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## DIGITAL HEALTH SYSTEMS COMMUNICATION.SENSORS.ANALYSIS.

RESEARCH AND DEVELOPMENT SERVICES FROM A SINGLE SOURCE



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for Integrated Circuits IIS**

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## DEVELOPMENT PARTNERS FOR DIGITAL HEALTH AND MEDICAL TECHNOLOGY

Medical equipment must be closely tailored to the needs of individual customers and patients. This in turn requires a precise understanding of future health challenges and the requirements of our customers.

### To ensure this, we provide the following services:

- Contract-based development projects and technology licensing
- Technology and feasibility studies
- Rapid prototyping (hardware and software)
- Standards-compliant software development and testing
- Field studies and validation of wearables
- Intelligent sensor modules and algorithms to capture and analyze psychophysiological signals
- Development and testing of medical control systems
- Customer-specific communications solutions and interoperability testing services
- Concepts and solutions for integrated healthcare provision
- AI-based algorithms and software systems for microscopy
- Semantic video analysis for endoscopy and surgery

### Diverse opportunities for collaboration with Fraunhofer

- Individual contracts and development partnerships
- Collaborative projects with several partners
- Flexible and extensive network structures (industry, research, public bodies)
- Extensive in-house capacity (electronics/optics labs, endoscopy studio, deep-learning clusters etc.)

## CONCENTRATING SYNERGIES UNDER ONE ROOF

All medical devices share certain attributes: they have to be innovative, provide help for doctors and patients alike, and deliver precise and secure data. Such systems must meet a wide range of requirements. Together with you, we define your needs to arrive at the best solution for your application. At the same time, we also keep a close eye on the entire development chain.

### Medical equipment solutions on demand – an overview of our portfolio of services

#### Functionality and intuitive operability: Hardware and software development

- Requirements analysis and technical specification
- Application development (operating concept, user interface etc.)
- HW/SW integration (interface programming, activation etc.)
- Cross-platform development (desktop, web, embedded)
- Standards-compliant testing routines and services (e.g., IEC 62304, IEC 82304, IEC 62366, DIN EN ISO 14971 and the EN 60601 series of standards)

#### Development of biosignal algorithms: Data usage made easy

- Signal processing and artifact suppression
- Calculation of secondary parameters (e.g., heart rate and heart-rate variability based on ECG)
- Calculation of pulse frequency (also image-based)

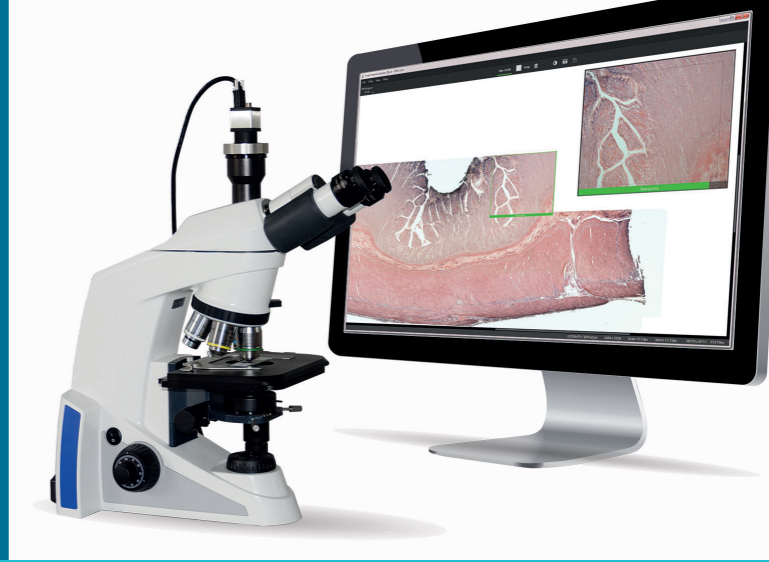
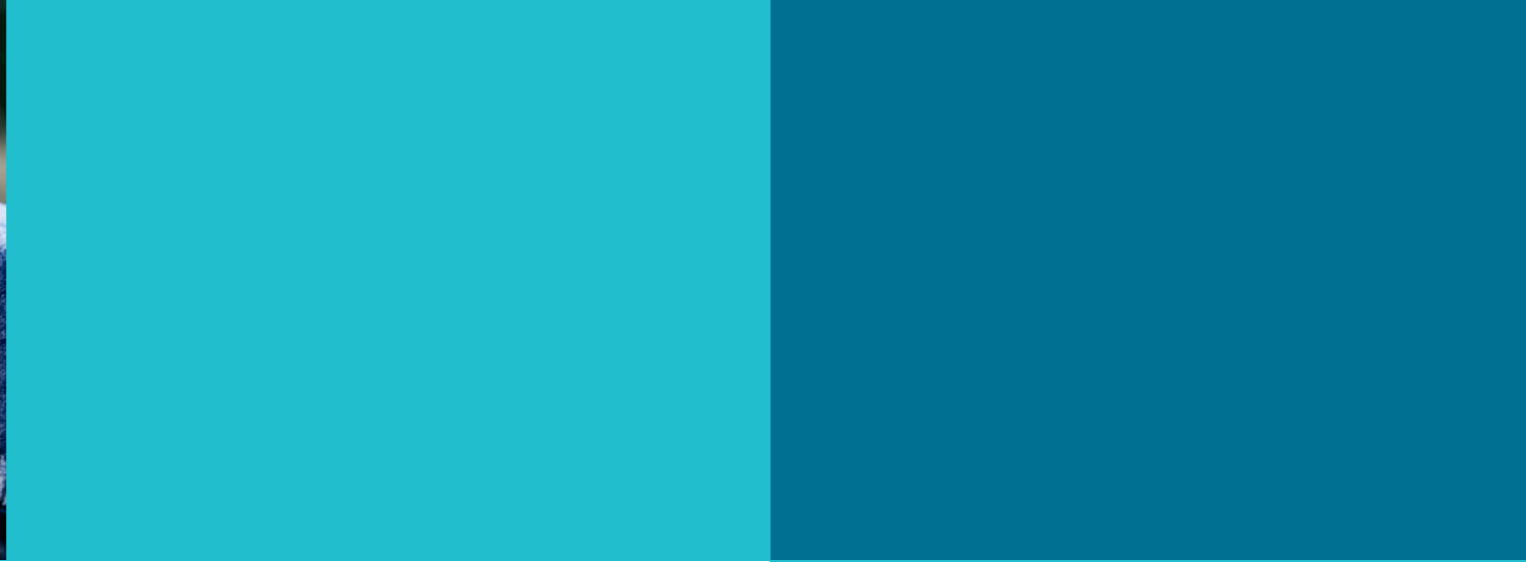
- Analysis and reconstruction of human movements (e.g., walking, running, cycling)

#### Smaller, more powerful, more flexible: Electronics development and rapid prototyping

- Circuit design (analog-digital) for the entire signal-processing chain, including PCB layout
- Production, commissioning and validation of prototypes (measurement series)
- Onboard power management
- Firmware development and onboard signal processing (optimization for embedded processors and DSPs)

#### Noninvasive sensor technology: Capturing data from within the body

- Multiparameter systems integrated in clothing (FitnessSHIRT) and multichannel ECG (CardioTEXTIL)
- Recording of muscle activity and electrodermal activity
- Determination of cardiological and respiratory parameters and activity



- Integration in clothing, furniture and vehicles (e.g., seats, steering wheel, gearshift knob)
- Detection of ions and electrolytes in sweat and body fluids

**Imaging: In-depth insights for precise diagnosis and efficient therapy**

- Development of automated image analysis for microscopy and endoscopy
- Machine-learning systems for analysis of large data volumes
- Semantic video analysis in real time

**Noninvasive medical-imaging technology**

- Microscopy, including, in particular, digital pathology and fluorescence microscopy, especially in the areas of clinical pathology, pathology, microbiology and pharmacology
- Endoscopy, including, in particular, production of panoramic images and detection of objects and pathologies (e.g., polyps), especially in the areas of gastroenterology and urology

**Machine learning helps stem the flood of data**

Our core expertise lies in image processing and image analysis on the basis of:

- “Conventional” algorithms, which are often faster and only require a limited amount of sample data
- Deep Learning, which often delivers more-precise results but requires large volumes of training data

**Solutions for integrated healthcare and interoperability**

We are working to ensure that everybody benefits from the advances of digital medicine. To this end, we are connecting healthcare providers across all sectors and creating decentralized infrastructure for medical communication.

- Development of the Digital Patient Manager, a generic telemedicine platform based on a decentralized infrastructure enabling data transfer between all relevant parties
- Creation of Digital Health Pathways, an integrated healthcare concept
- Patient-centric development and validation studies
- Standards-compliant software development according to IEC 62304
- Development of interoperability standards for point-of-care diagnostic equipment (POCT1-A/POCT1-A2)

**EXAMPLES OF OUR DEVELOPMENT PROJECTS**

**iSTIX®: Manual whole-slide imaging for simple and cost-effective sample scanning**

Whole-slide images are the basis of digital pathology and automated image analysis.

However, digital slide scanners are expensive and not necessarily available to all labs.

With the aid of iSTIX®, any standard microscope equipped with a camera can be used to scan whole-slide images. Simply mount the camera on the microscope, connect to a computer, and launch iSTIX®. Operate the microscope as normal to examine areas of interest. Meanwhile, the computer compiles a panoramic image.

Features and benefits:

- Easy-to-use interface
- Can be used with objectives up to 100x, and with oil immersion
- Anywhere resync – if the microscope stage is moved too quickly and iSTIX® loses sync, simply return to any part of the panorama
- Export to common formats (JPEG, BMP, TIFF) and to WSI formats (Aperio SVS, VMscope VSF)
- Manage all WSIs in a single workspace
- Manage camera settings (exposure, white balance, gamma) for each objective
- Native support for IDS cameras and compatible with most other cameras via DirectShow

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#### CardioTEXTIL: For that added security

Cardiovascular disease often remains undiagnosed until it's too late. CardioTEXTIL is a mobile multichannel ECG comprising a special shirt with integrated electrodes and plug-in electronics. It helps prevent heart disease by detecting pathological changes to the coronary arteries at an early stage.

CardioTEXTIL records an ECG with as many as nine channels, thereby delivering medical data of the quality required to enable rapid and reliable diagnosis. It also features wireless data transfer via Bluetooth and can therefore be used for continuous monitoring of heart functions at home or as a cardiac event recorder while on the go.

Features and benefits:

- Comfortable long-term ECG without adhesive electrodes
- ECG featuring up to nine channels
- Medical-grade signal acquisition
- Storage and wireless transfer of measurement data via Bluetooth
- Easy to use

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#### DPM – The Digital Patient Manager for telemedicine applications

How can we ensure that the intersectoral infrastructure required for telemedicine meets government regulations and provides the requisite data security? And how can we guarantee that patients, despite being connected to a network, still retain control over their own data?

A solution is now on offer from the Mobile Health Lab at Fraunhofer IIS in Bamberg. The development of Digital Patient Manager (DPM), a generic telemedicine platform, has involved the creation of a decentralized infrastructure enabling data transfer between all relevant parties. This will also facilitate the introduction of new IT-based services, thereby advancing digitalization in medicine.

Features and benefits:

- Substantial cost savings through use of generic DPM software platform
- Comprehensive measurement of vital parameters via already compatible wearables
- DPM is GDPR-compliant and approvable as a Class IIa medical device
- Compatible with the gematik telematics infrastructure and other IT systems (KIS, PVS)
- Application-specific support for therapy through integration of AI-supported Digital Health Pathways
- Medical APIs can be used to create your own visualizations and apps based on DPM

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