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SEMI VIRTUAL HEALTHTECH SUMMIT

Microtechnology-Enabled Solutions in Overcoming COVID-19

JULY 16, 2020 | 3:00PM - 4:30PM CEST

Summit Program

3:00 pm - 3:05 pm
Welcome Remarks

3:05 pm - 3:20 pm
Global Pandemic and Healthtech Community Response

3:20 pm - 3:35 pm
Impact of the COVID-19 Pandemic on the Diagnostics Industry: a Microfluidic Point-of-view

3:35 pm - 3:50 pm
Alertgy Technology for Corona Virus Screening

3:50 pm - 4:05 pm
Remote Vital Sign Monitoring Technologies for the New Standard of Care

4:05 pm - 4:20 pm
Industry Events & Trends and Serving the Medical Device Community with Technology that Improves Lives

4:20 pm - 4:30 pm
Q&A

Cassandra Melvin
Director of Operations, SEMI Europe

Jesus Rueda Rodriguez
Director International Affairs, MedTech Europe

Sébastien Clerc
Market & Technology Analyst, Yole Développement

John Hubert
VP of Engineering, Alertgy

Carlos Agell
Program Manager - Principal Member of Technical Staff, imec

Steven Dean
Director of Business Marketing for Signal Processing, Wireless, and Medical Division, ON Semiconductor

Thanks to our Sponsor

Alertgy™

Improving Diabetic Health Through Innovation

European MedTech Advisory Council

Henry Leistner
Team Leader in Micro Dosing Systems

Fraunhofer EMFT

Hilary Lashley-Renison
Senior Director, GE Licensing

Zohaib Gulzar
Business Development Manager, Connected Health Solutions

imec

Patrick Boisseau
Director EU Research and Innovation Partnership Policy

MedTech Europe
from diagnosis to cure

Jerome Mouly
Senior Analyst and Business Developer

YOLE Développement

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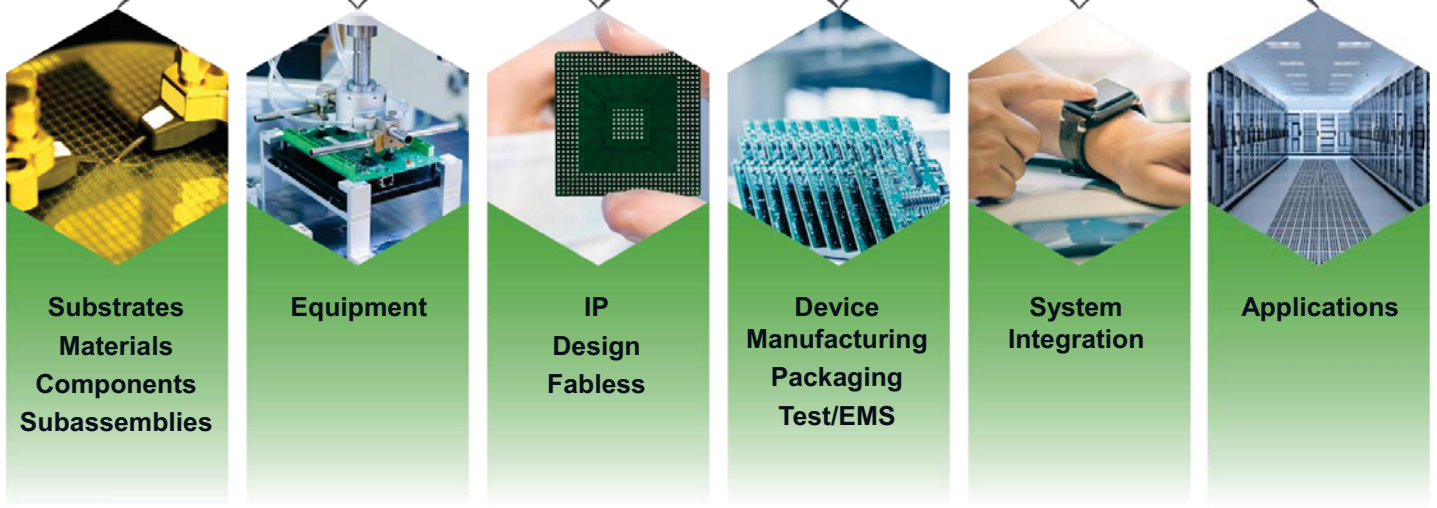

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KEYNOTES

Al Gore
Former US Vice President

Gary Dickerson
Applied Materials

John E. Kelly III
IBM Research

John Hagel
Center for the Edge
Deloitte

Lea Gabrielle
Global Engagement Center
US State Department

Nicholas Burns
Harvard Kennedy School
of Government

Paul Saffo
Forecaster for Large-Scale
Technology Change

Steve Brown
The Innovation Ultimatum

Terry Higashi
Tokyo Electron (TEL)

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SMART MEDTECH FORUM

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CONTINUUM OF HEALTHCARE POWERED BY SEMICONDUCTOR TECHNOLOGIES

11–12 NOV 2020
10 am–5 pm

Inspiration Hub, Hall C1
Munich Germany

SMART MEDTECH VIRTUAL WORKSHOP SERIES

Overview:

Biomarker Sensing and Diagnostics for Telemedicine

AUGUST 5 - 26, 2020

Aug 5, 10:00 am - 12:00 am PDT
From Bio-markers to Bio Chemical Sensors & Physiological Relevancy

Aug 12, 10:00 am - 12:00 am PDT
En Route Care (ERC) and Point of Care (POC) Diagnostics

Aug 19, 10:00 am - 12:00 am PDT
Human Wearables Enabling Rapid Decision Making in the Integrated Care Continuum

Aug 26, 10:00 am - 12:00 am PDT
Automation, Augmentation, and AI

General Remarks

- All attendees are muted.
- Submit questions via the question box in your GoToWebinar control panel. Please specify to whom your question is addressed.
- Questions will be answered at the end of the Summit during the Q&A.
- Attendees will receive recording and Summit slides by end of the week.

MedTech Europe
from diagnosis to cure

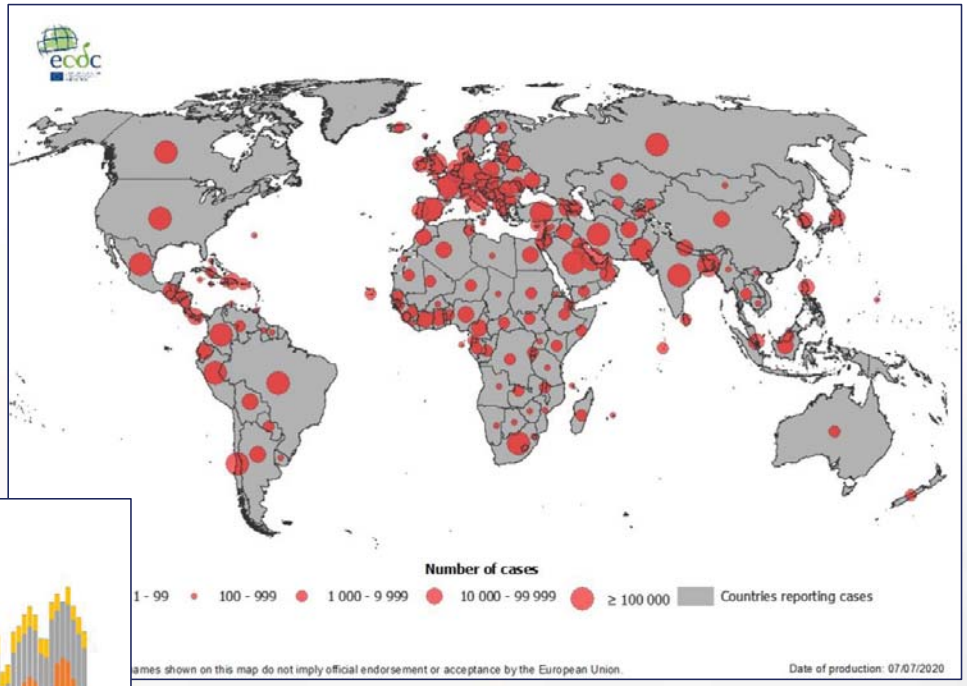
Global Pandemic – Health Technology Community Response

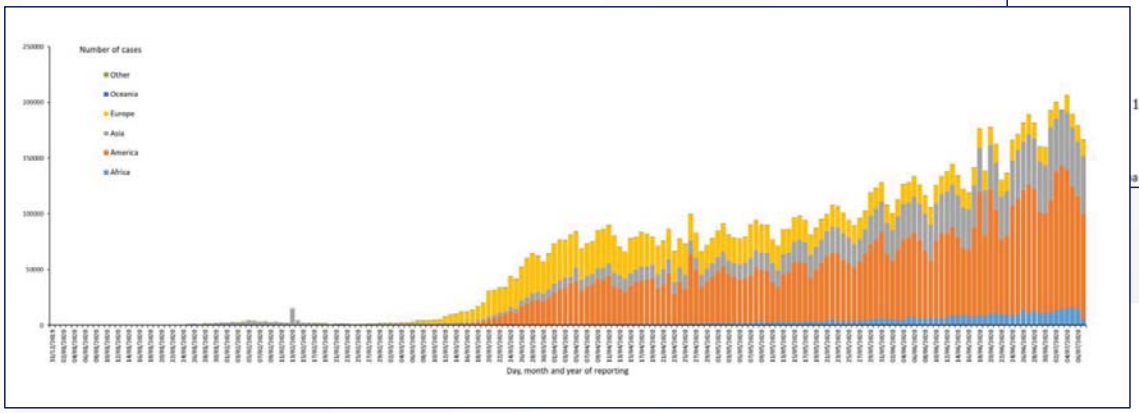
Jesus Rueda Rodriguez

Director International Affairs

What is going on…

- Global reach of the pandemic is not a surprise.
- On a global level the pandemic is still consistently growing.
- With it grows the demand for health technology





MedTech Europe
from diagnosis to cure

Healthcare systems under stress – critical components

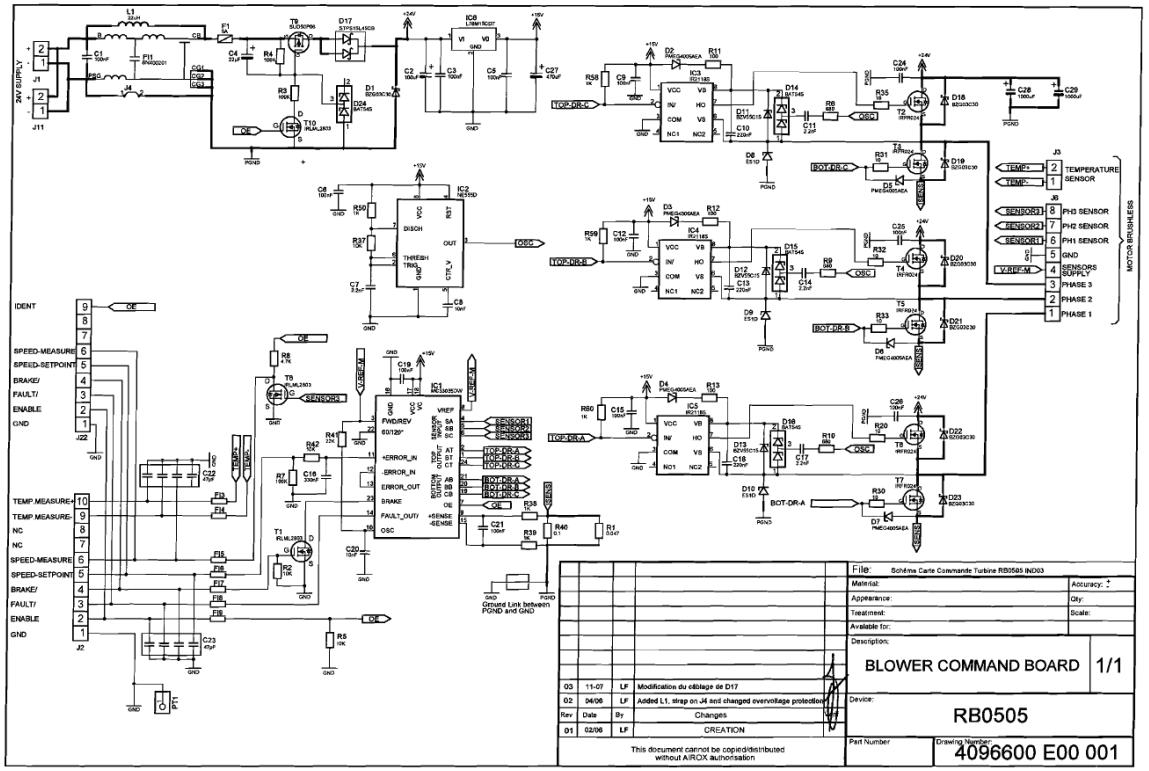
Protective equipment

Diagnostic Capacity

ICU care

Key Priority – Keep healthcare systems running!

Key elements of the response



- Research
- Production
- Logistics
- Digital health
- Health Policy

MedTech Europe
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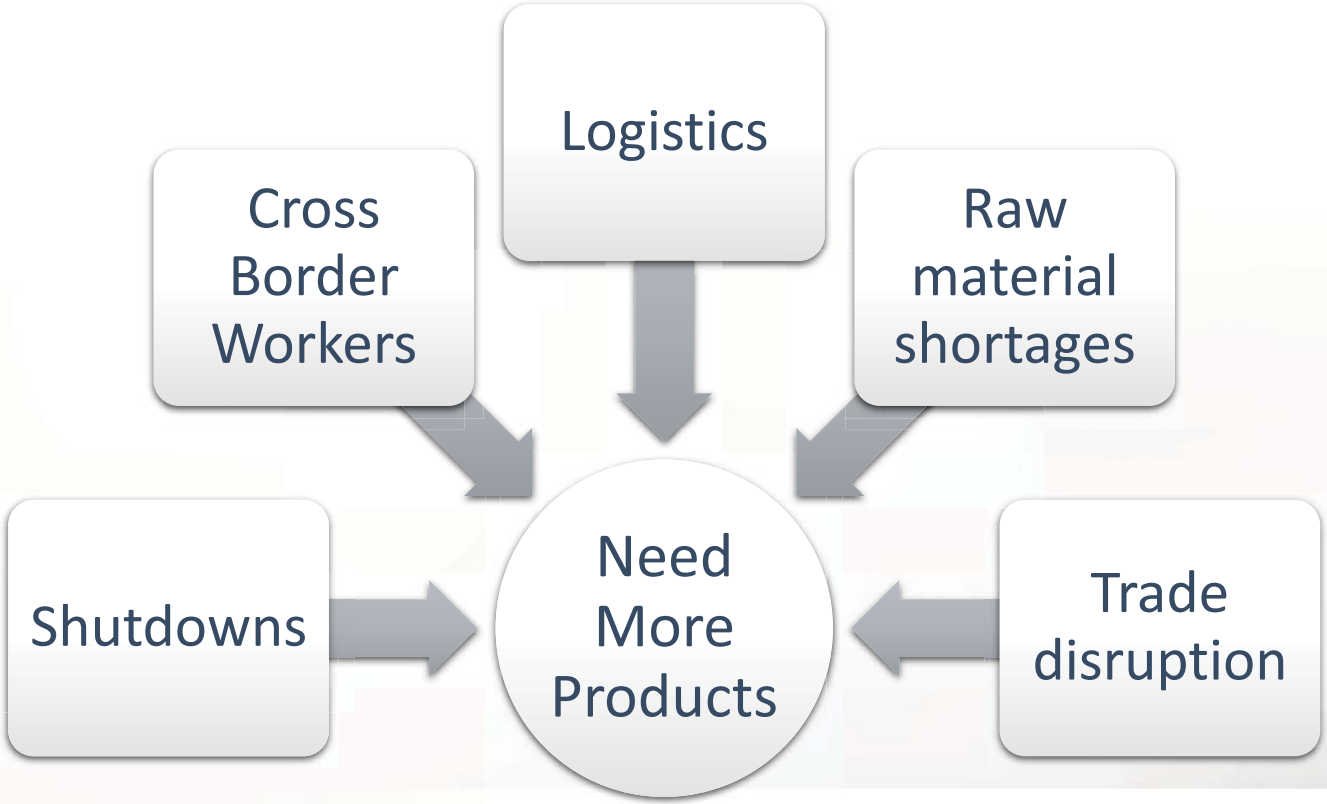
Where is my mask! Production – Capacity - Availability



MedTech Europe
from diagnosis to cure

What about if you don’t have COVID?

- Continuity of Care
- Chronic disease management
- Acute care
- Managing elective procedures

Trade, health policy, resilience and the future

- Resilience – minimizing supply chain disruptions
- Global Cooperation – WHO, FIND, Global Fund, BMGF etc.
- Preparing for the second wave
- Flu season impact – overlap and preparation
- Lessons Learned – Preparing for the next pandemic.

Jesus Rueda Rodriguez

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www.medtecheurope.org

MedTech Europe
from diagnosis to cure

From Technologies to Markets

Impact of the COVID-19 Pandemic on the Diagnostics Industry: a Microfluidic Point-of-view

Sébastien Clerc
Yole Développement
2020-07-16

sebastien.clerc@yole.fr

YOLE Développement

Courtesy of Curiosity Diagnostics' – PCR|ONE cartridge

PART OF YOLE GROUP OF COMPANIES

Market, technology, and strategy consulting

M&A and evaluation of companies

Direct acces to the analysts

Structure, process and cost analysis

Teardown and reverse engineering

Cost simulation tools

FIELDS OF EXPERTISE COVERING THE SEMICONDUCTOR INDUSTRY

Including:

- **Microfluidics**
- MEMS, BioMEMS
- Medical Imaging & Biophotonics
- Inkjet printing

Photonics & Sensing

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- Lighting
- Imaging
- Sensing & Actuating
- Display

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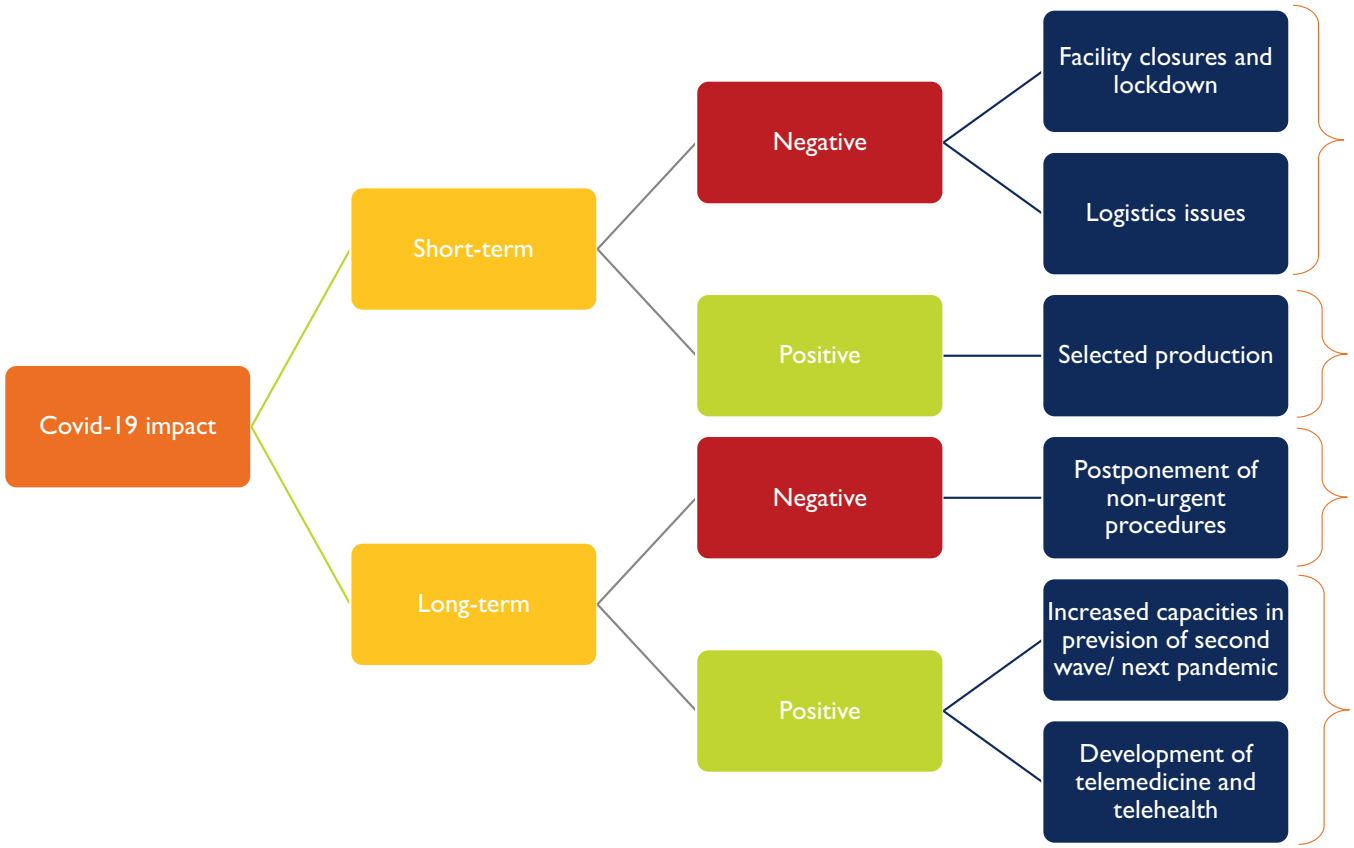
- Semiconductor Packaging and Substrates
- Semiconductor Manufacturing
- Memory
- Computing and Software

Power & Wireless

- RF Devices & Technologies
- Compound Semiconductors & Emerging Materials
- Power Electronics
- Batteries & Energy Management

COVID-19 IMPACT

Short and long-term impacts on the healthcare industry



Details

- Some labs stopped activities during lockdown
- No travel allowed – reduced business development
- Possible delays in both supply and shipment

- Strong focus on certain products (diagnostics tests, ventilators, non-contact thermometers,…) to meet the sudden increased demand

- Non-urgent procedures are postponed (surgeries, sleep apnea diagnostics,…)

- Increased awareness and anticipation for improved response next time?
- Telehealth and telemedicine had a strong jump, enabling the use of portable and wearable devices (smartwatches, patches,…)

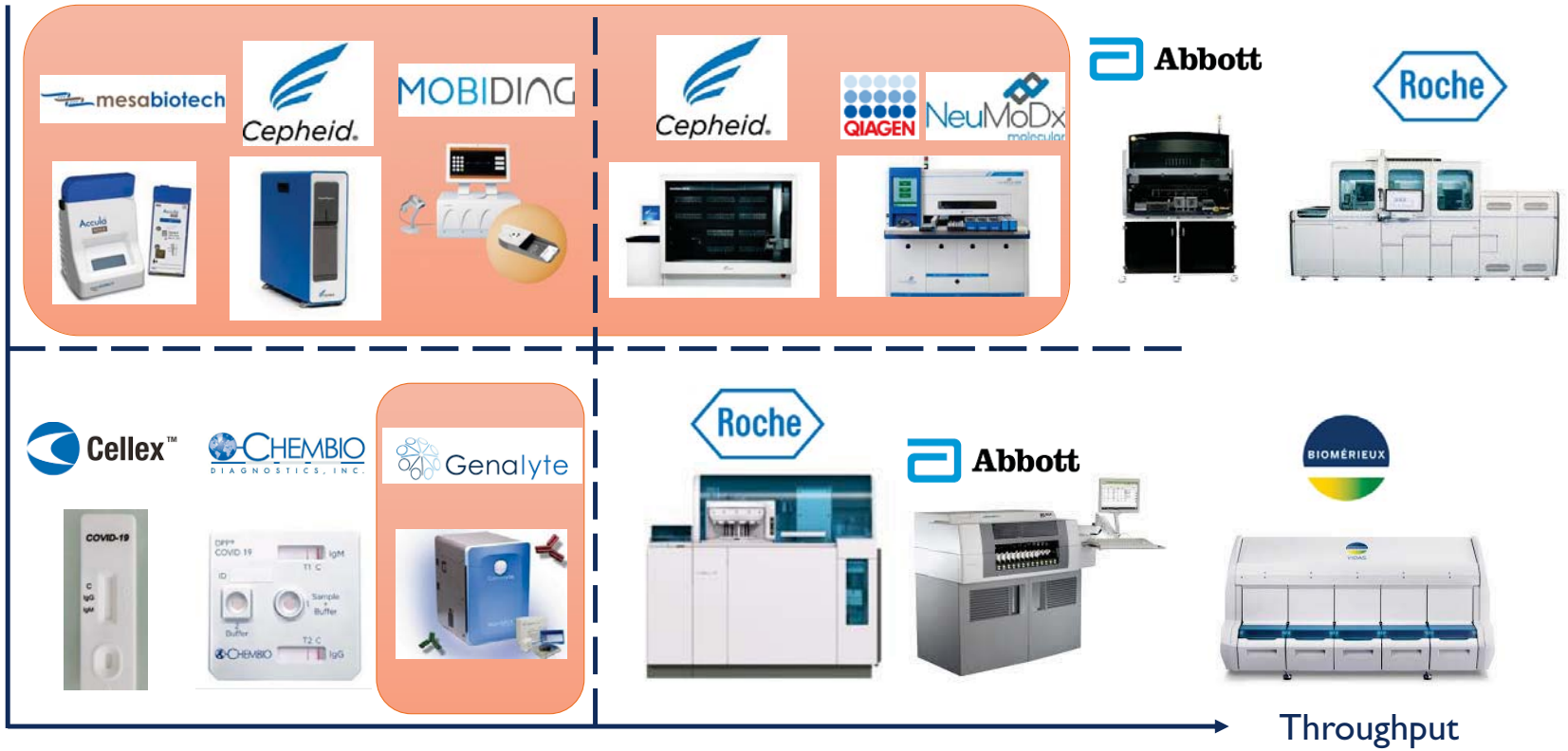
TESTS TO DETECT COVID-19

Different types of tests for different purposes – all complementary

Microfluidics = what we track at Yole

Molecular
Detect the virus itself

Immunoassay
Detect the body's immune response



Low (POC)
Usually 1 sample per run, sometimes up to 4 or 8

High (central lab)
48, 96 or even more samples per run

TESTS TO DETECT COVID-19

Strong demand since mid-March

The demand for all these tests is incredibly high (millions tests per month)

There are apparently some clear winners in this respiratory testing area

GenMark Dx

Q1 revenue up 80% (46% above initial expectations)
80% of instruments placements driven by COVID-19 interest
Q2 should be even more impressive…

Abbott Alere

IDNOW was already the most widely available POC MDx platform in the US. Scaled up production capacity to 50k cartridges per day in April (1.5M per month, aiming at 2M per month in June)

Cepheid

Shipped 2M cartridges in one month from EUA of the test – capacity of 6M cartridges per quarter

mesabiotech

Shipped 10k tests per week in April, with production scale-up

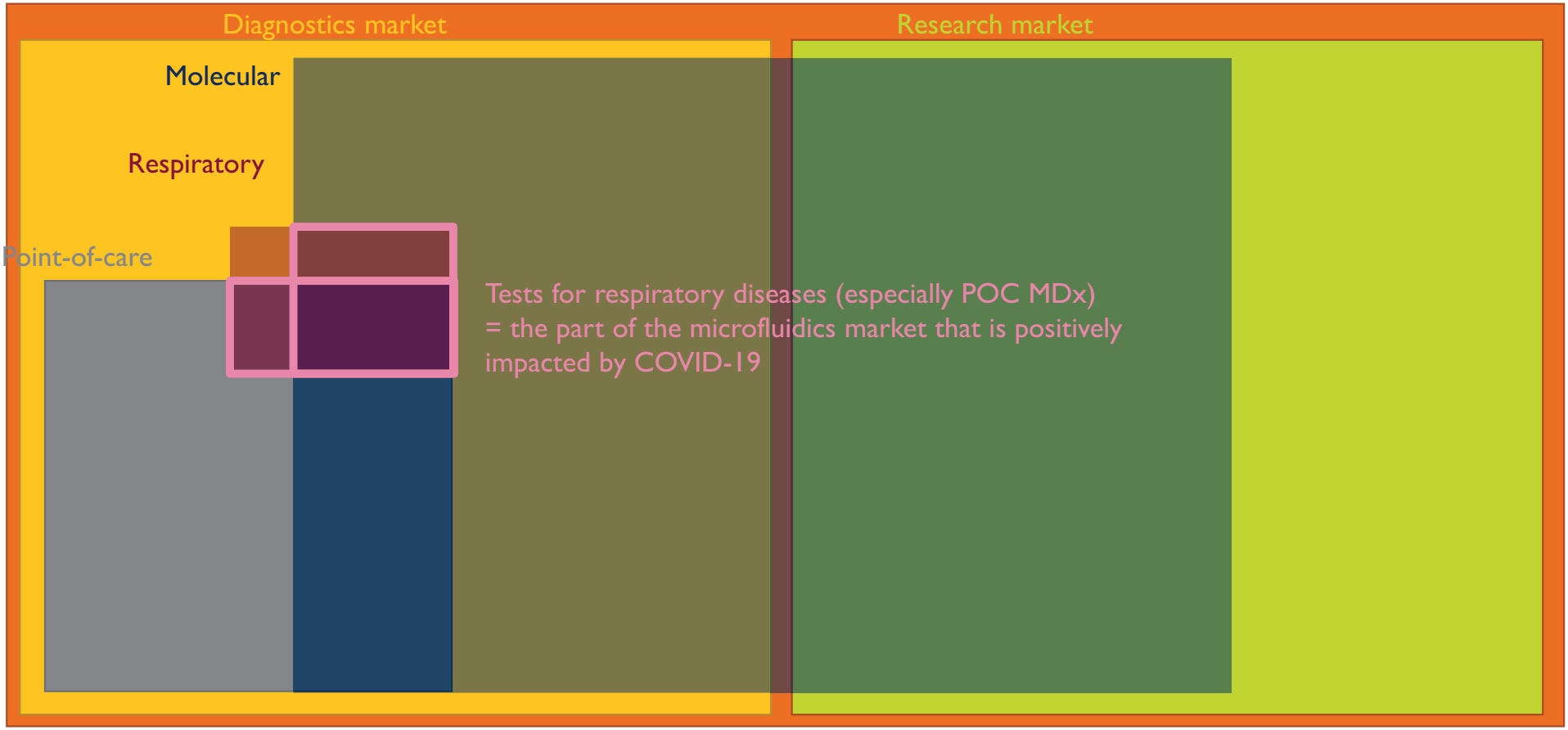
BIOMÉRIEUX BIOFIRE

FilmArray product line recorded growth of 67% in Q1, led by exceptionally high use of Respiratory panels and the Pneumonia panel. More than 1,400 new systems installed during the quarter. But the SARS-CoV-2 test did not generate any sales in Q1

TESTS TO DETECT COVID-19

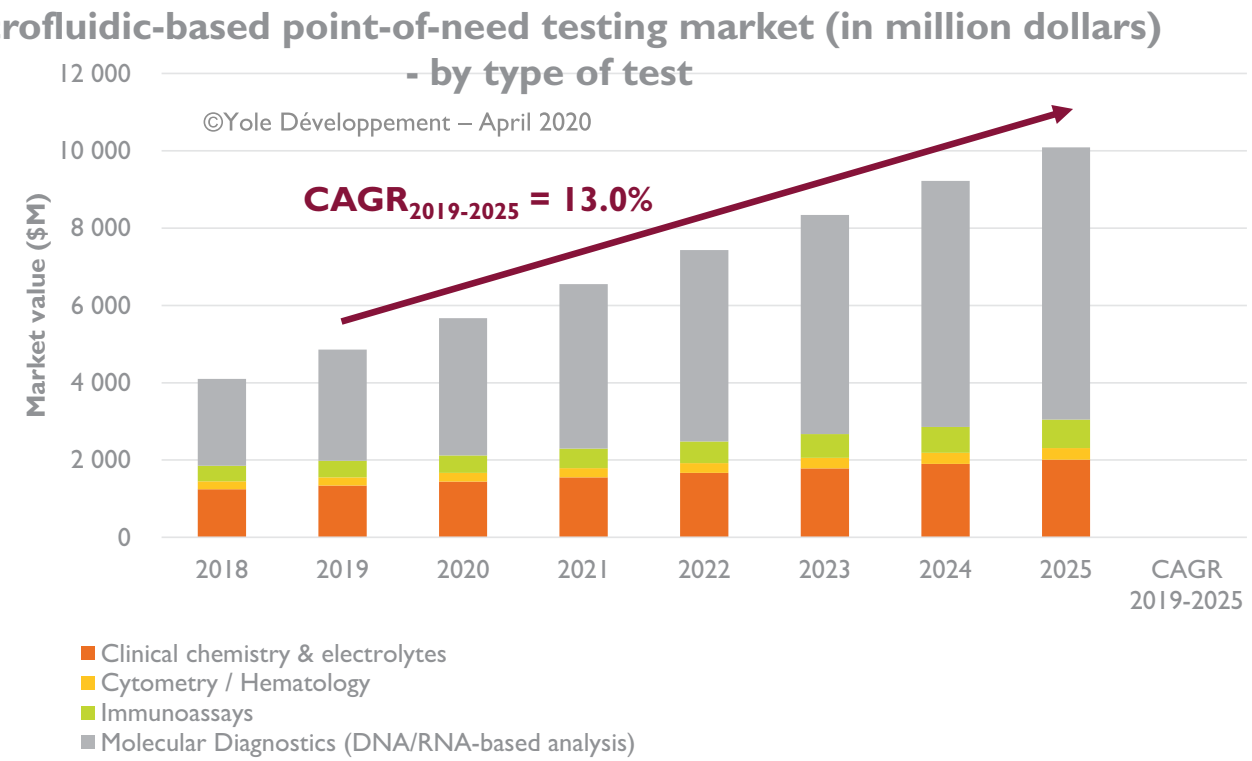
But what's the impact on the overall microfluidic market?

Microfluidics market



TESTS TO DETECT COVID-19

But what's the impact on the overall point-of-care microfluidic market?

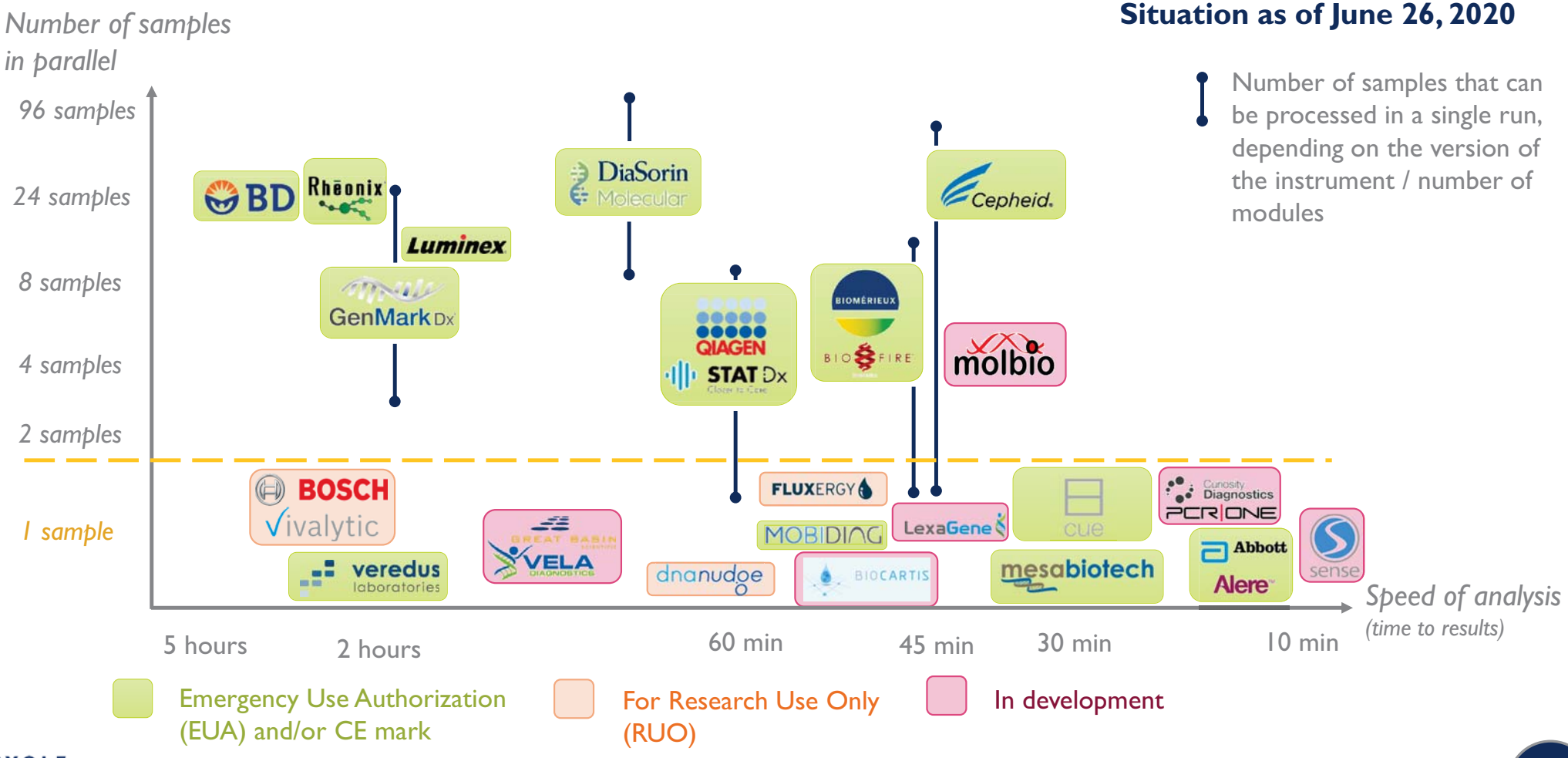


Feedback from microfluidic device contract manufacturers: overall no impact / slightly positive impact (but, variability from project to project)

- Strong positive impact on a small part of MDx
- Slightly negative to no impact at all on the other parts

} Equilibrium

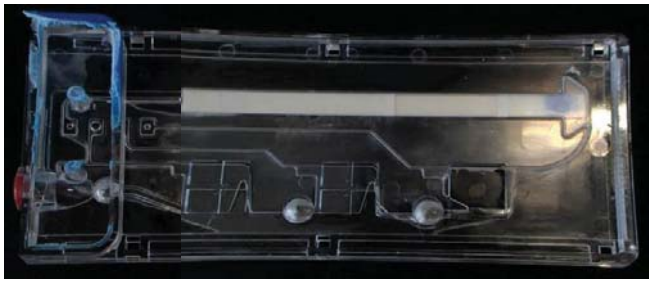
SARS-COV-2 POINT-OF-CARE* MOLECULAR DIAGNOSTIC TESTS



*point-of-care = out of reference laboratories

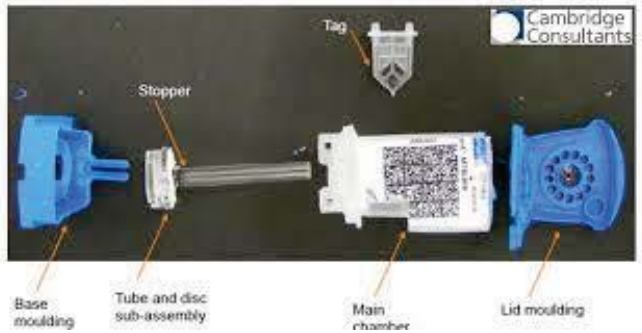
SARS-COV-2 POINT-OF-CARE* MOLECULAR DIAGNOSTIC TESTS

mesabiotech



Accula Cartridge Teardown – Courtesy of SystemPlus Consulting

Cepheid



Picture: GeneXpert Cartridge teardown – Cambridge Consultants

MOBIDIAG

Picture: Novodiag cartridge – Mobidiag

*point-of-care = out of reference laboratories

SARS-COV-2 POINT-OF-CARE* MOLECULAR DIAGNOSTIC TESTS

GenMark Dx

Picture: ePlex cartridge – GenMark Diagnostics

QIAGEN

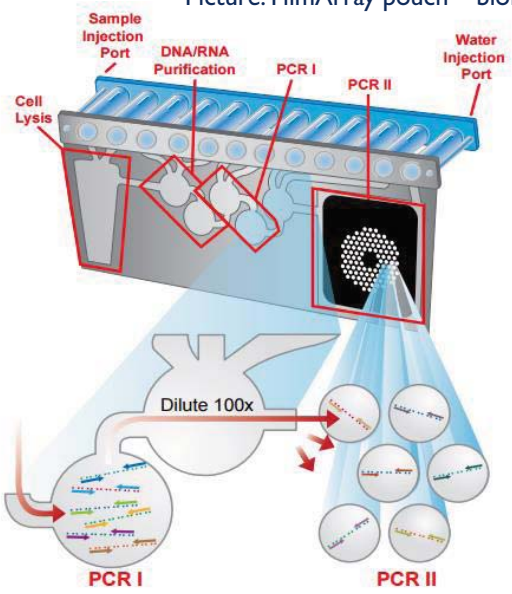
STAT Dx
Closer to Care

Picture: QiaStatDx cartridge – Qiagen

BIOMÉRIEUX

BIOFIRE DIAGNOSTICS

Picture: FilmArray pouch – bioMérieux

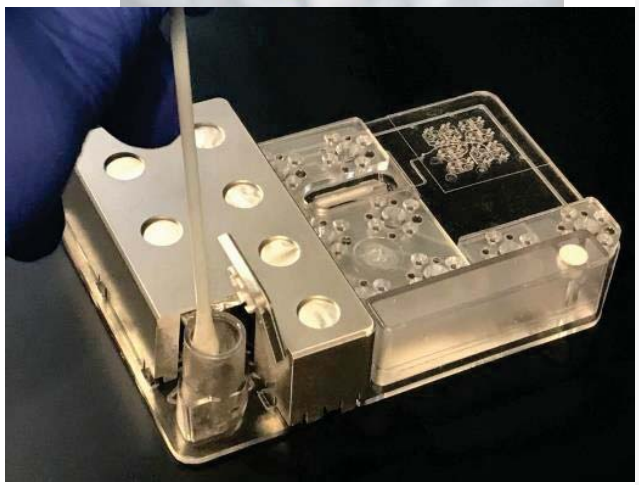


*point-of-care = out of reference laboratories

SARS-COV-2 POINT-OF-CARE* MOLECULAR DIAGNOSTIC TESTS

Scope Fluidics

PCR|ONE



Picture: PCR|ONE cartridge – Scope Fluidics

FLUXERGY

sense

YOLE Développement

*point-of-care = out of reference laboratories

OPPORTUNITIES DON'T COME WITHOUT RISKS!

Start-up companies put important resources in COVID-19 tests development

FLUXERGY

dnanudge

LexaGene

BIOCARTIS

Curiosity Diagnostics

PCR|ONE

sense

These companies have put millions in the development of a COVID-19 test. Most won't be ready before this fall.

This is good for their image, and this could be rewarding if there is a second wave or if the virus becomes seasonal.

→ But what if the virus disappears?

Dangerous move from these companies when it might be easier for already established companies to expand their production capabilities. These new tests must provide significant added value!

→ **Respiratory disease panel** including SARS-CoV-2 will be interesting

MID- AND LONG-TERM IMPACT

New opportunities for POC test makers

Airport / travel
Rapid passenger screening

Workplace
Rapid employee / visitor screening

MID- AND LONG-TERM IMPACT

Too many unknowns to predict what will happen

Second wave?

Immunity?

Seasonality?

Treatment?

Vaccine?

We could need as many tests every year on the long term… Or it could be over by Q3 this year. Who knows?

THANKS FOR YOUR ATTENTION

Some slides of this presentation have been taken from the following report:

Point-of-Need Testing 2020
Released in April 2020
290+ slides of market & technology analysis

Or will be included in the upcoming report:
Status of the Microfluidics Industry 2020
To be released in September 2020

Sébastien CLERC

Technology and Market Analyst,
Microfluidics, Sensing & Actuating

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Please take a look at our website www.i-micronews.com for industry news and for more information about our reports

Alertgy

Alertgy Technology for Corona Virus Screening

SEMI Virtual Healthtech Summit
July 16, 2020
Munich Germany

Microtechnology-Enabled Solutions in Overcoming COVID-19

Speaker: John Hubert
VP of Engineering
John.Hubert@alertgy.com

The Covid Testing Problem

Covid testing general issues…

- Lab-based
- Requires physical samples
- Not continuous
- Expensive
- Time consuming
- Suffer from false positives or negatives
- Not done in vivo

If an Active Infection test yields false negative result	**If an Antibody test yields false positive result**
People think they don't have Covid	People think they are immune
Are less cautious & could spread Covid	Are less cautious
Deaths are not counted as Covid related	Could contract Covid

Virus is mutating

Most accurate Method of Testing

Bronchoalveolar lavage

Active Virus Infection test

~ 93% accurate

Surgical procedure

Invasive

Expensive

Time consuming

May cause pneumonia

https://image.slidesharecdn.com/slidesharepneumoniacheckmaster-130729162329-phpapp01/95/pneumoniacheck-by-arc-medical-the-link-between-diagnosis-and-treatment-of-pneumonia-33-638.jpg?cb=1384451195

Active Virus vs Antibodies Testing

Molecular tests (Active Virus Infection tests)

Samples; nose, throat, or more recently, saliva or feces

Active virus appears in various samples at different times

Times vary with different people

Serological tests (Antibodies After Exposure tests)

Samples; Blood

Immunoglobulin M (IgM)/Immunoglobulin G (IgG) antibodies

Antibodies present 2-3 weeks after virus infection

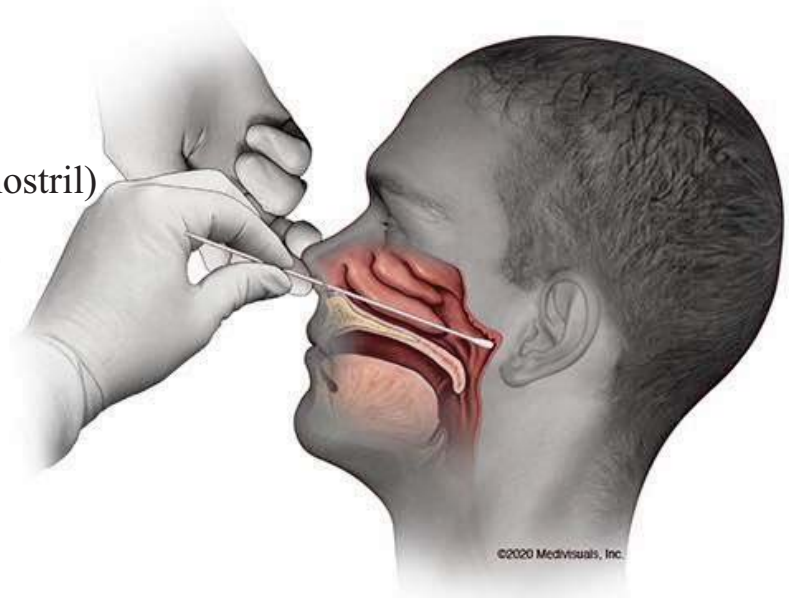
Even with antibodies a person could still be a carrier

https://www.app.com/story/news/local/emergencies/2020/03/19/coronavirus-drive-thru-tests-marlboro-immediate-care/5072854002/
https://thedailycable.com/wp-content/uploads/2020/04/200427-antibody-testing-coronavirus-se-246p_0368b5c24b5c3709db1365a6552e2b6a.nbcnews-fp-1200-630.jpg

Popular Method of Testing

Nasopharyngeal sample for Molecular Active Virus Infection testing…

- Popular due to highest accuracy for non-surgical test (~ 70 %)
- Very uncomfortable (causes coughing or sneezing)
- Technique dependent (must scrap nasopharynx, 6-10 seconds per nostril)
- ~ 7 day active virus window (Inaccurate if tested too soon too late)
- Sample Degrades over time
  - ~ 8 hrs if kept at 22 °C (72 °F)
  - ~72 hrs if kept much colder
- Pool testing (If group sample is positive then individual testing)



https://www.al.com/opinion/2020/04/the-problems-with-covid-19-testing-and-its-not-what-you-think.html
https://www.wthr.com/article/news/health/verify-photo-showing-covid-19-swab-test-real/531-1c6f0729-c50b-4525-b2aa-6df4c45bdd58

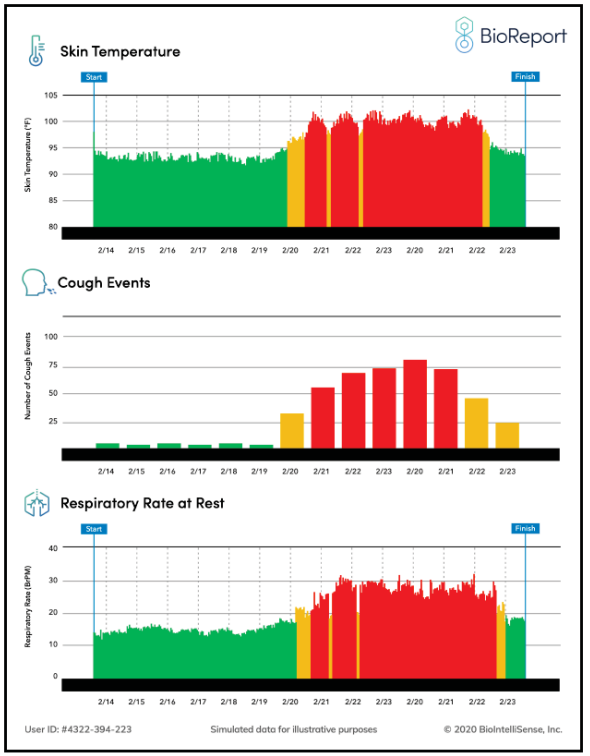
Smartwatches Tracking-Class Metrics

Bio-Trackers; Apple Watch, Fitbit fitness…

Department of Health and Human Services

Chartered Spir to build early-detection models based on metrics; including skin Temp, cough events and respiratory rates.

Study concluded with promising preliminary results.



Major issues…

Covid symptoms vary from person to person

Some people are asymptomatic (People could be carriers)

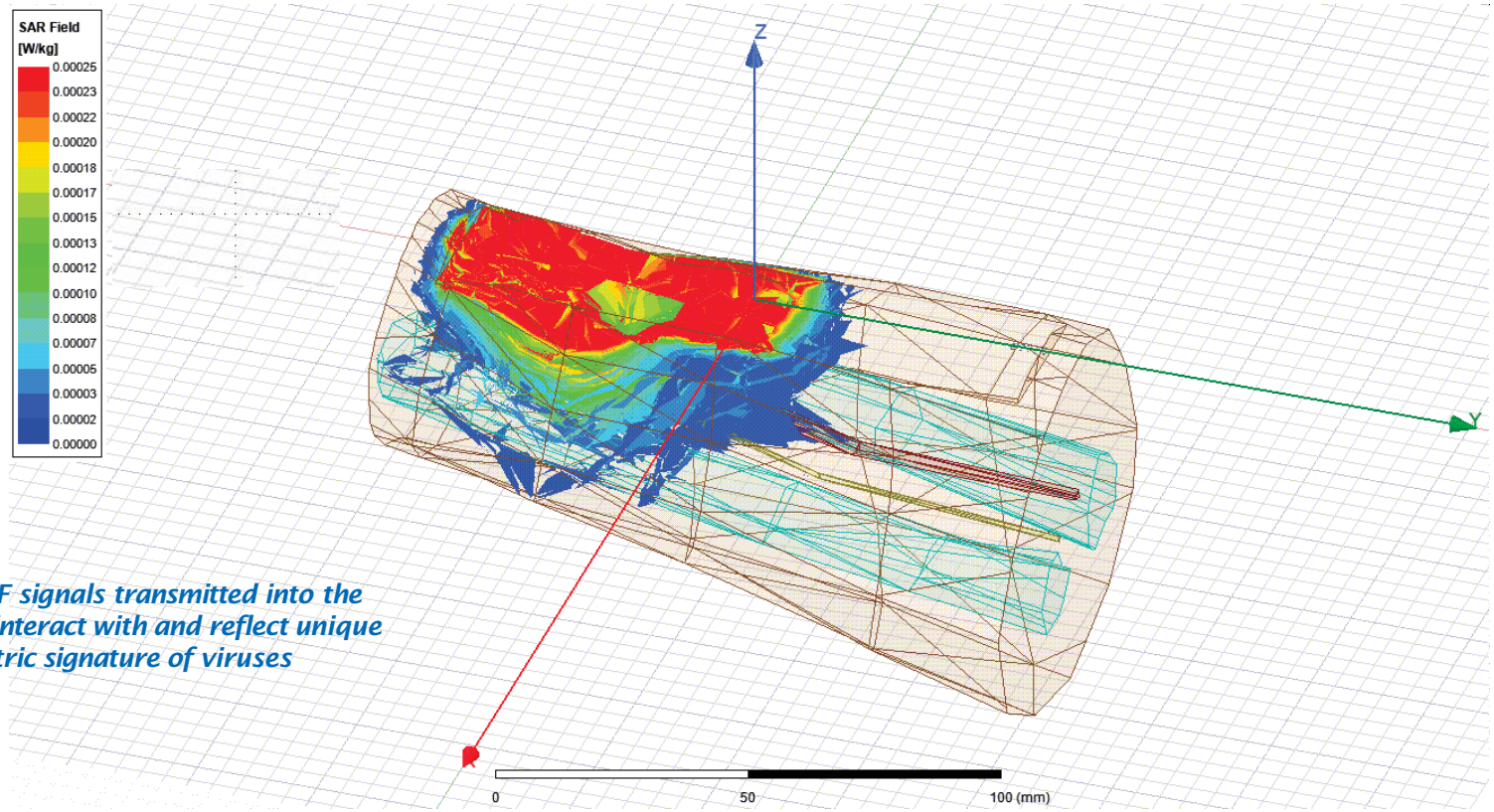
Not Virus specific

https://www.msn.com/en-us/news/technology/could-wearables-like-apple-watch-fitbit-fitness-trackers-help-detect-coronavirus/ar-BB127mzS

Alertgy's Solution

- Molecular Active Virus Infection testing by Dielectric Spectroscopy
- Portable or Wearable Dielectric Sensor System
- Non-invasive (wearable)
- No physical samples required (wearable)
- Rapid measurements Less than 30 minutes
- Continuous (wearable)
- Can be used for multiple viral type detection

Alertgy screening by Dielectric Spectroscopy



Low level RF signals transmitted into the human body interact with and reflect unique dielectric signature of viruses

Viral Screening by Dielectric Spectroscopy is Proven Science

- Demonstrated for human and feline immunodeficiency viruses (HIV and FIV)

United Arab Emirates University

- Demonstrated for Mad Cow Disease (vCJD, sCJD, non-CJD)
  Variant Creutzfeldt-Jakob Disease (vCJD)

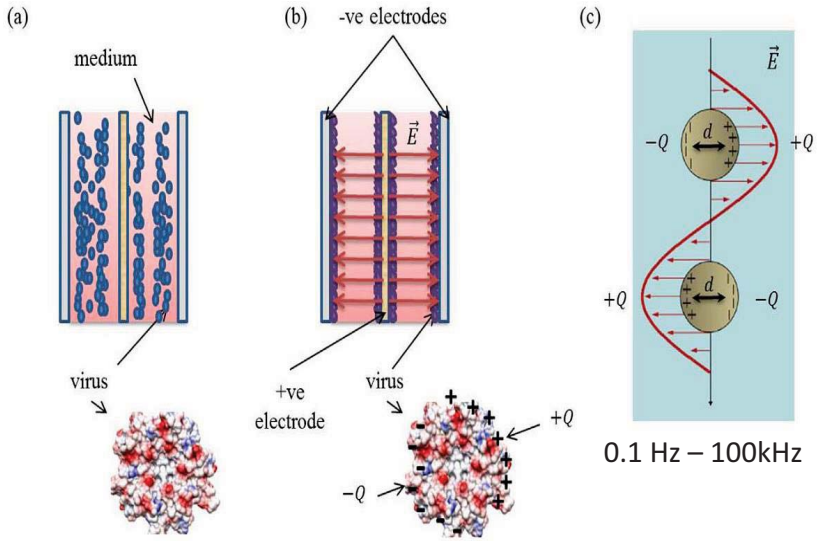
Hunter College, NY

- Demonstrated for Adenovirus type 5 (AV 5), Herpes simplex virus type 1 (HSV1), Simian virus 40 (SV40), Vaccinia (MVA), and Cowpea mosaic virus (CPMV).
  Sponsored by *National Institutes of Health (NIH)*.

- Demonstrated for Human Respiratory Syncytial Virus (RSV)

Iksan, South Korea

Alertgy HIV / FIV Viral Screening by Dielectric Spectroscopy



Human Immunodeficiency Virus (HIV)
Feline Immunodeficiency Virus (FIV)

Accuracy and reproducibility of the electrical method. The accuracy and reproducibility of the presented method has been checked using repeated electrical measurements against multiple virus stocks prepared at different times; i.e., all within the employed frequency range and over the same applied bias voltage. As detailed, the accuracy of these measurements using the outlined methodology is comparable with other conventional techniques.

Conclusion. In summary, the methodology presented here is a basic attempt to demonstrate and explore the use of a new technique for virus detection, classification and identification. The outlined technique should be applicable to any type of virus, provided it can be electrically polarized, as well as other types of particles in suspended solutions.. In addition, the proposed methodology provides a better combination of high sensitivity, selectivity, quick response, low cost, high throughput, and ease of use without the need of any biomarker or labelling techniques. When compared with other conventional identification and quantification techniques, this approach was found to be the fastest (within minutes) and cheaper than any other known technique. Finally, the proposed technique can be upgraded to be applied in situ, which will not only pave the way for direct and rapid detection of viruses in biological samples….

United Arab Emirates University

Source: Virus Detection and Quantification Using Electrical Parameters, Mahmoud Al Ahmad et al, October 2014, in SCIENTIFIC REPORTS | 4 : 6831 | DOI: 10.1038/srep06831

Mad Cow Screening by Dielectric Spectroscopy

Variant Creutzfeldt-Jakob Disease (vCJD)

Method: Using Atomic Dielectric Resonance Spectroscopy (ADRS) reflectivity and penetration of radio/microwaves, to analyze blood samples. Pulsed Tx from up to 25GHz.

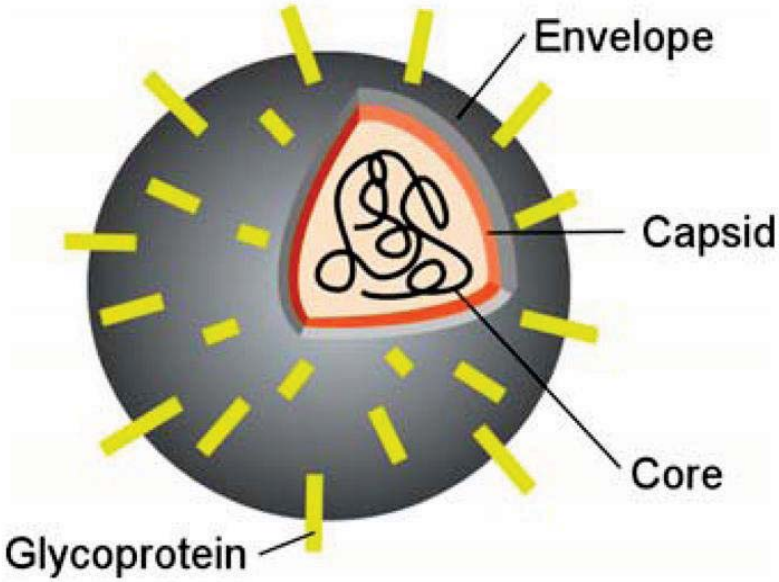
Results: Blood sample groups from Variant Creutzfeldt-Jakob Disease (vCJD), sCJD, non-CJD neurological diseases and normal healthy adults (blood donors) screened by ADRS were classified with 100% specificity and sensitivity, discriminating these by a co-variance expert analysis system.

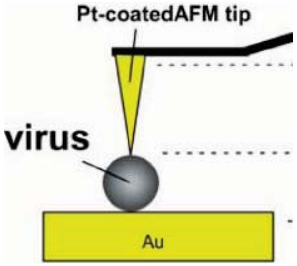
Conclusion: ADRS appears capable of recognising and discriminating serum samples from vCJD, sCJD, non-CJD neurological diseases, and normal healthy adults, and might be developed to provide a system for primary screening or confirmatory assay complementary to other screening systems.

Hunter College, NY

Source: Application of Atomic Dielectric Resonance Spectroscopy for the screening of blood samples from patients with clinical variant ands poradic CJD, Timothy J Fagge et al, Published: 30 August 2007 Journal of Translational Medicine 2007, 5:41 doi:10.1186/1479-5876-5-41

AV 5, HSV1, SV40, MVA, CPMV Screening by Dielectric Spectroscopy





100 Hz – 10 MHz

CONCLUSIONS: AC capacitance scanning probe microscopy probed that five viruses, AV5, CPMV, MVA, SV40, and HSV1 possessed distinguishable and characteristic capacitances. A mutation on the capsid in HSV1 virus with green fluorescence proteins (GFP) increased capacitance... virus decreased capacitance when its envelope and glycoproteins were chemically extracted. These control experiments indicate that dielectric properties of capsid proteins and glycoproteins significantly influence the observed overall capacitances of viruses. Because those capsid proteins and glycoproteins are characteristic to the viral type, this AC-SPM technique could be applied to detect and identify viruses at the single viron level using their distinct capacitance spectra as fingerprints without labeling.

THE UNIVERSITY of EDINBURGH

Adenovirus type 5 (AV 5), Herpes Simplex Virus type 1 (HSV1),
Simian Virus 40 (SV40), vaccinia (MVA), and Cowpea Mosaic Virus (CPMV)

Source: Comparison of Electrical Properties of Viruses Studied by AC Capacitance Scanning Probe Microscopy, Robert I. MacCuspie, et, al J Am Chem. 2008 January 23; 130(3): 887–891. doi:10.1021/ja075244z.

RSV Viral Screening by Dielectric Spectroscopy

Respiratory Syncytial Virus (RSV)

It is shown that the RSV and RSV + antibody can be differentiated from BSA by three distinct features: (a) the real part of the complex permittivity spectra, (b) the ionic loss characteristic below 1 GHz, and (c) the relaxation frequency. These three features enable us to identify the presence of RSV in an aqueous biological material.

원광대학교 WONKWANG UNIVERSITY

Iksan, South Korea

Source: Dielectric spectroscopy technique for detection of human respiratory syncytial virus, Young Seek Cho , et al published: 08 July 2019 https://doi.org/10.1002/mop.31920

Why Alertgy

- Alertgy has developed and demonstrated a wristband dielectric spectrometer for continous blood glucose monitoring.

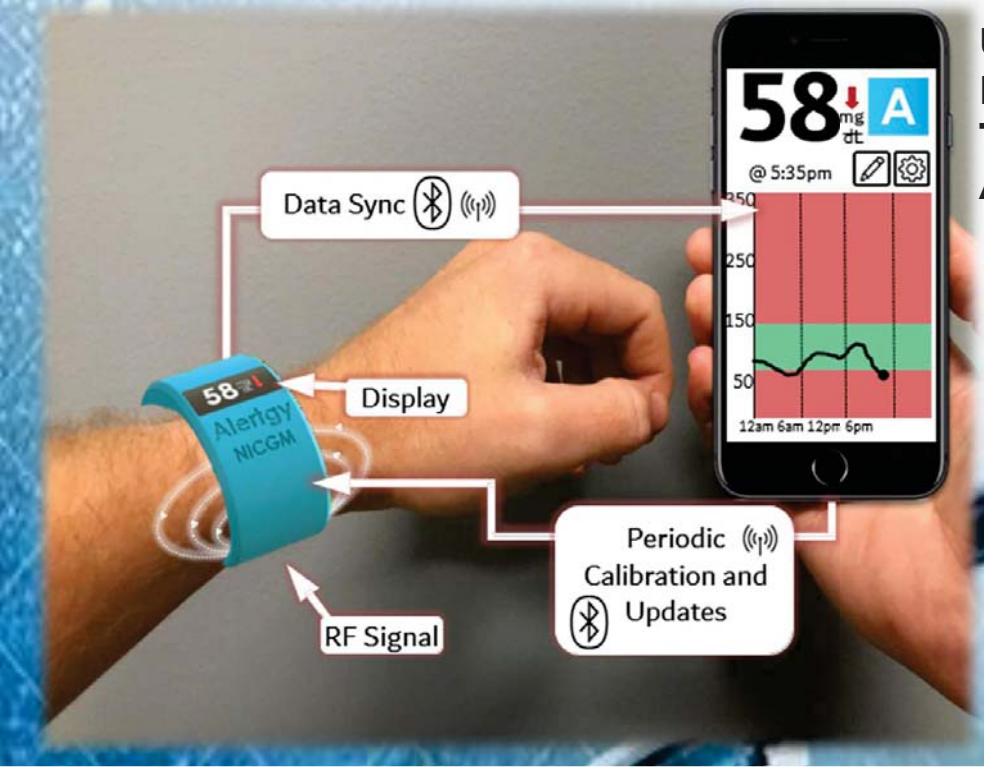
- Alertgy has developed a dielectric spectrometer test platform that can be used to develop viral detection applications on various sample types.

- Alertgy is working with Dr. James Hartman, a leading virology and immunology professor and research scientist at Florida Atlantic University who will act as Principal Investigator in the development of viral applications .

- Alertgy has a proven track record in achieving difficult goals on schedule and within low budgets.

Alertgy – Setting Diabetics Free

Providing a wearable Non-Invasive Continuous Glucose Monitor (NICGM) and alert system for real-time blood glucose measurements



Using DeepGluco™ a Dielectric Spectroscopy Technology with Artificial Intelligence

Transforming Health Through Innovation

Evolution of Technology/Miniaturization

- 4D Dielectric Spectroscopy
- Advanced Dielectric Materials
- Advanced Data Extraction / Processing

Lab System (2017)
Proof of Principle

1st Prototype (2018)
First portable prototype

2nd Prototype (2019)
Used in Studies 1 and 2

1st Gen wearable (2020)
Semi FlexTech / COTS Version

2nd Gen wearable (2022)
SoC / Consumer Version

Milestones for Project Corona

- Raise needed funding
- Recruit clinical study partners
- Develop test method using Alertgy's benchtop spectrometer system
- Develop AI analytics algorithm for calibration
- Conduct clinical trials to demonstrate adequate sensitivity and selectivity
- If possible, transition to wearable sensor platform

Alertgy

Thank you for your interest…

Any questions?

Please contact:

John Hubert VP engineering

John.hubert@Alertgy.com

Phone 00 1 407 342 7732

Remote vital sign monitoring for a new standard of care

Carlos Agell - Program Manager

About imec

Remote vital signs context

Remote vital sign monitoring

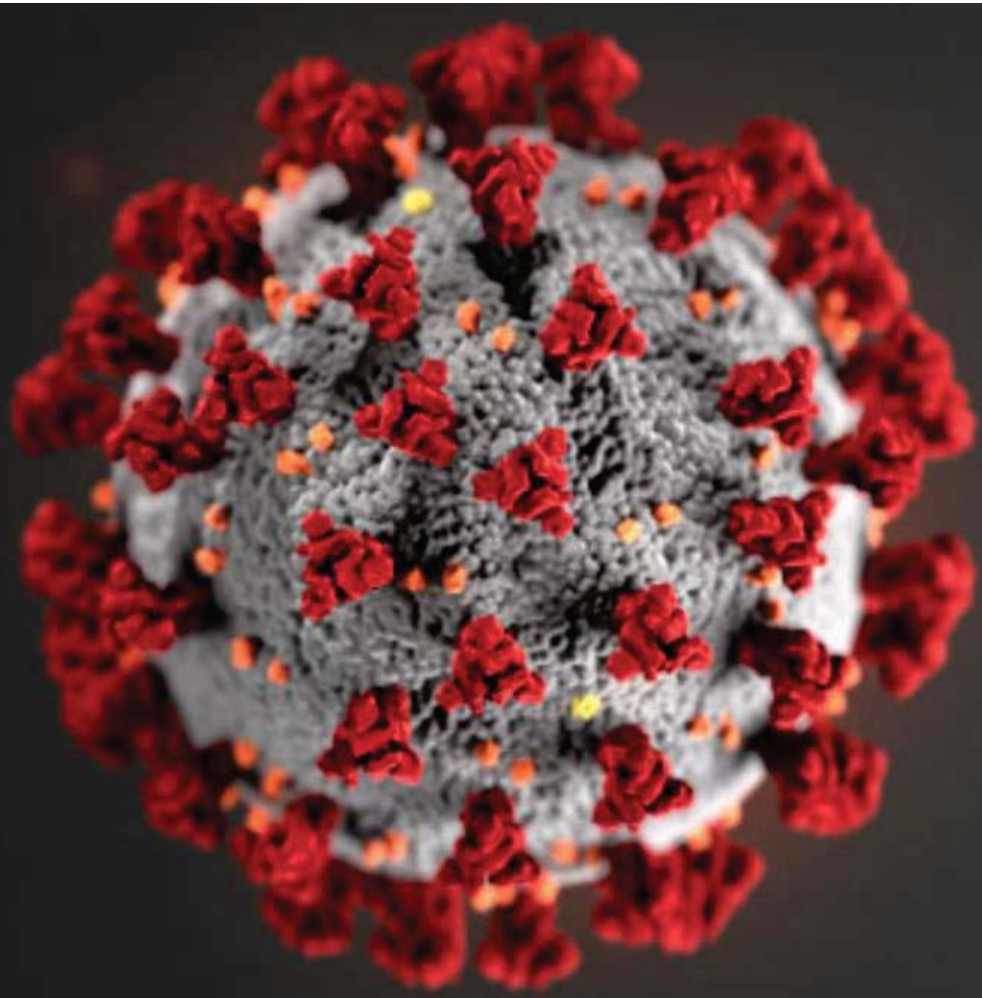
What do we mean?

- Sensing health-related parameters at a distance
  - What health parameters?
  - What distance?

Healthcare in the *new normal*

Covid-19 outbreak

Shaking the foundations



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WORKHARD
ANYWHERE

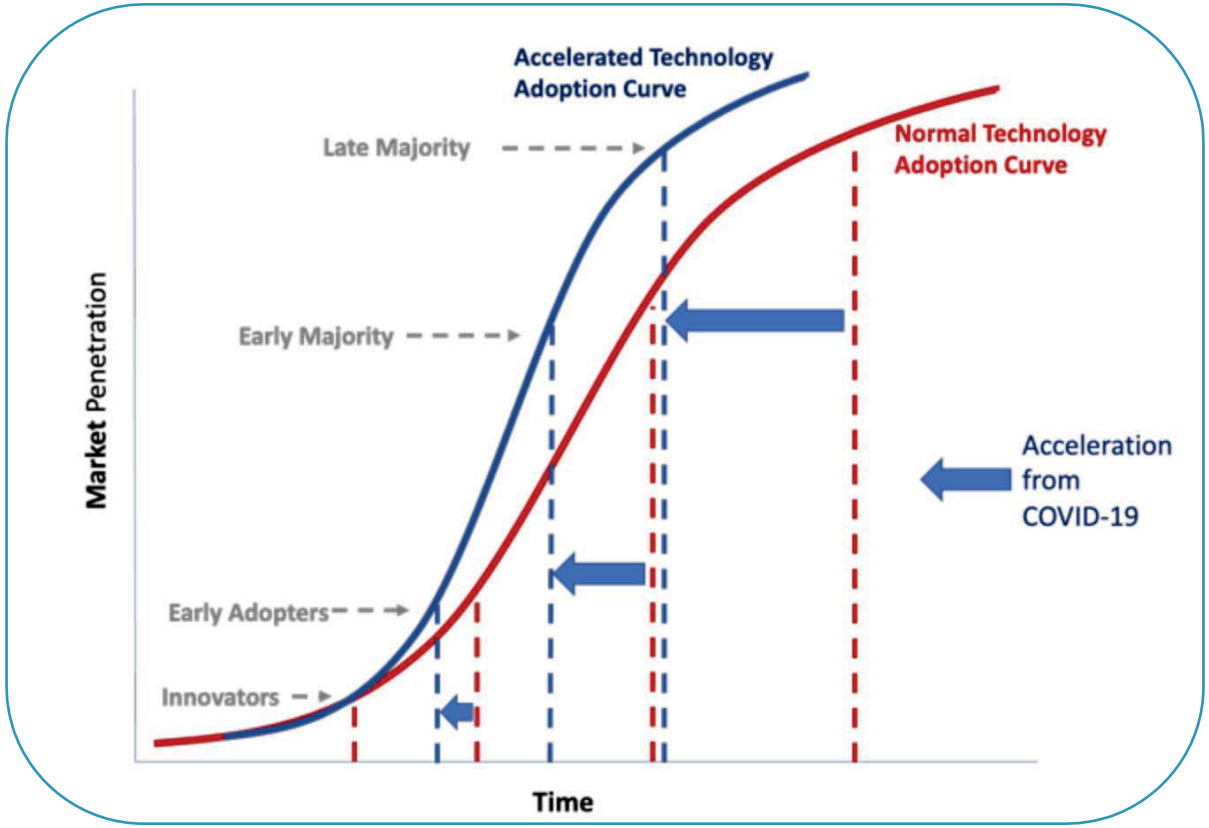
Corona changes the way we live

For some things … but not for others...

Fundamental changes

Starting to happen – some of them will stick

Accelerating the adoption curve



Source: Seeking Alpha, COVID-19 may trigger a Tech Revolution, Michael McGrath

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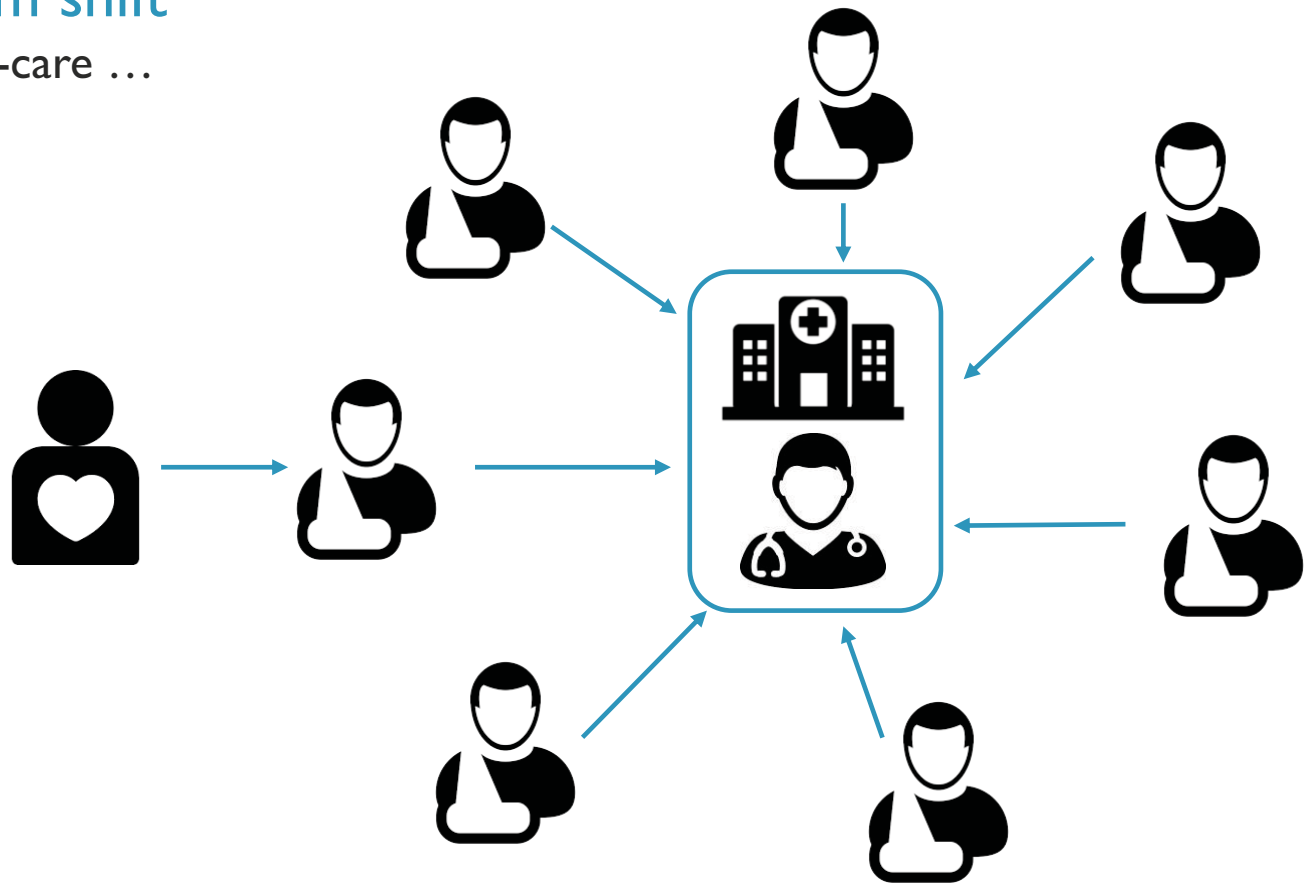
Paradigm shift

From sick-care …



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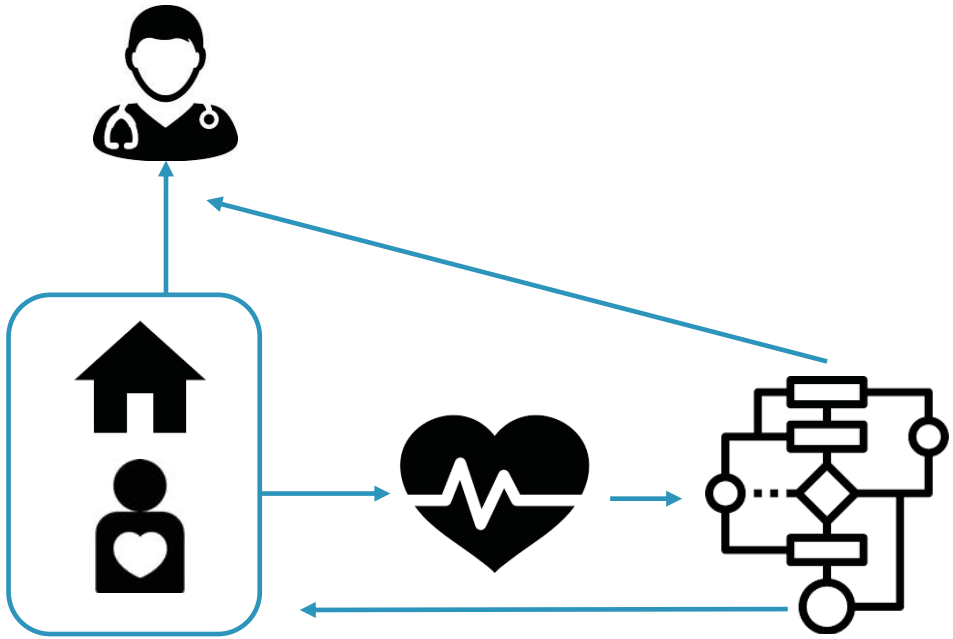
Paradigm shift

… To healthcare



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Remote care helps, not only for virus contention

Nosocomial infection

***Healthcare-associated infections**, or infections acquired in healthcare settings, are **the most frequent adverse event** in healthcare delivery worldwide.*

World Health Organization

Source WHO, Health care-associated infections FACT SHEET

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Why remote vital sign monitoring and why now?

- **Leverage** the accelerated adoption curve for remote vital signs monitoring
  - Let's **keep healthy**, not only treating the sick
  - Take a **patient-centric** approach – with ownership of your health
  - Keep healthcare **at home** as much as possible
- It is **a must**, given the situation
  - We cannot delay the rest of care indefinitely

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Health beyond *healthcare*

Vision on remote vital sign monitoring
2020 and beyond

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

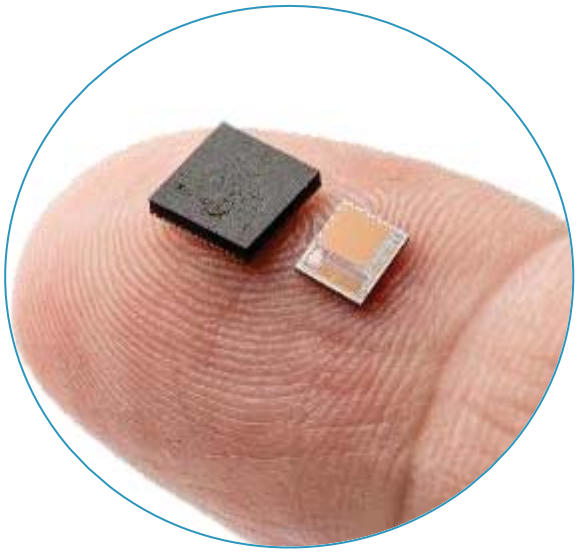
Making monitoring multiparameter

Next-gen chips as foundation for next-gen 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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Using wearables as support for Clinical Trials

Using them for pharma trials

- Great starting point for **next-generation experimental trials**
- Pervasive and ambulatory companion for **classical Randomized Control Trials** or their Distributed versions (**Randomized Distribute 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

Investigational devices

(Semi) continuous multi parameters supplying full raw data trace

Access to modalities AND raw data traces, with fully cleaned & high-quality data

Imec-partner device, not yet public			
Cardio Watch Cardiac monitoring	**imec Chill+:** Mental Health platform	**imec Nightingale** Re-usable and flexible multi-signal	**imec Healthpatch** Disposable and comfortable

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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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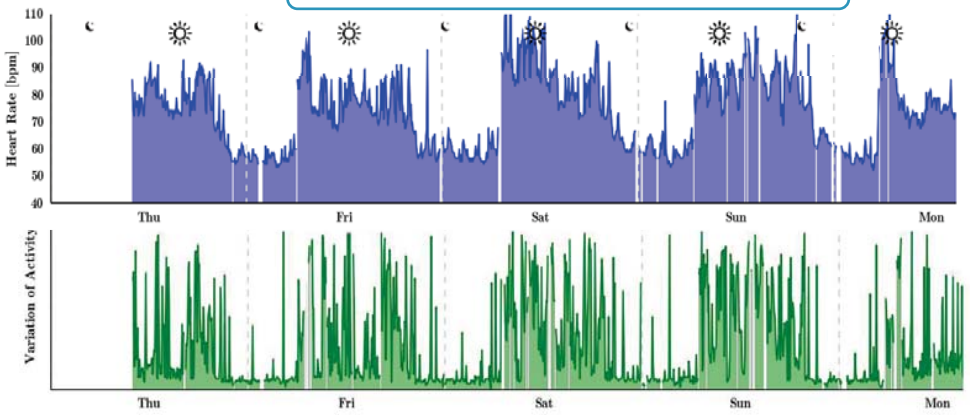
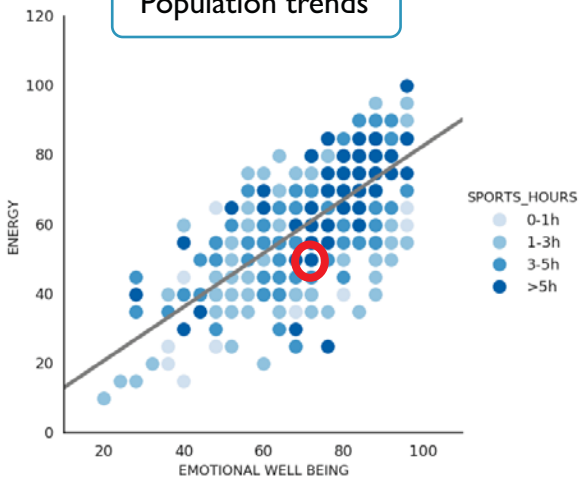
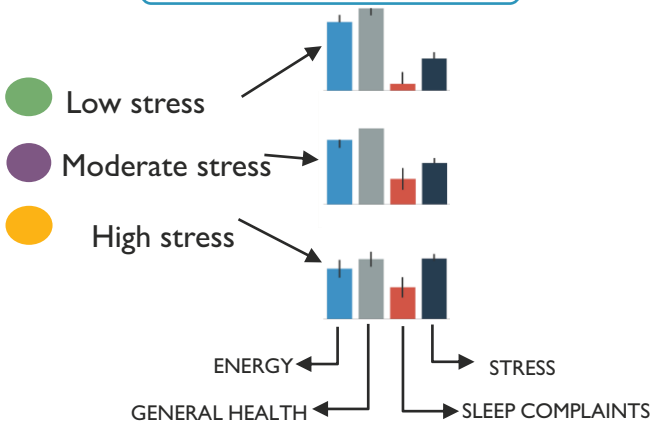
Daily dynamics of the individual's traits



Population trends

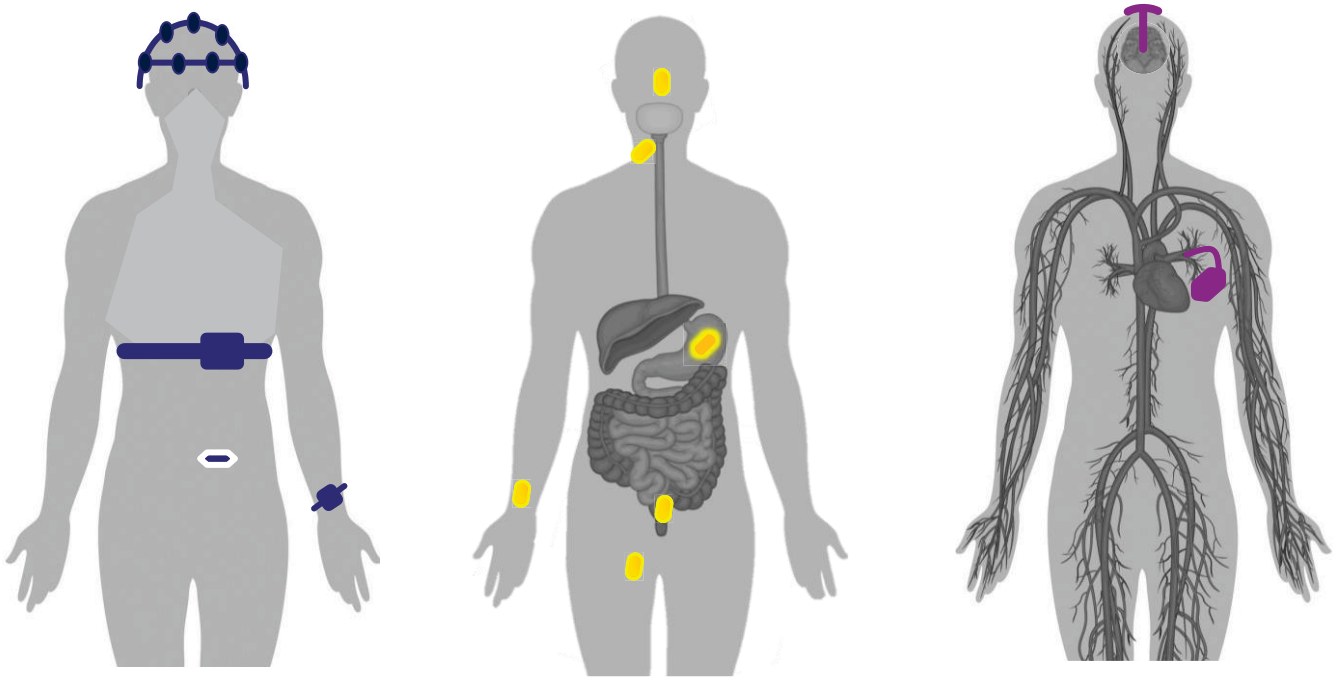


Link to Health Indicators



Going deep

Implantable technology



Wearables **Insertables** **Implantables**

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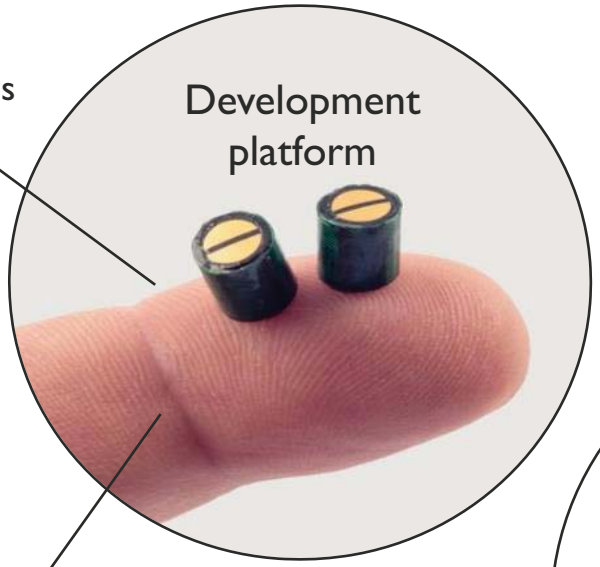
Going implantable: flexible development platform

Wireless

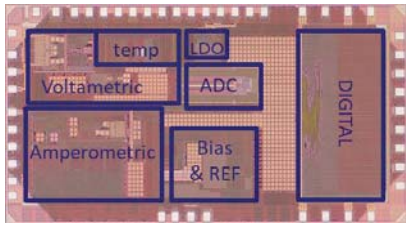
Development platform



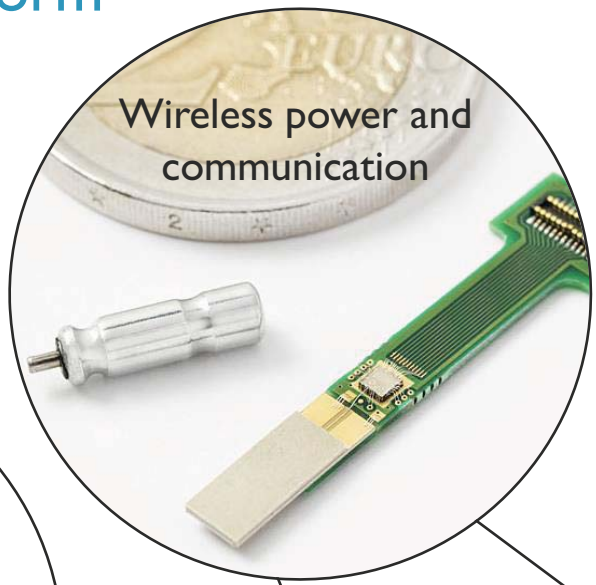
Sensor & stimulator

Passively powered

Microwatt biochemical sensor readout circuits



Wireless power and communication



Zero-BOM Wireless TRx

Small size 400MHz antenna

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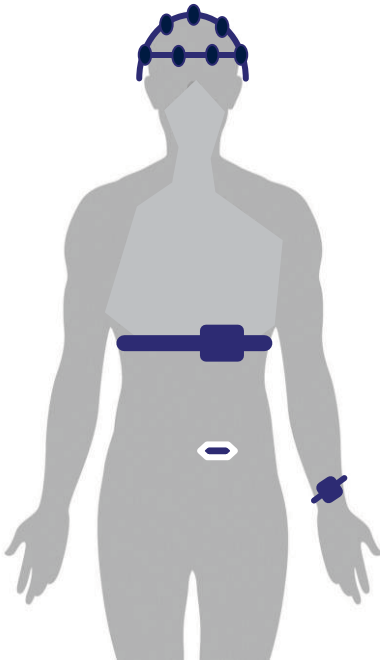
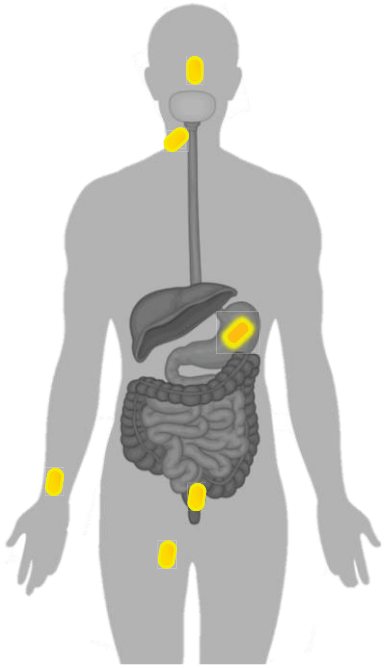
https://www.imec-int.com/implantables

Seamless integration

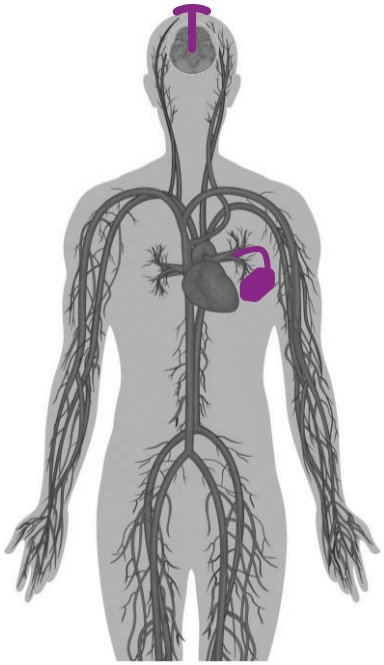
Non-contact technology



Wearables



Insertables



Implantables

Invisibles

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Imec's invisible sensing platform

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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

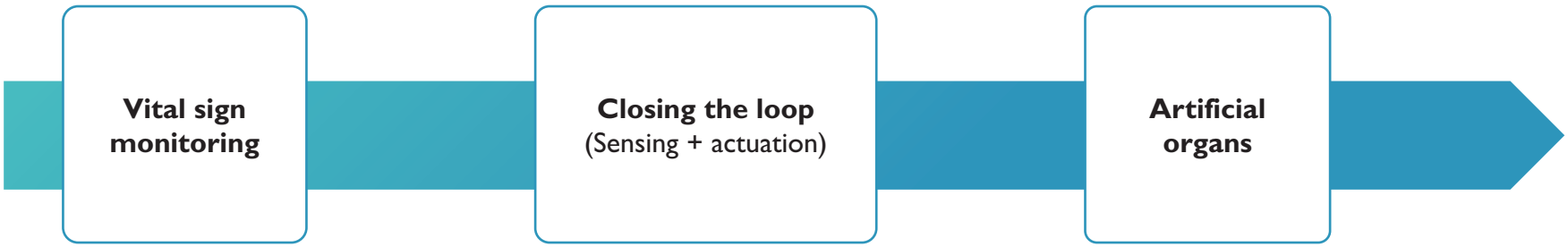
Interaction

Algorithms

Actuation

Horizon: artificial organs

Where sensing is just a tiny piece



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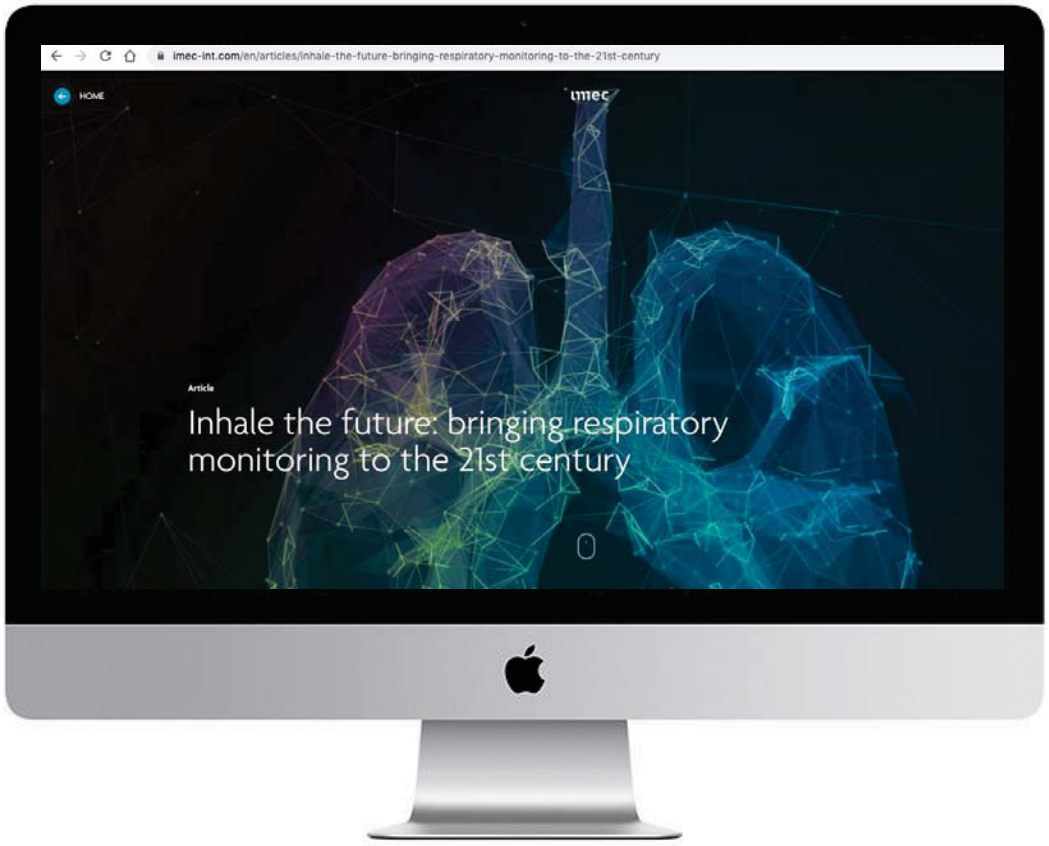
Therapeutic areas

Respiratory technologies



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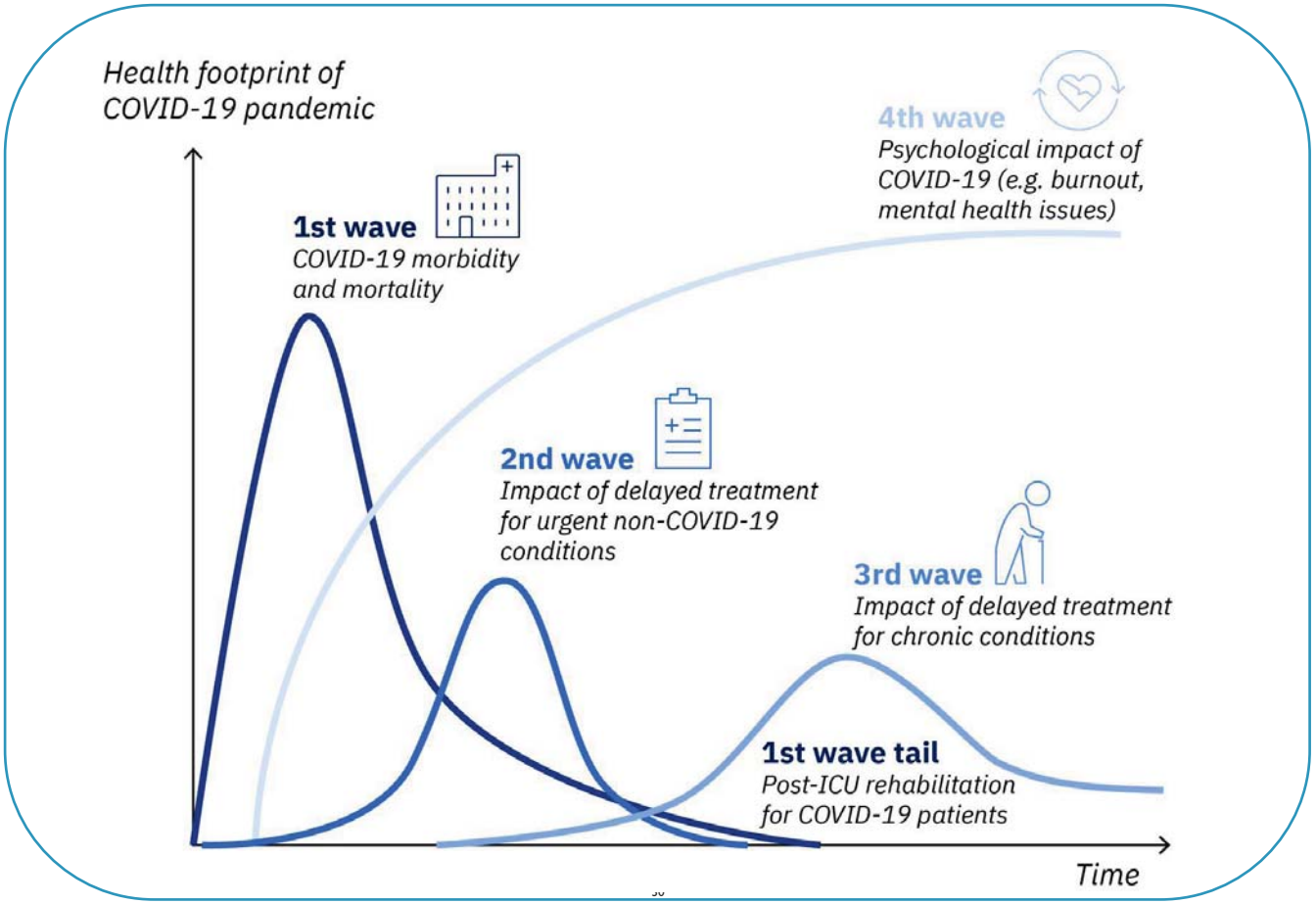
Mental health



Source: IBM

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Platforms for mental health monitoring

Platform for the acquisition of **brain electrical activity (EEG) using dry electrodes**

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

Mental health wrist-based platform

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

DATWYLER

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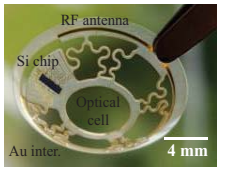
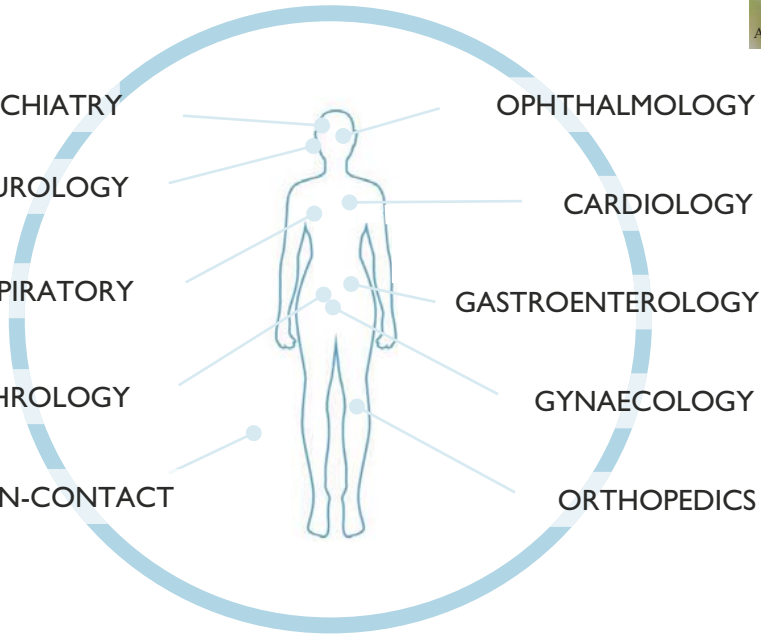
CHS application fields

Our existing portfolio of medical capabilities





Conclusion

Conclusions

- COVID has pushed **vital signs monitoring high on the agenda**
- Remote vital signs monitoring **will stay in the standard of care** after the pandemic
- **Imec has a vision going beyond wearable monitoring** towards new form factors, actuation feedback and ultimately to artificial organs
- **Remote vital monitoring wearable technology** is now mature enough to fit the needs of pharma companies for clinical trial applications
- Respiration is high on the list, but **let's not forget all other therapeutic areas**

Thank you!

Questions? health@imec.be
For more information, visit www.imec-int.com/chs

Carlos Agell, Program Manager - Principal Member of Technical Staff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THINK ON.

www.onsemi.com

Industry Events & Trends

Serving the Medical Device Community during, and post COVID-19

July 2020

Public Information

MEDICAL DEVICE TRENDS

OTC Hearing Aids closer to reality

- OTC Hearing Aid Act of 2017 Passes
- HIA was not successful at limiting the bill to '**Mild Loss**' only
- Now focuses on the FDA & Labeling
- July 24th 2018: FDA issues letter 'mandated process to publish proposed HH reg's by 18AUG2020 deadline
- Jul 2019: US House introduced H.R.4056 Bill that would provide Audiologists Services under the Medicare Program

Source: The Hearing Review, August 19, 2017

Source: congress.gov, July 25, 2019

The Spin:

- Fuels Market Expansion
- OTC requires wireless connectivity

MEDICAL DEVICE TRENDS

The Day the Earth Shook (and ears rang)

- October 5th, 2018
  (Ahead of the August 2020 FDA process mandate)
- FDA approved the worlds first Hearing Aid which can be self-fit, programmed, and controlled by the user. A 'direct-to-consumer' device, or DTC
- Aug 2019: HIA argues against the FDA's authorization of Bose's self-fitting HA relied on flawed Phase II clinical study
- Oct 2019: FDA published its final order on the Bose De Novo application, classifying their self-fitting HA as Class II, requiring special controls

The Spin:

- Bose Created their own Market w/Monster Consumer Brand
- Requires wireless connectivity
- Let the arm-wrestling begin

Following the news of Bose's approval, the stocks of some of the largest international hearing aid manufacturers—Sonova, William Demant and GN Store Nord—each dropped about 10%.

Source: FierceBiotech, October 8, 2018


THE VERGE TECH REVIEWS SCIENCE CREATORS ENTERTAINMENT MORE

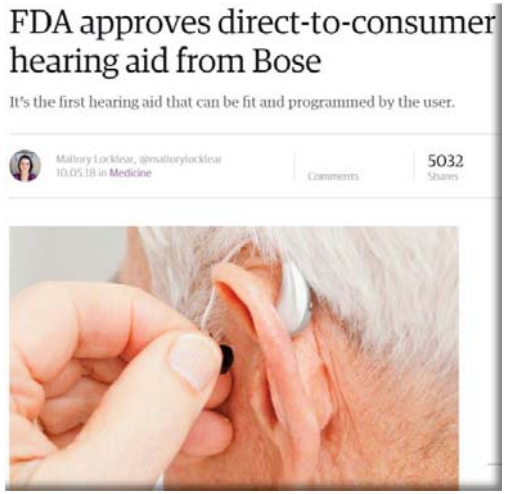
TECH BOSE

Bose is closing all of its retail stores in North America, Europe, Japan, and Australia

The move will result in hundreds of employees being laid off

By Chris Welch | @chriswelch | Jan 15, 2020, 4:34pm EST

Source: theverge.com, January 15, 2020


FDA approves direct-to-consumer hearing aid from Bose

It's the first hearing aid that can be fit and programmed by the user.

Mallory Locklear, @mallorylocklear
10.05.18 in Medicine

Comments

5032
Shares

Source: engadget, October 5, 2018

Events & Trends

The COVID effect

MEDICAL DEVICE TRENDS

- 13Mar US: National Emergency declared
- 17Mar: CMS: Medicare Telehealth Benefits Expanded to include any healthcare facility
  - Physicians Office
  - Hospital
  - Nursing Home
  - Rural Health Clinic
  - And from Homes
- 18Mar: Defense Production Act (DPA) is invoked to mitigate medical supply shortages

Trump to invoke Defense Production Act to boost medical supplies

Wednesday, March 18, 2020

President Donald Trump said Wednesday that he would invoke the Defense Production Act to mitigate challenges with obtaining medical supplies.

Source: FierceHealthcare, March 18, 2020

Medicare Telehealth Benefits Expanded During COVID-19 Crisis

Mar 20, 2020 | Legislation, Medicare & Insurance, TeleHealth |

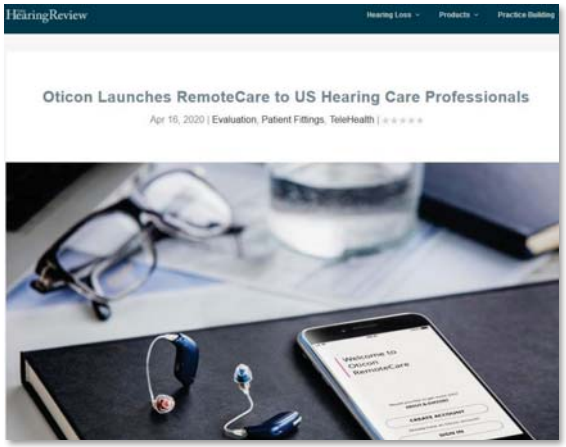
Source: HealthcareITnews, March 17, 2020

The Spin:

- Follow the money
- Will reimbursed Telehealth stick?

MEDICAL DEVICE TRENDS

- 16Apr: Oticon® launches “Oticon RemoteCare”
- 17Apr: Starkey® partners with Google Cloud Storage™ service, expanding its “Hearing Care Anywhere” project
- 23Apr: GN Resound® joins in with Resound Assist Live at-home services
- Remote programming capability:
  - First Fit capabilities
  - Settings are reviewed and modifications can be uploaded
- 24Jun: Apple® introduces Personal Sound Amplification Product (PSAP) features in iOS14 using AirPods®



Source: TheHearingReview, April 16, 2020

Source: TheHearingReview, April 17, 2020

Source: TheHearingReview, June 24, 2020

The Spin:
- Customers get service remotely
- It’s all connected via Bluetooth® Low Energy

MEDICAL DEVICE TRENDS

- 09Mar: FDA Clears RRp (Respiration Rate from Photoplethysmography) monitor from Masimo®
  - Critical vital sign + SpO2
- 10Apr: Full Market Release of Masimo SafetyNet™ for remote monitoring
  - Telehealth Solution
  - Masimo SET SpO2, RR, Pulse Rate, Perfusion Index, more

Source: LinkedIn, May 6, 2020

Source: medgadget, March 9, 2020

Source: businesswire, April 10, 2020

The Spin:

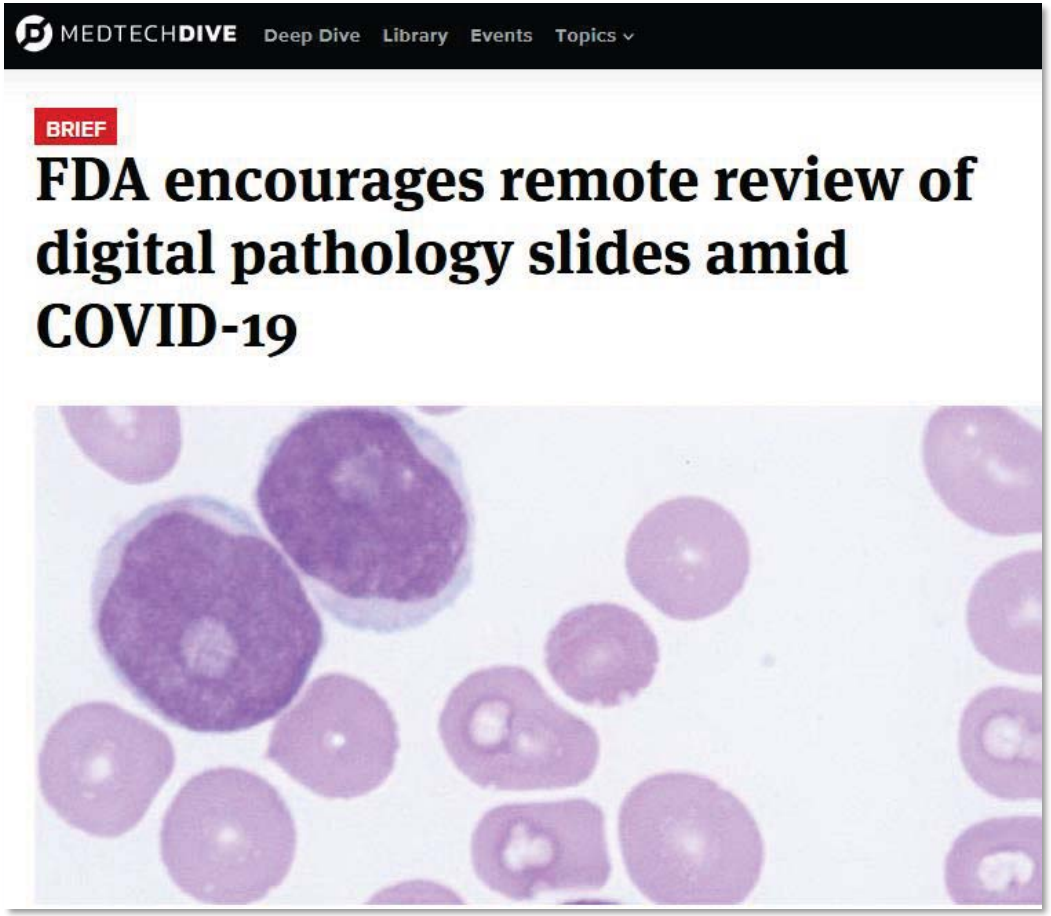
- The timing wrt COVID-19
- And its Bluetooth Low Energy connected

MEDICAL DEVICE TRENDS

- 27Apr: FDA relaxes requirements for remote viewing of scanned images of slides
- Primary diagnosis by clinicians can now be remote, including to/from home
- Follows new policy by CMS

The Spin:

- Follow the money
- Digital pathology gets a shot in the arm



Source: MedtechDive, April 27, 2020

ON Semiconductor

To improve Lives through Innovative Solutions

Improving Lives Through Innovative Medical Solutions

Implantables

ULP Custom ASICs
Medical Grade Discretes
ULP Serial SRAM
Full Foundry Services
Custom Manufacturing Services
FDA Compliant 3D Modules and SiPs

FDA

Clinical & Consumer

Custom ASICs
Bluetooth Low Energy
Custom Manufacturing Services
FDA Compliant 3D Modules and SiPs

Hearing Health

Ezairo Pre-Suite Tool Kit
Complete DSP Based Modules
Bluetooth Low Energy
Power Management
Custom Manufacturing Services
3D Modules and SiPs

Medical Imaging

Mixed-Signal Custom ASICs
CCD & CMOS Sensors:

- Large format CCD
- Large format CMOS
- Small format CMOS

Medical Quality
Process & Product Longevity

Success Story

Beacons: Contact Tracing and Healthcare IoT

Challenge:

- Maintaining or reducing the current product size, provide a BLE Solution that more than doubles battery life with ultra-low power Sleep, Rx, and Tx power.

ON Semiconductor Solution:

- RSL10 (Bluetooth 5 certified radio SoC)
  - Displacing a leading competitor
  - Improved RF power & Battery performance
  - Small size

Intelligent Locations Benefits:

- Higher performance beacon with industry leading processing and RF efficiency increasing accuracy and reliability
- Able to use the same form factor as existing product
- More than doubles the battery life of their beacon

Intelligent locations logo and graphics used with their approval

FOR ENERGY EFFICIENT INNOVATIONS

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To improve Lives through Innovative Solutions

Signal Processing, Wireless, and Medical (SWM) Division

Public Information

Q&A Session

Get in touch!

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