

Optics and optical instruments — Contact lenses —

Part 1: Specification for rigid corneal and scleral contact lenses

The European Standard EN ISO 8321-1:1996 has the status of a
British Standard

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/78, upon which the following bodies were represented:

- Association for Consumer Research (ACRE)
- Association of British Dispensing Opticians
- Association of British Health-care Industries
- Association of Contact Lens Manufacturers
- British College of Optometrists
- British Contact Lens Association
- British Medical Association
- British Spectacle Frame Makers' Association
- British Universities Committee of Contact Lens Educators
- College of Ophthalmologists
- Consumer Policy Committee of BSI
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Federation of Manufacturing Opticians
- Federation of Ophthalmic and Dispensing Opticians
- Flat Glass Manufacturers' Association
- Optic (UK)

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National foreword

This British Standard was prepared by Technical Committee CH/78 (formerly HCC/78). It is the English language version of EN ISO 8321-1:1996 *Optics and optical instruments — Contact lenses — Part 1: Specification for rigid corneal and scleral contact lenses*, published by the European Committee for Standardization (CEN). Apart from Annex ZA, it is identical with BS EN ISO 8321-1:1997, published by the International Organization for Standardization (ISO). Prior to adoption by CEN, this British Standard was published as BS EN ISO 8321-1:1997, which, together with BS 7208-3:1992, superseded BS 7208-1:1989.

A previous specification for contact lenses, BS 5562, had been published in 1978 but was withdrawn in 1985 because rapidly evolving contact lens technology at that time had made it obsolete. In addition the measurement of certain lens properties had proved impractical.

The first edition of BS 7208-1 was developed as the result of improvements in methods of measurement and to provide requirements in accordance with current practice. The text of the 1989 edition was considered by ISO Technical Committee 172 in its preparation of BS EN ISO 8321-1:1997. Nevertheless ISO 8321-1 shows a number of differences from the 1989 edition of the British Standard. Those of significance are as follows.

- a) A method for presenting the prescription for contact lenses which, together with examples, is given in Annex A.
- b) For corneal lenses, the tolerances on back peripheral (zone) diameter have been doubled to ± 0.20 mm, tolerances on the back optic zone radii for toroidal surfaces have been introduced, and the tolerance on prescribed prism greater than 1.0Δ has been reduced to $\pm 0.25 \Delta$.
- c) Requirements for freedom from defects and freedom from strain have been included.
- d) The omission of a number of test procedures that had been appended to BS 7208-1:1989.

In order to rectify this latter omission and to provide access to test methods that are suitable for use with this specification, the missing details are included in BS 7208-3:1992.

The committee concerned in the preparation of this Part of BS 7208 was aware that the materials used for contact lenses have to be compatible with the tissues and fluids of the eye. At present there are no generally acknowledged criteria for assessing this compatibility although test methods are described in BS 5736. When such criteria become established, this Part of BS 7208 will be amended.

This Part of BS 7208 does not cover the fitting of lenses nor the quality assurance procedures to be used by the manufacturers. However, it is assumed in the drafting of this British Standard that it will be used and applied by those who are appropriately qualified and experienced.

It has not yet been possible to prepare a standard that includes requirements for soft lenses as the validity of techniques used for measuring soft lenses has to be established. However, the committee responsible for preparing BS 7208 is continuing to monitor the development of test methods for use with soft lenses and it intends, in due course, to prepare a further Part of this standard.

Other Parts of BS 7208 include:

- *Part 2: Method of classifying contact lens materials;*
- *Part 3: Methods of test for contact lenses;*

Cross-references

International standard	Corresponding British Standard
ISO 8320:1986	BS 3521 <i>Terms relating to ophthalmic optics and spectacle frames</i> Part 3:1988 <i>Glossary of terms and symbols relating to contact lenses</i> (Identical)

ISO 9340 and ISO 9341, to which reference is made in this standard, were still in preparation at the time of publication of this British Standard. The Technical Committee has reviewed the provisions of ISO/DIS 9340 and ISO/DIS 9341 and has decided that they are acceptable for use in conjunction with this standard.

Additional information. When considering compliance with item c) of clause 8 of this standard, manufacturers should be aware of BS 7208-2 which describes a method by which the lens material can be indicated.

Textual errors. When adopting the text of the international standard, the textual errors listed below were discovered. They have been marked in the text and have been reported to ISO in a proposal to amend the international standard.

In Table 1, the tolerance for the back optic zone radius for scleral lenses of “ $\pm 0,010$ mm” should read “ $\pm 0,10$ mm”.

In clause 8, item a) should read “a) details of the composition of the solution, if any, in which the lens is delivered;” and item b) should read “b) whether the lens is supplied sterile;”.

NOTE 1 In the heading for clause 7, the word “delivey” should read “delivery”.

NOTE 2 Information regarding product certification and/or registration as a firm of assessed capability is available from BSI. Enquiries regarding third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users of this standard should consider approaching an appropriate body from the list of Association members.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN ISO title page, pages 2 to 12, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

