DRAFT FOR DEVELOPMENT

DD ENV 12719:2001

Medical thrombosis prophylaxis hosiery

医用血栓予防靴下

ICS 11.120.20

National foreword

This Draft for Development is the English language version of ENV 12719:2001.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature because it is believed that the requirements and recommendations of this DD ENV will be valuable to industry and the user, in particular to allow acquisition of experience of the compression class and the use of the method for measuring compression. This experience will be taken into account when reviewing this DD ENV, together with any aspects of durability testing gained from the review of DD ENV 12718. DD ENV 12719 should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion into a European Standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its three-year life. The commencement of the review period will be notified by an announcement in *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the prestandard or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee CH/39, Compression hosiery and elastic hose supports, at 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this committee can be obtained on request to its secretary.

Attention is drawn to DD ENV 12718 *Medical compression hosiery* and the following related British Standards: BS 6612:1985 *Specification for graduated compression hosiery*, BS 7563:1999 *Specification for non-prescriptive graduated support hosiery* and BS 7672:1993 *Specification for compression, stiffness and labelling of anti-embolism hosiery*.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

This Draft for Development, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 11 September 2001

Summary of pages

This document comprises a front cover, an inside front cover, the ENV title page, pages 2 to 36, an inside back cover and a back cover.

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EUROPEAN PRESTANDARD
PRÉNORME EUROPÉENNE
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ENV 12719

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ICS 11.120.20

English version

Medical thrombosis prophylaxis hosiery

Bas médicaux prophylaxiques anti-thromboses

Medizinische prophylaxische Antithrombosestrümpfe

This European Prestandard (ENV) was approved by CEN on 18 June 2001 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This European Prestandard has been prepared by Technical Committee TC 205 'Non-active medical devices' the secretariat of which is held by BSI.

This European Prestandard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this prestandard.

Annexes A, B and C are normative and form part of this European Prestandard. Annexes D and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

An important property of hosiery is its durability, i.e. the retention of its designated compression during its lifetime. Hitherto the durability of hosiery has been achieved by the choice of the materials of construction and the methods by which hosiery has been manufactured.

1 Scope

This European Prestandard applies to medical thrombosis prophylaxis hosiery, knitted from threads made of natural fibres or synthetic fibres and elastic threads, which is used as a medical device for prophylaxis of venous thrombosis. The prestandard specifies requirements and test methods, except for custom-made hosiery.

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN 20139:1992, *Textiles — Standard atmospheres for conditioning and testing (ISO 139:1973).*

EN 26330:1993, *Textiles — Domestic washing and drying procedures for textile testing (ISO 6330:1984).*

EN 60456:1999, *Clothes washing machines for household use — Methods for measuring the performance (IEC 60456:1998, modified.)*

ISO 376, *Metallic materials — Calibration of force proving instruments used for the verification of uniaxial testing machines.*

3 Terms and definitions

For the purposes of this Prestandard, the following terms and definitions apply:

3.1
compression
pressure exerted on the leg by the hosiery

3.2
durability
ability of the hosiery to retain its designated compression properties

3.3
elastic material
material which increases its dimension under the action of an applied force and returns to almost its original form when the force is removed

3.4
extensibility
maximum degree, expressed as a percentage of the unloaded size of the hosiery, in which the hosiery can be stretched in the circumferential or in the longitudinal direction under the test procedure specified in this European Prestandard

3.5
practical elongation
elongation of hosiery in the circumferential direction with the hosiery on the leg, expressed as a percentage of the unloaded circumference of the hosiery

3.6
pressure profile
representation of the compression exerted by the hosiery along the leg

3.7
residual pressure
compression at a certain point expressed as a percentage of the compression at the ankle

3.8
standard size hosiery
hosiery manufactured in the types and sizes specified in this European Prestandard

3.9
tolerance of standard size hosiery
limits of the girth and length of the leg between which the standard size hosiery is intended to be used

3.10
medical thrombosis prophylaxis hosiery
hosiery which when worn on the leg exerts graduated compression on the leg surface and is principally intended to reduce the incidence of venous thrombosis in non-ambulant patients

NOTE Abbreviated in this prestandard to 'hosiery'.

4 Compression

The compression of the hosiery at the ankle shall be between 13 mmHg and 18 mmHg (respectively 17,5 hPa and 24 hPa). The compression at the ankle shall have a tolerance not exceeding ± 3 mmHg (4,0 hPa). The compression shall be measured in accordance with annex B.

5 Nominal dimensions and standard sizes

5.1 General

Hosiery size shall be designated by the lengths and girths on the human leg at the measuring points given in Table 1 and Figure 1.

5.2 Measurement of length

If measured, length shall be measured and codes allocated in accordance with Table 2.

5.3 Measurement of girth

If measured, girths shall be measured and codes allocated in accordance with Table 3.

5.4 Sizes

NOTE In order to facilitate the use of hosiery and to give a unique basis for the test methods specified in this European Prestandard, this system of sizes is based on the ankle girth (cB).

5.4.1 Length

Length and range of lengths shall be chosen from Table 4.

5.4.2 Girth

Girths and range of girths shall be chosen from Table 5.

5.5 Designation of type and size of hosiery

5.5.1 Hosiery shall be designated by the type code according to Table 6 followed by three pairs of numbers indicating the dimensions of the legs that the hosiery is intended to fit as follows:

— the range of girth at the ankle according to Table 5;

— the range of girth at the upper end of the hosiery according to Table 5;

— the range of length according to Table 4.

Where values for intermediate measuring points fall in the same vertical column of Table 5 or on the straight lines drawn from the smallest and widest ankle dimension to the smallest and widest girth dimension at the upper end of the hosiery, no further information is required.

If values of intermediate measuring points don't fall on the straight lines, then a diagrammatic representation of the range of leg sizes that the hosiery is intended to fit shall be supplied either on the package, or in a leaflet in that package. The same applies in the figurative sense to the dimensions of the length given in Table 4.

NOTE 1 An example of type and size designation is AD 22-24 (34-36/41-45)

where

AD is the code for below-knee hosiery;

22-24 is the range of girth at the ankle (22 cm to 24 cm);

34-36 is the range of girth at the upper end of the hosiery (34 cm to 36 cm);

41-45 is the range of length (lD) (41 cm to 45 cm).

For the measuring points between the ankle and the upper end of the hosiery according to Figure 1 the range of girths shall be marked according to clause 13.

NOTE 2 A further example of type and size designation is AG 22-24 (52-64/70-75)

where

AG is the code for thigh hosiery;

22-24 is the range of girth at the ankle (22 cm to 24 cm);

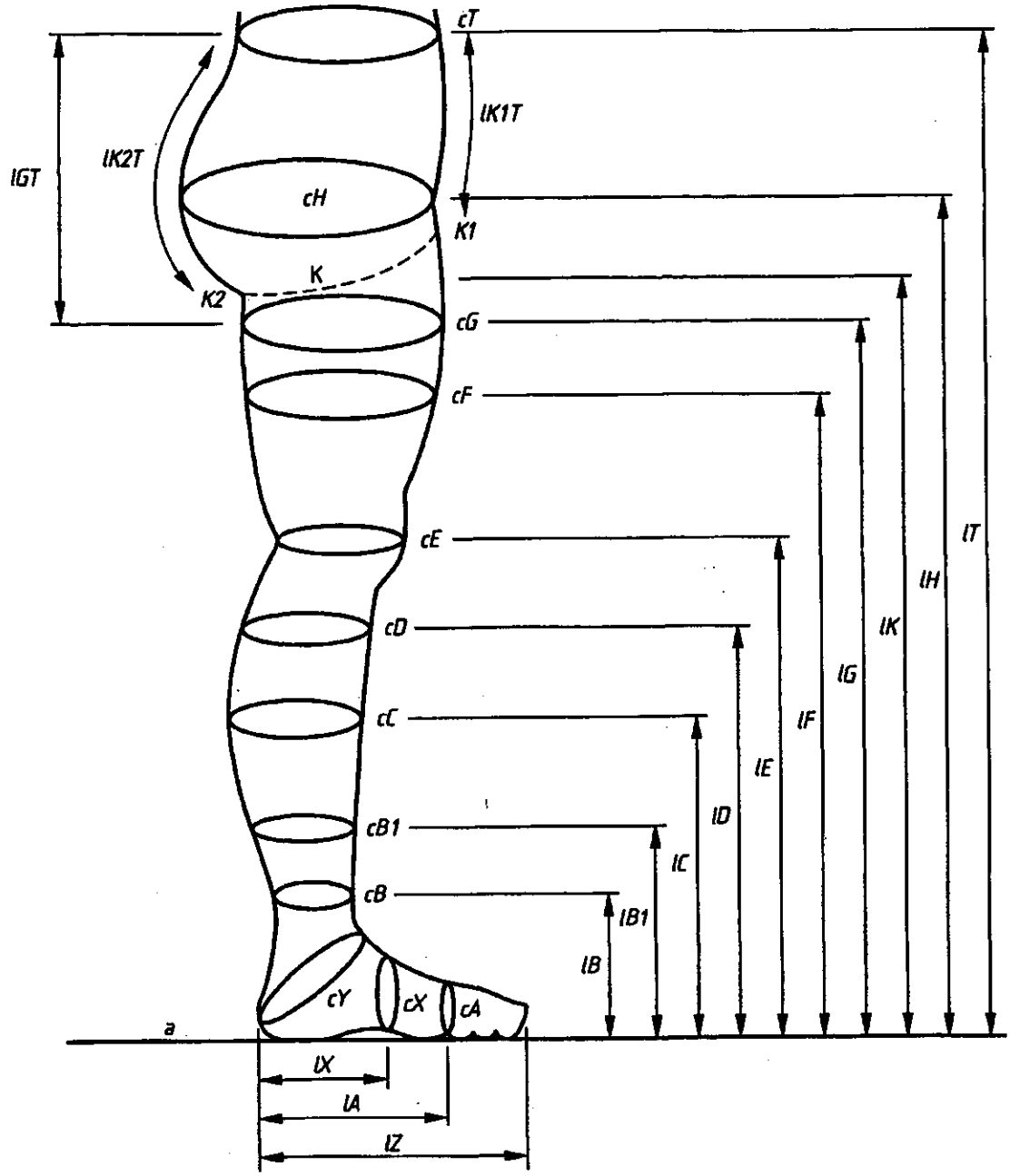
52-64 is the range of girth at the upper end of the hosiery (52 cm to 64 cm)

70-75 is the range of length (lG) (70 cm to 75 cm)

5.5.2 Alternatively a type code specified by the manufacturer shall be available on the hosiery. For this type code the range of dimensions of the leg that the hosiery is intended to fit shall be indicated on the package or leaflet, at least for the measurement points B,C and the upper end (D or G) and the length.

5.5.3 Hosiery intended for multi-patient use shall be optically size and type coded. The coding shall be wash-resistant (see annex A). The optical size and type code shall be easily identified.

NOTE The coding should be explained in or on the package (see 13.2).



NOTE Measurements should be preferably taken at the leg of the recumbent patient.

Figure 1 — Measuring points, lengths and girths on the human leg (see Table 1)

Table 1 — Nominal measuring points

Measuring point	Description of the measuring point
a	sole of the foot at the heel
B	ankle at the point of its minimum girth
B1	point at which the Achilles tendon changes into the calf muscles
C	calf at its maximum girth
D	just below the tibial tuberosity
E	centre of the patella and over the back of the knee
F	between *K* and *E*
G	5 cm below *K* with the patient in the upright position

Table 2 — Nominal measurement of length

Length code	Length of the leg
lB	distance measured from *a* to *B*
lBl	distance measured from *a* to *Bl*
lC	distance measured from *a* to *C*
lD	distance measured from *a* to *D*
lE	distance measured from *a* to *E*
lF	distance measured from *a* to *F*
lG	distance measured from *a* to *G*

Table 3 — Nominal measurement of girth

Girth code [a]	Girth of the leg
cB	girth measured at B
cB1	girth measured at B1
cC	girth measured at C
cD	girth measured at D
cE	girth measured at E
cF	girth measured at F
cG	girth measured at G
[a] c = girth.	

Table 4 — Nominal leg lengths for standard size hosiery

Length code	Length cm						
	short hosiery		normal hosiery			long hosiery	
IG	65	68	71	74	77	80	83
IF	54	57	59	62	64	67	69
IE	41	43	45	47	49	51	53
ID	35	37	38	40	41	43	44
IC	27	29	30	32	33	35	36
IB1	19	20	21	22	23	24	25
IB	10	11	11	12	12	13	13

Table 5 — Nominal leg girths

Size of hosiery																										
Girth code	Slender supplement					18	19	20	21	22	23	24	25	26	27	28	29	30	Sturdy supplement							
Circumferences in cm																										
cG	43	45	46	48	49	51	52	54	55	57	58	60	61	63	64	66	67	69	70	72	73	74	76	77	79	80
cF	35	37	38	40	41	43	44	46	47	49	50	52	53	55	56	58	59	60	61	62	63	65	66	68	69	71
cE	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	---
cD	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	49	---	---
cC	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	---	---	---
cB_1	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	---	---	---	---
cB	---	---	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	---	---	---	---	

Table 6 — Designation of types of hosiery

Type of hosiery	Code
Below-knee hosiery	AD
Thigh hosiery	AG

6 Heel

Hosiery shall have a closed and knitted heel with the appropriate anatomic form. Testing shall be carried out by visual inspection.

7 Inspection facility

The hosiery should be designed so that the patient's local circulation can be easily checked.

8 Seams

Seams shall be smooth on the inside of the hosiery.

NOTE Seams can be overlocked.

Testing shall be carried out by visual inspection.

9 Edges

Edges shall be non-fray.

Testing shall be carried out by visual inspection.

10 Achievement of compression profile

The compression profile shall be achieved by knitting and not by shaping or forming.

NOTE There can be boarding for presentation.

11 Mechanical properties

11.1 Extensibility

Hosiery shall be capable of being stretched at least 120 % in the circumferential direction at the measuring points B, B1, C, D, E and G where appropriate. The stretch capability in the longitudinal direction shall be at least 30 % at the measuring points B, B1, C, D, E and G, where appropriate.

Testing shall be carried out in accordance with annex C.

11.2 Practical elongation

The practical elongation shall be not less than 15 % at the measuring points B, B1, C, D, E and G.

Testing shall be carried out in accordance with annex B.

11.3 Residual pressure

In order to avoid irregularities of the pressure profile along the leg, the residual pressure shall be measured at measuring points B, B1, C, D, E and G, where applicable.

The residual pressure of the hosiery at measuring points C and G, where applicable, shall lie within the range given in Table 7.

The residual pressure shall at no measuring point along the leg, except E, be of a higher value than the residual pressure at the measuring point situated distally.

NOTE The residual pressure can be lower at the E-level, than that which follows from the interpolation of the values D and G.

The pressure profile along the leg shall conform to the values given in Table 7.

Testing shall be carried out in accordance with annex B.

Table 7 — Ranges of pressure profiles

% of compression exerted at ankle		
at B1	at C	at G
80 to 100	60 to 80	30 to 70

11.4 Durability of compression

Hosiery shall maintain its specified properties after washing. The testing shall be in accordance with annex A.

12 Packaging

Hosiery shall be packaged so that exposure of the hosiery to light is minimized.

13 Marking and instructions for use

The information supplied by the manufacturer shall comply with EN 980 and EN 1041.

Specification for ranges of length and girth, which differ, according to 5.5, from Table 4 and 5, shall be made available for the supplier/distributor in a suitable form.

13.1 Marking of hosiery

Hosiery shall be durably marked at least with the following information:

a) name or trade name of the manufacturer or authorized representative or importer within EEA;

b) name of the product;

c) fibre content (unless marked on the package);

d) type and size designation as specified in 5.5.1 and/or 5.5.2.

13.2 Marking of the package

The package shall be marked at least with the following information:

a) name and address of the manufacturer or authorized representative or importer within EEA;

b) name of the product;

c) country of origin if manufactured outside the European Economic Community;

d) fibre content (unless marked on the hosiery);

e) compression according to clause 4;

f) type and size designation as specified in 5.5.1 and/or 5.5.2.

NOTE A diagrammatic representation of the range of leg sizes that the hosiery is intended to fit can also be given.

13.3 Instructions for usage and handling

The package or a leaflet with the hosiery shall contain at least the following information:

a) instructions for washing and drying;

b) instructions for use and warnings about misuse (e.g. pulling too hard, folding the upper part onwards);

c) contra-indications

NOTE A diagrammatic representation of the range of leg sizes that the hosiery is intended to fit can also be given.

Annex A
(normative)

Method for testing the durability

A.1 Principle

Measurement of compression properties after repeated washing and drying.

A.2 Apparatus

A.2.1 Washing machine according to EN 26330:1993, clause 3.1, type A.1.

A.2.2 Tumble dryer according to EN 26330:1993, clause 3.2.

A.3 Detergent

Detergent A according EN 60456:1999, clause 7.4.2, Table 2, consisting of basic powder, sodium perborate tetrahydrate (bleach) and tetraacetylenediamine (bleach activator).

A.4 Washing procedure

Wash at least two samples of each size and length according to EN 26330:1993, procedure 1A, g of detergent A (A.3), following each washing procedure by a drying process according to procedure E at a temperature of approximately 70 °C.

A.5 Measurement

Measure the compression and mechanical properties of the hosiery in accordance with B.3.3 to B.3.5. Carry out the washing procedure 10 times in accordance with A4. Retest the compression and mechanical properties of the hosiery. The hosiery shall conform to the requirements specified in clauses 4, 11.1, 11.2 and 11.3.

Annex B
(normative)

Method for testing compressive properties of hosiery

B.1 Principle

Measurement of the force exerted by hosiery across its width when it is stretched simultaneously both sideways and lengthways according to its size designation. The measured force is transformed into pressure using the Laplace formula.

Other measuring devices (e.g. those listed in annex D) can be used provided that the results obtained correlate to those obtained from the device used in this reference method with an accuracy of ± 10 %.

Compressive properties are determined by measuring the circumferential force at certain positions necessary to stretch the hosiery specimen to the extent according to its size designation.

B.2 General conditions

B.2.1 Identification of hosiery

Identify the hosiery in accordance with the requirements of this prestandard and permanently mark it for future identification.

B.2.2 Number of test samples

For each size and length of standard hosiery to be tested, test at least two specimens. For custom made hosiery test one specimen.

B.2.3 Measuring positions

Measure compression at the measuring positions specified in 10.3.

B.2.4 Measurement of compression at minimum and maximum sizes

If the manufacturer states a range of girths and/or lengths, take compression measurements at both minimum and maximum girths for each measuring position, and/or both the minimum and maximum lengths.

If the difference between minimum and maximum girths indicated by the manufacturer does not exceed 10 % (based on the minimum girth) for each applicable measuring position, compression measurements are determined at minimum girths only.

If the difference between minimum and maximum lengths indicated by the manufacturer does not exceed 15 % (based on the minimum length), compression measurements are determined only at the mean of the minimum and maximum values, rounded down to whole numbers.

B.2.5 Stiffness

If stiffness is to be determined, take force (pressure) measurements on the hosiery at reference point B for girths that are 1 cm smaller and 1 cm larger than the ankle girth stated by the manufacturer. Always measure the smallest girth first.

B.3 Apparatus

B.3.1 Washing machine, conforming to EN 26330:1993.

B.3.2 Device for marking of measuring positions

The device shall comprise a marking-board (see Figure B.1), on which an adjustable clamp is mounted that is capable of fixing the lower end of the hosiery with either one of two different systems as follows:

a) for circular knitted specimens, a system of clamps or needles shall be used (see Figure B.2a);

b) for flat knitted specimens, a foot frame (see Figure B.2b) made from a round metal bar of approximately 6 mm diameter shall be used.

B.3.3 Metre rule, graduated in millimetres.

B.3.4 Coloured felt tipped pen.

B.3.5 Gripping device, in accordance with Figures B.4 and B.5, with:

a) a distorting parallelogram to prevent necking, as in Figure B.4.

b) a set of stretcher bars to prevent necking, as in Figure B.5.

NOTE Referring to Figure B.5, the hosiery is stretched across its width by the use of rods with embedded needles. The rods are positioned inside the hosiery and the needles pushed through the fabric at marked positions. Clamps attached to a tensile tensometer are used to grip the needles in order to stretch the hosiery at the given measuring position.

Three rods are used to hold one side of the specimen. Their needles are gripped to hold the rods in a straight line, with the outer needles held rigidly to the traverse beam, and the middle needle held to the load cell of the tester.

The middle rod is separated from the outer rods, so that it is free to give an accurate measure of the force in the middle part of the stretched fabric. The forces on the outer rods, are transmitted directly to the traverse beam. Thus the end effects that occur at the outer ends of these rods, due to the distortion of the fabric at these points, do not affect the measurement accuracy.

In order to ensure that the three rods are aligned for the test, they can be held in a close fitting sleeve before positioning inside the specimen. Then the sleeve is immediately removed. These rods are to be held in position on the machine.

The other side of the hosiery is held by a single rod, with two needles. The unit gripping these needles can pivot on its attachment to the base of the tester, which allows for measurements on tapered areas of a hosiery.

All the rods are 6 mm in diameter.

Each of the upper rods are 30 mm in length. During measurement they shall not touch. The lower rod is equal in length to the total length of the three upper rods.

The fabric at each side of the measurement position is impaled upon vertical rows of pins, in order to keep the area of measurement stretched along the hosiery length, and avoid necking. The pins can be part of parallelograms which expand vertically with the fabric, as shown in Figure B.4, or they can be attached to each end of the "stretcher" bars, as shown in Figure B.5.

The vertical spacing of the pins should be such that, at maximum stretch, there is not more than 20 mm between adjacent pins.

B.3.6 A tensile tensometer, with a constant traverse facility.

B.3.7 Devices for force measurement, calibrated in accordance with ISO 376.

B.4 Test procedure

B.4.1 Washing

Before testing, wash the hosiery once according to EN 26330:1993/6A, followed by hydroextraction for not more than 2 min and a flat drying process according to mode C of EN 26330:1993.

Ensure that the hosiery gains weight during the ensuing conditioning.

B.4.2 Conditioning

Condition the hosiery for at least 12 h immediately prior to testing, and carry out measurements in an atmosphere according to 2.2.1 of EN 20139:1992.

B.4.3 Definition and marking of the measuring points

B.4.3.1 Place the leg of the hosiery onto the marking and measuring device to enable the marking of the measuring points and fix the hosiery to the ground clamp as follows:

a) Circular knitted hosiery

Fix the lower end (the first course above the heel surrounding the hosiery) of the stocking in the fixing device of the marking board and adjust the movable clamp so that the lower end is positioned at 45 mm on the graduated scale (this fixing position is to take account of the height of the heel from the sole of the foot).

b) Flat knitted hosiery

With the foot frame inside the foot, fix the hosiery in the ground clamp. Set the lowest position of the heel on a position of -2,5 cm below the zero point of the scale.

B.4.3.2 Stretch the hosiery lengthways so that the upper end of hosiery (AD, AG) resp. compressive knit (AF, ATG, AT hosiery) is stretched up to its specified length, and fix the upper end by pins or an appropriate clamp.

To be able to measure compression by means of the reference method, at either the upper end of the garment or the compressive knit, the stated length at this point has to be lowered by 15 mm in order for the middle rod to be fully covered by the material to be tested. With hosiery bearing a less or non-compressive section above the uppermost measuring point, measurement is determined with the middle rod covered by the elastic knit, the end of the rod being near the change in construction.

With hosiery having an adhesive welt, two measurements are performed: One with the middle rod covered by the welt, and another one with the middle rod covered by the elastic knit below. Each time one end of the middle rod is positioned near the change from the elastic knit to the welt.

B.4.3.3 At each measurement position, mark the following measurement points on the centre line of the hosiery leg with a felt pen, using the graduated scale or the reference lines on the device. (see diagram B.3 which illustrates the points marked on the centre line for each measuring position).

a) The centre of the measurement position.

b) Two equi-spaced points, at the spacing of the needle clamps which hold the outer needle rods in the gripping device.

c) Two equi-spaced points, at the spacing of the stretcher pins.

Follow the courses from the marked positions, to mark the three upper and two lower needle insertion points, and to mark the lines for the stretcher pins.

B.4.4 Unstretched girth (C_{min})

Measure the lay flat width W (cm) at each measuring position with the stocking laying flat without preload and multiply by 2 to obtain the girth.

B.4.5 Calculation of minimum and maximum rod distances

a) Calculate the minimum distance between the rods in position as follows:

$$L_{min} = \frac{unstretched\ girth - 3{,}0^{1)}\,cm)}{2}$$

b) Calculate the maximum distance between the rods in position as follows

$$L_{max} = \frac{unstretched\ girth - 3{,}0^{1)}\,cm)}{2}$$

c) $$L_{min} = \frac{C_{min} - C_0}{2} = \frac{(2W - 3)}{2}$$

and

d) $$L_{max} = \frac{C_{max} - C_0}{2} = \frac{(G - 3)}{2}$$

Cycling extension

$$\Delta L = L_{max} - L_{min} = \frac{(G - 2W)}{2}$$

[1)] NOTE

See Figure B.7 for meaning of these symbols:

C_0 (zero setting girth) = $2d + \pi d$ = 3,05 cm rounded value = 3,0 cm

C_{min} (flat hose girth) = $2W$ where W (flat width) is in centimetres

C_{max} (hose girth at practical elongation) = G where G is the girth from size table or indicated in centimetres

B.4.6 Zeroing of test apparatus prior to testing

B.4.6.1 Zero the force with the upper rods clamped in position (without test sample).

B.4.6.2 Zero the distance between the rods with upper and lower rods clamped in position. Consider the zero position to be when the rods are just touching (see Figure B.7)

B.4.7 Positioning of test sample

Position the rods to the calculated minimum distance L_{min}.

Remove the rods from the clamps and introduce them inside the hosiery and position the test sample onto the tensile tensometer.

To make up the correct stretch length direction either:

a) press the fabric onto the parallelogram pins along the marked lines across the hosiery, or;

b) press the pins of the spacer bars onto the fabric along the marked lines across the hosiery, at intervals of the needles of approximately 10 mm.

The spacer bars have to be used where the top of the hosiery cannot be fixed to the parallelogram pins (D, F, G).

B.4.8 Tensile testing

Carry out the tensile test, stretching the test specimen continuously with a traverse rate of 200 mm/min five times, from the minimum distance L_{min} to the maximum distance L_{max} and return. Continue with a sixth extension to L_{max} and immediately record the force in cN when reaching L_{max}.

B.5 Calculation and expression of results

B.5.1 Practical elongation

$$EP(\%) = \frac{C_{max} - C_{min}}{C_{min}} \times 100 = \frac{G - 2W}{2W} \times 100$$

B.5.2 Compression

The compression is calculated in accordance with the Laplace formula:

$$P_1 \text{ in hPa} = \frac{F_1 \times \Pi}{C_{max} \times l} = 1{,}047 \frac{F_1}{C_{max}}$$

where

P_1 = compression = force in fabric per hose length / leg girth in hPa

F_1 = 6th cycle load at L_{max} (2 x force in fabric) in cN

C_{max} is the hose circumference at L_{max} = girth in cm

l = centre rod length in cm

B.5.3 Residual pressure

The residual pressure (RP) is the compression at the measuring positions (other than B) expressed as a percentage of the compression at the ankle, the compression at the ankle being 100 %.

$$RP(\%) = \frac{P'}{P_1} \times 100$$

where

P_1 is the compression at ankle

P' is the compression at any other measuring point other than the ankle

RP is the residual pressure expressed as a %

B.5.4 Stiffness

Determine the compression of the hosiery for the circumference cB-1 cm and for cB+1 cm. Indicate these pressures with P_{B-1} and P_{B+1}. (see B.2.5).

$$\text{The stiffness } S_1 = \frac{P_{B+1} - P_{B-1}}{2} \text{ hPa/cm and/or in mmHg/cm}$$

B.5.5 Test report

The test report shall include at least the following particulars:

a) Identification of the hosiery tested (manufacturer, name, and type of hosiery).

b) Size (girth and length).

c) The method used.

d) The number of test samples tested.

e) Compression at measuring point B expressed in hectopascals.

NOTE Compression can also be expressed in millimetres of mercury (1 mmHg = 1,333 hPa).

f) Compression class.

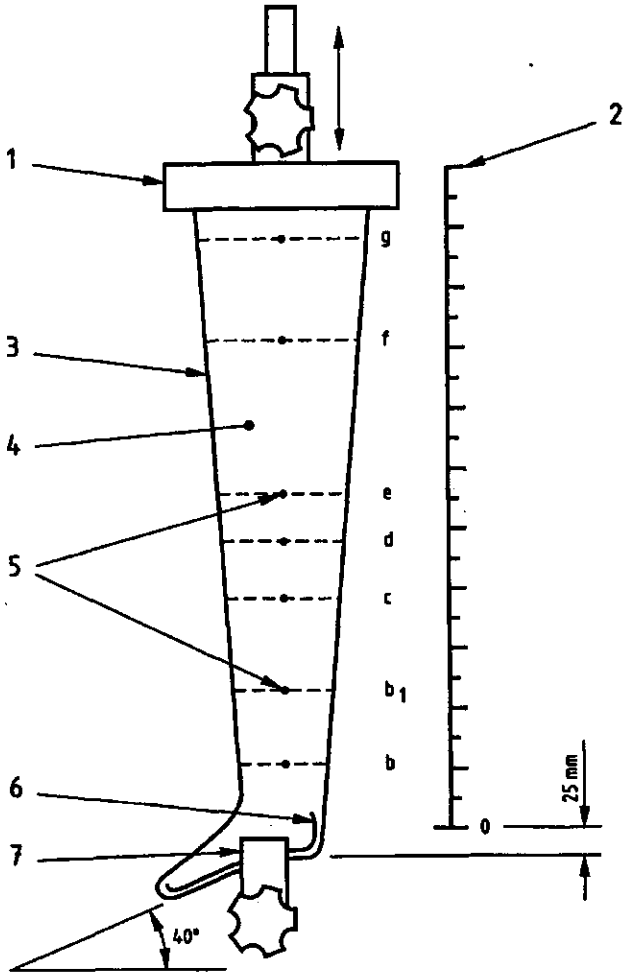
g) Residual pressure at all relevant measuring points and its correspondence with the limits specified in this European Prestandard.

h) Reference to this European Prestandard.

i) If appropriate, pressure profile.

j) If appropriate, stiffness at measuring point B.

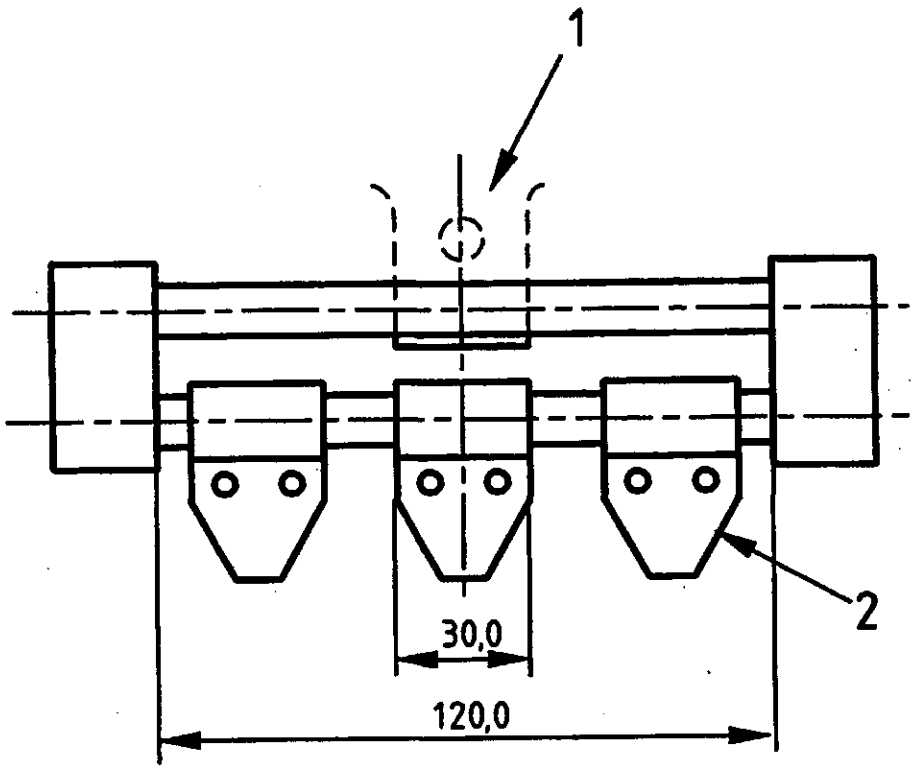
k) If appropriate, comparisons with the reference method.



Keys

1 Fastening by clamp or pins
2 Rule graduated in centimetres
3 Hosiery
4 Base board
5 Measuring points
6 Foot frame
7 Base clamp

Figure B.1 — Device for marking of measuring points — Example for flat-knitted hosiery



Keys

1 Clamp of marking board
2 Clamp to fit the hosiery

Figure B.2a) — Footclamp for round knitted hosiery

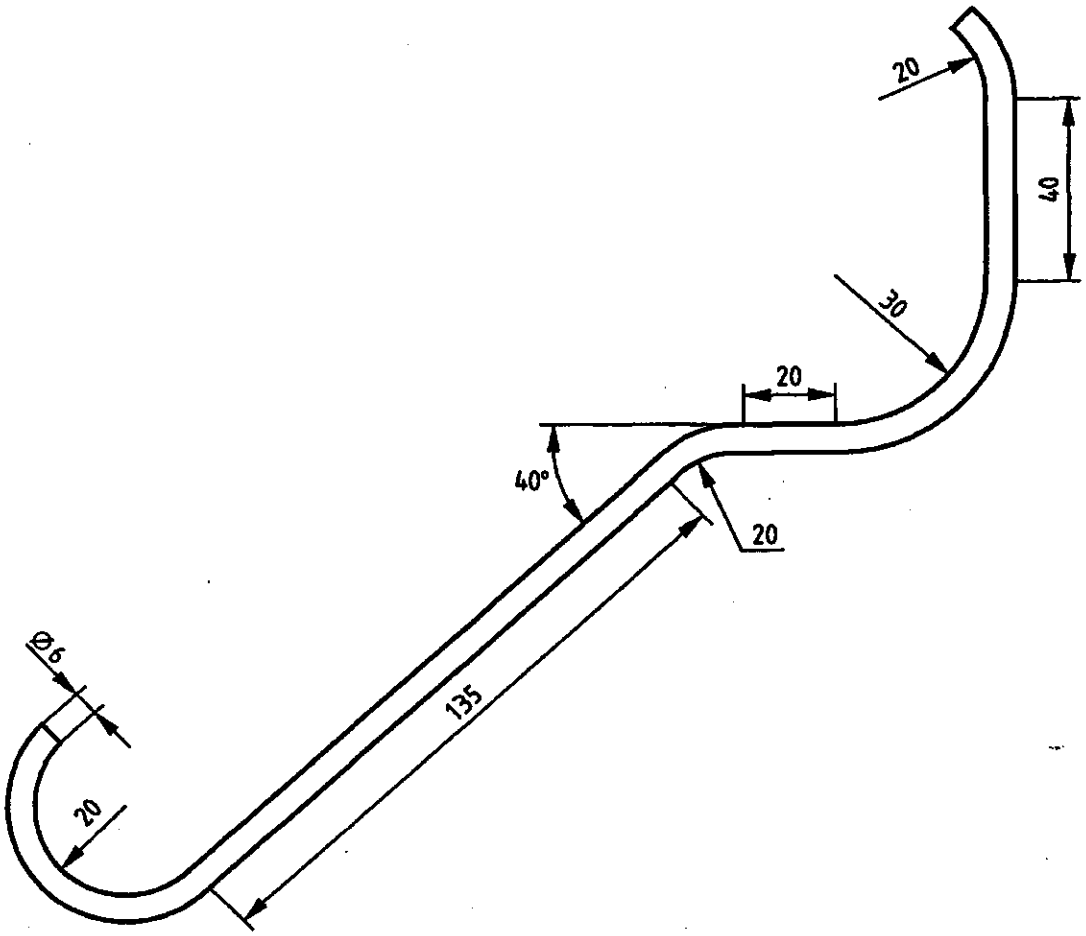
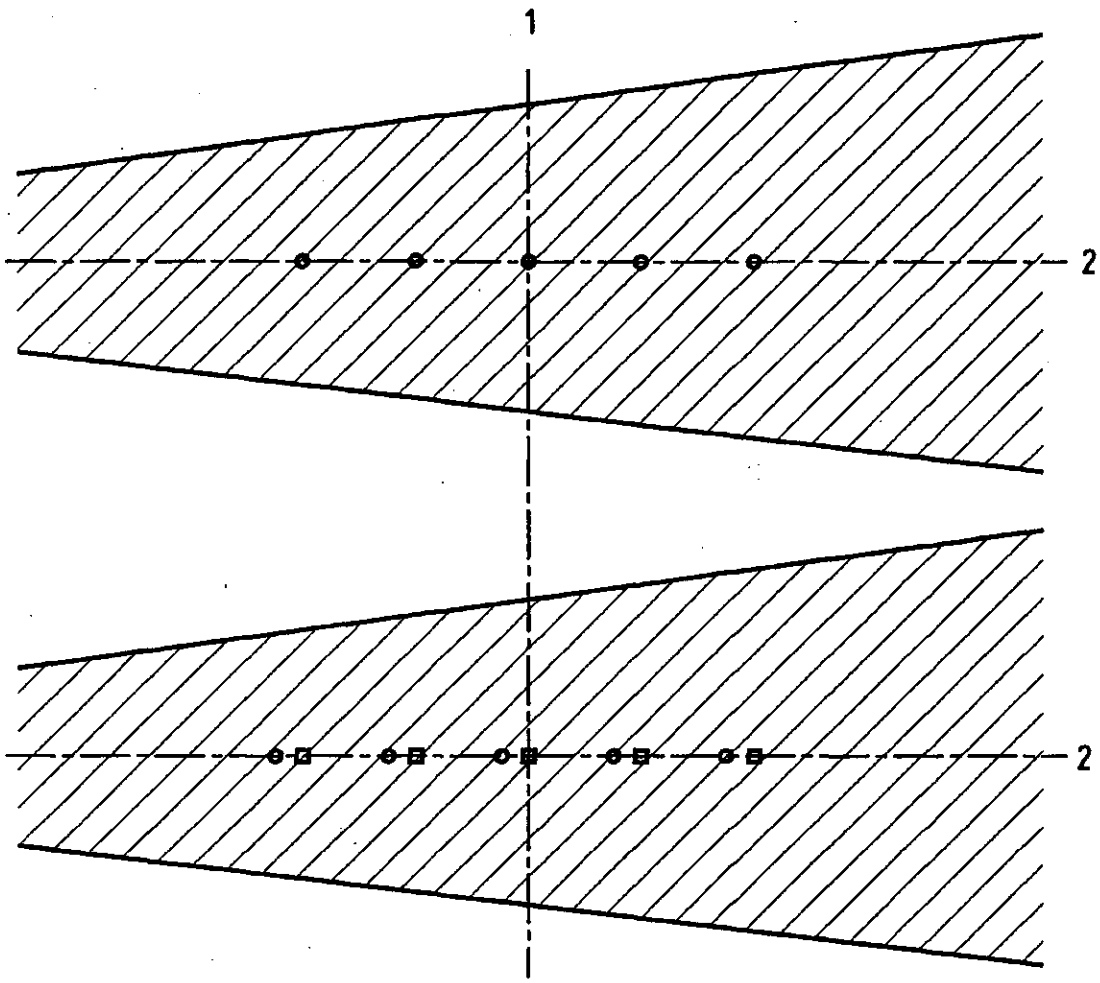


Figure B.2b) — Foot frame for flat knitted hosiery



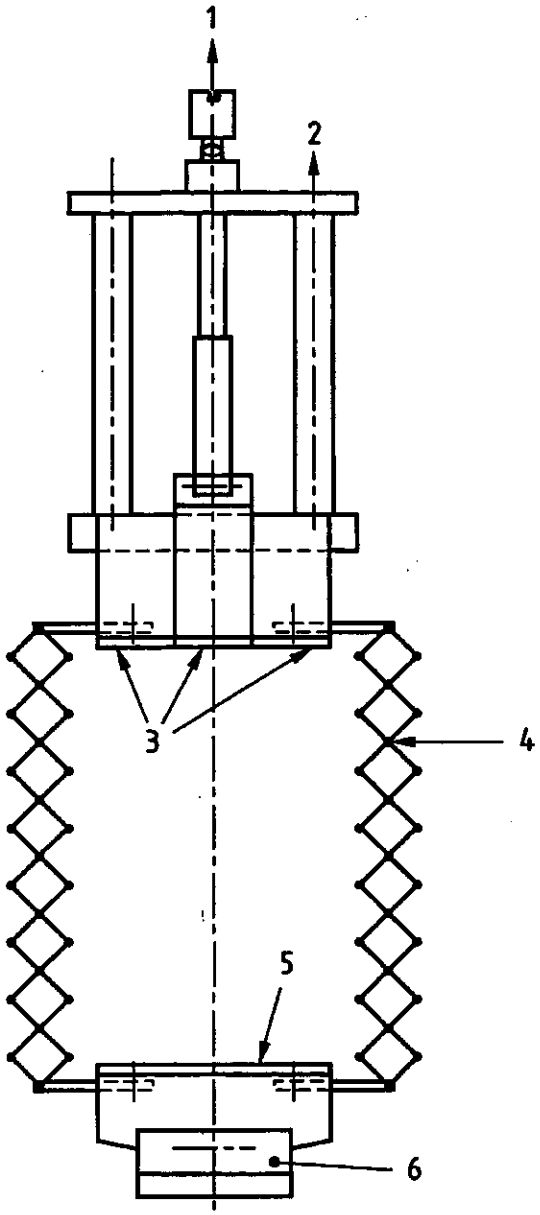
Keys

1 Measuring position
2 Centre line of hosiery

NOTE 1 Points marked along centre line of hosiery

NOTE 2 Needle insertion points and stretcher pin lines referenced to the points marked along the centre line

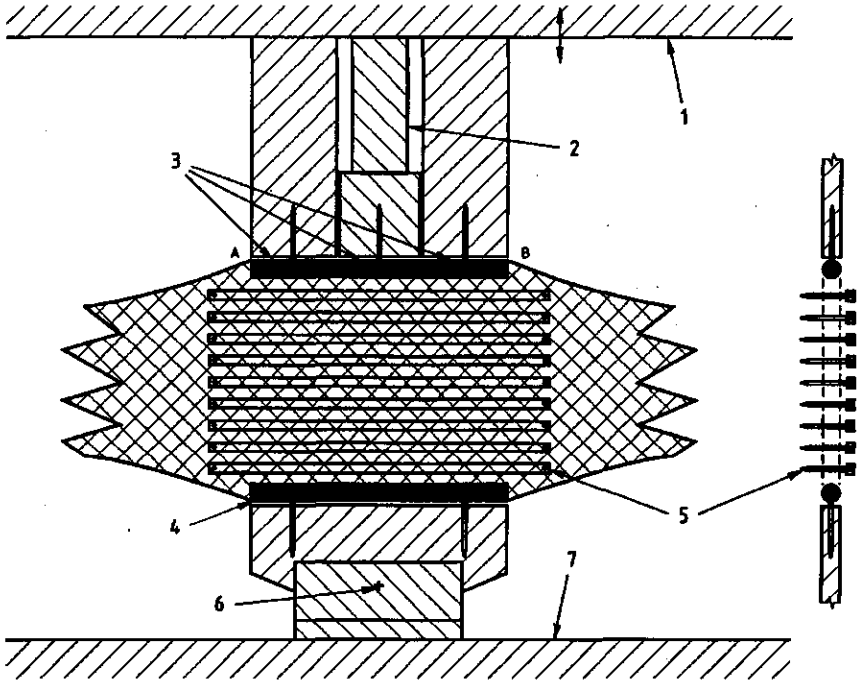
Figure B.3 — Marking of the measurement points



Keys

1 To force cells placed on the traverse
2 To the traverse
3 Needle rods (3)
4 Anti-necking spacers
5 Needle rod (1)
6 In the lower jaw

Figure B.4 — Compression measurement device



Keys

1 Traverse beam of tensile tester
2 Load cell
3 Upper needle rods
4 Lower needle rod
5 Anti-necking rods and pins
6 Pivot axis
7 Base of tensile tester

Figure B.5 — Schematic diagram of measurement device

Dimensions in millimetres

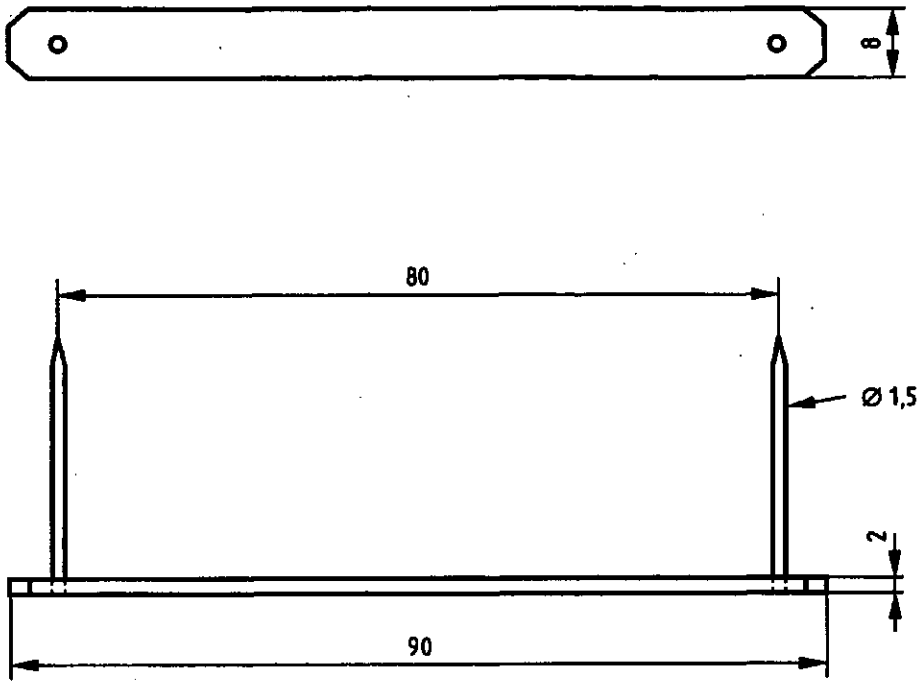


Figure B.6 — Anti-necking spacers

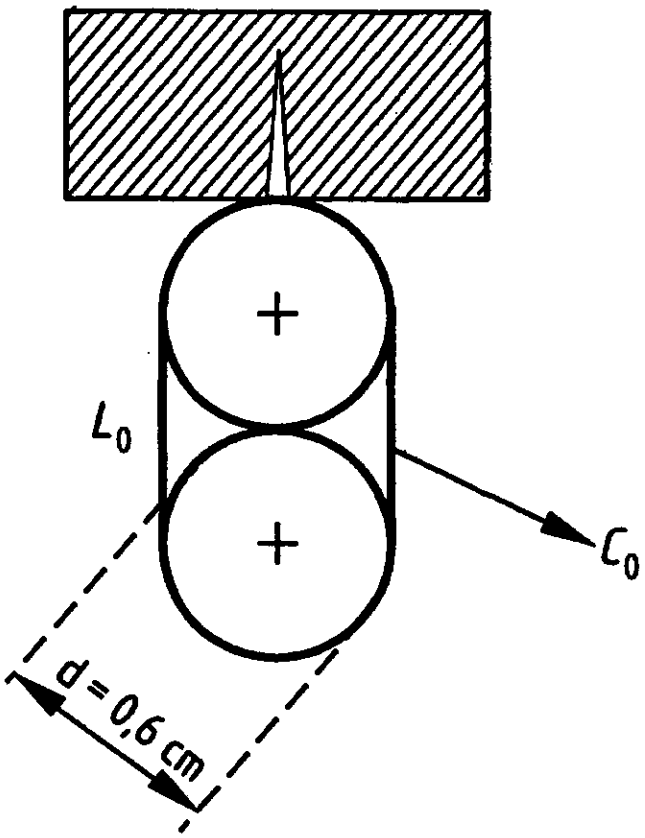


Figure B.7a) — Zero setting

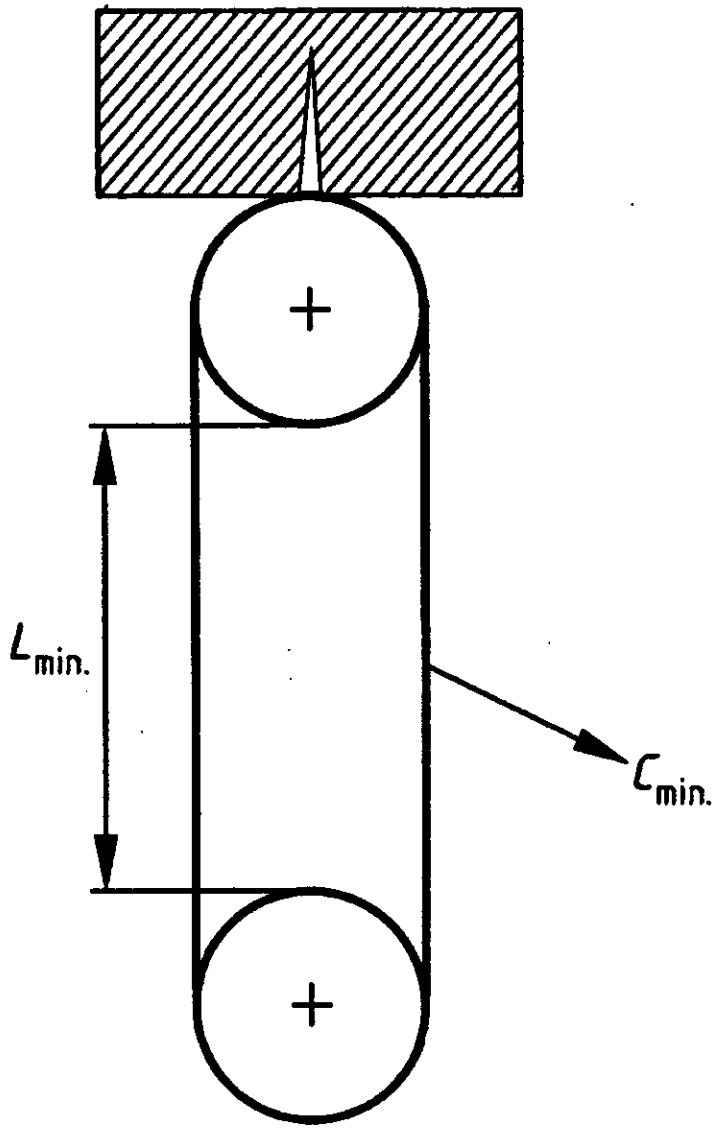


Figure B.7b) — Lower cycling limit

Annex C
(normative)

Method of determination of extensibility of hosiery

Cut open the hosiery lengthwise. Cut out test samples in both test directions (length and width) of size 100 mm long by 50 mm wide at measuring points B and at the uppermost measuring points (D or G), keeping the stitches and courses straight. Overlock the lengthwise edges of the test pieces in the stretch direction with highly stretchable overlock seams.

Clamp the test sample into a tensile tester, keeping the width at 50 mm by holding the sample at equal distances on three sets of "anti-necking spacers".

Apply a load of 5 daN to the test piece at a speed of 50 mm/min. Record the resulting length (l_1) in millimetres.

Determine the extensibility E, as a percentage, using the expression:

$$E = \frac{l_1 - l_0}{l_0} \times 100\,\%$$

where

l_1 is the length at a load of 5 daN expressed in millimetres;

l_0 is 50 mm;

E is the elongation expressed as a percentage.

Repeat the test and record the average value.

Annex D
(informative)

Examples of methods of compression testing

Examples of systems for measuring the compression of hosiery are as follows:

Name of method	Information from
HATRA	Segar Design 14 Cheslyn Drive Aspley Nottingham NG8 3NB UK
HOSY	Forschungsinstitut Hohenstein Schloss Hohenstein D - 7124 Bonnigheim Germany
EMPA	Eidgenossische Materialprufungs und – Forschungsanstalt Lerchenfeldstrasse 5 CH-9014 St. Gallen Switzerland
AFNOR	AFNOR Avenue Francis de Préssensé 11 F-93571 Saint Denis La Plaine Cedex France
	Centexbel Grotesteenweg Noord 2 B-9710 Gent (Zwijnaarde) Belgium
TNO	TNO Institute of Industrial Technology P.O. Box 6031 2600 JA DELFT The Netherlands
MST	MST Mark III (Medical Stocking Tester) Salzmann AG Salzmann MEDICO Unterstrasse 52 CH-9001 St Gallen Switzerland

Annex ZA
(informative)

Clauses of this European Prestandard addressing essential requirements or other provisions of EU Directives

This European Prestandard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU directive 93/42/EEC of 14 June concerning medical devices.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Prestandard.

The following clauses for this prestandard (see Table ZA1) are likely to support requirements of Council Directive 93/42/EEC concerning medical devices.

Compliance with the clauses of this prestandard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Prestandard and EU Directives

Clauses/sub-clause of this European Prestandard	Corresponding Essential Requirements of Directive 93/42/EEC	Comments
1	1, 3	
4	1, 2, 3	
5	1, 2, 3	
6	1, 2, 3	
7	1, 2, 3	
8	1, 2, 3	
9	1, 2, 3	
10	1, 2, 3	
11	1, 2, 4, 7.1, 8.1	
12	1, 2, 3, 5, 8.6	
13	1, 2, 3	
13.1	13.1	
13.1 b)	13.3 b)	
13.1 c)	13.3 b)	
13.1 d)	13.3 b)	
13.2	13.1, 13.6 a)	
13.2 a)	13.3 a), 13.1	
13.2 b)	13.3 b), 13.6 b)	
13.2 c)	13.3 a), 13.3 b)	
13.2 d)	13.6 b)	
13.2 e)	13.6 b)	
13.2 f)	13.3 b)	
13.2 g)	13.3 b)	
13.3	13.1, 13.6 a)	
13.3 a)	13.3 i), 13.6 h)	
13.3 b)	13.3 j), 13.3 k), 13.4, 13.6 h), 13.6 k)	
13.3 c)	13.3 k), 13.4, 13.6 k)	
Annex A	1, 2, 3, 4, 7.1, 8.1	
Annex B	1, 2, 3	
Annex C	1, 2, 3	
Annex D	1, 2, 3	

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