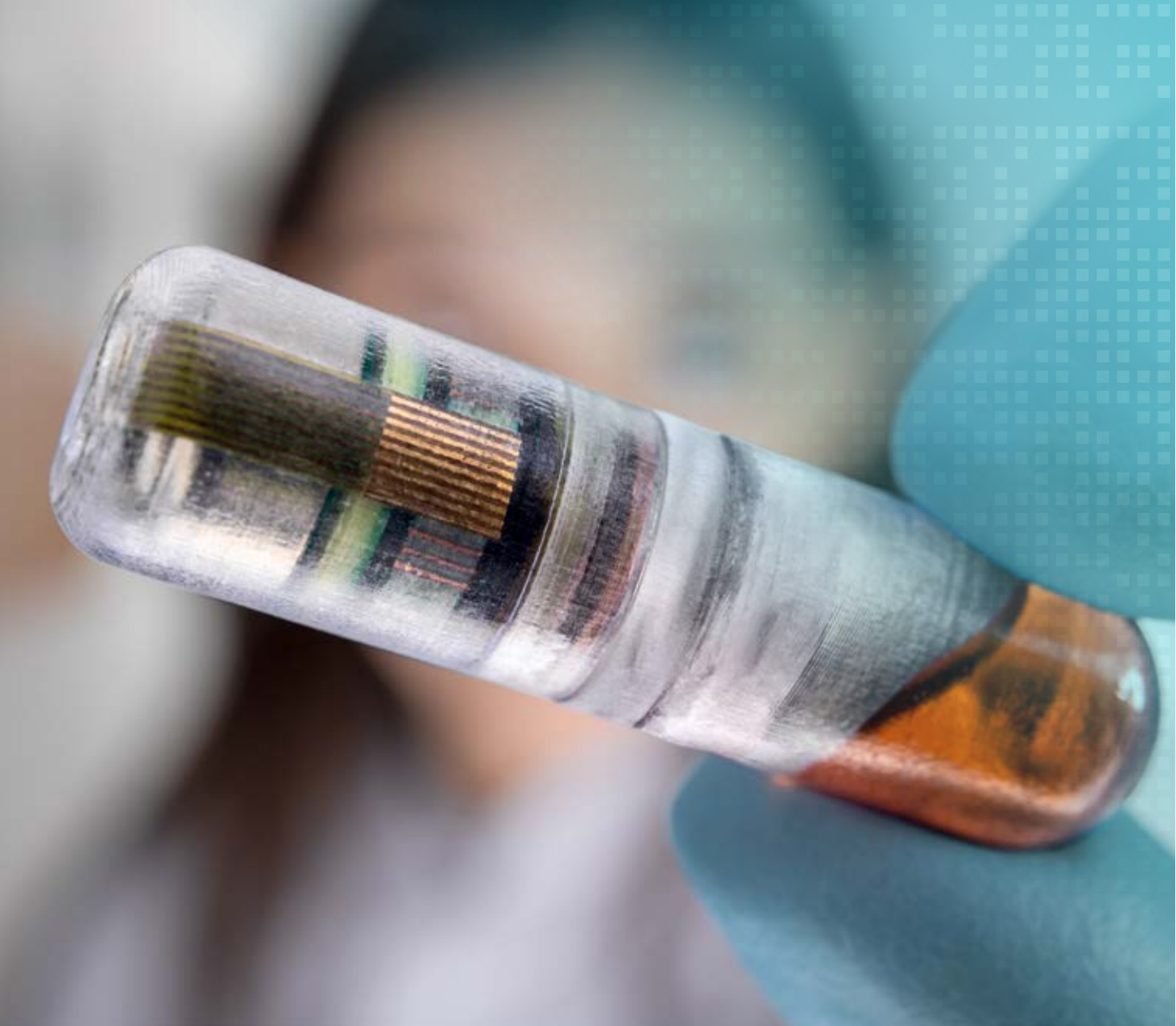


Business Unit

Medical Engineering



Medical Progress Through Microsystem Technology

Fraunhofer IZM – Your Partner in Medical Engineering

Over the past decades, microsystems technology has revolutionized medical and safety solutions, addressing critical needs across various sectors. Today's hearing aids are so small that they can be completely hidden in the ear canal. Pacemakers offer more functionality and last longer. Neural stimulators help patients get urinary incontinence under control.

Notably, miniaturized diagnostic and monitoring devices have facilitated healthcare provision for rural and remote areas, where access to medical facilities is limited. Point-of-care (PoC) diagnostics, enabled by advances in microfluidics and integrated sensors, allow rapid testing from blood, saliva, or urine samples, enabling timely interventions without the need for centralized laboratories.

Medical devices for military purposes, too, have leveraged microsystem technology, resulting in wearables designed for both vital parameter monitoring and enhanced safety/security. Military-grade wearables equipped with bio-sensors can continuously monitor vital parameters, aiding in triage and remote care in combat zones. These devices also incorporate environmental and physiological sensors, enhancing situational awareness and improving safety protocols by alerting personnel to potential hazards in real time.

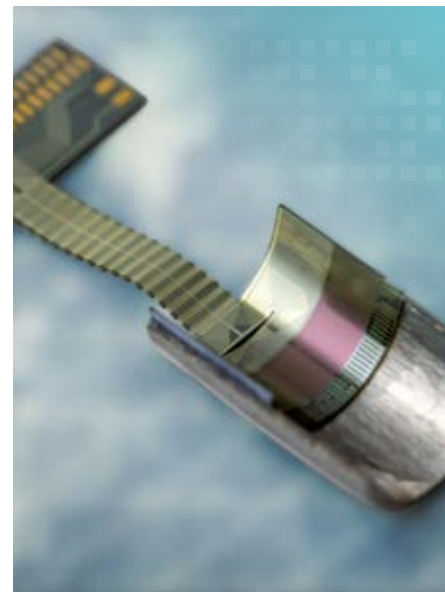
Fraunhofer IZM aims to provide comprehensive solutions for research and industry

partners seeking advanced miniaturization of microelectronic, microsensors, microfluidic, and micro-optical systems. With an extensive array of integration technologies, clients receive unbiased consultancy, rapid prototyping with high first-pass success rates, and validated manufacturing processes to expedite clinical trials and scalable production.

Our technological innovations hold significant benefits for patients, especially through customizable, biocompatible implants that can perform therapeutic or diagnostic functions while reducing the need for invasive procedures.

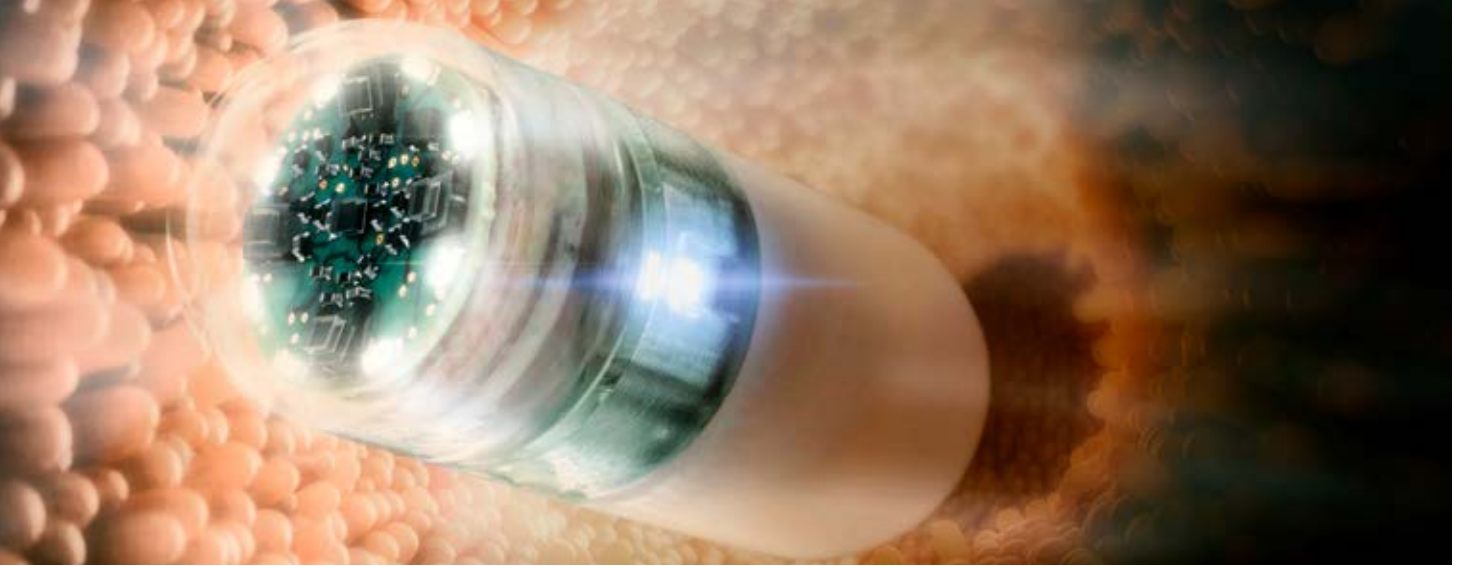
A core focus is interfacing implanted devices with biological tissue, exploring bio-inert, biocompatible, and biomimetic surfaces for clinical applications, using ISO 10933 standards from early development stages. Additionally, Fraunhofer IZM collaborates on industrial and third-party-funded projects that drive innovations in "ambient assisted living" (e.g., fall sensors for elderly care) and "personal assisted health" devices like chronic health monitoring systems.

Fraunhofer IZM regularly collaborates with industry in market-sensitive areas, ensuring rigorous IP protection, patent assistance through the Fraunhofer patent office, and maintaining strict confidentiality to maximize partners' market reach.

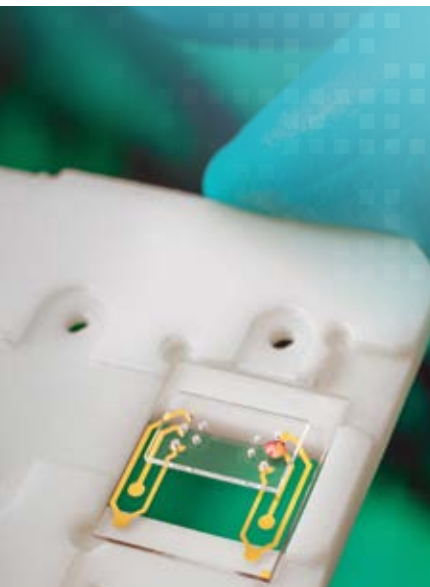


MEMS ultrasound transducer array for precise stimulation of nerve bundles

left: Demonstrator of a swallowable capsule microsystem for sensor-based drug dosing within the gastrointestinal tract



Diagnostic Systems



Hybrid chip cartridge for point-of-care tests

top: Miniaturized modular encapsulated camera for endoscopy, equipped with integrated image capture and storage, developed in the EndoTrace project

Correct diagnosis is the vital first step in medical treatment and comprises a number of processes, which are continually being advanced in terms of both technique and technology.

Point-of-care diagnostics

Fraunhofer IZM is advancing diagnostic systems with groundbreaking technology aimed at enhancing patient outcomes through precise, fast, and accessible tools. At the forefront is the microfluidic point-of-care (PoC) system, designed to provide rapid, accurate diagnostic results from samples like blood and urine, ensuring timely diagnoses at the patient's location. Fraunhofer's expertise in microfluidics has yielded highly integrated systems that unite capillary and digital microfluidics, maximizing diagnostic power in compact, user-friendly devices.

Electronic micro pills for gastrointestinal diagnostics

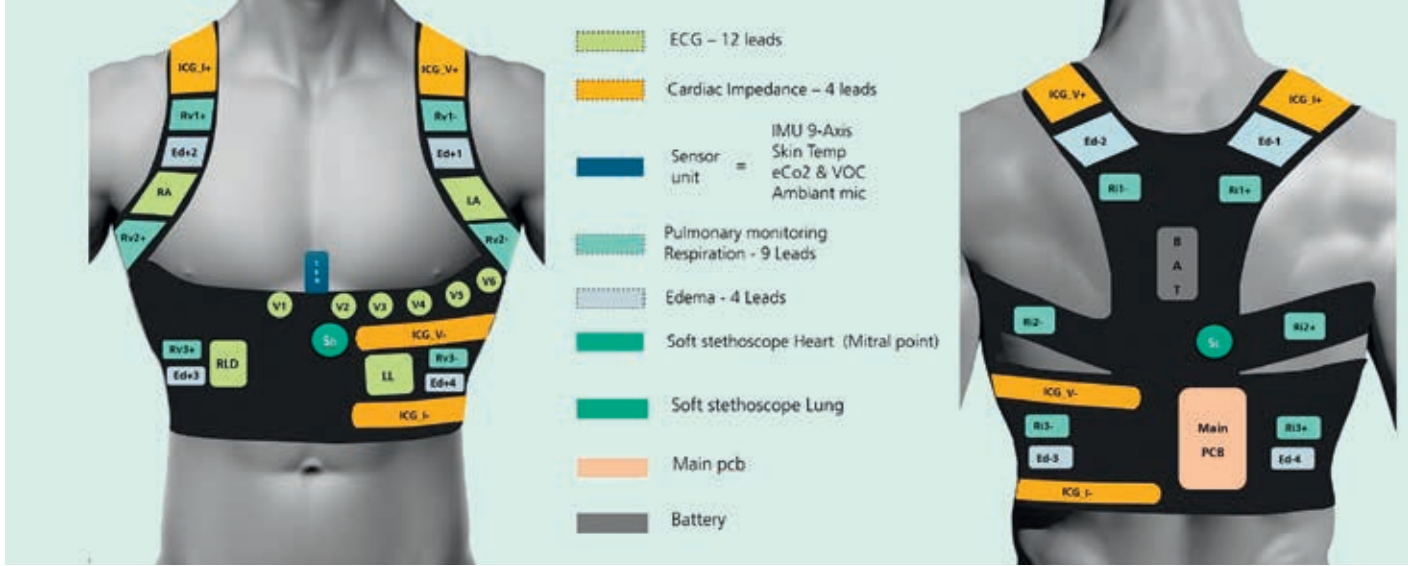
Fraunhofer IZM has developed various electronic pills for gastrointestinal diagnostics and treatment. The **EndoTrace** pill includes a multi-camera system for high-resolution imaging of the small intestine, capturing fewer, targeted images to enhance diagnostic speed. It contains high tech, crammed into the smallest of spaces. In total, there are five cameras, a tracer, an LED light, an FPGA for image compression, flash memory for image storage, a microcontroller, and three micro-batteries in a capsule measuring just 10 mm x 20 mm.

It moves through the body over the course of several hours, propelled by the natural bowel motions. The **nuEndo** capsule enables tubeless gastroscopy, using an integrated magnet for precise navigation through the GI tract, minimizing patient discomfort.

Another example of a micro pill developed by IZM researchers is the world's smallest impedance spectroscopy system, which enables precise monitoring of battery cells and other electrochemical processes in compact devices. This miniaturized technology enhances measurement accuracy and device integration, offering significant advancements for applications in energy storage, medical devices, and sensor technology by providing detailed, real-time insights into material behaviors and device health in challenging environments.

AI-enhanced smart textile system for cardio monitoring

As part of the **Maia** project, IZM scientists have developed an AI-powered wearable system for non-invasive cardiac diagnostics, focusing on early detection of cardiac issues. Using bioimpedance spectroscopy (BIS) and additional sensors like ECG and PPG, the system synchronously monitors over 110 cardiac parameters with clinical precision, thanks to collaborations with Charité Berlin. This technology is embedded into a biocompatible smart textile vest, providing continuous heart health data while ensuring comfort for



patients. Machine learning enhances diagnostic accuracy by analyzing patient-specific and clinical data for high sensitivity and specificity. This innovation represents a leap toward wearable, continuous cardiac care, offering patients more accessible, personalized cardiovascular monitoring and advancing non-invasive diagnostics.

Cardiological monitoring with a patch

Researchers from Fraunhofer IZM, along with 31 partners from industry and academia, have developed an advanced, stretchable, wireless patch for cardiac monitoring, intended to support high-risk patients in their everyday environments. This innovation is part of the EU-funded **APPLAUSE** project, aiming to strengthen Europe’s semiconductor value chain for medical technology by enhancing manufacturing techniques for such devices. The compact, plaster-like patch monitors vital metrics, including oxygen levels, chest movement, and bio-impedance, transmitting data to a monitoring app for clinical review. Unlike traditional bulky monitoring devices, this patch offers a discreet, long-term solution that integrates seamlessly with the skin.

The patch uses thermoplastic polyurethane (TPU) for comfort and flexibility, enabling the application of common PCB (printed circuit board) technologies for cost-effective production. Würth Elektronik and OSYPKA AG contributed to developing an ultra-flexible

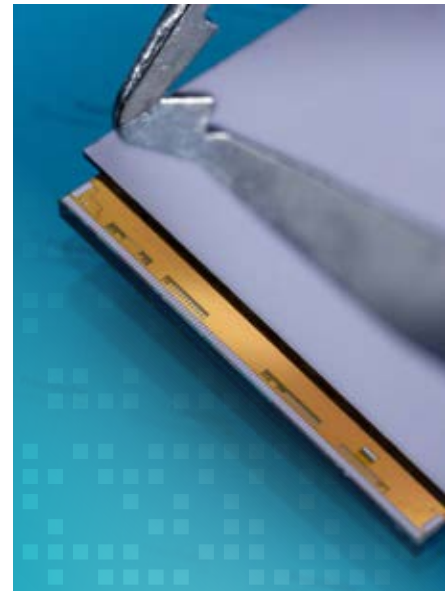
PCB, while Fraunhofer IZM integrated densely packed circuit carriers into the patch. Notably, electrodes are printed directly onto the flexible circuit, resulting in a robust, biocompatible form factor suitable for daily wear.

Radar monitoring of cardiovascular functions

Radar systems for medical applications enable non-contact measurement of parameters of the cardiovascular system using electromagnetic waves in the millimeter-wave frequency range. The millimeter-wave signal processing can be performed by low-cost semiconductors integrated by PCB technologies with planar antennas. The radar modules enable compact electronic solutions for monitoring the cardiovascular condition by nursing staff or in point-of-care applications at home.

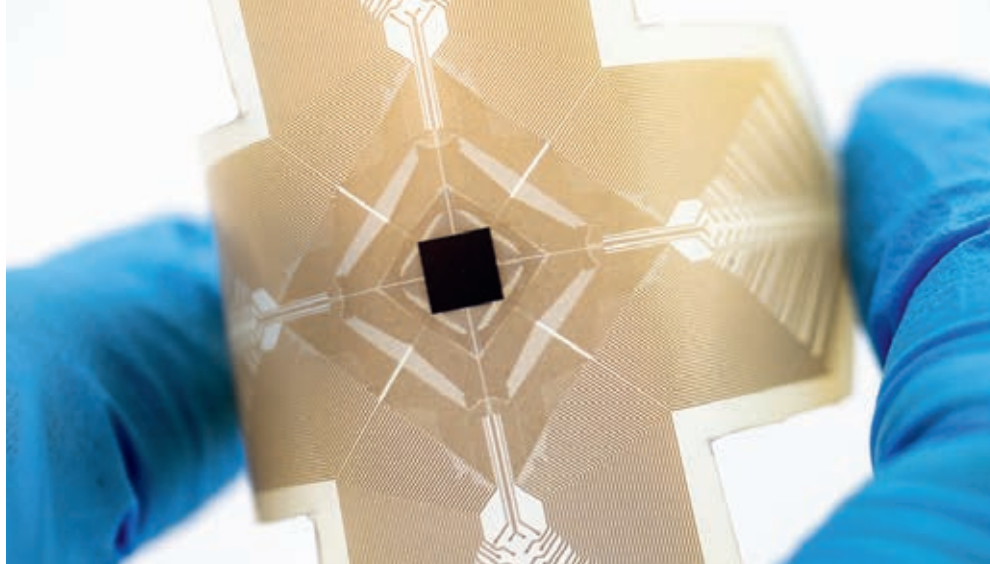
Detector packaging for medical X-ray imaging

Hybrid pixel detector modules are essential in advanced X-ray cameras, widely used in both scientific and medical imaging. These detectors, critical in synchrotron research for tasks like X-ray crystallography and biomolecular structure analysis, offer significant advantages in medical imaging, providing a broader dynamic range and higher resolution at a much lower radiation dose than traditional detectors. IZM scientists have contributed to this research by focusing on the packaging of these hybrid pixel detectors.



Hybrid X-ray detector module with CdTe sensor chip; 65kPix single chip module with pixel pitch of 55µm

top: Front and back view of AI-enhanced smart textile vest



Implants and Therapeutic Systems



Fraunhofer IZM has a long history of advancing the adoption of implanted medical devices as standard healthcare, with developments including pioneering chip-scale packages for pacemakers, implantable chemo-therapy pump control systems, assemblies for retinal implants and wireless brain computer interfaces attached directly to the cortex. The institute's expertise spans from material selection and miniaturization technology to reliability testing and risk assessment on technical and biological levels according to ISO 14971 and ISO 10993.

Fraunhofer IZM's bioelectronics advancements promise to revolutionize patient care by creating ultra-thin, biocompatible coatings that ensure long-lasting implant functionality. These innovations include neural interfaces enabling precise nerve stimulation, potentially treating blindness and other conditions while reducing side effects. The **Nerve Repack** project, for example, combines prosthetics with neural interfaces, enabling amputees to regain tactile feedback and smoother movements, greatly enhancing autonomy and life quality for patients with paralysis or limb loss.

The **NewLife** project, on the other hand, advances personalized medicine by developing biocompatible, miniaturized implants capable of continuous, real-time health monitoring. These cutting-edge sensors detect

and analyze critical biomarkers, providing early warnings for health issues and enabling timely interventions. The project aims to improve patient outcomes by allowing seamless integration of health data for proactive and precise medical care.

The institute collaborates with leading companies and research institutes in Europe and overseas on such projects. One example is the Neuralace™ project where IZM researcher together with the US American company Blackrock Neurotech work on next-generation neural interfaces.

Improving drug therapy with the e-pill

The **e-Pille** research project, conducted by Fraunhofer Institutes ITMP, EMFT and IZM, aims to miniaturize and enhance electronic capsules for precise drug dosing. This modular capsule releases medication in targeted GI tract areas, offering an alternative to intubation. The "research pill" focuses on precise dosing in studies, featuring separate fluid and electronic sections, while the "pharma pill" is designed for patient use, optimized for daily dosing. Sustainability concerns, such as lifecycle analysis and waste impact, are also central, with completion expected by late 2024.

A flexible active microsystem for recording and stimulation of neural tissue



Fraunhofer IZM Services

Fraunhofer IZM develops and provides the following services for bio- and biomedical devices:

- Packaging technology and reliability analysis for miniaturized medical devices and implants
- Lab-on-substrate technologies for patient-friendly laboratory diagnostics
- Improved functionality of neural interfaces and intelligent prostheses
- Flip chip assembly processes for small to large volume fabrication processes
- Thin chip assembly on ultrathin flexible and stretchable materials
- Integration of electronic modules and sensors in / on textiles
- Opto-electro-mechanical systems integration targeting medical devices
- Sensor integrated microfluidics for point-of-care diagnostic devices
- Biohermetic encapsulation for ISO 10993 compatibility
- Technology support from your medical device idea to the product implementation, reliability evaluation and prediction for medical risk assessment
- Wireless transmission concepts for secure medical data
- Energy scavenging technology for prolonged autonomous operation
- Lifetime modeling and failure assessment
- RoHS, WEEE, EuP / ErP and REACH consultancy

Start-A-Factory offers aspiring start-ups and forward-thinking small to medium-sized enterprises unparalleled access to the advanced facilities and the invaluable network of Fraunhofer IZM researchers and cooperation partners to turn their ideas into professional working prototypes in record time.

All of this is made possible with an uncompromising commitment to inclusion and participation for your developer team: Every solution is a unique and custom result, and 100 % of the intellectual property remains with the developers.

Start-A-Factory brings together research and development professionals with motivated support and cooperation partners – to give projects the best possible conditions for a successful outcome.

We can support medical technology innovators with

- Risk assessments
- Certification acc. to ISO 13485 (general) and
- ISO 14971 (medical device risk management)

Want to know more? Then visit us at www.start-a-factory.com or contact us directly.



START:FACTORY



Cover: ECG patch with sensors, electronics and battery that can easily be stuck on the upper body



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