




## Medtech-Innovation through the Fusion of Microelectronics with Sensors

### Citation from Robert Bosch




“ It is inherent to the nature of medicine that its greatest concern is to cure the suffering and, where this is not possible, to alleviate pain.”

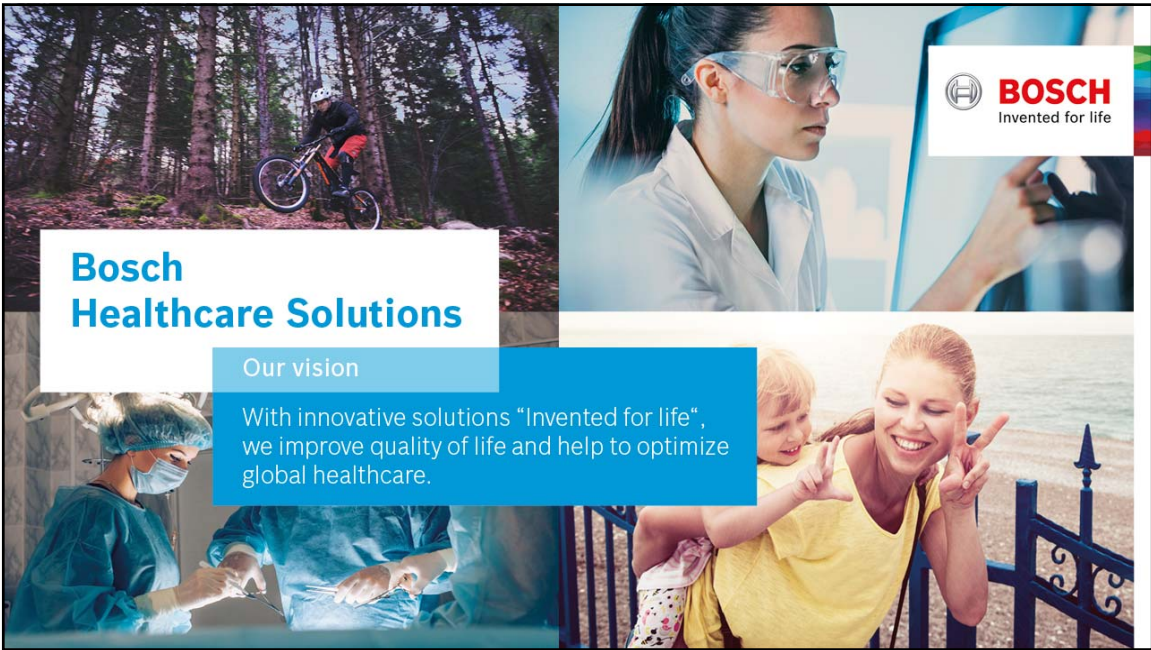
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ROBERT BOSCH

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## Bosch Healthcare Solutions

**Our vision**

With innovative solutions “Invented for life”, we improve quality of life and help to optimize global healthcare.



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**BOSCH**  
Invented for life


## Laboratory Diagnostics

**Our vision**

We make complex laboratory tests ingeniously simple – for faster decisions that can save lives.

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## Medtech-Innovation through the Fusion of Microelectronics with Sensors




**NEED**

- ▶ Universal laboratory platform for complex DNA tests, for use at the point-of-care.


**MARKET**

- ▶ The global market volume of molecular diagnostics is estimated to EUR 9,5 bn in 2021.<sup>1)</sup>
- ▶ Infectious diseases are the largest market segment in molecular diagnostics.<sup>2)</sup>

**PRODUCTS**







Vivalytic Analyser




Vivalytic cartridges


**CORE COMPETENCIES**

-  Miniaturization
-  Automation
-  Sensors
-  Interconnectivity


**USE CASES**




Laboratory




Hospital



Doctor's ambulance

 The wide range of applications and the quick and easy performance of the tests enable physicians to diagnose and treat patients faster.

<sup>1)</sup> Markets and Markets: Molecular Diagnostics Market by Application – Forecast to 2021  
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<sup>2)</sup> Markets and Markets: IVD Market by Product Technology by Application – Forecast to 2021  
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### Automation of complex Molecular Diagnostic Workflows

Conventional: complex **manual** workflow in diagnostics labs

Lab-on-Chip: Integrated microfluidic System for **Automation** of Diagnostics

Depending on the application, test results can be available within 30 minutes.

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### Operation of Vivalytic

- ① **Scan Sample Code**
- ② **Scan Cartridge Code**
- ③ **Load Sample and close Lid**
- ④ **Enter Cartridge and push START**

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### Universal Vivalytic Analyser (Processing Station)

- Optics and camera**
- Electronics**  
power supply, hardware control, image acquisition
- Pneumatics**  
pumps, valves, manifold
- Thermal management**  
heaters, ventilators

- Man-machine-interface**  
touch-display, scanner
- Mechanics**  
cartridge feeder, clamping, reagent release
- Scanner**
- Ultrasonics**  
universal sample lysing

**Connected and combinable**  
The Bosch Analyser supports HL7, GDT, and POCT-1A out-of-the-box. Connectivity options include Ethernet, WLAN, Bluetooth, and GSM.

**Software**  
incl. clinical information system

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### Application specific Vivalytic Cartridges

**Lab-on-Chip cartridge**

- Cover
- Fluidic layer
- Reagent bars
- Elastic Membrane (carrier film)
- Pneumatic layer
- PC seal film (carrier film)

**Exploded view of cartridge components**

**Reagent bars**

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### Cartridge pneumatic actuation principle

- ▶ Full Process Automation
- ▶ Small sample volumes
- ▶ Precisely controlled operating conditions

$P_a \gg P_{ref}$

$P_a \ll P_{ref}$

$P_a$ : Actuation pressure  
 $P_{ref}$ : Reference pressure

valve      pump      mix

Circulating liquid plug

10 mm

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### Processing of Infectious Disease Assay

**Sample input**  
50...1000µl  
Blood, urine, tissue, swabs, sputum

**Reagent storage**  
at room temperature  
for 2 years

**Sample purification**  
Bacteria, virus, fungi, human cells – Purification of DNA and RNA

**Amplification**  
2 individual strands for PCR  
Highly sensitive PCR

**Detection**  
2 individual strands for qPCR and melting curve  
50x Multiplex µArray  
Quantitative und semi-quantitative detection  
Combination of detection mechanisms possible

Melting Curve

qPCR

µArray

PCR: Polymerase Kettreaktion  
qPCR: quantitative PCR (real-time PCR)

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### Cartridge Assembly Line: Scalable Technology

- ▶ Automated Manufacturing Line
- ▶ Reliable assembly and laser welding processes
- ▶ Scalable to high-volume manufacturing
- ▶ Economy-of-Scales with increasing Production Volumes



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### Business model

- ▶ Open Platform Solution
- ▶ Bosch Technology for Automation of ANY Molecular Diagnostics Workflow
- ▶ Broad Test Portfolio
- ▶ Fast Market Access for new Tests



***“So, you are like Apple.  
The analyser is your iPhone,  
and others can develop their  
apps for it.  
That’s genius!”***

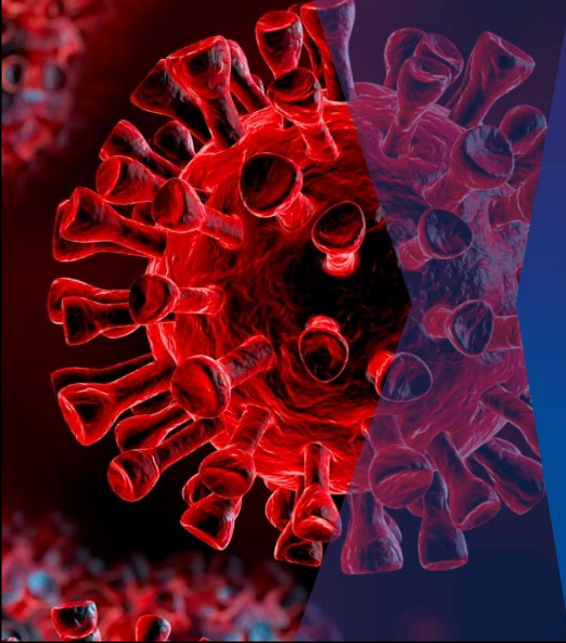
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### Fighting the SARS-CoV-2-Pandemics

- ▶ 1<sup>st</sup> SARS-CoV-2 PCR-Test available on our Vivalytic Platform in April'20: 2,5 h test duration sample-to-result,
- ▶ 2<sup>nd</sup> generation of Rapid PCR-Test available in October'20: 39 min's test duration sample-to-result
- ▶ 3<sup>rd</sup> generation of Rapid PCR-Test with duration of <30 min's in 2021 funded by BMBF „Vivalytic Light“ (16ME0174)

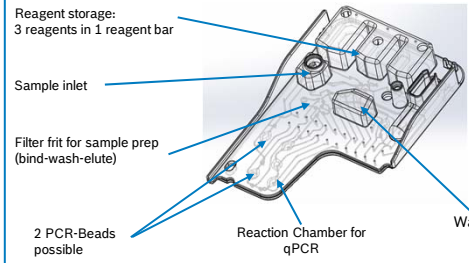


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### “Vivalytic Light”: new 2-in-1 cartridge concept for low-plex tests

**Construction of „Vivalytic Light“ cartridge**



💡


- ▶ Lower costs by **2-in-1-approach**.
- ▶ Only **1 reagent bar** containing 3 reagents
- ▶ **Production output** doubled

“New” vs. “Old”

Funded by BMBF (AZ: 16ME0174)

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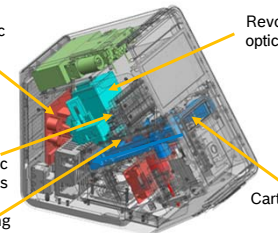


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### “Vivalytic Light”: new concept for Analyser Light

New Cartridge enables reduction of Analyser complexity

Analyser Specification	New Analyser Concept
<ul style="list-style-type: none"> <li>3 plungers to open reagents (instead of 9)</li> <li>6 heaters (instead of 12)</li> <li>Reduced number of pneumatic ports</li> <li>Revolutionary optics concept</li> <li>New electronic concept for process control and signal generation</li> </ul>	 <ul style="list-style-type: none"> <li>Smarter electronic control board</li> <li>Compact pneumatic interface and valves</li> <li>New heating concept</li> <li>Revolutionary optics solution</li> <li>Cartridge slot</li> </ul>

▶ Short Time-to-Market

Funded by BMBF  
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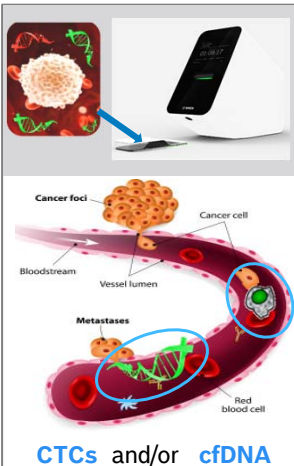
### Future Potentials in Oncology: Vivalytic and Liquid Biopsies

Today

- ▶ Tissue Samples (FFPE\*) from Surgery or „Solid Biopsy“
- ▶ Patient Stratification from genetic information of Tissue Samples: Decision on Personalized Therapy
- ▶ Genetic information for Therapy Monitoring: done rarely

Tomorrow

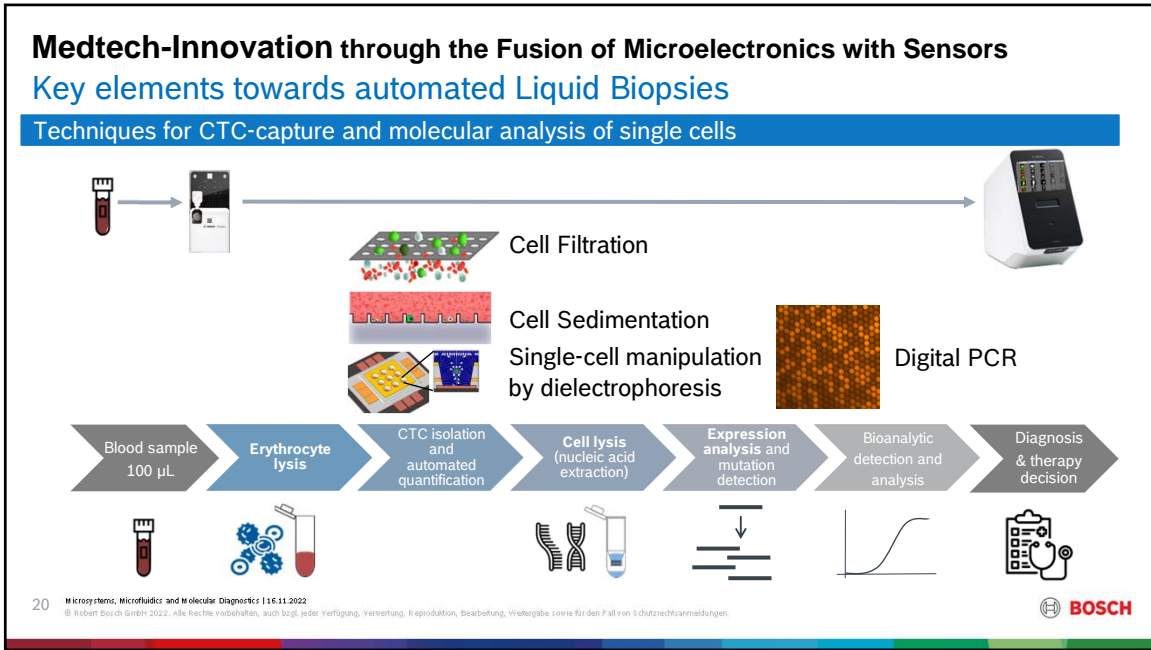
- ▶ Minimally invasive repetitive „Liquid Biopsies“: CTC's and/or cfDNA harvested from the blood-stream
- ▶ Genetic Information for Therapy Monitoring and for regular Adaptation of Treatment



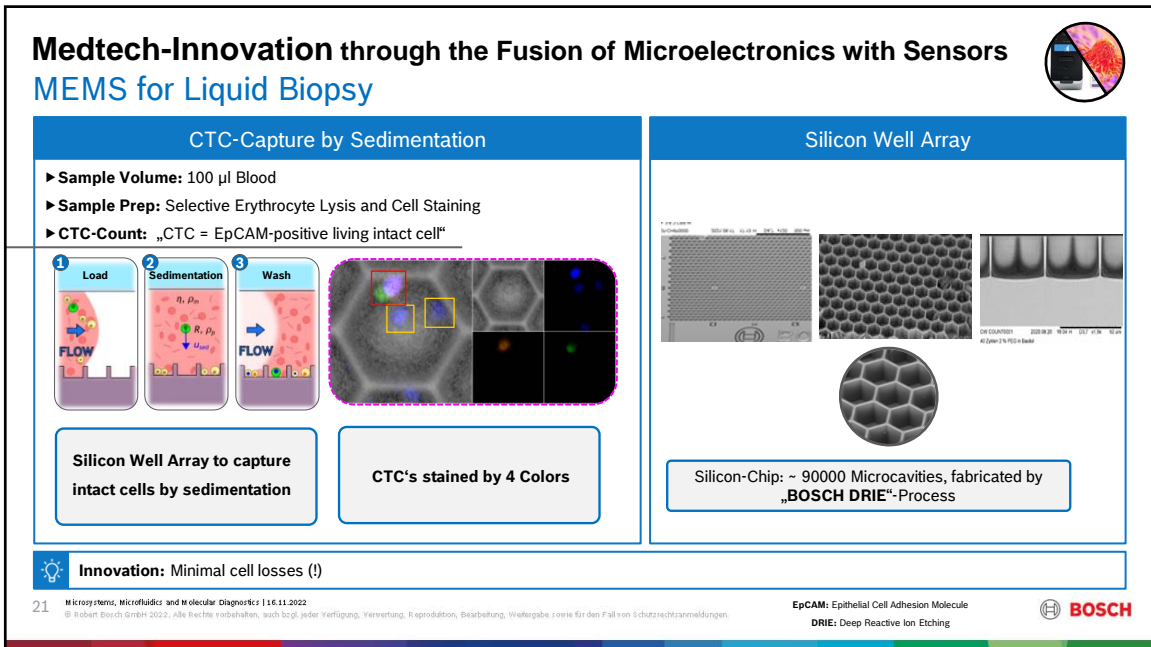
CTCs and/or cfDNA

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### Summary and Outlook

- ▶ Move Diagnostics “from central laboratories to the Point of Care”
- ▶ **Vivalytic** for Laboratory Diagnostics:
  - Open Platform for the Automation of a wide variety of complex Molecular Diagnostics Assays
- ▶ Application-specific Cartridges driven by the same universal Processing Station (Vivalytic Analyser)
- ▶ “Vivalytic Light”: efficient solutions for low-plex Assays (e.g. SARS-CoV-2 detection)
- ▶ Scope of Applications: Infectious diseases, Oncology, Personalized Therapy
- ▶ Boosting Medtech-Innovation by Microelectronics and Microsystems technologies

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# THANK YOU

**Therapy Management**

**Laboratory Diagnostics**

**Hightech Components**

**Medical Screening**

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