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
WE PROPOSE TO ADD A NEW GUIDELINE

Guideline 5.1a: Compression pressure – Ulcer

...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 therapy should be used in future studies. These measures, which...
“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>
<thead>
<tr>
<th>TABLE 1. Characteristics of an &quot;Ideal Sensor&quot;</th>
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</thead>
<tbody>
<tr>
<td>• Size-insensitive to force concentrations</td>
</tr>
<tr>
<td>• Flexibility-insensitive to bending, but not distensible</td>
</tr>
<tr>
<td>• Durability</td>
</tr>
<tr>
<td>• Reliability</td>
</tr>
<tr>
<td>• Overload tolerance</td>
</tr>
<tr>
<td>• Electronic simplicity</td>
</tr>
<tr>
<td>• Low cost</td>
</tr>
<tr>
<td>• Low hysteresis</td>
</tr>
<tr>
<td>• Little creep</td>
</tr>
<tr>
<td>• Insensitive to temperature and humidity changes</td>
</tr>
<tr>
<td>• Continuous output</td>
</tr>
<tr>
<td>• Linear response to applied pressure</td>
</tr>
<tr>
<td>• High sampling rate–locomotion studies</td>
</tr>
<tr>
<td>• Operating range consistent with biological parameters</td>
</tr>
<tr>
<td>• Accuracy</td>
</tr>
<tr>
<td>• Resolution (time &lt; 0.1 sec, amplitude &lt; 0.1 mmHg)</td>
</tr>
<tr>
<td>• Thin</td>
</tr>
<tr>
<td>• Variable sensor sizes</td>
</tr>
</tbody>
</table>
# Advantages and Dis-advantages

## TABLE 3. Some Advantages and Disadvantages of Sensors

<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumatic transducers</td>
<td>Thin and flexible probes, Cheap, easy, and handy</td>
<td>Dynamic measurement is only possible with additional special equipment. Sensitive for temperature and hysteresis.</td>
</tr>
<tr>
<td>Fluid filled</td>
<td>Flexible, dynamic measurements</td>
<td>Thick when filled, problems during motion</td>
</tr>
<tr>
<td>Resistance</td>
<td>Thin sensors, dynamic measurement</td>
<td>Sensitive to curvature, stiff and thick, not useful for long-term measurements</td>
</tr>
</tbody>
</table>
Existing devices

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

\[ P = \frac{T}{R} \]

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

\[ P = \frac{T(D + t)}{\frac{1}{2}wd^2 + wt(D + t)} \]
Pressure Sensor

\[ R \propto \frac{k}{P} \]

- **Resistance (Ohms)**
  - LOW: 0 Ohms
  - MEDIUM: 1000 Ohms
  - HIGH: 10000 Ohms

- **Applied Pressure**
  - LOW: 0
  - MEDIUM: 250
  - HIGH: 250

- **Digital Output**
  - LOW: 0
  - MEDIUM: 50
  - HIGH: 100
  - Saturation: 200

Capacitive Sensing Principle
Sensing Principle

Iontronic sensor using microfluidic principle

\[ \Delta C = C_0 \left( \frac{H}{H - K \cdot P} - 1 \right) \]
**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

Utility
Calibration Setup

Iontronic Pressure Sensor

Mobile Device

Microchip/Bluetooth Module

Picopress®
Iontronic pressure sensor sensitivity (0.2nF/mmHg) was characterized as capacitive change ($\Delta C$) versus pressure load (P) with exact linearity as Picopress®.
Mechanical Response & Repeatability

Mechanical Response

Repeatability

Clinical Application

[Image of a leg with a device attached]

- Upper Limit Pressure: 60 ± 5 mmHg
- Lower Limit Pressure: 40 ± 5 mmHg

[Bar graph showing interface pressure for different segments]

Compliance
Compliance

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

Proprietary data
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 caregivers 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
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