PD IEC/TR 62471-3:2015

BSI Standards Publication

Photobiological safety of lamps and lamp systems

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

bsi.

...making excellence a habit.™

AVA Documents Document Sharing Hub

National foreword

This Published Document is the UK implementation of IEC/TR 62471-3:2015.

The UK participation in its preparation was entrusted to Technical Committee EPL/76, Optical radiation safety and laser equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015.
Published by BSI Standards Limited 2015

ISBN 978 0 580 84356 3
ICS 29.140.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 28 February 2015.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: PD IEC/TR 62471-3:2015

IEC TR 62471-3

Edition 1.0 2015-01

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 29.140

ISBN 978-2-8322-2207-2

Warning! Make sure that you obtained this publication from an authorized distributor.

® Registered trademark of the International Electrotechnical Commission

Documents
Document Sharing Hub

Full document details: PD IEC/TR 62471-3:2015

CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope and object 7
1.1 Scope 7
1.2 Object 7
2 Normative references 7
3 Terms and definitions 7
4 Responsibility for safe working conditions 8
5 Risks from exposure to IPL optical radiation 9
5.1 Risks to the eye 9
5.1.1 Inadvertent eye exposure 9
5.1.2 Treatment adjacent to the eye 9
5.2 Skin burns 9
5.3 Scars 9
5.4 Hyper/hypo-pigmentation 10
5.5 Purpura 10
5.6 Unrecognised malignancies or premalignant conditions on the treatment site 10
5.7 Delicate anatomy or inappropriate treatment sites 10
5.8 Drug-induced photosensitivity 10
5.9 Contra-indicated CLIENT conditions 10
6 Causes of risks 11
6.1 General 11
6.2 Operator errors 11
6.2.1 SKIN TYPE 11
6.2.2 Failure to recognize contra-indicated CLIENT conditions or photosensitizing drug use 11
6.2.3 Incorrect or non-use of protective eyewear 11
6.2.4 Failure to perform patch tests adjacent to the area of treatment 11
6.2.5 Failure to maintain optical components 11
6.2.6 Failure to use the appropriate filter 12
6.2.7 Inappropriate or inadequate skin cooling 12
6.2.8 Inappropriate technique 12
6.3 Poor CLIENT compliance 12
6.4 IPL OUTPUT variability from older equipment 12
6.4.1 Incorrect display of the settings 12
6.4.2 Excessive power peaks 12
6.4.3 Uneven energy distribution 13
6.5 Risks from other potential hazards 13
6.5.1 Airborne contaminants 13
6.5.2 Electrical safety 13
6.6 Cleansing and disinfecting 13
7 Risk assessment 13
8 Education and training 14
Annex A (informative) Biological effects, SKIN TYPES 16
A.1 Optical radiation spectrum 16

AVA Documents
Document Sharing Hub
Full document details: PD IEC/TR 62471-3:2015

A.2 Fitzpatrick skin classification 16
A.3 Structure of the eye 16
A.4 Penetration of light in the eye 17
A.5 Structure of the skin 17
A.6 Biological effects 19
A.6.1 General 19
A.6.2 Ultraviolet radiation 20
A.6.3 Visible radiation 21
A.6.4 IR-A 21
A.6.5 IR-B 22
A.6.6 IR-C 22
Annex B (informative) Personal eye protection 23
Annex C (informative) IPL technology, classification 24
Annex D (informative) Warning sign 25
Annex E (informative) 26
E.1 Local rules 26
E.2 Sample template 26
Bibliography 30

Figure A.1 – Structure of the eye 17
Figure A.2 – Penetration of different wavelengths through the eye 17
Figure A.3 – The structure of the skin 18
Figure A.4 – Penetration of different wavelengths through the skin 18
Figure A.5 – Absorption of skin main chromophores, log scale, arbitrary units 19
Figure D.1 – Warning symbol for use with IPL equipment 25

Table A.1 – Division of the optical radiation spectrum 16
Table A.2 – Fitzpatrick Classification Skin Type Scale 16
Table A.3 – Biological effects of optical radiation to the eye and skin 19
Table C.1 – Classification of risk group (IEC 62471) 24

Documents
Document Sharing Hub
Full document details: PD IEC/TR 62471-3:2015

INTERNATIONAL ELECTROTECHNICAL COMMISSION

PHOTOBIOLOGICAL SAFETY OF LAMPS AND LAMP SYSTEMS –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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

Documents
Document Sharing Hub
Full document details: PD IEC/TR 62471-3:2015

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.

Documents
Document Sharing Hub

Full document details: PD IEC/TR 62471-3:2015

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.

Documents
Document Sharing Hub
Full document details: PD IEC/TR 62471-3:2015

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.

AVA Documents
Document Sharing Hub

Full document details: PD IEC/TR 62471-3:2015

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.

AVA Documents
Document Sharing Hub
Full document details: PD IEC/TR 62471-3:2015

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.

AVA Documents
Document Sharing Hub
Full document details: PD IEC/TR 62471-3:2015