Patient wearables – how effective are they?

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Outline

- What does it mean “wearable devices”?
- What does it mean “wearable biomedical devices”?
- What is a digital health ecosystem?
- What and how to measure to assess respiratory function?
- Patient wearables – how effective are they?

Wearable devices

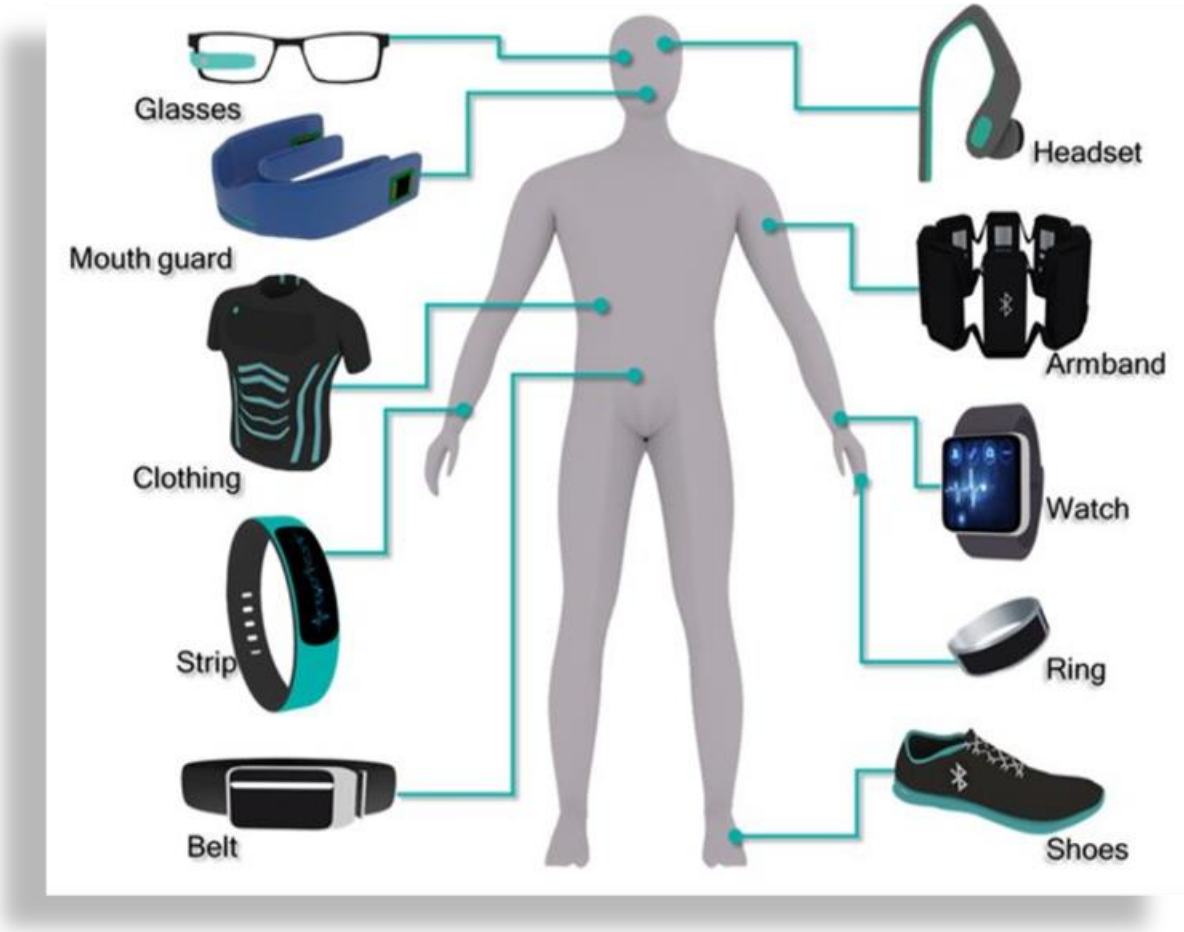
"**Wearable**" means whatever a subject can wear, as sweaters, hats, pants, eyeglasses, bras, socks, watches, patches or devices just fixed on the belt, without encumbering daily activities or restricting the mobility.

The concept of **wearability** is of particular importance in fields like monitoring for healthcare, wellbeing and fitness/sport.

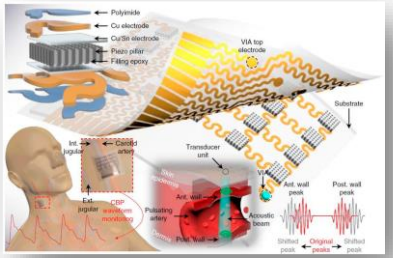
Wearable technology

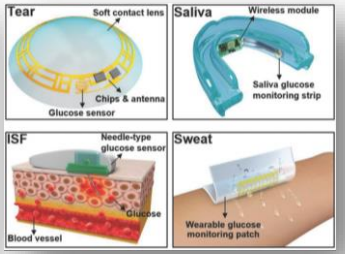
conventional
'rigid' electronics

more disruptive
'soft' technology
(e.g. apparel and textiles with distributed functions, in which electronics is intimately combined)



Technological trend





lab devices

Handheld/ portable devices

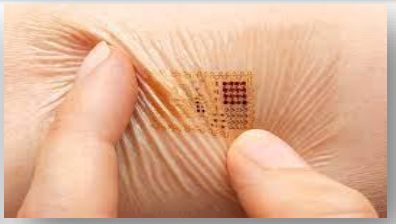
wearable devices (rigid electronics)

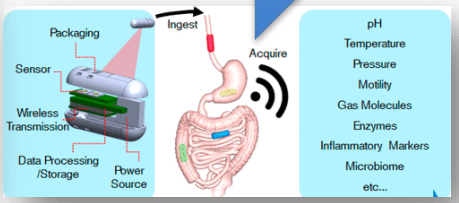
wearable devices (flexible, e-textile)

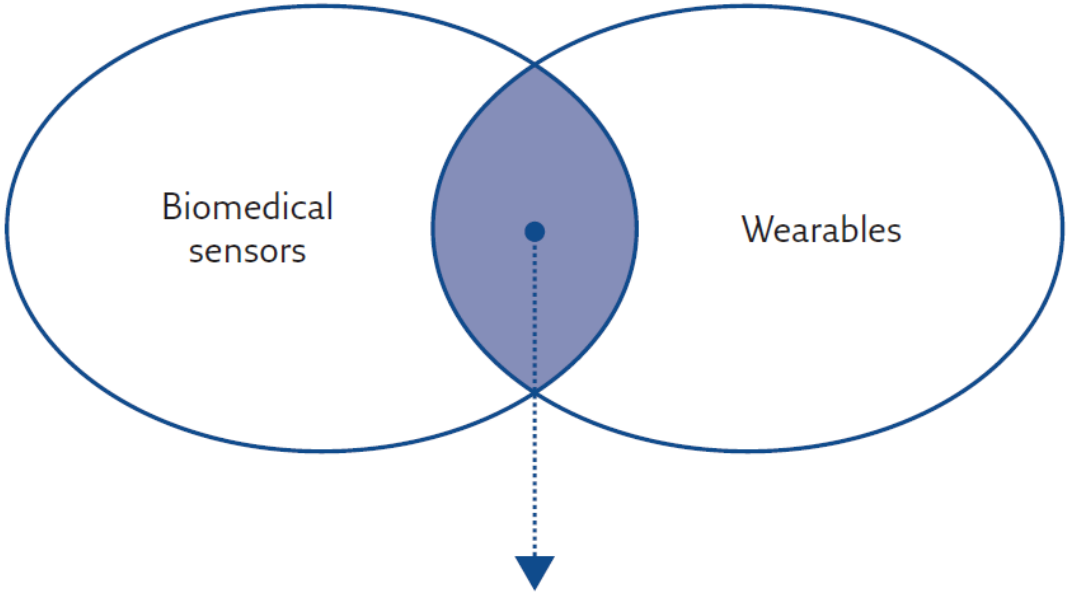
attachable devices (e-tattoos)

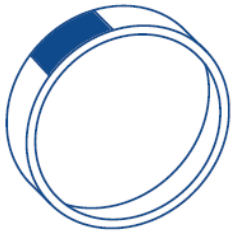
implantable Devices (under skin)

ingestible devices





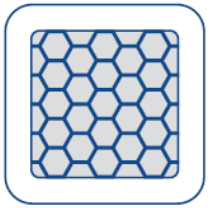




Activity trackers

Smart watches

Smart clothing



Patches/ tattoos

Ingestibles/ smart implants

Aliverti A. Wearable technology: role in respiratory health and disease
Breathe 2017; 13: e27–e36

European
Medical Device (new) Regulation

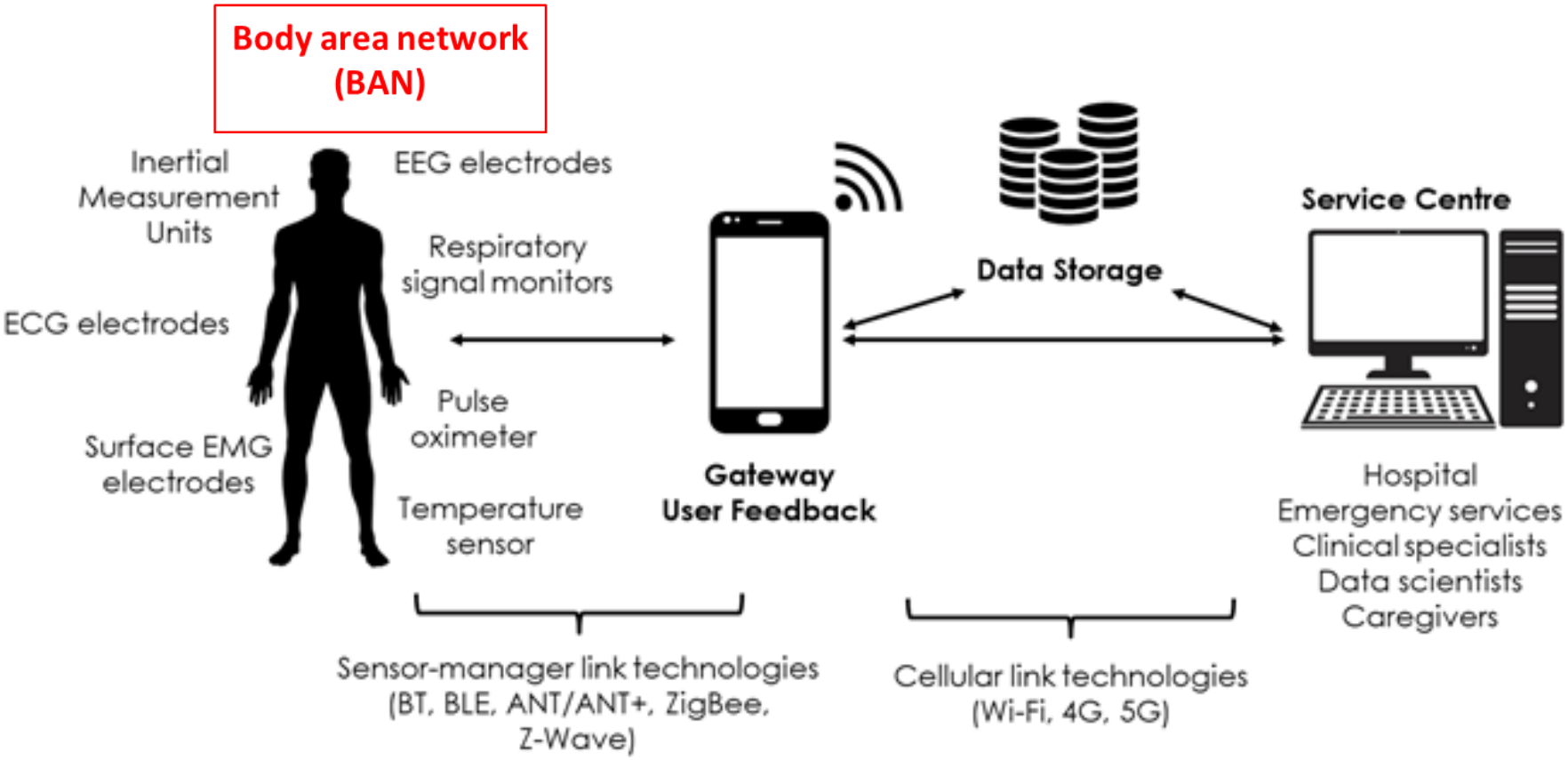
The medical device (MD) sector is regulated by Directives 93/42/EC and 90/385/EEC. **From 26 May 2021, the new Regulation 2017/745/EU is fully applied in Europe.**

Classification of medical devices (estimated to be more than 500.000) drives many **pre- and postmarket requirements**.

Due to the large variety of products, the level of control made by a thirdparty (the “notified body”) before placing them in the market depends on the level of impact on the human body that their use might imply.

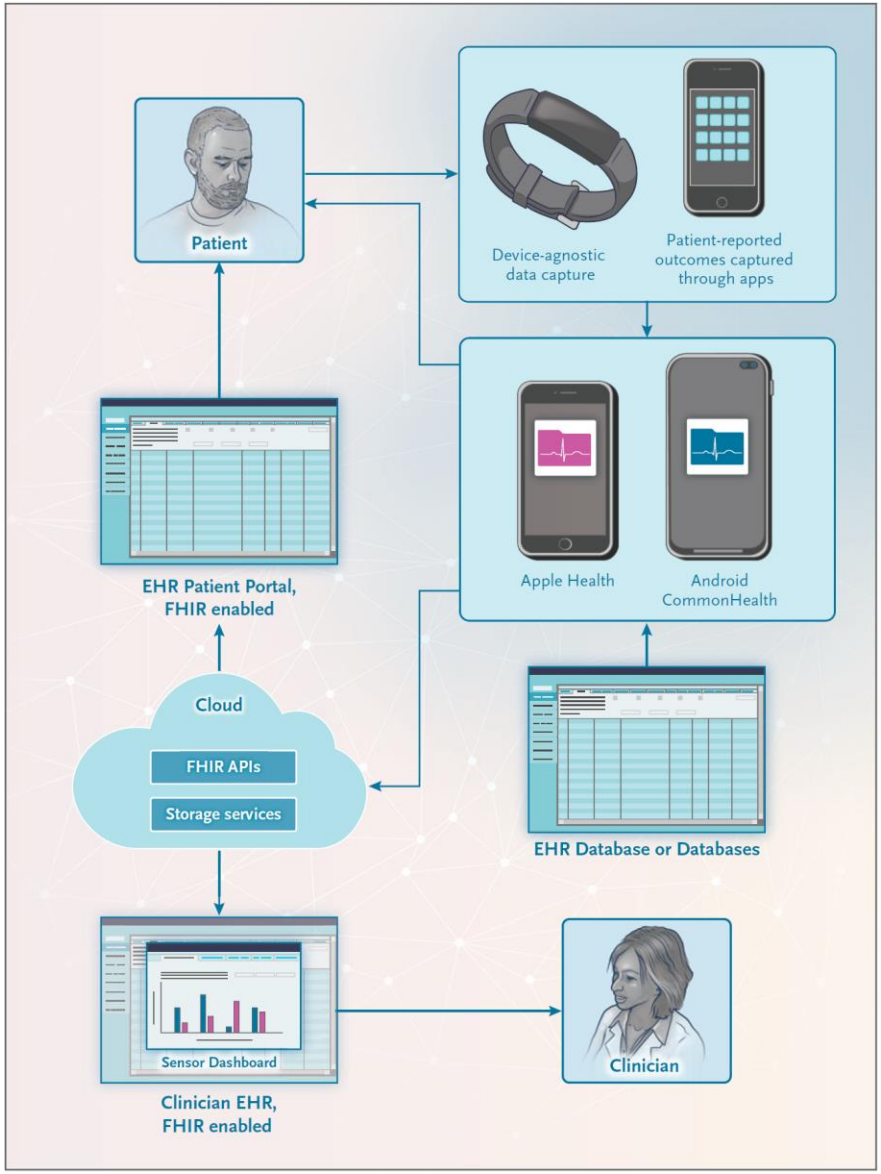
The same notified body is involved post-market to ensure the continued safety and performance of medical devices.

Telemonitoring systems
“two-hop” data transmission architecture



Aliverti, Breathe, 2017
Angelucci, Sensors, 2021

Digital Healthcare Ecosystem

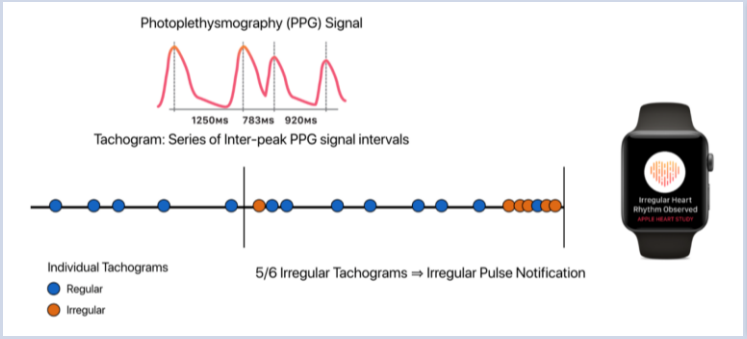
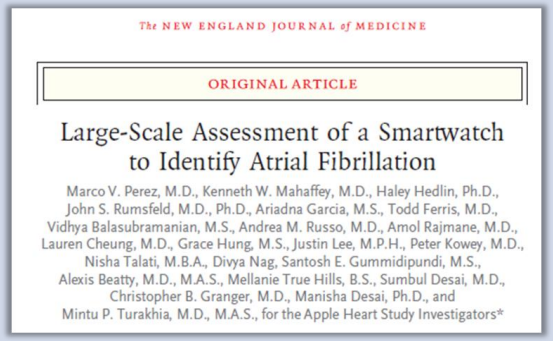


- infrastructure that supports the shift from an organization-centric to a **patient-centric model** of delivering healthcare services using digital platforms to encourage cross-organizational, multidisciplinary, and collaborative healthcare delivery

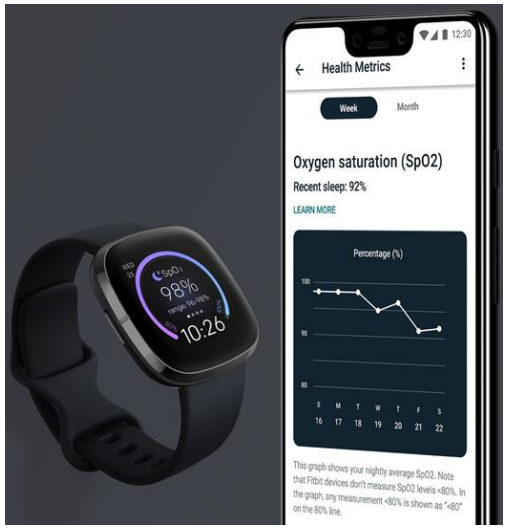
- the infrastructure comprises an internet platform that offers digital healthcare services. It promotes **interoperability** by allowing intercommunication among healthcare professionals. It also enables the sharing of **Electronic Health Records (EHR)**

Sim, N Engl J Med, 2019

Cardiac function

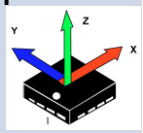
Sensors	Measurements
Photo-plethysmography (PPG)	HR, HRR, HRV, cuff-less BP, SaO2, cardiac output, stroke volume, pulse-based rhythm detection, sleep and its stages  
ECG	Single-lead and multi-lead ECG, continuous or as-needed ECG monitoring, interval measurements such as QTc, arrhythmia detection

Pulse oximeters



Ding et al, IEEE Reviews in Biomedical Engineering, 2020

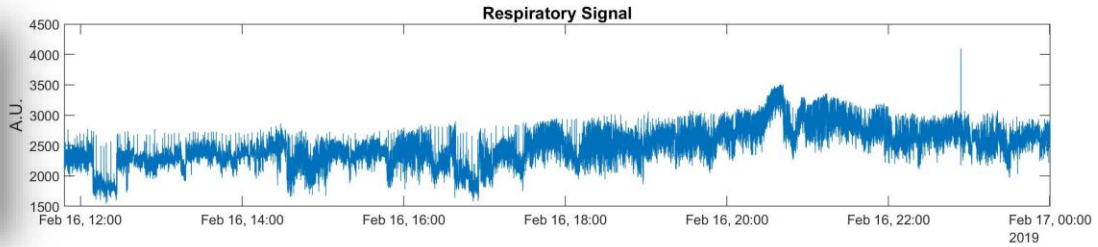
Physical activity / actigraphy

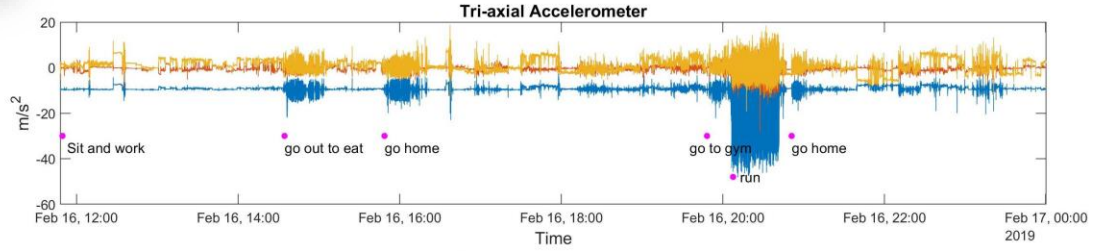
Sensors	Measurements	Clinical applications
Accelerometer 	Step count, impact force, speed, sedentary time, exercise	• Risk assessment in healthy individuals and those with established chronic respiratory disease • Physical activity behavioural interventions in primary and secondary prevention • Telerehabilitation • COPD or asthma management
Barometer	Stair count	
GPS	Distance traveled	
	Calories burned estimated from multiple measurements	

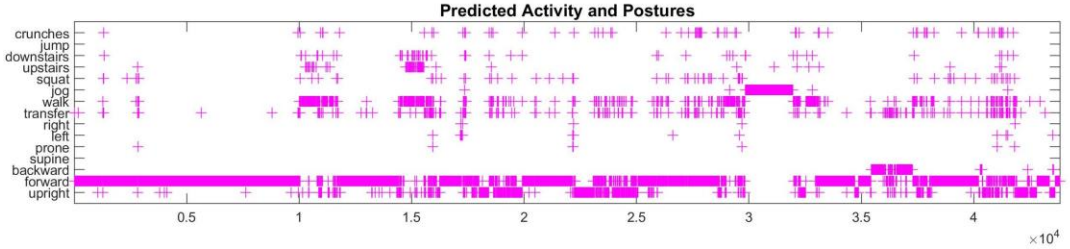
IEEE JOURNAL OF BIOMEDICAL AND HEALTH INFORMATICS 1

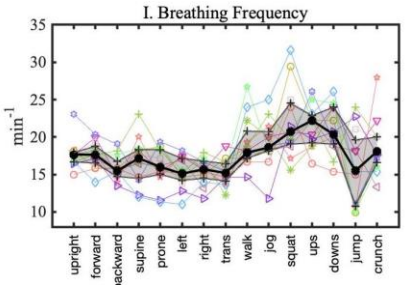
A Multimodal Wearable System for Continuous and Real-time Breathing Pattern Monitoring During Daily Activity

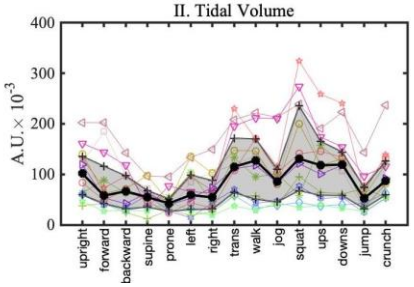
Wen Qi and Andrea Aliverti

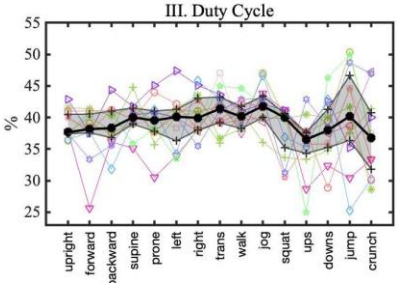








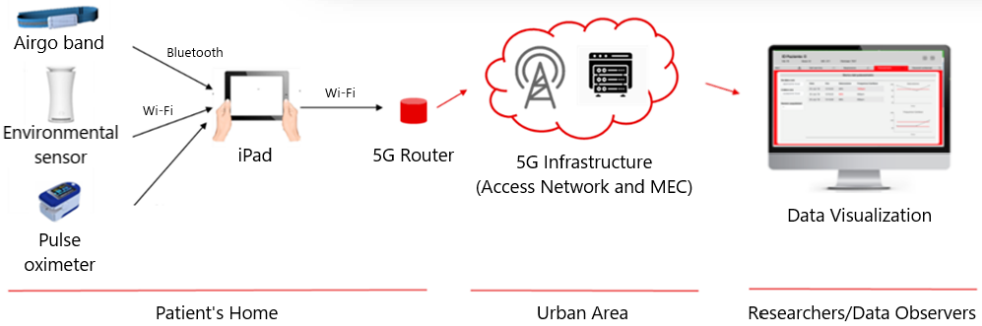


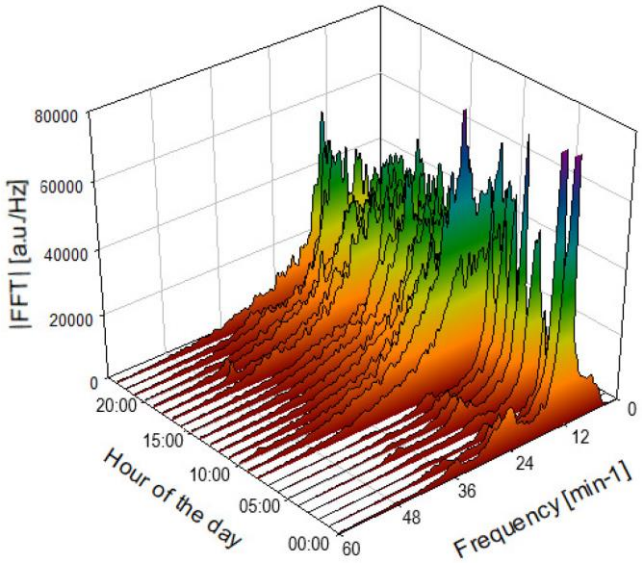


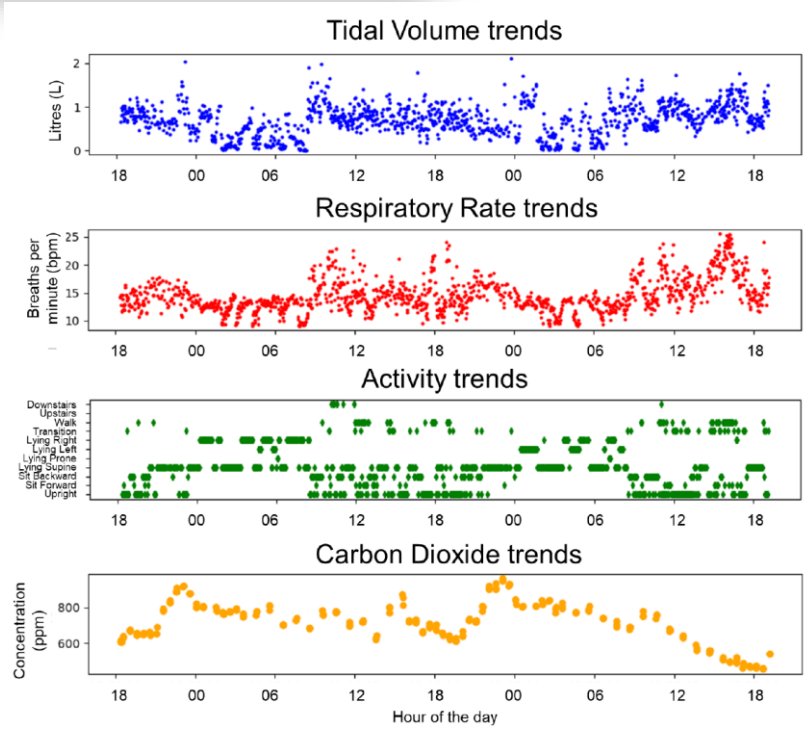
IEEE JOURNAL OF BIOMEDICAL AND HEALTH INFORMATICS, VOL. 25, NO. 4, APRIL 2021 1247

A Home Telemedicine System for Continuous Respiratory Monitoring

Alessandra Angelucci, David Kuller, and Andrea Aliverti







Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Qualitative and quantitative evaluation of a new wearable device for ECG and respiratory Holter monitoring

Antonio Sarmento [a,1], Carlo Vignati [b,c,1], Stefania Paolillo [d], Carolina Lombardi [e], Alessandra Scoccia [b], Flavia Nicoli [b], Massimo Mapelli [b], Alessandra Leonardi [f], Dario Ossola [f], Rudy Rigoni [a,f], Piergiuseppe Agostoni [b,c,*], Andrea Aliverti [a]

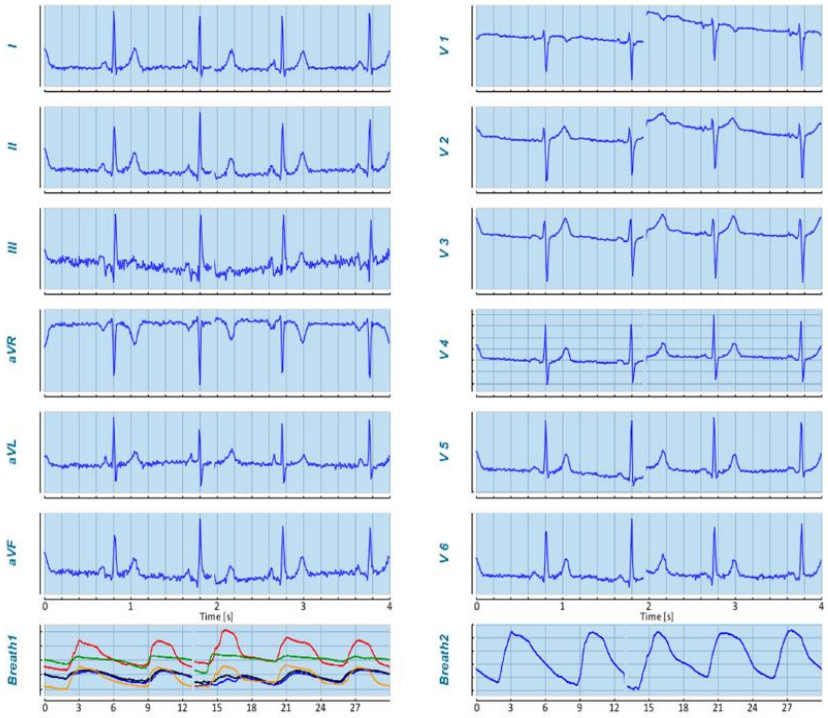


Fig. 1. Example of all 12-lead ECG and the five respiratory traces recorded by L.I.F.E. device.

PLOS ONE

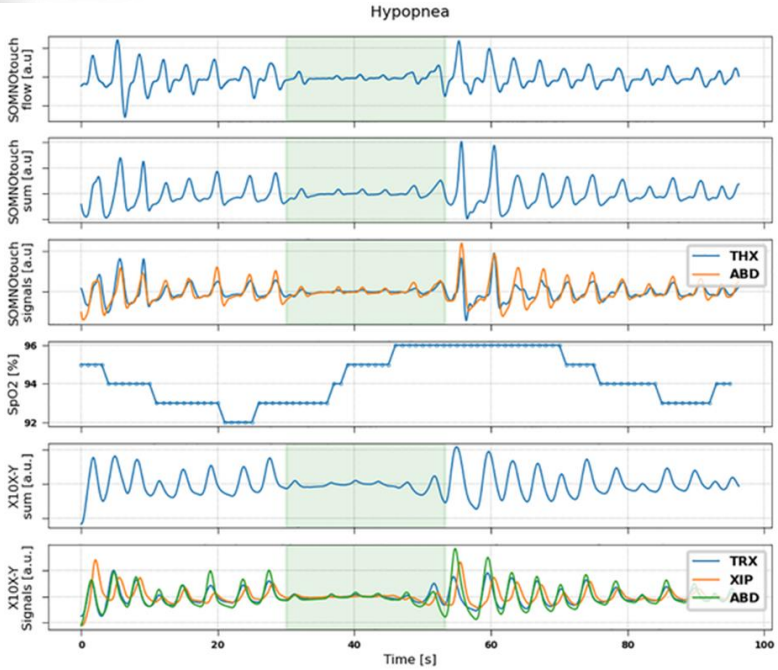
RESEARCH ARTICLE

Validation of a new wearable device for type 3 sleep test without flowmeter

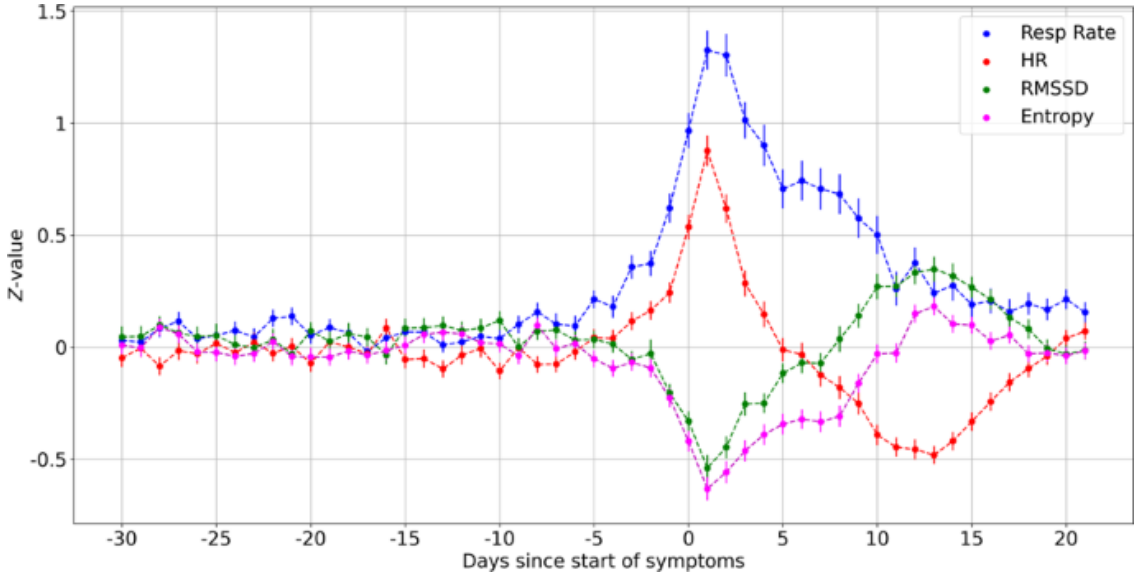
Mauro Contini[1☯], Antonio Sarmento[2☯], Paola Gugliandolo[1], Alessandra Leonardi[3], Gianluigi Longinotti-Buitoni[3], Camilla Minella[4], Carlo Vignati[1,5], Massimo Mapelli[1], Andrea Aliverti[2]*, Piergiuseppe Agostoni[1,5]

1 Centro Cardiologico Monzino, IRCCS, Milano, Italy, **2** Dipartimento di Elettronica, Informazione e Bioingegneria, Politecnico di Milano, Milano, Italy, **3** L.I.F.E. Corporation S.A., Luxembourg, Luxembourg, **4** L.I.F.E. Italia S.r.l., Milano, Italy, **5** Department of Clinical Sciences and Community Health, Cardiovascular Section, University of Milano, Milano, Italy

☯ These authors contributed equally to this work.
* andrea.aliverti@polimi.it



COVID-19



npj | Digital Medicine
www.nature.com/npjdigitalmed
ARTICLE OPEN
Check for updates

Assessment of physiological signs associated with COVID-19 measured using wearable devices

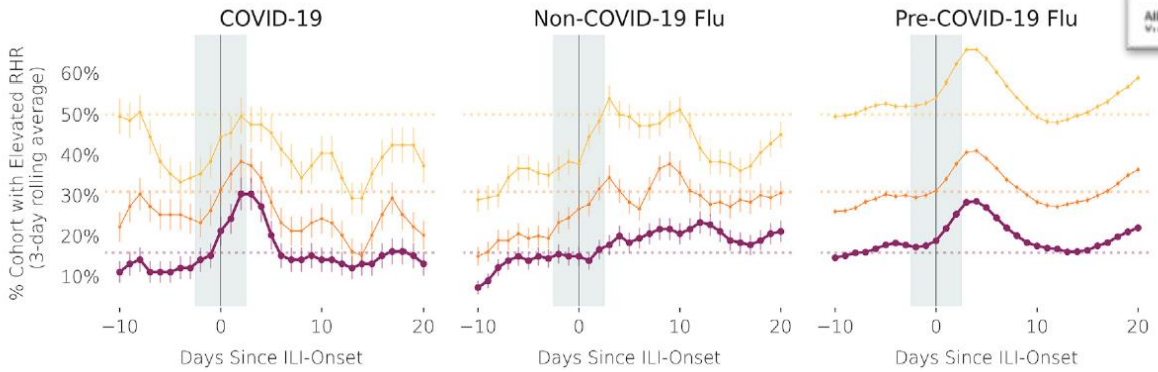
Aravind Natarajan[1✉], Hao-Wei Su[1] and Conor Heneghan[1]

data on 2745 subjects diagnosed with COVID-19 using the active infection PCR swab test with test dates ranging from February 16 to September 9, 2020. All subjects wore Fitbit devices

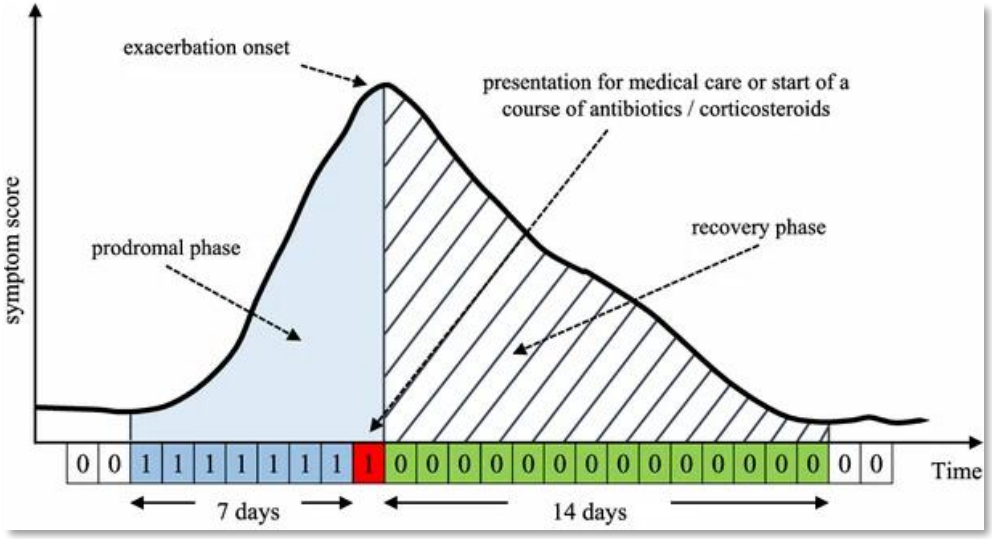
Patterns
CellPress
OPEN ACCESS
Article

Characterizing COVID-19 and Influenza Illnesses in the Real World via Person-Generated Health Data

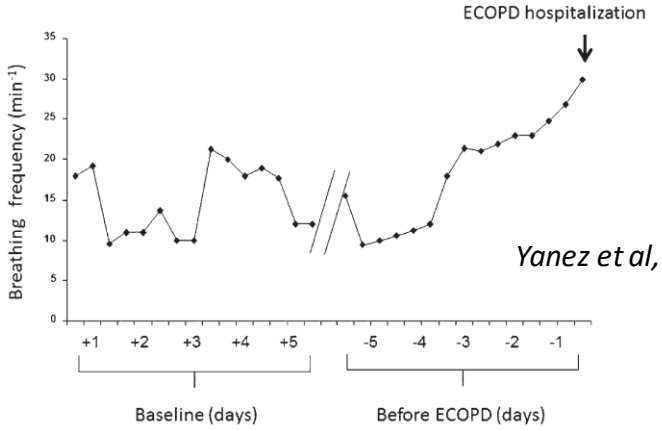
Allison Shapiro,[1,2] Nicole Marinsek,[1,2] Ieuan Clay,[1] Benjamin Bradshaw,[1] Ernesto Ramirez,[1] Jae Min,[1] Andrew Trister,[2]



COPD exacerbation



Several (>15) studies showing positive results in predicting/detecting an exacerbation episode via monitoring of physiological parameters (HR, SaO2, respiratory rate)



Yanez et al, Chest, 2012

→ promising, but further well-designed clinical trials are required to investigate the true magnitude and time-course pre, during, and post an exacerbation episode of changes in physiological parameters

Asthma

- large number of asthma-related apps for education, symptom tracking, environmental alerts, and medication reminders.

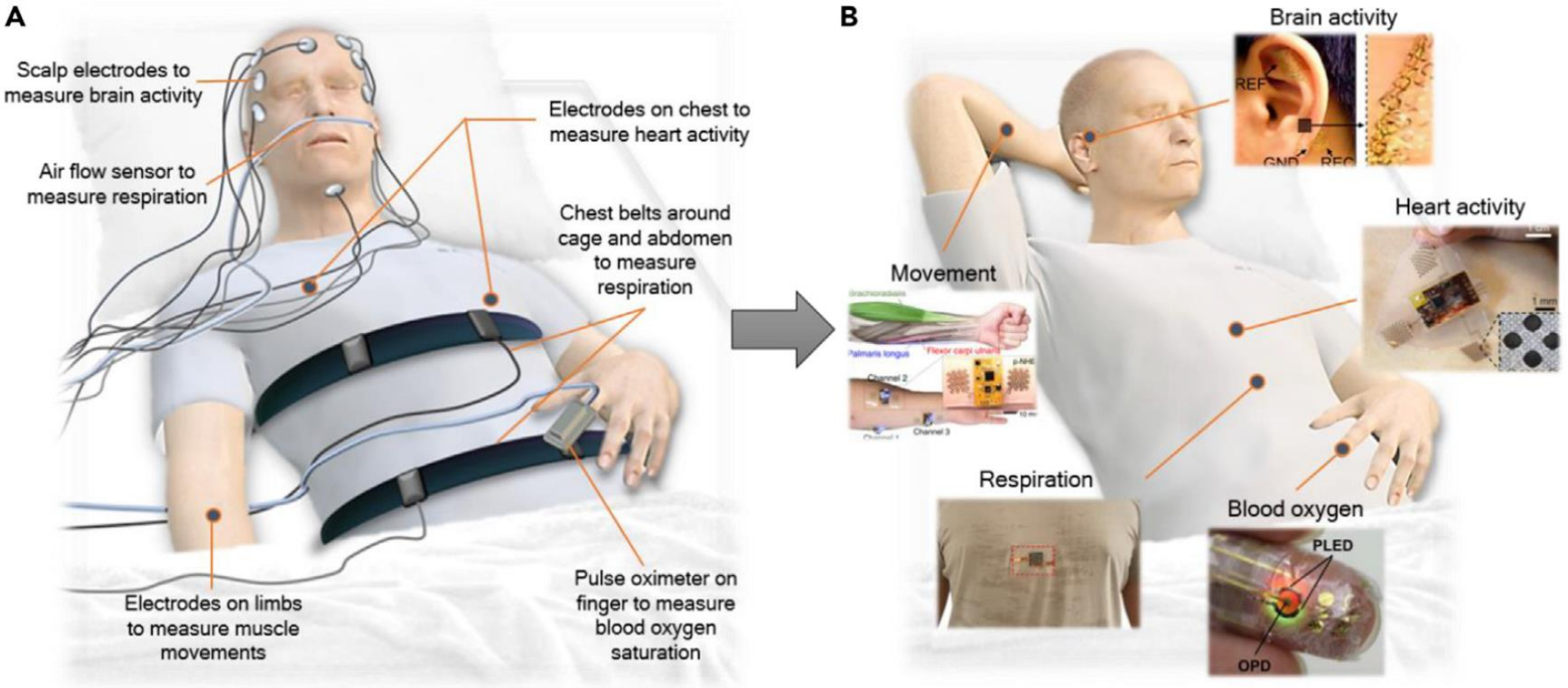
  Himes et J Allergy Clin Immunol Pract. 2019

- Very few effectiveness evaluations have been conducted.

  Marcano Belisario et al, Cochrane Database Syst Rev. 2013.
  Farzandipour M, Appl Clin Inform. 2017;

  → mHealth apps improved asthma control in five studies, lung function in two studies, and quality of life in three studies. There was no significant impact on economic outcomes such as hospitalization rates.

Sleep



iScience

CellPress
OPEN ACCESS

Review

Recent advances in wearable sensors and portable electronics for sleep monitoring

Shinjae Kwon,[1] Hojoong Kim,[1] and Woon-Hong Yeo[1,2,3,*]

Neuromuscular disorders

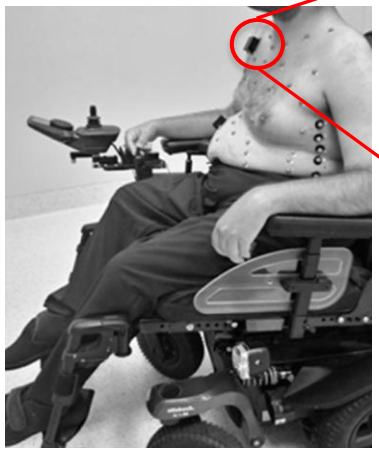
sensors

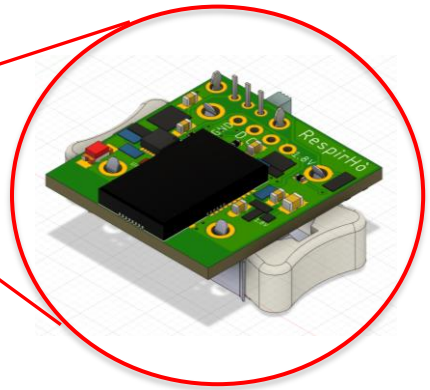
MDPI

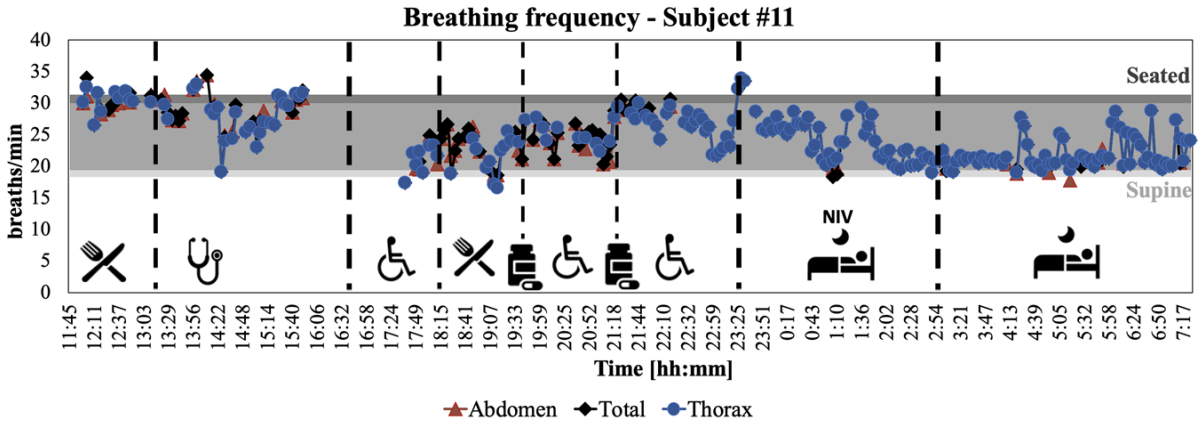
Article

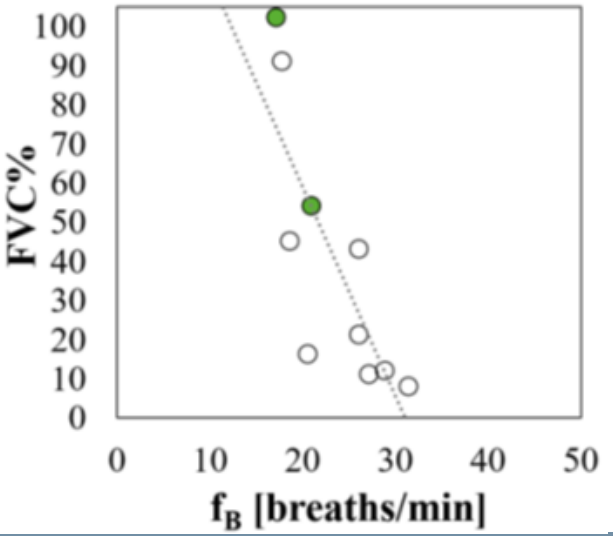
A Wearable Device for Breathing Frequency Monitoring: A Pilot Study on Patients with Muscular Dystrophy

Ambra Cesareo [1], Santa Aurelia Nido [2], Emilia Biffi [1], Sandra Gandossini [3], Maria Grazia D'Angelo [3] and Andrea Aliverti [2,*]









Conclusions

- Consumer-grade wearable sensors have drastically expanded Remote Patient Monitoring (RPM) capabilities to the entire population aiding in early diagnosis and real-time disease management.

- Need of developing solutions which provide medical grade measurements, are certified as medical devices, offers the highest safety to protect patient privacy

- Home monitoring enabled by automated alert systems tailored specifically to the needs of the patient by the provider will be the cornerstone of a more continuous, patient-centric healthcare model.

- Need of studies to study effectiveness