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BS 661210:2018+A1:2022



BSI Standards Publication

Graduated compression hosiery, anti-embolism hosiery and graduated support hosiery — Specification



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Foreword

Publishing information

This British Standard is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 30 November 2018. It was prepared by Panel CH/205/1, *Medical textiles*, under the authority of Technical Committee CH/205, *Non-active medical devices*. A list of organizations represented on these committees can be obtained on request to the committee manager.

Supersession

This British Standard supersedes BS 661210:2018, which is withdrawn.

Information about this document

This British Standard is a merger of <u>BS 6612:1985</u>, <u>BS 7563:1999</u> and <u>BS 7672:1993</u> and introduces the following principal changes.

- It comprises separate sections specifying performance requirements for graduated compression hosiery (Section 2), anti-embolism hosiery (Section 3) and graduated support hosiery (Section 4).
- <u>Section 2</u> includes guidance detailing the use of graduated compression hosiery (flight socks) for people at moderate-high risk of developing travel-related deep vein thrombosis (DVT).
- Performance requirements have been updated to reflect current clinical guidance and a new annex added (Annex D) which explains the variety of classes and compression profiles used in the UK.
- Annex A specifies a unified method of test for compression value and stiffness of compression/ support hosiery using a Mark II HATRA Hosiery Pressure Tester, based on the three previously published methods.
- Annex B specifies a method for determining the heel position of non-prescriptive thigh length stockings and tights that do not possess a reciprocated heel.
- Annex C has been added to provide the rationale for the major changes made as part of the revision.
- Annex D has been included to provide information on various pressure classes referenced in national and industry standards and clinical guidance documents.

Compliance with this British Standard cannot be used to claim compliance with other national standards (e.g. AFNOR G 30.102, DIN 58133) as these have different test methods and performance requirements.

Text introduced or altered by Amendment No. 1 is indicated in the text by tags (A). Minor editorial changes are not tagged.

Amendment A1 resolves an anomaly identified post publication in BS 661210:2018, where current post-washing requirements have the effect of potentially failing hosiery, which would still exert a satisfactory compression profile in compliance with <u>Clause 5</u>, <u>Clause 9</u> and <u>Clause 14</u> after washing. This was an unnecessary restriction on manufacturers and had no clinical benefit for users and patients. This amendment resolves that issue. This change is also applicable for the other types of hosiery in BS 661210 namely graduated compression and graduated support hosiery.

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WARNING. This British Standard calls for the use of substances and/or procedures that can be injurious to health if adequate precautions are not taken. It refers only to technical suitability and does not absolve the user from legal obligations relating to health and safety at any stage.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

Requirements in this standard are drafted in accordance with the Rules for the structure and drafting of UK standards:2017, subclause G.1.1, which states, "Requirements should be expressed using wording such as: 'When tested as described in Annex A, the product shall ...'". This means that only those products that are capable of passing the specified test will be deemed to conform to this standard.

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Section 1: General

1 Scope

This British Standard specifies requirements and test methods for the compression and stiffness of graduated compression hosiery, anti-embolism hosiery and graduated support hosiery.

The test method in Annex A might also be suitable for assessing the compression of dual layer compression kits (e.g. ulcer kits) and other tubular compression devices, e.g. arm sleeves. There are some garments for which this test method is not suitable, and where the former settings of the test instrument might not accommodate all potential designs, especially some made to measure garments.

Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN ISO 139, Textiles - Standard atmospheres for conditioning and testing

BS EN ISO 6330, Textiles - Domestic washing and drying procedures for textile testing

Terms and definitions

For the purposes of this British Standard, the following terms and definitions apply.

3.1 anti-embolism hosiery

hosiery which, when worn on the supine leg, exerts graduated compression on the leg surface and is intended to reduce the incidence of deep venous thrombosis in non-ambulant patients

3.2 compression profile

pressure exerted by the hosiery along the leg it is intended to fit

3.3 defined heel

coloured area, or a reciprocated heel (pouch formed within the knit of the garment) defining the heel area

Some graduated support hosiery might not have a defined heel, and for these garments the heel position can be located in accordance with Annex B.

3.4 graduated compression hosiery

hosiery which, when worn on the leg, exerts compression on the leg surface which reduces progressively towards the upper leg

3.5 graduated support hosiery

hosiery which, when worn on the leg, exerts support pressure on the leg surfaces, for sub-clinical indications such as relief of aching legs, which reduces progressively towards the upper leg