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 (rigid electronics)
- Wearable devices (flexible, e-textile)
- Attachable devices (e-tattoos)
- Implantable Devices (under skin)
- Ingestible devices

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Wearable technology: role in respiratory health and disease.
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

Body area network (BAN)
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)**.
<table>
<thead>
<tr>
<th>Sensors</th>
<th>Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photo-plethysmography (PPG)</td>
<td>HR, HRR, HRV, cuff-less BP, SaO2, cardiac output, stroke volume, pulse-based rhythm detection, sleep and its stages</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Photo-plethysmography (PPG) Signal" /></td>
</tr>
<tr>
<td>ECG</td>
<td>Single-lead and multi-lead ECG, continuous or as-needed ECG monitoring, interval measurements such as QTc, arrhythmia detection</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="AliveCor® KardiaMobile 6L" /></td>
</tr>
</tbody>
</table>
Pulse oximeters

Ding et al, IEEE Reviews in Biomedical Engineering, 2020
# Physical activity / actigraphy

<table>
<thead>
<tr>
<th>Sensors</th>
<th>Measurements</th>
<th>Clinical applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerometer</td>
<td>Step count, impact force, speed, sedentary time, exercise</td>
<td>• Risk assessment in healthy individuals and those with established chronic respiratory disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Physical activity behavioural interventions in primary and secondary prevention</td>
</tr>
<tr>
<td>Barometer</td>
<td>Stair count</td>
<td>• Telerehabilitation</td>
</tr>
<tr>
<td>GPS</td>
<td>Distance traveled</td>
<td>• COPD or asthma management</td>
</tr>
<tr>
<td></td>
<td>Calories burned estimated from multiple measurements</td>
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</tbody>
</table>
A Multimodal Wearable System for Continuous and Real-time Breathing Pattern Monitoring During Daily Activity

Qi and Aliverti

IEEE JOURNAL OF BIOMEDICAL AND HEALTH INFORMATICS

Respiratory Signal

Tri-axial Accelerometer

Predicted Activity and Postures

I. Breathing Frequency

II. Tidal Volume

III. Duty Cycle

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Qi and Aliverti, IEEE J Biomed and Health Informatics, 2020
A Home Telemedicine System for Continuous Respiratory Monitoring

Alessandra Angelucci, David Kuller, and Andrea Aliverti

Diagrams showing data visualization and trends for tidal volume, respiratory rate, activity, and carbon dioxide over time.

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

Antonio Sarmento a,1, Carlo Vignati a,c, Stefania Paolillo b, Carolina Lombardi a, Alessandra Scocca a, Flavia Nicoli a, Massimo Mapelli b, Alessandro Leonardi b, Dario Ossola b, Rudy Rigoni b, Piergiuseppe Agostoni a,c, Andrea Aliverti a

![Image of wearable device]

Fig. 1. Example of all 12-lead ECG and the five respiratory traces recorded by LIFE device.

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

Mauro Contini1, Antonio Sarmento2, Paola Giugliandolo3, Alessandra Leonardi4, Gianluigi Longinotti-Bultoni5, Camilla Minella6, Carlo Vignati7, Massimo Mapelli8, Andrea Aliverti9, Piergiuseppe Agostoni1

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

4 These authors contributed equally to this work.
5 andrea.aliverti@polimi.it
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.
COPD exacerbation

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

→ 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 al, J Allergy Clin Immunol Pract. 2019

- Very few effectiveness evaluations have been conducted.

  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

A
Scalp electrodes to measure brain activity
Air flow sensor to measure respiration
Electrodes on chest to measure heart activity
Chest belts around cage and abdomen to measure respiration
Electrodes on limbs to measure muscle movements
Pulse oximeter on finger to measure blood oxygen saturation

B
Brain activity
Movement
Respiration
Blood oxygen

iScience
Review
Recent advances in wearable sensors and portable electronics for sleep monitoring
Shinjae Kwon, Hojoong Kim, and Woon-Hong Yeo

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Neuromuscular disorders
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