

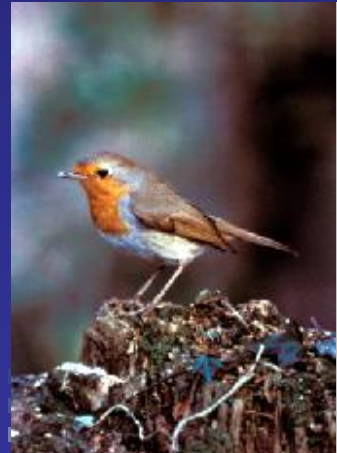
Centre Européen de Normalisation CEN TC 205 / WG 2 + PR 1



Experiences about classification

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Normalisation: an easy way?



CEN

Comité Européen de Normalisation

European Committee for Standardization = CEN
Europäisches Komitee für Normung

DIN

BSI

NNI

AFNOR

NEN

DS



Who is who?

- The CEN
 - TC 205
 - PR 1
- The Industry
- Medical professionals
- Others



Aim

- A European norm for medical compression hosiery
- No barrier for trade
- Safety for patients

Delegation

- ★ all EU members
- ★ trade associates



Members

- ★ manufactures
- ★ technical institutes of textile
- ★ medical profession

★ *all at their own costs*



CEN TC205/WG 1(PR1)

Technical Committee = TC

205 : medical devices



Workgroup (WG) 1 :	compression hosiery
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Project group (PR) 1 :	anti-thrombosis hosiery
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What can be normalised ?

- ★ Only requirements !
- ★ How to measure ?



Requirements

- ★ technical:

 - compression / lifetime, etc.

- ★ labeling / package



Measurement techniques

official technique (AFNOR)

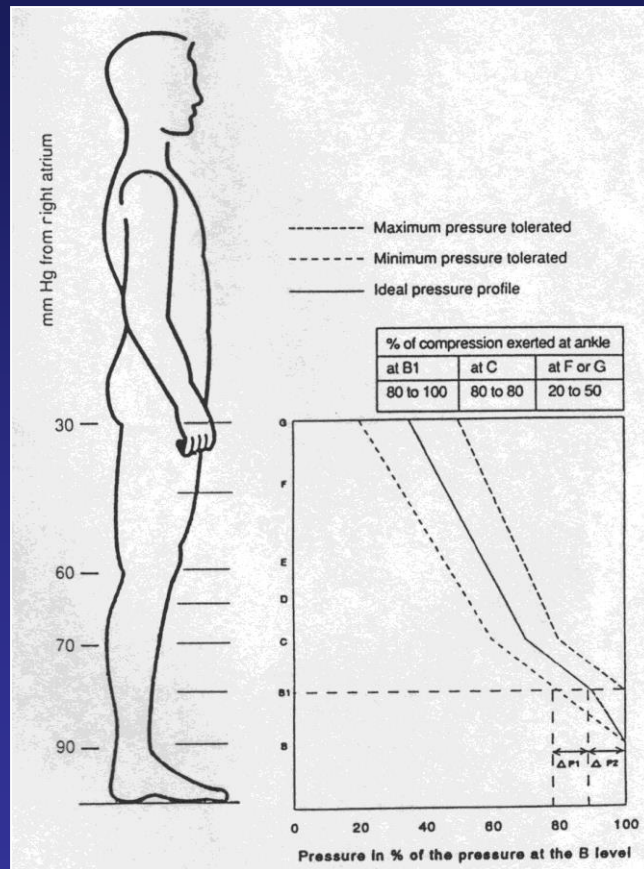


possible

“to translate” to your own method



Pressure profile



Representation of the compression exerted by the MEC along the leg

Pressure reduction from ankle to hip in the same range as the decrease of the influence of gravitation

Pressure profile for an elastic stocking fulfilling the CEN criteria for a class II stocking

Whats new ?

- ★ elasticity coefficient
- ★ dynamic measurement



Problems 1

- Different interests
 - *Industry versus medical profession*
 - *Industry versus industry*
 - *Thread industry versus hosiery industry*
- Different existing national norms

Problems 2

- A lack of evidence on compression
- A lack of testing methods:
 - compression
 - hysteresis
 - durability
- Compression classes
- BSI / DIN norm versus other countries

What about compression classes?

- Is there a need for low compression classes?
- What will be the cut-off point per class?
- Why to introduce classes which will not be reimbursed?

Compression classes

acc. to European Committee for Standardisation (CEN)

Compression class	Compression at the ankle ¹	
	hPa	MmHg ²
Ccl A light	13 to 19	10 to 14
Ccl I mild	20 to 28	15 to 21
Ccl II moderate	31 to 43	23 to 32
Ccl III strong	45 to 61	34 to 46
Ccl IV very strong	65 and higher	49 and higher

1 The values indicate the compression exerted by the compression stockings at a hypothetical cylindrical ankle.

2 1mmHg = 1,333hPa

Solutions

- **Clear uniform medical statement about compression classes**
- **Separation of trade and science**
- **One goal: optimum patient care**

Participation of all partners ?



*Where was
the medical profession ?*

What did we learn?

- * Medical profession was not prepared for this aim
- * Trade barriers are more important than the norm
- * 15 years work are lost
- * The patient pays the bill
- * Frustrates research



Is there a task for IIC ?

- **YES**



