lambda) \cdot \Delta\lambda$	300 – 700	0,25 – 10	0,011·√(t/10)	10 ⁶ /t
			10-100	0,011	10 ⁶ /t
			100-10000	0,0011·√t	10 ⁶ /t
			≥ 10000	0,1	100
Retinal thermal	$L_R = \sum L_\lambda \cdot R(\lambda) \cdot \Delta\lambda$	380 – 1400	< 0,25	0,0017	50000/(α·t ^{0,25})
			0,25 – 10	0,011·√(t/10)	50000/(α·t ^{0,25})
Retinal thermal (weak visual stimulus)	$L_{IR} = \sum L_\lambda \cdot R(\lambda) \cdot \Delta\lambda$	780 – 1400	> 10	0,011	6000/α

IEC 62471			
Clause	Requirement + Test	Result – Remark	Verdict

Table 6.1 Emission limits for risk groups of continuous wave lamps									P
Risk	Action spectrum	Symbol	Units	Emission Measurement					
				Exempt		Low risk		Mod risk	
				Limit	Result	Limit	Result	Limit	Result
Actinic UV	$S_{UV}(\lambda)$	E_s	$W \cdot m^{-2}$	0,001	n/a	0,003	n/a	0,03	n/a
Near UV		E_{UVA}	$W \cdot m^{-2}$	10	n/a	33	n/a	100	n/a
Blue light	$B(\lambda)$	L_B	$W \cdot m^{-2} \cdot sr^{-1}$	100	n/a	10000	n/a	4000000	n/a
Blue light, small source	$B(\lambda)$	E_B	$W \cdot m^{-2}$	1,0*	n/a	1,0	n/a	400	n/a
Retinal thermal	$R(\lambda)$	L_R	$W \cdot m^{-2} \cdot sr^{-1}$	$28000/\alpha$	n/a	$28000/\alpha$	n/a	$71000/\alpha$	n/a
Retinal thermal, weak visual stimulus**	$R(\lambda)$	L_{IR}	$W \cdot m^{-2} \cdot sr^{-1}$	$6000/\alpha = 60000$	6124,57	$6000/\alpha$	n/a	$6000/\alpha$	n/a
IR radiation, eye		E_{IR}	$W \cdot m^{-2}$	100	8,16	570	n/a	3200	n/a

* Small source defined as one with $\alpha < 0,011$ radian. Averaging field of view at 10000 s is 0,1 radian.
 ** Involves evaluation of non-GLS source

EN 62471 - ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 62471 EUROPEAN GROUP DIFFERENCES AND NATIONAL DIFFERENCES Photobiological safety of lamps and lamps systems			
Differences according to.....: EN 62471:2008			
Attachment Form No.....: EU_GD_IEC62471A			
Attachment Originator: IMQ S.p.A.			
Master Attachment.....: 2009-07			
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	CENELEC COMMON MODIFICATIONS (EN)		-
4	EXPOSURE LIMITS		-
	Contents of the whole Clause 4 of IEC 62471:2006 moved into a new informative Annex ZB		—
	Clause 4 replaced by the following:		-
	Limits of the Artificial Optical Radiation Directive (2006/25/EC) have been applied instead of those fixed in IEC 62471:2006	See appended Table 6.1	P
4.1	General		-
	First paragraph deleted		—

EN 62471			
Clause	Requirement + Test	Result – Remark	Verdict

Table 6.1 Emission limits for risk groups of continuous wave lamps (based on EU Directive 2006/25/EC) P

Risk	Action spectrum	Symbol	Units	Emission Measurement					
				Exempt		Low risk		Mod risk	
				Limit	Result	Limit	Result	Limit	Result
Actinic UV	$S_{UV}(\lambda)$	E_s	$W \cdot m^{-2}$	0,001	n/a	-	-	-	-
Near UV		E_{UVA}	$W \cdot m^{-2}$	0,33	n/a	-	-	-	-
Blue light	$B(\lambda)$	L_B	$W \cdot m^{-2} \cdot sr^{-1}$	100	n/a	10000	n/a	4000000	n/a
Blue light, small source	$B(\lambda)$	E_B	$W \cdot m^{-2}$	0,01*	n/a	1,0	n/a	400	n/a
Retinal thermal	$R(\lambda)$	L_R	$W \cdot m^{-2} \cdot sr^{-1}$	$28000/\alpha$	n/a	$28000/\alpha$	n/a	$71000/\alpha$	n/a
Retinal thermal, weak visual stimulus**	$R(\lambda)$	L_{IR}	$W \cdot m^{-2} \cdot sr^{-1}$	545000 $0,0017 \leq \alpha \leq$ $0,011$	n/a				
				$6000/\alpha =$ 60000 $0,011 \leq \alpha \leq 0,1$	6124,57 (for pulsed lamp shall be tested 1.7mrad)				
IR radiation, eye		E_{IR}	$W \cdot m^{-2}$	100	8,16	570	n/a	3200	n/a

* Small source defined as one with $\alpha < 0,011$ radian. Averaging field of view at 10000 s is 0,1 radian.

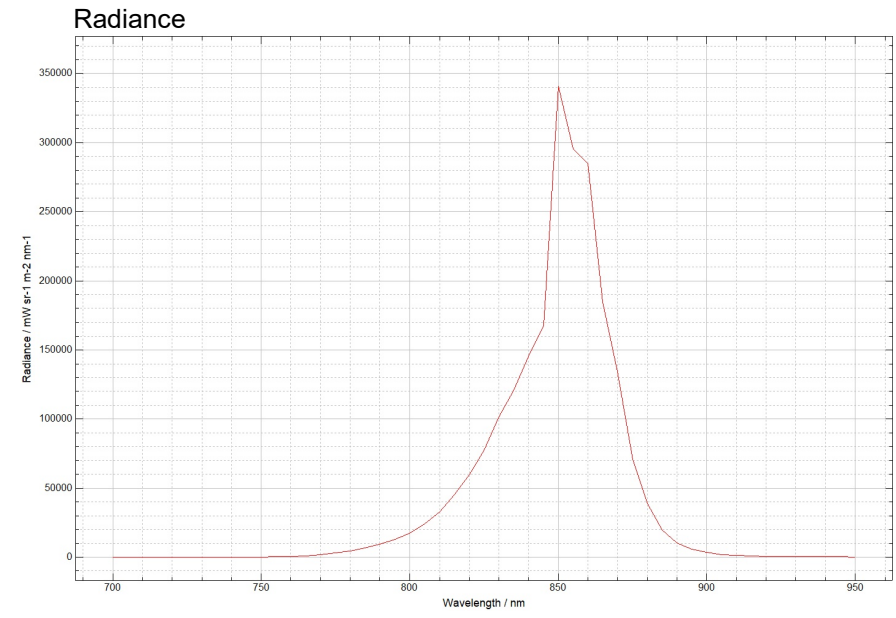
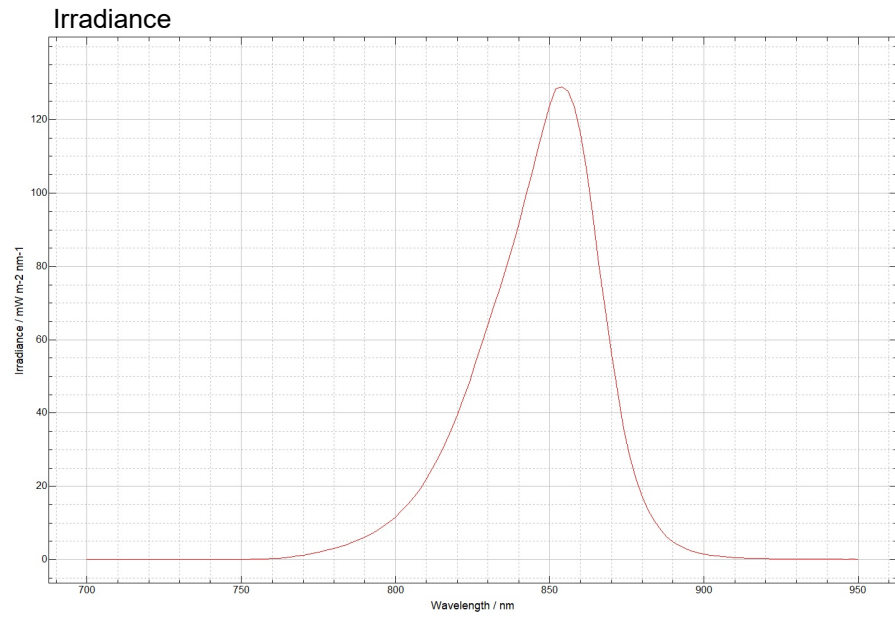
** Involves evaluation of non-GLS source

NOTE The action functions: see Table 4.1 and Table 4.2
 The applicable aperture diameters: see 4.2.1
 The limitations for the angular subtenses: see 4.2.2
 The related measurement condition 5.2.3 and the range of acceptance angles: see Table 5.5.

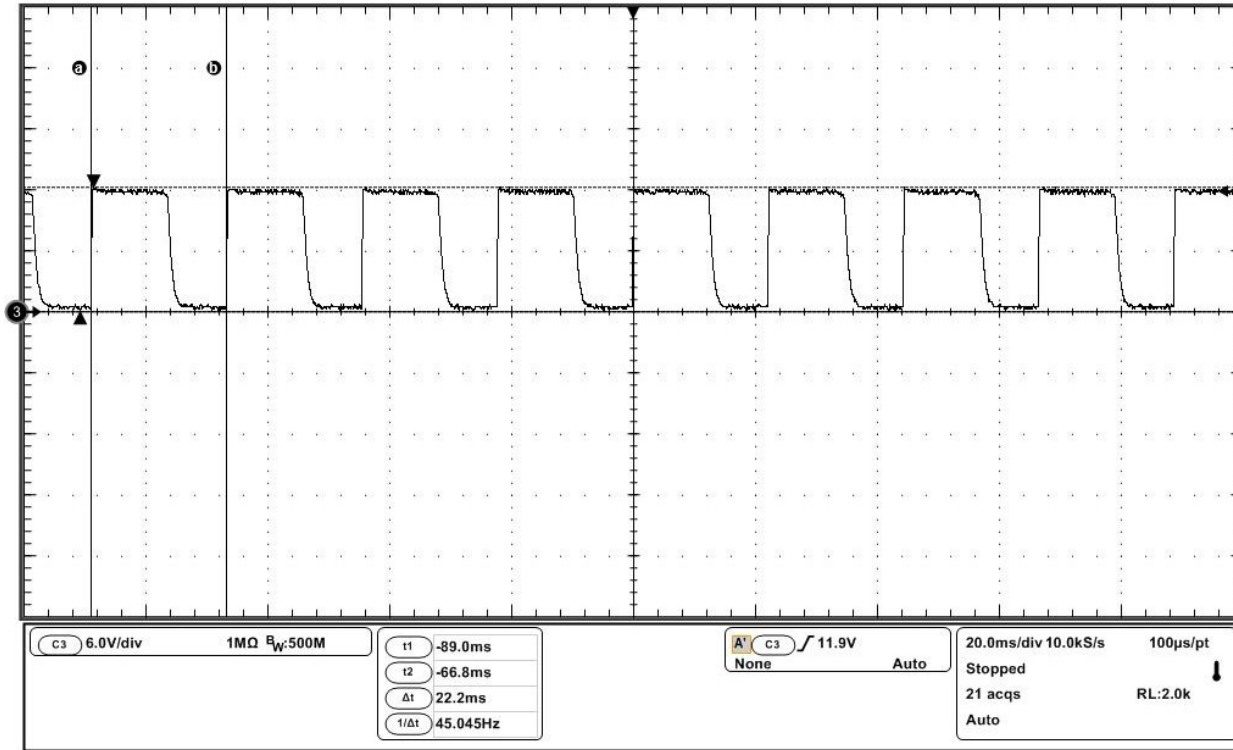
Furthermore remarks:

- Spectral graphs

: Relative Values at Measured Wavelength



- Pulsed source characteristics



- Photographs



--- END OF REPORT ---