

Market surveillance of eye-protectors for lasers or intense pulsed light in the cosmetic industry

Prepared by the Health and Safety Executive

RR1148

Research Report

© Crown copyright 2019

Prepared 2018

First published 2019

You may reuse this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view the licence visit www.nationalarchives.gov.uk/doc/open-government-licence/, write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email psi@nationalarchives.gsi.gov.uk.

Some images and illustrations may not be owned by the Crown so cannot be reproduced without permission of the copyright owner. Enquiries should be sent to copyright@hse.gov.uk.

Lasers and intense pulsed light (IPL) sources are used for a variety of medical and cosmetic treatments. The light sources used, whether laser or IPL, are designed to cause damage to hair follicles and/or pigmented skin, and as such have the potential to cause damage elsewhere on the body. Eye protection is required for both the patient and the practitioner for many kinds of IPL and laser treatments. Eye protectors sold in the UK must comply with the current European market surveillance legislation, which is achieved by the equipment conforming to a relevant harmonised standard. These standards define essential markings and provision of information that advises the user of the filtering capability of the eye-protector.

This report describes market surveillance testing of nine laser eye protector and nine IPL eye protector models available on the UK market. The purpose of this study was to examine the marking and information provided to determine compliance with the requirements of the relevant standards. Only five models of each type had safety markings consistent with the standards. Two laser eye protectors had no markings and no accompanying safety information, whilst three IPL eye protector models had markings for laser protection which are different and therefore incorrect.

No testing was performed to verify the accuracy of the markings.

This report and the work it describes were funded by the Health and Safety Executive (HSE). Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect HSE policy.

Market surveillance of eye-protectors for lasers or intense pulsed light in the cosmetic industry

Rhiannon Mogridge
Health and Safety Executive
Harpur Hill
Buxton
Derbyshire SK17 9JN

KEY MESSAGES

Laser and Intense Pulsed Light (IPL) sources are commonly used for medical and cosmetic procedures in the UK. The purpose of this study was to examine eye-protectors marketed for use with these light sources. The markings on the eye-protectors and the information provided with them were examined and compared to the relevant standards: EN 207 for laser eye-protectors; ISO 12609-1 or EN 166/EN 169 for IPL eye protectors. Only the markings and information were examined; no performance testing was conducted. All eye-protectors were purchased from suppliers in the UK. Based on a visual inspection, all of the eye-protectors purchased for this study were found to be in good condition and undamaged.

Products sold as laser eye-protectors

Of the nine eye-protectors purchased for this project, five had markings that were consistent with the relevant standard (EN 207), and the majority of the information required by EN 207 was provided. The following issues were identified with the remaining four eye-protectors:

- One had markings consistent with EN 207, but no information provided. Without the manufacturer's information, the potential for misuse of the eye-protector is increased.
- One had markings that were consistent with EN 207, but the markings were on a sticker that was easy to peel off. If the markings became detached, the user would have no way of knowing if the eye-protectors were suitable for their task.
- Two had no markings and no information provided with them. If they are laser eye-protectors, they lack crucial information required by the user in order to use them safely. It is also possible that they are not laser eye-protectors, but were mis-sold as laser eye-protectors.

Products sold as IPL eye-protectors

Of the nine IPL eye-protectors purchased for this project, five had markings consistent with a relevant IPL eye-protector standard (EN 166/EN 169 or ISO 12609-1), and the majority of the required information was provided. The following issues were identified with the remaining four eye-protectors:

- One had markings consistent with the relevant standard, but the information provided was for laser eye-protection. The performance characteristics and marking of laser eye-protectors and IPL eye-protectors are different, and some of the information provided was therefore incorrect (for example, the explanation of the markings).
- Two had markings on the oculars that were consistent with EN 166 and EN 169, but no relevant markings on the frames (EN 166 requires markings to be present on both ocular and frame). The information provided was for laser eye-protectors, not IPL eye-protectors (see above).
- One referenced EN 166 in markings on the frame, but was not marked according to EN 166 on the ocular. There were no markings to identify the filtering capability of the eye-protector. Some information was provided, but this did not include anything about the capability of the eye-protector. There was insufficient information for a user to determine whether this eye-protector would be suitable for their task.

EXECUTIVE SUMMARY

Background

Laser and Intense Pulsed Light (IPL) sources are used for a variety of medical and cosmetic treatments, including hair removal, tattoo removal and photo-rejuvenation. The light sources used, whether laser or IPL, are designed to cause damage to hair follicles and/or pigmented skin, and as such have the potential to cause damage elsewhere on the body. Eye protection is required for both the patient and the practitioner for many kinds of IPL and laser treatments.

Under current European market surveillance legislation, the UK's responsible authorities carry out market surveillance on non-food products, including Personal Protective Equipment (PPE). At the time the work described in this report was carried out, the European legal framework on PPE was in the process of transitioning from the EU PPE Directive 89/686/EEC (EEC, 1992) to the EU PPE Regulation 2016/425 (EEC, 2016). Compliance with both the PPE Directive and the PPE Regulation is usually achieved by compliance with the relevant harmonised standard. In the case of eye protection, the standards define essential markings and provision of information that advise the user of the filtering capability of the eye-protector. There is a risk to the wearer of damage to the eye and potential impairment of sight if unsuitable eye-protectors are used as PPE.

Aim

This report describes a study in which eye-protectors for use with lasers and IPL were purchased. The aim was, to examine the marking and information provided with them for consistency with the requirements of the relevant standards. No testing was performed to verify the accuracy of the markings.

The standard for laser eye-protectors is EN 207:2009 *Personal eye-protection equipment – Filters and eye-protectors against laser radiation (laser eye-protectors)*.

NOTE: After all purchasing and examination described in this report had been carried out but prior to the report being issued, an updated version of EN 207 was issued. EN 207:2017 supersedes EN 207:2009. While the work described here was carried out according to EN 207:2009, there are no material differences between the 2009 and 2017 version of EN 207 with respect to markings and required information.

The standard for IPL eye-protectors in the UK is ISO 12609-1:2013 *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications – Specification for products*, but many IPL eye-protectors are tested and marked as welding eye-protectors, using EN 166:2001 *Personal eye-protection – Specifications* and EN 169:2002 *Personal eye-protection – Filters for welding and related techniques – Transmittance requirements and recommended use*.

Method

The eye-protectors to be examined were selected using the following criteria:

1. Available from suppliers in the UK; and

2. Recommended by the supplier for use with either lasers or IPL by the following means:
 - a. By directly stating that the eye-protector was for use with lasers or IPL; or
 - b. By claiming compliance with a relevant standard (either EN 207 for lasers or ISO 12609-1 for IPL).

Nine laser eye-protectors were purchased from six different suppliers, with six manufacturers represented. Nine IPL eye-protectors were purchased from seven different suppliers with five manufacturers represented. All eye-protectors were purchased in the UK.

Results

All of the eye-protectors purchased for this study were found to be in good condition and undamaged, based on a visual inspection.

Products sold as laser eye-protectors:

- Five had markings consistent with EN 207, and provided the majority of the information required by EN 207. The missing information would not prevent users from identifying whether the eye-protector was suitable for their task.
- One had markings consistent with EN 207, but with no information provided. Without the manufacturer's information, the potential for misuse of the eye-protector is increased.
- One had markings consistent with EN 207, except that they were printed on a label that was easy to peel off (EN 207 states that: "The following shall be marked permanently on the filters or the frames for identification"). If the markings became detached, the user would have no way of knowing if the eye-protectors were suitable for their task. The majority of the information required by EN 207 was provided.
- Two had no markings and no information provided with them. If they are laser eye-protectors, they lack crucial information required by the user in order to use them safely. It is also possible that they are not laser eye-protectors, but were mis-sold as laser eye-protectors.

Products sold as IPL eye-protectors:

- One had markings consistent with ISO 12609-1. All of the required information was provided.
- Four had markings consistent with EN 166 and EN 169. The majority of the required information was provided. The missing information would not prevent users from identifying whether the eye-protector was suitable for their task.
- One had markings consistent with EN 166 and EN 169, but the information provided was for laser eye-protectors, not for IPL eye-protectors. The performance characteristics and marking of laser eye-protectors and IPL eye-protectors are different, and some of the information provided was therefore incorrect (for example, the explanation of the markings).
- Two (from the same manufacturer) had markings on the oculars consistent with EN 166 and EN 169, but no relevant markings on the frames (EN 166 requires markings to be present on both ocular and frame). The information provided was for laser eye-protectors, not for IPL eye-protectors. The performance characteristics and marking of laser eye-protectors and IPL

eye-protectors are different, and some of the information provided was therefore incorrect (for example, the explanation of the markings).

- One referenced EN 166 in markings on the frame, but was not marked according to EN 166 on the ocular. There were no markings to identify the filtering capability of the eye-protector. Some information was provided, but this did not include anything about the capability of the eye-protector. There was insufficient information for a user to determine whether this eye-protector would be suitable for their task.

CONTENTS

KEY MESSAGES	4
EXECUTIVE SUMMARY	5
1. INTRODUCTION	9
1.1 Background	9
1.2 Laser treatments.....	9
1.3 Intense pulsed light treatments	9
1.4 Relevant standards	10
1.5 Study objectives.....	10
2. METHODS	11
1.7 Selection of eye-protectors for testing.....	11
1.8 Visual examination.....	11
1.9 Marking.....	11
1.10 Manufacturer’s information	16
3. RESULTS AND DISCUSSION	20
1.11 Selected eye-protectors	20
1.12 Visual examination.....	21
1.13 Markings.....	21
1.14 Manufacturer’s information	23
1.15 Declarations of conformity	27
1.16 Further actions.....	28
4. CONCLUSIONS	29
REFERENCES.....	31

1. INTRODUCTION

1.1 BACKGROUND

Lasers and Intense Pulsed Light (IPL) are used for a variety of medical and cosmetic treatments, including hair removal, tattoo removal and photo-rejuvenation. These treatments are becoming more widely available in the UK, from a variety of clinics and practitioners.

The light sources used, whether laser or IPL, are designed to cause damage to hair follicles and/or pigmented skin, and as such have the potential to cause damage elsewhere. The eyes are particularly sensitive to light, and are therefore also particularly susceptible to light damage. Eye protection is required for both the patient and the practitioner for many kinds of IPL and laser treatments. Since patients do not need to be able to see during the treatment, provision of suitably opaque eye-protectors is relatively easy. Practitioners, on the other hand, need to be able to see, and therefore more complex filtering eye-protectors are required. There is a risk to the wearer of damage to the eye and potential impairment of sight if unsuitable eye-protectors are used as PPE.

Tattoo and hair removal treatments involving the use of laser and IPL equipment are popular, with a UK manufacturer of such equipment predicting that the volume of tattoo removal will continue to increase over the next three years. A Department of Health review into the regulation of cosmetic interventions found an increase in the number of people reporting complications from non-surgical cosmetic procedures, including laser/IPL treatments (Department of Health, 2013). Given the concerns raised, investigation of the safety of PPE eye-protectors used with laser and IPL equipment for cosmetic applications is appropriate.

1.2 LASER TREATMENTS

Lasers are coherent and monochromatic light sources, which means that they only emit light at one specific wavelength. Different types of laser are available, producing different wavelengths of light, i.e. different colours of light. It should be noted that laser light emitted in the infra-red and ultraviolet wavelength bands is invisible to the naked eye, but still potentially capable of doing harm. The type of laser being used will depend upon the procedure being undertaken, and may also depend upon the colour of the patient's skin and hair. Eye-protectors for practitioners using cosmetic and medical lasers are no different from eye-protectors used against similar lasers in any other industry.

Since lasers only emit light at a specific wavelength, only that specific wavelength needs to be filtered by the eye-protector. Eye-protectors must therefore be matched to the laser being used in order to be effective. No single eye-protector will protect against every type of laser.

1.3 INTENSE PULSED LIGHT TREATMENTS

IPL treatment uses a bright, non-coherent and polychromatic light source. The light source nominally covers the wavelength range from 500 nm to 1200 nm, which includes portions of ultraviolet, visible and near infra-red wavelengths.

Unlike laser eye-protectors, IPL eye-protectors need to protect across the majority of the visible spectrum. High levels of IPL eye protection will therefore inevitably be accompanied by lower visible light transmission, which means that additional lighting may be required in the workplace in order

for the practitioner to be able to see clearly. Active eye-protectors, which only turn dark during a flash, fall outside the scope of this project.

1.4 RELEVANT STANDARDS

PPE sold in the UK must comply with the relevant EU legislation. The work described in this report was carried out during the transition period between the EU Directive 89/686/EEC (the PPE Directive) and the EU Regulation 2016/425 (the PPE Regulation). All of the work described in this report was carried out prior to the PPE Regulation coming into full force. Compliance with both the PPE Directive and the PPE Regulation is usually achieved through compliance with harmonised European standards. This is the case with laser eye-protectors, using the European standard EN 207:2009 *Personal eye-protection equipment – Filters and eye-protectors against laser radiation (laser eye-protectors)*. If a manufacturer complies with the requirements of EN 207, it is presumed that they are complying with the essential requirements of the PPE Directive, with respect to laser eye-protectors.

NOTE: After all purchasing and examination described in this report had been carried out but prior to the report being issued, an updated version of EN 207 was issued. EN 207:2017 supersedes EN 207:2009. While the work described here was carried out according to EN 207:2009, there are no material differences between the 2009 and 2017 version of EN 207 with respect to markings and required information.

The standard for IPL eye-protectors in the UK is ISO 12609-1:2013 *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications – Specification for products*, but this is not a harmonised European standard, and is not necessarily recognised across all of Europe. Some IPL eye-protectors are therefore tested and marked as welding eye-protectors, using EN 166:2001 *Personal eye-protection – Specifications* and EN 169:2002 *Personal eye-protection – Filters for welding and related techniques – Transmittance requirements and recommended use*. The requirements for filtering performance are similar (although not identical) for ISO 12609-1 and EN 169, with a note in ISO 12609-1 stating that: “The F-numbers ... are related to the shade numbers with some relaxation in the infrared region.” ISO 12609-1 uses F-numbers; EN 169 uses shade numbers. For both F-numbers and shade numbers, a higher number represents increased protection, but also makes it harder to see. Someone who is using eye-protectors with a high F-number or shade number may require increased lighting in the workplace.

1.5 STUDY OBJECTIVES

The purpose of this study was to purchase eye-protectors for protection against lasers and IPL, and to examine the marking and information provided with them for consistency with the requirements of the relevant standards. These standards define the essential markings and information that advise the user of the filtering capability of the eye-protectors. No testing was performed to verify the accuracy of the markings.

2. METHODS

1.7 SELECTION OF EYE-PROTECTORS FOR TESTING

The eye-protectors to be examined were selected using the following criteria:

1. Available from suppliers in the UK; and
2. Recommended by the supplier for use against either lasers or IPL by the following means:
 - a. By directly stating that the eye-protector was for use with lasers or IPL; or
 - b. By claiming compliance with a relevant standard (either EN 207 for lasers or ISO 12609-1 for IPL).

A range of different manufacturers and models were sought. All purchased eye-protectors were identified online, so only suppliers with a web-presence were represented in this study. All eye-protectors were purchased using normal HSE purchasing procedures. None of the suppliers were informed that the eye-protectors were being purchased for market surveillance.

1.8 VISUAL EXAMINATION

Each eye-protector was visually inspected for damage, and the results recorded.

1.9 MARKING

Any markings on the eye-protectors were recorded and compared with the requirements of the relevant standard(s). For laser eye-protectors, the relevant standard is EN 207. For IPL eye-protectors, the relevant standard is ISO 12609-1. IPL eye-protectors are frequently marked as welding eye-protectors; in such cases the markings were compared to the requirements of EN 166 (personal eye protection) and EN 169 (welding eye-protectors).

1.9.1 Laser eye-protectors

For a full explanation of the markings on laser eye-protectors, see EN 207. A summary of the markings required for laser eye-protectors is given in Table 1.

Table 1 Summary of the markings required by Clause 6 of EN 207

Requirement	Comments
The following shall be marked permanently on the filters or the frames for identification:	
a) Wavelength(s) or wavelength range (given in nanometres (nm)) in which the filter provides protection.	
b) The symbol for the test condition.	<p>Comment: D : Continuous wave laser (tested for 5 s continuously) I : Pulsed laser (pulse length $>10^{-6}$ to 0.25 s, at least 50 pulses) R : Q switch pulsed laser (pulse duration $>10^{-9}$ to 10^{-6} s, at least 50 pulses) M : Mode-couples pulse laser (pulse duration $<10^{-9}$ s, at least 50 pulses)</p>
c) Scale number. If the filter guarantees protection in one or several spectral ranges, the lowest scale number shall be given in the corresponding spectral range.	<p>Comment: The scale number is given for each wavelength range and test condition. Scale numbers range from LB1 to LB10, with higher values offering increased protection. Eye-protectors with high scale numbers over large portions of the visible spectrum will result in low visible light transmission, meaning that increased lighting may be needed in the workplace.</p>
d) If the eye-protector is not tested with low repetition rates (≤ 25 Hz), the suffix Y shall be added to the scale number, e.g. R LB5Y	
e) Manufacturer's identification mark. In order to prevent multiple use, only marks granted at European or national level shall be used.	
f) If the eye-protector satisfies the mechanical strength requirement of 3.10.2, one of the marks specified in Clause 9 of EN 166:2001 shall also be added.	<p>Comment: Spectacles can be marked "S" for increased robustness or "F" for low energy impact. In addition, "T" means that they fulfil these requirements even at extremes of temperature. Impact protection is optional for IPL eye-protectors.</p>
If the symbols are marked on the filters, they shall not impair vision nor the protective effect.	
If several marks apply to a laser radiation eye-protector, all these marks shall be applied, or alternatively the manufacturer's identification mark, the certification mark and the mechanical strength symbol shall be specified only once; the other identification elements shall be separated by a +.	

EN 207 Example marking:

315-534 + 730-740 D LB5 + IRM LB6

- 315-534 + 730-740: Wavelength ranges 315-534 nm and 730-740 nm
- D LB5: Scale number LB5 under test condition D (continuous wave laser)
- IRM LB6: Scale number LB6 under test conditions I, R and M (pulsed lasers, Q switch pulsed lasers and mode-coupled pulse lasers)

1.9.2 IPL eye-protectors

For a full explanation of the markings on IPL eye-protectors, see EN 166, EN 169 and/or ISO 12609-1.

Table 2 and Table 3 give a summary of the required markings for the different standards.

Table 2 Summary of the markings required by Clause 9 of EN 169

Marking	Comments
All markings shall be clear and permanent. The marking shall be fully visible when the complete eye-protector is assembled and shall not encroach into the minimum field of vision. Outside of this area the marking shall not impede vision when worn. The frame and ocular shall be marked separately.	
Marking of oculars	
The marking of oculars shall contain the relevant technical information presented as follows:	
Scale number	IPL eye-protectors are most likely to be marked with welding scale numbers. Welding scale numbers range from 1.2 to 16, but scale numbers for IPL are likely to range from 1.2 to 6. Higher numbers give more protection, but reduce the visible light transmission.
Identification of the manufacturer	
Optical class	The optical class ranges from 1 to 3, where optical class 1 provides the highest clarity.
Symbol for mechanical strength (where applicable)	Spectacles can be marked “S” for increased robustness, or “F” for low energy impact. Impact protection is optional for IPL eye-protectors.
Marking of frames	
The marking of frames shall contain the relevant technical information presented as follows:	
Identification of the manufacturer	
The number of this standard	
Field(s) of use (where applicable)	Fields of use are optional for IPL eye-protectors.
Symbol of increased robustness/resistance to high speed particles/extreme of temperature	These markings are optional for IPL eye-protectors, but can included “F” for high speed, low energy impact or “FT” for high speed, low energy impact at extremes of temperature.
Marking of eye-protectors where the frame and ocular form a single unit	
Eye-protectors in which the frame and ocular form a single unit shall be marked on the frame.	
The marking shall comprise the full ocular marking, a hyphen, the number of this standard and then any appropriate symbols for field of use and level of impact.	

EN 169 Example marking on ocular:

5 X 1 FT

- 5: Shade number
- X: Manufacturer's mark
- 1: Optical class 1 (best quality)
- FT: High speed, low energy impact at extremes of temperature

EN 169 Example marking on frame:

X 166 FT

- X: Manufacturer's mark
- 166: Number of the standard
- FT: High speed, low energy impact at extremes of temperature

Table 3 Summary of the markings required by Clause 8 of ISO 12609-1

Marking	Comments
Each IPL eye-protector shall be clearly and permanently marked to indicate the following:	
a) model number	
b) manufacturer's identification	
c) eyewear classified according to clause 4.2 and/or clause 4.3 shall be marked F-# and/or B-#, respectively, where # = 1 to 6	F-numbers are similar, though not identical, to welding scale numbers, but are intended specifically for IPL eye-protectors. They range from 1 to 6, with higher numbers giving higher protection, but reducing the amount of visible light transmission. For high F-numbers, increased lighting may be needed in the workplace.
If the information is marked on the filters, they shall not impair vision or the protective effect	

Example marking:

F-3 X 1 F M

- F-3: F-number, similar, but not identical to, a shade number
- X: Manufacturer's mark
- 1: Optical class 1 (best quality)
- F: High speed, low energy impact
- M: Model identification

1.10 MANUFACTURER'S INFORMATION

Any information provided with laser eye-protectors by the manufacturer was compared with the requirements of EN 166 and EN 207. Information provided with IPL eye-protectors was compared with either ISO 12609-1, or EN 166 and EN 169, depending upon whether the markings on the eye-protector were consistent with ISO 12609-1 or EN 166.

Table 4, Table 5 and Table 6 give the requirements for the information provided by the manufacturer for EN 207, EN 166 and ISO 12609-1 respectively.

Laser eye-protectors marked to EN 207 must have provided with them the information required by EN 166 as well as the information required by EN 207.

Table 4 Requirements for information to be supplied by the manufacturer for laser eye-protectors, from EN 207

Information supplied by the manufacturer	Comments
The information shall be in the language(s) of the country in which the eye-protector is sold	
In addition to the requirements of EN 166:2001 Clause 10 the selection criteria and instructions for use shall contain at least the following:	See Table 5 below for requirements from EN 166
a) luminous transmittance;	
b) if the luminous transmittance is less than 20 %, this shall be indicated and the user shall be recommended to increase the intensity of illumination at the workplace;	
c) in the case of tinted and coloured filters a warning to the user that the recognition of warning lights or warning signals can be impaired;	
d) the information that the eye-protectors are only intended to give protection against accidental radiation and that both the limit values and the resistance tests are based on a maximum period of 5 s;	
e) a warning that eye-protectors and filters against laser radiation which have been damaged, have scratched oculars or which have undergone a colour change shall not be used anymore;	
f) an explanation of the symbols used in the marking;	
g) details regarding an appropriate cleaning method;	

h) in case of filters with angle dependent transmittance information shall be given that the protection is only provided for angles of incidence up to 30°.	
Instructions shall include a warning of risk of exposure to laser radiation due to reflection from reflective parts (including eye-protectors), tilting or misalignment of optical components.	
Instructions shall include a recommendation that in areas where there is a risk of exposure to laser radiation appropriate eye-protection should be worn by all personnel	
In addition, the manufacturers shall supply additional data in the form of transmission curves.	

Table 5 Requirements for information to be supplied by the manufacturer, from EN 166

Clause 10: Information supplied by the manufacturer	Comments
The manufacturer shall provide with each eye-protector ... at least the following information:	
a) name and address of the manufacturer;	
b) the number of this standard;	
c) the eye-protection model identification;	
d) instructions for storage, use and maintenance;	
e) specific instructions for cleaning and disinfection;	
f) details of the field of use, protection capabilities and performance characteristics;	Optional for laser/IPL eyewear
g) details of suitable accessories and spare parts. Instructions for fitting shall be included with the original eye-protection and/or with the spare part or accessory;	May not be required, depending on whether spare parts exist
h) the obsolescence deadline or period of obsolescence, if applicable, for the complete eye-protector and/or component parts;	
i) the type of packaging suitable for transport, if applicable;	
j) the significance of marking on the frame and the ocular;	
k) a warning that optical class 3 oculars are not intended for long term use, if applicable;	
l) a warning concerning the compatibility of marking	Not relevant to laser/IPL eye-protectors
m) a warning that the materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals;	
n) a warning that scratched or damaged oculars should be replaced;	
o) a warning that eye-protectors against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer;	Protection against high speed particles is optional for laser/IPL eye-protectors

p) a note to instruct that if protection against high speed particles at extremes of temperature is required then the selected eye-protector should be marked with the letter T immediately after the impact letter, i.e. FT, BT or AT. If the impact letter is not followed by the letter T then the eye-protector shall only be used against high speed particles at room temperature.	Protection against high speed particles is optional for laser/IPL eye-protectors
--	--

Table 6 Requirements for information to be supplied by the manufacturer for IPL eye-protectors, from ISO 12609-1

Clause 9: Information to be supplied by the manufacturer	Comments
Each ILS (intense light source) eye-protector shall be supplied with printed user information in the language(s) of the country in which the eye-protector is sold. This information shall include:	
a) a clear statement of the model number of the eye protection	
b) a reproduction of the labelling in accordance with Clause 8 and an explanation of its meaning	
c) spectral transmittance in accordance with Clause 4, in graphical or tabular form at 10 nm intervals	
d) an explanation of the F-# and/or B-# marking conforming with clause 4.2 or clause 4.3 as appropriate, in tabular or graphic form at 10 nm intervals	
e) luminous transmittance in accordance with clause 4.4	
f) the CIE colour coordinated (x, y) of the protective filters in accordance with clause 5.2, with optional presentation on a CIE chromaticity chart	
g) PD or PD range, if applicable	PD is pupillary distance – the distance apart of the pupils. Non-prescription eye-protectors may not have a specified PD.
h) for auto darkening filters, the minimum luminous transmittance in the light and dark states	This type of eye-protector falls outside the scope of this study
i) for auto darkening filters powered by electrical mains, batteries or photovoltaic cells, specification of power settings and power tolerances	This type of eye-protector falls outside the scope of this study
j) instructions for use, care, storage, cleaning and disinfection of the eye-protector	
k) instructions for inspection and guidance on when the eye-protector should be replaced	

l) the name and address of the manufacturer or supplier of the eye-protector	
--	--

3. RESULTS AND DISCUSSION

1.11 SELECTED EYE-PROTECTORS

Table 7 summarises the eye-protectors purchased for this study.

Table 7 Summary of eye-protectors purchased for this study

Model ID	Manufacturer ID	Supplier ID	Approximate price	Protection type
A	M3	S2	£20	Unclear
B	M4	S1	£140	Laser
C	M4	S3	£122	Laser
D	M4	S3	£116	Laser
E	M4	S4	£144	Laser
F	M5	S5	£268	Laser
G	Unclear	S6	£4	Unclear
H	M7	S1	£240	Laser
I	M1	S1	£210	Laser
J	M1	S7	£39	IPL
K	M1	S7	£39	IPL
L	M1	S8	£36	IPL
M*	M1	S1	£44	IPL
N	M6	S7	£59	IPL
O	M4	S9	£54	IPL
P	M4	S3	£59	IPL
Q	M5	S5	£45	IPL
R	M7	S10	£46	IPL
S	M7	S1	£36	IPL

* When received, Model M was found to be identical to Model L in both its markings and information.

Attempts were initially made to restrict purchases to a maximum of two eye-protectors (one laser, one IPL) per manufacturer, but this was found to be impractical. Although a wide range of eye-protectors is available worldwide, there appears to be a limited number of manufacturers whose products are readily available in the UK. When purchasing, it was not always clear who the manufacturer was from the suppliers' websites. Model M was found, on receipt, to be identical to Model L, which had been ordered from a different supplier. An additional eye-protector, Model S, was purchased to replace it.

In total, nine different eye-protectors marketed for protection against laser radiation were purchased from six different suppliers, with six manufacturers represented. Excluding the duplicate Model M, nine different eye-protectors marketed for IPL protection were purchased from seven different suppliers with five manufacturers represented.

1.12 VISUAL EXAMINATION

All of the eye-protectors purchased for this study appeared to be in good condition based on a visual inspection. No visible faults were found.

1.13 MARKINGS

The markings of all eye-protectors were examined for compliance with the relevant standards. Only the method and format of marking was assessed; no tests were performed to assess the accuracy of the markings.

Table 8 and Table 9 summarise the markings on the laser eye-protectors and the IPL eye-protectors respectively.

Table 8 Summary of markings on laser eye-protectors

Model ID	Markings	Relevant standard
A	Sticker on side with a pictogram showing someone looking at a laser through glasses, with a red "don't" symbol across it. No formal marking.	-
B	>315-534 + 730-740 D LB5 + IRM LB6 180-315 D LB7 + R LB4 >740-1070 D LB6 + IRM LB7 MM* CE	EN 207
C	180-315 D LB6 + R LB4 >315-400 DR LB4 720-725 DM LB5 720-750 + >1064-1075 IR LB5 >725-1075 DM LB6 >750-1064 IRM LB7 MM* CE	EN 207
D	720-840 D LB5 720-830 I LB7 + R LB6 >830-840 I LB6 + R LB5 MM* CE	EN 207
E	180-315 D LB6 + R LB4 >315-400 DR LB4 720-725 DM LB5 720-750 + >1064-1075 IR LB5 >725-1075 DM LB6 >750-1064 IRM LB7 MM* CE	EN 207
F	180-315 D LB9 + IR LB4 >315-532 D LB5 + IR LB6 + M LB5 800-1068 D LB6 + IR LB7 + M LB6 900-1020 D LB6 + IR LB7 + M LB6 >1020-1068 D LB6 + IR LB7 + M LB6 <i>Manufacturer's name</i>	EN 207
G	None	-
H	180-315 D LB5 + R LB4 >315-375 D LB4 + R LB5 >375-390 DR LB3 730-<755 DIR LB4 755-840 DR LB5 + I LB7Y >840-855 DIR LB4 MM* CE	EN 207
I	315-532 DLB5 + IR LB6 800-839 DIR LB3 840-864 DIR LB4 865-1063 DIR LB5 1064 D LB6 + IR LB7 MM* CE	EN 207

*MM represents the manufacturer's mark

Models B, C, D, E, H and I had markings etched permanently into the oculars. The markings were consistent with EN 207.

Model F had markings consistent with EN 207, but the markings were printed on a sticker which was easy to peel off. EN 207 states that: "The following shall be marked permanently on the filters or the frames for identification". If the markings became detached, the user would have no way of knowing if the eye-protectors were suitable for their task. The printed marks were small, blurred and difficult to read.

Models A and G were not marked to any standard, and did not bear the CE mark. If they are laser eye-protectors, the lack of marking means the user would have no information about their performance. It is also possible that they are not laser eye-protectors, but were mis-sold as laser eye-protectors. They might, for example, be laser-level glasses, which are designed to make a laser-level line easier to see in bright conditions, and are not intended to provide protection. Laser-level glasses are not PPE, do not provide protection from lasers and do not require a CE mark. However, both of these pairs of glasses were being sold as laser eye-protectors, which may be a failing on the part of the supplier.

Table 9 Summary of markings on IPL eye-protectors

Model ID	Marking on oculars	Marking on frames	Relevant standard(s)
J	3.0 MM* 1 FT	MM* 166 FT CE MM* 230.1 FT Manufacturer's name	EN 166 EN 169
K	4.0 MM* 1 FT	MM* 166 FT CE MM* 230.1 FT Manufacturer's name	EN 166 EN 169
L & M	F-3 MM* 1 F - 166 F CE Model name	MM* 166 F CE Manufacturer's name	ISO 12609-1
N	No UK markings. US marking for impact protection "Z87+", which is not valid within Europe.	Manufacturer's name Z87+ IPL CE 166	-
O	3 MM* 1 F CE	Model name Manufacturer's name	EN 166 EN 169
P	2 MM* 1 F CE	Model name Manufacturer's name	EN 166 EN 169
Q	5 MM* 1 FT K CE 09/13	MM* - 166 FT CE Manufacturer's name Model name	EN 166 EN 169
R		4 MM* 1 FT W 166 CE	EN 166 EN 169
S		5 MM* 1 S MM* 166 CE	EN166 EN169

*MM represents the manufacturer's mark.

Model L was marked to ISO 12609-1, which specifically describes eye-protectors for use against IPL. All required markings were present, and were permanently etched onto the ocular. Model L was additionally marked to EN 166 for low-energy impact, and bore separate markings on the oculars and frames to reflect this. The manufacturer's mark on the frames was different to that on the ocular.

The markings on the oculars and frames of models J, K and Q were consistent with EN 166, with the oculars bearing a shade number from EN 169, which covers eye-protectors intended for welding. The use of a welding standard to mark eye-protectors for IPL may be due to the lack of a European standard for IPL. In 2008, the British Standard for IPL was published: BS 8497-1:2008 *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications. Specification for products*. BS 8497-1 was superseded by ISO 12609-1 in 2013. Prior to these two standards, the welding standard EN 169 was likely the most relevant standard for IPL eye-protectors within the UK. EN 169 may still be the most relevant standard in any EU countries which have not adopted ISO 12609-1. A note in ISO 12609-1 states that: "The F-numbers ... are related to the shade numbers with some relaxation in the infrared region."

The ocular and frame of Models R and S formed a complete unit, so they were only marked on the frame. The markings on both were consistent with EN 166.

Models O and P, which were from the same manufacturer, were marked on the oculars, but not on the frames. Nowhere on these two models of eye-protector was compliance with EN 166 claimed (the "166" mark is usually on the frame), although the markings on the oculars were consistent with EN 166, and both of them bore the CE mark. It is therefore not clear to which standard they were marked.

Model N carried no ocular markings, and the only relevant marking on the frame was "IPL CE 166", which is not consistent with EN 166, as it does not include a manufacturer's mark. It also did not carry a shade number or an F-number.

1.14 MANUFACTURER'S INFORMATION

EN 207, EN 166 and ISO 12609-1 all require that certain information be provided with eye-protectors. Table 10 summarises any information that is missing for each of the models of laser eye-protector.

Table 10 Incorrect and missing information for laser eye-protectors

Model ID	Information missing from instructions
A	<ul style="list-style-type: none"> • No information provided.
B	<ul style="list-style-type: none"> • Multiple models mentioned. The specific model is not identified in the information, but is identified on the case. • No warning about potential allergic reaction is given. • States that the eye-protector is tested for 10 s, (EN 207 requires 5 s). • No mention of the risk of exposure to laser radiation due to reflection from reflective parts (including eye-protectors). • No transmission curves given.
C	<ul style="list-style-type: none"> • Multiple models mentioned. The specific model is not identified in the information, but is identified on the case. • No warning about potential allergic reaction is given. • States that the eye-protectors is tested for 10 s, (EN 207 requires 5 s). • No mention of the risk of exposure to laser radiation due to reflection from reflective parts (including eye-protectors). • No transmission curves given.
D	<ul style="list-style-type: none"> • Multiple models mentioned. The specific model is not identified in the information, but is identified on the case. • No warning about potential allergic reaction is given. • States that the eye-protector is tested for 10 s, (EN 207 requires 5 s). • No mention of the risk of exposure to laser radiation due to reflection from reflective parts (including eye-protectors). • No transmission curves given.
E	<ul style="list-style-type: none"> • No information provided.
F	<ul style="list-style-type: none"> • No transmission curves given.
G	<ul style="list-style-type: none"> • No information provided.
H	<ul style="list-style-type: none"> • The specific model is not identified in the information. • The luminous transmittance is not given. • No transmission curves given.
I	<ul style="list-style-type: none"> • The specific model is not identified in the information. • The luminous transmittance is not given. • No transmission curves given.

The information provided with Model F was complete, except that no transmission curves were provided.

The information supplied with Model I did not identify the model, and also did not give the luminous transmittance. Both the model and luminous transmittance were identified in markings on the eye-protector. No transmission curves were provided.

The information supplied with Model H did not identify the model, and also did not give the luminous transmittance. While the model was identified in markings on the eye-protector, the luminous transmittance was not. No transmission curves were provided.

Models B, C and D were all from the same manufacturer, and had identical information sheets. The information provided listed many models of laser eye-protector available, including all three purchased for this project. Two of the eye-protectors had the model number on a sticker on the case, but the third bore no identifying marks, and the model was only identified by comparing the visual light transmission and scale numbers on the eye-protector to those listed in the information. The information with models B, C and D contained no warning about potential allergic reaction. The information stated that the eye-protector can offer protection for a maximum exposure of 10 s. The standard test is for 5 s, and EN 207 requires that this be stated in the information. No transmission curves were given.

Models A, E and G had no information provided. Model E was from the same manufacturer as Models B, C and D, all of which came with instructions. Models A and G had no markings in addition to having no information, and may not be manufactured as laser eye-protectors, as discussed in section 3.3.

Table 11 Incorrect and missing information for eye-protectors claiming to protect against IPL

Model ID	Information missing from instructions
J	<ul style="list-style-type: none"> The model of eye-protector is not identified.
K	<ul style="list-style-type: none"> The model of eye-protector is not identified. Also includes instructions for EN 207.
L & M	<ul style="list-style-type: none"> All required information was provided.
N	<ul style="list-style-type: none"> No standard number is given. The model of the eye-protector is not given. No markings are explained. No warning about potential allergic reaction is given.
O	<ul style="list-style-type: none"> Instructions reference EN 207, not EN 166. A list of models is given, but this model is not included. Protection/performance/markings information is for laser eye-protectors, not for IPL. No mention is given that eye-protectors worn over standard ophthalmic spectacles may transmit impacts, or that eye-protectors for impact protection at extremes of temperature should be marked with a "T" (the eye-protector is marked for low energy impact "F").
P	<ul style="list-style-type: none"> Instructions reference EN 207, not EN 166. A list of models is given, but this model is not included. Protection/performance/markings information is for laser eye-protectors, not for IPL. No mention is given that eye-protectors worn over standard ophthalmic spectacles may transmit impacts, or that eye-protectors for impact protection at extremes of temperature should be marked with a "T" (the eye-protector is marked "F" for low energy impact).
Q	<ul style="list-style-type: none"> Instructions reference EN 207, not EN 166. Protection/performance/markings information is for laser eye-protectors, not for IPL. No warning about potential allergic reaction is given. No mention is given that eye-protectors worn over standard ophthalmic spectacles may transmit impacts (the eye-protector is marked "FT" for low energy impact at extremes of temperature)
R	<ul style="list-style-type: none"> The model of eye-protector is not identified in the information.
S	<ul style="list-style-type: none"> The model of eye-protector is not identified in the information.

The information provided with Model L was complete according to the requirements of ISO 12609-1.

The information provided with Models J, K, R and S did not identify the specific model of eye-protector. Models J and K were from the same manufacturer as each other, and the information for

them was identical; Models R and S were from the same manufacturer as each other, but the information provided for them was not identical.

Models O and P were from the same manufacturer as each other, and the information provided with them was identical and referenced EN 207 for laser eye-protectors, rather than either EN 166 or ISO 12609-1 for IPL eye-protectors. A list of eye-protector models was included; neither model O nor model P was on the list. The description of markings was for EN 207, and was therefore incorrect for IPL eye-protectors.

The information provided with model Q referenced EN 207, rather than EN 166 or ISO 12609-1. The model of eye-protector was not identified. All aspects of use and markings referenced EN 207.

Model N carried no relevant markings, and the information provided with it was limited. No standard was referenced, the model of eye-protector was not given, and no markings were explained.

1.15 DECLARATIONS OF CONFORMITY

Declarations of conformity were obtained from the supplier’s website or requested from the supplier for all eye-protectors that were CE-marked.

1.15.1 Laser eye-protectors

Models A and G were not CE-marked, so no declaration of conformity was requested.

Table 12 shows where the declarations of conformity for the laser eye-protectors were obtained.

Table 12 Suppliers of declarations of conformity for laser eye-protectors

Model ID	Supplier of certificate of conformity	Notes
A	<i>No CE mark</i>	-
B	S1	Received with eye-protector
C	S3	Supplier’s website
D	S3	Supplier’s website – this certificate states: “This EC-type examination certificate is valid until 2016...” It was sourced from the supplier’s website in January 2017.
E	S4	Received by email on request
F	S5	Received by email on request
G	<i>No CE mark</i>	-
H	S1	Received with eye-protector
I	S1	Received with eye-protector

All of the declarations of conformity received for the laser eye-protectors appeared to be for the correct product.

The declarations of conformity for Models C, D, E and F claimed compliance with EN 207.

The declaration of conformity for Models B, H and I did not reference a standard.

Declarations of conformity do not typically have an expiry date, but the declaration of conformity for Model D stated that it was valid until 2016. It was downloaded from the supplier’s website in January 2017.

Table 13 shows where the declarations of conformity for the IPL eye-protectors were obtained.

Table 13 Suppliers of declarations of conformity for IPL eye-protectors

Model ID	Supplier of certificate of conformity	Notes
J	S7	Received by email on request
K	S7	Received by email on request
L	S8	Received by email on request
N	S7	Received by email on request
O	S9	Received by email on request
P	S3	Supplier’s website
Q	S5	Received by email on request
R	S10	Not yet received
S	S1	Received with eye-protector

No declaration of conformity for Model R had been received from the supplier at the time this report was issued.

All of the declarations of conformity received for the IPL eye-protectors appeared to be for the correct product.

The certificates of conformity for Models J, K and L claimed compliance with EN 166, EN 169, EN 170 and ISO 12609-1.

The certificate of conformity for Model O claimed compliance with EN 207.

The certificate of conformity for Model P claimed compliance with EN 166 and EN 169.

The certificate of conformity for Model N claimed compliance with EN 166.

The certificates of conformity for Models Q and S did not reference any standards.

1.16 FURTHER ACTIONS

A copy of this report will be sent to each manufacturer/importer, with additional information on their own products. In the case of Models A, G, O, P and N, which all had anomalies that would make correct selection more difficult, the relevant Trading Standards authority will receive the same information as the manufacturer/importer.

4. CONCLUSIONS

All of the eye-protectors purchased for this study were found to be in good condition and undamaged, based on a visual inspection.

Products sold as laser eye-protectors:

Of the nine laser eye-protectors purchased for this project, five had markings that were consistent with the relevant standard (EN 207), and the majority of the information required by EN 207 was provided. The missing information would not prevent users from identifying whether the eye-protector was suitable for their task. The following issues were identified with the remaining four eye-protectors:

- One had markings consistent with EN 207, but with no information provided. Without the manufacturer's information, the potential for misuse of the eye-protector is increased.
- One had markings consistent with EN 207, except that they were printed on a label that was easy to peel off (EN 207 states that: "The following shall be marked permanently on the filters or the frames for identification"). If the markings became detached, the user would have no way of knowing if the eye-protectors were suitable for their task. The majority of the information required by EN 207 was provided.
- Two had no markings and no information provided with them. If they are laser eye-protectors, they lack crucial information required by the user in order to use them safely. It is possible that they are not laser eye-protectors, but were mis-sold as laser eye-protectors.

Products sold as IPL eye-protectors:

Of the nine IPL eye-protectors purchased for this project, one had markings and information consistent with ISO 12609-1. Four had markings consistent with EN 166/EN 169, and the majority of the information required was provided. The missing information would not prevent users from identifying whether the eye-protector was suitable for their task. The following issues were identified with the remaining four eye-protectors:

- One had markings consistent with EN 166/EN 169, but the information provided was for laser eye-protectors, not for IPL eye-protectors. The performance characteristics and marking of laser eye-protectors and IPL eye-protectors are different, and some of the information provided was therefore incorrect (for example, the description of the markings).
- Two (from the same manufacturer) had markings on the oculars consistent with EN 166/EN 169, but no relevant markings on the frames (EN 166 requires markings to be present on both ocular and frame). The information provided was for laser eye-protectors, not for IPL eye-protectors.
- One referenced EN 166 in markings on the frame, but was not marked according to EN 166 on the ocular. There were no markings to identify the filtering capability of the eye-protector. Some information was provided, but this did not include anything about the capability of the eye-protector. There was insufficient information for a user to determine whether this eye-protector would be suitable for their task.

A copy of this report will be sent to each manufacturer/importer, with additional information on their own products. Where anomalies were identified that would make correct selection more

difficult, the relevant Trading Standards authority will receive the same information as the manufacturer/importer.

REFERENCES

British Standards Institution. (2008) BS 8497-1:2008 Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications. Specification for products. London: British Standards Institution.

Department of Health. (2013) Review of the regulation of cosmetic interventions.
<https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>
(Accessed 9th March 2017)

EEC. (1989) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment. Official Journal L 399, 30/12/1989, p18.

EEC. (2008) Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products. Official Journal L 218, 09/07/08, p30.

EEC. (2016) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. Official Journal L 81/51, 09/03/18.

European Committee for Standardization. (2001) EN 166:2001 Personal eye-protection – Specifications. Brussels: European Committee for Standardization.

European Committee for Standardization. (2002) EN 169:2002 Personal eye-protection – Filters for welding and related techniques – Transmittance requirements and recommended use. Brussels: European Committee for Standardization.

European Committee for Standardization. (2009) EN 207:2009 Personal eye-protection equipment – Filters and eye-protectors against laser radiation (laser eye-protectors). Brussels: European Committee for Standardization.

International Organisation for Standardization. (2013) ISO 12609-1:2013 Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications – Specification for products. Geneva: ISO.

Market surveillance of eye-protectors for lasers or intense pulsed light in the cosmetic industry

Lasers and intense pulsed light (IPL) sources are used for a variety of medical and cosmetic treatments. The light sources used, whether laser or IPL, are designed to cause damage to hair follicles and/or pigmented skin, and as such have the potential to cause damage elsewhere on the body. Eye protection is required for both the patient and the practitioner for many kinds of IPL and laser treatments. Eye protectors sold in the UK must comply with the current European market surveillance legislation, which is achieved by the equipment conforming to a relevant harmonised standard. These standards define essential markings and provision of information that advises the user of the filtering capability of the eye-protector.

This report describes market surveillance testing of nine laser eye protector and nine IPL eye protector models available on the UK market. The purpose of this study was to examine the marking and information provided to determine compliance with the requirements of the relevant standards. Only five models of each type had safety markings consistent with the standards. Two laser eye protectors had no markings and no accompanying safety information, whilst three IPL eye protector models had markings for laser eye protection which are different and therefore incorrect.

No testing was performed to verify the accuracy of the markings.

This report and the work it describes were funded by the Health and Safety Executive (HSE). Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect HSE policy.