Conclusions

- **Remote vital monitoring wearable technology** is now mature enough to fit the needs of pharma companies for clinical trial applications

- **New technologies will face resistance** from the medical community **and require grounded scientific evidence**
  - Publication in technical outlets
  - Publication in peer-reviewed scientific outlets
  - Membership of standardization bodies

- Respiration is high on the list, but **let's not forget all other therapeutic areas**

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Cisco Webex Events

File Edit View Communicate Participant Event Help

IW imec webinars (Host)

Carlos Agell

ZG Zohaib Gulzar

Q&A

Wearables

Over the hype

- **18 years since we started**
  - **11 years from the first Fitbit**
- The wearables market in 2020 expected to be **~US$ 19,000 Million**
- More than **440 Million Users in 2020**
- Diverse market such as
  - Entertainment
  - Payments
  - Wellbeing
- Slow but steady adoption in medical environments

First version of Fitbit released in 2009, *source Fitbit*

Abbott's FreeStyle Libre remote glucose monitoring system, *Source Diabetes vereniging Nederland*

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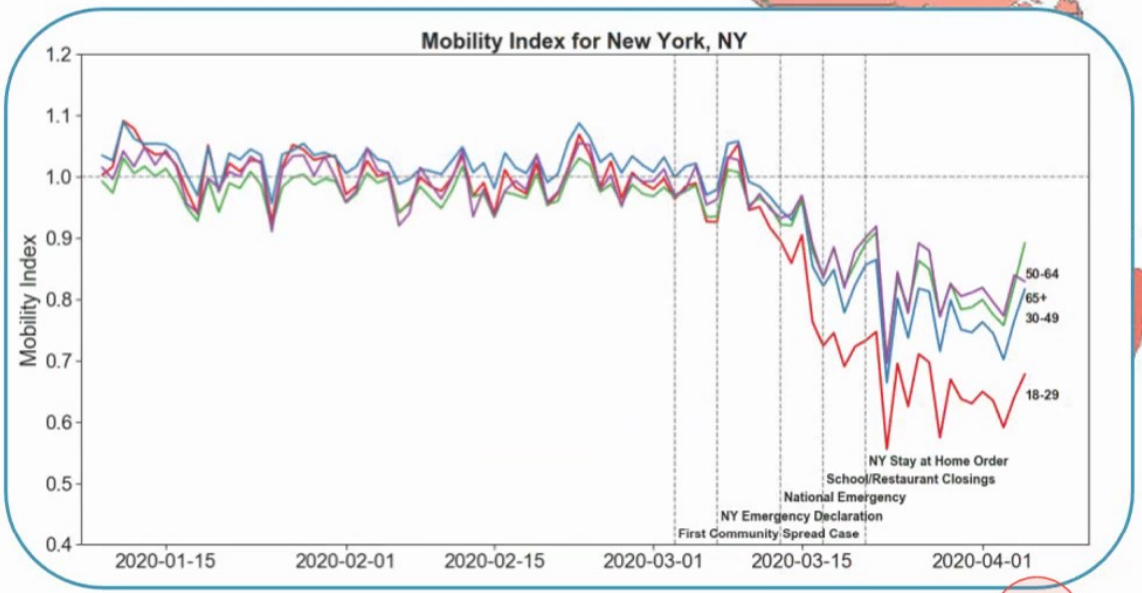
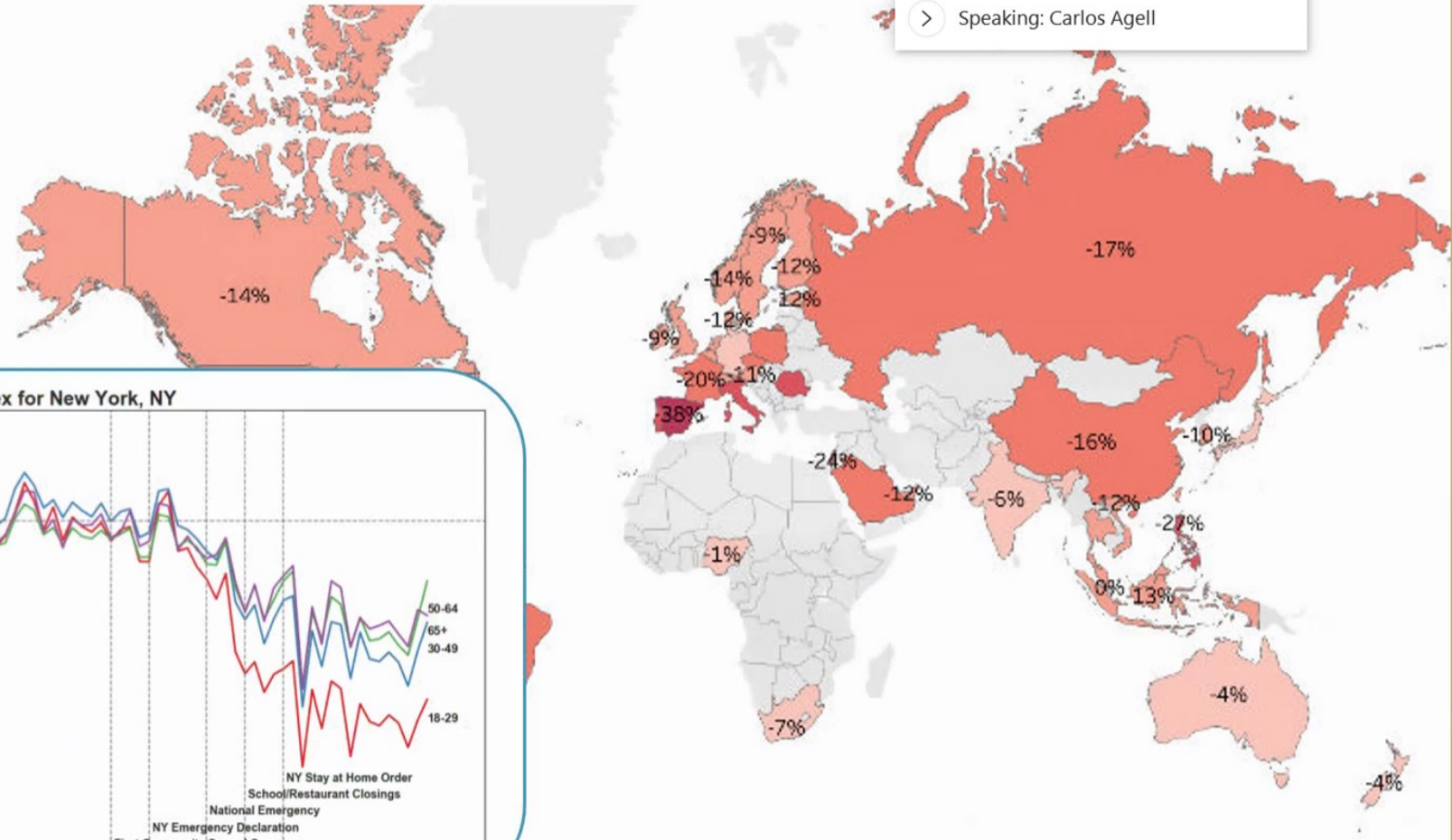
ここに入力して検索

16:18
2020/06/04

Wearables provide valuable metrics

Fitbit dashboards





Speaking: Carlos Agell

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Source Fitbit NEWS

fitbit

Present healthcare view

Remote vital sign monitoring

- Mostly wearable-based sensors
- Wearable – Smartphone – Cloud architecture
- Process with AI, trend detection
- Detect anomalies (notify the user)
- Generate doctor's report

Source BioTelemetry

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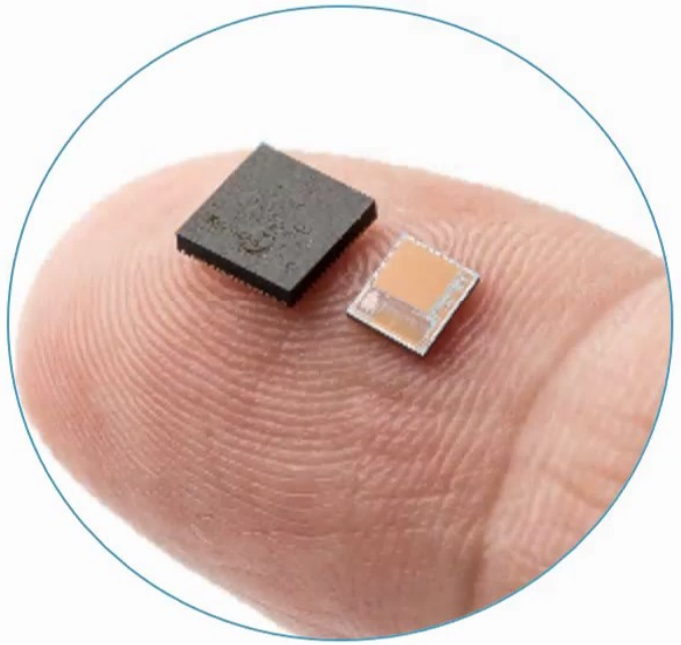
Imec multimodal acquisition chipsets: Museic

Foundation for next generation wearables

- Going from single mode …
- … to multimode
  - Cardiac activity (ECG)
  - Heart rate
  - Respiration rate

Museic family of chipset:

available for licensing



Vital signs sensing with one single chip Museic v3

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Beyond today's wearables

- Use existing wearable tech to perform **seamless trials**

- Beyond wearables: **new form factors**

- Beyond sensing: **closing the loop**

- On the horizon: **artificial organs**

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Getting most out of current wearables

Using them for pharma trials

- Great starting point for **next-generation experimental trials**
- Pervasive and ambulatory companion for **classical Randomized Control Trials**
- Promising tool for **Real World Evidence** trials
- Envision trials where you **receive a device kit** at home, **sign in through an app** and then live your usual life

Source Experitest

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Imec investigational devices for Real World Evidence

Set of **wearable devices enabling data collection in the real world, including** patch and wrist form factors:

- A great starting point for feasibility studies and proof of concepts for your next application
- Enabling unobtrusive 24/7 data collection
- Potential to create longitudinal studies for the processing of data across populations, conditions, interventions, etc.

- A tool for the **pharma/medical device** industry
  - Where the data from the investigational device can help back up medical evidence and endpoints.
  - Raw data, features, analysis and high-level conclusions all available for investigational purposes

Stress at work

Examples of wearable-based

Real-world Study

Large-scale wearable data reveal digital phenotypes for daily-life stress detection

Elena Smets, Emmanuel Rios Velazquez, Giuseppina Schiavone, Imen Chakroun, Ellie D'Hondt, Walter De Raedt, Jan Cornelis, Olivier Janssens, Sofie Van Hoecke, Stephan Claes, Ilse Van Diest & Chris Van Hoof

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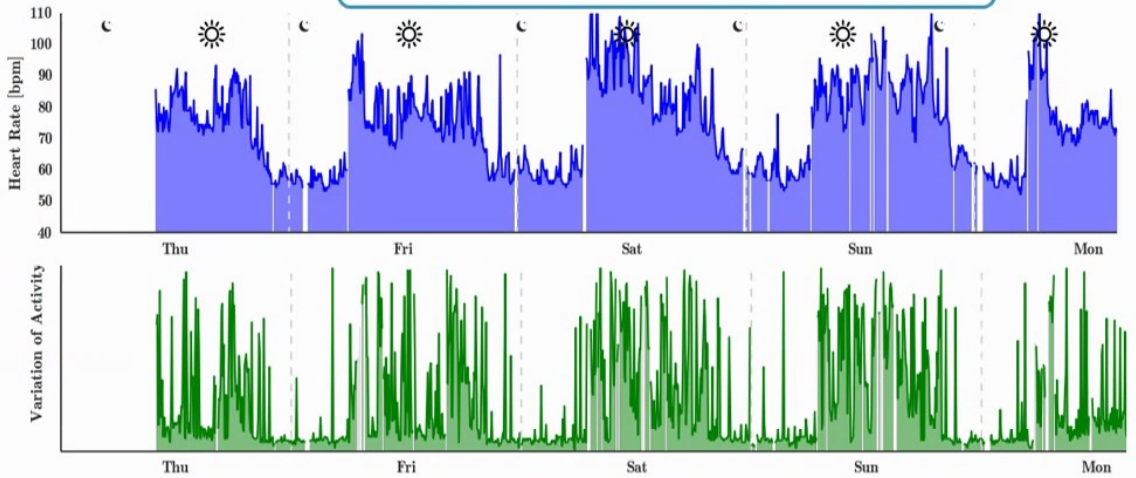
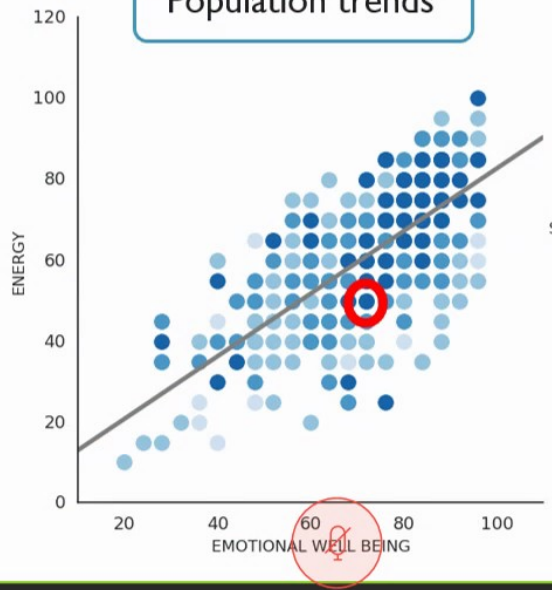
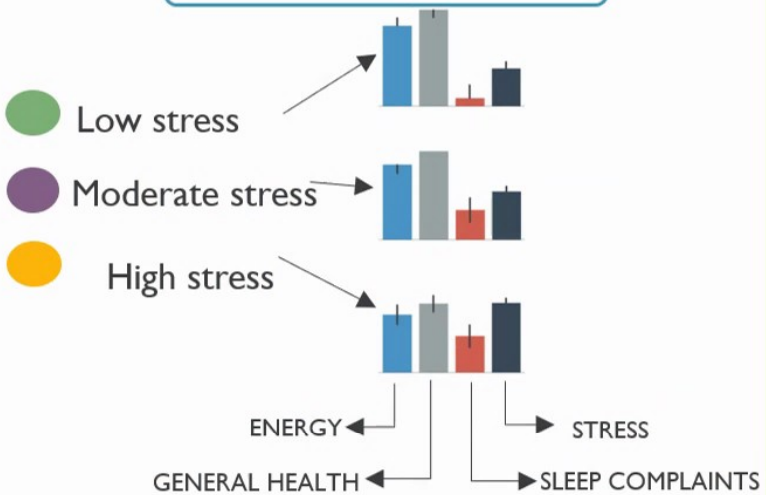
Daily dynamics of the individual's traits



Population trends



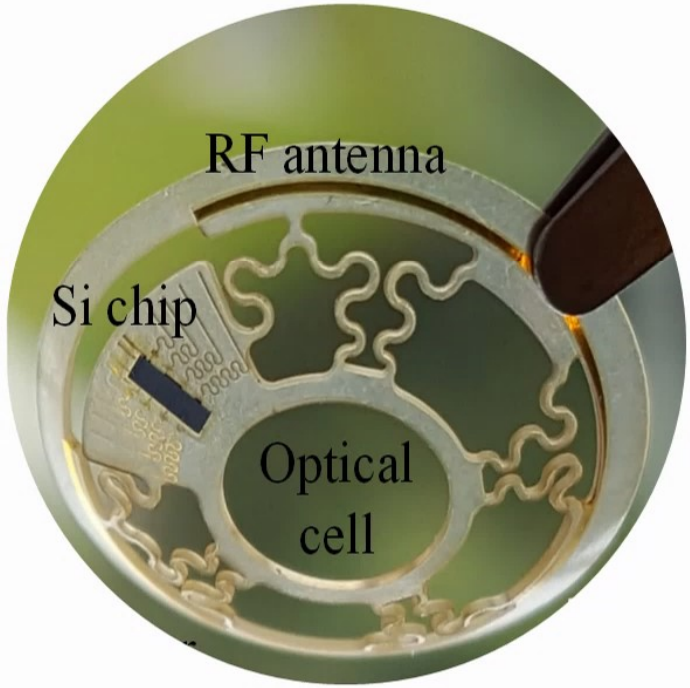
Link to Health Indicators



Insertables: smart lens platform

In-eye and actuation platform

- **Lens inserts**
  - Lens insert based on custom ultra-thin silicone chipset and **unique stretchable interconnect**
  - **< 150 µm (6 mil)** wrinkle-free thermoformed insert
  - **Polyimide carrier**
- **Integrated antenna design**
  - **NFC** and **charging**
- **Custom chipset:** driving signal generation, power management, sensor signal conditioning & communication
- **Example ophthalmological devices:**
  - Unique silicon, integration and process technology



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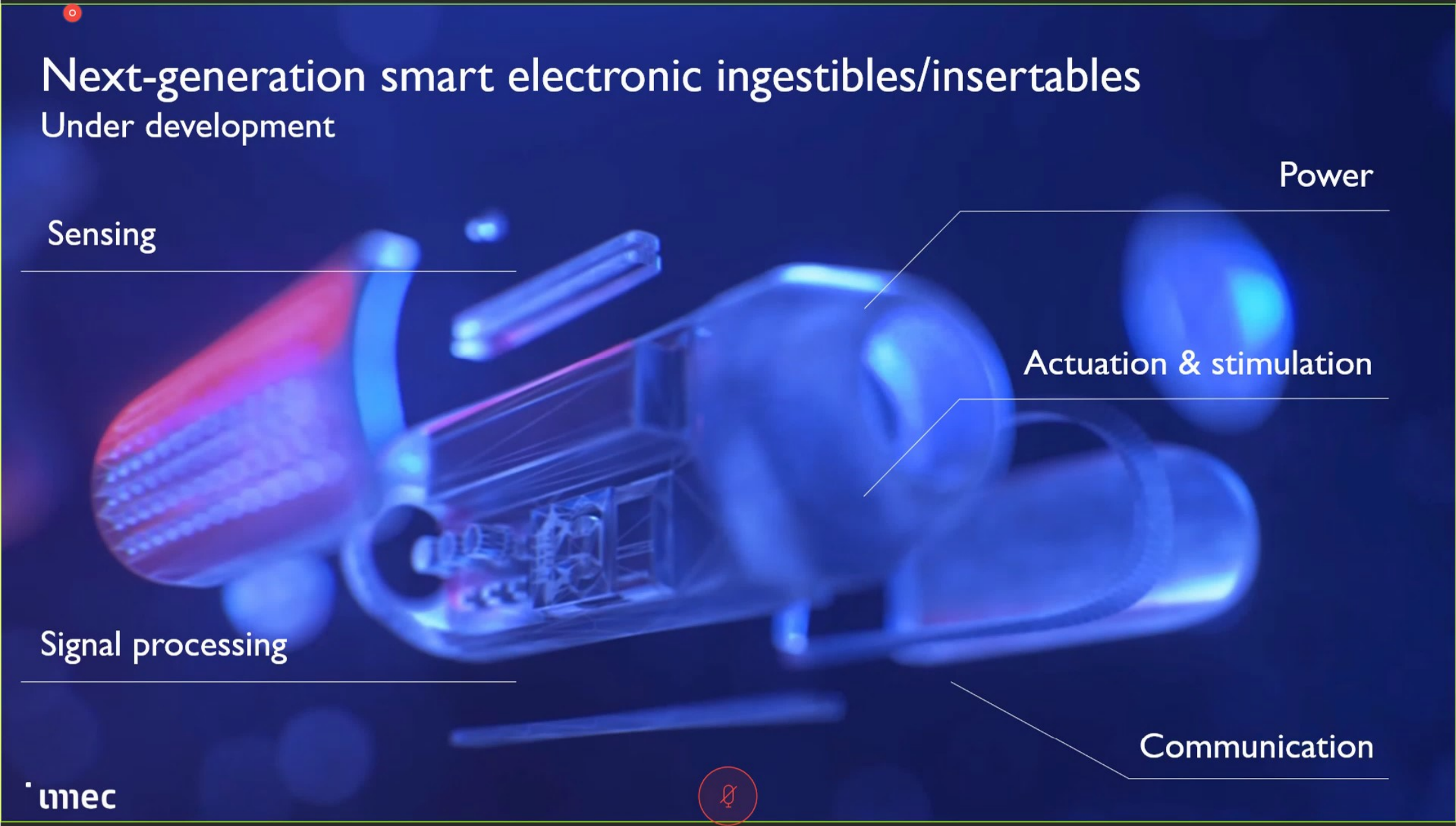
Next-generation smart electronic ingestibles/insertables

Under development



Going implantable: flexible development platform

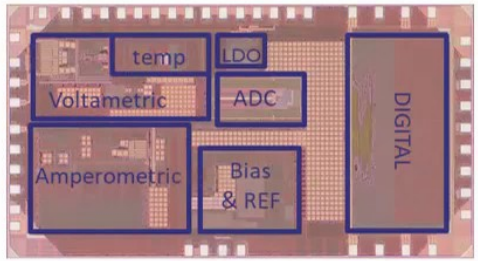
Wireless

Development platform

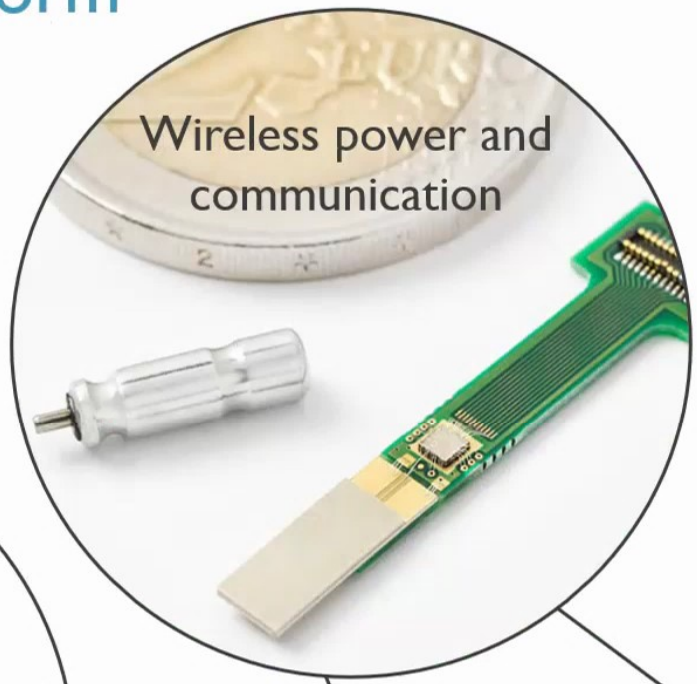
Sensor & stimulator

Passively powered

Microwatt biochemical sensor readout circuits



Wireless power and communication



Zero-BOM Wireless TRx

Small size 400MHz antenna

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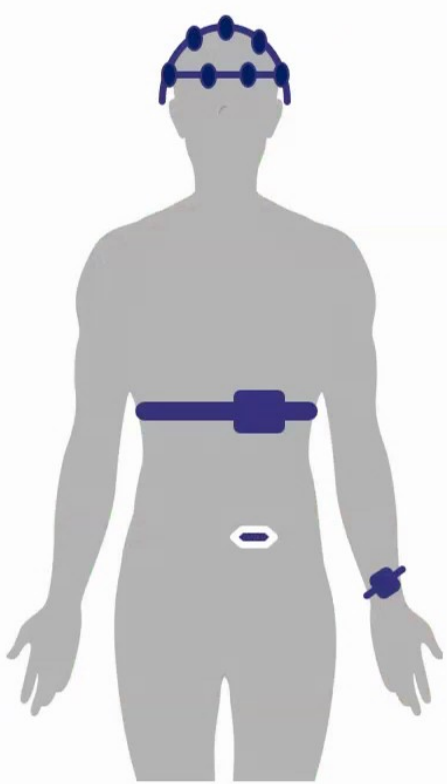
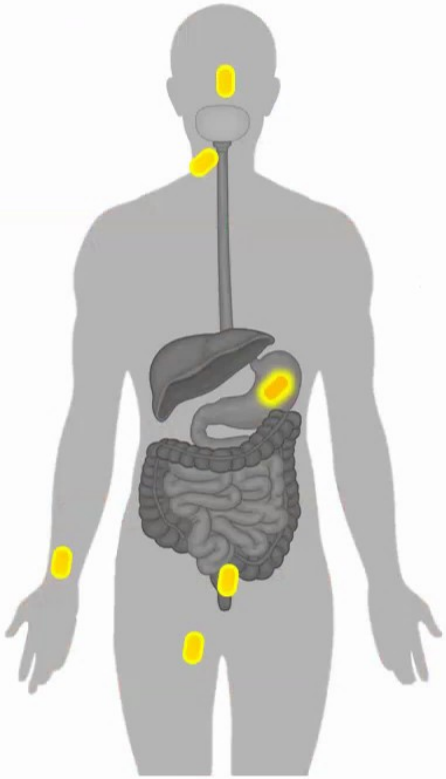
https://www.imec-int.com/implantables

Seamless integration

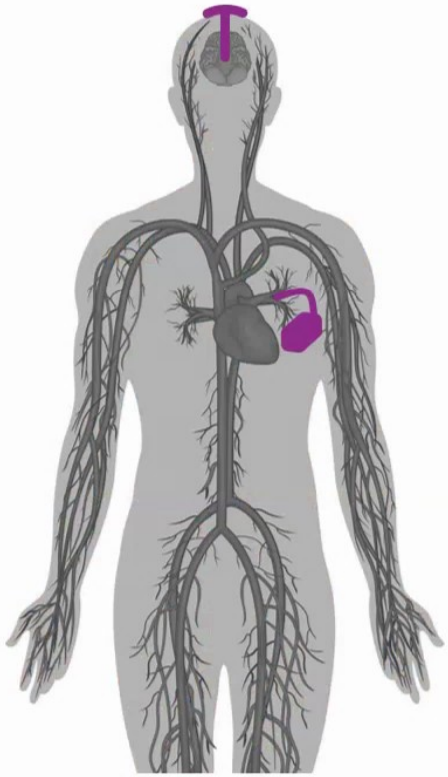
Non-contact technology



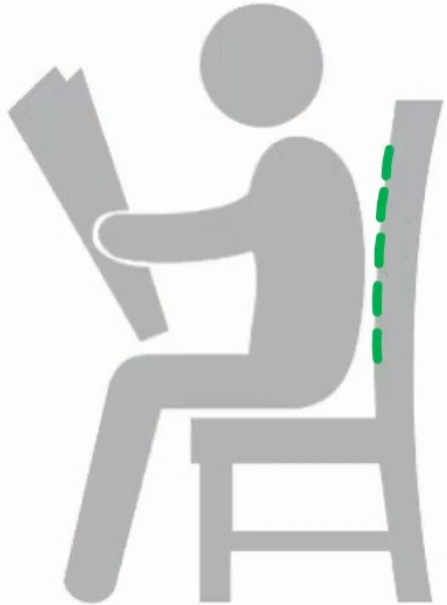
Wearables



Insertables



Implantables



Invisibles

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Imec's invisible sensing platform

Capacitive sensing:

- Biopotentials (ECG, EEG, ...)
- bioimpedance (respiration,...)
- auxiliary sensors (ETI, motion,...)

Through multiple layers of textile

RF-radar sensing

- pulse: HR, HRV, ...
- respiration
- fall detection
- localization & tracking

Remote (up to several meters)

Other sensors

- Exploratory
- COTS

Algorithms for sensor fusion & motion artifact handling

- Sensor fusion of signals from different sensor types
- Adaptive motion artifact reduction in non-contact signals
- Signal quality indicators and array selection

Application validation

- Building application demonstrators and increasing TRL level
- Validation in real-life scenarios e.g. automotive, clinical, office, ...

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Voice-based heart rate monitoring

- **Heart rate** extraction from **audio**
- **Non-contact** and invisible **vital signs monitoring**
- Heart rate within **15 – 20 sec**
- Can be used with devices such as **smartphone, voice assistants, mics and other audio inputs.**

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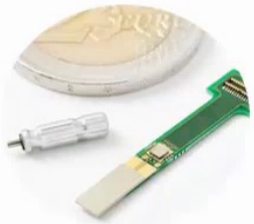
Creating new healthcare technology

Building blocks to enable next generation of closed loop devices

Device development towards “closing the loop”

Sensing

Interaction



Algorithms

Actuation

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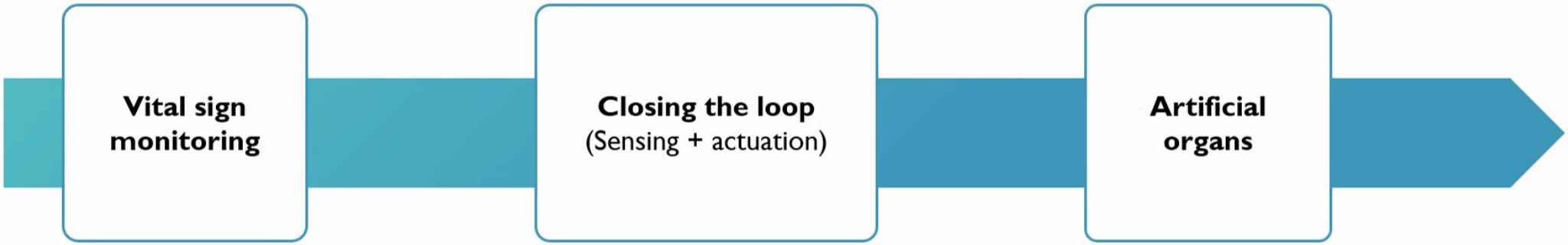
Horizon: artificial organs

Where sensing is just a tiny piece



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Adaptation and the medical community

Approach for internal research

Need for a strong scientific foundation

- **Technology** is published in technical venues (conferences, papers)

- **Clinical results** are published in medical and scientific journals

CHF
The added Value of In-Hospital Tracking of the Efficacy of Decongestion Therapy and Prognostic Value of a Wearable Thoracic Impedance Sensor in Acutely Decompensated Heart Failure with Volume Overload: Prospective Cohort Study,
https://cardio.jmir.org/2020/1/e12141/

COPD and respiratory
Chest Movement and Respiratory Volume both Contribute to Thoracic Bioimpedance during Loaded Breathing
https://www.nature.com/articles/s41598-019-56588-4

Cardiorespiratory fitness
Using Biosensors and Digital Biomarkers to Assess Response to Cardiac Rehabilitation: Observational Study
https://www.jmir.org/2020/5/e17326/

Stress
Large-scale wearable data reveal digital phenotypes for daily-life stress detection
https://www.nature.com/articles/s41746-018-0074-9

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Standarization: paving the future

- **Imec experts** are **members of standardization organizations** at International, European and National levels
  - International Standarization Organization (**ISO**)
  - International Electrotechnical Comission (**IEC**)
  - European Commitee for electrotechnical standardization (**CEN-CENELEC**)

- **Imec** has an active role **in defining the future standards and roadmaps** in the fields of
  - **Cardiovascular**: CHS experts are members of Joint Working Group 22 working on electromedical diagnostic and patient monitoring equipment, developing the next-generation standards for cardiac monitoring
  - **Renal**: working with the US FDA setting a roadmap for the future towards kidney replacement technologies

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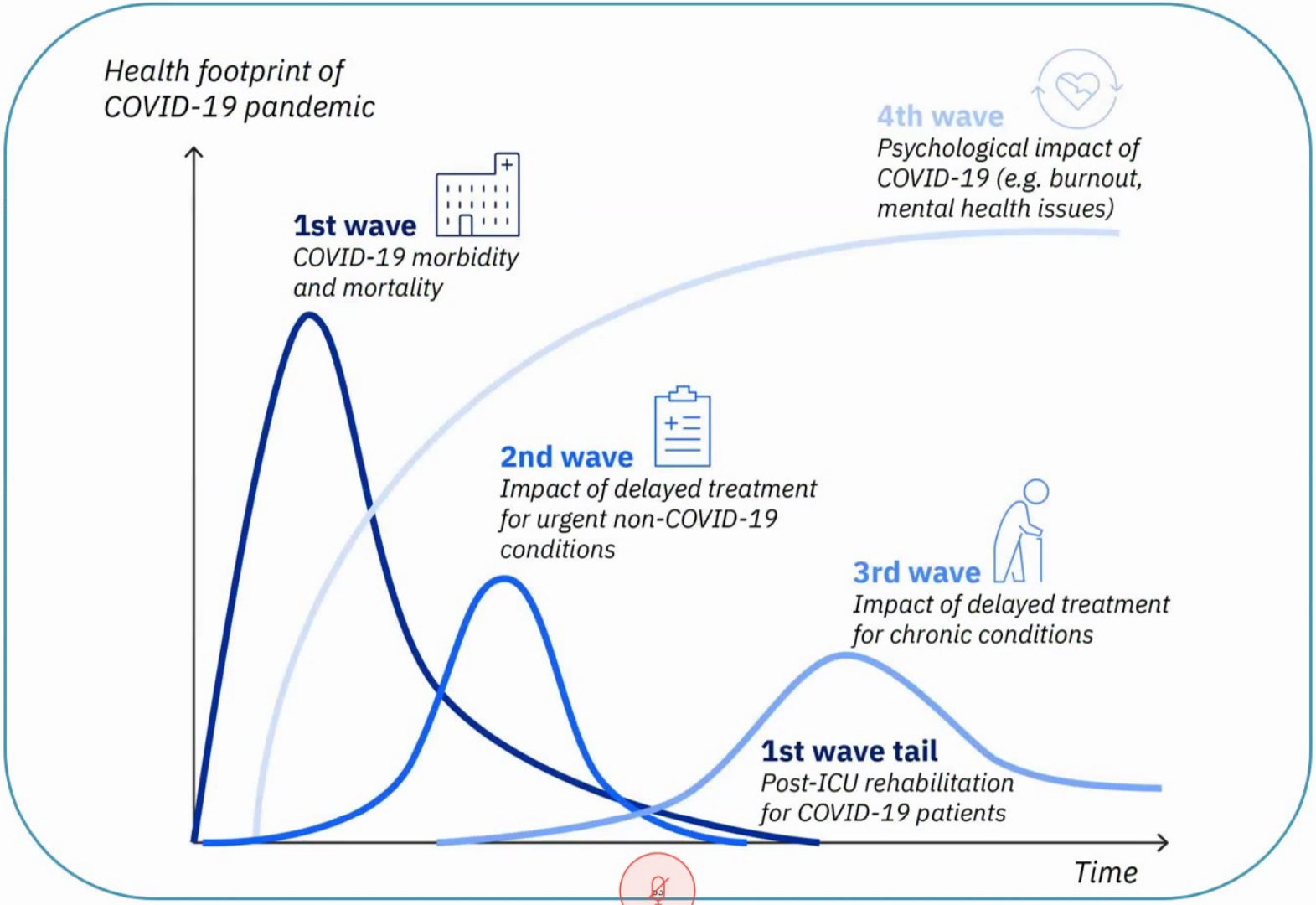
Mental health



Source: IBM

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Platforms for mental health monitoring

Acquisition of **brain electrical activity (EEG)** using dry electrodes

- **Simple** EEG acquisition setup: no wiring, signals available within seconds
- EEG can be taken **on the go**
- **Modular platform** enables plug-and-play benchmarking of components

Mental health **wrist-based** platform

- **GSR, PPG, temperature & motion**
- High-level features (**HR, HRV**)
- **Data models for multiple applications** from stress, activity recognition to pain monitoring

DATWYLER

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CHS application fields

Our existing portfolio of medical capabilities

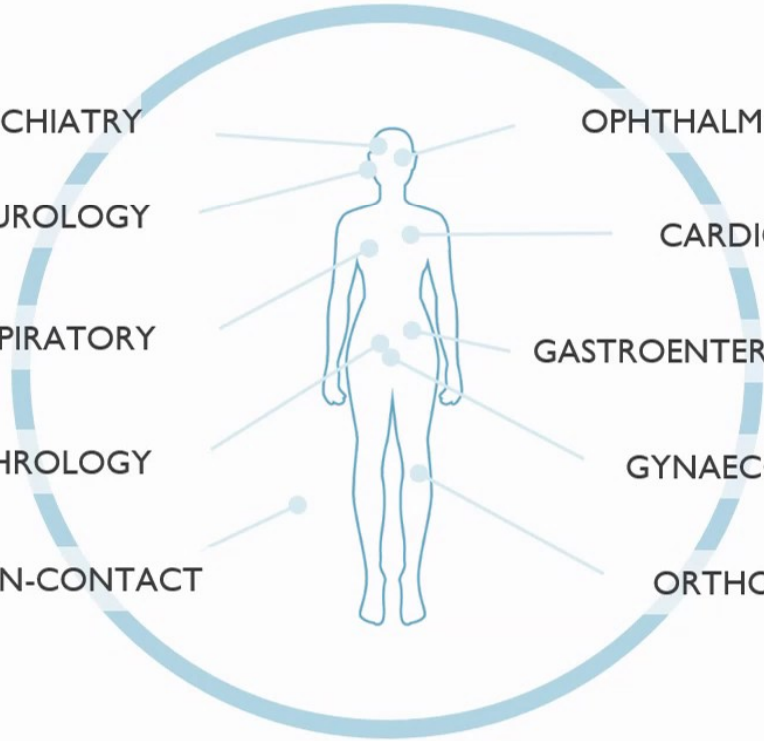
PSYCHIATRY

NEUROLOGY

RESPIRATORY

NEPHROLOGY

NON-CONTACT



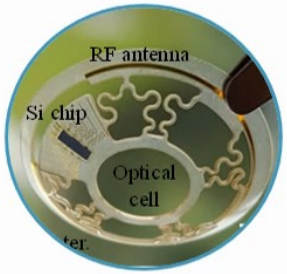
OPHTHALMOLOGY

CARDIOLOGY

GASTROENTEROLOGY

GYNAECOLOGY

ORTHOPEDICS



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Conclusions

- **Remote vital monitoring wearable technology** is now mature enough to fit the needs of pharma companies for clinical trial applications

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