

Comparative Study of Three Pressure Monitors: PicoPress, Kikuhime, and Juzo

Prepared for Juzo Inc.
By Design Interface Inc.
February 13, 2017

Introduction

This paper summarizes the findings from performing two comparative tests on three electronic pressure monitors; Kikuhime, PicoPress, and Juzo. Pressure monitors can be used to measure the pressure exerted from a compression garment or bandage on the user wearing the garment for the treatment of venous disease or lymphedema. In the United States, pressure monitors are currently not widely used in a clinical setting. They are often very difficult to obtain and, if they are sourced, very costly to acquire, making them impractical for use in monitoring bandage and garment pressures.

In the clinical setting, pressure monitors can take on an increasing importance due to the prevalence of short-stretch compression bandages and Velcro garments where the amount of pressure is variable depending on the tension used when applying the bandage or garment. Pressure monitors can also offer the additional benefit of monitoring both working and resting pressure when a garment is worn.

Pressure monitors are designed to be positioned against the patient's body (i.e. the patient's arm or leg) between the compression garment and the limb. The Kikuhime and PicoPress transducers are most often positioned against the appendage before the garment is applied and can only be used to measure a single position at one time. The Juzo monitor, by contrast, is inserted between the appendage and garment after the garment has been applied. The Juzo monitor can then be re-positioned at any time to take multiple readings at different positions while leaving the garment in place.

Devices Tested

Figure 1. The Pressure Monitors



PicoPress Monitor
The transducer is an empty bladder that is filled with a preset amount of air by means of a piston on the monitor. The sensor is connected to the monitor with flexible tubing.



Kikuhime Monitor
The transducer is a bladder that is filled with a preset amount of air by means of a piece of compressible foam sealed inside. The sensor is connected to the monitor with flexible tubing.



Juzo Monitor
The transducer is a bladder that is filled with a preset amount of air by means of a piece of compressible foam sealed inside. The sensor is connected to the monitor with flexible tubing. The tubing passes through a rigid wand to allow insertion into a compression garment.

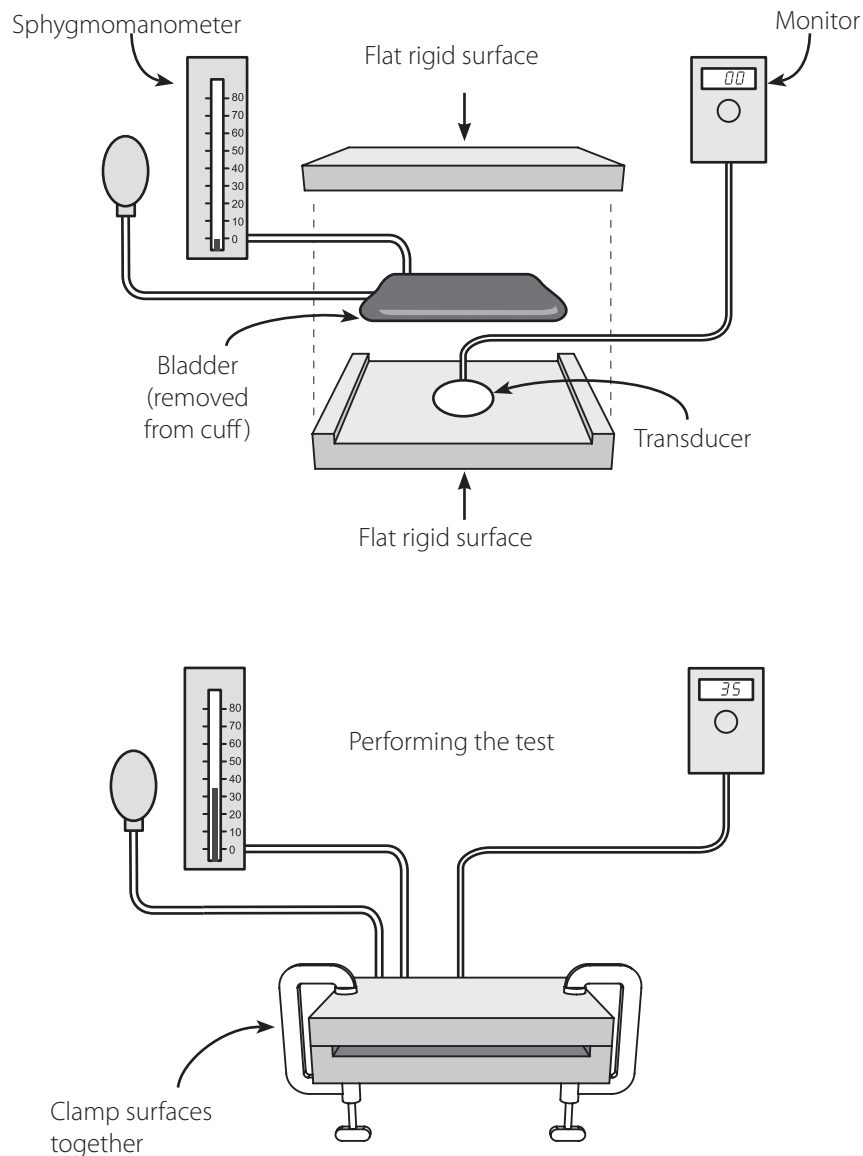
Test Method A

Transducer Under Compression from a Sphygmomanometer Bladder

Method A Description

A sphygmomanometer is an instrument that directly measures the pressure exerted by a column of mercury and is a reliable standard for revealing the accuracy of an electronic pressure sensor. For this test, the rubber bladder from a sphygmomanometer is first removed from its cuff and fully deflated. The sphygmomanometer bladder and the transducer being tested are placed on top of one another and positioned between two flat, rigid surfaces that are spaced approximately 0.375" apart (Figure 2). The surfaces are clamped together and the test begins with both devices reading 0 mmHg. The sphygmomanometer is then inflated to 70 mmHg and simultaneous readings are taken of both devices at intervals of 10 mmHg as the sphygmomanometer is slowly deflated.

Figure 2. Method A Setup



Method A Results

A summary of the tests is seen in Figures 3-4. The Sphygmomanometer was pressurized to 70 mmHg and then slowly deflated in increments of 10 mmHg while readings were recorded from the transducer being tested.

The PicoPress transducer returned readings that has a strong correlation with the Sphygmomanometer (0 to -1). When the data is graphed (Figure 4), the readings track in linear fashion (Figure 4) which the test method would indicate.

The Kikuhime transducer returned readings that were notably higher than the Sphygmomanometer. (+3 to +11). The readings for the Kikuhime were less linear which is contrary to what the test method would indicate.

For the Juzo Pressure Monitor, five prototype transducers (identical in construction) were removed from their wands and tested individually and their data was averaged. They readings correlated very well with the readings on the Sphygmomanometer. (+1 to +2). The readings also tracked in a nearly linear fashion.

Figure 3. Method A: Results (Bar Chart)

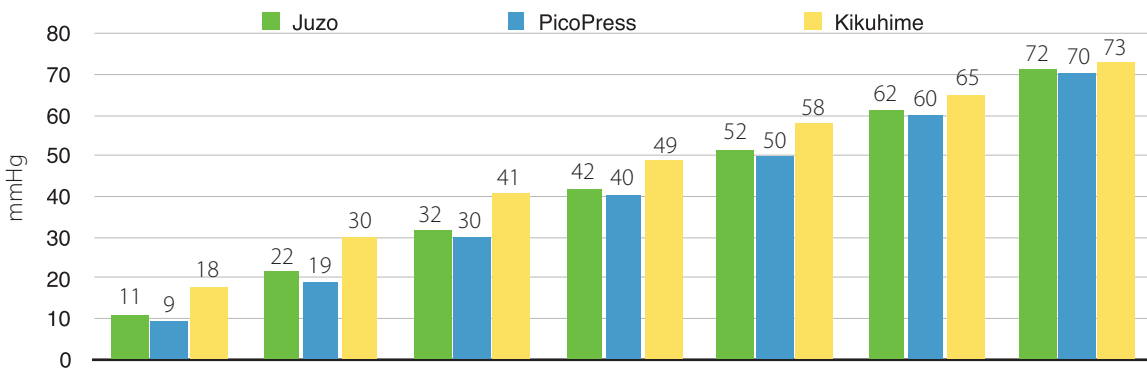
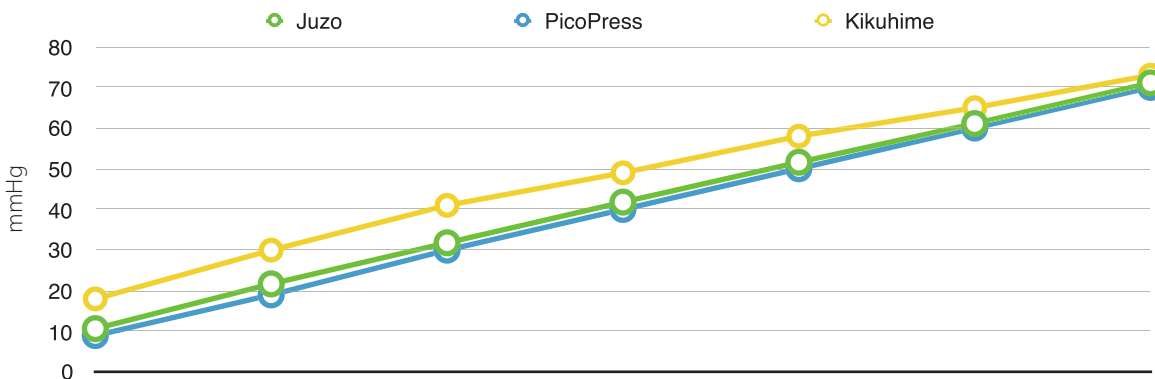


Figure 4. Method A: Results (Graph)



Test Method B

Devices Tested in a Compression Stockinet on a Cylinder

Method B Description

Two transducers are compared simultaneously while under pressure. The test uses a rigid cylinder that is covered by a tubular compression stockinet to simulate a limb under pressure. In the first test, the PicoPress transducer is taped to the cylinder and the stockinet is pulled up over the transducer so it's positioned under the midpoint of the stockinet. Next the Juzo device is inserted into the top of the stockinet on the opposite side of the PicoPress and pressure measurements are taken from both devices. In the second test, the PicoPress and Kikuhime transducers are affixed to opposite sides of the cylinder and a reading is taken from both devices.

The compression stockinet is designed to deliver a fairly uniform pressure around the circumference of the cylinder and return similar readings from both devices. This test is conducted using four different cylinder/stockinet combinations to achieve a range of pressures. Cylinders A, B, and C are straight while cylinder D is contoured to approximate the shape of a lower leg having a larger circumference at the top and a smaller circumference at the base.

Figure 5. Method B Setup

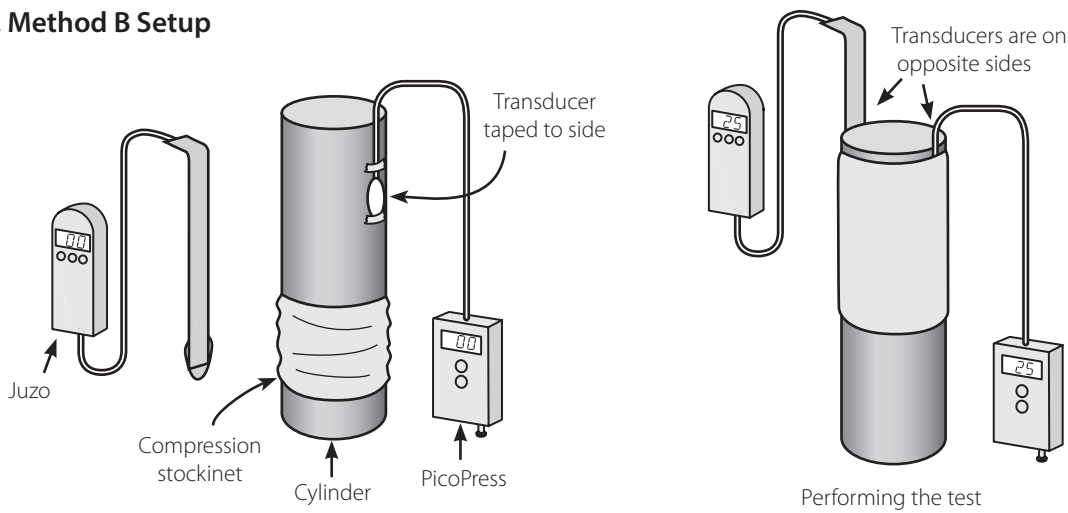
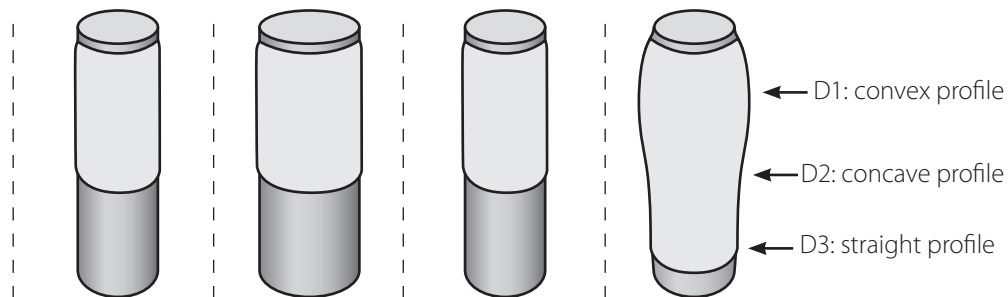


Figure 6. The Four Cylinder/Stockinet Combinations



	A	B	C	D
Diameter	Ø3.5"	Ø4.5	Ø3.5"	Ø4" at D1 , Ø3.5" at D3
Stockinet Width*	4"	3.5"	2.5"	3"
Approx. Pressure	~16-18 mmHg	~24-26 mmHg	~32-34 mmHg	~30-32 mmHg (D1) ~20-22 mmHg (D2) ~22-24 mmHg (D3)

* All stockinet material was applied double-layered thick to achieve higher compression levels

Method B Results

During the test it was important to keep the stockinet and transducer as smooth and flat as possible as the stockinet was pulled into position over the transducer. As expected, the elastic properties of the material introduced a variable that produced results that were in less agreement with each other than in the Sphygmomanometer test. Due to this variable, the test was conducted three times per cylinder and the readings averaged. It is important to bear in mind that, unlike a real human leg, the cylinders are rigid. How this variable affects the readings is not clear.

A summary of the tests is seen in Figures 7-8. The findings indicate that the comparison measurements taken from the PicoPress and the Juzo Pressure Monitor offer a stronger correlation than the comparison measurement taken between the Kikuhime and PicoPress devices.

Figure 7. Method B: Results Data (Table)

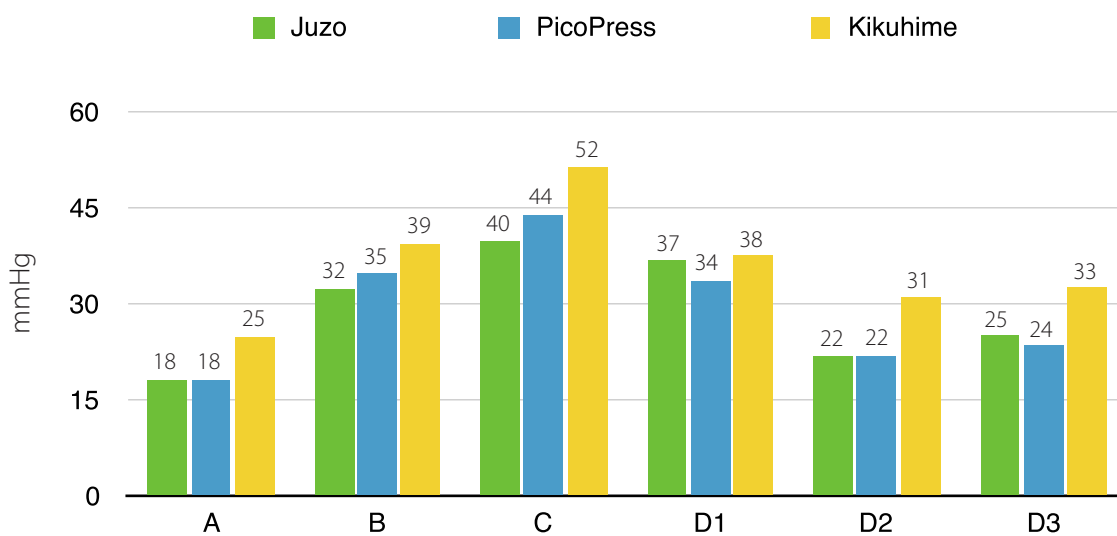
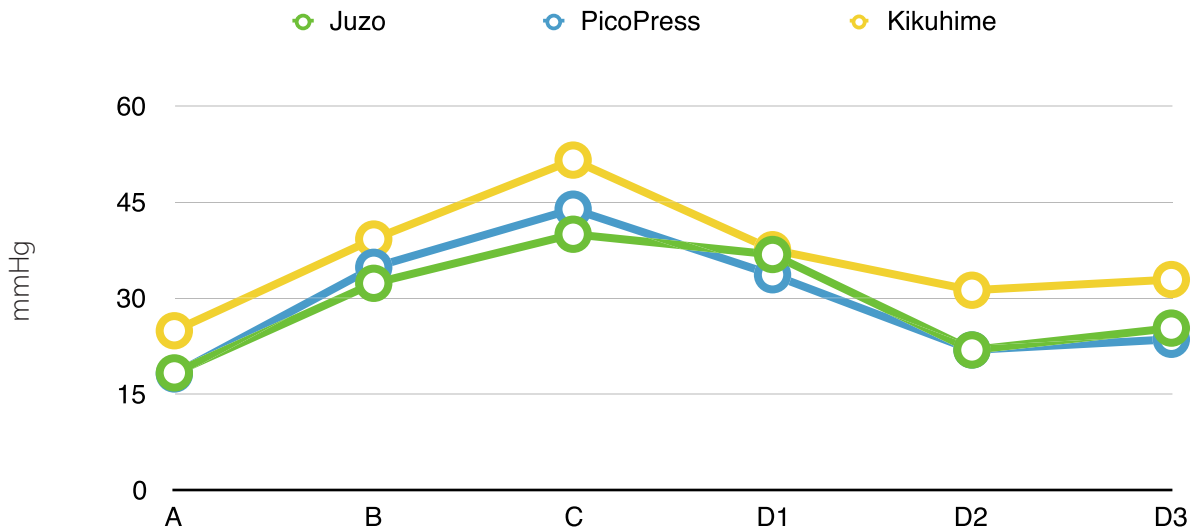


Figure 8. Method B: Results Data (Graph)



Conclusion

PicoPress Device

The PicoPress pressure monitor was shown to offer the strongest correlation to the readings of the Sphygmomanometer. It read pressures in a linear fashion which indicates optimal performance.

Juzo Device

This Juzo Pressure Monitor had a very good correlation, and only slight deviations, when tested against the Sphygmomanometer. It also measured pressure in a linear fashion which indicates a more optimal performance.

Kikuhime Device

The Kikuhime pressure monitor did not correlate as strongly with the Sphygmomanometer test method as compared to the performance of both the PicoPress and the Juzo Pressure Monitor. The device consistently returned higher readings than what was indicated on the Sphygmomanometer.

Device Comparison

Test Method B was a test method that was created that is more comparable to the practical application of these types of pressure measuring devices. The disadvantage of this method, is that the methodology introduces additional variables that may affect the accuracy of these devices. Keeping this in mind, it was found that there was the strongest correlation between the PicoPress device the and Juzo Pressure Monitor.

Discussion

The Juzo Pressure Monitor is a device developed by Juzo that will allow clinicians to monitor the amount of pressure their patients are getting from short-stretch bandaging or Velcro compression devices. This additional information, when used in the clinical setting, may result in improved patient outcomes.

The testing performed and outlined by this paper, shows that the Juzo Pressure Monitor can be a reliable tool used to measure pressure values of short-stretch bandages and garments on patient's limbs. It compares favorably to other pressure monitoring devices used found in the international market, but not readily available in the United States. The Juzo Pressure Monitor also has a significantly lower cost and an added value featured of an insertion wand that allow the transducer to be easily inserted and removed from under a bandage or garment saving valuable time of having to remove bandages or garments to position or reposition the transducer.