



Hosiery systems for the treatment of patients with leg ulcers

Quality and test specifications

in accordance with
RAL-GZ 387/1

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Preamble

The quality and test specifications of hosiery used for the treatment of patients with leg ulcers as provided here are based on the proven procedure for medical compression hosiery (HOSY-Prüfgerät). In this procedure, the components of the hosiery system are tested separately; pressure values for the respective measuring points are totalled, which fulfils the practical requirements for conventional versions of the leg ulcer hosiery systems. In order to take into account the interaction between individual hosiery components in particular, it would be desirable to further develop the measurement procedures, which would allow for the direct measurement of the entire system.

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Quality and test specifications for hosiery systems for the treatment of leg ulcers

(in accordance with RAL-GZ 387/1)

1. Scope

These quality and test specifications apply to hosiery systems used for the treatment of leg ulcers (hereafter "hosiery" or "hosiery systems").

They do not apply to medical compression hosiery, medical armsleeves or support hosiery and thrombosis prophylaxis hosiery.

These quality and test specifications will be supplemented and updated according to advances in technical standards.

2. Terms and definitions

2.1 Extensibility

Change in size of hosiery in longitudinal or transverse direction under influence of defined force, expressed as percentage ratio to the respective size when not stretched.

2.2 Compression

Compression exerted on the leg by the hosiery.

2.3 Custom-made hosiery

Hosiery manufactured according to the specific leg dimensions of the patient.

2.4 Residual pressure ratio

Pressure exerted by the hosiery at a point of the leg above the ankle, expressed as a percentage ratio in relation to pressure at the ankle.

2.5 Standard size hosiery

Hosiery manufactured in pre-defined sizes according to the size table provided.

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2.6 Tolerance of standard size hosiery

Leg circumference and length limits within which standard size hosiery guarantees the required pressure characteristics.

2.7 Leg ulcer hosiery

Hosiery systems used for the treatment of leg ulcers that exert a defined graduated pressure along the length of the leg.

3. Requirements

3.1 General

3.1.1 Manufacture

The design and manufacture of the hosiery has to ensure that the risks posed by substances released by the product are reduced to a minimum.

Verification according to section 4.3

3.1.2 Packaging

The packaging used by the manufacturer of the hosiery has to be designed to protect hosiery from soiling and light.

Testing according to section 4.1

3.2 Design

3.2.1 Knitting types

The hosiery can be made using the following types of knit:

3.2.1.1 Flat bed knitted hosiery, knitting-based forming.

3.2.1.2 One and double-face knitted, seamless hosiery, knitting-based forming.

3.2.1.3 Combination of 3.2.1.1 and 3.2.1.2.

Testing according to section 4.1

3.2.2 Varieties

3.2.2.1 Heels

The hosiery must have a closed heel.

Testing according to section 4.1

3.2.2.2 Seams

All seams have to be free of bulges on both sides. Seams have to be durable and professionally executed.

Testing according to section 4.1

3.2.2.3 Edges

Edges have to be clean, e.g. linked or hemmed.

Testing according to section 4.1

3.2.2.4 Toes

The hosiery can be produced with open or closed toes.

3.2.3 Forming

Hosiery system forming appropriate for the leg must not be realised by chemical finishing or heat, but by knitting in the mechanical manufacturing process. Smoothing for presentation purposes is permitted.

Testing according to section 4.1 and verification according section 4.2

3.3 Materials

3.3.1 General

Only materials and dyestuffs that are human-ecologically harmless may be used. In particular, the materials must not contain azo dyestuffs which may release carcinogenic amines, allergenic dispersion dyestuffs and pesticides. Limits for nickel and formaldehyde have to be observed. The pH value must be between 5 and 7.

Both natural and chemical fibres may be used.

Verification according to section 4.3

3.4 Types of hosiery

Usually, types of hosiery in accordance with table 1 are manufactured, corresponding to the part of the leg that is to be treated. The labelling is based on the measuring points specified in figure 1. Other types are possible.

3.5 Hosiery sizes

3.5.1 Custom-made hosiery

Manufacture according to the specific leg circumferences and lengths of the patient.

3.5.2 Standard size hosiery

Manufacture according to standard sizes as indicated by the leg circumference and length at the measuring points specified in figure 1.

3.5.2.1 Hosiery sizes and lengths

Base leg circumferences and parts are shown in columns in table 2, leg lengths and parts in table 3. Deviating combinations of leg measurements are possible.

3.5.2.2 Labelling of the type of hosiery and size when manufactured takes place according to the leg measurements shown in tables 2 and 3 or according to manufacturer-specific standard size hosiery tables.

Labelling consists of a letter code for the type of hosiery (corresponding to table 1), followed by three sets of signs. These indicate the leg measurements for which the hosiery is intended:

a) Circumference at the ankle (measuring point B)

b) Circumference at the top of hosiery (depending on type, measuring points C, F or G)

c) Length (referring to total length of the respective type of hosiery).

Information relating to type of hosiery and circumference at the ankle has to be highlighted. The following example illustrates the labelling:

Example: **AD 22-24**
(34-36 / 40-43)

Whereby:

AD: Letter code for below-knee hosiery

22-24: Leg circumference at measuring point B (22-24 cm)

34-36: Leg circumference at measuring point C (34-36 cm)

40-43: Length (here AD: 40-43 cm)

3.6 Compression behaviour

3.6.1 Extensibility

Hosiery must be capable of stretching of at least 20% in longitudinal and 120% in transverse direction. In custom-made hosiery, extensibility must be at least 80% in transverse direction at measuring points F and G.

Testing according to section 4.8

3.6.2 Compression

Compression is calculated for the tested measuring points according to sections 4.4.2 and 4.6.

Compression of the leg around the ankle amounts to between 34 and 46 mmHg (4.5 and 6.1 kPa).

3.6.3 Residual pressure ratio and pressure characteristics

Hosiery must ensure continuous decline of pressure from the ankle to proximal end, according to anatomic conditions.

Residual pressure ratios are calculated for the measuring points B, C, D, E, F, and G (as applicable) according to section 4.7

They must be between 70 and 100 % at measuring point B₁, 50 and 70% at measuring point C, and 20 and 40% at measuring point G.

The residual pressure ratio of the hosiery system is calculated from the sum of the measurements of individual components.

(Exceptions: see 4.4.4.2, Notes)

4. Test specifications

4.1 Visual inspection, as needed:

Visual inspection from a distance of 0.25 m with normal eyesight.

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Visual inspection under magnifying glass with 6 times magnification.

Stereomicroscopic inspection with 10 to 25 times magnification.

4.2 Suppliers' declaration

Declaration of supplier or pre-supplier

4.3 Human-ecological safety

Verification by, e.g., Öko-Tex Standard 100 – product class II (products in contact with skin) or equivalent certificate or suppliers' declaration, e.g. Öko-Tex certificates or equivalent certificates of pre-supplier and binding declaration of the manufacturer that no dyeing process or chemical treatment took place.

4.4 Pressure characteristics

4.4.1 Number of test samples

Two samples are used for each of the lengths and circumferences to be tested (double test).

4.4.2 Measuring at minimum and maximum lengths and sizes

Measuring takes place at the minimum and maximum lengths and circumferences specified by the manufacturer.

If the minimum and maximum lengths at the topmost measuring point (D, F or G) specified by the manufacturer do not deviate by more than 15% (the smaller value being the base), testing will be done for the mean length only. If lengths other than those shown in table 3 are used at the topmost measuring point, the values for measuring points below that will be interpolated accordingly.

If the minimum and maximum circumferences specified by the manufacturer deviate by, at most, 10% (the lower value being the base), only the lower circumference will be tested.

4.4.3 Pre-treatment

4.4.3.1 Washing

Before testing, the hosiery is washed once according to DIN EN ISO 6630/7A. Afterwards, the samples are spun-dried for two minutes and dried flat according to DIN EN ISO 6630, method C.

4.4.3.2 Climatisation

After drying, the hosiery is spread out to dry in a standard atmosphere according to DIN EN ISO 139, section 3.1, for at least 12 hours.

It has to be ensured that the hosiery gains mass in the subsequent adjustment to the standard atmosphere.

4.4.4 Determination of measuring points

4.4.4.1 Marking device

A device as shown in figure 2 is required for the determination and marking of the measuring points. This device consists of a base plate with base clamp, in which a holding fixture for the foot appropriate for the knitting construction can be secured. The base plate may be additionally equipped with a length measuring device, with mm graduation, and markings for measuring points.

4.4.4.1.1 Circular knitted hosiery

With circular knitted hosiery, the first continuous row of stitches above the heel is defined as the lower end of the marking. The hosiery is fixed in the clamp (fig. 3, example) along this row of stitches, the clamp being attached to the base clamp in turn. The base clamp has to be adjusted so that the row of stitches defined as base is located +45 mm above the zero line of length measuring device.

4.4.4.1.2 Flat knitted hosiery

Flat knitted hosiery is fixed in the base clamp using a foot frame (fig. 4). The base clamp has to be adjusted so that the horizontal bottom edge of the frame is located 25 mm under the zero line of length measuring device.

4.4.4.2 Labelling of samples

Following the fixing of the foot part in the base clamp according to section 4.4.4.1, the hosiery is stretched in longitudinal direction so that it corresponds to the specified length and is then fixed with pins or a suitable clamp. The measuring points specified are then marked with felt-tip pen in correspondence with the length values.

Notes:

The hosiery covers the leg up to the specified measuring point. At the top, up to 5 cm may deviate due to the knitting technique (edge).

The hosiery is measured along its entire length.

For calculation of the pressure gradients, the measurement value of the clamp still completely in the compressing area is used. The residual pressure ratio at the topmost clamp may be 15% higher than the residual pressure ratio at the clamp below at most, but not higher than specified in section 3.6.3.

Individual components of a hosiery system have to be marked and measured separately.

4.4.5 Measuring compression

4.4.5.1 Measuring principle

The force hosiery exerts in longitudinal direction, when stretched in longitudinal direction up to the specified length and then stretched in transverse direction according to its size specifications, is measured.

4.4.5.2 Test device

Testing is done with the compression test device System Hohenstein (HOSY¹). The device consists of up to 20 separate, directly sequential tensile test rigs, each 5 cm wide. Tensioning and measuring clamps are each designed as double rollers. The hosiery is inserted between these rollers and fixed in the clamps by spiral string sections inserted into the hosiery.

Each tensile test until is driven by a stepper motor the number of pulses of which gives information about the distance, i.e. the distance between both clamps of one unit. The measuring of force takes place at the fixed row of clamps via short-distance electronic force transducers. The entire test sequence is computer-controlled.

4.4.5.3 Test sequence

The hosiery is placed in the fixed row of clamps using a highly flexible spiral spring section and attached to the adjustable holding devices at the foot and top. Then the holding device is moved until the mark for the measuring point B is located at the centre of clamp 2 and the end of the hosiery corresponds to the specified leg length. Then the second covered spiral spring section is inserted into the hosiery and the force indicators of all measuring clamps set to zero.

Now, the tensioning clamps are initially raised to the hosiery, so that it can be inserted into the lower clamp as well. Subsequently, the clamps are moved far enough apart that each measuring clamp has selectable initial load (= table dimension).

The computer program then calculates for each tensioning clamps the distance necessary to reach the specified circumference, the resulting elongation of the hosiery and the required number of pulses, so that all clamps will attain this position simultaneously after 20 seconds.

Subsequently, the hosiery is stretched to the leg circumference and released to table dimension again six times.

The computer then provides a table for each clamp or measuring point listing elongation, tension force, pressure and residual pressure ratio for the conditions at the circumferences given and provides a graphic depiction of pressure characteristics along the entire length of the leg.

Note:

The pressure at measuring point B determines the compression of the hosiery. In order for this value to be measured and not interpolated from the values of two neighbouring clamps, the hosiery, independent of lengths, always has to be fixed in the test device so that measuring point B is in the centre of clamp 2.

¹ A detailed description of the test procedure is provided in the Hohensteiner research paper of January 1982 and Phlebol. u. Proktol. 11: 34-41 (1982).

Pressure values for components that are to be measured separately are totalled for the respective measuring points.

4.5 Force

The force determined at the pressure point (leg circumference) during the sixth loading cycle is calculated for a leg covered to a height of 10 mm.

$$F_i = \frac{F_s}{10}$$

F_i = Force in N/cm at measuring point i

F_s = Force in N during loading cycle at the measuring point i during elongation that corresponds to practical elongation

i = Represents measuring points B to G and measuring clamps 1 to 20

4.6 Compression

The compression exerted on the leg can be calculated from

$$P_i = 20 \pi \frac{F_i}{U_i}$$

P_i = Compression in kPa at measuring point i

F_i = Tension in N/cm at measuring point i

U_i = Leg circumference in cm at measuring points i

i = Represents measuring points B to G and measuring clamps 1 to 20

4.7 Residual pressure ratio

The residual pressure ratio at the measuring points above B results from

$$Rd_i = \frac{P_i}{P_x} \times 100$$

Rd_i = Residual pressure ratio at measuring point i

P_i = Compression in kPa at measuring point i

P_x = Compression at measuring point B (clamp 2)

i = Represents measuring points B to G and measuring clamps 1 to 20

4.8 Extensibility

4.8.1 In longitudinal direction

Testing at measuring point B

The hosiery is cut in longitudinal direction and a test sample of 100 mm in length (leg longitudinal direction) and 50 mm in width (leg circumference) is taken at measuring point B, keeping the courses straight. Measuring point B has to be in the geometric centre of the sample. The longitudinal edges of the sample progressing in test direction

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are trimmed with highly stretchable overlock seams.

Testing is carried out as described in 4.8.2. In flat knit hosiery, three stretcher pins are used, in circular knitted hosiery, only one is used at measuring point level.

4.8.2 In transverse direction

Testing at the measuring points B, D, F, and G (as applicable)

The hosiery is cut in longitudinal direction. A test sample of 100 mm in length (leg longitudinal direction) and 50 mm in width (leg circumference) is taken at measuring point B, keeping the rows straight. The longitudinal edges of the sample progressing in test direction are trimmed with highly stretchable overlock seams.

The samples are fixed in the measuring clamps of a tensile test machine with 50 mm clamping length, with the width of 50 mm being ensured by using three stretcher pins distributed evenly along the length.

The deformation speed is set in such a way that the loading of the test sample with 5 daN will be attained within 30 seconds. The elongation of the sample occurring during this process is documented in mm (l).

4.8.3 Calculation of extensibility

The extensibility E (%) is calculated as follows:

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

with

E = Extensibility in %

l_0 = Distance in mm of measuring marks or clamps in unloaded condition (50 mm)

l_1 = Distance in mm of measuring marks or clamps after loading

5. Monitoring

5.1 Third party tests

5.1.1 Inspection authorities

The Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V. keeps a list of inspection authorities authorised to carry out approval and quality assurance testing.

5.1.2 Approval test

5.1.2.1 Sampling

The testing is done using ready to sell hosiery, which is submitted by the manufacturer.

5.1.2.2 Scope of testing

The approval test as precondition for the granting of the right to display the Quality Mark includes the scope of the sections 3 and 4.

5.1.3 Quality assurance test

5.1.3.1 Quality assurance agreement

The producing company is obliged to conclude a quality assurance contract with the inspection authority when conducting third party tests, which has to be approved by the Quality Mark Association [Gütezeichengemeinschaft].

5.1.3.2 Sampling

When testing standard size hosiery, the hosiery is taken from current production or the warehouse of the manufacturer or from specialist shops.

When testing custom-made hosiery, the inspection authority selects random measurements out of approx. 700 available size charts and orders hosiery for these leg dimensions from specialist shops or directly from the manufacturer.

if there is justified suspicion of irregularities, the office instructs the commissioned inspection authority to carry out routine or non-routine tests.

5.1.3.3 Scope of testing

The quality assurance covers the scope of testing detailed in sections 3 and 4. The identity of the hosiery submitted at the inspection authority (prototype) has to be verified.

With custom-made hosiery of series manufactured in standard and custom sizes, only the compression behaviour according to section 3.6 and the labelling according to section 6 are tested.

5.1.3.4 Deviations

In a case of deviation from prototypes or from pertinent guidelines, the procedure is as follows:

In cases of deviations that do not affect the medical properties, the manufacturer is obliged to remedy the deviations within four weeks and to notify the Quality Mark Association and commissioned inspection authority of complete execution in written form. In case of major deviations from the prototype and/or pertinent guidelines, especially when these affect the compression, repetitive tests have to be carried out on two additional hosiery systems (same size and length), which the manufacturer has to provide within four weeks.

If the defects are not remedied by then, the inspection authority will notify the office.

5.1.4 Changes to product or of name

5.1.4.1 Hosiery name

If (only) the name of the quality-marked hosiery is changed or if it is marketed under another name, the manufacturer has to provide the inspection authority commissioned for quality assurance and the

office of the Quality Mark Association with a written notification thereof.

5.1.4.2 Product design

If the design of the hosiery is changed, this has to be communicated to the inspection authority commissioned for quality assurance. A quality assurance test follows.

A passage describing the changes is added to the quality assurance report.

The same procedure is observed when a simultaneous change in labelling, but no extension of the product programme, occurs.

If the change of design and labelling also extends the product programme, an approval test is required.

5.2 Internal quality assurance

5.2.1 Management system

The manufacturer undertakes to establish and implement a documented internal management system for quality assurance.

5.2.2 Traceability

The manufacturer undertakes to ensure traceability in accordance with medical product law. This can take place in the form of marking the lot of the hosiery, marking of the packaging, operating instructions, inspection tickets or in any other appropriate manner

5.2.3 Production control

In order to maintain quality requirements, testing at least in accordance with sections 3.2, 3.3, and 3.6.1 to 3.6.3 has to be done and documented during current production and when manufacture conditions are changed.

6. Labelling

6.1 Quality Mark

Hosiery systems that comply with the quality provisions set out in section 3, may display the Quality Mark illustrated below:



For use of the Quality Mark, the statutes and the sign charter of the Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V., Düren apply exclusively.

6.2 Labelling of the hosiery

Additionally, the labelling of hosiery systems carrying the Quality Mark has to include the following information:

- Details of the manufacturer or number issued by the Quality Mark Association,
- Product name or type designation,
- Compression class,
- Type of hosiery and size (in accordance with section 3.5.2.2) or label "custom-made size"
- Textile mark (if not shown on the packaging),
- Labelling for traceability (if not shown on packaging or in the operating instructions),
- Care label (in accordance with DIN EN 23 758), production or expiry date- (if not shown on packaging or in the operating instructions).

The labelling of the hosiery must be complete, permanently legible, and durable.

Testing in accordance with section 4.1

6.3 Labelling of the packaging

In addition to the labelling specified in 6.2, the following information must be provided on the packaging:

- Name and address of the manufacturer or the distributor,
- Textile mark (if not shown on the hosiery),
- Labelling for traceability (if not shown on hosiery or in the operating instructions),
- Care label and production or expiry date- (if not shown on hosiery or in the operating instructions).

Testing in accordance with section 4.1

6.4 Operating instructions

The hosiery must be accompanied by operating instructions for the end user, above all containing information on the points listed below:

- Name and address of the manufacturer or the distributor,
- Labelling for traceability (if not shown on hosiery or on the packaging),
- Storage of hosiery,
- Storage life and duration of use of the hosiery,

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- Intended use of the hosiery,
- Possible contraindications and risks,
- Washing instructions, if possible using the washing and care symbols in accordance with DIN EN 23 758,
- Information that skin oils, lotions, etc. may limit effect and durability.

Testing in accordance with section 4.1

6.5 Information for the relevant agency

The relevant agency has to be provided with information regarding the following in the appropriate form:

- Available lengths and scope of ranges of standard size hosiery,
- Proper storage,
- Storage life.

6.6 Alterations

Alterations of the quality and test specifications, including those of editorial nature, require the written approval of the executive board of the Quality Assurance Association. This will enter into force following an appropriate period of time after being announced by the executive board of the Quality Mark Association.

7. Implementing provisions for the awarding and display of the Quality Mark for Medical Compression Hosiery

The implementing provisions of RAL GZ-387/1 (section 1 to 8) apply accordingly.

Table 1: Types of hosiery

Type of hosiery	Letter code
Below-knee hosiery	AD
Mid-thigh hosiery	AF
Thigh hosiery	AG
Tights	AT

16 **Table 2: Leg circumference and sizes**

Leg circumference and size																										
Circumference letter code	Extensions for slender legs					Sizes ^{*)}														Extensions for stocky legs						
						18	19	20	21	22	23	24	25	26	27	28	29	30								
Circumference 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	---	---	---	---	---
cA	---	---	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	---	---	---	---	---
cY	---	---	---	---	---	---	28	29	30	31	32	33	34	35	36	37	38	---	---	---	---	---	---	---	---	---
*) corresponding to the circumferences cB																										

Table 3: Leg lengths

Length letter code	Leg length in cm						
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
IB ₁	19	20	21	22	23	24	25
IB	10	11	11	12	12	13	13

Table 4: Test plan

Type of testing	Approval test				Quality assurance			
	Only standard size	Standard and custom		Only custom-made	Only standard size	Standard and custom		Only custom-made
		Standard	Custom			Standard	Custom	

Time of testing		On application				At least annually			
Type of hosiery		The longest type of hosiery offered (acc. to Table 1)				According to choice of inspection authority			
Number of sizes/ lengths to be submitted (hosiery systems)		4 each in 2 sizes/ lengths ⁵⁾⁶⁾	4 each in 2 sizes/ lengths ⁵⁾⁶⁾	4 ²⁾	8 ²⁾	4, in 1 size and 1 length ¹⁾⁶⁾	4, in 1 size and 1 length ¹⁾⁶⁾	2 ²⁾	2 ²⁾
Scope of testing	Compression testing ³⁾	All sizes and lengths submitted	All sizes and lengths submitted	4	8	2	2	2	2
	Other testing ⁴⁾	2	1	1	2	2	1	1	1

1) Choice of sizes/ lengths by the commissioned inspection authority according to submitted size chart

2) According to sizes specified by the commissioned inspection authority

3) In accordance with sections 3.6.2 and 3.6.3

4) In accordance with sections 3.1, 3.2, 3.3, 3.4, 3.5, 3.6.1

5) 4 units in 2 sizes (when only produced in one length) or 4 units in 2 lengths (when produced in varying lengths)

6) Plus sizes and diverging widths of clinging band are to be regarded as separate sizes and are to be tested regarding compression, information according to sizes, information on sizes in accordance with section 6.5, if applicable

Figure 1: Measuring points, leg lengths and circumferences

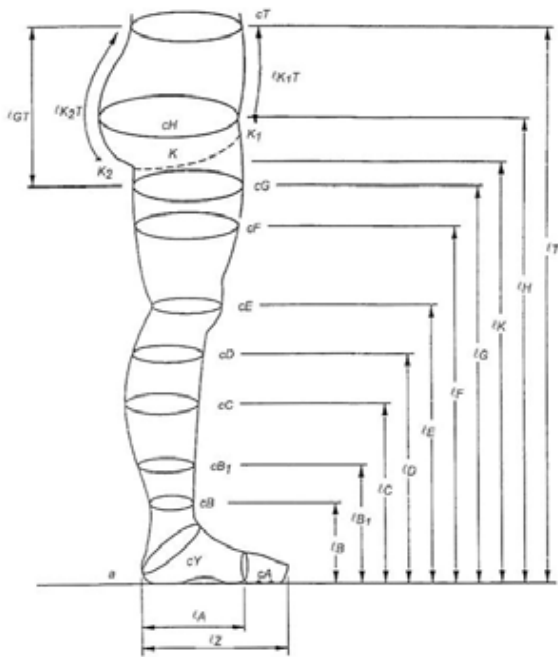
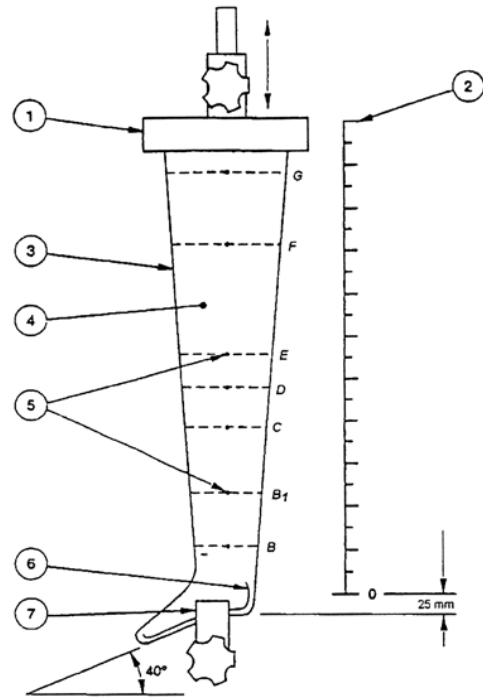


Figure 2: Device for marking of measuring points

Example for flat knit hosiery



- 1 Fixing device (clamps or pins)
- 2 Ruler
- 3 Hosiery
- 4 Base board
- 5 Measuring points
- 6 Foot frame
- 7 Base clamp

Figure 3: Foot clamp for circular knit hosiery

(Available for: NV Varitex, Zulweg 103/105, 2013 De Haarlem Postbus 723, NL)

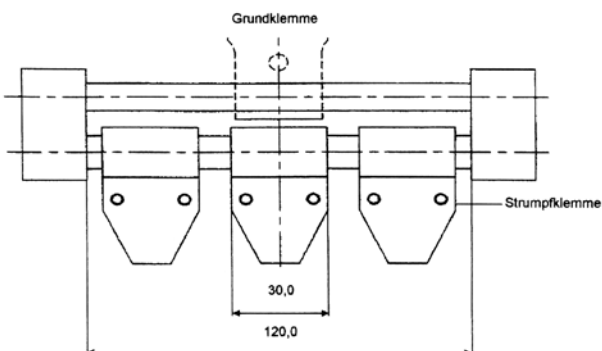
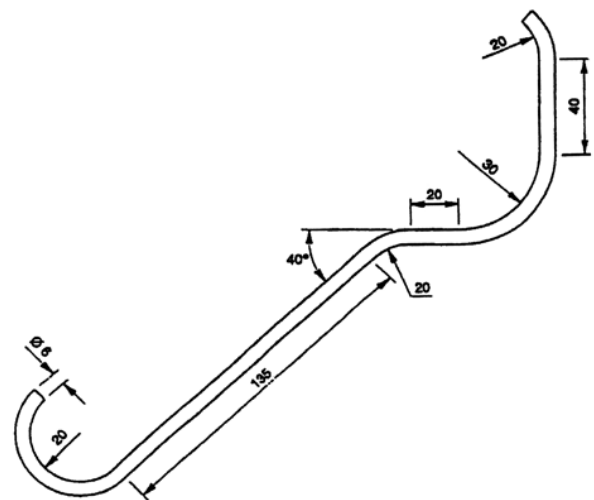


Figure 4: Foot frame for flat knit hosiery



Translation Figure 3

Deutsch/ German	Englisch/ English
Grundklemme	Base clamp
Strumpfklemme	Hosiery clamp

