Classification
of
compression stockings

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0. Testing in vivo vs. testing in vitro

Medical compression stockings today are important devices in the phlebological and lymphological therapy.

In order to understand the mechanisms behind the therapy with those devices there exist many studies in the medical societies and it is clear, that for all of these studies it is very interesting, what the real values of pressure for example in vivo at the patients are.

These are normally only unique results, not really reproducible, where we have to know about the patient´s leg.

In order to have the possibility to choose the adequate stocking out of all the stockings on the market, we need as basis a **neutral and reproducible** testing method.

This is why we have for example the RAL-GZG standard with exactly defined procedures how to classify a MCS.

This is the only way to make stockings comparable without the influences of the individual patient.

Conclusion:

We need the in vitro tests to classify the stockings and it is very interesting, what the performance of the product is used in the special study (in vivo) – but always keeping in mind, that the results are very much influenced by the constitution of the patient.

I. Pressure values

I.1. Status quo

Today, mainly three standards for medical compression stockings exist:

- Germany and others : RAL-GZG standard
- France : AFNOR
- Great Britain : BSI

There has been a strong effort to create an European standard, but in the end the preliminary ENV 12718 was refused by the majority of the members of the standardization committee after more than 13 years.

Only the German standard and – following this example – the Dutch norm took over the reasonable requirements of the ENV 12718, so that today the German RAL-standard reflects best the proposed European standard.
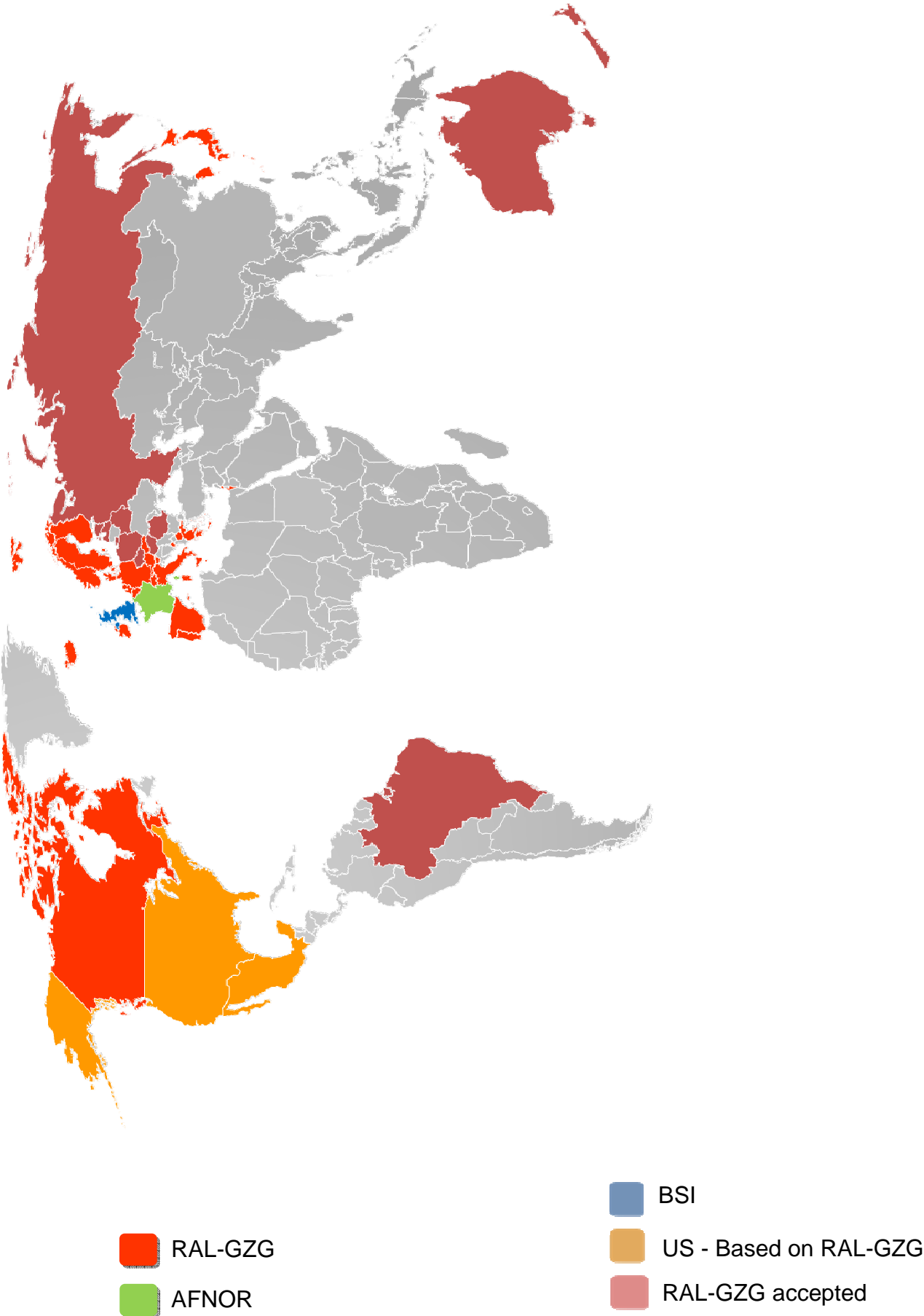
There are several requirements defined in order to provide MCS with exactly defined performances – see later in this document.

After this process, there was an effort in the US-market to get a standard for this area in order to provide the medical society with **real** quality controlled MCS. The end of that process was a compromise without defining a binding standard. The standardization group nevertheless agreed basically on the requirements of the European ENV 12817 (mainly realized in RAL-GZG standard), except from the pressure ranges, historically used in US.

Looking on this situation, the worldwide situation today shows, that either the RAL-GZG standard is used as basic requirement for certifying MCS or at least it builds the common understanding in several countries, that the **German standard guarantees** the highest quality of MCS.

And this now since **nearly 60 years**!!

- **BSI** (blue)
- **RAL-GZG** (red)
- **US - Based on RAL-GZG** (orange)
- **AFNOR** (green)
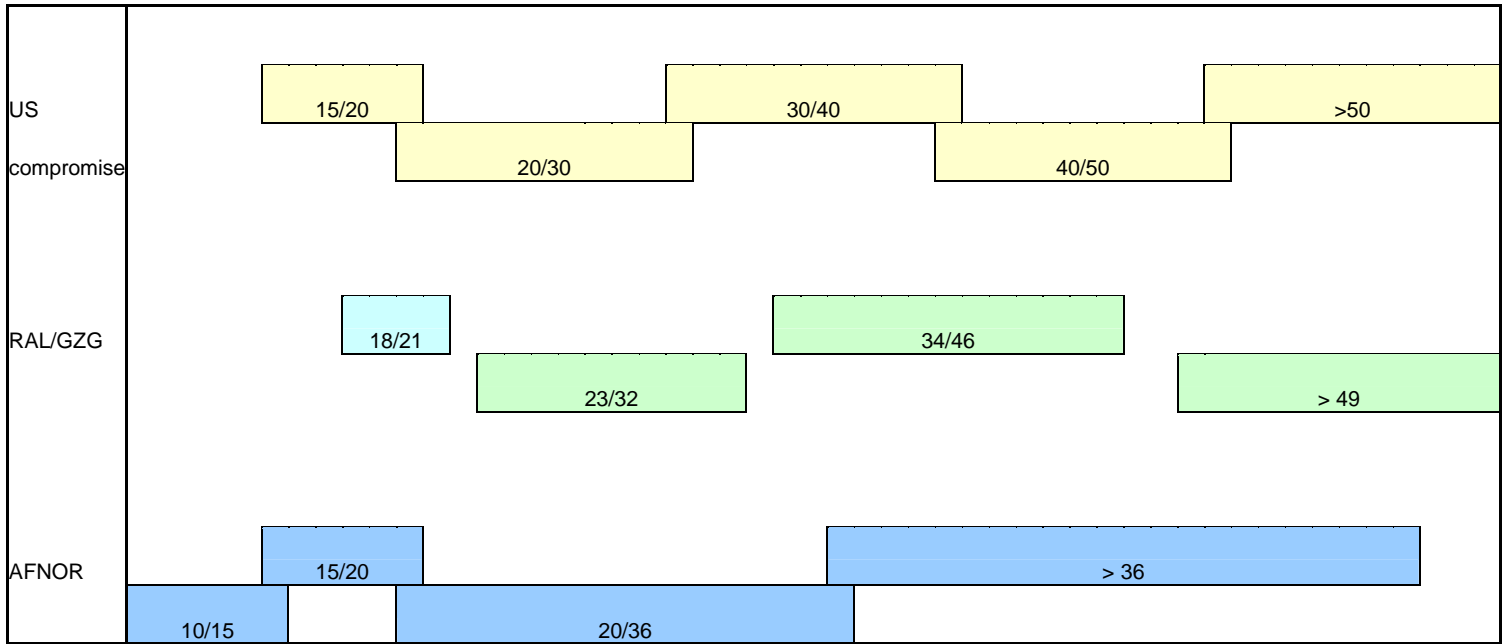- **RAL-GZG accepted** (light red)

I.2. Table of compression values

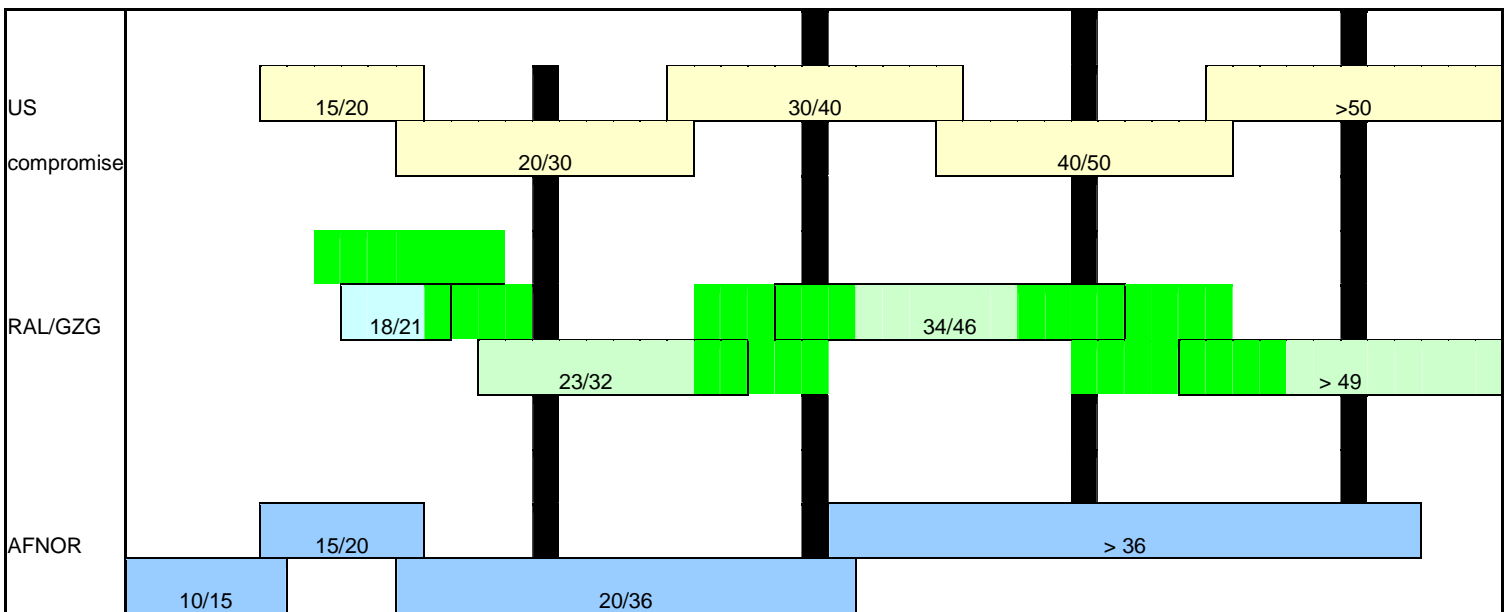You find below a table of the today used different pressure ranges

Compression class (US Standard)	Compression class (AFNOR)	Compression class (AFNOR)	Compression class (RAL - GZG / ENV)	Compression at the ankle 1)	
Ccl	Ccl	Ccl	Ccl	HPa	mmHg 2)
	I légère	10/15			
15/20	II moyenne	15/20	not applicable	20 to 23	15 to 17
20/30			I mild high	24 to 28	18 to 21
30/40	III forte	20/36	II moderate	31 to 43	23 to 32
40/50	IV extra forte	>36	III strong	45 to 61	34 to 46
50 high			IV very strong	65 and higher	49 and higher
			1) The values indicate the compression exerted by the hosiery at a hypothetical cylindrical ankle.		
			2) 1 mmHg = 1,333 hPa.		

I.2.1. Table of compression values (graphically)

| mmHG | 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 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 55 56 57 58 59 60 |

US	15/20 30/40 >50
compromise	20/30 40/50
RAL/GZG	18/21 23/32 34/46 > 49
AFNOR	15/20 > 36
	10/15 20/36

| mmHG | 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 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 55 56 57 58 59 60 |

US	15/20 30/40 >50
compromise	20/30 40/50
RAL/GZG	18/21 23/32 34/46 > 49
AFNOR	15/20 > 36
	10/15 20/36

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The second table shows the effect of the elastic material:

Compression stockings are produced with elastic threads, therefore there **have to be** certain tolerances (marked in green).
In order to have a clear definition, in what range the stocking is supposed to belong, there <u>have to</u> be "gaps" between the pressure ranges.

This is absolutely necessary, because there must be the possibility of quality checks "in the field". With no clear possibility to identify the stocking, it is not clear, in what compression-value range it belongs.
In respect to the costs of a stocking, it is absolutely required, that it must be possible to take samples with the dealer, the pharmacy or a clinic and to test the performance of the sample stocking. This is today only guaranteed by the members of the GZG – on top of the dedication of a yearly recertification of each type of stocking. **Both quality guarantees are unique in the world!**

Otherwise – for example in the US compromise – a stocking with a pressure around 20 mmHG could either belong to 15-20 or to 20-30 mmHG.

In order to be sure to meet the required pressure and to have the medical effect the MCS is supposed to have, a manufacturer certainly tries to produce his product somehow around the middle value of the pressure range.

In the end, this means only slight differences between stockings produced according to the different requirements (middle meridian: black lines).

For example:

The mean value according to pressure range II of the RAL-standard is 27 mmHG, the mean value of the proposed scaling is 25 mmHG. The difference is less than the necessary production tolerance of 10% with elastic threads!

So – why change a scaling with nearly 60 years of good experience and proof of effectiveness?

II.   Testing method and device

In order to have a worldwide understanding of MCS, we first have to define the testing method and the testing device. In the process of standardization in Europe, several testing institutes reported, that it is honestly not possible to find a reliable correlation between the testing devices used today.

II.1.1. Device for definition of measuring points

To check and determine the pressure value of a stocking, you **first** have to define exactly, what area of the stocking you are testing.

The historically used device to find the different measuring point cB, cC etc. or for length lC etc. has been the "wooden leg". It was very difficult to find a way that guarantees reproducible results, because the procedure of applying the stocking to the wooden leg has been very individual.

This was the reason why in the European process the committee agreed on the device "marking board", because the reproducibility was much better and guaranteed similar results in different testing labs.

This device is independent from the condition of the testing person.

Device for identification of measuring points
Recommended device of ENV 12718

II.1.2. Testing device for stockings

In order to fix international pressure ranges it is also necessary to **define the testing procedure and the device**. This has been also a very long – but in the end successful – procedure for the ENV 12718. There have been the

- HOSY System
- Tensile testing device
- HATRA
- today new device: MST

It is well known, that the values you get differ with different devices.

The RAL-Standard still uses the HOSY-System, because in that procedure you are able to respect the influences from one measuring point on the other (similar: MST). With other devices you measure pressure only in one point separate from the others.

II.2. Pressure profile, funnel

In order to provide stockings off the shelf in standard sizes for having the possibility of an immediate treatment or also for having a cost effective treatment, the manufacturers provide stockings in standard sizes. These stockings are supposed to be applied according to so-called tolerance-tables for the measurements of the patient.

The RAL-standard requires a compression profile, that guarantees for all situations the claimed pressure, that means for example for a leg with a high circumference at the ankle and a low circumference at measuring point C. The RAL calls this the "funnel". Here we realize, that the existence of the marking board is a fundamental requirement!
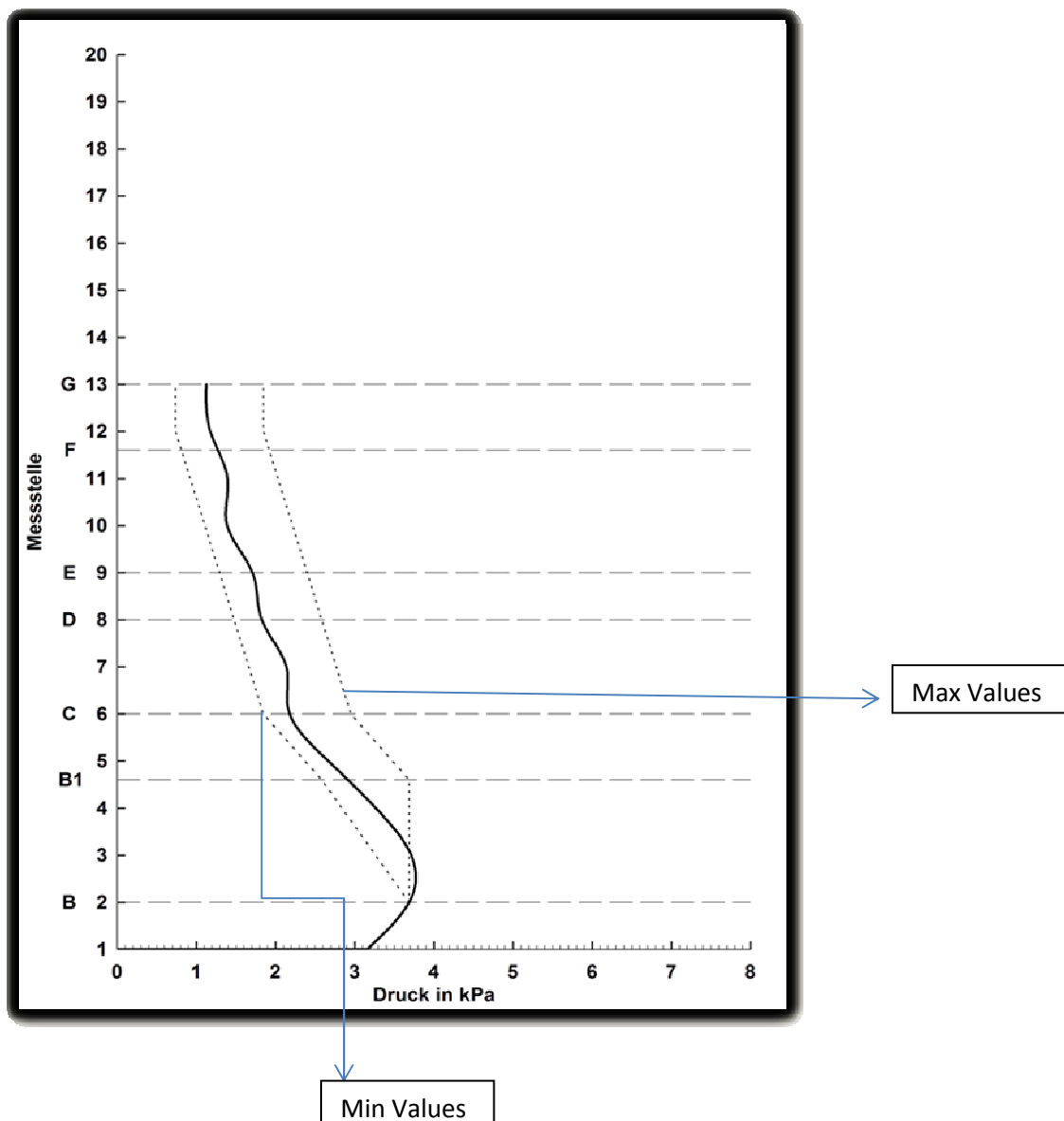
III. Conclusion

Looking at all the different aspects of defining the pressure performance of a stocking, the Gütezeichengemeinschaft medizinische Kompressionsstrümpfe(GZG) and the eurocom are recommending:

1. We have **nearly 60 years of positive experiences** with the pressure ranges of the RAL-standard.

2. The **gaps** in the RAL-Standard are **technically inevitable and necessary.**

3. The **RAL standard is the most modern standard** because of respecting the preliminary European standard ENV 12718.

4. In order to have the possibility of **international comparable medical studies**, the pressure range, the stocking is created for, should be marked on the box and on the stocking.

5. For all **future studies** it is required, that the authors **mention, what pressure range** the used stockings had and according to what standard (so the testing method is clear).

6. In this way, it is not at all necessary to mix up the national existing treatments, manufacturing methods, testing methods and last but not least – reimbursement systems.

IV. __Stiffness__

Stiffness of compression stockings is discussed for many years and found in the end also in the ENV 12718.

In order to define future classification of stiffness ranges, we first have to define the exact testing procedures (again in vitro to make stockings comparable on a neutral basis). There are today different ideas and approaches to solve this problem.

On top we have to understand, what influence the stiffness of a stocking has on the result of the treatment – treatment phlebological or treatment lymphological.

This brings us probably to the necessity of a general investigation and, as a result of that, we are able to define the testing method, value ranges and recommendations.