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TECHNICAL REPORT

colour inside

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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PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

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

FOREWORD

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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- withdrawn,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.