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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This British Standard supersedes BS 661210:2018, which is withdrawn.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 [BS 6612:1985](#), [BS 7563:1999](#) and [BS 7672:1993](#) 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](#)).
- [Section 2](#) 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  . 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 [Clause 5](#), [Clause 9](#) and [Clause 14](#) 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.

Hazard warnings

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.

NOTE 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.

2 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*

3 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

NOTE 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

3.6 hip girth

horizontal girth of a human body measured round the buttocks at the level of maximum circumference

[SOURCE: BS EN 13402-1:2001, 3.11]

NOTE See [Annex A, Figure A.6](#).

3.7 negative pressure gradient

higher pressures at proximal region (the end of the garment closest to the groin) compared to distal region (the end of the garment furthest away from the groin), i.e., higher pressure at calf compared to ankle

3.8 nominal compression value/range

nominal compression figure or range in whole numbers of millimetres of mercury (mmHg) characterizing the compression performance of a garment at the ankle

NOTE This is assigned by the manufacturer on the basis of measurements of similar garments and is equal to the compression which the garment is intended to exert at the ankle when worn on a leg of a size designated by the manufacturer.

3.9 measuring positions

3.9.1 ankle girth

horizontal girth of a human leg just above the medial malleolus, if possible, measured with the subject standing and with the weight of the body equally distributed between both feet

NOTE See [Annex A, Figure A.5](#).

3.9.2 calf girth

girth of a human calf measured at its maximum circumference, the upper edge of the tape measure passing horizontally through the point of maximum circumference, if possible, measured with the subject standing with the weight of the body equally distributed on both feet

NOTE See [Annex A, Figure A.5](#).

3.9.3 normal position

positions at the ankle, calf and thigh of a garment at which compression is to be measured

NOTE 1 Additional measuring positions could also be defined by the manufacturer.

NOTE 2 Testing of designated sizes is achieved by use of the HATRA test equipment, which simulates human leg dimensions. Details of the corresponding girths and the set-up procedure are given in [Annex A, Table A.1](#) and [Table A.2](#).

3.9.4 thigh girth

horizontal girth of a human leg measured three quarters of the length up the leg between the knee joint and the crotch, if possible, measured with the subject standing with the weight of the body equally distributed on both feet

NOTE See [Annex A, Figure A.5](#).

3.10 sample set

comprises 15 individual garments

3.11 stiffness

measure of the change in the compression exerted by a garment when the girth is increased or decreased from that designated by the manufacturer by an amount equivalent to a change in the size of the adjustable former of the compression testing machine by one position

NOTE See [Annex A](#).

3.12 welt

area at the stocking top used to retain the position of the hosiery on the leg

NOTE The welt of the stocking should be designed to ensure that the compression exerted by the welt does not exceed that exerted by the adjacent section of the garment.

Section 2: Graduated compression hosiery

COMMENTARY ON SECTION 2

Graduated compression hosiery are designed to exert compression on the legs while standing or walking. They include pantyhose, thigh length garments and knee length garments which have a defined heel for men and women.

All garments are expected to produce a graduation of pressure on the leg which decreases from the distal to the proximal region. The compression measured at the ankle measurement position is used to designate graduated compression hosiery. The degree of compression required depends on the clinical condition and examples taken from the Drug Tariff [1] include:

- *Class I Light (Mild) compression (ankle pressure 14 mmHg – 17 mmHg) to treat indications such as superficial or early varices, varicosis during pregnancy;*
- *Class II Medium (Moderate) compression (ankle pressure 18 mmHg – 24 mmHg) to treat indications such as varices of medium severity, ulcer treatment and prevention of recurrence, mild oedema, varicosis during pregnancy; and*
- *Class III Strong compression (ankle pressure 25 mmHg – 35 mmHg) to treat indications such as gross varices, post-thrombotic venous insufficiency, gross oedema, ulcer treatment and prevention of recurrence.*

Based on expert opinion, graduated compression hosiery (e.g. flight socks) are also recommended by NICE for people assessed as having relatively moderate or high risk of developing travel-related deep vein thrombosis (DVT) [2]. NICE advises that the use of below-knee graduated compression stockings with a compression level of 14-17 mmHg at the ankle (such as that exerted by Class 1 stockings) are generally sufficient, however, for some people, a higher compression range could be indicated to manage other conditions.

The intention of this British Standard is to provide a method to measure the pressure exerted by graduated compression garments. This information can then be used by manufacturers to provide evidence of compression values to enable prescribers/users to choose the appropriate garment to treat particular clinical conditions. Information regarding ankle pressure values and associated compression classes referenced in national and industry standards, UK prescribing specifications and other relevant guidance documents are presented in [Annex D](#).

Requirements are specified for compression, compression profile, durability of compression under repeated washing, stiffness, marking and labelling. The method of test for determining the compression exerted by hosiery is given in [Annex A](#).

4 Compression value/range

The manufacturer shall assign a nominal compression value or range in whole numbers of millimetres of mercury (mmHg) to each garment on the basis of compression measurements on the sample set of garments.

The compression value shall be determined from the compression class, range or value specified by the manufacturer or from the published specification the garment is to be assessed against.

NOTE See [Annex D](#) for further information.

For testing purposes, if a manufacturer states a range rather than an individual compression value, the mid-point of the range (to one decimal place) shall be used to determine compliance to the nominal compression value, see [Table 1](#).

5 Compression profile

When a sample set of garments is tested in accordance with [Annex A](#), the mean compression profile shall conform to [Table 1](#).

Table 1 — Compression profile

Compression class / value mmHg	Proportion of ankle compression at calf %	Proportion of calf compression at thigh %
Compression value $\pm 20\%$	50–85 max.	50–85 max.

Individual stockings shall not exhibit a negative pressure gradient at any measurement position.

NOTE The welt of the stocking should be designed to ensure that the compression exerted by the welt does not exceed that exerted by the adjacent section of the garment.

6 Durability of compression after repeated washing

COMMENTARY ON CLAUSE 6

The durability of compression after repeat washing is designed to assess the compression exerted by the garment following a series of washing cycles, i.e. the pressures produced by a garment should remain unaffected by washing provided that it is performed in accordance with the manufacturer's instructions.

If the manufacturer specifies a maximum number of washes, the sample set of garments shall be washed to this number of cycles and tested. If this information is not available, the garments shall be washed 30 times then tested. Domestic washing machine and washing powders can be used, however the washing cycle shall be validated (e.g. spin speed, washing temperature) and be in accordance with the washing cycles in BS EN ISO 6330. In cases of dispute, garments shall be washed using the machine, washing cycle and detergent in accordance with BS EN ISO 6330 as the reference method.

After completing the required number of washes using a washing cycle that emulates an appropriate 40 °C wash procedure in accordance with BS EN ISO 6330 (or at a temperature as stated in the manufacturer's instructions), and after drying in accordance with the manufacturer's instructions, on retesting the sample set of garments in accordance with [Annex A](#), [A1](#) the mean pressures shall meet all of the requirements of Clause 5 (Compression profile). [A1](#)

If drying instructions are not supplied by the manufacturer, garments shall be line, drip or flat dried in accordance with BS EN ISO 6330.

7 Stiffness of elastic garments

COMMENTARY ON CLAUSE 7

The stiffness test assesses the possible change in pressures exerted by compression garments when applied to limbs smaller or larger than the nominal size.

Some garments are designed to have high elasticity with low stiffness properties and apply similar levels of compression when tested at a defined larger and smaller patient limb sizes. The requirement for low stiffness high elasticity in these garments is due to the requirement that they exert similar pressures if

the limb changes in size, or a measurement error has been made. The stiffness of these garments can be measured in accordance with [Annex A, A.5](#).

It is recognized that there are a number of low elasticity garments that require high stiffness, specifically requiring that the compression level increases significantly when the diameter of the leg increases. High stiffness low elasticity garments (e.g. flat knit garments) are intended to provide high compression when the wearer walks, e.g. to give resistance for the calf muscle and foot venous pumps, and are used to treat clinical conditions such as limb shape distortion, chronic oedema and lymphoedema. They are designed to be stiffer than traditional circular knit elastic garments. The test method given in [Annex A, A.5](#) can be used to measure stiffness of garments intended for chronic oedema, however, this British Standard does not stipulate stiffness performance requirements for such garments.

When tested in accordance with [Annex A, A.5](#), the mean compression of the sample set of elastic garments at each measuring position, obtained on formers one size smaller and one size larger than the size appropriate to the claim on the label, shall lie within $\pm 25\%$ of the mean obtained when the measurements are taken on the sample set with the former set to the size appropriate for the garment.

8 Marking and labelling

8.1 The garment or label shall be marked with, or shall bear a label giving, as a minimum, the following information:

- a) manufacturer's or distributor's name or logo;
- b) size of garment (or alternative sizing indicator, e.g. colour code); and
- c) symbol(s) denoting the relevant washing and care instructions.

8.2 The package or a leaflet contained within the package shall contain, as a minimum, the following information, with the exception of made to measure garments which do not need to conform to 4) to 8) as this is to be detailed in the supporting documents used for orders:

- 1) manufacturer's or distributor's name;
 - 2) size of garment;
 - 3) nominal compression value or range;
 - 4) leg length range in centimetres;
- NOTE 1 If the leg length is not stated on the packaging, the manufacture needs to provide this on request.*
- 5) ankle girth range in centimetres;
 - 6) calf girth range in centimetres;
 - 7) thigh girth range in centimetres;
 - 8) for pantyhose, the hip girth range in centimetres;
 - 9) garment fibre content information which should comply with the relevant labelling laws for the country it is sold in;

NOTE 2 Attention is drawn to REGULATION (EU) No 1007/2011 [3] for textile fibre names and related labelling and marking of the fibre composition of textile products for sales within the European Union.

- 10) instructions for fitting and use; and
- 11) washing and care instructions including any contraindications, e.g. "Do not tumble dry".