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TECHNICAL REPORT

**Photobiological safety of lamps and lamp systems –
Part 3: Guidelines for the safe use of intense pulsed light source equipment on humans**

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colour inside

Photobiological safety of lamps and lamp systems – Part 3: Guidelines for the safe use of intense pulsed light source equipment on humans

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Part 3: Guidelines for the safe use of intense pulsed light source equipment on humans

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IEC/TR 62471-3, which is a technical report, has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
76/497/DTR	76/505/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this technical report, terms printed in SMALL CAPITALS are used as defined in Clause 3.

A list of all parts in the IEC 62471 series, published under the general title *Photobiological safety of lamps and lamp systems*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This technical report describes possible adverse incidents that may occur in respect of the use of IPL devices and recommends measures to avoid them. Some of the described incidents represent serious adverse effects, ranging from cosmetically significant to physically or medically significant. Provided the IPL operator is appropriately educated and trained and the guidelines in this document are followed, the use of IPL in a cosmetic setting should be no more hazardous to the CLIENT or staff personnel than similar IPL interventions in medical settings.

PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

Part 3: Guidelines for the safe use of intense pulsed light source equipment on humans

1 Scope and object

1.1 Scope

This part of IEC 62471, which is a technical report, provides guidelines for the safe use of INTENSE PULSED LIGHT (IPL) source equipment in professional premises.

This technical report sets out the control measures recommended for the safety of recipients of IPL treatment, staff, service, maintenance personnel and others. Engineering controls which form part of the IPL equipment or the installation are also briefly described to provide an understanding of the general principles of protection.

1.2 Object

The object of this report is to provide information which helps to protect persons from hazardous exposure to optical radiation and other associated hazards by providing guidance on how to establish safety measures and procedures.

NOTE Although the manufacturers provide treatment information in their instructions for use, such information may not be exhaustive or applicable to all CLIENT treatment conditions.

If IPLs are applied to patients in medical premises, the physician is deemed to be responsible for all medical aspects of the treatment including his or her decisions about questions of indication and contraindication such as found in Clauses 5 and 6.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

None.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
CLIENT
person receiving the IPL treatment

EXAMPLE Customers in beauty salons or patients in medical environments.

3.2
CONTROLLED AREA
area around the IPL where the local rules apply

Note 1 to entry: Generally the room where the IPL is used.

3.3
INTENSE PULSED LIGHT
IPL
equipment, containing a flash lamp, e.g. xenon or krypton, housed in a handheld device, having an emission window with an area of several cm^2, typically providing a filter which restricts the emission to a band in the visible and infra-red

Note 1 to entry: Pulse lengths are in the order of tens of ms or less and pulse repetition rates are typically two per second or less. The IPL OUTPUT is in the order of up to 50 J/cm^2. The wavelengths range typically from 400 nm to1 200 nm.

Note 2 to entry: "IPL" may be covered by trademark rights in certain countries. Generally, users and recipients of IPL treatment comprehend the generic meaning of "IPL" as intense pulsed light.

3.4
IPL OUTPUT
radiant exposure measured at the IPL emission window, as received by the human skin in contact mode application

Note 1 to entry: The IPL output is expressed in J/cm^2.

Note 2 to entry: The erroneous term "fluence" is found in some brochures or in the instructions for use.

3.5
OCULAR HAZARD DISTANCE
OHD
radial distance from the emission window of an IPL within which the applicable exposure limit value to the unaided and non-protected eye is exceeded

3.6
RESPONSIBLE PERSON
person who is made responsible for assessing the risks of IPLs, determining the safety measures and the local rules, either the owner/operator of the facility or a person upon appointment by the owner/operator

3.7
SKIN TYPE
Fitzpatrick skin type

Note 1 to entry: Refer to literature about Fitzpatrick SKIN TYPES.

Note 2 to entry: SKIN TYPE varies with pigmentation and sensitivity to UV and also to visible light. Different SKIN TYPES will respond differently to light exposure. In particular, darker SKIN TYPES are more likely to develop hyperpigmentation following light exposure.

4 Responsibility for safe working conditions

Generally, the owner/operator or RESPONSIBLE PERSON of the facility, where IPLs are used, is deemed responsible for all decisions which are related to safety. The owner or operator of the facility may appoint another competent or knowledgeable person who then deals with safety issues on behalf of the owner or operator of the facility. Hence either the owner/operator of the facility or the appointed competent person assumes responsibility for the conditions necessary to safely apply the IPL, called the RESPONSIBLE PERSON. It is recommended that the responsibilities are clearly allocated. Only one RESPONSIBLE PERSON should be appointed within a facility.

All employees of the facility should know who the RESPONSIBLE PERSON is, in order to be able to consult him or her when safety issues arise.

NOTE The RESPONSIBLE PERSON may be seen in analogy with the laser safety officer, who is in charge of safety when high power lasers are used.

5 Risks from exposure to IPL optical radiation

5.1 Risks to the eye

5.1.1 Inadvertent eye exposure

Permanent eye damage resulting in loss of vision can occur when the handpiece is directed to the face of any person and the IPL is fired inadvertently. The OHD (OCULAR HAZARD DISTANCE) could be in the range of 0,5 m, but the actual distance according to IEC 62471 as available from the manufacturer should be considered. A direct eye exposure should under all circumstances be avoided, for example by the use of IPL protective eyewear, see Annex B.

Transient flash blindness, dazzling or after images may occur as a result of specular or diffuse reflection especially from the treatment area, be it inadvertent or during regular use.

The level of the ambient light should be chosen as bright as possible. This normally reduces the aperture of the eye's pupils allowing less light to enter the eye.

Some users choose not to wear safety glasses but instead temporarily close their eyes when they fire the IPL, so that the flashes are not seen. This should not be regarded as a safe procedure.

5.1.2 Treatment adjacent to the eye

Except for chronic effects related to frequent exposures, the CLIENT is subject to the same risks as the operator.

In addition if the treatment site is close to the eyes or on the eyelid, then the heat produced by the IPL may cause clinical problems ranging from iritis up to serious damage to the iris which may be permanent. The damage may lead to the loss of the contractibility of the iris because the muscle cells within the iris are seriously damaged or destroyed. The iris may no longer be circular and the iris colour may change or may become de-pigmented.

When treating the face with an IPL, always use occlusive IPL eyewear.

If treatments are conducted within the orbital rim, then intraocular metal shields and the appropriate medical lubricant should be utilized.

5.2 Skin burns

Skin burn to the client is a major risk. Skin injury may result from excessive high dose, skin pigmentation, failure or lack of cooling of the skin, presence of a tan, inappropriate selection of the wavelength band of the light and of pulse parameters. The skin has varying sensitivity at different locations on the body. It depends on the skin colour, the skin thickness and contour.

Skin burn injuries can range from mild erythema, which may be an expected side effect, to blistering. Although first degree burns normally heal without permanent effects such as hyperpigmentation, hypopigmentation and scarring, second degree burns will occasionally result in scars and third degree burns will regularly result in permanent scars. Secondary effects of burns may follow such as infections, triggering of herpes, hyperpigmentation and hypopigmentation.

5.3 Scars

Some CLIENTS develop hypertrophic scarring/keloids after IPL treatment, others do not. CLIENTS should be screened for history of hypertrophic keloids and scarring prior to consideration for IPL treatment.

5.4 Hyper/hypo-pigmentation

Unexpected hyperpigmentation can result from IPL treatment inducing increased pigment production by the melanocytes. In most cases, this effect is transient, in other cases it lasts for several months or can be permanent. Occasionally an injured area can result in long lasting hypopigmentation, which may be permanent.

5.5 Purpura

Purpura is a purple red discoloration due to rupture of small vessels. This may be an unacceptable side effect and could be a result of IPL treatment with inappropriate dosage. The effects are often transient.

5.6 Unrecognised malignancies or premalignant conditions on the treatment site

The presence of premalignant lesions or malignant lesions is contraindicated to IPL treatment. Failure to recognise this presents a serious risk to the CLIENT. Some skin lesions can lead to pre-malignant lesions progressing to malignancy, existing malignant lesions becoming more aggressive and making histological examination more difficult. Subsequent medical treatment of the condition may also be compromised. As for any aesthetic skin treatment, this concern should be understood in a general manner, as any unidentified disease should be excluded by medical specialist examination prior to IPL treatment.

5.7 Delicate anatomy or inappropriate treatment sites

The sensitivity of the skin to IPL radiation varies considerably due to the location, thickness of the skin, bone and bony prominences. For instance, off-face locations may require more conservative (lower) settings than locations on the face.

5.8 Drug-induced photosensitivity

Prior treatment with specific photosensitizing drugs such as antibiotics, herbal supplements and isotretinoin can induce sensitivity to UV and visible light. Although most IPLs block the UV and the blue from the IPL OUTPUT, the remaining visible output may cause unexpected outcomes such as burns and delayed wound healing. An interval of at least 6 months should be observed after the last dose of isotretinoin has been taken. Waiting times for drugs other than isotretinoin are variable. The user should check with the CLIENT's medical practitioner for advice.

5.9 Contra-indicated CLIENT conditions

Conditions which should be considered prior to undertaking IPL procedures include but are not limited to:

- presence or history of skin cancer;
- presence or history of systemic infections or diseases such as herpes simplex, systemic lupus, diabetes;
- recent natural, sunbed/solarium or chemical tanning;
- treatment over tattoos;
- current treatment with any photosensitizing drug, see 5.9;
- dark SKIN TYPE;
- immunosuppressive diseases, including AIDs and HIV infections and/or use of immunosuppressive drugs;
- history of keloid and scarring;
- history of bleeding disorders or use of anticoagulants;
- pregnancy or nursing;
- history of epileptic disorder.

NOTE 1 Some manufacturers do not recommend the use of IPL on pregnant and nursing women. However, it seems that there is currently no scientific evidence for pregnancy or nursing to be a contraindication.

NOTE 2 Some national regulations classify epilepsy as a contraindication for IPL treatment. However it seems that there is up to now no scientific evidence supporting the occurrence of epilepsy or seizure disorders being caused by IPL treatment at typical flash repetition rates of one pulse per second or less. CLIENTS with suspected epileptic disorder may be considered for use of opaque eye shielding.

6 Causes of risks

6.1 General

The causes of risks specified in 6.2 should be considered when the risks are assessed. Safety measures should be chosen so that these risks are minimised. See Clause 7. Additional risks may be necessary to be considered for particular uses of IPLs or for different settings.

6.2 Operator errors

6.2.1 SKIN TYPE

Operator error may result in either expected treatment-related side effects or unexpected complications and adverse effects:

- SKIN TYPE not considered;
- SKIN TYPE not determined correctly;
- energy setting of the IPL not corresponding to the SKIN TYPE in the area of treatment although the SKIN TYPE was correctly assessed;
- any error which may result in over-dosage leading to adverse incidents or under-dosage causing ineffective or sub-optimal treatment.

6.2.2 Failure to recognize contra-indicated CLIENT conditions or photosensitizing drug use

The CLIENT was not correctly screened or questioned regarding the presence of existing medical conditions or pharmaceutical/herbal supplement use which may be relevant for the safety of the treatment.

The operator not being able to recognize skin lesions like possible pre-malignancies, thus ignoring contraindicating situations.

6.2.3 Incorrect or non-use of protective eyewear

Incorrect eyewear, or non-use of appropriate eyewear may result in ocular injury to client or other persons.

6.2.4 Failure to perform patch tests adjacent to the area of treatment

The operator is not performing a test exposure and is not assessing the outcome, where necessary, to exclude excessive skin reactions. Patch tests should not be overly aggressive. Pulse-stacking should be avoided. The reaction of the tissue can change from day to day. The user should observe the reaction and should adjust the treatment parameters accordingly.

6.2.5 Failure to maintain optical components

If the following manufacturer's device maintenance and operating instructions are not observed, then damage to equipment or incorrect treatment may occur:

- optical IPL OUTPUT window not kept clean;
- damage to the optical window or filters not recognized;
- optical system not calibrated (according to the manufacturer's instructions);

– coupling gel not properly applied if the use of gel is recommended by the manufacturer;
– possibility of IPL OUTPUT increase following replacement of the lamp has not been taken into consideration;
– disregard of the manufacturer's recommended lamp life.

6.2.6 Failure to use the appropriate filter

The filter used is not appropriate for the SKIN TYPE and/or for the intended application.

6.2.7 Inappropriate or inadequate skin cooling

No cooling is provided at all or the means of cooling used is different from the manufacturer's recommendations. Since the cooling protects the epidermis, failure or deficiency of cooling increases the risk of damaging the epidermis.

6.2.8 Inappropriate technique

The settings of the IPL (pulse duration, energy, filtering, etc.) deviate from the settings which are recommended by the manufacturer according to the actual treatment procedure.

Unsuitable overlapping of the irradiated areas will cause over-dosage in the zone of overlap, as the produced heat provides accumulated heat in that overlap area.

The interval between consecutive exposures on overlapping areas is too short, not allowing the tissue to cool down during the interval.

Elapsed time between treatment sessions is too short, leading to inadequate tissue recovery from the preceding treatment session.

6.3 Poor CLIENT compliance

Adverse effects may be caused by the CLIENT not complying with the agreed pre and post treatment protocols, for example active tan, sun-bed use, sun exposure, skin care, etc.

6.4 IPL OUTPUT variability from older equipment

6.4.1 Incorrect display of the settings

Some IPL equipment may show discrepancies between the display of settings and the actual IPL OUTPUT. If for instance the display shows 20 J/cm^2 and the actual IPL OUTPUT is 24 J/cm^2, the user is misguided and an overdose will occur. The user should be aware of this possibility.

NOTE As IPL devices are in most cases not self-calibrating, the factory calibration of a particular energy density setting will normally reflect a 'mid value' for the applicator handpiece. For a new applicator, the actual output will probably be up to 20 % above the device displayed value and by the end of the normal lifetime of the applicator, the energy will probably be 20 % below the displayed value.

6.4.2 Excessive power peaks

Old equipment designs may deliver pulse shapes including excessive power peaks at the beginning of the pulse whereas newer IPL equipment delivers a rather flat power distribution over the pulse. The tissue reaction is not the same although the total energy may be identical. Although one would expect mixed effects resulting from a combination of a short pulsed and of a long pulsed IPL it is not easy to predict the outcome. If in doubt, the user should consult the manufacturer,

6.4.3 Uneven energy distribution

Some older equipment designs may exhibit significant variation of the energy distribution over the window area, which may cause burns from highly localized excessive energy deposition adjacent to areas where the desired effect is not achieved.

6.5 Risks from other potential hazards

6.5.1 Airborne contaminants

Because vaporized cosmetics and hair breakdown products and other airborne contaminants may result from some procedures, the worksite should be well ventilated.

6.5.2 Electrical safety

Many IPL systems employ high voltage sources. Under normal conditions, IPL systems do not present a high voltage risk, but it is imperative for all personnel to follow manufacturer's instructions when using or maintaining the equipment.

6.6 Cleansing and disinfecting

Infectious particles or contamination may be transferred from one CLIENT to the other, when the applicator's surface is not cleaned and disinfected during the interval between treatments. Cleaning or disinfectant agents should be used according to the manufacturer's recommendations. Care should be taken not to use cleaning agents that might damage optical coatings of the equipment. Similarly, routine precautions should be taken to clean and disinfect CLIENT protective eyewear, especially ocular shields, to prevent cross-contamination between CLIENTS.

7 Risk assessment

The user should assess the risks involved with the use of IPLs. A clear distinction should be made between risks for the user/personnel and risks for the CLIENT. The risk assessment should be documented. It should list the risks including the hazards. Safety measures should be derived and added to the documented risks, which ensure that injuries are prevented and side-effects minimized.

In order of importance (hierarchy), as a general safety rule, avoidance of emission is ranked highest (if the intended effect can be achieved by technically different and safer means), followed by reduction of intensity, limitation of the propagation, reducing the on-time, limiting the number of persons involved, and using personal protective equipment.

When using IPLs, the measures applicable to avoid hazards to inadvertent eye exposure to IPL emission would be:

label the treatment room with clearly visible warning signs indicating use of IPL;

use movable partitions; orient the user and the CLIENT so that the potential action range of the emitted flashes is directed towards the nearby wall or partition rather than towards other persons, a door or a window;

use window shielding; shorten the on-time, use the stand-by-mode, prevent people from entering the IPL work zone;

control access to the IPL equipment and to the IPL equipment key;

employ local rules, make them known to everybody in the environment of the IPL. A template of the local rules is given in Annex E;

limit access to the IPL to trained personnel;

make personal protective equipment available at a given location; provide rules on how to check, use and maintain equipment;

maintain appropriate documentation including policies and procedures, incident reporting and incident follow-up, audit reports, chart review and case reports.

The measures applicable to avoid skin injuries would be:

- assess the intended treatment area (refer to Clause 5);
- use the least possible power or energy to achieve the desired result;
- in view of the fact that personal skin protection is not feasible, if the least possible energy setting still causes intolerable side effects, the IPL must not be used for this type of application.

Management and control measures should include:

- personnel who are qualified to use the IPL;
- education and training (see Clause 8);
- safe usage protocol (written description of the procedures, including revision and/or audits);
- preparation of the treatment room;
- provisions for protective eyewear;
- calibration and equipment testing;
- service and maintenance procedures;
- protocols in the event of incidents (see Clause 5), including referral to appropriate medical care;
- preventive actions to be taken;
- documentation of every treatment case, including incremental treatment parameters;
- incident reporting procedure.

NOTE Documentation of every treatment case provides a learning opportunity, since documentation allows the user to keep track of the cases, of the CLIENT personal data, of IPL use parameters, treatment success and failures, incidents and near-incidents.

8 Education and training

Education should be on-going and knowledge be kept up to date. As technology (including equipment software updates) or treatment modalities change, additional training may be necessary.

Providers of education and training should be suitably qualified.

Unless training is defined by the national regulatory authority, the user should assess the quality and relevance of IPL training offerings according to the criteria below.

Education should include:

- fundamentals of how IPL devices and delivery systems work;
- wavelengths of light and bio-effects, tissue interactions;
- skin typing;
- risk assessment and hazard identification;
- basics of safety and applicable standards;
- CLIENT assessment, follow up and management of complications;
- appropriate and acceptable clinical applications;
- conditions to be considered prior to IPL application;
- CLIENT education and preparation;

- procedural operations and staff responsibilities;
- discharge planning including CLIENT instructions and support measures;
- documenting and reporting.

Training should include:

- practical application of the recommendations of the safety standards;
- room set-up, equipment positioning;
- use of engineering controls, operation, handling and testing of the equipment;
- selecting the dose and assessing IPL's effects on tissue;
- CLIENT preparation and positioning;
- application techniques;
- cleaning and care of all equipment;
- safe and professional conduct during procedures.

Annex A
(informative)

Biological effects, SKIN TYPES

A.1 Optical radiation spectrum

The optical radiation spectrum is generally divided up, by wavelength, as given in Table A.1:

Table A.1 – Division of the optical radiation spectrum

Ultraviolet “C” (UV-C)	100 nm – 280 nm
Ultraviolet “B” (UV-B)	280 nm – 315 nm
Ultraviolet “A” (UV-A)	315 nm – 400 nm
Visible light	400 nm – 700 nm
Infrared “A” (IR-A)	700 nm – 1 400 nm
Infrared “B” (IR-B)	1 400 nm – 3 000 nm
Infrared “C” (IR-C)	3 000 nm – 1 000 000 nm (3 µm – 1 mm)

A.2 Fitzpatrick skin classification

The Fitzpatrick Classification Scale (see Table A.2) was developed in 1975 by Harvard Medical School dermatologist, Thomas Fitzpatrick. This scale classifies a person's tolerance of sunlight. It is used by many practitioners to determine how someone’s skin will respond to UV or light exposure.

Table A.2 – Fitzpatrick Classification Skin Type Scale

	Skin colour	Characteristics
I	Very fair, red or blond hair, blue eyes, freckles	Always burns, never tans
II	White, fair, red or blond hair, blue, hazel, or green eyes	Usually burns, tans with difficulty
III	Cream white, fair with any eye or hair colour, very common	Sometimes mild burn, gradually tans
IV	Brown, typical Mediterranean caucasian skin	Rarely burns, tans with ease
V	Dark Brown, mid-eastern skin types	Very rarely burns, tans very easily
VI	Black	Never burns, tans very easily

A.3 Structure of the eye

The basic anatomical structure of the eye is shown in Figure A.1

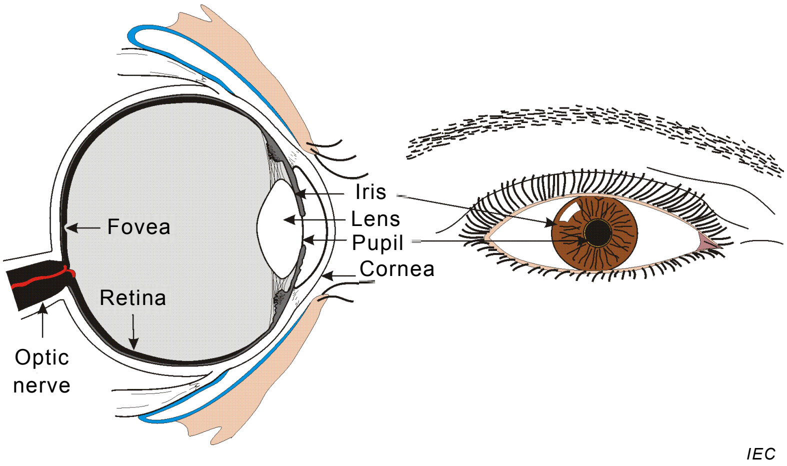

Figure A.1 – Structure of the eye

A.4 Penetration of light in the eye

As shown in Figure A.2, visible and IR-A optical radiation entering the eye passes through the cornea, aqueous humour, then through a variable aperture (pupil), and through the lens and vitreous to be focused on the retina. With respect to the other wavelength ranges, radiation of UV-C, UV-B, most of UV-A, IR-B and IR-C incident on the eye are absorbed at various depths by the anterior segments of the eye, thus blocking their propagation onto the retina.

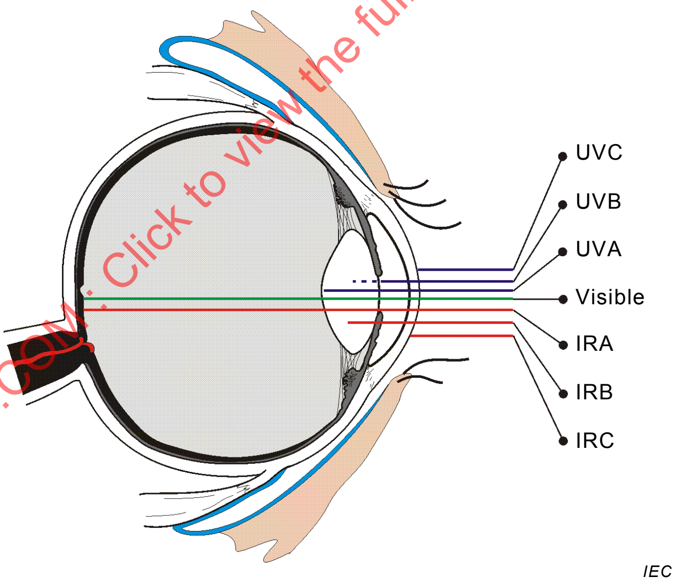

Figure A.2 – Penetration of different wavelengths through the eye

A.5 Structure of the skin

The basic structure of the skin is shown in Figure A.3, and penetration of light through the skin in Figure A.4.

The outer layer of the skin, the epidermis, contains mainly keratinocytes (squamous cells) which are produced in the basal layer and rise to the surface to be sloughed off. The dermis is composed mainly of collagen fibres and contains nerve endings, sweat glands, hair follicles and blood vessels.

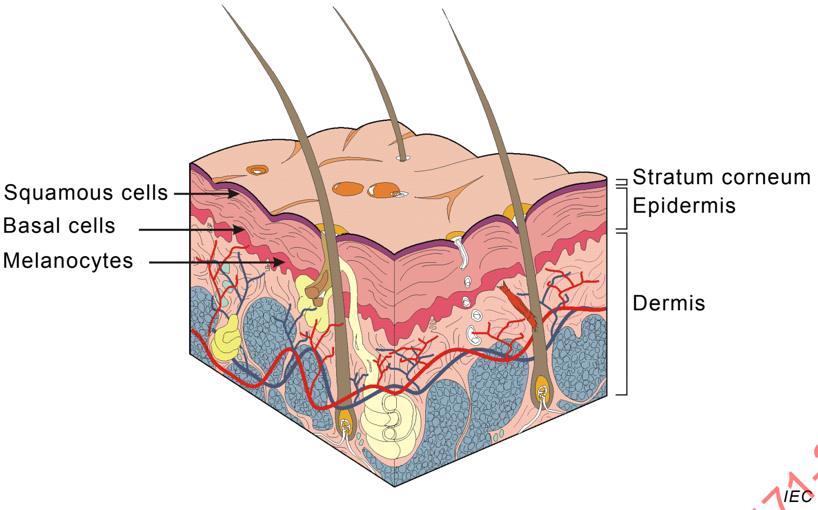

Figure A.3 – The structure of the skin

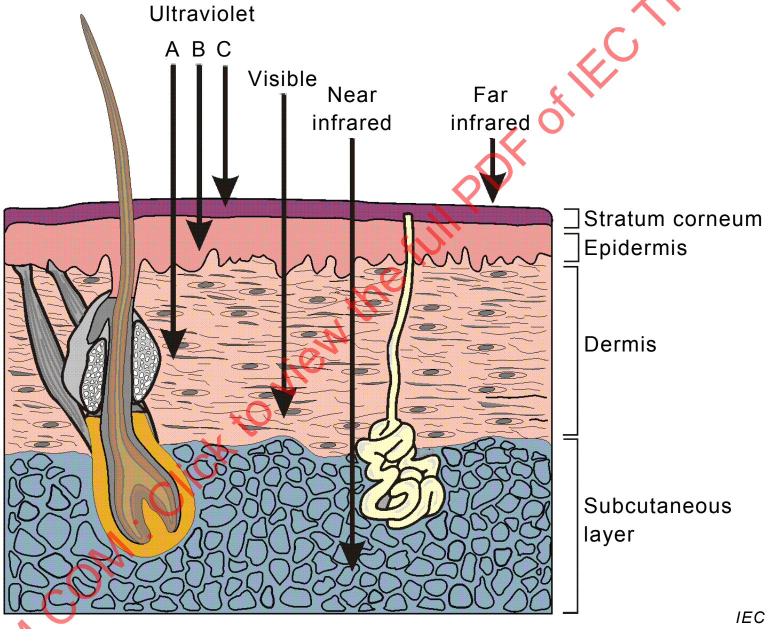

Figure A.4 – Penetration of different wavelengths through the skin

The most important tissue chromophores are (see Figure A.5):

- melanin;
- oxyhaemoglobin and haemoglobin;
- water.

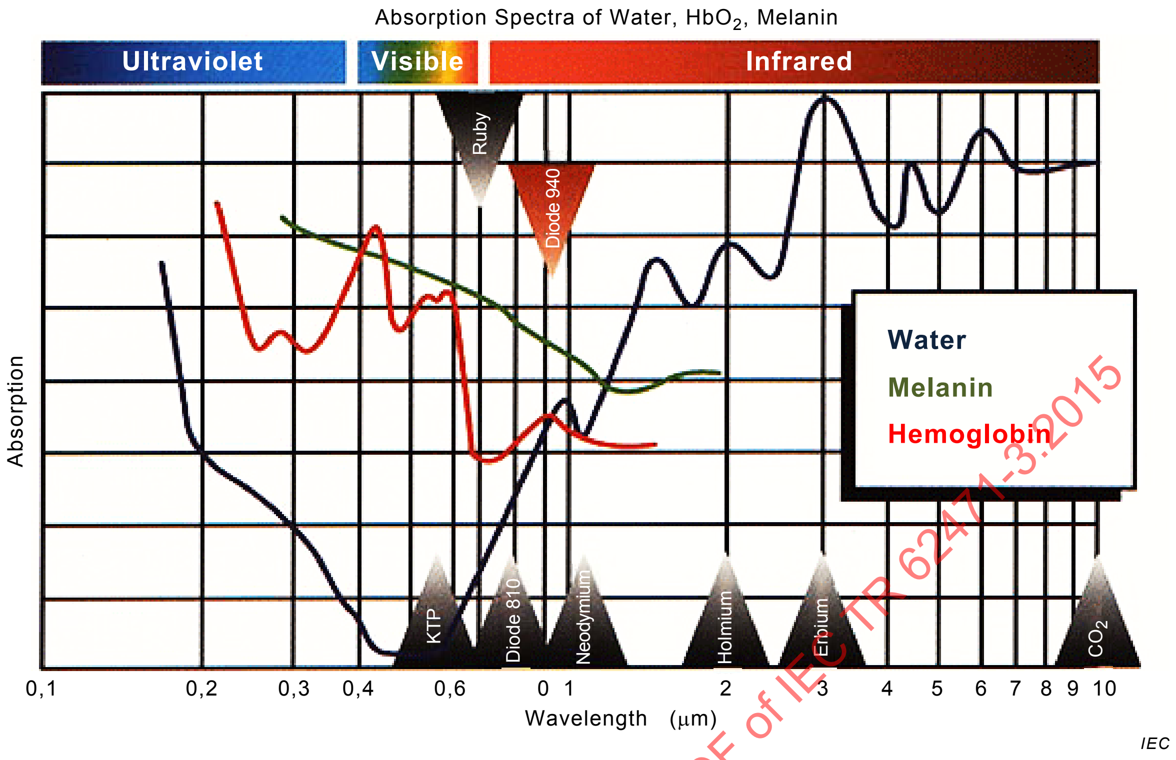

Figure A.5 – Absorption of skin main chromophores, log scale, arbitrary units

A.6 Biological effects

A.6.1 General

The biological effects of optical radiation are in part dependent on the wavelength, as described in Table A.3.

Table A.3 – Biological effects of optical radiation to the eye and skin

Wavelength Nm		Eye	Skin
100 – 280	UV-C	Photokeratitis Photoconjunctivitis	Erythema Skin cancer
280 – 315	UV-B	Photokeratitis Photoconjunctivitis Cataracts	Erythema Elastosis (photoageing) Skin cancer
315 – 400	UV-A	Photokeratitis Photoconjunctivitis Cataracts Photoretinal damage	Erythema Elastosis (photoageing) Immediate pigment darkening Skin cancer
400 – 700	Visible	Photoretinal damage (Blue LIght hazard) Retinal burn	Burn
700 – 1 400	IR-A	Cataracts Retinal burn	Burn
1 400 – 3 000	IR-B	Cataracts	Burn
3 000 – 10^6	IR-C	Corneal burn	Burn

A.6.2 Ultraviolet radiation

The biological effects of UV radiation can be divided into acute (rapidly occurring) and chronic (occurring as a result of prolonged and repeated exposures over a long time). It is generally the case that acute effects will only occur if the exposure exceeds a threshold level, which will usually vary from person to person.

Chronic effects often do not have a threshold below which they will not occur. As such, the risk of these effects occurring cannot be reduced to zero. The risk can be reduced by reducing exposure, observance of the exposure limits should reduce risks from exposure to artificial sources of optical radiation to levels below those which society has accepted with respect to exposures to natural optical radiation.

a) *Biological effects on the skin*

Excessive short-term exposure to UV radiation causes erythema – a reddening of the skin, and swelling. Symptoms can be severe, and the maximum effect occurs 8 h to 24 h after exposure, subsiding over 3 to 4 days with subsequent dryness and skin peeling. This may be followed by an increase in skin pigmentation (delayed tanning). Exposure to UV-A radiation can also cause an immediate but temporary change in skin pigmentation.

Some people have abnormal skin responses to UV radiation exposure (photosensitivity) because of genetic, metabolic, or other abnormalities, or because of intake or contact with certain drugs or chemicals.

The most serious potential long-term effect of UV radiation is the induction of skin cancer. The non-melanoma skin cancers (NMSCs) are basal cell carcinomas and squamous cell carcinomas. They are relatively common in white people, although they are rarely fatal. Malignant melanoma is the main cause of skin cancer death, although its incidence is less than NMSC. Both acute burning episodes of sun exposure and chronic occupational and recreational exposure may contribute to the risk of malignant melanoma.

Chronic exposure to UV radiation can also cause photo-ageing of the skin. There is evidence suggesting that exposure to UV radiation can affect immune responses.

b) *Biological effects on the eyes*

UV radiation falling on the eye is absorbed by the cornea and lens. The cornea and conjunctiva absorb strongly at wavelengths shorter than 300 nm. UV-C is absorbed in the superficial layers of the cornea and UV-B is absorbed by the cornea and lens. UV-A passes through the cornea and is absorbed in the lens.

Responses of the human eye to acute overexposure of UV radiation include photo-keratitis and photo-conjunctivitis (inflammation of the cornea and the conjunctiva, respectively), more commonly known as snow blindness, arc-eye or welder’s flash. Symptoms, ranging from mild irritation, light sensitivity and tearing to severe pain, appear within 30 min to a day depending on the intensity of exposure and are usually reversible in a few days.

Chronic exposure to UV-A and UV-B can cause cataracts due to protein changes in the lens of the eye. Very little UV radiation (less than 1 % UV-A) normally gets through to the retina due to absorption by the anterior tissues of the eye. However, there are some people who do not have a natural lens as a result of cataract surgery, and unless there is an implanted artificial lens which absorbs it, the retina can be damaged by UV (even at wavelengths as short as 300 nm) entering the eye. This damage is a result of photo-chemically produced free radicals attacking the structures of the retinal cells. The retina is normally protected from acute damage by involuntary aversion responses to visible light, but UV does not produce these responses: persons lacking a UV absorbing lens are, therefore, at higher risk of suffering retinal damage if working with UV sources.

Chronic UV exposure is a major contributor to the development of corneal and conjunctival disorders such as climatic droplet keratopathy (an accumulation of yellow/brown deposits in the conjunctiva and cornea), pterygium (an overgrowth of tissue which may spread over the cornea) and probably pinguecula (a proliferative yellow lesion of the conjunctiva).

NOTE Most IPLs provide filters which block UV-A and UV-B/C.

A.6.3 Visible radiation

a) Biological effects on the skin

Visible radiation (light) penetrates into the skin and may raise the local temperature enough to cause burning. The body will adjust to gradual temperature rises by increasing blood flow (which carries heat away) and perspiration. If the irradiation is insufficient to cause an acute burn (in 10 s or less), the exposed person will be protected by natural aversion responses to heat.

For long exposure durations, heat strain from thermal stress (increased core body temperature) is the principal adverse effect. The ambient temperature and work load should be considered.

b) Biological effects on the eyes

Because the eyes act to collect and focus visible radiation, the retina is at greater risk than the skin. Gazing at a bright light source can cause retinal damage. If the lesion is in the fovea, e.g. if looking directly into an IPL, severe visual handicap may result. Natural protective measures include aversion reactions to bright light: the blink reflex operates in about 0,25 s, the pupil contracts and can reduce retinal irradiance by about a factor of 30. However, the flash emitted by an IPL has a little emission duration so that the blink reflex is late. Hence a natural protective reaction to the first flash of a series emitted by an IPL is not possible. Another aversion response takes place when the head is turned involuntarily away. However, this aversion response should take longer than 0,25 s to become effective.

Retinal temperature increases of 10 °C to 20 °C can lead to irreversible damage due to denaturation of proteins. If the radiation source covers a large part of the field of view so that the retinal image is large, it is difficult for the retinal cells in the central region of the image to shed heat quickly.

Visible radiation can cause the same type of photo-chemically induced damage as UV radiation (although, at visible wavelengths, the aversion to bright light can act as a protective mechanism). This effect is most pronounced at wavelengths around 435 nm to 440 nm, and so it is sometimes called the “blue-light hazard”. Chronic exposure to high ambient levels of visible light may be responsible for photochemical damage to the cells of the retina, resulting in poor colour and night vision.

A.6.4 IR-A

a) Biological effects on the skin

IR-A penetrates several millimetres into the skin, that is, well into the dermis. It can produce the same thermal effects as visible radiation.

b) Biological effects on the eyes

Like visible radiation, IR-A is also focussed by the cornea and lens and transmitted to the retina. There, it can cause the same sort of thermal damage as visible radiation can. However, the retina does not detect IR-A, and so there is no protection from natural aversion responses. The spectral region from 380 nm to 1 400 nm (visible and IR-A) is sometimes called the “retinal hazard region”.

Chronic exposure to IR-A may also induce cataracts.

IR-A does not have sufficiently energetic photons for there to be a risk of photo-chemically induced damage.

A.6.5 IR-B

a) *Biological effects on the skin*

IR-B penetrates less than 1 mm into tissue. It can cause the same thermal effects as visible radiation and IR-A.

b) *Biological effects on the eyes*

At wavelengths around 1 400 nm, the aqueous humour is a very strong absorber, and longer wavelengths are attenuated by the vitreous humour, thus the retina is protected. Heating of the aqueous humour and iris can raise the temperature of the adjacent tissues, including the lens, which is not vascularised and so cannot control its temperature. This, along with direct absorption of IR-B by the lens induces cataracts, which have been an important occupational disease for some groups, principally glass blowers and chain makers.

As for visible, IR-A and IR-B wavelengths, heat strain and discomfort from thermal stress must be considered.

A.6.6 IR-C

a) *Biological effects on the skin*

IR-C penetrates only to the uppermost layer of dead skin cells (stratum corneum). Powerful optical radiation, which may be capable of ablating the stratum corneum and damaging underlying tissues, are the most serious acute hazard in the IR-C region. The damage mechanism is mainly thermal.

b) *Biological effects on the eyes*

IR-C is absorbed by the cornea, and so the main hazard is corneal burns. The temperature in adjacent structures of the eye may increase due to thermal conduction, but heat loss (by evaporation and blinking) and gain (due to body temperature) will influence this process.

NOTE IPLs don't emit IR-C.

Annex B
(informative)

Personal eye protection

Usually, safety eyewear is specified and recommended by the vendor of the IPL equipment. The user should observe these recommendations. Eyewear that is not specifically designated for protection against exposure to IPL emissions, including sunglasses, welding glasses and laser safety glasses, must not be used by clients or staff. The absorption spectrum of such eyewear is not compatible with IPL emissions, and while it may appear to be safe, it is not.

The following is a list of requirements, meant as information to the user only, which vendors of IPL protective eyewear should comply with: .

- ability to protect against specific workplace hazards;
- emergency controls and warnings should be clearly visible through protective eyewear;
- should fit properly and be reasonably comfortable to wear;
- should provide least restricted vision and movement;
- should be durable and cleanable;
- should allow unrestricted functioning of any other required personal protective equipment.

If the user needs prescribed correction glasses, the safety eyewear should not compromise the prescribed correction. It may be worn on top of the prescription glasses like goggles or it may contain a prescription glass insert/clip.

Different types of protective eyewear may be required for CLIENTS and users. Protective eyewear for CLIENTS may be opaque.

The requirements for protection against hazardous visible light and luminous transmission need to be balanced.

Possible options include:

- selection of eyewear with attenuation only in the hazard wavelength range and high transmission outside hazardous spectral region;
- active filtering eyewear.

Annex C
(informative)

IPL technology, classification

IEC 62471 defines various risk groups for light sources other than lasers (see Table C.1), and these risk groups also apply to IPLs.

Table C.1 – Classification of risk group (IEC 62471)

	Exempt group	**Risk group 1**	**Risk group 2**	**Risk group 3**
Description of risk group	Safe under reasonably foreseeable conditions	Low risk – does not pose a hazard due to normal behavioural limitations on exposure	Moderate risk – does not pose a hazard due to aversion response to very bright light sources or due to thermal discomfort	High risk – may pose a hazard even for momentary or brief exposure

Risk groups are defined regarding photo-biological safety of lamps and lamp systems in the context of the reference standard. The rationale behind the risk group classification is inadvertent worker's exposure. IPLs are generally classified as risk group 3 since they emit strong flashes of light, posing a rather high risk at short distances for the unshielded eye. In non-contact, the IPL is normally not expected to be harmful for the skin. But at close distance down to contact-mode, an IPL produces strong effects at the skin.

With respect to both, the eye hazard to personnel or CLIENT and the potential skin injury upon using the IPL improperly, IPL equipment intended for medical application must comply with IEC 60601-2-57. That standard requires that certain safety features must be provided by the equipment, such as

– key control,
– emergency stop,
– optical radiation indicator,
– standby/ready,
– automatic overexposure termination, and
– informational requirements.

The user is recommended to become familiar with the safety features provided by the IPL equipment.

Annex D
(informative)

Warning sign

Warning signs at the entrances to the intense pulsed light (IPL) controlled area may include the warning symbol ISO 7010-W027 (2011-05) (see Figure D.1) and include additional information about the type of IPL equipment in use and about personal protective equipment, if required.

It may contain warnings such as "no unauthorized entry", "knock and wait for permission to enter" or similar, as appropriate.

Warning signs are more effective if they are displayed only when the IPL equipment is connected to the power supply or in use.

All warning should be placed at eye level to maximize visibility. An example of the warning symbol is shown below, see Figure D.1.

In some circumstances, it may be useful to add an illuminated warning. If used, it should either incorporate or be additional to the warning symbol recommended above. A typical illuminated warning may be in the form of a lamp placed outside each entrance to the CONTROLLED AREA. This lamp should be energized only when the IPL is in use.

Alternatively, a light may be used to illuminate a translucent sign with wording such as "IPL controlled area", as long as the wording is not visible when the light is off.

Figure D.1 – Warning symbol for use with IPL equipment