A Critical Consideration of the Blink Reflex as a Means for Laser Safety Regulations

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Abstract. The eye blink reflex has been regarded as a physiological protective measure in international standards dealing with class 2 lasers since many years.
In lab and field trials we have irradiated volunteers with a laser beam (0.8 mW, 250 ms exposure time) from a specially designed ophthalmologic apparatus in order to stimulate the blink reflex. The laser wavelength has been chosen to be 670 nm, 635 nm or 532 nm. In addition to a collimated laser beam investigations have been done with a divergent laser beam and with light emitting diodes under various ambient illumination conditions to search for the respective dependency.
In total 503 volunteers have been irradiated in the lab and 690 in field trials with laser radiation. Out of these only 15.5 % or 18.26 % respectively have shown a blink reflex. The respective numbers as a function of wavelength have been 15.7 % (670 nm), 17.2 % (635 nm), and 22.4 % (532 nm). An increase from 4.2 % up to 28.1 % in blink reflex frequency was achieved when the ambient illuminance has been decreased from 1 700 lx to 1 lx using an LED as a large extended optical source instead of a collimated laser beam. A further dependency was found concerning the irradiated area on the retina, i.e. increasing the retinal spot from 6.4 mm^2 up to 46.8 mm^2 resulted in an increase of the blink reflex percentage from 20 % to 33.3 %.
The relatively small number of blink reflex cases claim for a modification of the safety rules concerning laser class 2 products in the International Standard.

1. Introduction

Laser are used in an increasing number of applications in industry, medicine, science and even for the in general public. Internationally laser products are classified according to the Standard IEC 60825-1 [1]. In the case of laser products which belong to class 2 or 2M, the laser radiation is restricted to the visible part of the optical spectrum, i.e. between 400 nm and 700 nm, and the continuous mode (CW) power is limited in the case of class 2 to 1 mW. The CW mode is defined for exposure durations larger than 0.25 s, which is equivalent to the time base for laser class 2, and the respective devices are regarded as safe for the human eye in the case of an accidentally intrabeam viewing.
The definition in the IEC-Standard 60825-1 assumes that the eye protection is normally afforded by aversion responses, including the blink reflex, and this reaction is expected to provide adequate protection under reasonably foreseeable conditions of operation even if optical instruments are used for viewing. As a result of this definition several regulations for the prevention of accidents around the world state that no further requirements or protective measures are necessary for this laser class.
Expecting a new European Directive on Optical Radiation in the near future the German Federal Ministry of Labour and Social Affairs decided to compile a Regulation for the Protection of Industrial Accidents on this topic. In this context we have reinvestigated an earlier report [2] and we also found that the blink reflex does not always occur when persons are irradiated by means of a bright incoherent optical light source [3, 4], e.g. a photoflash light, and the question was whether the same situation could happen with lasers belonging to class 2.
According to the European Standard EN 165:1995 [5] the eye blink reflex is defined as a property of humans to close the eyes due to an intensive "bright" light stimulus within 0.25 s. The statement that the safety of class 2 laser products is normally afforded by aversion responses, including the blink reflex, is used since many years in the International Standard IEC 60825-1 and has been extended to the new laser class 2M, which exists in the International and in the European Standard since 2001,

and a physiological reaction is expected to provide adequate protection under reasonable foreseeable conditions of operation of the respective laser.
In spite of the uncertainty the German Federal Institute for Occupational Safety and Health (FIOSH, BAuA) announced a research project in 1999 in order to review and verify the existence of the blink reflex as a function of physical parameters like laser power, exposure duration, wavelength, beam diameter, and physiological or psychological parameters like stress, fatigue, alcohol, nicotine, drugs to name but a few. The final report of this research project has been published recently [6].

2. Method

In 2000 it has been reported [3,4] that between 12.7 % and about 20 % showed no blink reflex when they have been irradiated with a commercially available photo flash light. These results concerning the lack of the blink reflex in more than 10 % initiated a research project on the "examination of laser classification with regard to the eye blink reflex".
According to IEC 60825-1 the power P of laser belonging to class 2 in the wavelength region from 400 nm to 700 nm is given by

$$P_{Laser} = \begin{cases} 39\ \mu\text{W to } 1\ \text{mW} & \text{for } 400\ \text{nm} \leq \lambda \leq 450\ \text{nm} \\ 10^{0{,}02\times(\lambda/\text{nm} - 450)} \times 39\ \mu\text{W to } 1\ \text{mW} & \text{for } 450\ \text{nm} \leq \lambda \leq 500\ \text{nm} \\ 389\ \mu\text{W to } 1\ \text{mW} & \text{for } 500\ \text{nm} \leq \lambda \leq 700\ \text{nm}, \end{cases} \qquad (1)$$

i.e. this is the range between the upper limit of laser class 1 with a time base of 100 s and the upper limit of class 2 (fig. 1).

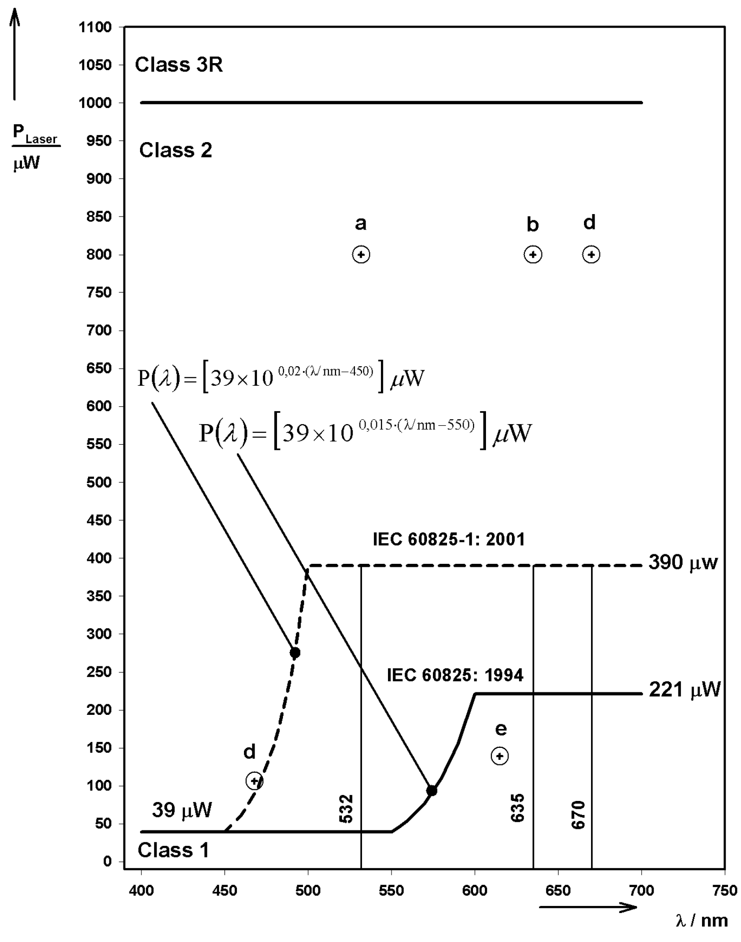

FIG. 1: Class 2 power range and maximum accessible emission limit for laser class 1 with a time base of 100 s and output power of the applied lasers and LEDs (marked a, b, c, d, e)

It should be mentioned that the upper limit of class 1 (time base: 100 s) has been increased in the current standard for wavelengths larger than 450 nm due to the photochemical and photothermal limits, which have to be considered simultaneously (cf. dashed line in fig. 1).

Taking into account that the relative spectral visibility of the human eye is different in the wavelength range between 400 nm and 700 nm, three laser wavelengths at 670 nm, 635 nm, and 532 nm have been chosen in order to cover a representative part of the visible spectrum for the investigation. Compared to 670 nm laser radiation at 635 nm is about 6.7 times brighter and about 27 times for the frequency doubled Nd:YAG laser at 532 nm. Additional to the three laser wavelengths investigations have been done with two light emitting diodes in the red and blue region of the visible spectrum.

The applied output power of the three different lasers has been 0.8 mW in order not to exceed the MPE value at the wavelength of 670 nm, 635 nm, and 532 nm and taking into account the uncertainty of measurement simultaneously. For the two LEDs the power was 1.8 mW (correction factor $C_6 = 13$) and 7.1 mW ($C_6 = 66,7$) at a dominant wavelength of 615 nm or 468 nm, respectively (cf. marked points d, e in fig. 1).

In lab and field trials volunteers were irradiated with a laser beam (0.8 mW, 250 ms exposure time) emitted from a specially designed ophthalmologic apparatus in order to stimulate the blink reflex. A detailed description of the special apparatus used in the research study has been given recently [7 - 9]. Fig. 2 shows a schematic diagram of the test apparatus.

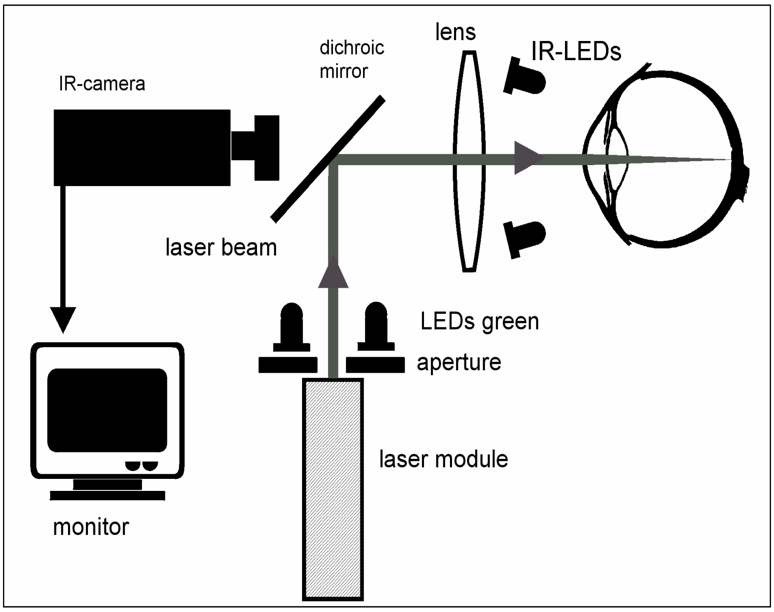

FIG. 2. Schematic set-up of the test apparatus for the blink reflex investigations

The same blink reflex apparatus has been used after relatively simple modifications together with different LEDs instead of laser devices.

In addition to a collimated laser beam investigations with a divergent laser beam and with large extended sources under various ambient illumination conditions have been done in order to search for the respective dependency.

The extension of light emitting diodes might be described by its respective correction factor C_6 and the correct positioning of the test person has been achieved at a distance between the outlet of the respective light beam and the eye when the diode chip could be imaged clearly on the retina. A divergent laser beam was achieved either using a specially designed focussing lens system in front of the cornea or as a result of an emerging laser radiation from a multimode optical fibre with a relatively large numerical aperture positioned close to the eye. Since the respective distance between the focal point of the lens or the optical fibre and the cornea was about 10 to 15 mm only the control and monitoring has been done with two video cameras and a mechanically robust construction.

The spot size on the retina was between 6.4 up to 46.8 mm^2 in the case of a divergent beam emerging from a lens system, whereas the pupil size has been chosen as a parameter to determine the amount of radiation and the angle of acceptance of the eye in the case of an irradiation from the distal end of an

optical fibre. As is well-known that the pupil size is a function of the adaptation condition which depends on the ambient light. In the range from 1 lx to 1,700 lx the pupil size changed from 8 mm to 2 mm.
The volunteers have been informed about the intended purpose of the investigations and were seated in front of the test apparatus in a similar manner like in an ophthalmologic examination. Since it was the intent to stimulate all persons in the fovea centralis of one eye the final position was adjusted by the operator via the illumination of the pupil of the eye with 4 IREDs and simultaneously positioning the image of the pupil on a monitor, which is equivalent to a co-linearity of the beam direction and the eye axis. Due to the chin rest which has been used to fixate the optical eye axis and the direction of the laser beam the volunteers were not able to move the head free. Normal aversion responses were not possible. The laser beam was switched-on deliberately by an operator and hit the test persons unexpected while the operator and a second person observed the reaction of the upper eyelid (palpebra) and the pupillary response, i.e. the lid closure (normal blink or blink reflex) or lid movement (twitching) and the constriction of the pupil. A more detailed description of the applied test procedure together with the 4 steps of the whole examination with an interview at the beginning, alignment of the apparatus, irradiation and observation, and a final inquiry, is given in recent publications [6, 7, 9 - 11].

3. Results

503 volunteers have been irradiated in the lab and 690 in 4 different field trials with laser radiation. Out of these only 15.5 % or 18.26 % respectively have shown a blink reflex. The respective numbers as a function of wavelength are: 15.7 % (670 nm), 17.2 % (635 nm), and 22.4 % (532 nm).
An increase from 4.2 % up to 28.1 % in blink reflex frequency was achieved when the ambient illuminance was decreased from 1 700 lx to 1 lx using an LED as a large extended stimulating optical source instead of a collimated laser beam.
A further dependency was found concerning the irradiated area on the retina, i.e. increasing the retinal spot from 6.4 to 9.4 mm^2 up to 33.7 to 46.8 mm^2 resulted in an increase of the blink reflex percentage from 20 % to 33.3 %.
Table I shows the results of the field trials with lasers of different wavelength, whereas Table II contains the respective results for LED-irradiation.

Table I. Results of the field trials on blink reflex stimulation with lasers (P = 0.8 mW, t = 250 ms) [11]

wavelength	number of volunteers	blink reflex quantity	frequency %
λ = 670 nm	261	41	15.7 ± 0.4*
λ = 635 nm	215	37	17.2 ± 0.5
λ = 532 nm	214	48	22.4 ± 0.5
all wavelengths	690	126	18.26 ± 0.11

*influence of a single test person more or less showing a blink reflex on the respective results

Table II. Results of the field trials on blink reflex stimulation with LEDs (t = 250 ms) [13]

wavelength	number of volunteers	blink reflex quantity	frequency %
λ = 615 nm	14	2	14.3 ± 7.1
λ = 468 nm	194	48	24.7 ± 0.6

In table III the results are given for a divergent laser beam which results in an increased spot size on the retina and table IV belongs to the investigations concerned with the fibre optic irradiation under various ambient light conditions. The focal length f of 60 mm equals a correction factor C_6 = 47.87 and f = 120 mm equals C_6 = 27.46 in the accomplished investigation [6].

Table III. Frequency of the blink reflex as a function of the retinal spot size irradiated by a laser beam (parameters: λ = 633 nm, P = 0.8 mW, t = 250 ms)

focal length mm	number of volunteers	retinal spot size mm^2	blink reflex quantity	frequency %
120	15	6.4 ...9.4	3	20 ± 6.7
120	23	9.4...13.1	5	21.7 ± 4.3
120	12	13.1...17.4	1	8.3 ± 8.3
60	17	22.7...33.7	5	29.4 ± 5.9
60	24	33.7...46.8	8	33.3 ± 4.2
	91		22	24.2 ± 1.1

Table IV. Blink reflex as a function of pupil size (parameters: λ = 632.8 nm (He:Ne-laser), P = 1 mW, t = 194 ms, ambient illumination 1 lx up to 1,700 lx, age of the volunteers: 15 till 30)

pupil size mm	number of volunteers	blink reflex quantity	frequency %	squinting %
2	3	0	0 + 33.3	66.7
3	48	2	4.2 ± 2.1	18.8
4	53	3	5.7 ± 1.9	24.5
5	18	2	11.1 ± 5.6	44.4
6	15	2	13.3 ± 6.7	40
7	32	9	28.1 ± 3.1	18.8
8	8	1	12.5 ± 12.5	62.5
2 till 8	177	19	10.7 ± 0.6	

4. **Discussion**

In our first investigations we have found that about 20 % did not show a blink reflex when they have been irradiated by a commercially available photo flashlight [3, 4]. These results confirm previous investigations which showed that only 3 out of 16 (18.75 %) had a blink reflex, when they became irradiated unexpected by a bright light [2]. Even though the total number of volunteers has been relatively low to deduce the respective relationships, it has been shown by Geratewohl and Strughold [2] at that time that the mean value of the blink reflex time was about 350 ms, when the volunteers did not look directly into the light source, i. e. about 40 % longer than the given time of 250 ms in the International Standard.

Anyhow a time interval of 250 ms has been used in the International Standard IEC 825 since 1984 (1st edition, now IEC 60825-1:2001). The International Commission on Non-Ionizing Radiation Protection (ICNIRP) recommended a quarter of a second for aversion responses in its Guidelines on laser radiation and broad-band incoherent optical radiation [14, 15] and this might be regarded as the rational base for the maximum permissible exposure (MPE) values.

Our investigations have shown that the current safety philosophy which states that the human eye is protected by aversion responses including the blink reflex might not be any longer based on the blink reflex alone as an inherent physiological property of human beings, since its frequency is much to small. This is true even at the wavelength close to the maximum visibility. The investigated volunteers showed a blink reflex frequency less than 25 %, which is by far too less for a convincing safety regulation.

A closer look onto the results achieved thus far shows that there exists a wavelength dependence of the blink reflex for both laser and LED irradiation (cf. table I and II), but this relationship is much weaker than might be expected from the visibility function [6, 12]. The dependency on the irradiated area on the retina and the pupil size are influencing variables too like the respective investigations have shown (cf. table III and IV), but even for the larger spot size on the retina the frequency of the blink reflex has been shown to be less than 35 % and the same is true for the maximum of the pupil size, i. e. for low ambient light conditions.

Although the results of the research project clearly show that the assumption of the blink reflex as a physiological protective property is no longer valid our findings do not state that class 2 laser are no longer safe, since there exists certainly a margin of safety concerning the intrabeam viewing of such a laser. Since an exposure duration of more than 250 ms at a power level of 1 mW is equivalent to exceeding the present MPE-values, i. e. a nominal ocular hazard area (NOHA) exists and therefore protective measures have to be applied in this area at the work place in order to be conform with part 3 of IEC 60825-1, i. e. the user's guide.

Since it is a well-established tradition in science and research that a result has to be confirmed at least by one further group using the same test parameters, the reported convincing results of the research project taken from 1,454 volunteers should be treated as preliminary. On the other hand the results have been discussed at various occasions, e. g. at the Laser Bioeffects Meeting [10] and at the International Laser Safety Conference (ILSC) [12], with the respective experts already.

In addition the question whether aversion responses limit the exposure of the human retina to less than 0.25 s is still open to be answered. This is currently being investigated in a new research project on "aversion response of humans against visible laser radiation" where the planned completion dates on April 2005. First results have been published on this topic very recently [13].

Intermediate results with about 200 volunteers in a scanning line laser method or applying an eye-tracking method have shown that aversion responses, like movement of the head side- or backwards and so on, in order to move the eye out of the laser beam, does not happen in the expected frequency in the case of laser beam irradiation likewise [13]. Up to now it might be preliminary stated that the blink reflex is the quickest and most often occurring reaction belonging to aversion responses against "bright light".

These up to now unpublished results have been reported to the TC 76 meeting (Technical Committee "Optical radiation safety and laser equipment", 29th September - 3rd October 2003) of the IEC in order to support a proposal of the German National Committee to change the classification of laser class 2 from 1 mW at a time base of 0.25 s to 0.6 mW at a time base of 2 s.

This proposal was based on a prudent precaution whereupon the increase of the time base with a simultaneous decrease of the continuous wave (CW) laser power should increase the safety margin taking into account the absence of "aversion responses including the blink reflex".

Prudent precaution should neither be directly confused with the "Precautionary Principle" declared in a Communication of the Commission of the European Communities nor with "Prudent Avoidance" but is solely the attempt to describe a situation where the safety could be increased without restricting the usual approach too much and simultaneously takes into account a somewhat changed argumentation regarding the customary safety interpretation.

A change from physiological reactions like the blink reflex and other aversion responses to "active protection reactions" like the active closure of the eye and the active movement of the head away from the beam could represent a minor but important modification of the safety philosophy of laser class 2.

Without any doubt the combination of 1 mW and 0.25 s has not only a tradition of more than a quarter of a century, is easy to be kept in mind, but is mainly based on the blink reflex.

Therefore a modified definition of laser class 2 will be circulated in a Committee Draft of the IEC which is responsible for the classification of lasers, as an intermediate result of the previous research results, whereas the limiting values are dealt with by ICNIRP.

Since user guidelines given in standards like the IEC 60825-1, which is valid in Europe as EN 60825-1 and therefore exists for the members of the European Normalization Committee (CEN and CENELEC, resp.), are not mandatory, national regulations might be defined legally. This national regulations should be based on a respective safety analysis and might be given as a mandatory statement or as a recommendation, e. g. to use laser belonging to class 2 up to an upper power limit of 0.6 mW or to instruct potential laser users in active protection reactions in future applications in order to fulfil the global demands of the European Union to improve safety and health at the work place and in the environment.

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