New Interface Pressure Measuring Device

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Disclosure

- Shareholder, VenoSense Inc.
- Patent #US20140174189-A1
- Non-FDA and Non-CE Mark use

Agenda

- Politics of interface pressure
- Existing devices
- What’s on the horizon

Where are we with interface pressure?

CON

WE PROPOSE TO ADD A NEW GUIDELINE

Guideline 5.1a: Compression pressure – Ulcer

Indic

longed compression therapy alone. Finally, methods for assessing the patient's compliance with wearing of these garments/devices that are better than "patient diaries" should be developed. These monitoring devices are being employed in the treatment of other diseases, like the diabetic foot.

exist. Objective measures of the "dose" of compression should be used in future studies. These measures, which

Corresponding Fa … DON-MOLLARD … BERNER (Germany), D. KOLBACH (The N … HART (USA), U. MEYER (Germany), J. LEAL MONEDERO (Spain), C. MOFFATT (UK), H. SCHEPERS (Switzerland), S. SHAW (USA), N. VELAZQUEZ (Spain), A. VIRKUS (Germany).

Dermatol Surg 2006;32:224–233 (ICC Consensus 2006)
Int Angiol 2008;27:193-219
J Vasc Surg 2014;60:3S-59S
Int Angiol. 2015 Jun;34(3):202-18

Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD)

"Furthermore, while mechanical compression therapies are routinely used postoperatively as an adjunct to invasive interventions for the treatment of LE chronic venous insufficiency/incompetence/reflux and for treatment of venous ulceration, there is little evidence to inform decisions about which of the many types of compression therapies to prescribe or ***the optimal dosing*** *and* ***duration of compression therapy*** *for chronic venous insufficiency with or without venous ulcers. "*

HHS AHRQ Technology Assessment 6/28/2016

Ideal Sensor

TABLE 1. Characteristics of an "Ideal Sensor"

- Size–insensitive to force concentrations
- Flexibility–insensitive to bending, but not distensible
- Durability
- Reliability
- Overload tolerance
- Electronic simplicity
- Low cost
- Low hysteresis
- Little creep
- Insensitive to temperature and humidity changes
- Continuous output
- Linear response to applied pressure
- High sampling rate–locomotion studies
- Operating range consistent with biological parameters
- Accuracy
- Resolution (time <0.1 sec, amplitude <0.1 mmHg)
- Thin
- Variable sensor sizes

Dermatol Surg 2006;32:224–233 (ICC Consensus 2006)

Advantages and Dis-advantages

TABLE 3. Some Advantages and Disadvantages of Sensors

	Advantages	*Limitations*
Pneumatic transducers	Thin and flexible probes, Cheap, easy, and handy	Dynamic measurement is only possible with additional special equipment. Sensitive for temperature and hysteresis.
Fluid filled	Flexible, dynamic measurements	Thick when filled, problems during motion
Resistance	Thin sensors, dynamic measurement	Sensitive to curvature, stiff and thick, not useful for long-term measurements

Dermatol Surg 2006;32:224–233 (ICC Consensus 2006)

Existing devices

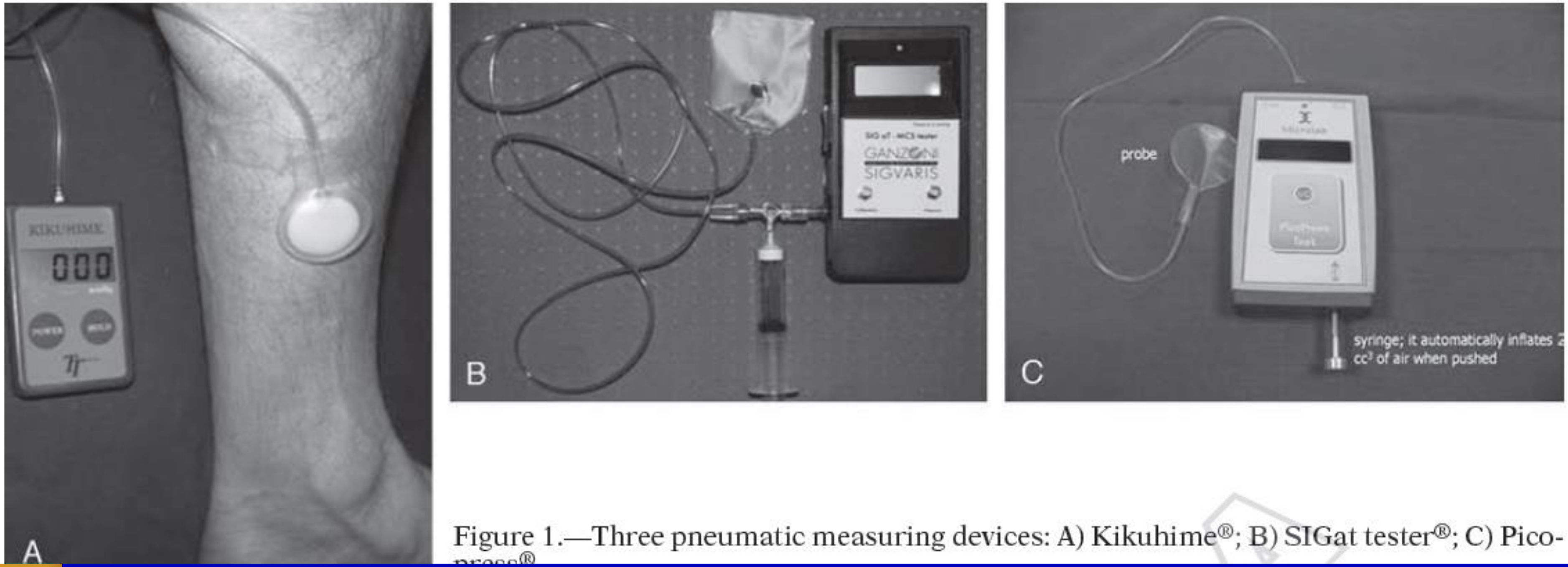
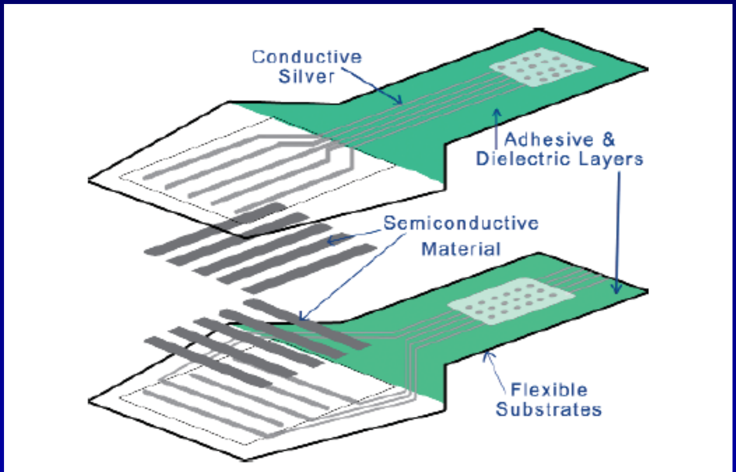


Figure 1.—Three pneumatic measuring devices: A) Kikuhime®; B) SIGat tester®; C) Pico-press®

Int Angiol 2010;29:426-30

Piezoresistive



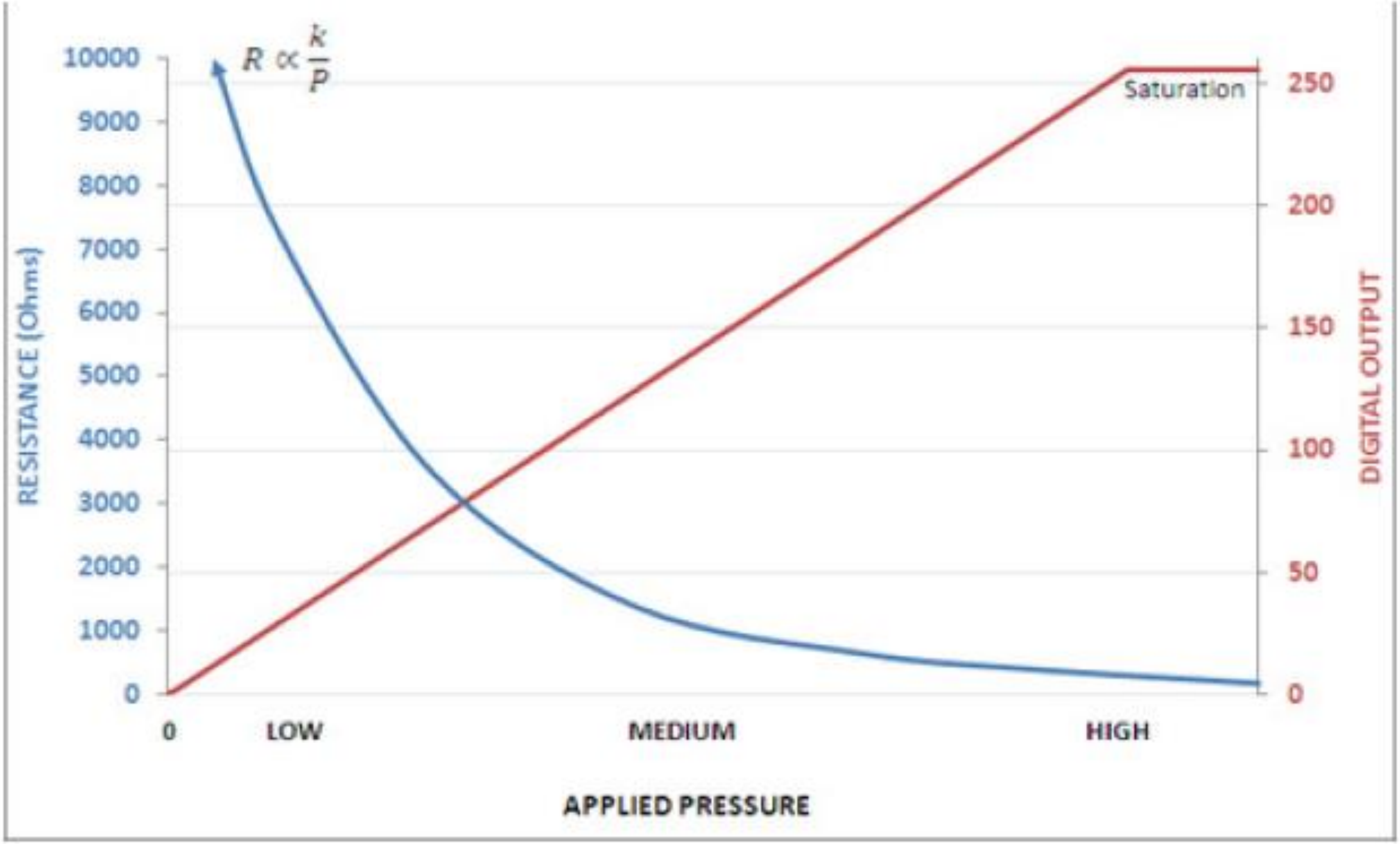
$$P = \frac{T}{R}$$

Where P is the interface pressure in (N/m^2), T is tension in bandage in (N) for $(1m)$ width of fabric and is the curvature radius in (m).

$$P = \frac{T(D+t)}{\frac{1}{2}wD^2 + wt(D+t)}$$

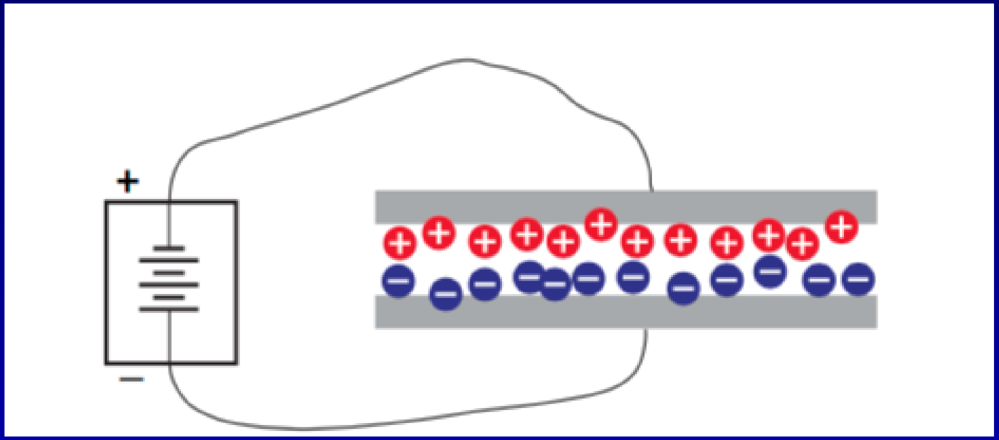
Khaburi JW et al. 2011 IEEE (10) pp 289-294

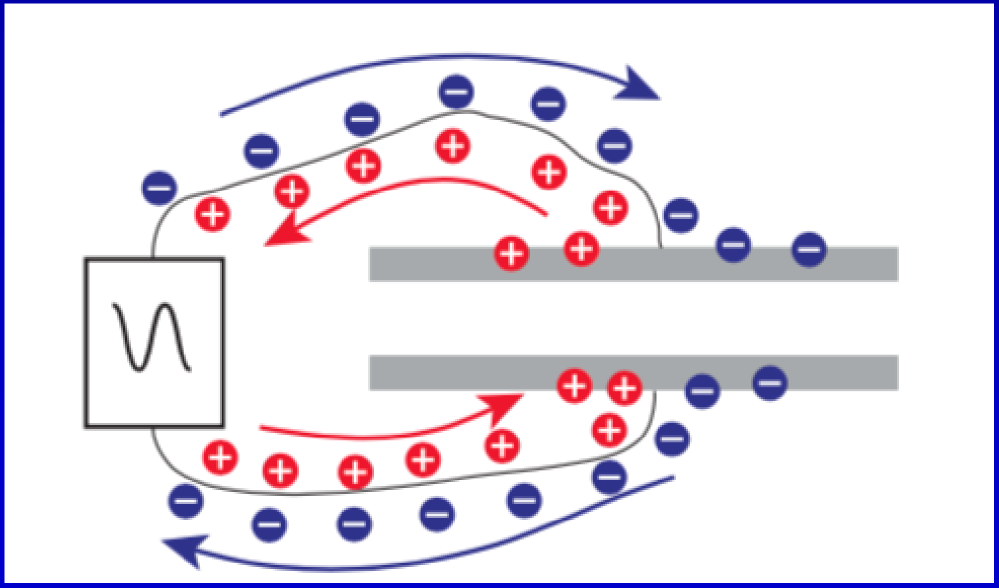
Pressure Sensor



Comparison of Interface Pressure Measurement Options. Tekscan White paper . 2012

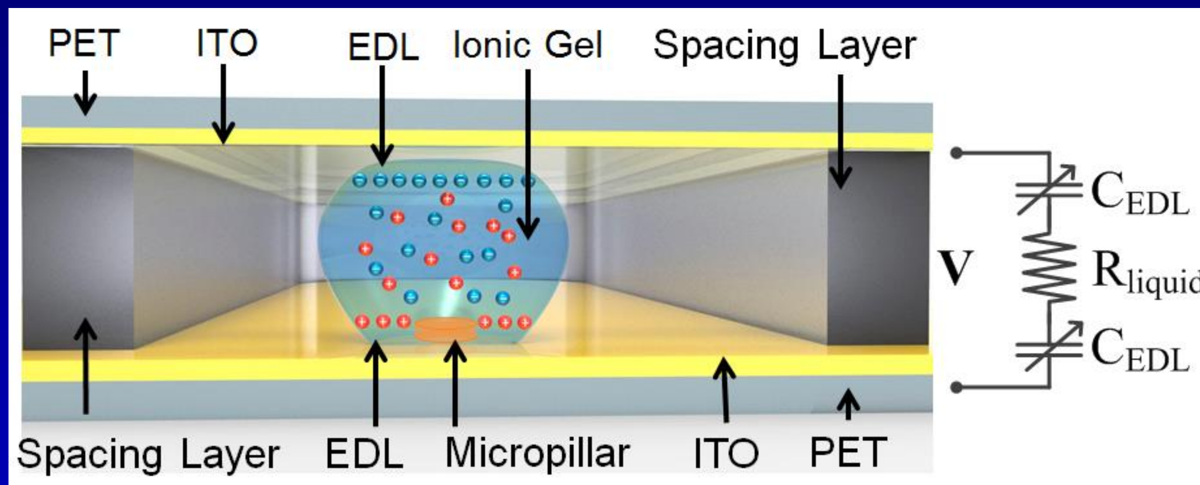
Capacitive Sensing Principle





Sensing Principle

Iontronic sensor using microfluidic principle



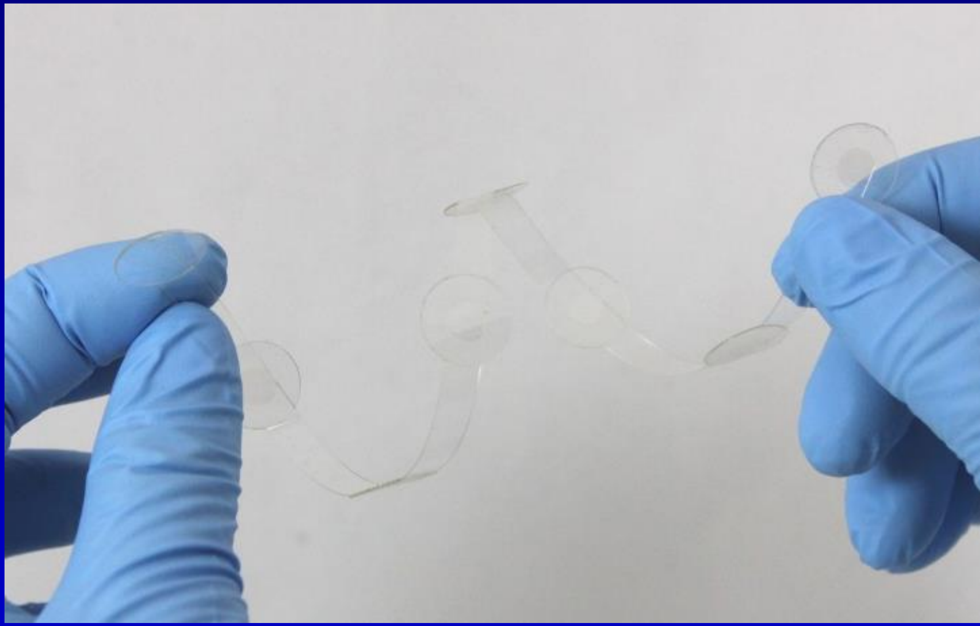
$$\Delta C = C_0\left(\frac{H}{H - K \cdot P} - 1\right),$$

Patented technology

Ann Biomed Eng. 2016 Jul;44(7):2282-91

Our Work: Capacitive Sensor

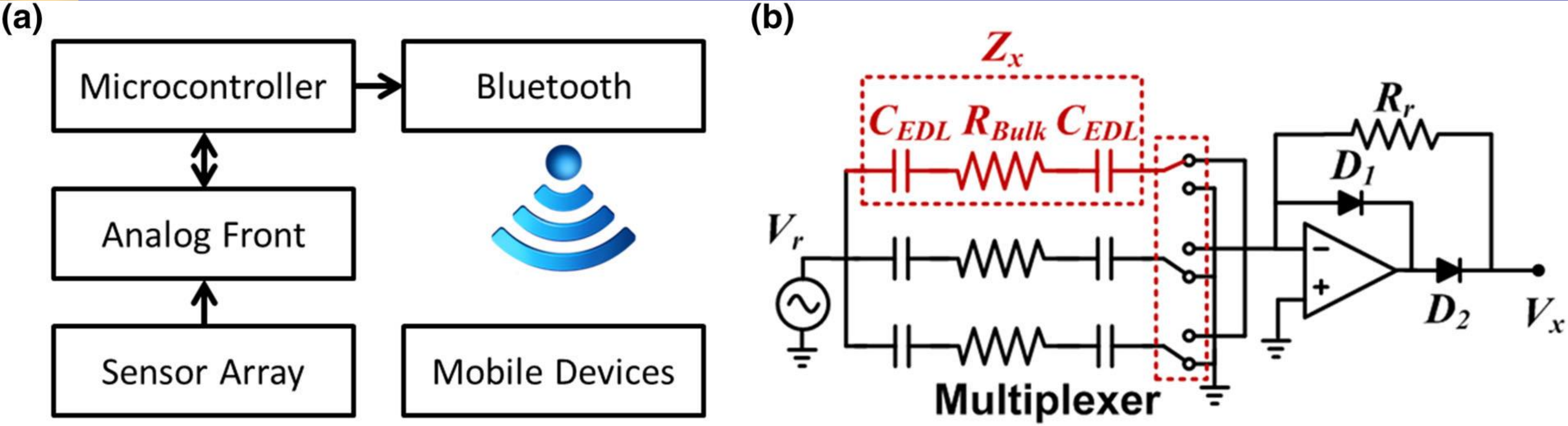
- A novel flexible iontronic pressure sensor for interfacial pressure sensing
- Innovations
  - Iontronic sensing array
    - Ultrahigh sensitivity
    - Flexibility
    - Ultrathin
  - Stand-alone unit with wireless data processing
  - Distributed pressure measurement through an array



Patented technology

Ann Biomed Eng. 2016 Jul;44(7):2282-91

Utility



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Calibration Setup

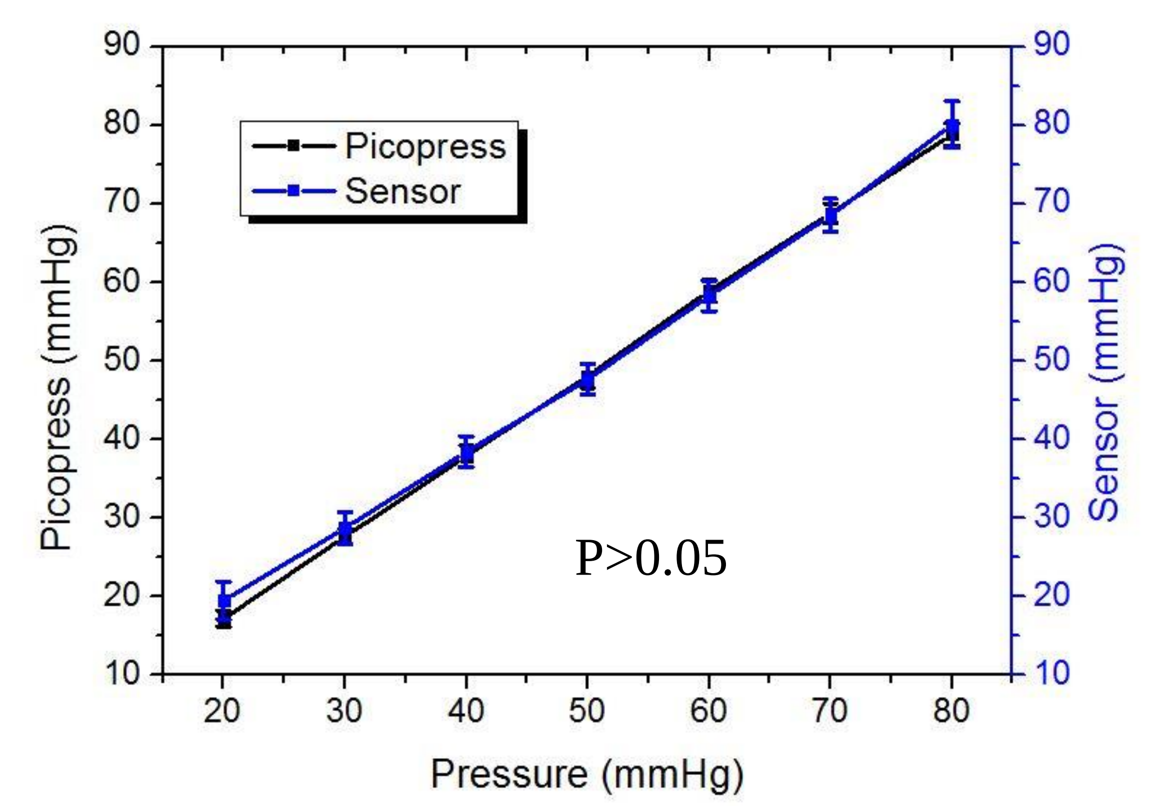
Iontronic Pressure Sensor

Microchip/ Bluetooth Module

Mobile Device

Picopress®

Sensitivity Calibration Result

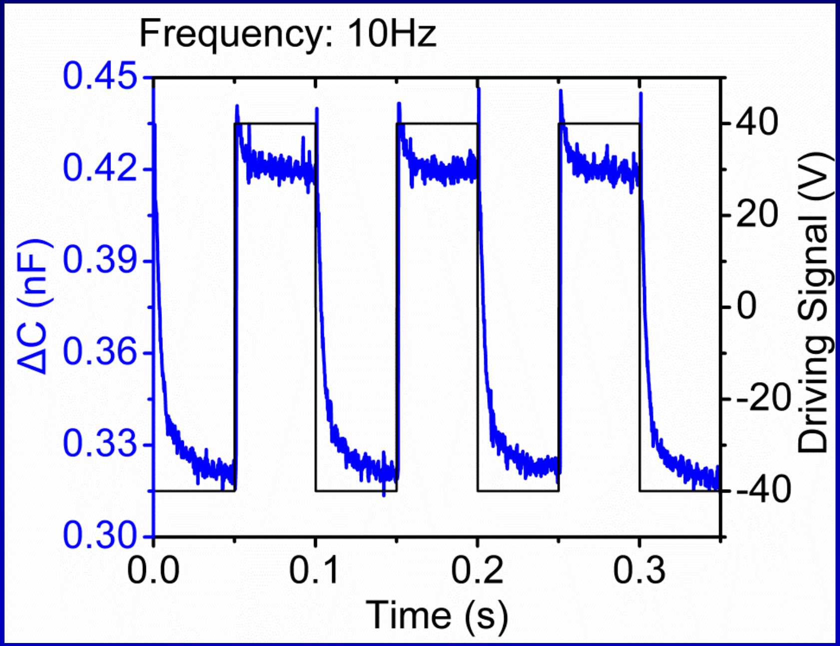


Iontronic pressure sensor sensitivity (0.2nF/mmHg) was characterized as capacitive change (ΔC) versus pressure load (P) with exact linearity as Picopress®

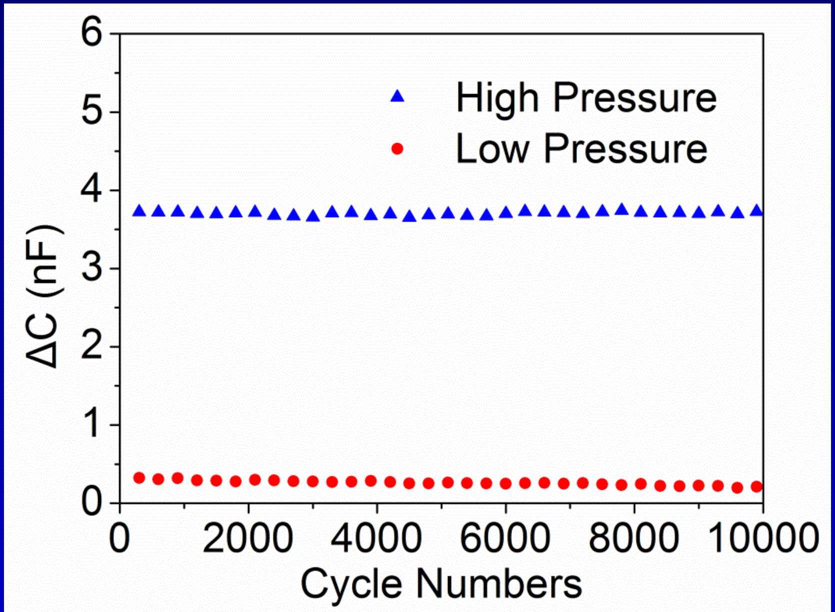
ACP 2015 Oral Abstract. BSN award

Ann Biomed Eng. 2016 Jul;44(7):2282-91

Mechanical Response & Repeatability



Mechanical Response



Repeatability

ACP 2015 Oral Abstract. BSN award

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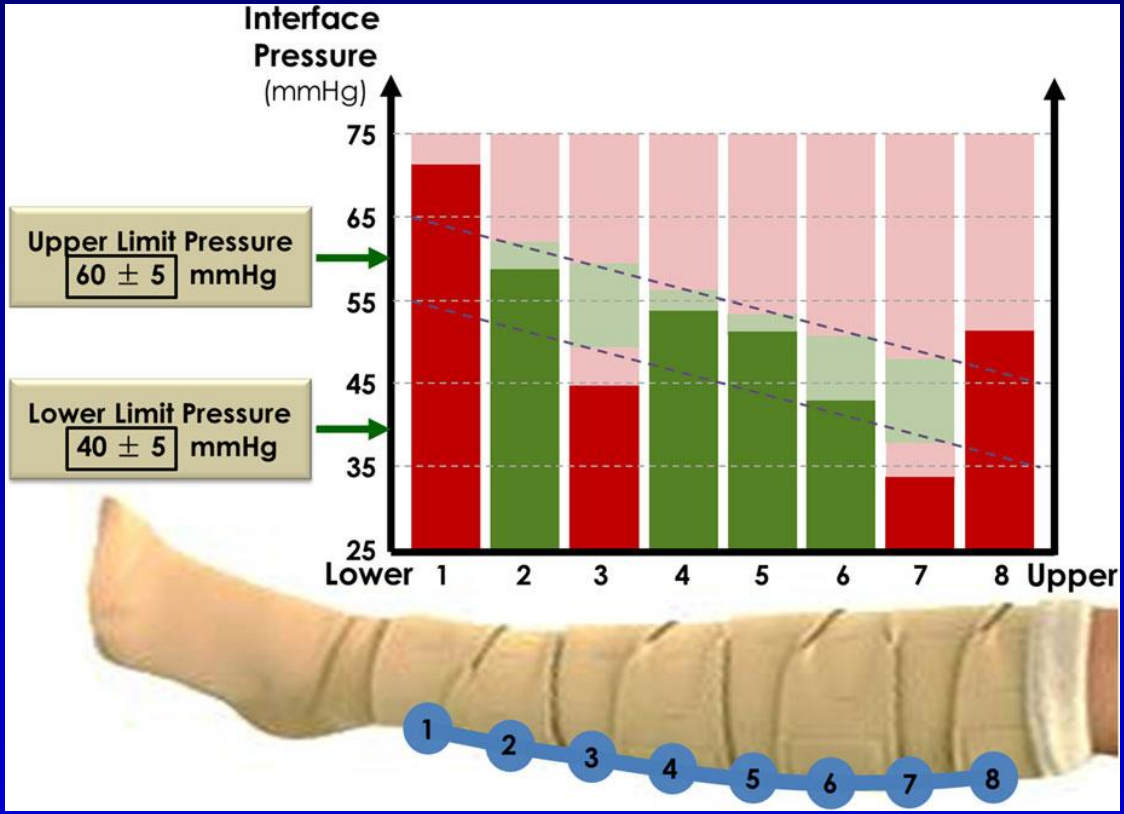
Clinical Application



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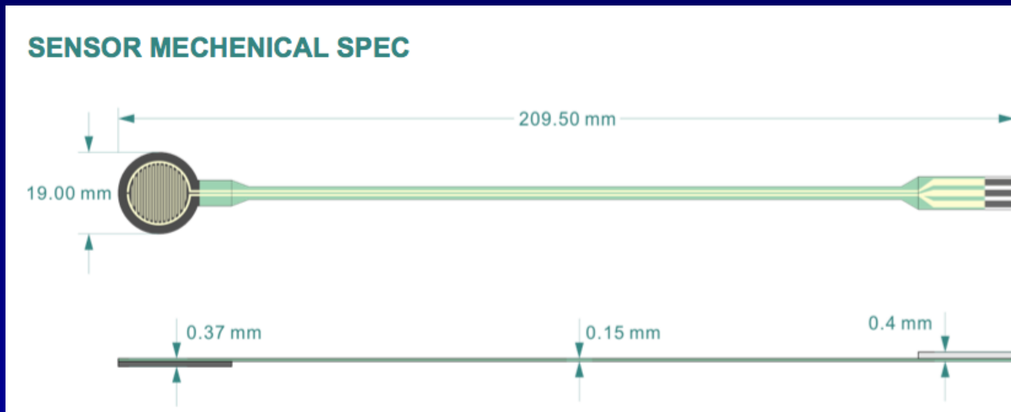
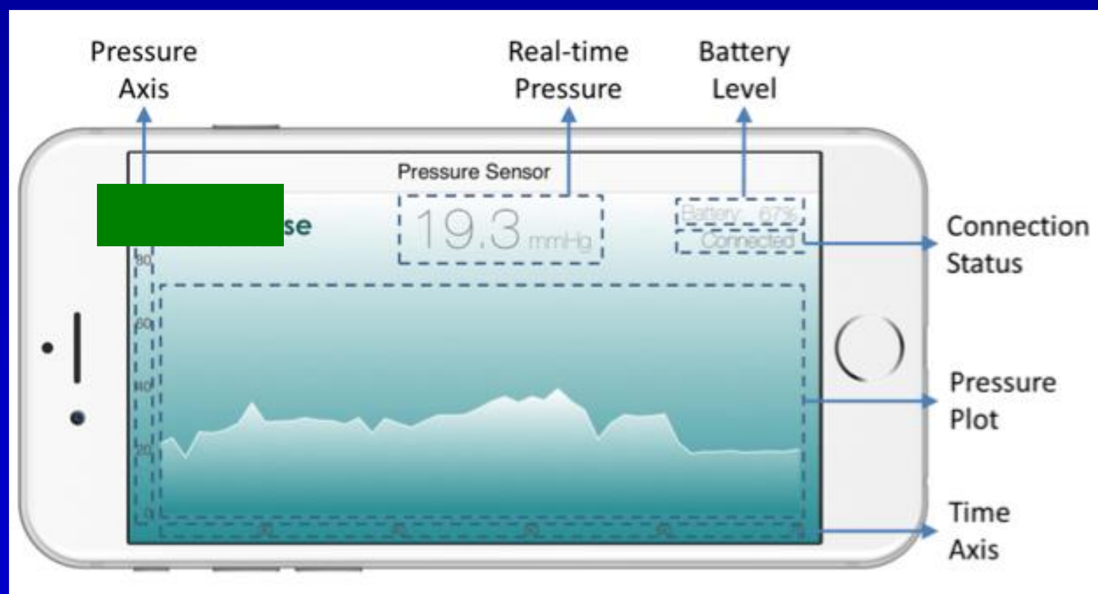
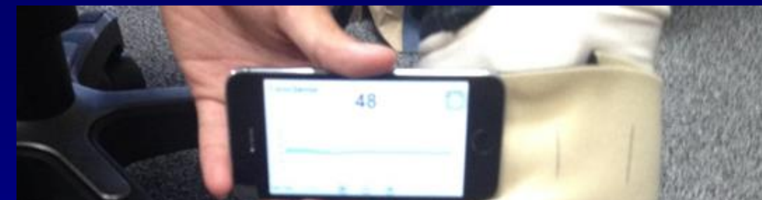
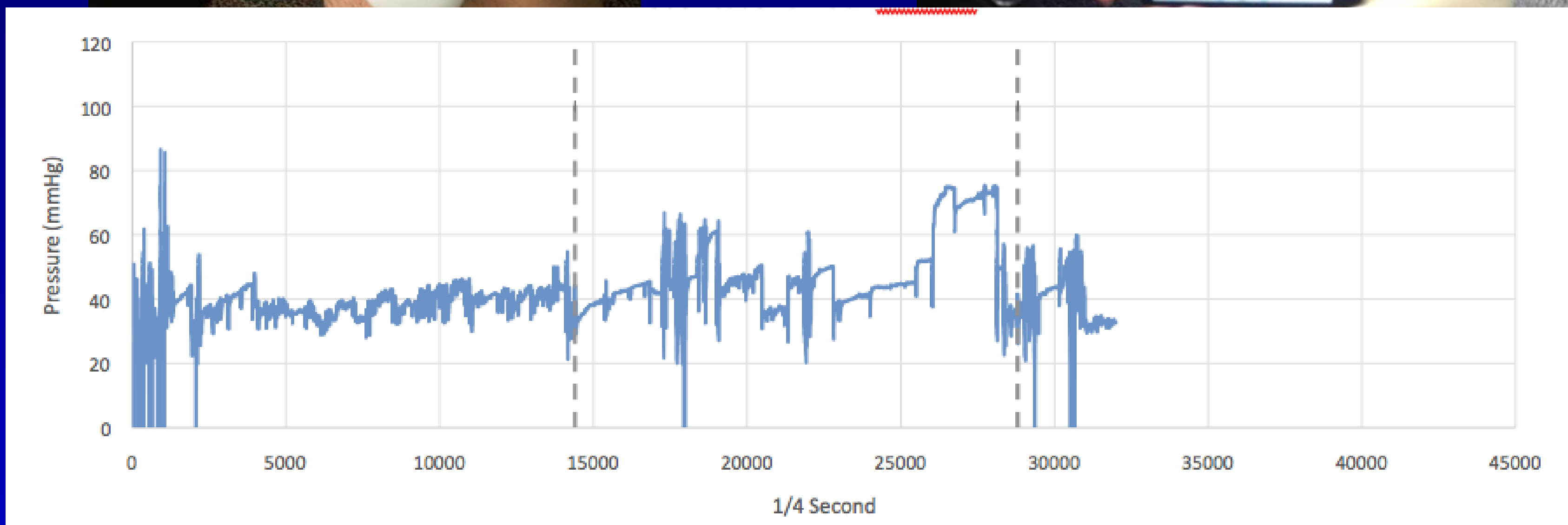
Compliance


SENSOR MECHENICAL SPEC
209.50 mm
19.00 mm
0.37 mm
0.15 mm
0.4 mm


Pressure Axis
Real-time Pressure
Battery Level
Pressure Sensor
se
19.3 mmHg
Connection Status
Pressure Plot
Time Axis

Compliance





Average: 41.99mmHg
In range 30~50 mmHg: 87.4%

Proprietary data

It is very clear that

Unfortunately, none of the reported studies measured the pressure; thus a "high level of compression" is only supposed. Furthermore when applying bandages, the expertise of care-givers is extremely important to achieve the target pressure, but once again, if pressure is not measured, even expert personnel may not exert the desired pressure when applying compression bandages as results from many studies.[6 7 8 9]

by compression materials.

Effectiveness of Vascular Surgery, Bioengineered Tissue, and Electrical Stimulation

Author: Thakral G. et al

Adv Skin Wound Care. 2015 Apr;28(4):164-72.

Contributing Editor/Reviewer: Giovanni Mosti, MD

Associate Editor: Mark Forrestal, MD, FACPh

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Adv Skin Wound Care. 2015 Apr;28(4):164-72; http://issuu.com/phlebologyforum/docs/phlebology_forum_january_2016

Conclusion

- Politics of interface pressure measurement
- Update on device
- Any new device needs to accurately measure pressure, user-friendly and provide COMPLIANCE info
- Measure, Measure and Measure compression pressure