Sensors Converge

A Gait Lab in a Textile Sensor-Infused sock

Maurizio Macagno, CTO & Co-Founder, Sensoria Health Inc.

June 20–22, 2023 | Santa Clara, CA

#SensorsConverge

The Garment is the Computer

sensoria HEALTH

Passion & Background

- Experience in **Healthcare** and **Direct-to-Consumer Tech**
- Founders Former **Microsoft Executives**
- Based in Redmond (WA) **USA** with R&D unit already active and operating in **Italy**
- Multiple **utility and design patents obtained**
- **Sensoria Italia Srl** R&D controlled company established in Naples at UNINA Campus.

Microsoft

XBOX LIVE

Core Capabilities

*Full stack integrated **sensor-infused smart garments**, AI/ML Algos, mobile patient apps and clinician cloud dashboards.*

- Delivered **new textile sensors** and **microelectronics**, generating novel datasets for patients and clinicians
- Developed **signal processing** capabilities, **ML/AI algorithms** coupled to footwear, apparel and other accessories. From analog to digital patient experiences
- Built a full **mobile** + **cloud-based remote patient monitoring platform (RPM)** including a mobile set of interfaces improving quality of life and patient outcomes.

www.sensoriahealth.com

Multidisciplinary Team

- **Healthcare** experts
  Software engineers
  Materials engineers
  Signal processing engineers
  Data scientists
  Electrical engineers
  Mechanical engineers
  Hardware and software designers and UX **Designers**
- Prestigious research academic

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

Shepherd Center

THE UNIVERSITY OF CALIFORNIA UCLA

Baylor College of Medicine

Keck Medicine of USC

What is Gait?

- Gait is the pattern of movement when a person walks, runs or engage in any other form of locomotion
- It encompasses the coordinated actions of various body parts, as well as the rhythm and timing of those movements

- Each individual has a unique gait pattern, influenced by:
  - Body structure
  - Muscle strength
  - Neurological control

Gait Analysis

- WHAT: studying and evaluating the characteristics of an individual's gait
- WHY: assess and diagnose movement abnormalities, detect musculoskeletal or neurological problems, design appropriate interventions or treatments in the rehab process
- WHERE: clinical, research and sports science (biomechanics, rehabilitation, orthopedics, etc.)

- HOW:
  - Quantitative analysis
  - Qualitative analysis

Qualitative Gait Analysis

- Visual observation
- Subjective assessment
- Expert clinician / trained professional to observe:
  - Posture
  - Symmetry
  - Range of motion
  - Foot strike pattern
  - Observable abnormalities from normal gait
- Subjective, relies on the expertise and experience of the observer

Quantitative Gait Analysis

- Use of objective measurements and technology to analyze and quantify different gait parameters

- Technology used:
  - Motion Capture systems
  - Force plates
  - Electromyography (EMG)
  - Wearable sensors

- **Usually expensive tech, confined in the lab**

(Some) Gait Parameters

Temporal Parameters	Spatial Parameters	Derived Metrics
Step Count	Step Length	Gait Velocity
Cadence	Stride Length	Symmetry Index
Step time	Distance	Balance (Center of Pressure / Mass)
Stride Time (Gait Cycle)	…	…
Single Support / Double Support		
Stance Time / Swing Time		
…		

Gait Assessments: Many Conditions

- Frailty (Aging, fall detection, risk of fall analysis)
- Neuropathy
- Neurological Disorders (Parkinson's, MS, ALS, Cerebral Palsy, Stroke, Ataxia, etc.)
- Circulatory Disorders (ie: PAD, etc.)
- Diabetic Foot Ulcers (DFU)
- Pre and post-surgery: TKA/TKR and TKH
- All lower body rehabilitation scenarios (post traumatic events, etc.)
- Amputees, using a prosthetic device
- …

Taking the lab outside of the lab with wearables

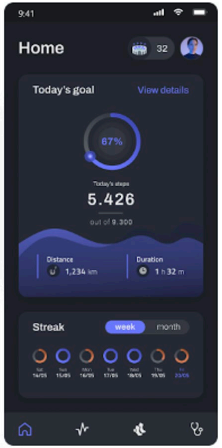
- Counting steps is not enough to properly monitor, diagnose and treat any of the previous conditions
- A wrist worn device may never be able to provide accurate gait data from gait impaired subjects
- Traditional gait labs systems:
  - are expensive, bulky, hard to set up
  - cannot be used outside the clinic
  - are only a snapshot in time of each patient
  - require patients to travel
- A wearable device able to perform gait assessments:
  - is not a replacement for a gait lab
  - should be its natural extension, complementing its data in small clinics, at home and in the community
  - ENABLING RPM: Remote Patient Monitoring (or asynchronous telemonitoring) is the device driven, automatic collection of health data from a subject, often from outside conventional care settings, which is then electronically and securely transmitted to a provider for use in care and related support services

How about a smart sock?

Monitoring All Core Patient Gait Metrics & Balance

Sensoria Smart Sock(s) specs

- Sensoria Smart Sock:
  - Traditional sock
  - 3 textile pressure sensors
  - Dock for electronic device
- Sensoria Core device:
  - Bluetooth Smart
  - Onboard 9-axis IMU
- Data collection apps for research and analysis
- End user (Consumer + Healthcare apps)
- Several utility patents assigned and pending



#SensorsConverge

Sensors Converge

Sensoria® Sock for Gait Analysis

Clinically proven to be on par or better than gold standard gait labs

Gathers gait data for post-stroke or neuro condition monitoring and rehab

Sensoria Walk app provides actionable feedback to patient

Haptic motor provides feedback to users

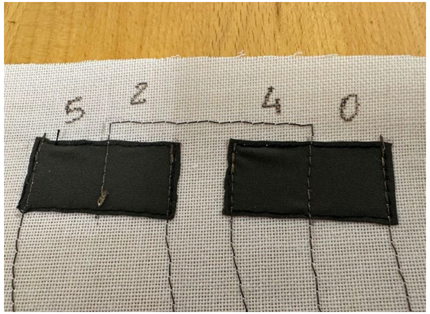
Balance and fall detection

Real time data shared with user and clinicians

Enables GDPR and HIPAA Compliant RPM Dashboards

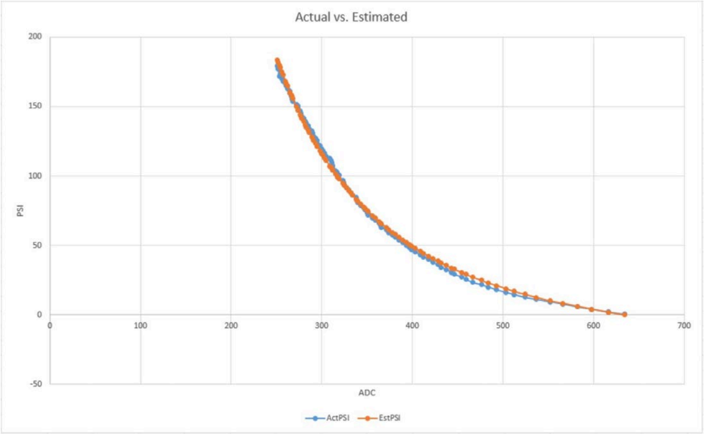
Easy to wear and use at home and in the community

Textile Sensor's characteristics



- Characteristic curve similar to traditional FSRs
- 10-12 mils (0.25-0.30mm) thick
- Wearable, washable
- Suited for integration in a garment
- Pressure estimation curve fit:

$$P_{est} = \frac{a \times ADC^{-b} + c}{Surface}$$



Sensoria Sock vs. Gait Lab

- Sensoria sock has been independently studied by several researchers
- Noteworthy study:
  - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8472002/
  - University of Sherbrooke
  - Comparing Sensoria Smart Socks to traditional gait lab systems

"We proposed a system to determine the spatio-temporal parameters of gait based on an easy-to-use non-cumbersome sock system that could be worn with all shoe types. These characteristics are very important for a wearable system to be used in a free-living environment and for a long period of time. ***The proposed system has been proven to be accurate for the estimation of temporal gait parameters and had better accuracy than a system commonly used in clinical applications (Mobility Lab) in estimating spatial parameters.*** *The IMU-instrumented sock systems could potentially be used for the estimation of the spatio-temporal parameters of gait in clinical settings and in free-living conditions, but the data should be interpreted with spatial precautions in patients with severely reduced gait speed. Further studies are needed to validate the system in different conditions and populations." Prof. Patrick Boissy*

Study Description

- Objective: Assess the accuracy of Sensoria Smart Socks
- Using a validated algorithm (TEARDRIP) for the estimation of spatial-temporal gait parameters
- 25 healthy participants (HP) + 21 patients with foot impairment (psoriatic arthritis) PsA
- Estimations of:
  - Cadence (CAD)
  - Gait Cycle Duration (GCD)
  - Gait Speed (GS)
  - Stride Length (SL)
- Slow, Normal, Fast walking speeds
- Comparison vs. MoCap system (*) on treadmill walking
- Comparison vs. established multi-IMU (**) based overground and treadmill walking

(*) 8 x Optitrack Prime 13W cameras

(**) Mobility Lab (ML) system (APDM Wearable Technologies)

Overall results

- Good agreement between the Mo-Cap system and Sensoria Socks in estimating the spatio-temporal parameters at normal and fast speeds for both HP and PsA
- Better accuracy of GS and SL than ML (both HP and PsA)
- Precision (inter-session reliability):
  - Overground walking: excellent (all speeds)
  - Treadmill (fast speed): excellent
  - Treadmill (slow and normal speed): moderate-to-good

Table 1

Descriptions of the spatio-temporal parameters and the comparison between healthy and PsA patients.

Variables	Systems	Healthy Participants	PsA Patients	*p*
		Mean ± SD	Mean ± SD	
CAD (steps/min)	IMU-instrumented sock	116.45 ± 7.25	109.05 ± 7.79	0.002
	Mobility Lab	117.18 ± 7.23	107.14 ± 10.94	0.001
GCD (s)	IMU-instrumented sock	1.04 ± 0.06	1.11 ± 0.08	0.002
	Mobility Lab	1.03 ± 0.07	1.14 ± 0.14	0.003
GS (m/s)	IMU-instrumented sock	1.46 ± 0.16	1.18 ± 0.22	<0.001
	Mobility Lab	1.34 ± 0.14	1.04 ± 0.23	<0.001
SL (m)	IMU-instrumented sock	1.46 ± 0.13	1.13 ± 0.24	<0.001
	Mobility Lab	1.37 ± 0.12	1.14 ± 0.18	<0.001

Overground walking

Overall Results (cont.)

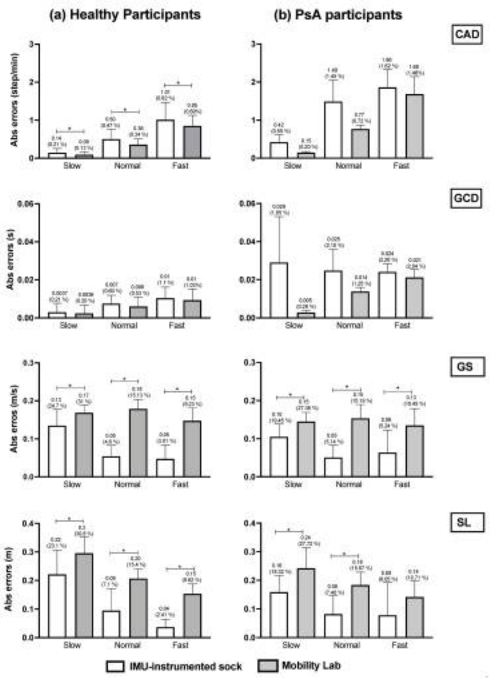


Table 2

Intersession reliability of the spatio-temporal parameters estimated by the TEADRIP algorithm applied to the IMU-instrumented sock recordings and those estimated by the Mobility Lab system for treadmill walking in HP. Intra Class Correlation Coefficient (ICCs) and their 95% CI for the treadmill 2MWT at slow, normal, and fast walking speeds.

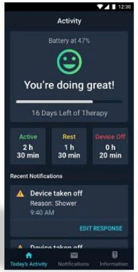
Parameter	System	Speed		
		Slow (0.45 m/s)	Normal (1.12 m/s)	Fast (1.6 m/s)
CAD	IMU-instrumented sock	0.712 (0.34 to 0.88)	0.88 (0.72 to 0.95)	0.934 (0.85 to 0.97)
	Mobility Lab	0.734 (0.40 to 0.88)	0.88 (0.7 to 0.95)	0.938 (0.86 to 0.97)
GCD	IMU-instrumented sock	0.755 (0.44 to 0.9)	0.902 (0.76 to 0.96)	0.936 (0.85 to 0.0.73)
	Mobility Lab	0.778 (0.5 to 0.9)	0.891 (0.725 to 0.95)	0.935 (0.85 to 0.972)
GS	IMU-instrumented sock	0.625 (0.14 to 0.84)	0.657 (0.2 to 0.85)	0.719 (0.4 to 0.88)
	Mobility Lab	0.746 (0.41 to 0.089)	0.835 (0.62 to 0.93)	0.757 (0.44 to 0.89)
SL	IMU-instrumented sock	0.633 (0.2 to 0.84)	0.681 (0.5 to 0.92)	0.914 (0.757 to 0.97)
	Mobility Lab	0.798 (0.54 to 0.91)	0.874 (0.7 to 0.95)	0.916 (0.8 to 0.97)

Sock vs. ML, 2 min treadmill walk

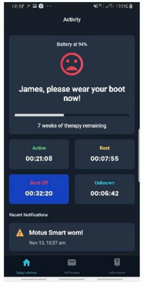
Enabling Telerehab and Remote Patient Monitoring

Mobile app provides behavioral feedback, positive reinforcement and alerts in case of non-adherence.

Patient Mobile App

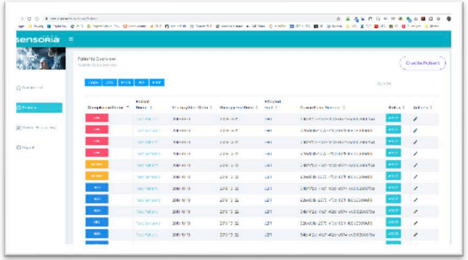


Behavioral Feedback



sensoria HEALTH
Cloud Services

Each event is recorded enabling data driven interaction by clinicians remotely. Patient population is color coded according to adherence and other programmable rules.



Clinician Dashboard

Sensoria Socks + Sensoria Core device connect wirelessly (BTLE) to Sensoria Walk mobile app that calculates and monitors patient's adherence and gait metrics.

Sensors Converge

THANK YOU!

Maurizio Macagno, CTO & Co-Founder, Sensoria Health Inc.

June 20–22, 2023 | Santa Clara, CA

#SensorsConverge

Baylor College of Medicine

Defender powered by Sensoria
Boot vs Garmin: Actigraphy and Adherence

Moin U. Atique
Postdoctoral Fellow
Department of Surgery
Baylor College of Medicine

NIH National Institute of Diabetes and Digestive and Kidney Diseases

Sensoria Core

- Nine Axis IMU
- Auto ON/OFF
- BTLE
- Rechargeable Battery
- Connects to dedicated smartwatch app.

National Institute of Diabetes and Digestive and Kidney Diseases

Sensoria Android 4G/LTE Watch Patient App

Garmin Vivosmart 4

can choose which app's notifications are sent to the fitness tracker so not to be bombarded constantly and I found they always arrived promptly.

As for battery life, Garmin promises up to seven days between charges, although that figure will drop by a few days if you choose to enable Pulse OX at night. If anything, however the Vivosmart 4 seemed to exceed those estimates. After three days of use with Pulse OX activated, the battery indicator icon still had three of its five bars filled, so I'd expect it to reach six days with the SPO2 sensor enabled and yet more still without it.

Garmin Vivosmart 4 review: Verdict

There are a few things that prevent the Vivosmart 4 from gaining a five-star review and Best Buy award, namely its lack of GPS and cycling mode. Plus, you can easily make the case that its rivals such as the Fitbit Charge 3 are better looking.

However, if you're not looking for a device that lets you track outdoor activities to the nearest ten metres, Garmin's Vivosmart 4 does everything you could ask a fitness tracker to do.

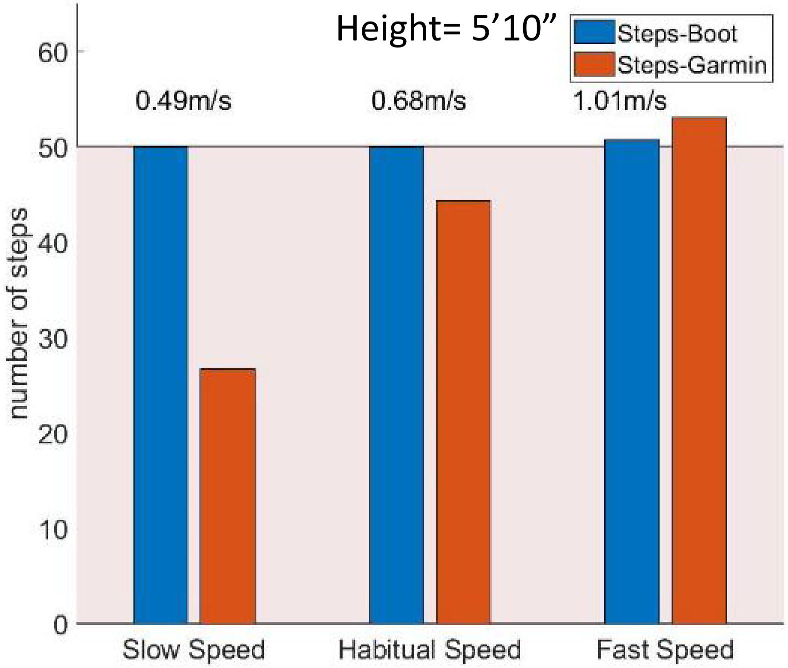
With automatic activity, sleep and stress tracking, it builds a detailed picture of your overall fitness and health that its rivals simply can't match. Crucially, this wealth of data is summarised in bite-sized form in the excellent Body Battery score, which can inform your exercise schedule, so you get fitter without over-training.

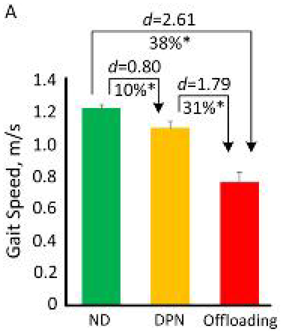
Consider that the Vivosmart 4's smart features are more reliable than those of its main rival, the Fitbit Charge 3, and there's no question which device I'd recommend. The Garmin beats the Fitbit on pretty much all counts.

Mean Step Counts (Sensoria vs Garmin)

Defender Boot – Sensoria Core

- Three speed levels (Slow, Habitual, Fast)
- 3 trials per speed
- 50 steps on each walk.





Comparison between ND, DPN, and Offloading groups for, gait speed[1].

(1) Ling, E., Lepow, B., Zhou, H., Enriquez, A., Mullen, A. and Najafi, B., 2020. The impact of diabetic foot ulcers and unilateral offloading footwear on gait in people with diabetes. *Clinical Biomechanics*, *73*, pp.157-161

National Institute of Diabetes and Digestive and Kidney Diseases

Mean Error (Defender Boot vs Garmin watch)