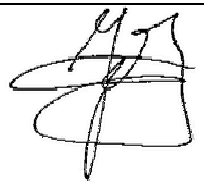
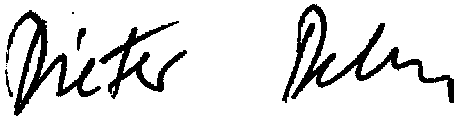
Testbericht IEC 60825-1:2007 **Beschreibung der Anforderungen**	**Remarks**	**Verdict** **N / P / F / NC**

Checkliste der Übereinstimmungen mit den Anforderungen der **IEC 60825-1:2007**

Hersteller: Reimers & Janssen GmbH	**Typbezeichnung:** Laserpen Expert und Practice
Tel.: +49-7682-6558	**Medizinprodukte Klasse:** IIa
Datum: 25. Mai 2010 (Überarbeitung)	**Ergebnis:** Der Test wurde bestanden.
Plausibilitätsprüfung: Josephus Janssen	**Durchgeführt von:** Dr. Dieter Debus
Unterschrift: 	**Unterschrift:** 

Test case verdicts

Test case does not apply to the test object .... :	N (Not Applicable).
Test item does meet the requirement ..... :	P(ass)
Test item does not meet the requirement ..... :	F(ail)
Test object not checked ..... :	NC

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4 Engineering specifications		
4.1 General remarks		
Laser products require certain built-in safety features, depending on the class to which they have been assigned by the manufacturer. The requirements for these are given in 4.2 to 4.12.The manufacturer shall ensure that the personnel responsible for the classification of laser products and systems have received training to an appropriate level that allows them to understand the full implications of the classification scheme. • **Modification** If the modification of a previously classified laser product affects any aspects of the product's performance or intended functions within the scope of this standard, the person or organization performing any such modification is responsible for ensuring the reclassification and relabelling of the laser product.	Qualifikation Dr. Debus Keine Modifizierung	P
4.2 Protective housing		
4.2.1 General Each laser product shall have a protective housing which, when in place, prevents human access to laser radiation (including errant laser radiation) in excess of the AEL for Class 1, except when human access is necessary for the performance of the function(s) of the product. When the classification of a laser product is based on the prevention of human access to a level of energy that is equivalent to Class 4 (for instance, for laser processing machines), the protective housing must withstand exposures under reasonably foreseeable single fault conditions (see 9.1), without human intervention. If the protective housing is of a size that permits human entry, see 4.12. Maintenance of Class 1, 1M, 2, 2M, or 3R laser products shall not permit human access to levels of laser radiation of Class 3B or Class 4. Maintenance of Class 3B laser products shall not permit human access to levels of laser radiation of Class 4.	Schutzgehäuse entspricht den Anforderungen, Klasse 3B Laser Zugang zu Strahlung der Klasse 4 nicht möglich.	P
4.2.2 Service Any parts of the housing or enclosure of a laser product (including embedded laser products) that can	Schutzgehäuse entspricht den Anforderungen	N

be removed or displaced for service and which would allow access to laser radiation in excess of the AEL assigned and are not interlocked (see 4.3) shall be secured in such a way that removal or displacement of the parts requires the use of a tool or tools.		
4.2.3 Removable laser system If a laser system can be removed from its protective housing or enclosure and operated without modification, the laser system shall comply with the manufacturing requirements of Clauses 4 and 5 that are appropriate to its class.		N
4.3 Access panels and safety interlocks		
4.3.1 A safety interlock shall be provided for access panels of protective housings when both of the following conditions are met: a) the access panel is intended to be removed or displaced during maintenance or operation, and b) the removal of the panel gives access to laser radiation levels designated by "X" in Table 1 below. Table 1 below indicates (X) the applicability of a safety interlock. Table 1 below indicates (X) the applicability of a safety interlock. **Table 1 – Requirements for safety interlocking** **Product class** / **Accessible emission during or after removal of access panel** **1, 1M** / **2, 2M** / **3R** / **3B** / **4** 1, 1M – – X X X 2, 2M – – X X X 3R – – – X X 3B – – – X X 4 – – – X X Removal of the panel shall not result in emission through the opening in excess of the AEL for Class 1M or Class 2M, as applicable according to the wavelength. When a safety interlock is required, the safety interlock shall prevent access to accessible emission levels above the applicable AEL in Table 1 when the panel is removed. Inadvertent resetting of the interlock shall not in itself restore emission values above the applicable AEL in Table 1. These interlocks shall conform to the requirements in the	No access panel	N

applicable IEC product safety standard (see Clause 1). NOTE The requirements of 9.1 also apply to interlocks, i.e. interlocks need to be failsafe or redundant.		
4.3.2 If a deliberate override mechanism is provided, the manufacturer shall also provide adequate instructions about safe methods of working. It shall not be possible to leave the override in operation when the access panel is returned to its normal position. The interlock shall be clearly associated with a label conforming to 5.9.2. Use of the override shall give rise to a distinct visible or audible warning whenever the laser is energized or capacitor banks are not fully discharged, whether or not the access panel is removed or displaced. Visible warnings shall be clearly visible through protective eyewear specifically designed or specified for the wavelength(s) of the accessible laser radiation.	No access panel	N
4.4 Remote interlock connector Each Class 3B and Class 4 laser system shall have a remote interlock connector. When the terminals of the connector are open-circuited, the accessible radiation shall not exceed the AEL for Class 1M or Class 2M as applicable.	See IFU Safety plug on the backside of the Laserpen	P
4.5 Manual reset Each Class 4 laser system shall incorporate a manual reset to enable resumption of accessible Class 4 laser radiation emission after interruption of emission caused by the use of the remote interlock connector or an interruption of longer than 5 s of electrical mains power. NOTE Manufacturers may include a second interlock connector that does not require active action for starting emission, but it is not required for a product to have two connectors.		N
4.6 Key control Each Class 3B and Class 4 laser system shall incorporate a key-operated master control. The key shall be removable and the laser radiation shall not be accessible when the key is removed. NOTE In this Part 1 the term "key" includes any other control devices, such as magnetic cards, cipher combinations, computer passwords, etc.	See IFU Safety plug on the backside of the Laserpen	P
4.7 Laser radiation emission warning **4.7.1 Each Class 3R laser** system in the wavelength range below 400 nm and above 700 nm and each Class 3B and Class 4 laser system shall satisfy the following.		

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4.7.2 A warning device shall give an audible or visible signal when the laser system is switched on or if any capacitor banks of a pulsed laser are being charged or have not positively discharged. The warning device shall be fail-safe or redundant. Any visible warning device shall be clearly visible through protective eyewear specifically designed for the wavelength(s) of the emitted laser radiation. The visible warning device(s) shall be located so that viewing does not require exposure to laser radiation in excess of the AEL for Class 1M and 2M.	Indicator LED on the frontpanel	P
4.7.3 Each operational control and laser aperture that can be separated by 2 m or more from a radiation warning device shall itself be provided with a radiation warning device. The warning device shall be clearly visible or audible to the person in the vicinity of the operational control or laser aperture.		N
4.7.4 Where the laser emission may be distributed through more than one output aperture, then a visible warning device shall clearly indicate the output aperture or apertures through which laser emission can occur, in accordance with 4.7.2.		N
4.8 Beam stop or attenuator Each Class 3B and Class 4 laser system shall incorporate one or more permanently attached means of attenuation (e. g., beam stop, attenuator, switch). The beam stop or attenuator shall be capable of preventing human access to laser radiation in excess of the AEL for Class 1M or Class 2M as applicable.	REMOTE CONTROL INTERLOCK,	P
4.9 Controls Each laser product shall have controls located so that adjustment and operation do not require exposure to laser radiation equivalent to Class 3R, Class 3B or Class 4.	See IFU	P
4.10 Viewing optics Any viewing optics, viewport or display screen incorporated in a laser product shall provide sufficient attenuation to prevent human access to laser radiation in excess of the AEL for Class 1M, and, for any shutter or variable attenuator incorporated in the viewing optics, viewport or display screen, a means shall be provided to: a) prevent human access to laser radiation in excess of the AEL for Class 1M	No viewing optics	N

when the shutter is opened or the attenuation varied; b) prevent opening of the shutter or variation of the attenuator when exposure to laser radiation in excess of the AEL for Class 1M is possible.		
4.11 Scanning safeguard Laser products intended to emit scanned radiation and classified on this basis, shall not, as a result of scan failure or of variation in either scan velocity or amplitude, permit human access to laser radiation in excess of the AEL for the assigned class, unless exposure of people is not reasonably foreseeable during the time interval between failure and when the scanning safeguard reduces emission to levels below the AEL of the class of the product (also see 9.1).	No scanning safeguard	N
4.12 "Walk-in" access If a protective housing is equipped with an access panel which provides "walk-in" access then: a) means shall be provided so that any person inside the housing can prevent activation of a laser hazard that is equivalent to Class 3B or Class 4; b) a warning device shall be situated so as to provide adequate warning of emission of laser radiation equivalent to Class 3R in the wavelength range below 400 nm and above 700 nm, or of laser radiation equivalent to Class 3B or Class 4 to any person who might be within the housing; c) where “walk-in” access during operation is intended or reasonably foreseeable, emission of laser radiation that is equivalent to Class 3B or Class 4 while someone is present inside the enclosure of a Class 1, Class 2, or Class 3R product shall be prevented by engineering means. NOTE Methods to prevent human access to radiation when persons are inside the protective housing may include pressure sensitive floor mats, infrared detectors, etc.	No access panel	N
4.13 Environmental conditions The laser product shall meet the safety requirements defined in this standard under all expected operating conditions appropriate to the intended use of the product. Factors to be considered shall include: – climatic conditions (e.g. temperature, relative humidity); – vibration and shock. If no provisions are made in the product safety standard, the relevant subclauses of IEC 61010-1 shall apply. NOTE Requirements related to electromagnetic susceptibility are under consideration.	See test protocol DIN EN 60601-1 and IFU	P
4.14 Protection against other hazards	See test protocol DIN EN 60601-1	P

4.14.1 Non-optical hazards The requirements of the relevant product safety standard shall be fulfilled during operation and in the event of a single fault for the following: – electrical hazards; – excessive temperature; – spread of fire from the equipment; – sound and ultrasonics; – harmful substances; – explosion. If no provisions are included in the product safety standard, the relevant subclauses of IEC 61010-1 shall apply. NOTE Many countries have regulations for the control of harmful substances. Contact the appropriate national agency for these requirements.		
4.14.2 Collateral radiation The protective housing of laser products will normally protect against the hazards of collateral radiation (e.g. ultraviolet, visible, infrared radiation). However, if a concern exists that accessible collateral radiation might be hazardous, the laser MPE values may be applied to conservatively evaluate this hazard.	No hazardous collateral radiation	N
5 Labelling		
5.1 General Each laser product shall carry label(s) in accordance with the requirements of the following clauses. The labels shall be durable, permanently affixed, legible, and clearly visible during operation, maintenance or service, according to their purpose. They shall be so positioned that they can be read without the necessity for human exposure to laser radiation in excess of the AEL for Class 1. Text borders and symbols shall be black on a yellow background except for Class 1, where this colour combination need not be used. The wording of labels shown in Clause 5 is recommended but not mandatory. Other wording that conveys the same meaning may be substituted. If the size or design of the product makes labelling impractical, the label shall be included with the user	See IFU	P

information or on the package. NOTE Direct printing or engraving of equivalent labels on the laser product or panels is acceptable.		
5.2 Class 1 and Class 1M Except as permitted in Clause 1, each Class 1 laser product shall have affixed an explanatory label (Figure 2) bearing the words: CLASS 1 LASER PRODUCT Each Class 1M laser product shall have affixed an explanatory label (Figure 2) bearing the words: LASER RADIATION DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS CLASS 1M LASER PRODUCT Instead of the above labels, at the discretion of the manufacturer, the same statements may be included in the information for the user. The type of optical instrument which could result in an increased hazard may be added in parenthesis after the word "instruments" on the Class 1M label. The added wording could in particular be "(BINOCULARS OR TELESCOPES)" for a laser product with a collimated, largediameter beam, which is classified 1M because it fails condition 1 (see Clause 9), or "(MAGNIFIERS)" for a laser product which is classified 1M because it fails condition 2 (see Clause 9) (highly diverging beam). Alternatively, the second line of the Class 1M label could read “DO NOT EXPOSE USERS OF BINOCULARS OR TELESCOPES” If the accessible emission exceeds the AEL of Class 3B as determined with a 3,5 mm diameter aperture placed at the closest point of human access, an additional warning is to be given on a product label and in the information for the user: SKIN EXPOSURE NEAR APERTURE MAY CAUSE BURNS NOTE Only applies if condition 2 is used to determine the AEL.		N
5.3 Class 2 and Class 2M Each Class 2 laser product shall have affixed a warning label (Figure 1) and an explanatory label (Figure 2) bearing the words: LASER RADIATION DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT Each Class 2M laser product shall have affixed a warning label (Figure 1) and an explanatory label (Figure 2) bearing the words:		N

LASER RADIATION DO NOT STARE INTO THE BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS CLASS 2M LASER PRODUCT The type of optical instrument which could result in an increased hazard may be added in parenthesis after the word "instruments". The added wording could in particular be "(BINOCULARS OR TELESCOPES)" for a laser product with a collimated, large-diameter beam which is classified 2M because it fails condition 1 (see Clause 9), or "(MAGNIFIERS)" for a laser product which is classified 2M because it fails condition 2 (see Clause 9) (highly diverging beam). Alternatively, the second line of the Class 2M label could read “DO NOT EXPOSE USERS OF BINOCULARS OR TELESCOPES” If the accessible emission exceeds the AEL of Class 3B as determined with a 3,5 mm diameter aperture placed at the closest point of human access, an additional warning is to be given on a product label and in the information for the user: SKIN EXPOSURE NEAR APERTURE MAY CAUSE BURNS NOTE Only applies if condition 2 is used to determine the AEL.		
5.4 Class 3R Each Class 3R laser product shall have affixed a warning label (Figure 1) and an explanatory label (Figure 2) bearing the words: LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCT NOTE Labels using AVOID EXPOSURE TO BEAM in the second line would also be acceptable.		N.
5.5 Class 3B Each Class 3B laser product shall have affixed a warning label (Figure 1) and an explanatory label (Figure 2) bearing the words: LASER RADIATION AVOID EXPOSURE TO BEAM CLASS 3B LASER PRODUCT	Label on the carrying case See IFU	P
5.6 Class 4 Each Class 4 laser product shall have affixed a warning label (Figure 1) and an explanatory label		N

(Figure 2) bearing the words: LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT		
5.7 Aperture label Each Class 3R, Class 3B and Class 4 laser product shall have affixed a label close to each aperture through which laser radiation in excess of the AEL for Class 1 or Class 2 is emitted. The label(s) shall bear the words: LASER APERTURE or APERTURE FOR LASER RADIATION or AVOID EXPOSURE – LASER RADIATION IS EMITTED FROM THIS APERTURE	Label on the Laserpen near the aperture See IFU	P
5.8 Radiation output and standards information The name and publication date of the standard to which the product was classified shall be included on the explanatory label or elsewhere in close proximity on the product. Each laser product, except those of Class 1, shall be described on the explanatory label (Figure 2) by a statement of the maximum output of laser radiation (see definition 3.55), the pulse duration (if appropriate) and the emitted wavelength(s). For Class 1 and Class 1M, instead of the labels on the product, the information may be contained in the information for the user.	Label on the Laserpen See IFU	P
5.9 Labels for access panels		
5.9.1 Labels for panels Each connection, each panel of a protective housing, and each access panel of a protective enclosure which, when removed or displaced permits human access to laser radiation in excess of the AEL for Class 1, shall have affixed labels bearing the words (for the case of an embedded Class 1M laser, the statement instead may be included in the information for the user): a) CAUTION – CLASS 1M LASER RADIATION WHEN OPEN DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS if the accessible radiation does not exceed the AEL for Class 1M where the level of radiation is	No access panels	N

measured according to 9.2 g) and 9.3; b) CAUTION – CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM if the accessible radiation does not exceed the AEL for Class 2 where the level of radiation is measured according to 9.2 h) and 9.3; c) CAUTION – CLASS 2M LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS if the accessible radiation does not exceed the AEL for Class 2M where the level of radiation is measured according to 9.2 h) and 9.3; d) CAUTION – CLASS 3R LASER RADIATION WHEN OPEN AVOID DIRECT EYE EXPOSURE if the accessible radiation does not exceed the AEL for Class 3R; NOTE Labels using AVOID EXPOSURE TO THE BEAM in the second line would also be acceptable. e) CAUTION – CLASS 3B LASER RADIATION WHEN OPEN AVOID EXPOSURE TO THE BEAM if the accessible radiation does not exceed the AEL for Class 3B; f) CAUTION – CLASS 4 LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION if the accessible radiation exceeds the limits for Class 3B. This information may be provided in more than one adjacent label on the product.		
5.9.2 Labels for safety interlocked panels Appropriate labels shall be clearly associated with each safety interlock which may be readily overridden and which would then permit human access to laser radiation in excess of the AEL of Class 1. Such labels shall be visible prior to and during interlock override and be in close proximity to the opening created by the removal of the protective housing. This label shall bear the words specified in items a) to f) of 5.9.1, as applicable, with the introduction of an additional line, positioned after the first line, with the following words: AND INTERLOCKS DEFEATED		N

5.10 Warning for invisible laser radiation In many cases, the wording prescribed for labels in Clause 5 includes the phrase "LASER RADIATION". If the output of the laser is outside the wavelength range from 400 nm to 700 nm, this shall be modified to read "INVISIBLE LASER RADIATION", or if the output is at wavelengths both inside and outside this wavelength range, to read "VISIBLE AND INVISIBLE LASER RADIATION". If a product is classified on the basis of the level of visible laser radiation and also emits in excess of the AEL of Class 1 at invisible wavelengths, the label shall include the words "VISIBLE AND INVISIBLE LASER RADIATION" in lieu of "LASER RADIATION".	See labels	P
5.11 Warning for visible laser radiation The wording "LASER RADIATION" for labels in Clause 5 may be modified to read "LASER LIGHT" if the output of the laser product is in the (visible) wavelength range from 400 nm to 700 nm.	See labels	P
6 Other informational requirements		
6.1 Information for the user Manufacturers of laser products shall provide (or see to the provision of) user instructions or an operation manual that contains all relevant safety information. It remains the responsibility of the manufacturer to provide the safety information indicated below and to decide which additional information is relevant and, therefore, shall be provided. NOTE The information that is relevant or not relevant depends on the specific product including its intended application and may even be subject to national legislation. The following information shall be provided: a) Adequate instructions for proper assembly, maintenance, and safe use, including clear warnings concerning precautions to avoid possible exposure to hazardous laser radiation and description of the classification limitations, if appropriate (see Annex C for a description of the classes and possible limitations). b) An additional warning for Class 1M and 2M laser products. For diverging beams, this warning shall state that viewing the laser output with certain optical instruments (for example, eye loupes, magnifiers and microscopes) within a distance of 100 mm may pose an eye hazard. For collimated beams, this warning shall state that viewing the laser output with certain optical instruments designed for use at a distance (for example, telescopes and binoculars) may pose an eye hazard. c) For laser radiation levels above the AEL of Class 1, a description of any radiation pattern(s) emitted	See IFU	P

from the protective housing during the performance of operation and maintenance procedures. Where applicable, this shall include a statement in appropriate units of: • wavelength, • beam divergence, • pulse duration and repetition rate (or description of irregular pulse pattern), • maximum power or energy output. The values shall, where appropriate, include cumulative measurement uncertainties and any expected increase in the measured quantities at any time after manufacture. Duration of pulses resulting from unintentional mode-locking need not be specified; whereas, those conditions associated with the product known to result in unintentional mode-locking shall be specified. For ultrashort pulses, the bandwidth of the radiation (i.e. the wavelength range of emission) shall be specified. d) For embedded laser products and other incorporated laser products, information to describe the incorporated laser (see item c)). The information shall also include appropriate safety instructions to the user to avoid inadvertent exposure to hazardous laser radiation. This is particularly relevant for embedded laser products that are classified as Class 1, Class 1M, Class 2 or Class 2M but where intrabeam viewing to accessible emission levels in excess of the AELs of these classes is possible during maintenance. In this case the manufacturer shall include a warning that intrabeam viewing of the laser shall be prevented. e) Where appropriate and relevant, the applicable MPE and NOHD for Class 3B and Class 4 laser products. Since the NOHD greatly depends on the beam delivery system and optical elements placed in the beam, when this is considered as relevant, it is recommended that the different NOHD values are given for the different attachments or beam delivery systems. If there is a variable beam divergence, the NOHD could be given for some selected values of divergence. When an MPE and NOHD value is stated, the assumed exposure duration for the determination of these values shall also be stated. For collimated-beam Class 1M and Class 2M lasers, the extended NOHD (ENOHD) shall be stated, where appropriate and relevant. NOTE Specific information on the NOHD is typically not required for collimated beams that are to be used indoors. In that case, it is usually sufficient to give only an indication of the extent of the range where the MPE can be exceeded. f) Where appropriate, information for the selection of eye protection. This shall include the required optical density as well as irradiance or radiation exposure levels that might be incident on the surface of the eye protection equipment, so that resistance levels can be determined. NOTE Many countries have regulations and standards for personal protective equipment. Contact the appropriate national agency for these requirements. g) Legible reproductions (colour optional) of all required labels and hazard warnings to be affixed to the laser product or provided with the laser product. The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in		

which they were supplied shall be provided. h) A clear indication in the manual of all locations of laser apertures through which laser radiation exceeding the Class 1 AEL is emitted. i) List of controls, adjustments and procedures for operation and maintenance, including the warning "Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure" (or alternatively, equivalent appropriate warnings). j) In the case of laser products that do not incorporate the laser energy source necessary for laser emission, a statement of the compatibility requirements for a laser energy source to ensure safety.		
6.2 Purchasing and servicing information Manufacturers of laser products shall provide or cause to be provided the following. a) In all catalogues, specification sheets and descriptive brochures, the classification of each laser product and any warning shall be stated, including those specified by 6.1 b), if appropriate. b) To servicing dealers and distributors, and to others upon request, adequate instructions for service adjustments and service procedures for each laser product model, which include: – clear warnings and precautions to be taken to avoid possible exposure to laser radiation above Class 1 and other hazards; – a schedule of maintenance necessary to keep the product in compliance; – a list of those controls and procedures which could be utilized by persons other than the manufacturer or his agents to increase accessible emission levels of radiation; – a clear description of the location of displaceable portions of the protective housing which could allow access to laser radiation in excess of the accessible limits in Tables 4 to 9; – protective procedures for service personnel; and – legible reproductions (colour optional) of required labels and hazard warnings.	See IFU and prospect	P
7 Additional requirements for specific laser products		
7.1 Other parts of the standard series IEC 60825 For specific applications, one or other of the following IEC 60825 series may be applicable (see also Bibliography).		N
– IEC 60825-2, *Safety of optical fibre communication systems* (provides application notes and examples)		N
– IEC 60825-4, *Laser guards* (provides design and construction information for laser guards and materials especially where high power lasers are used)		N
– IEC 60825-12, *Safety of free space optical communication systems used for transmission*		N

of information.		
– IEC/TR 60825-3, *Guidance for laser displays and shows*		N
– IEC/TR 60825-5, *Manufacturer's checklist for IEC 60825-1* (suitable for use in a safety report)		N
– IEC/TR 60825-8, *Guidelines for the safe use of laser beams on humans*	Low Level Laser	P
– IEC/TR 60825-9, *Compilation of maximum permissible exposure to incoherent optical radiation* (broadband sources)		N
Further information may be found in:		
– IEC/TR 60825-10, *Application guidelines and explanatory notes to IEC 60825-1*		P
– IEC/TR 60825-13, *Measurements for classification of laser products*		P
– IEC/TR 60825-14, *A user's guide*		P
– IEC 62471 (CIE S009), *Photobiological safety of lamps and lamp systems*		N
7.2 Medical laser products Each medical laser product shall comply with all of the applicable requirements for laser products of its class. In addition, any Class 3B or Class 4 medical laser product is subject to IEC 60601-2-22.	See testreport IEC60601-2-22	P
7.3 Laser processing machines		N
7.4 Electric toys		N
7.5 Elektronische Endverbraucherprodukte		N

8 Classification ***8.1 Introduction*** Because of the wide ranges possible for the wavelength, energy content and pulse characteristics of a laser beam, the potential hazards arising in its use vary widely. It is impossible to regard lasers as a single group to which common safety limits can apply. Annex C describes the hazards associated with the classes and possible limitations (e.g. as may arise from optically aided viewing) in more detail.		
8.2 Classification responsibilities It is the responsibility of the manufacturer or his agent to provide correct classification of a laser product (however, see 4.1). The product shall be classified on the basis of that combination of output power(s) and wavelength(s) of the accessible laser radiation over the full range of capability during operation at any time after manufacture which results in its allocation to the highest appropriate class. A laser product can only be assigned to a particular class when it has met all of the requirements within this Part 1 for that class, for example engineering controls, labelling and information for the user.		P
8.3 Classification rules For the purpose of classification rules, the following ranking of the classes (in increasing order of hazard) shall be used: Class 1, Class 1M, Class 2, Class 2M, Class 3R, Class 3B, Class 4. NOTE For classification of a laser product as Class 1M or 2M, the use of an aperture specified as condition 3 limits the amount of radiation that is collected from large diameter or highly diverging beams. For example, when measured under the applicable conditions, Class 1M and Class 2M products may have higher measured total energy or power than Class 2 or Class 3R. For such laser products, a classification of 1M or 2M is appropriate. The accessible emission limits (AELs) for Class 1 and 1M, Class 2 and 2M, Class 3R and Class 3B are given in Tables 4 to 9. The values of the correction factors used are given in Table 10 as functions of wavelength, emission duration, number of pulses and angular subtense		P

a) Radiation of a single wavelength A single wavelength laser product, with a spectral range of the emission line narrow enough so that the AELs do not change, is assigned to a class when the accessible laser radiation, measured under the conditions appropriate to that class, exceeds the AEL of all lower classes but does not exceed that of the class assigned.	Single wavelength	P
b) Radiation of multiple wavelengths 1) A laser product emitting two or more wavelengths in spectral regions shown as additive in Table 2 is assigned to a class when the sum of the ratios of the accessible laser radiation (measured under the conditions appropriate to that class) to the AELs of those wavelengths is greater than unity for all lower classes but does not exceed unity for the class assigned. 2) A laser product emitting two or more wavelengths not shown as additive in Table 2 is assigned to a class when the accessible laser radiation, measured under the conditions appropriate to that class, exceeds the AELs of all lower classes for at least one wavelength but does not exceed the AEL for the class assigned for any wavelength		N

Table 2 – Additivity of effects on eye and skin of radiation of different spectral regions

Spectral region[a]	UV-C and UV-B 180 nm to 315 nm	UV-A 315 nm to 400 nm	Visible and IR-A 400 nm to 1 400 nm	IR-B and IR-C 1 400 nm to 10^6 nm
UV-C and UV-B 180 nm to 315 nm	o s			
UV-A 315 nm to 400 nm		o s	s	o s
Visible and IR-A 400 nm to 1 400 nm		s	o [b] s	s
IR-B and IR-C 1 400 nm to 10^6 nm		o s	s	o s

o Eye
s Skin

a For definitions of spectral regions, see Table D.1.

b Where AELs and ocular MPEs are being evaluated for time bases or exposure durations of 1 s or longer, then the additive photochemical effects (400 nm to 600 nm) and the additive thermal effects (400 nm to 1 400 nm) shall be assessed independently and the most restrictive value used.

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c) Radiation from extended sources The ocular hazard from laser sources in the wavelength range from 400 nm to 1 400 nm is dependent upon the angular subtense of the apparent source ⟨. NOTE 1 A source is considered an extended source when the angular subtense of the source is greater than $\langle_{min}$, where $\langle_{min}$ = 1,5 mrad. Most laser sources have an angular subtense ⟨ less than $\langle_{min}$, and appear as an apparent "point source" (small source) when viewed from within the beam (intra-beam viewing). Indeed a circular laser beam cannot be collimated to a divergence less than 1,5 mrad if it is an extended source, thus any laser where a beam divergence in any plane of 1,5 mrad or less is specified cannot be treated as an extended source. NOTE 2 For retinal thermal hazard evaluation (400 nm to 1 400 nm), the AELs for extended sources vary directly with the angular subtense of the source. For the retinal photochemical hazard evaluation (400 nm to 600 nm), for exposures greater than 1 s, the AELs do not vary directly with the angular subtense of the source. Depending on the emission duration (see 9.3.3b) 1), a limiting angle of acceptance ©ph of 11 mrad or more is used for measurement, and the relation of the limiting acceptance angle ©ph to the angular subtense ⟨ of the apparent source can influence the measured value. NOTE 3 For the default condition where C_6 = 1, a simplified Table 4 is provided for the AEL of Class 1 and 1M. For sources subtending an angle less than or equal to $\langle_{min}$, the AEL and MPE are independent of the angular subtense of the apparent source ⟨. For classifying laser products at the most restrictive position where condition 1 applies (see 9.3.3), the 7. magnification of the angular subtense ⟨ of the apparent source may be applied to determine C_6, i.e. $C_6 = 7 \cdot \langle / \langle_{min}$. The expression (7 . ⟨) shall be limited to $\langle_{max}$ prior to the calculation of C_6. The 7. value of ⟨ shall be used for the determination of T_2 of Table 10. NOTE For cases where ⟨ < 1,5 mrad but 7 . ⟨ > 1,5 mrad, the limits for ⟨ > 1,5 mrad of Table 5 and 8 apply. d) Non-uniform retinal image irradiance profile, non-circular and multiple sources For comparison with the thermal retinal limits, if: the wavelength range is from 400 nm to 1 400 nm; and the AEL depends on C_6 then if: the retinal image does not have a uniform irradiance profile*; or the retinal image profile consists of multiple points, then measurements or evaluations shall be made for each of the following scenarios: for every single point; and for various assemblies of points; and for partial areas. This is necessary in order to ensure that the AEL is not exceeded for each possible angle ⟨ subtended in each scenario. For the evaluation of assemblies of points or for partial areas, the angle of acceptance © is to be varied between $\langle_{min}$ and $\langle_{max}$, i.e. $\langle_{min} < © < \langle_{max}$, to determine the partial accessible emission associated with the respective scenario. For the comparison of these partial accessible emission levels with the respective AEL, the value of ⟨ is set equal to ©. Classification is to be based on the case where the ratio between: the partial accessible emission within a partial area over the angular subtense ⟨ of that area; and the corresponding AEL is a maximum.	Max. Laserpower <= 500mW Siehe 9.1	P

The angular subtense of a rectangular or linear source is determined by the arithmetic mean value of the two angular dimensions of the source. Any angular dimension that is greater than ⟨max or less than ⟨min shall be limited to ⟨max or ⟨min respectively, prior to calculating the mean. The photochemical limits (400 nm to 600 nm) do not depend on the angular subtense of the source, and the source is analysed with the limiting angle of acceptance specified in 9.3.3 b). For sources that are larger than the limiting angle of acceptance, the accessible emission has to be determined for the partial apparent source which produces the maximum emission value.		

d) Non-uniform retinal image irradiance profile, non-circular and multiple sources For comparison with the thermal retinal limits, if: the wavelength range is from 400 nm to 1 400 nm; and the AEL depends on C_6 then if: the retinal image does not have a uniform irradiance profile*; or the retinal image profile consists of multiple points, then measurements or evaluations shall be made for each of the following scenarios: for every single point; and for various assemblies of points; and for partial areas. This is necessary in order to ensure that the AEL is not exceeded for each possible angle ⟨ subtended in each scenario. For the evaluation of assemblies of points or for partial areas, the angle of acceptance © is to be varied between ⟨min and ⟨max, i.e. ⟨min < © < ⟨max, to determine the partial accessible emission associated with the respective scenario. For the comparison of these partial accessible emission levels with the respective AEL, the value of ⟨ is set equal to ©. Classification is to be based on the case where the ratio between: the partial accessible emission within a partial area over the angular subtense ⟨ of that area; and the corresponding AEL is a maximum. The angular subtense of a rectangular or linear source is determined by the arithmetic mean value of the two angular dimensions of the source. Any angular dimension that is greater than ⟨max or less than ⟨min shall be limited to ⟨max or ⟨min respectively, prior to calculating the mean. The photochemical limits (400 nm to 600 nm) do not depend on the angular subtense of the source, and the source is analysed with the limiting angle of acceptance specified in 9.3.3 b). For sources that are larger than the limiting angle of acceptance, the accessible emission has to be determined for the partial apparent source which produces the maximum emission value.		N

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e) Time bases The following time bases are used in this standard for classification: 1) 0,25 s for Class 2, Class 2M and Class 3R laser radiation in the wavelength range from 400 nm to 700 nm; 2) 100 s for laser radiation of all wavelengths greater than 400 nm except for the cases listed in 1) and 3); 3) 30 000 s for laser radiation of all wavelengths less than or equal to 400 nm and for laser radiation of wavelengths greater than 400 nm where intentional long-term viewing is inherent in the design or function of the laser product. Every possible emission duration within the time base must be considered when determining the classification of a product. This means that the emission level of a single pulse must be compared to the AEL applicable to the duration of the pulse, etc. It is not sufficient to only average the emission level for the duration of the classification time base, or to merely perform the evaluation for the value of the time base without considering shorter emission durations. NOTE For a multi wavelength emission laser product with emission in the visible and in the non-visible part of the spectrum, where the emission is assessed as additive (see Table 2), and where the visible part on its own would be classified as Class 2 or 2M or 3R and the non-visible part on its own would be classified as Class 1 or Class 1M, the time base for the assessment of the added emission may be 0,25 s even for the non-visible part.	Timebase 100 sec.	P

f) Repetitively pulsed or modulated lasers The following methods shall be used to determine the class of the laser product to be applied to repetitive pulsed or modulated emissions. For all wavelengths requirements, 1) and 2) shall be assessed. In addition, for wavelengths from 400 nm to 10^6 nm, requirement 3) shall also be assessed for comparison with thermal limits. Requirement 3) does not need to be assessed for comparison with photochemical limits. The class (see Tables 4 to 9) is determined by applying the most restrictive of 1), 2) and, where applicable, 3). 1) The exposure from any single pulse within a pulse train shall not exceed the AEL for a single pulse. 2) The average power for a pulse train of emission duration T AEL_T shall not exceed the power corresponding to the AEL for a single pulse of duration T. NOTE For comparison with AELsingle or AEL s.p.train, AELT should be divided by N and is termed AEL s.p.T. 3) a) For constant pulse energy and pulse duration: The energy per pulse shall not exceed the AEL for a single pulse multiplied by the correction factor C_5. $AEL_{s.p.\ train} = AEL_{single} . C_5$ where $AEL_{s.p.\ train}$ is the AEL for a single pulse in the pulse train; AEL_{single} is the AEL for a single pulse (Tables 4 to 9); N is the effective number of pulses in the pulse train within the assessed emission duration (when pulses occur within T_i (see Table 3), N is less than the actual number of pulses, see below). The maximum emission duration that needs to be considered for the assessment, for wavelengths between 400 nm and 1 400 nm, is T_2 (see Table 10) or the applicable time basis, whichever is shorter. For wavelengths greater than 1 400 nm, the maximum duration to be considered is 10 s. $C_5 = N^{-0,25} C_5$ is only applicable to individual pulse duration shorter than 0,25 s. If multiple pulses appear within the period of T_i (see Table 3), they are counted as a single pulse to determine N and the energies of the individual pulses are added to be compared to the AEL of T_i. The energy from any group of pulses (or sub-group of pulses in a train) delivered in any given time shall not exceed the AEL for that time.	The Laserpen expert 40W/904nm emits a pulsed radiation with a max. **average power** of 160mW. Hence it is classified in class 3B Umrechnung Impuls --> cw = Leistung * Frequenz * Impulslänge Frequenz = 40.000 Hz Leistung = 40 Wimp Impulslänge = 100 ns Daraus berechnete **cw Leistung (W) = 0,16 W**	P

Table 3 – Times below which pulse groups are summed

Wavelength nm	T_1 s
400 ≤ λ < 1 050	18×10^{-6}
1 050 ≤ λ < 1 400	50×10^{-6}
1 400 ≤ λ < 1 500	10^{-3}
1 500 ≤ λ < 1 800	10
1 800 ≤ λ < 2 600	10^{-3}
2 600 ≤ λ ≤ 10^6	10^{-7}

b) For varying pulse widths or varying pulse durations:
The total-on-time-pulse (TOTP) method shall be used. The AEL is determined by the duration of the TOTP, which is the sum of all pulse durations within the emission duration or T_2, whichever is smaller. Pulses with durations less than T_i are assigned pulse durations of T_i. If two or more pulses occur within a duration of T_i, these pulse groups are assigned pulse durations of T_i. For comparison with the AEL for the corresponding duration, all individual pulse energies are added.

9 Determination of the accessible emission level

9.1 Tests

Tests shall take into account all errors and statistical uncertainties in the measurement process (see IEC 61040) and increases in emission and degradation in radiation safety with age. Specific user requirements may impose additional tests.
Tests during operation shall be used to determine the classification of the product. Tests during operation, maintenance and service shall also be used as appropriate to determine the requirements for safety interlocks, labels and information for the user. The above tests shall be made under each and every reasonably foreseeable single-fault condition. However, if the emission is reduced to a level below the AEL by automatic reduction in a duration within which it is not reasonably foreseeable to have human access, then such faults need not be considered.
NOTE 1 Automatic reduction includes physical limitation of the emission such as component or system failure to a safe condition. It does not include manual reduction or termination of the emission.
NOTE 2 For example, a scanning safeguard may not react fast enough to prevent emission above the AEL during the fault condition; however, this might be acceptable for products where exposure of people is unlikely.
NOTE 3 Acceptable modes of analysis of the probability and risk regarding failures are FMEA (failure mode and effect analysis), etc (see for instance IEC 61508). Probability analysis may be used to assist in determining "reasonably foreseeable single fault conditions".
NOTE 4 Classification is determined during operation, and restrictions on maintenance are then dependent upon the classification of the product.

When assessing the suitability of protective housings for the prevention of human access to a level of energy that is equivalent to Class 4, single fault events for all reasonably foreseeable changes of direction of the beam must be considered. The analysis shall include whether the single fault event will result in sufficient energy to degrade or destroy the protective housing. For example, when during operation or single fault condition, the introduction of robotics or other beam manipulation mechanisms, or the use of optics or workpieces would result in energy being directed onto the surface of the protective housing, one of the following shall occur:
– the single fault shall be eliminated by engineering means; or
– the housing material shall withstand the energy without degradation of its protective properties sufficient to allow a hazardous exposure to laser energy; or
– the fault shall be detected and emission of laser radiation through the protective housing shall be prevented before degradation can occur.

The AEL is not measured because the average power of all used laser-diodes is less than 500mW and more than the AEL of class 3R. Hence all lasers are classified as 3B.
See Table 9.

P

Evaluation times of the protective housing of less than 30 000 s as specified in IEC 60825-4 are not applied for the classification of the product. or energy added by the amplifier plus the necessary input signal power or energy to achieve that condition should be used.NOTE 1 This is because the classification must be considered without human intervention (see 4.2.1) and therefore inspection of the protective housing by the user is not considered. NOTE 2 Protective housing evaluations that consider human inspection, or intervention, may be used to establish levels of safety, or for the detection of potential degradation of the housing which results from reasonably unforeseeable fault events, or multiple fault events, independent of the product classification. Equivalent tests or procedures are acceptable. Optical amplifiers shall be classified using the maximum accessible total output power or energy, which may include maximum rated input power or energy. NOTE In those cases where there is no clear output power or energy limit, the maximum power or energy added by the amplifier plus the necessary input signal power or energy to achieve that condition should be used.		

9.2 Measurement of laser radiation Measurement of laser radiation levels may be necessary to classify a laser product in accordance with 9.1. Measurements are unnecessary when the physical characteristics and limitations of the laser source place the laser product or laser installation clearly in a particular class. Measurements shall be made under the following conditions and procedures.		N
a) Conditions and procedures which maximize the accessible emission levels, including startup, stabilized emission and shut-down of the laser product.		N
b) With all controls and settings listed in the operation, maintenance and service instructions adjusted in combination to result in the maximum accessible level of radiation. Measurements are also required with the use of accessories that may increase the radiation hazard (for example, collimating optics) which are supplied or offered by the manufacturer for use with the product. NOTE This includes any configuration of the product which it is possible to attain without using tools or defeating an interlock, including configurations and settings against which the operation and maintenance instructions contain warnings. For example, when optical elements such as filters, diffusers or lenses in the optical path of the laser beam can be removed without tools, the product must be tested in the configuration which results in the highest hazard level. The instruction by the manufacturer not to remove the optical elements cannot justify classification as a lower class. Classification is based on the engineering design of the product and cannot be based on appropriate behaviour of the user.		N
c) For a laser product other than a laser system, with the laser coupled to that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission of accessible radiation from the product. d) At points in space to which human access is possible during operation for measurement of accessible emission levels (for example, if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration).		N

e) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument.		N
f) Appropriate provision shall be made to avoid or to eliminate the contribution of collateral radiation to the measurement.		N
g) Class 1 and 1M Class 1 is applicable to the wavelength range of 180 nm to 1 mm. Class 1M is applicable to the wavelength range of 302,5 nm to 4 000 nm. For determination of the accessible emission under condition 1, condition 2 and condition 3, see Table 11. For wavelengths less than 302,5 nm and greater than 4 000 nm, if the accessible emission is less than the AEL of Class 1 for condition 3, then the laser product is assigned to Class 1. For wavelengths between 302,5 nm and 4 000 nm: If the radiation level is: – less than the AEL of Class 1 for condition 1, and condition 2 and condition 3, then the laser product is assigned to Class 1. If the accessible emission is: – greater than the AEL of Class 1 for condition 1 or condition 2, and – less than the AEL of Class 3B for condition 1 and condition 2, and – less than the AEL of Class 1 for condition 3, then the laser product is assigned to Class 1M. NOTE 1 Typically, the accessible emission of a Class 1M product exceeds the Class 1 AEL for either condition 1 or condition 2. However, it may also be classified as Class 1M when it exceeds that AEL for both condition 1 and condition 2. NOTE 2 The reason for verifying the AEL of Class 3B is to limit the maximum power passing through an optical instrument. If the accessible emission exceeds the value given in Table 9 for the AEL of Class 3B as determined with a 3,5 mm diameter aperture placed at the closest point of human access, an additional warning regarding a potential skin hazard is to be given (see 5.2). NOTE 3 It is possible that a Class 1M laser product with a highly diverging beam can produce high enough irradiance levels near to or in contact with the source (for instance a fibre tip) so that skin injury is possible.		N

h) Class 2 and 2M Classes 2 and 2M are applicable to the wavelength range of 400 nm to 700 nm. For determination of the accessible emission under condition 1, condition 2 and condition 3, see Table 11. If the accessible emission exceeds the limits as required for Class 1 and for Class 1M (see item g)), and is: – less than the AEL of Class 2 for condition 1, and condition 2 and condition 3, then the laser product is assigned to Class 2. If the accessible emission exceeds the limits as required for Class 1 and for Class 1M (see item g)) and is: – greater than the AEL of Class 2 for condition 1 or condition 2, and – less than the AEL of Class 3B for condition 1 and condition 2, and – less than the AEL of Class 2 for condition 3, then the laser product is assigned to Class 2M. NOTE 1 The reason for verifying the AEL of Class 3B is to limit the maximum power passing through an optical instrument, and to preclude high irradiance levels near to or in contact with diverging sources which may lead to skin injury. NOTE 2 Typically, the accessible emission of a Class 2M product exceeds the AEL of Class 2 for either condition 1 or condition 2. However, it may also be classified as Class 2M when it exceeds the AEL of Class 2 for both condition 1 and condition 2. If the accessible emission exceeds the AEL of Class 3B as determined with a 3,5 mm diameter aperture placed at the closest point of human access, an additional warning regarding a potential skin hazard is to be given (see 5.3). NOTE 3 It is possible that a Class 2M laser product with a highly diverging beam can produce high enough irradiance levels near to or in contact with the source (for instance, a fibre tip) so that skin injury is possible.		N
i) Class 3R, 3B If the level of radiation, as determined according to 9.3, for condition 1, condition 2 and condition 3 is less than or equal to the AEL of Class 3R or Class 3B, the laser product is assigned to Class 3R or Class 3B, respectively. See also Note below first paragraph of 8.3.		N

j) Class 4 If the level of radiation, as determined according to 9.3, either for condition 1, or condition 2 or condition 3, exceeds the AEL for Class 3B, the product shall be assigned to Class 4.		N

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9.3 Measurement geometry		N
9.3.1 General		
9.3.2 Default (simplified) evaluation		