Fully Wireless Insoles for Monitoring Fall risk Index (FRI)

Joint Medical + ICT R&D Experience in the framework of the FP7 European Project Wiisel (www.wiisel.eu)

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WIISEL (FP7 – ICT) Project Facts & Figures

- Title: Wireless Insole for Independent and Safe Elderly Living
- Period: 1/9/2013 to 31/3/2015
- Budget: 3.9M€ (2.9M€funding)
- Web site: www.wiisel.eu
- Leader: CETEMMSA (now EURECAT)
- 8 partners + 3 subcontractors
Addressed Challenges

- **Build** a flexible research tool to collect and analyze gait data from real users and correlate parameters related with the risk of falls from the elderly population.
- **Continuous** monitoring of elderly people through a sensor insole connected to a data analysis system.
- **Fall risk assessment** through data analysis and pattern recognition.
- **R&D** moved the concept up to TRL5-6.
- Planning a new generation of wearable ICT products.

**Insole Technology**
- CETEMMSA
- UAB
- ACREO
- GEISA

**Data Management**
- SPRING
- ACREO

**Medical Validation**
- NUI GALWAY
- INRCA
- TASMC

**TRL** = Technology Readiness Level
## Commercial Solutions for Wireless Motion Detection & Gait Analysis

<table>
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</thead>
<tbody>
<tr>
<td>WII SEL</td>
<td>Continuous gait monitoring, analysis and fall risk assessment</td>
<td>piezoresistive (14) Inertial pressure (99)</td>
<td>350</td>
<td>0.34</td>
<td>Yes</td>
<td>33.3</td>
<td>BLE</td>
<td>16</td>
<td>Pending</td>
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<tr>
<td>Pedar By Novel</td>
<td>Footwear design and injury prevention</td>
<td>pressure (99)</td>
<td>600</td>
<td>2.5</td>
<td>No</td>
<td>100</td>
<td>BT</td>
<td>1</td>
<td>15,450€</td>
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<tr>
<td>F-Scan (insole) By Tekscan</td>
<td>gait analysis &amp; biomechanics, diabetic offloading, sports medicine</td>
<td>pressure (960)</td>
<td>862</td>
<td>No</td>
<td>165</td>
<td>USB Wifi</td>
<td>0.2</td>
<td></td>
<td>16,000$</td>
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<tr>
<td>BioFoot By IBV</td>
<td>Sports Gait analysis, Footwear design</td>
<td>pressure (64)</td>
<td>1200</td>
<td>0.1</td>
<td>No</td>
<td>500</td>
<td>Wire</td>
<td>1</td>
<td>12,995€</td>
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<tr>
<td>paroLog (paro) Tecc by paromed</td>
<td>Foot pressure analysis</td>
<td>Pressure (32) Inertial</td>
<td>625</td>
<td>No</td>
<td>300</td>
<td>WIFI</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot Pressure MS By Medilogic</td>
<td>Gait, Sports, Health Prevention, Prosthesis and Orthotics, Diabetics</td>
<td>SSR sensors (240)</td>
<td>640</td>
<td>No</td>
<td>300</td>
<td>Wireless</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>SmartStep™ By Medilogic</td>
<td>rehabilitation process</td>
<td>No</td>
<td>Card</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,000$</td>
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<tr>
<td>SmartInsoles™ By 24eight, LLC</td>
<td>medical, sports and gaming</td>
<td>Pressure (4) Inertial</td>
<td>241</td>
<td>Yes</td>
<td></td>
<td>Wireless</td>
<td>~100</td>
<td></td>
<td>~100</td>
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<tr>
<td>OpenGo science By Moticon</td>
<td>Medical and sports science, Rehabilitation and training analysis</td>
<td>Pressure (13) Inertal, Temp</td>
<td>400</td>
<td>2.5</td>
<td>Yes</td>
<td>100</td>
<td>Wireless</td>
<td></td>
<td>2,000€</td>
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<tr>
<td>Footswitches Insole from B&amp;L Engineering</td>
<td>Gait analysis</td>
<td>4 pressure sensors</td>
<td>No</td>
<td></td>
<td></td>
<td>Wireless</td>
<td></td>
<td></td>
<td>299$ + 9,000$ SW</td>
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</table>

1 Resolution & Accuracy, 2 Integrated Electronics, 3 Max Data acquisition rate, 4 Data Transfer Type, 5 Battery Autonomy
**WIISEL Wireless Insoles**

**Electronics**
- 14 pressure sensors
- 3D Gyroscope/Accelerometer
- Flexible PCB
- Semiflexible Battery
- Bluetooth low energy 4.0
- Qi Inductive charge

**Material layers**
- Artificial leather
- Pressure Sensors+PU
- EVA+Electronic layer
- Rigid fiber
- EVA
A wearable and unobtrusive sensing insole – Easy to wear, connect to smartphone, know status, recharge.

Continuously captures gait and balance data:
- Stride time, single support time, swing time, double support time, cadence, steps per day, stride length, gait speed, heel acceleration slope, maximum pressure values.

To obtain large data base (big data) – Real-life & long-term data monitoring.

With a highly parameterized Fall detection algorithm.

That allows a Personalized Fall Risk Index (FRI) System Description.
Patient/Clinician User Experience
Utility: Validation

• Refers to the ability of the product to perform a task
• Elderly volunteers at 3 clinician sites
• Addressed aims:
  (1) Assess the comfort and durability of the insole,
  (2) evaluate the functionality in collecting gait data,
  (3) measure & recognition of walking patterns, activity and sedentary periods and to identify risky behaviors,
  (4) assess the users’ feasibility to operate at home
  (5) evaluate the usability

• 2 clinical phases:
  • Pilot: 3 days of assessment (1 in a laboratory + 2 at home)
  • Validation: ~2 weeks for patient’s daily living with weak support
Usability: Patients

• Extent to which a system, product or service can be used by specified users **to achieve specified goals with effectiveness, efficiency and satisfaction** in a specified context of use

• **Patient: Comfort Wearing Insoles + Smartphone**
  • 6 experts carried out an ergonomic inspection of insoles
  • 10 volunteers carried out a controlled comfort study

• App UI Evolution
Usability: Clinicians

• Clinicians:
  • Complete collection of gait parameters
  • Robust against Connection breaks
  • Fall detection without false positives
  • New FRI with sensitivity parameters
  • Results consistent with “gold” Standards
  • Big Data Architecture for parallel uploads
  • Individual Fact sheet
Desirability: Clinicians

• “I like the way the product looks and feels”
• Experts WIISEL Surveys: Interest

<table>
<thead>
<tr>
<th>Feature</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
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<tr>
<td>Fall detection algorithm</td>
<td>1</td>
<td>4</td>
<td>14</td>
<td></td>
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<td>Fall risk index</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td></td>
<td></td>
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<tr>
<td>Real life and long term human gait data</td>
<td>2</td>
<td>6</td>
<td>11</td>
<td></td>
<td></td>
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<tr>
<td>Analysis framework for research in gait</td>
<td>2</td>
<td>7</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Constant monitoring system</td>
<td>1</td>
<td>10</td>
<td>8</td>
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</table>

- Not at all interested
- Interested
- Very interested

- Clinician expert in gait and posture assessment
- Expert in wearable technologies
- Researcher in the field of fall detection-prevention
- Researcher in the field of gait and posture analysis
- Other
### Desirability: Experts

**Experts’ WIISEL Surveys: Details**

<table>
<thead>
<tr>
<th>Desired Characteristic</th>
<th>Frequency</th>
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<tr>
<td>In real life settings</td>
<td>22</td>
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<tr>
<td>Constant monitoring</td>
<td>13</td>
</tr>
<tr>
<td>Through wearable and unobtrusive device</td>
<td>12</td>
</tr>
<tr>
<td>Long term monitoring</td>
<td>11</td>
</tr>
<tr>
<td>Measurement of multiple parameters</td>
<td>9</td>
</tr>
<tr>
<td>Facility to include new functionalities</td>
<td>4</td>
</tr>
<tr>
<td>Other: Variability</td>
<td>1</td>
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</table>
Conclusions
What WIISEL have achieved

- WIISEL system is useful for studying fall risk and as a clinical tool for long-term monitoring in the home and community settings, saving time and cost
- Wireless insoles are easier to use than wired insoles
- User’s acceptance is encouraging
- Flexible SW platform adaptable to any users’ group
- New Fall Risk Index captures fall risk similar that conventional performance-based tests like the Tinetti gait and balance test and the Dynamic Gait Index.
Facts

• 657 hours collecting data
  – 15 subjects tested during pilot
  – 39 subjects tested during validation studies
• 16 experts tested the usability/ergonomics

• 180 insoles manufactured (different phases)
  – 22 Smartphones (Nexus 4)
  – 15 Battery extenders
  – 35 Inductive Chargers & adapters

Current cost of WIISEL pair of insoles ~ 800€
Scientists and researchers experts in gait, posture and movement analysis, fall prevention and intervention
On-going Development

• Update the insole platform to **decrease cost and increase reliability** to address a **wider market**
  – Use new wireless protocols for data transfer and charging
• **Validate** the system on a **wider population set**
• **Develop and validate a service model**

• **Move from TRL5-6 to TRL9-10**
  – **Specific applications** in ageing, geriatric deontology, clinicians (geriatricians, neurologists), specialists in orthopaedics, allied health professionals, care providers, rehabilitation & clinical care, research for insurances
  – **Non-clinical context**: researchers & scientists in sports, arts performers, military, high-risk workers, wearable ehealth devices, smart homes, etc.
Moltes gràcies per la vostra atenció