AS/NZS 4173:2018
Incorporating Amendment No. 1

Australian/New Zealand Standard

Safe use of lasers and intense light sources in health care

Superseding AS/NZS 4173:2004

AS/NZS 4173:2018

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Australian and New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
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Safe use of lasers and intense light sources in health care

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Sub-Committee HE-003-12, Lasers in Medical Procedures, under the responsibility of Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 4173:2004, *Guide to the safe use of lasers in health care*.

This Standard incorporates Amendment No. 1 (March 2019). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.

The objective of this Standard is to specify requirements for the safe use of lasers and intense light sources, including intense pulsed light (IPL) for diagnostic, cosmetic and therapeutic uses in health care facilities (including hospitals, private medical facilities and dental practices) and the cosmetic industry. To this end, it identifies engineering and administrative control measures designed to avoid the most significant hazards, and includes in Appendices explanations of basic laser and light physics as they apply to this Standard, and radiation/tissue interactions. Protocols to be observed during certain specialist medical and dental procedures are also included.

This Standard was prepared in the knowledge that separate Standards exist for medical laser and IPL equipment (AS IEC 60601.2.22, *Medical electrical equipment*, Part 2.22: *Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*, and AS IEC 60601.2.57, *Medical electrical equipment*, Part 2.57: *Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*, respectively). These Standards incorporate mandatory engineering and installation requirements to be observed by the manufacturers and constructors. Accordingly, this Standard concentrates on identifying those administrative needs and user precautions which are of equal importance. In particular, the importance of staff training is emphasized and this Standard—

(a) identifies appropriate levels of staff training (i.e. not all staff are required to be trained to the same level); and

(b) recommends that relevant educational organizations insist on formal medical laser/ILS training and certification of post graduate specialists.

This Standard differs from the second (2004) edition in the following respects:

(i) Changes to the IEC laser classification scheme.

(ii) The terminology and language used is intended to make it easier to read, interpret, and implement where applicable, for users and administrators alike.

(iii) Normative material has been separated from informative material, the latter being in Appendices.

(iv) Descriptions and definitions have been updated, taking into account the changes in the technology and science of lasers in health care since the second edition.

(v) Inclusion of consideration of intense light sources, in particular IPLs which, while using incoherent light and thus not lasers, have similar operator and patient safety issues.

The term ‘informative’ has been used in this Standard to define the application of the appendix to which it applies. An ‘informative’ appendix is only for information and guidance.

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FOREWORD

Laser technology applied to health care offers the potential for practical solutions to clinical procedures in areas hitherto regarded as difficult to manage. These include areas where the tissue is delicate (e.g. the retina), extremely vascular (e.g. the liver and tumours), or where access is difficult (e.g. the central trachea), cosmetic treatments, dentistry and veterinary medicine. Lasers are also increasingly used in non-destructive tissue applications for pain relief and tissue repair (photobiomodulation, sometimes known as low level laser therapy), as well as in diagnostic procedures such as laser Doppler flowmetry, optical coherence tomography, and laser-induced fluorescence.

Complementary to lasers is a new class of devices known as intense light sources, predominantly, but not exclusively, used in cosmetic medicine. The most common device in this class is called intense pulsed light (IPL).

The development of super-powerful, quasi-monochromatic light emitting diodes (LEDs) which can be mounted in planar arrays or articulated arms also provide a further source of high light intensity in clinically useful narrow bandwidths for cutaneous phototherapy. The primary clinical use of LED arrays is in photodynamic therapy (PDT) whereby biological tissue including a photosensitizer may absorb more heat than without a photosensitizer. The risks, including non-linear effects are dealt with in a separate IEC standard in development (IEC 60601-2-75) at the time of publication.

Use of intense light sources, including IPLs and by extension LED arrays, has been included as this is a rapidly growing technology in medical care, and, while they are incoherent (i.e. not laser) sources, the patient and operator safety issues are very similar. Some laser users may also use intense light sources, and some clinical applications can use either technology.

It is not intended that the recommended control measures should restrict or limit the use of laser and intense light source radiation which may be intentionally administered to a patient for diagnostic, cosmetic, therapeutic, surgical or medical research purposes. However, the controls are those considered necessary for the safety of all attending staff, as well as those which should be considered as fundamental to patient safety.

The laser types and applications addressed in this Standard are current at the time of writing. Given the rapid development in the field, efforts will be made to revise the Standard as the technology and its applications change.

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