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Method for testing compression in medical hosiery

Verfahren zur Kompressionsprüfung von medizinischen Strümpfen

Méthode d'essai de compression des bas médicaux

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Method for testing compression in medical hosiery

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Foreword

This document (CEN/TR 15831:2009) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

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This document supersedes ENV 12718:2001, ENV 12719:2001.

This document is based on the test methods described in ENV 12718:2001 and ENV 12719:2001 which have been withdrawn.

1 Scope

This document applies to medical compression hosiery and thrombosis prophylaxis hosiery.

An important property of hosiery is the compression it exerts on the limb. This document is intended to provide a reference for testing the compressive properties in medical hosiery.

2 Terms and definitions

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

2.1
compression
pressure exerted on the leg by the hosiery

2.2
custom made hosiery
hosiery manufactured individually to suit the leg dimensions of an individual patient

2.3
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

2.4
pressure profile
representation of the compression exerted by the hosiery along the leg

2.5
residual pressure
compression at a certain point expressed as a percentage of the compression at the ankle

2.6
standard size hosiery
hosiery manufactured in the types and sizes specified

2.7
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 document to 'hosiery'

2.8
medical compression hosiery
hosiery for treating leg diseases by means of graduated compression exerting a definite pressure on the leg in a specific way

NOTE Abbreviated in this document to 'hosiery'

2.9
stiffness
increase in compression per centimetre increase in the circumference of the leg, expressed in hectopascals per centimetre and/or millimetres of mercury per centimetre

3 Nominal dimensions and sizes

3.1 General

Hosiery size can be designated by the lengths and girths on the human leg at the measuring points.

3.2 Measurement of length

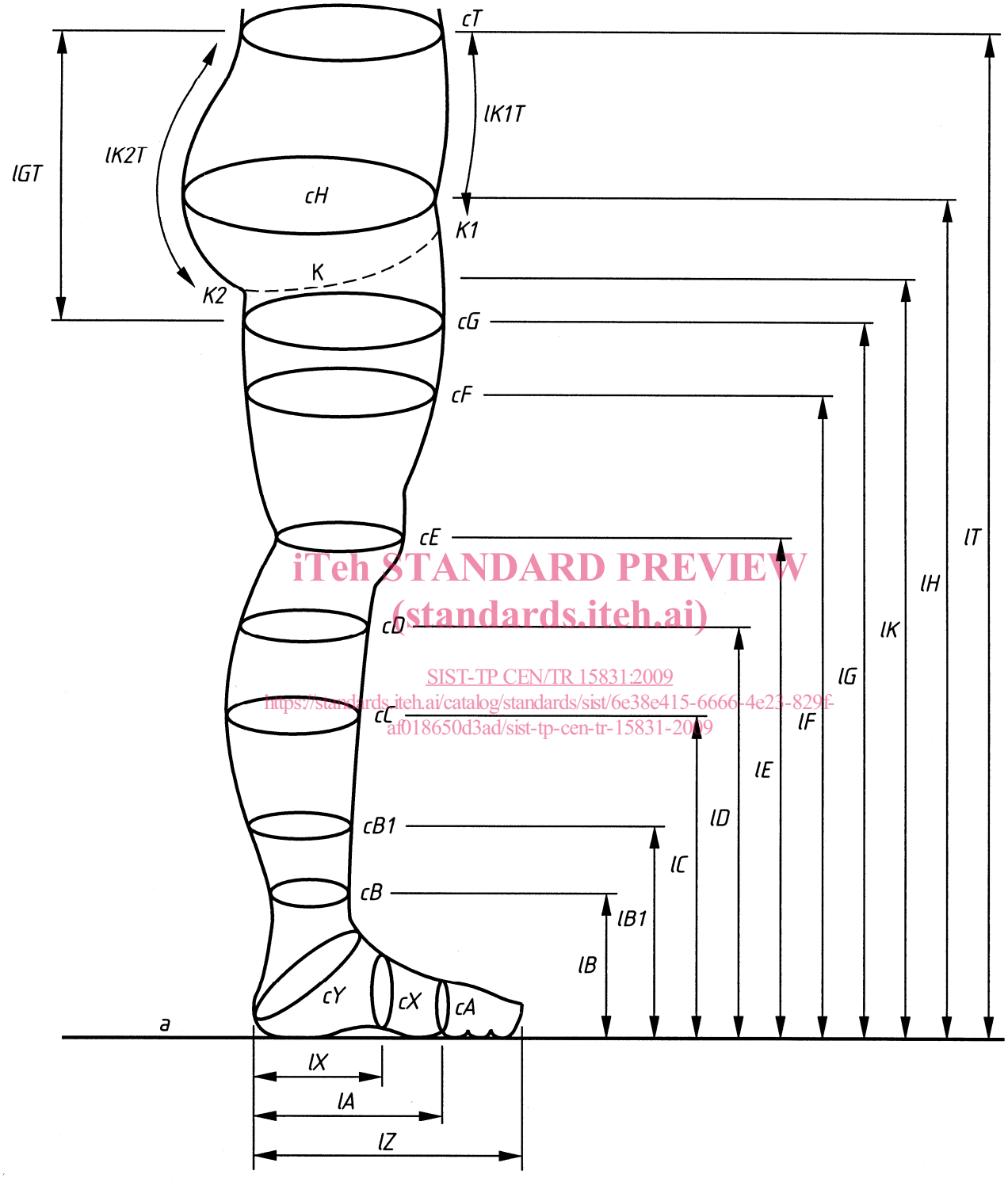
If measured, length can be measured and codes allocated as described in Table 2.

3.3 Measurement of girth

If measured, girths can be measured and codes allocated as described in Table 3.

3.4 Designation of type of hosiery

Hosiery can be designated by the type code according to Table 4.



Measurements should preferably be taken at the patient's leg in a standing position

Figure 1 — Measuring points, lengths and girths on the human leg

Table 1 — Nominal measuring points (see Figure 1)

Measuring point	Description of the measuring point
a	sole of the foot at the heel
A	forefoot at the implantation of the toes
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
H	greatest lateral trochanteric projections of the buttock
K	centre point of the crutch
K1	level at the pubic symphysis
K2	level at the infra-gluteal fold
T	natural waistline
X	middle of the foot
Y	instep
Z	tip of toe

Table 2 — Nominal measurement of length

Length code	Length of the leg
lB	distance measured from a to B
lB1	distance measured from a to B1
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
lH	distance measured from a to H
lK	distance measured from a to K
lT	distance measured from a to T
lX	distance measured from the most prominent part of the heel to X
lA	distance measured from the most prominent part of the heel to A (foot length without toe)
lZ	horizontal distance between the perpendiculars in contact with the end of the most prominent toe and the most prominent part of the heel (total foot length)
lGT[1)]	distance measured from G to T
lK1T[1)]	distance measured from K1 to T
lK2T[1)]	distance measured from K2 to T

1) For panty hose only, measured along the body.

Table 3 — Nominal measurement of girth

Girth code	Girth of the leg
cA	girth measured at A
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
cH	girth measured at H
cT	girth measured at T
cX	girth measured at X
cY	girth at Y, measured with the foot in maximum dorsal flexion

Table 4— Designation of types of hosiery

Type of hosiery	Code
Below-knee hosiery	AD[1)]
Mid-thigh hosiery	AF[2)]
Thigh hosiery	AG[3)]
Single leg panty	AGTL[4)] , AGTR[5)]
Panty hosiery	AT[4)]

[1)] Upper end of hosiery corresponds to measuring position D. An area of maximum 10 mm below can be less or non-compressive.

[2)] Compressive up to measuring position F. There can be a less or non-compressive welt or part above.

[3)] Upper end of hosiery corresponds to measuring position G. An area of maximum 50 mm (stretched condition) below upper end can be less or non-compressive.

[4)] Compressive at least up to measuring position G.

[5)] L = left leg; R = right leg

4 Method for testing compressive properties of medical hosiery

4.1 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.

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

4.2 General conditions

4.2.1 Number of test samples

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

4.2.2 Measuring positions

The compression can be measured at the relevant measuring positions given in Figure 1.

4.2.3 Measurement of compression at minimum and maximum sizes

If the manufacturer states a range of girths and/or lengths, compression measurements should be taken 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 should be 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 should only be determined at the mean of the minimum and maximum values, rounded down to whole numbers.

4.2.4 Stiffness

If stiffness is to be determined, 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 should be taken. Always the smallest girth should be measured first.

4.3 Apparatus

4.3.1 Washing machine, described in EN ISO 6330:2001

4.3.2 Device for marking of measuring positions

The device would preferably comprise a marking-board (see Figure 2), 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 should be used (see Figure 3a);

b) for flat knitted specimens, a foot frame (see Figure 3b) made from a round metal bar of approximately 6 mm diameter should be used.