The importance of measuring the sub bandage pressure and the presentation of a new measuring device.

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Summary

Introduction: compression therapy by means of bandage is extremely effective for venous ulcers on condition that the bandage is applied correctly. If applied too loosely the bandage will be ineffective, if too tight it will cause pain, could be intolerable and even harmful. Checking the sub-bandage pressure is therefore extremely useful but the measuring device must be easy to use and the resulting data accurate and reproducible. The aim of this study is to underline the need of assessing the sub-bandage pressure and to present a new measuring device.

Materials and methods: PicoPress® is a new pneumatic measuring device equipped with an ultra flat probe into which 2 cc of air are inflated before each measurement. As the instrument does not require calibration, a series of successive measurements can be carried out even with the probe positioned under the bandage. Accuracy, linear response at different pressures and reproducibility, have been verified in the laboratory and in vivo.

Results: both in the laboratory in vivo, PicoPress® showed accuracy, linearity with the theoretical pressure values applied and high reproducibility. These parameters are reliable in the devices already available on the market but even more with PicoPress®. The calculation of the Static Stiffness Index was more accurate too.

Discussion and conclusions: there are many indications to measure the sub bandage pressure but accurate and reproducible devices are required. PicoPress® seems to have these characteristics.

Key words: bandage; sub bandage pressure; PicoPress®

Introduction:

Compression therapy by means of an elastic bandage is one of the most effective therapeutic methods in the treatment of venous and mixed vascular ulcers of the lower leg that represent 80-90% of all ulcers (1,2).

The elastic bandage must be applied correctly to be effective while, very often, it is applied in an improper way: too loose or too stretched (3).

In the first case the pressure exerted by the bandage (interface pressure) will result too low both in the supine and standing position and therefore ineffective to counteract both standing and working venous hypertension. The Static Stiffness Index, an important indicator of the bandage performance (4,5), will also result unreliable.

In the second case the bandage will provide a very high pressure and will be painful; it could also be harmful and cause skin damage because of a too high pressure.

Therefore measuring the sub-bandage pressure and calculating the stiffness is strongly recommended (6).

During an International Consensus Meeting (Vienna 2005) the recommendations for the measurement of the interface pressure and the calculation of stiffness were defined (7).

In particular, in the section "measurement techniques" an "ideal" instrument is described. It should be easy to calibrate before each measurement; have an external computer connection for the continuous measurement of pressure and a high sample rate during movement; support several sensors for simultaneous measurements in different points.

With regards to the sensor, it should be thin (no more than 0.5 mm) and flexible; have an adaptable area for different applications (leg, hand, finger): small "for mapping of a circumferential pressure pattern"(7), or bigger (• 5 cm) for measuring the pressure of larger areas; not cause irritation when in contact with the skin for long periods.

In conclusion the device should be long lasting, reliable, accurate, electronically simple, low cost and unaffected by changes of temperature and humidity; it must have an operative range in accordance with the biological parameters and a linear response to the pressure applied.

Currently two devices seem to have many of these characteristics: the Kikuhime® (TT Medi Trade, Soleddet 15, DK 4180 Soro) and the SIGaT® tester (Ganzoni-Sigvaris, St Gallen, Switzerland). The

Kikuhime®, however does not have an external connection and cannot be used for dynamic tests; furthermore its calibration does not allow a series of sequential measurements because the device cannot be re-calibrated under the bandage.
The SIGaT® does not present these problems but it is very difficult or impossible to find on the market.
The aim of this study is to emphasize the need for measuring the sub bandage pressure in different clinical and experimental situations and to present a new measuring device.

Materials e methods:
PicoPress® is a pneumatic measuring system fitted with an ultra flat probe (mm. 0.22) with a diameter of 5 cm. and a surface of 19,62 cm^2 in which, before the measurement, 2 cc of air are inflated by means of an electronically controlled syringe integrated in the system. Calibration can also be carried out under the bandage and this allows a series of sequential measurements. The data can be stored in the device's memory and then transferred to a computer. The system can be connected to a computer by a USB port for continuous pressure measurement during dynamic tests.
During the validation process we had to control the correspondence between the values measured by the device and the pressure applied; this was done in the laboratory and in vivo.
a) Tests in the laboratory.

- We fixed the sensor to a rigid tube 11 cm. in diameter and applied the cuff of a sphygmomanometer above it; the cuff was inflated to a pressure varying from 20 to 120 with steps of 10 mm Hg. while checking the values provided by PicoPress®. This method was considered unsatisfactory because, at low pressure level, it is greatly influenced by the force of closure of the cuff.
- We made an aluminium disk of the same dimensions as the probe and a series of disks with known weight. By superimposing these disks one on top of the other on the aluminium disk we were able to apply a series of theoretically calculated pressures by using the formula: Pressure = Weight/Surface. The range of pressure was from 30 to 102 mm. Hg. We compared this theoretical pressure with the pressure given by the device after having inflated 1.5 – 2 – 2.5 cc. of air in the probe. The measurements were repeated three times in order to calculate the reproducibility.
- We simultaneously fixed the sensors of the three devices (Kikuhime®, SIGaT®, Picopress®) on the rigid cylinder and on top we placed a pneumatic cuff connected to a mercury manometer. This way we created the same experimental condition for all three devices, applied pressure varying from 20 to 120 mm Hg (with steps of 10) and checked the corresponding values provided by the three devices (accuracy). This test was repeated three times at 1 minute intervals with and without recalibrating the devices between each test to calculate the reproducibility.

b) Test in vivo

- We fixed in succession, the sensors of the three devices to the calf at point B1 (medial aspect of the calf where the tendinous part of the gastrocnemius muscle turns into its muscular part) and superimposed the same pneumatic cuff (applying a pressure from 20 to 120 mm. Hg with step of 10) in order to check accuracy and reproducibility in vivo.
- With the cuff pressure of 50 mm. Hg. in the supine position we also asked the patient to stand up and measured the standing pressure and the Static Stiffness Index.

The graphics were created with GraphPad Prism4.

Results:
In the laboratory:

- there is no significant difference between the theoretical pressure value applied by superimposing several weights and the value measured by PicoPress®a (accuracy) when a volume of air varying from 1.5 to 2.5 cc. (Fig. 1) is inflated into the probe; the best results are obtained when using 2 cc of air and for this reason we have chosen this volume of air. In this test the device has demonstrated a noticeable accuracy, linearity with the theoretical pressure values applied by superimposing different weights and reproducibility (Fig 2). Also when applied to a rigid tube, the accuracy, the linearity with the mercury manometer and the reproducibility remained excellent (Fig. 3).

In vivo:

- when applied to the leg, the test with the pneumatic cuff confirmed a high accuracy, linearity and reproducibility. These parameters, already reliable with Kikuhime® and SIGaT®, are even more so with PicoPress® (Tab 1 e Fig.5, 6).
- by applying (with the pneumatic cuff) a pressure of 50 mm Hg. in the supine position the pressure measured by Kikuhime® was 49, by SIGaT® 46 and by PicoPress® 50 (average of 3 measurements); in the standing position the pressure applied by the pneumatic cuff raised to 85; this standing pressure corresponded to 78 (average of 3 measurements) when measured by Kikuhime® (SSI 29), 76 by SIGaT® (SSI 30) and 85 by PicoPress® (SSI 35). The variability of SSI is shown in Tab. 1.

Discussion: in our theoretical/practical courses on elastic compression we always ask the participants (doctors and nurses) to apply a bandage and to control the applied pressure with a measuring device; many of them despite having considerable practical experience in bandaging, do not apply the bandage with the pressure recommended by the manufacturer and the most common error is to apply it with a to low pressure.

This emphasizes once again the importance of applying a bandage "guided" by the measurement of the pressure we are exerting especially when learning how to apply a particular bandage. Therefore there are several indications to use a sub bandage pressure measuring system (7):

- verify the correct application of the bandage by measuring the pressure that the bandage must exert (both in the horizontal and standing position) to produce its haemodynamic effectiveness. This is also very useful in order to learn the bandaging technique and the right stretch to apply to the material (e.g. are we applying a decreasing pressure?).
- correlate the bandage pressure with the clinical result.
- test the bandage's characteristics in vivo and understand what their impact on venous hemodynamic will be. This is particularly significant when testing new compression systems.
- classify the bandages and the bandaging system: e.g. elastic and non elastic. This is very important for multilayer bandages where the various bandages produce a combined result independent of the single bandages used. For example: only through careful measurement of the interface pressure and stiffness were we able understand that Profore®, made up of four elastic bandages and therefore considered as being elastic, is in fact a non elastic bandage (8): in the same study we documented that by modifying 1 or more layers of the multilayer bandage the characteristics of the final bandage are completely modified.
- assess the bandage pressure and its performance over a period of time to establish the right time to replace it.
- classify the stockings by the pressure they reach and not by class.
- control the pressure of the "stocking kits" for the treatment of vascular ulcers that various companies put on the market.
- apply the bandages with the same pressure when joining multi-centre studies on compression. There have been so far significant limits in compression studies: what is the pressure reached by the bandage? were all the bandagers equally able to apply the agreed pressure?
- verify the skill and the possible progress of the students attending the bandaging courses.

We would like to underline that there is another possible clinical indication for PicoPress®: as it is extremely easy to use the device could be used directly by the patient on a daily basis to monitor the pressure exerted by the bandage and therefore its continuous therapeutic effectiveness (due to the pressure). In fact it is well known that especially when applied to a leg with oedema the bandage rapidly looses pressure and therefore its effectiveness as the oedema heals. The patient could be advised to return and have the bandage replaced when the pressure is lower than a predetermined values. On the other hand a badly applied bandage or the non-adherence of the elastic compression on the patient's part can worsen a leg oedema that can be indicated by an anomalous behaviour in the interface pressure values.

Provided that measuring the sub bandage pressure is so important it is absolutely necessary that the accuracy and reproducibility of the measuring devices are carefully tested both in the laboratory and in vivo especially when dealing with new devices.

Our results demonstrate that PicoPress® has higher accuracy and reproducibility compared to other good quality devices based on the same method of measurement (pneumatic).

At present time the possibility of storing all measured pressure values and subsequently download them onto a microprocessor is a unique characteristic of PicoPress® providing useful information on the overall performance of the bandage and its effectiveness over time.

Last but not least, the possibility of using the continuous output of the pressure data, when connected to a computer, allows us to conduct dynamic tests without any limit of time.

In conclusion there are many indications to measure sub bandage pressure and they could increase in the next future (e.g. medical-legal implications?).

PicoPress® for its mentioned characteristics offers new opportunities for studying interface pressure and overall performance in the elastic compression therapy previously precluded.

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Tab. 1: Variability in the different devices in different conditions tested: on a rigid plastic tube 11 cm. in diameter (with and without recalibrating the probe), on the leg and during the Static Stiffness Index measurement; the tests were repeated at 1 minute intervals.

	Rigid tube no recalibration	Rigid tube recalibration	Leg recalibration	SSI
Kikuhime®	2.9±1.6	0.8±0.8	9.1±2.9	0.4±0.6
SIGaT®	1.5±1.2	0.7±0.7	0.2±0.5	0.1±0.3
PicoPress®	0.4±0.5	0.7±0.8	0.1±0.2	0.1±0.1

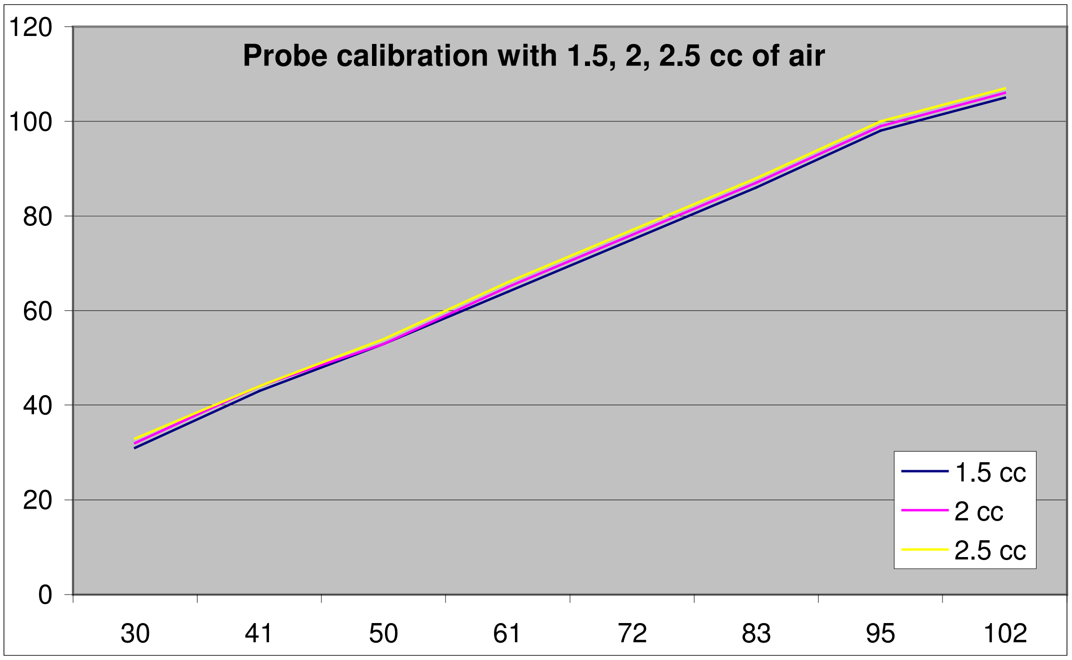

Fig. 1: probe calibration in the laboratory with 1.5, 2, 2.5 cc. of air, superimposing the known weights that produce a theoretical weight varying from 30 to 102 mm. Hg. The pressure was obtained from the calculation: Pressure = Weight/Surface.

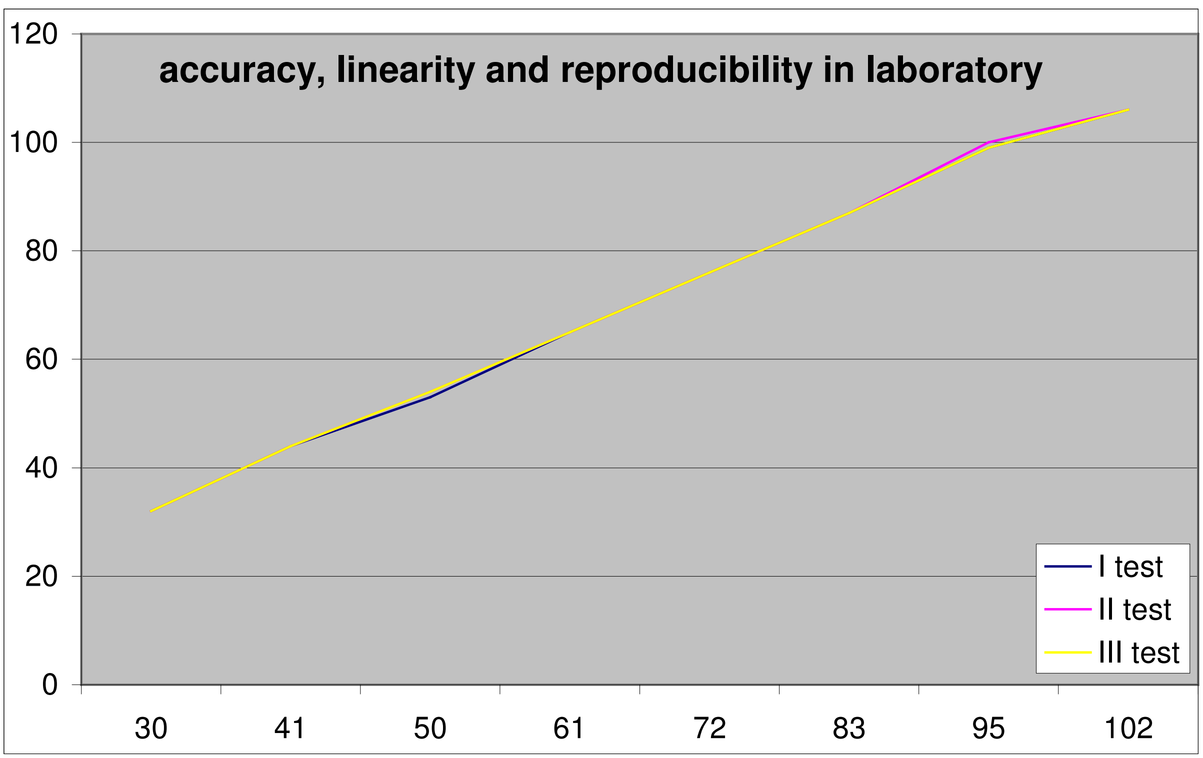

Fig. 2: accuracy, linearity and reproducibility in the measurements carried out in the laboratory by superimposing known weights with a theoretical pressure varying from 30 to 102 mm. Hg. obtained from the calculation: Pressure = Weight/Surface.

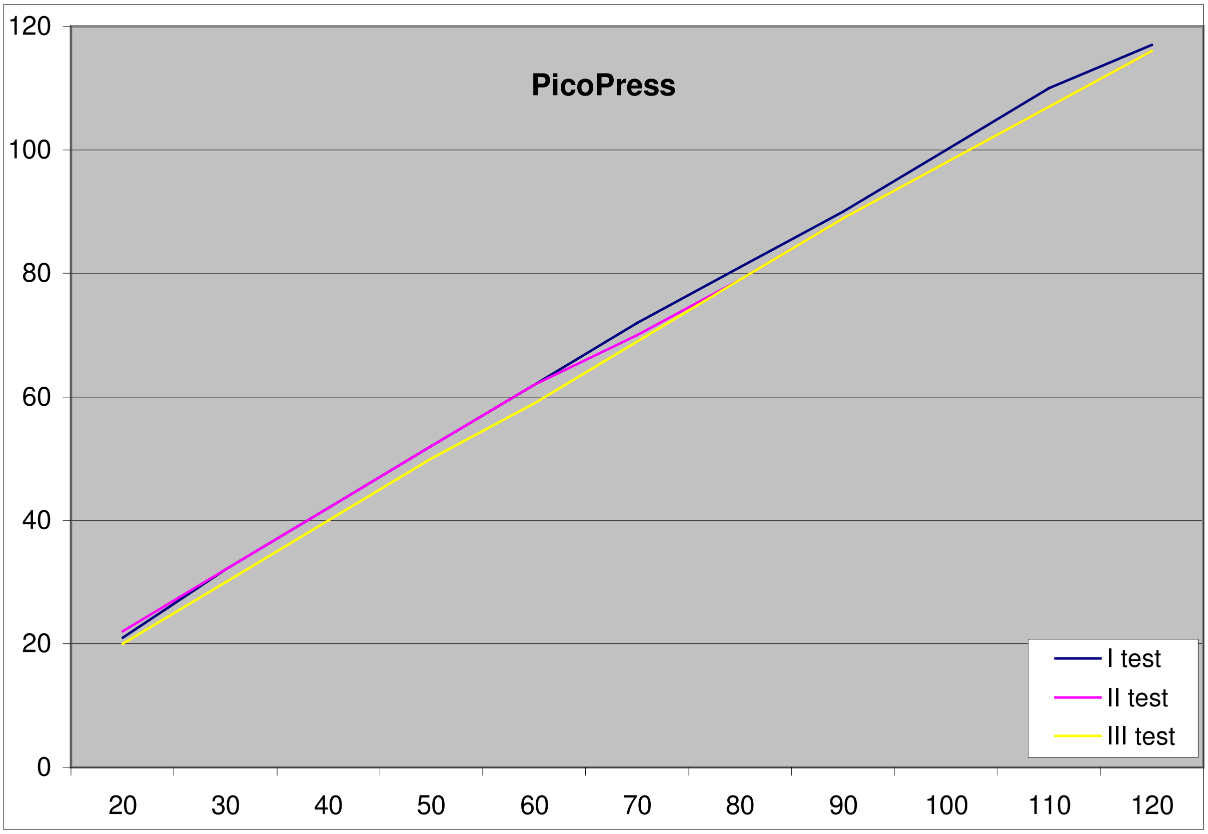

Fig. 3: accuracy and linearity with the pressure of the Hg manometer that produces a pressure of 20 to 120 mm. Hg. and reproducibility of PicoPress®; probe fixed on a rigid tube 11cm. In diameter

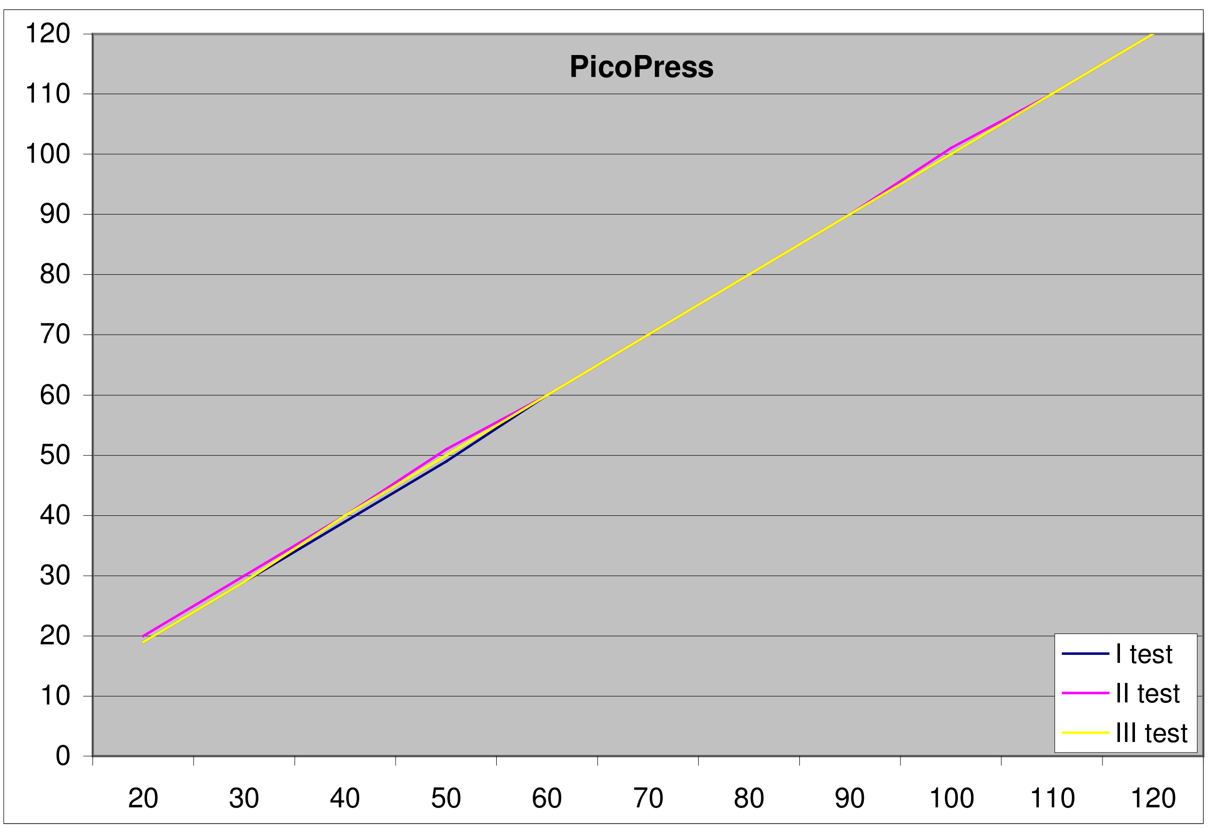

Fig. 4: accuracy, linearity with the pressure of the Hg. manometer that exerts a pressure varying from 20 to 120 mm. Hg. and reproducibilty of PicoPress® with the probe fixed to the leg.

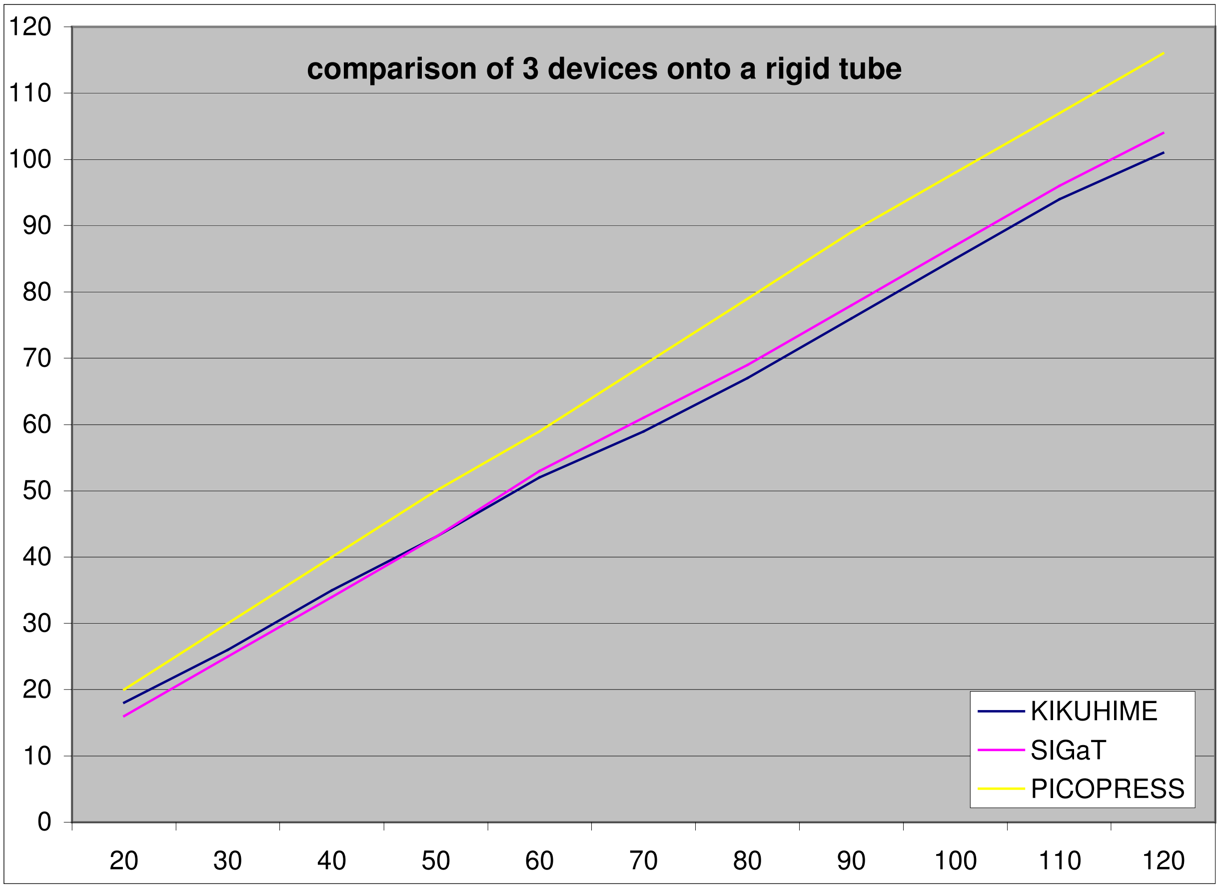

Fig. 5: comparison between Kikuhime, SIGaT, PicoPress® (average of 3 measurements) for measurement accuracy with the probe fixed onto a rigid tube; the manometer superimposed on the probe exerts a pressure varying from 20 to 120 mm. Hg.

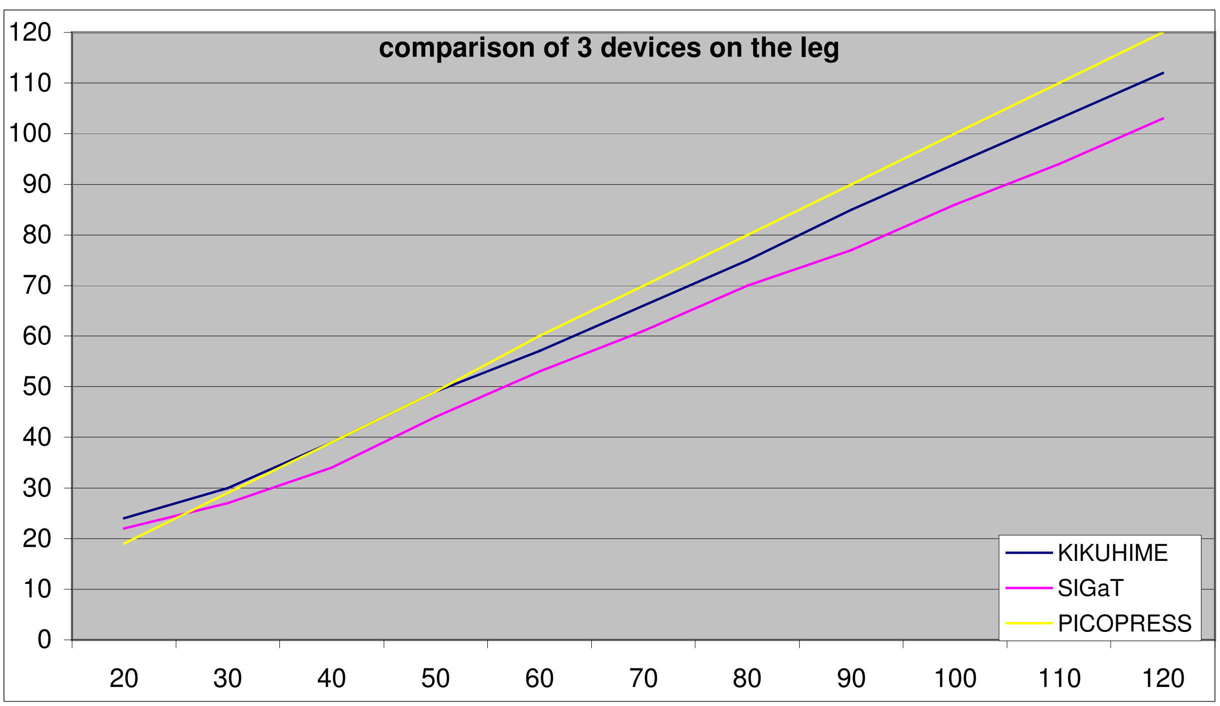

Fig. 6: comparison between Kikuhime, SIGaT, PicoPress® (average of 3 measurements) for measurement accuracy with a probe fixed on the leg; the manometer superimposed on the probes exerts a pressure varying from 20 to 120 mm. Hg.