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The measurement of interface pressure applied by sports compression garments: a comparative study of two portable devices

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## Abstract

The interface pressure applied by compression clothing is an important measure in evaluating the efficacy of the bio-physical impact of compression. The aim was to compare two portable pneumatic pressure measuring devices (PicoPress and Kikuhime), against a non-portable, Hohenstein System (HOSY) reference standard, used by medical regulatory agencies. Interface pressure obtained *in-vivo* (calf) by the PicoPress and Kikuhime, were compared with HOSY. The mean bias and limits of agreement indicate the PicoPress satisfies the *a priori* thresholds for acceptable validity at the posterior and lateral orientation with calf stockings (-0.4[-3.3;2.5]; 0.5[-3.4;4.4] mmHg) and tights (0.2[-4.7;5.1]; 1.2[-0.3;5.4] mmHg) respectively. The Kikuhime did not satisfy thresholds for acceptable validity at any orientation, overestimating the pressure compared with HOSY. We recommend using the PicoPress, specifically at the posterior or lateral aspect of the calf. This is of particular relevance when the hosiery is applying relatively low levels of pressure, applicable to sports compression.

**Keywords:** pressure device, compression clothing, measurement and verification, bias, validity

## ***Introduction***

Compression garments are popular clothing choices among recreational and professional athletes during and after exercise. These garments have been shown to enhance athletic performance and accelerate recovery following strenuous exercise (Hill et al. 2014, Engel et al. 2016).

Despite the prospective benefits, little is known regarding the optimal ‘interface-pressure’ a compression garment should apply to a particular limb, to produce the greatest athletic benefit (Brophy-Williams et al. 2013). In contrast, the application of pressure to the lower extremities via tight fitting, elastic garments, is extensively researched in the clinical field and is part of standard care in patients with chronic venous insufficiency and lymphatic disease (Parsch 2012). Unlike sports compression garments, medical compression stockings undergo a standardised assessment procedure to quantify the pressure applied; therefore recommendations can be made in relation to the treatment protocol including a desired interface pressure (Stout et al. 2012). Such recommendations cannot be made with regard to athletic performance or recovery due to a number of methodological limitations.

Heterogeneity of published literature relating to research design is commonplace, including but not limited to; variation in garment design, duration of wear, type of garment and limb coverage. Furthermore, authors fail to measure the pressure of garments (Ménétrier et al. 2011) or values are provided by the garment manufacturer and are not directly measured (7).

If garment pressure is reported, the measurement devices used by researchers vary greatly, ranging from portable units and force-transducers to medical-grade devices. Until the measurement of the interface pressure elicited by sports compression garments is standardised, developing a consensus and furthering the field regarding dose-response will continue to be a challenge. The reporting of pressure, obtained directly by research scientists and clinicians would progress the field of sports compression and enable the investigation of

optimal interface pressures (dosage) and gradients required for improved performance and recovery outcomes (Brophy-Williams et al. 2013).

A critical aspect of effective compression therapy is that the appropriate level of pressure is applied to the limb. Portable pressure sensing devices offer quick, low cost, *in-vivo* assessment during dynamic movement. Validation of measures made *in-vivo* by these devices is necessary to establish preferable devices and inform best practice.

Current guidelines for the assessment of *in-vivo* interface pressure list 22 portable devices (Partsch et al. 2006), including pneumatic, piezoelectric, resistive and capacitive sensors. The authors state that the quantification of interface pressure will enable comparisons between clinical trials to assess dosage and the correlation with clinical and physiological measurements. However, many of the portable devices listed in the guidelines have not been validated nor compared with alternative methods of pressure assessment i.e. fixed, non-portable reference devices.

Portable devices must undergo rigorous assessment to identify if variation exists between units. Furthermore, the accuracy of these devices versus a clinically relevant reference standard is necessary to provide a comparative assessment of performance. By identifying portable devices with acceptable accuracy, guidelines can be developed further and ultimately assist with understanding the bio-physical impact of interface pressure on physiological response and performance outcomes.

In light of this, we assessed the criterion validity of interface pressure measures from two commercially-available devices *in-vivo* by comparing pressure measurements against a reference standard.

## 91 *Methods*

92 We compared two portable devices (Kikuhime and PicoPress) commonly used with a  
93 ‘reference standard’ system (HOSY). The HOSY is a mandatory testing system for interface  
94 pressure compliance, required for the classification and certification of medical compression  
95 hosiery. Two warp knitted compression garments were used, including calf- stockings,  
96 covering the ankle to below the knee and full-length tights, covering the body from ankle to  
97 waist. The fabric properties of the two compression garments were investigated for  
98 performance including fabric weight using Sartorius balance. Fabric thickness was measured  
99 using a Shirley thickness gauge (Mitutoyo, Japan) (BS EN ISO 5084 1997). Fabric count  
100 (number of wales and courses) was measured with a simple eye piece lens that had 5x  
101 magnification. Stretch and recovery was also evaluated to determine the stretch  
102 characteristics of fabric in length and cross wise direction using Fryma Extensiometer (BS  
103 EN ISO 4294 1968) and 3 kg load was applied (Table 1). All fabrics were conditioned in  
104 standard laboratory conditions ( $20 \pm 2^{\circ}\text{C}$ ,  $65 \pm 0\%$  relative humidity) for 24 h prior to the  
105 fabric tests (BS EN ISO 139 2005). Garments did not undergo pre-treatment washing prior to  
106 or between measurements.

107

108 **\*\*\*\*Table 1 \*\*\*\***

109

## 110 **Reference Standard Device**

111 The Hohenstein System (HOSY, Bönningheim, Germany) is used to measure interface  
112 pressure and determine if garments meet the German ‘medical compression hosiery’  
113 standards RAL GZ 387/1,2 (RAL-GZ 387/1 2008). The HOSY measures interface pressure  
114 (maximum resolution of 0.01 kPa), wear stretch (elongation %), tensile force (N/cm) and

residual pressure (%). The device (Figure 1) comprises twenty individual tensile testing ‘rods’, each with a width of 50 mm. The force measurement takes place at the fixed clamp rod via short-distance electronic transducers. The measurement principle of the HOSY is based on the force exerted by compression fabric in circumferential direction, when stretched in a longitudinal direction to a specified length and subsequently in a transverse direction according to its size. For further details of the HOSY see the RAL GZ 387/1 standards (RAL-GZ 387/1 2008).

### ***Calibration***

Pressure was measured on both garments at the location that corresponded with the maximum calf girth. The maximum calf girth (commonly referred to as ‘location C’ in published guidelines (Partsch et al. 2006) and standards (RAL-GZ 387/1 2008) was chosen as interface pressures exerted in this region are commonly cited in both medical (Mosti and Partsch 2013) and sports compression literature (Dascombe et al. 2011). Prior to the measurement process, the ankle location (also referred to as ‘location B’) was manually identified on both garments and subsequently location C is marked at a height of 200 mm above this point. Calibration of the HOSY device takes place annually by attaching a 5 kg weight to each of the 20 tensioning clamps.

### **Reference Standard Protocol**

A qualified technician attached the garments and operated the HOSY device in a controlled laboratory environment ( $18 \pm 0^{\circ}\text{C}$ ,  $65 \pm 0\%$  relative humidity). Briefly, two clamps held the bottom of the garment in place (Fig 1.a) with the remaining garment placed in each fixed clamp rod (Fig 1.b). Once correctly fastened into the HOSY, the distance of location C (Fig 1.c) from the bottom clamps was entered into the operating computer. The garment was stretched (loaded) and relaxed (unloaded) six times in the cross-wise direction. Each loading

cycle extended the garment to the leg circumference. During the final loading phase the tensile force at each clamp was measured. The computer program calculates how far each tensioning clamp moves to achieve the desired circumference and the resultant elongation of the hosiery so that all clamps reach this position simultaneously after 20 seconds (RAL-GZ 387/1 2008). A minimum and maximum leg circumference of 370 and 400 mm at Location C was used for this investigation. Initially, the test-retest reliability of the HOSY was determined by measuring the tights twice. Between each assessment, the garment was unclamped and removed from the HOSY and reapplied by a qualified technician. The technical error of measurement (TEM) and coefficient of variation (CV) reported for the HOSY was 0.5 mmHg and 5.8% respectively. For all data analysis referring to the tights, the mean of the two repeated measures at minimum and maximum elongation was used. Calf stockings were measured on one occasion only.

Compression classification standards vary by country (Neumann et al. 2016, Nicolaides et al. 2018) but a unified classification of mild (10-19 mmHg) and moderate (20-29 mmHg) compression is proposed. With this in mind, when comparing portable devices with the reference standard and determining device validity, *a priori* thresholds are required. The criteria for acceptable validity was defined as a systematic bias of  $\pm 2$  mmHg and a limit of agreement  $\pm 5$  mmHg (of the mean bias). A bias of  $\pm 2$  mmHg accounts for technical error of the HOSY and the resolution of the portable devices. Limits of agreement of  $\pm 5$  mmHg identify the variability of the device vs. the reference standard accounting for the 10 mmHg classification range.

\*\*\*\*Figure 1 \*\*\*\*



## **Portable Devices**

The PicoPress (Microlab, Padua, Italy) is a battery-operated device and comprises a 50 mm circular sensor manufactured from 200  $\mu$ m thick flexible plastic tubing attached to the base unit. The Kikuhime (Meditrade, Soro, Denmark) comprises 30 x 38 mm oval sensor made from 3 mm polyurethane foam and connected to a transducer via silicone tubing. Both the PicoPress and Kikuhime operate through pressure being applied to the sensor, thereby displacing the air and acting on the pressure transducer housed in the battery-operated units. The PicoPress can measure pressure up to 189 mmHg; and the Kikuhime up to 120 mmHg both with a resolution of 1 mmHg

## ***Calibration***

We calibrated devices according to the manufacturers' instructions. A self-calibration procedure is performed when switching the PicoPress unit on. Digital prompts on the device outline the calibration procedure by inserting 2 ml of air into the sensor, setting the unit to read 0 mmHg when hanging freely. In the same position, the Kikuhime requires the user to manually zero the potentiometer. In light of the Kikuhime calibration method and unit resolution, there is an inherent calibration offset error of up to  $\pm 0.49$  mmHg (Thomas 2014).

## **Portable Device Protocols**

### ***Water-column method***

To certify measurement validity and linearity from air-filled portable pressure systems such as the PicoPress and Kikuhime devices, the water column method provides a quick and inexpensive method making use of hydrostatic pressure.

As previously described (Brophy-Williams et al. 2013), by placing the pressure sensor flat at the bottom of a water column, and filling the column with a specific volume of fluid, a

known pressure will be placed on the sensor. Water depths were calculated to determine incremental pressures of 5 mmHg, from 5 to 25 mmHg, whereby the depth measurement was taken from the lowest point of the meniscus and the middle of the sensor. The depth of water (mm) to achieve the target pressures was calculated using the following equation,

$$a \text{ mmHg} = b \text{ mmH}_2\text{O} \times [7.356 \times 10^{-2}]$$

Five repeated measures were undertaken for each depth, which required the removal of water from the column each time, before returning it to achieve the predetermined depth.

### *In-vivo protocol*

Twelve recreationally active males (mean  $\pm$  SD: age  $19.1 \pm 1.0$  y, body mass  $74.6 \pm 4.8$  kg, stature  $1.77 \pm 0.05$  m) gave written informed consent to participate in the study in accordance with Declaration of Helsinki. The ethical committee at the University of Essex approved the current investigation.

All testing was performed in a controlled laboratory environment ( $18 \pm 0^\circ\text{C}$ ,  $50 \pm 2\%$  relative humidity). Upon arrival, the circumference of the participants calf was measured (location C =  $380 \pm 12$  mm). All participants possessed a maximum calf girth between 370 and 400 mm. To ensure that garment Location C was accurately positioned at the correct limb height in-situ, position-markers on each garment were aligned with anatomical markings at the maximal calf-girth. The anterior, posterior, medial and lateral aspect were identified with a segmometer (Cescorf, Porto Alegre, Brazil). Limb width was measured at each orientation and the mid-point marked as the location for the portable device sensor. Using the PicoPress and Kikuhime devices, interface pressure at the anterior, posterior, medial and lateral aspect around the maximum calf girth was measured. The investigator placed the air-filled sensor of each device between the garment and skin, ensuring that the sensor remained flat.

Participants stood upright with feet shoulder width apart during all measurements. Garment order was determined using a balanced two-Latin square design to minimize device and orientation order effect. For each anatomical site, three repeated measures were obtained at 30-second intervals.

### **Portable Devices Data Treatment**

*In-vivo* interface pressures were measured at four anatomical orientations and a fifth value calculated as the average of all four measures (i.e. lateral + medial + anterior + posterior / 4 = mean of four orientations ( $\bar{x}$ )). A Pearson's Product Moment correlation was used to analyse the linearity of the PicoPress and Kikuhime against the water column reference values. Data analyses were conducted using Graphpad Prism 7 (Graphpad Software, San Diego, California) and reported as mean  $\pm$  standard deviation (SD) unless otherwise stated.

### **Data Analysis Agreement**

Prior to comparing *in-vivo* portable devices with a reference standard, interface pressures must be established for each participant for the reference device. The HOSY does not measure pressure directly applied to the individual, instead, pressures are determined by elongating the garment to a pre-determined length, simulating the circumference of a limb. Therefore, a simple linear regression was calculated to predict interface pressure based on the HOSY pressure values at minimum and maximum elongation. As the theoretical circumference increased by 10 mm, interface pressure applied by the stockings increased by 0.86 mmHg between 370 and 400 mm (19.3 – 21.9 mmHg;  $y = 0.87x - 12.77$ ). The interface pressure of the tights increased 0.62 mmHg for every 10 mm increase in circumference (12.5 – 14.4 mmHg;  $y = 0.62x - 10.32$ ). The regression equation was then used to determine individualized pressure from the reference standard by factoring the individuals' calf circumference. Calculation of the estimated HOSY interface pressure for each participant

produced a mean [95% CI] pressure of 20.1 mmHg [19.5, 20.8] and 13.1 mmHg [12.6, 13.6] for the stockings and tights respectively. Having established reference values, comparisons can now be made with the portable, *in-vivo* devices. Normalcy was assessed using the Kolmogorov-Smirnov test. The difference between the individualised HOSY values and portable device pressures were assessed for significance using a one-sample t-test (target value = 0). The method proposed by Bland and Altman (Bland and Altman 1986) was used to assess agreement between the HOSY and each portable device at all anatomical orientations. The difference between devices was calculated as the interface pressure (mmHg) of the HOSY minus the portable device (PicoPress or Kikuhime), therefore providing bias values and upper and lower limits ( $\pm 1.96$  SD). Difference was plotted as a function of the HOSY reference value (Krouwer 2008) and linear regression used to calculate slope ( $B$ ) of the HOSY versus portable device interface pressure. Analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 25 (SPSS Inc., Chicago, Illinois) and the level of significance was set at  $\alpha = 0.05$ .

## Results

The PicoPress and Kikuhime interface pressures produced a positive correlation when compared with the criterion water pressure. Correlation coefficients calculated to evaluate the linear association between the pressure applied by the water column and two portable pressure devices are shown in Figure 2.

\*\*\*\*Figure 2 \*\*\*\*

255 The interface pressures obtained by the reference standard, PicoPress and Kikuhime for the  
256 stockings and tights are shown in Table 2 and 3 respectively.

257 The PicoPress produced values which agreed with the reference standard when measured at  
258 the posterior (-0.4 [-3.3; 2.5] mmHg) and lateral (0.5 [-3.4; 4.4] mmHg) orientations (Table  
259 2). The positive mean bias values for measures at the anterior and medial orientation (Table  
260 2) show PicoPress produced systematically higher values when compared with the reference  
261 standard, Table 2 shows the Kikuhime produced values that were significantly higher  
262 ( $P<0.01$ ) compared with the reference standard at all measurement orientations, with a bias  
263 ranging from -6.1 - -17.6 mmHg.

264 Table 3 shows the between-device agreement for tights. When compared with the reference  
265 standard, the PicoPress (Table 3) produced significantly higher values at the anterior  
266 orientation ( $P<0.01$ ), but not at the posterior, medial and lateral orientation. Of the  
267 orientations, the posterior, lateral and mean satisfied the *a priori* thresholds for acceptable  
268 validity, reporting a bias of 0.2 [-4.7; 5.1], 1.2 [-0.3;5.4] and -0.6 [-4.5; 3.4] mmHg  
269 respectively. The Kikuhime produced interface pressure values that were higher than the  
270 HOSY. Regardless of orientation the Kikuhime had a mean bias  $>2$  mmHg at all orientations  
271 other than the medial aspect. At the medial orientation, the mean bias was 2.0 mmHg but the  
272 limits of agreement were unacceptably wide and did not satisfy the validity threshold.

273 Of all the measurements obtained using both portable devices, the unstandardized slope  
274 coefficient produced values ranging from -.02 – 2.4. With the exception of the posterior  
275 orientation using the Kikuhime with calf stockings, all remaining slopes were positive. At the  
276 posterior and lateral orientation, the PicoPress satisfied the validity thresholds with both  
277 garments, demonstrating a small bias, acceptable limits of agreement and a negligible slope.

This means the PicoPress, at two specific orientations, is an accurate proxy measure for interface pressure when compared with the reference standard.

\*\*\*\*Table 2 \*\*\*\*

\*\*\*\*Table 3 \*\*\*\*

## ***Discussion***

We investigated the validity of two portable pressure measurement devices. First, pressure values reported by two portable devices were compared with hydrostatic pressure using a water column method. Second, the two portable pressure devices were compared against reference standard values analogous to those used to determine the classifications of medical compression hosiery. In agreement with previous studies using the water column method (Van den Kerckhove et al. 2007, Brophy-Williams et al. 2013, Chassagne et al. 2015) we confirmed the Kikuhime and PicoPress devices produced reliable in-vitro measures of hydrostatic pressure (Figure 2). However, this method in isolation does not ensure validity *in-vivo* as measurement error is the sum of instrumental error and the geometry / mechanical properties of the interface surface. The water column method is undertaken with the sensor in a flat position, whereas *in-vivo* measures are commonly taken at locations where the surface is curved, potentially impacting upon the pressure sensor performance (Thomas 2014). At best, this technique offers the user a simple tool to assess unit precision and identify if inherent malfunctions with the pressure device exist. However, the water column method

should not be used in isolation to determine the performance of a portable pressure monitor and its comparability with alternative garment pressure sensing devices.

The present *in-vivo* assessment confirmed the extent to which the point pressures vary at different orientations. The results are similar to that previously reported, in that interface pressure at the anterior orientation of the lower leg is greatest (Veraart et al. 1997, Liu et al. 2006, Rong et al. 2007). This is likely due to variation in the anatomic structure and shape of individual human legs. According to Laplace's law, the pressure exerted by a compression garment is inversely proportional to the radius of curvature at a given location. It therefore follows that pressure applied at the tibialis anterior muscle will result in the highest circumferential pressure due to a smaller radius of curvature, when compared with the larger radius of the gastrocnemius (medial, lateral and posterior location).

The PicoPress showed acceptable agreement for posterior and lateral measures of interface pressure made in both garments. This prominent finding regarding device performance and location of assessment is important to advance the standardisation of compression testing. In contrast, the Kikuhime overestimated interface pressures in both garments and at all anatomical sites. Under a sphygmomanometer cuff at 20 mmHg, the Kikuhime has previously reported a pressure ~25 mmHg (Mosti and Rossari 2008). The Kikuhime systemic overestimation of interface pressure may misclassify compression hosiery. . However, at 30 – 50 mmHg both devices reported accurate and matching values (Mosti and Rossari 2008). The validity of devices at lower pressures is important when assessing sports compression garments which typically produce interface pressures of ~10 – 30 mmHg (Beliard et al. 2015, Hill et al. 2015). Differences in the size and shape of the air-filled sensors used in both devices might explain the observed bias. The PicoPress uses a circular sensor 40 mm in diameter whereas the Kikuhime uses smaller (38 x 30 mm) oval sensors with a smaller area (895 mm<sup>2</sup>). When placed on a cylindrical shape, a smaller sensor will result in a reduced

325 radius of curvature, possibly explaining the higher interface pressures reported by the  
326 Kikuhime.

327 The Kikuhime sensor is also 2 mm deeper than the PicoPress when inflated and also includes  
328 a foam insert. The increased depth of the Kikuhime creates a local protuberance when used  
329 *in-vivo*. Any additional protrusion will distend the fabric of tight fitting garments causing an  
330 increase in tension and the sensor bulge will reduce the radius of curvature and result in a  
331 further increase in observed interface pressure (Vinckx et al. 1990).

332 The  $B$  slope coefficient is a product of the calculated HOSY values and compared with the  
333 interface pressure obtained with a portable device. The PicoPress values at the posterior and  
334 lateral orientation for both garments report a low, positive  $B$  slope ( $<1.5$  mmHg). The  
335 positive slopes indicate that at the lower end of the reference standard interface pressure, the  
336 portable devices report a higher value, whereas at the higher end of the reference standard  
337 pressure, the portable devices tend to underestimate interface pressures.

338 The current results are a product of the garment and device interaction whereby the specific  
339 garment fabrics have shown to play a pivotal role in altering the interface pressure. The  
340 garments used in the present study, whilst commercially available, do not reflect the wide  
341 range of fabric compositions used for sport and medical compression and therefore caution  
342 should be used to extrapolate the present findings across alternative fabrics. Future research  
343 should compare the interface pressure reported by portable pressure devices with  
344 compression garments of a known pressure (i.e. 10, 20 and 30 mmHg). By using the  
345 PicoPress at the approved orientations, it will provide insight into the variability of pressure  
346 when off-the-shelf garments are measured.

347 The PicoPress and Kikuhime are commonly cited devices in medical literature (Mosti et al.  
348 2009, Schuren et al. 2010), sub-bandage pressure assessment (Mosti and Partsch 2010,



Weller et al. 2010), and as reference devices in the development of piezoresistive sensors (Chi et al. 2017). However, in the current study, and in agreement with previous research (Mosti and Rossari 2008, Partsch and Mosti 2010, Thomas 2014), significant discrepancies between the devices are evident. However, this study not only reports differences between portable devices, but also compares performance with a reference standard. This study contributes towards international standardization by identifying a portable pressure sensor (PicoPress) and assessment location (posterior and lateral) capable of replicating pressure values established from a reference standard. This is an important finding given the low-cost and speed in which garment pressure can be determined using a portable pressure monitor when compared with indirect methods. These findings are particularly relevant for researchers, garment designers and clinicians monitoring garment pressure, when interpreting the pressure applied in a wider context and comparing with the standardised pressure classifications.

## **Conclusion**

Two portable pressure devices were rigorously assessed in order to contribute much needed future standardization of pressure evaluations for sports compression. When compared with a reference standard, the PicoPress provides a valid measure of interface pressure at the posterior and lateral location of the calf. From a practical, *in-vivo* standpoint, we recommend using the PicoPress to assess interface pressure, specifically at the posterior or lateral aspect of the calf. This is of particular relevance when the hosiery is applying relatively low levels of pressure, applicable to sports compression.

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373

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379

380 ***Conflict of interest***

381 The authors have no conflicts of interest

382

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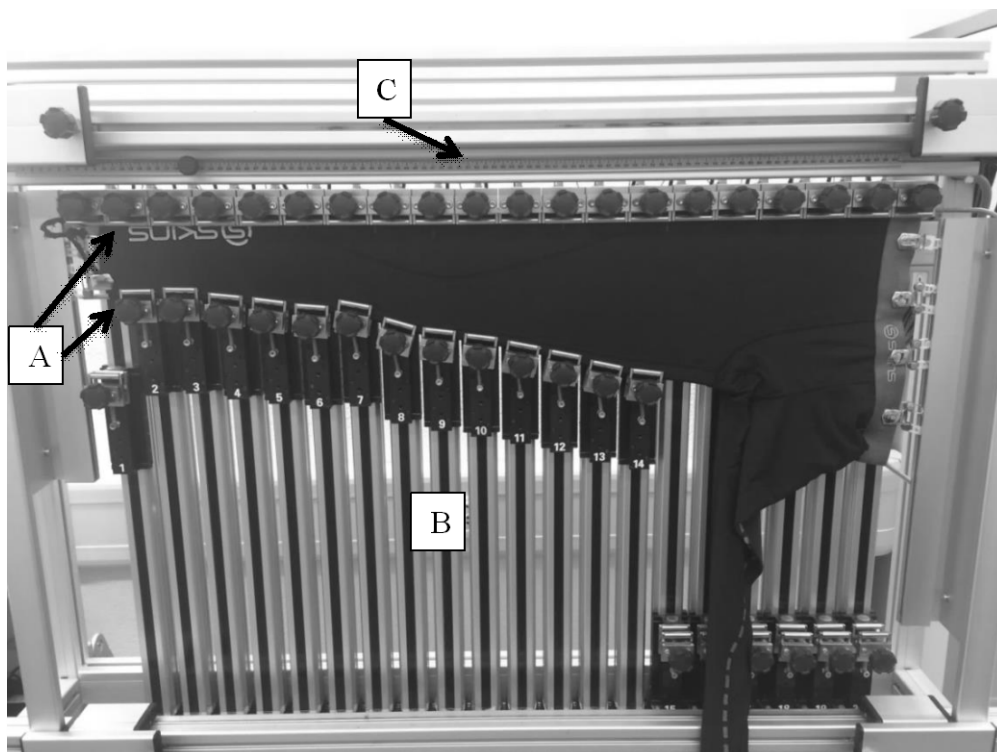
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**Figure 1.** The Hohenstein System (HOSY) showing (a) clamps holding the bottom of the garment, (b) 20 measuring rods with clamps and (c) measurement tape.



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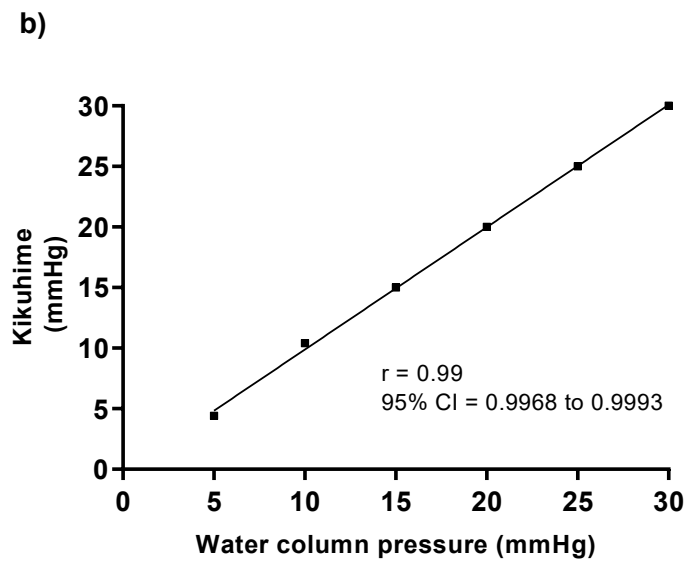
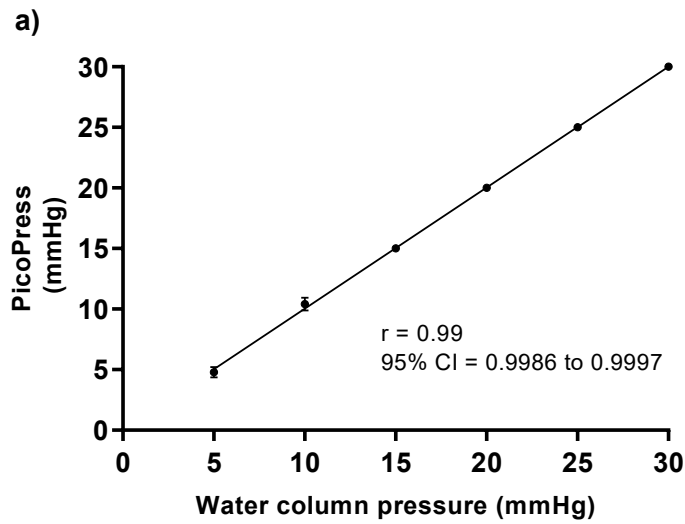
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490 **Figure 2.** Linearity and correlation coefficients for the (a) PicoPress and (b) Kikuhime  
491 device.



**Table 1.** Fabric characteristics of the compression garments.



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	Weight	Thickness	Composition	Count	Extension	Residual
	(g/m <sup>2</sup> )	(mm)		(wpc x cpc)	(%)	extension (%)
<u>Stockings</u>	298	0.69	65% Nylon	420 x		
	(2.83)	(0.00)	35% elastane	250		
Length					52.67	2.67
wise					(0.94)	(0.00)
Cross					96.67	2.00
wise					(4.71)	(0.94)
<u>Tights</u>	199.33	0.57	76% Nylon	520 x		
	(0.57)	(0.01)	24% elastane	500		
Length					164.89	8.0
wise					(13.87)	(3.52)
Cross					94.67	2.67
wise					(2.67)	(1.33)

*Number in the brackets indicates standard deviation; cpc – courses per mm; wpc – wales per mm*

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505 **Table 2.** Interface pressure, significance, agreement values (bias and limits) and slope

506 between HOSY and portable devices with stockings

Interface		<i>P</i> - <i>value</i>	Bias [95% LoA]	<i>B</i> [95% CI]
Pressure	(mmHg [SD])			
Orientation	PicoPress			
Anterior	29.3 [3.9]	<0.01	-9.2 [-1.8; -0.6]	2.4 [0.0 – 4.8]
Posterior	20.6 [1.5]	0.35	-0.4 [-3.3; 2.5]	0.5 [-0.4 – 1.4]
Medial	22.0 [2.1]	0.02	-1.8 [-6.5; 2.8]	1.1 [-0.3 – 2.5]
Lateral	19.6 [2.1]	0.37	0.5 [-3.4; 4.4]	0.4 [-0.9 – 1.7]
$\bar{x}$	22.9 [1.5]	<0.01	-2.7 [-6.4; 0.9]	1.1 [0.1 – 2.0]
	Kikuhime			
Anterior	37.7 [4.4]	<0.01	-17.6 [-26.8; -8.3]	1.7 [-1.2 – 4.6]
Posterior	26.2 [3.0]	<0.01	-6.1 [-11.4; -0.8]	-0.2 [-1.9 – 1.6]
Medial	27.0 [3.8]	<0.01	-6.9 [-15.0; 1.2]	1.5 [-1.0 – 4.0]
Lateral	26.5 [3.8]	<0.01	-6.3 [-14.3; 1.6]	1.3 [-1.2 – 3.8]
$\bar{x}$	29.4 [2.5]	<0.01	-9.2 [-14.6; -3.9]	1.1 [-0.5 – 2.7]

$\bar{x}$  = mean of four orientations; SD = standard deviation; LoA = limits of agreement; *B* = unstandardized beta coefficient of regression slope; CI = confidence interval. Mean [95% CI] HOSY pressure = 20.1 [19.5, 20.8] mmHg.

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**Table 3.** Interface pressure, significance, agreement values (bias and limits) and slope between the HOSY and portable devices with tights

Interface				
	Pressure (mmHg [SD])	<i>P</i> -value	Bias [95% LoA]	<i>B</i> [95% CI]
Orientation	PicoPress			
Anterior	16.9 [2.9]	<0.01*	-3.8 [-10.1; 2.5]	2.0 [-0.6 - 4.7]
Posterior	12.9 [2.3]	0.82	0.2 [-4.7; 5.1]	1.3 [-0.9 - 3.4]
Medial	13.0 [2.7]	0.93	0.1 [-5.8; 6.0]	2.2 [-0.2 - 4.6]
Lateral	11.9 [1.9]	0.07	1.2 [-3.0; 5.4]	1.3 [-0.5 - 3.1]
$\bar{x}$	13.7 [1.6]	0.35	-0.6 [-4.5; 3.4]	1.7 [0.3 - 3.1]
	Kikuhime			
Anterior	21.0 [4.4]	<0.01*	-7.9 [-16.7; 1.0]	1.2 [-2.9 - 5.3]
Posterior	15.9 [2.2]	<0.01*	-2.9 [-7.0; 1.3]	0.2 [-1.8 - 2.2]
Medial	15.1 [3.4]	0.69	-2.0 [-8.6; 4.7]	0.6 [-2.5 - 3.8]
Lateral	15.1 [2.6]	0.03*	-2.1 [-7.4; 3.3]	1.2 [-1.2 - 3.6]
$\bar{x}$	16.8 [2.1]	<0.01*	-3.7 [-8.1; 0.7]	0.8 [-1.2 - 2.8]

$\bar{x}$  = mean of four orientations; SD = standard deviation; LoA = limits of agreement; *B* = unstandardized beta coefficient of regression slope; CI = confidence interval. Mean [95% CI] HOSY pressure = 13.1 [12.6, 13.6] mmHg.