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Bavarian Ministry of Economic Affairs
and Media, Energy and Technology

Editorial

Development and trends reflected by the times

A population rapidly growing worldwide demands new „medical technologies“ solutions using efficient and sustainable healthcare.

Devices for environmental monitoring developed by industry stand in the focus of diagnostics for laboratory applications as well as in the medical field of cancer detection and support with therapies for tumours, diabetes and asthma.

With help and advice, experts from various areas stand by your side when it comes to troubleshooting, among other things:

- Wherein lies the success of the „Medical Valley“ in the Nuremberg Metropolitan Region?
- What focus is emphasized by the digitalisation in the medical sector?
- How can a lengthy, risky and expensive process for the market approval of medical devices be overcome?
- Where can a perfect imaging support safe and effective surgical action?
- Which competency in new developments and system adjustments in laboratory and hospital construction is essential?
- Can sensor technologies contribute to a mobile and comfortable training analysis?
- What potential developments are offered by new visualisation methods in surgery?
- Who does METEAN - the Medical Test and Demonstration Centre help?

In the particular case:
At this point, I would like to thank especially for his commitment, Dr Siegfried Balleis who wrote the forward for our publication from 1999 to 2013.

Walter Fürst, Managing Director

You can also find this publication on the Internet at www.media-mind.info

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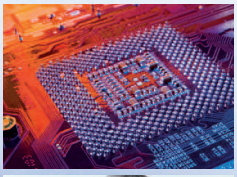





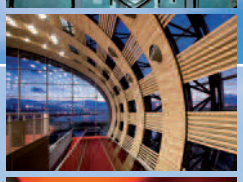
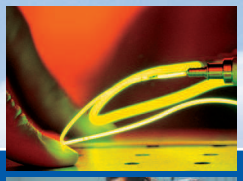


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Foreword

Global trends stimulate market growth and determine the opportunities within the medtec industry. Due to the demographic trend we can expect that almost 50% more people will be living on this planet by 2050. At the same time life expectancy is rising, resulting in an increase of illnesses. This is leading to a higher need for prevention, diagnostics, therapy and rehabilitation in healthcare. Innovative medical technology and services are required in order to enhance the effectivity and efficiency of healthcare for the benefit of the patients, while simultaneously, keeping healthcare systems affordable worldwide.

Already today in Bavaria, innovative solutions are being developed and globally commercialized in close cooperation between stakeholders in science, politics, healthcare and industry. Successful dialogue platforms such as the National Cluster of Excellence of Medical Technology earned by Medical Valley in the European Metropolitan Region of Nurnberg, strengthen the innovative and economic potential of the medtec companies located in Bavaria. This is done by supporting the dialogue of engineers, computer scientists, physicists, biologists and other medical engineering experts with physicians, health economists and nursing scientists. It also generates a creative and business-orientated environment within healthcare, it increases the global market shares of Bavarian companies, it catalyzes start-ups, and it creates and secures jobs.

Prof. Dr.-Ing. Erich R. Reinhardt

Chairman of the
Medical Valley EMN Association Board

Leading Cluster Medical Valley EMN

The Medical Valley European Metropolitan Region (EMN) is an internationally leading cluster in the field of medical technology. Here highly specialised research institutions, leading international companies and at the same time many growing firms are at work here. They cooperate closely with institutions known throughout the world in health research in the cluster seeking to find joint solutions for the healthcare challenges of today and tomorrow. This extraordinary concentration of players, in combination with the international market and competitive positions of the individual players, offers conditions that make it possible to develop products, processes and services from ideas faster. How outstanding this cluster is was emphasised in January 2010 when it was named the top national cluster by the Federal Ministry of Education and Research (BMBF).

Medical Valley – An ideal eco-system for developing medical devices

In the Medical Valley, science and business find optimum research and development conditions available and benefit from the growing expertise and international competency in developing and marketing medical technology devices. From the research labs of the top cluster, in the last few years alone, numerous significant product innovations have come onto the market. For instance, Siemens Healthcare developed the first medical whole-body scanner, magnetic resonance tomography (MRT) and positron emission tomography (PET) combined in one system. Thanks to it, the position of organs in the body, their function as well as cell metabolism can all be recorded at the same time. This procedure opens up new possibilities for diagnosis and therapy of diseases like cancer and dementia. Germany-wide, Medical Valley EMN has already taken up a top position in patent applications in the fields of diagnostics, surgery and identification.

In Medical Valley world's leading diagnostic imaging systems are developed and produced ■

As a cluster management organisation, since 2007 Medical Valley EMN.V., an association currently functions with 160 members from business, science, healthcare, networks and politics. The central tasks of cluster management are further development, coordination and marketing of the cluster. Concrete selected activities of Medical Valley are current global coordination of the BMBF top cluster (45 R&D projects with a total project volume of more than € 80 million), management of the „Model Region for Digital Health Business in Franconia“ (over € 8 million in its total project volume with a focus on „Optimisation of the Medication Process" and subsidised by the

Smart sensors support diagnosis and therapy ■

Bavarian Ministry of the Economy), management of the ZIM cooperation network „InnoPlan.NET“ (currently 12 companies and three research institutions: focus is on implants, transplants and bone replacement materials“) and another project supported by the Bavarian Ministry of the Economy, „Science2Market.“ In addition, there is MVEMN, consortial partners of InnoLIFE, a high-powered European consortium currently competing in connection with Horizon2020 for the knowledge and innovation community „Healthy Living & Active Ageing.“

With the activities of the last five years, Medical Valley has provided proof of being able to accelerate commercialisation of ideas through management of R&D allocations. Merely in connection with the top cluster, healthcare economic estimates of R&D projects show that the potential for savings of some estimated projects annually comes to a total of € 7.5 billion for all of Germany. In addition, gross sales potential of the products and services developed have already reached an estimated € 700 million. From the top cluster projects alone, more than 110 patent and invention applications have been filed and over 220 publications have been published.

Innovative technologies for health promotion and prevention ■

As a service, Medical Valley operates Medical Valley Centre Erlangen, one of the most successful German innovation and startup centres focused on medical technology, currently with 35 startup and growth companies and with a stake in setting up an additional medical valley centre in Forchheim by 2016. In connection with operating Medical Valley Centre Erlangen, young entrepreneurs are supported in obtaining capital (public or private capital) and in setting up distribution and marketing structures. In Medical Valley Centre Erlangen alone, in recent years 600 jobs have been created (direct jobs without secondary effects). Other services of MVEMN include subsidy counselling and recruitment, opportunities for networking (events, workshops, advance training, communities of practice) and marketing support (inbound and outbound). ■

Contact the Cluster

In the Medical Valley EMN Top Cluster, research institutions, internationally renowned companies as well as healthcare providers in the field of medical technology are setting standards worldwide. ■

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Europäische Metropolregion Nürnberg

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Digitization in Medicine: High Tech Trends at the International Congress „Medizin Innovativ – MedTech Pharma 2014“

“Digital Health“ in its various facets and application fields was a priority theme of the “Medizin Innovativ – MedTech Pharma 2014“ congress, held from July 2-3 at the congress and fair center in Nuremberg. With 900 participants, the congress has become one of the most important meeting points for the health sector in recent years.

Medicine and innovation – these terms are inseparably linked. In each phase of the history of medicine, the continuous expansion of medical knowledge and the development of technical solutions have played a central role. From the very beginning, medicine has been characterised by a high level of interdisciplinarity. In recent years, a comparatively new discipline has evolved as the main driver of innovation in medicine: the opportunities of information technology have triggered a trend towards digitization in all areas of the healthcare industry, the highlight of which is yet to come.

At the plenary session Professor Christoph Thuemmler, Institute for Informatics and Digital Innovation, Edinburgh Napier University, showed that the recent developments of IT are much broader and fundamental than some years ago.

Innovations that will be possible are not limited to technical solutions such as the evaluation of complex image data, tools for hospital logistics or navigation aids for surgery. Instead, it is about creating completely new solutions for efficient health care, realized by the IT progress.

100 exhibitors presented innovative technologies and products: Skeleton Edgar belongs to the “Peter Brehm” company and cycles with Titanium-joints ■

Key-Note-Speaker Prof. Christoph Thuemmler, Institute for Informatics and Digital Innovation der Edinburgh Napier University, gives an outlook on the digital future of medicine ■

Dr. Thomas Feigl, business unit manager "Health" at Bayern Innovativ GmbH and CEO of Forum MedTech Pharma, states that three aspects are relevant for the influence of IT to the health sector: patients want to be informed about health-relevant themes via digital devices. Therefore the self-determined handling with the own health status is important and leads to new concepts for prevention and care.

Another aspect is the rapid advancement of human-machine interfaces. Health-service providers can use the already existing interfaces and sensors from smartphones or tablets. The third aspect is the possibility to process large amounts of data: "Big Data" is used to compile and evaluate study results, registration data or genomic analysis as well as to find important/relevant findings for the optimization and personalization of therapeutic approaches/ treatments.

Combining a series of lectures on scientific-technical and operational market-related topics with a large exhibition with over 100 exhibitors, the congress provided ideal conditions to connect participants from various disciplines. The variety of participants from company representatives to scientists and clinical users has been a unique feature from the beginning of the congress. The two intensive and highly efficient days of "Medizin Innovativ" gave international participants the opportunity to acquire new knowledge and expand their contact network, giving them a competitive edge in the global market.

Networking at its best: state reception at the Imperial Castle Nuremberg ■

The congress was supported by the Bavarian Ministry of Economic Affairs and Media, Energy and Technology. As in previous years, the BMBF (Federal Ministry of Education and Research) Symposium "Medi-WING – Nano & Materials Research" was included in the congress agenda. ■

Further information:
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Medical Valley: Success in the European Metropolitan Region of Nuremberg and far beyond

The city of Erlangen and the European Metropolitan Region of Nuremberg (EMN) have a strong association with medical technology. The EMN's strategic development statement identifies "medicine and health", a technologically significant area of expertise and growth, as particularly capable of development. There was early recognition that healthcare services were under greater demand thanks to the population's increasing awareness of health issues, and that an aging population would mean a significant increase in the incidence of certain illnesses. The resulting challenges for healthcare provision, care management, medicine research and pharmacy have spawned new treatment methods, medicines and diagnostic procedures. New markets, an increasing secondary health market[1] and an export boom are just some of the positive aspects.

Medical Valley Start-up and Innovation Centre in Erlangen, in the heart of the EMN ■

Nevertheless, competition in the health market means that the pressure on companies is high. Increasingly, regions have to compete with each other for the qualified workforce. The regional economy and academia have the chance to position themselves in these spheres of activity. They are already taking advantage of this opportunity, using innovations to make healthcare provision more effective and efficient while offering dedicated people an interesting working environment.

Gait analysis of a patient with Parkinson's Disease using the Egait System. This is being developed and evaluated by the company Astrum in cooperation with the Department for Pattern Recognition (LME) at the FAU Erlangen-Nuremberg and the Department for Molecular Neurology at the Erlangen University Clinic. 3-D imaging in medicine at the Central Institute for Medical Technology (ZIMT) and the FAU Erlangen-Nuremberg ■

In the EMN Medical Valley, more than 500 businesses with over 45,000 employees are directly or indirectly active in the health economy.[2] In the catchment area for tertiary institutions, and in particular the Friedrich Alexander University (FAU) Erlangen-Nuremberg, there are currently 60 departments with a focus on medical technology, 20 non-university research institutions, 40 clinics and

In the BMBF's Medical Valley Leading-Edge Cluster Project "Imaging and external magnetic field for local tumor therapy with magnetic nanoparticles", the target area is depicted angiographically in 3-D. This is necessary to find the correct artery for access to the tumor, and to position the magnetic field in such a way that the nanoparticles can be efficiently concentrated.
Under the leadership of Professor Christoph Alexiou, the Section for Experimental Oncology and Nanomedicine (SEON) at the Erlangen HNO Clinic works together with the Central Institute for Medical Technology at the FAU in Erlangen to ensure existing "Magnetic Drug Targeting" technology is effectively transferred from the pre-clinical to the clinical phase ■

over 180 businesses that are enjoying economic success in medical technology. This abundance of expertise is the secret for the region's success. The region's excellent, internationally competitive credentials in medical technology's key areas are the foundation for this: electronics and microsystem technology, information and communication technology, optical technology and new materials. This extraordinary concentration of expertise in a small area, as well as the competitiveness and strength of certain players on the international market, offers optimal conditions for businesses to quickly turn initial ideas into products, processes and services. The cluster's excellence was highlighted in January 2010, when it was named Leading-Edge Cluster "Medical technology" by the Federal Ministry of Education and Research (BMBF).

"Medicine and Healthcare" has been an inherent part of the strategic regional development propagated by decision makers from the economy and politics since 1998. This area of expertise has been assigned huge importance as part of the development statement produced by the European Metropolitan Region of Nuremberg under the direction of the Nuremberg Chamber of Commerce and Industry (CCI). It seeks to emphasise the development of the field of medical technology and health in the local economy and academia, and to use the potential of new technologies to increase the efficiency of the health system. The varied initiatives of regional players and the support of the Bavarian state government led to the completion in 2003 of a start-up centre,

Edgar, a skeleton showing the various applications of titanium implants.
The Peter Brehm company in Weisendorf near Erlangen develops bio-compatible titanium implants, such as artificial hip joints, knee joints, vertebrae, knee replacements, etc. ■

the "Innovation Centre for Medical Technology and Pharmaceuticals" – in the direct vicinity of university medical research facilities, what is now the Medical Valley Center in Erlangen. It is one of the most successful start-up centres in Germany, with over 40 companies and up to 250 newly-created jobs. The Nuremberg Chamber of Commerce and Industry is a founding member and has remained a shareholder of the operating company to this day. The Chamber is also represented on the supervisory board of the Medical Valley Center and has been chair for years. It was in this context that the Medical Valley EMN e.V. was founded in 2007 to draw these activities together. This was preceded by the longstanding activities of the "Medicine | Pharmacy | Health Expertise Intiative", an initiative and promoter network. The society has since become an integral part of the EMN's overriding development strategy, and the Nuremberg CCI has been influential on the executive board since the society's founding.

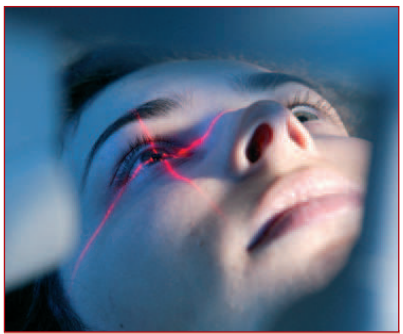
The CCI also supports technology transfer and networking with its own advice services and offerings, such as the "Medicine and Healthcare" CCI users' club. The Nuremberg CCI is currently promoting the development initiative for a systematic operational health management (BGM), to which numerous regional pilot companies are contributing. The CCI also represents the interests of the regional health economy at a federal level on the "Health Economy" committee of the Association of German Chambers of Industry and Commerce.

The Medical Valley EMN e.V. currently offers support at all levels of medicinal product development, including subsidy advice, networking, events, marketing activities, training and further training. It is through this dedication that the prerequisite for taking part in the

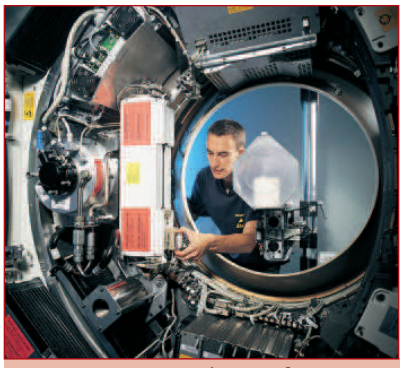
BMBF's Leading-Edge Cluster Competition could be fulfilled. The Medical Valley EMN Association was named National Leading-Edge Cluster, with the claim of "Centre of Excellence for Medical Technology", in 2010. The "Medical Technology" Leading-Edge Cluster is the culmination of expertise that has grown over the years regarding healthcare provision, medicine and medical technology. The members of Medical Valley EMN e.V. are representative of how innovative medicine and healthcare are in our region. Patent applications are indicative of this. The current CCI report "Patents in Bavaria 2014" credits the EMN with around 30 percent of all patents in Germany in the areas of "diagnostics", "surgery" and "X-ray technology". ■

Solutions for optimal and efficient healthcare from the Medical Valley EMN

Innovative medical technology is firmly rooted in our region. The interdisciplinary technologies of mechatronics, microsystem technology, optics, photonics, nanotechnology and biotechnology, concentrated in the EMN, contribute scientific know-how to medical technology. Biomedicine and bioinformatics in the Würzburg area provide the necessary supplements to interdisciplinary research and product development in the functional imaging, biomarkers and biomaterials sector. The functional textiles and nutrition sectors in Upper Franconia also provide developments. The result is a dense, extremely productive "Medical Technology Cluster" that spreads out far beyond the region and whose product portfolio and efficiency is unique within Germany. The partners of the Medical Valley EMN are also international leaders in the following important medical technology product categories: computer tomography; magnetic resonance tomography; interventional imaging (imaging diagnostics); refractive laser surgery; lithotripsy; endoscopy (therapy systems); sensor technology; medicinal information systems; home care; telerehabilitation; monitoring (telemedicine); pacemakers and revision implants (high-tech implants).



Treating a patient's cornea using a medical laser produced by WaveLight Laser Technology AG from Erlangen. Computer-controlled removal of corneal tissue ensures the highest level of precision. Uses for refractive laser surgery include improving vision (improving the eye's imaging ability) ■



Siemens AG, x-ray tube unit for computer tomography and angiography. Each unit is tested in a Siemens computer tomograph before it leaves the technology centre ■

The network of players in research, production and service provision strengthens and accelerates the development and implementation of new products and procedures in the healthcare sector. Yet start-up centres, such as the Innovation and Start-Up Centre (IGZ) and the Medical Valley Center, are also important points of call for start-ups, small and medium-sized businesses and academia.

But small and medium-sized businesses also provide highly innovative products: **Peter Brehm GmbH**, founded in 1981, manufactures titanium implants – hip, knee and spinal implants, jaw joints – while the instruments for inserting implants into the human body are also integral to the company's product portfolio. Professor Max Schaldach pioneered the first pacemaker in 1963. That provided the basis for numerous innovative developments in cardiovascular medical technology. Nowadays patients with active heart implants worldwide can be monitored with the Biotronik Home Monitoring System, an Internet-based solution for remote monitoring of patients with cardiac arrhythmia. **Corscience GmbH & Co. KG** in Erlangen is a leading medical technology company that specialises in research, development and manufacture of innovative technologies and products related to cardiovascular therapy and diagnosis. It uses electronic components in its automatic external defibrillators. Other companies include **Wavelight GmbH** (development and production of modern diagnostic and operations technology for correcting defective vision), **Sepp.med GmbH** (IT solutions with integrated quality assurance for complex safety applications), **ASTRUM IT GmbH** (software for the healthcare and medical technology sectors), **BioGate AG** (anti-microbial products), **PAUSCH Medical GmbH** (x-ray accessories).

These, as well as numerous other companies, provide the health market with innovative products. Last but not least, as the world's biggest provider of electromedical devices, systems and equipment, Siemens Healthcare is a driving force in the region.

These companies further benefit from the research activities of R&D departments at universities – in particular, the FAU Erlangen-Nuremberg, the Fraunhofer Institute for Integrated Circuits (IIS) and the Fraunhofer Institute for Integrated Systems and Device Technology (IISB), as well as the

Using an automatic defibrillator during an emergency situation in an open-plan office. Presentation by Corscience GmbH (defibrillator manufacturer in Erlangen) ■

Max Planck Insitute for the Science of Light. These and other institutions, such as the Diakonie Neuendettelsau, rehabilitation clinics, Rummelsberger institutions and other private clinics, not only contribute to the highest level of medical provision, but also create and test the ideas for new developments. With the Medical Valley's innovative technologies and services, the image of healthcare provision can be changed. If the new products and services can be successfully integrated into the existing healthcare system, new standards can be set for efficient healthcare provision – on an international level. ■

Skilled workers for the healthcare economy

Qualified young professionals are vital for the success of medical and healthcare players. The FAU and two universities for applied sciences offer degree courses in medical technology. The medical technology course at the FAU is coordinated by the Central Institute for Medical Technology (ZIMT).

The ZIMT acts as the interface between the Faculties of Engineering, Science and Medicine. Other highly specialised courses at the FAU include the Master of Health Business Administration and Integrated Life Science. The successful Medical Process Management course, created by the Faculty of Medicine, is the only one of its kind in Germany

Other programmes leading to careers in the healthcare economy, from chemical laboratory assistant, surgery mechanic, optometrist and hearing aid technician to nurse, are offered as professional training courses. Chambers in the EMN accompany and support businesses in training their employees; the publication "Health Career" is exemplary in this regard.

The region is positioned excellently to achieve its strategic goals for the future. These are: recognition worldwide as a point of reference for the medicine and healthcare sector; securing and expanding the international competitiveness of medical technology companies; accelerating knowledge and technology transfer to the greatest extent possible and increasing the attractiveness of the EMN to skilled workers. In the long term and with the support of the Nuremberg Chamber of Commerce and Industry, the EMN will become a model region for efficient and optimal healthcare provision. ■

1) The secondary healthcare market includes: non-refundable preventative services or disbursements for cures; non-prescription medicines; additional (private) insurance; so-called self-funded individual healthcare services offered by established doctors; expenses for health-conscious nutrition; fitness and wellbeing services; healthcare tourism; aesthetic medicine; advice and education, etc.

2) The healthcare economy is defined as the sum of all services and products for maintaining and regaining good health. The following sectors are affected: care for in-patients and out-patients; healthcare institutions; health insurance companies; pharmacies; the pharmaceutical industry; tourism; habitation; sport and leisure; nutrition.

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Health region Mainfranken

Gesundheitsregion mainfranken

The different segments of the health economy are highly potent growth markets that will decisively characterise our future. A whole palette of first-class players and optimal framework conditions form the basis for successful innovations from Mainfranken.

In recent years Mainfranken has developed especially dynamically in the key technologies of biotechnology and medical technology. The excellent academic environment, the proximity to the university, higher education institutes and university clinics, many successful traditional companies and innovative start-ups are the basis for this success.

In the Bavarian spa region Rhön – which, as well as Germany's most famous spa location, Bad Kissingen, contains four other traditional spas – the latest therapy, spa and rehabilitation procedures are conducted. ■

Region Mainfranken GmbH/Hub ■

Region Mainfranken GmbH/Hub ■

Top biomedicine research

The core of the university research is formed by the faculties of medicine, biology, physics and chemistry and pharmacy at the prestigious *University of Würzburg*. 25 institutes and research centres conduct research in the medical and human-biological field as well as in eight special research areas, for example the Biocentre, an interdisciplinary centre made up of 14 university chairs.

The Rudolf-Virchow Centre for Experimental Biomedicine, the DFG

Franken Tourismus/Bad Königshofen/Hub ■

Research Centre, do top-class research in the field of key proteins.

Fraunhofer ISC, Life Science division, does research and development particularly in the future fields „Biohybrid Materials“ as well as „Individualised Diagnosis“ and boasts many years of excellent experience in the dental materials field.

The *University of Applied Sciences Würzburg-Schweinfurt* enhances the regional competencies with application-related courses and research projects in the field of medical technology. ■

World-leading medical technology

Mainfranken is home to many innovative companies with world-leading medical technology. Regional strengths lie in the fields of dialysis technology, lung function diagnosis and magnetic resonance technology:

Fresenius Medical Care, Schweinfurt: Central production location for dialysis devices; CareFusion, Höchberg; *Ganshorn Medizin Electronic*, Niederlauer and *ZAN Messgeräte*, Oberthulba: Lung function/cardio-respiratory diagnosis; *SKF Linearsysteme*, Schweinfurt: Roller bearings, components and systems for medical technology; *Rapid Biomedical*, Rimpar: High-frequency coils for MR imaging. ■

Health region faces up to the competition

Under the leadership of Prof. Dr. Christoph Reiners, medical director of the University Clinic of Würzburg, and District Administrator Thomas Bold, a regional specialist forum founded at the end of 2011 is pursuing the objective of actively and positively shaping developments in the Mainfranken health economy through a strategy applying to the whole region. In this, the focus currently is on the implementation of medical care projects in the regional area, the use of telemedicine, the development of offerings for operational health management and the networking of education and training offerings.

In addition, Mainfranken offers a versatile and attractive range of relocation opportunities – depending on size, aim and medical focus.

Locally, there are state-of-the-art *Founder and Innovation Centres* available, specially designed for the needs of those starting up medical and biotech companies:

IGZ Würzburg

The innovation and founder centre for biotechnology and biomedicine offers fully fitted laboratories, technical facilities and proximity to the University of Würzburg.

RSG in Bad Kissingen

Alongside ideal office and laboratory space, the Rhön-Saale Gründerzentrum offers a versatile training program in the health

business field. Other relocation options offer *high-quality commercial land and business parks* in the best locations with optimal price-performance ratios. ■

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Funding for European Research and Innovation Projects in Medical Technology

Bavarian stakeholders active in the medical technology segment have a wide variety of options available to them for receiving funds for European and international research, development and innovation projects. However, the options offered as part of the new European Horizon 2020 Framework Programme for Research and Innovation differ considerably from those available in other EU programmes such as EUREKA Eurostars and EuroTransBio or the nationally funded IraSME programme. The respective calls for proposals involving research and innovation projects are either bottom-up (topic open) or top-down (topic set in advance by experts). In this context, the Bavarian Research Alliance (BayFOR) offers its support to ensure that scientists, researchers and companies can successfully acquire these funds. BayFOR helps identify the appropriate funding instrument and assists applicants throughout the entire application phase and project implementation. ■

Advances in imaging methods are one of the EU's key focused topics (Picture: © iStock) ■

Horizon 2020: Wide Variety of Opportunities for Bavaria's Medical Technology Segment

Horizon 2020, the new European Framework Programme for Research and Innovation, was launched on January 1, 2014. The successor to the 7th Framework Programme (FP7) aims to provide about EUR 80 billion to further research and innovation over a seven-year period (2014-2020). Horizon 2020 covers the entire innovation chain from the advancement of fundamental research up to market launch. The idea is to focus on implementing excellent research results and promptly translating them into marketable innovations, thus bolstering Europe's competitive edge and safeguarding jobs.

The framework programme is based on three pillars: The first pillar promotes excellence in sciences, the second pillar reinforces Europe's industrial leadership to overcome the major societal challenges cited under the third pillar.

Companies are also encouraged in addition to universities, colleges and research institutes to submit their innovative project ideas. In Horizon 2020, particular attention is placed on small to medium-sized enterprises (SMEs), since the EU Commission regards SMEs as an innovation driver. Consequently, a certain percentage of SME participation is in many calls for proposals a prerequisite for funding. Universities of applied sciences, which frequently maintain close contact with industry, can also benefit from this requirement. Moreover, Horizon 2020 has new funding quotas for all types of organisations: Research-based projects are funded by up to 100%, while market-related projects are funded by up to 70%. ■

Current Calls for Proposals for the Medical Technology Segment within Horizon 2020

Horizon 2020 offers the medical technology segment a wide variety of funding options, which are mainly anchored in pillars two and three. The societal challenge **„Health, demographic change and wellbeing“** in pillar three features calls for proposals focusing on the medical technology segment. Here attention is placed on translational research, i.e. taking results from fundamental research and translating them into clinical applications as well as development and validation of new therapies, procedures for promoting good health and prevention, diagnostic instruments and technologies.

For the main topic **„Personalizing health and care – PHC“**, a total amount of EUR 550 million is available in 2014. EUR 537 million have been allotted for 2015. This programme offers Bavarian medical technology experts some very interesting opportunities to participate in successful European projects and to bring their expertise into existing consortia.

Moreover, the second pillar (industrial leadership) focuses on medical technology topics in areas such as **„information and communications technologies“, „nanotechnologies, advanced materials, advanced manufacturing and processing as well as biotechnology“** (see box for list of current relevant calls for proposals). ■

Horizon 2020: A selection of current, relevant calls

Societal Challenge “Health, Demographic change and Wellbeing“
“Advanced ICT systems and services for Integrated Care” - PHC 25 – 2015
Deadline: 21/04/2015
Total budget: Euro 20 million

Industrial Leadership
Information and Communication Technologies (ICT)
“Robotics“ - ICT 24 – 2015
Deadline: 14/04/2015
Total budget: Euro 80 million

Nanotechnologies, Advanced Materials, Advanced Manufacturing and Processing, and Biotechnology
“Nanomedicine therapy for cancer” - NMP 11 – 2015
Deadline: 26/03/2015
Total budget: Euro 35 million

“Biomaterials for treatment and prevention of Alzheimer‘s disease” - NMP 12 – 2015
Deadline: 26/03/2015
Total budget: Euro 50 million

Finding Partners for Joint Research Projects

BayFOR works with Bavarian stakeholders, helping them look for suitable project partners in Germany and abroad. By leveraging its large international network of competent partners from science and industry, it is able to identify potential project partners active in the relevant field of research and thus support the establishment of a competitive consortium. As a partner in the Enterprise Europe Network (EEN), BayFOR also provides targeted advisory services for SMEs that are interested in participating in EU projects or want to cooperate with other SMEs on a transnational level.

Info days and brokerage events offer another opportunity for identifying appropriate projects or project partners. During these events, participants are able to present their project concepts or the expertise that they are able to contribute to a consortium. **Information about current specialist events can be found at:** http://ec.europa.eu/research/events. BayFOR regularly participates in such events in order to look for suitable international project partners for already existing consortia. ■

SME-relevant, Open-topic Funding Programmes

The “SME Instrument” offered under Horizon 2020 is an interesting EU funding instrument for small to medium-sized enterprises. It focuses on market-oriented projects from research and demonstration through to commercialization and is aimed at SMEs that are interested in conducting research either jointly or individually. There are several cut-off dates for this instrument over the course of the year. A current call for proposals from this segment is **„PHC-12-2014-1: Clinical research for the validation of biomarkers and/or diagnostic medical devices“** (cut-off date: 12/17/2014).

Outside of Horizon 2020, a wide variety of bottom-up funding options for SMEs do exist.

eurostars™

EUREKA Eurostars supports research-intensive SMEs that develop innovative products and promotes transnational initiatives. Cut-off dates here are in March and September. The **EuroTransBio** Initiative offers open-topic calls for proposals for select transnational R&D projects in order to support industry-related and applied biotechnology research between academia and SMEs. Through this initiative, the EU strives to better coordinate, network and bring together the technological strengths

and financial resources of participating companies in Europe.
Besides the described EU support instruments, the **IraSME** funding programme is also interesting for the medical technology segment. It promotes transnational RDI projects as well as technology transfer projects that focus on strengthening the cooperation between SMEs from member states Belgium, Germany, France (Nord-Pas-de-Calais region), Austria, Czech Republic and Russia. Universities from these countries are also entitled to participate under certain conditions. Each state participating finances its own national partners. IraSME is for example funded by Germany's Federal Ministry of Economic Affairs and Energy with the Central Innovation Programme (ZIM). Cut-off dates here are always in March and September. ■

Ways to a successful EU project

The large variety of available funding opportunities may confront potential applicants with a complex task as identifying a suitable funding programme and writing a successful proposal requires profound expertise. In this regard, the Bavarian Research Alliance (BayFOR), which is being funded by the Bavarian State Ministry of Education, Science and the Arts, can provide extensive assistance to Bavarian stakeholders. BayFOR provides information about different funding programmes and supports the initial stages of the proposal design as well as the proposal writing and assists the setting up of international consortia. Upon successful evaluation, BayFOR can also assist with the project implementation and, if required, provide support with project management and dissemination of results throughout the project. BayFOR has an excellent network at the regional and international level. Its EU Liaison Office in Brussels represents the interests of Bavarian universities, increases their visibility and provides contacts to relevant actors in the European institutions.
Moreover, BayFOR coordinates the joint activities of the Bavarian Research Associations and supports the expansion of their networks at the European level. Furthermore, the Scientific Coordination Office Bavaria-Québec/Alberta/International supports bilateral research projects in these regions and develops such initiatives further in the context of European research funding.
As a partner in the Bavarian "Haus der Forschung" (House of Research), BayFOR works closely with Bayern Innovativ GmbH, the "Innovations- und Technologiezentrum Bayern" (Bavarian Centre for Innovation and Technology, ITZB), and the "Bayerische Forschungsstiftung" (Bavarian Research Foundation, BFS).
Together, these four partners are able to cover all aspects of research and technology funding on a regional, national and European level. ■

Efficient support: The Bavarian Funding Programme for the Initiation of International Projects (BayIntAn)

In 2012, the Bavarian State Ministry of Education, Science and the Arts started the "Bavarian Funding Programme for the Initiation of International Projects" (BayIntAn) and commissioned BayFOR with the handling of this funding programme. BayIntAn promotes cooperation projects between scientists at Bavarian state and state-supported non-state universities and international research institutions. The funding programme offers grants for travel and subsistence. By providing support in the initial phase of cooperation projects, it enables researchers to exchange ideas and expertise in person and advance their work more efficiently. For further information on BayIntAn and current deadlines, please visit http://www.bayfor.org/promoting-cooperation

Links

www.bayfor.org/english
www.hausderforschung.de/en
www.bayfor.org/promoting-cooperation

Horizon 2020 –
The new Framework Programme for Research and Innovation
http://ec.europa.eu/programmes/horizon2020/en/

SME Instrument
http://ec.europa.eu/research/participants/portal/desktop/en/funding/sme_participation.html

EUREKA Eurostars
www.eurostars-eureka.eu

EuroTransBio
www.eurotransbio.eu

IraSME
www.ira-sme.net/

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A new standard in the operating theatre

Ten years of experience, several thousand successful operations: anyone applying for a job as surgical assistant with these kind of credentials has excellent prospects. If you add to that optimum precision and versatility, as well as the quality of never becoming tired, then it's clear: this is the right candidate for the job.

This is exactly the decision numerous hospitals have already made when they chose SOLOASSIST by AKTORmed - a robotic assistance system for holding an endoscopic camera during minimally invasive procedures. Now its successor the SOLOASSIST II is on the market, bringing with it new innovations.

For a wide variety of surgical interventions laparoscopic techniques have become established as standard procedure. Perfect imaging is the basis for safe and effective surgery. Both the stable support and flexible positioning of the endoscope are of paramount importance. The SOLOASSIST, which was developed in 2005, makes the surgeon's job easier and takes on the role of surgical assistant.

Joystick ■

SOLOASSIST II ■

Based on the proven concept of its predecessor, the SOLOASSIST II far outperforms the original device in terms of precision, versatility and ease of use. Of particular significance is the reduction in weight: at 9.5 kg, its weight has been reduced by almost half. This is very noticeable in the handling of the device: with the assistance of the SOLOASSIST II, the surgeon is able to adjust the endoscopic image with upmost precision using the joystick. Operation of the device is intuitive and easy to learn within a very short time. Along with the motorised control, the endoscope can also be positioned dynamically by hand.

The advantages are clear to see: using the SOLOASSIST II relieves some of the workload placed on valuable employees. Thanks to the flexible concept of sterilisable components, the equipment is ready for the next surgical intervention immediately after completion of the last one. It is compatible with all current operating tables and endoscopes and furthermore it is completely maintenance-free.

The assistance-system is specialised in visceral surgery, urology and gynaecology. Not operating the camera manually results in a stable and shake-free image, which not only increases the quality of the operation but also relieves the assistants of some of their workload, allowing them to focus on more important tasks.

About AKTORmed GmbH:

AKTORmed GmbH is based in Barbing near Regensburg and was founded in 2005. Both the development and manufacture of the products takes place at the company's location in Barbing. The company benefits from many years of experience in the development of patient positioning, robotics, sensor and actuator devices. Its objective is to develop, manufacture and market mechatronic assistance systems for minimally invasive ■

AKTORmed™
ROBOTIC SURGERY

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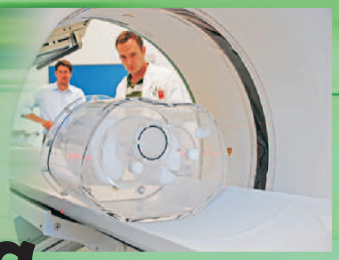

International Healthcare Engineering Activities

Erlangen Networkers working their way throughout the World

In Dezember 2013, a great international campaign for Medical Technology ended with great success. In 2011, the Federal Ministry of Education and Research (BMBF) had chosen an Erlangen consortium under the guidance of the Central Institute of Healthcare Engineering (ZiMT) at Friedrich-Alexander-Universitaet Erlangen-Nuernberg (FAU) as one of eight ambassadors within the international thematic campaign "Germany – Partner for Medical Technology". The aim was to globally promote the great environment for healthcare engineering research and business in Germany.

Healthcare engineering is one of the main focuses of the FAU and of its numerous spin-offs. Erlangen scientists are contributing essentially to fundamental topics of medical imaging, telemedicine, biomaterials, and therapeutic systems. The close cooperation with Siemens Healthcare, Fraunhofer IIS, and approximately 50 healthcare engineering organizations of the metropolitan area is adding to these excellent research settings.

In 1996, Erlangen's former mayor Dr Siegfried Balleis developed the vision to make Erlangen the "Federal Capital of Medical Products and Services". He was supported by the former Bavarian prime minister Dr. Edmund Stoiber who was strongly committed to this vision ("Healthcare Engineering in Bavaria focuses on Erlangen"). Since then, healthcare engineering has become the driving force and the cloud point of many new projects, spin-offs, and start-ups. In this premium growth market, the capability of and the readiness for innovation are decisive criteria for persistent success. Economy, science, and politics recognized the potential of those possibilities and came to trend-setting decisions.

Fig. 1: *Medical Valley Center (in front) and Headquarter of Siemens Healthcare (multi-story building in the rear) in good neighborhood* ■

Through the construction of the "Innovation Center for MedTech and Pharma (IZMP)" on an area of approximately 11,000 square meters, the Bavarian state government consolidated its denomination to the healthcare engineering location of Erlangen *(fig. 1)*. Today, the building - nowadays called "Medical Valley Center" - not only houses university labs, medium-sized enterprises, and start-up companies, but also the Medical Valley Cluster Management, the Central Institute of Healthcare Engineering, the Chamber of Industry and Commerce, venture capitalists, and numerous other facilities. Thus, Erlangen and its surroundings meanwhile feature a unique density of research facilities, medical technology companies, and healthcare organizations.

Besides university and research facilities, the industrial global player Siemens ensures an exceptionally high degree of innovation. This is underlined by the location of the Healthcare Sector headquarter in Erlangen.

Fig. 2: *Final event "BMBF MedTechPartners Conference" and participants "3-D Imaging in Medicine" in the Siemens Medicare Hall in 2014* ■

In 2010, the Medical Valley EMN (European Metropolitan Region Nuremberg)", succeeded in the BMBF leading-edge cluster competition that was funded with 40 million Euros for Erlangen's "Center of Excellence in Medical Technology". Imaging diagnostics, intelligent sensor systems, therapy systems, personalized medicine, and ophthalmology have been defined as the technological and scientific master topics within that cluster. Under the guidance of Prof Erich Reinhardt, the cluster is represented mainly by Siemens, the FAU, the university hospital, non-academic research institutions like Fraunhofer and numerous further technology partners, SMEs and service providers.
Already in 1998, it was Prof. Reinhardt himself in his role as CEO of Siemens Healthcare (Medical Solutions at that time), who gave the "heart" of the Bavarian "Medical Valley" the crucial size and encouragement by the decision to invest 200 million Deutsche Mark (~ 100 million Euro) in a state-of-the-art manufacturing plant for medical devices.

After the successful application for the federal leading edge cluster in 2010, the federal advancement of the Erlangen consortium "3-D Imaging in Medicine", initialized by Dr. Kurt Höller as managing director of ZiMT, was another milestone regarding international recognition within the international BMBF thematic campaign 2011 - 2013 *(fig. 2)*. The objectives – not only irrespective of, but actually absolutely complementary to the BMBF leading-edge cluster – was the involvement of international medical engineering competence regarding research, development, and training as well as scientific exchange and collaboration. One of the key messages was that Erlangen offers worldwide unique possibilities and chances for scientists and experts, especially in the field of medical imaging.

The thus initialized association focused particularly on the central innovation field of 3-D Imaging Modalities and Methods in Medicine. The members of the consortium have been university institutions, young spin-offs, and major partners of the university in this innovation domain. This shows the close interconnection of university and non-university research as well as industrial development.

FAU, the university hospital, Fraunhofer IIS, Medical Valley, Siemens Healthcare, and the city of Erlangen contributed significantly as associated partners to the network. Together with the coordinating ZiMT, the FAU spin-offs Metrilus GmbH, Explius GmbH, Chimaera GmbH, CT Imaging GmbH, and Cerbomed GmbH, represented an important part of the consortium. These start-ups delivered a brilliant performance as the driving force for innovation when applying emerging key technologies. It is crucial to maintain the high level of innovation potential and knowledge of their research focuses also during the SME phases of market entry. Besides basic research, the applied innovation capability

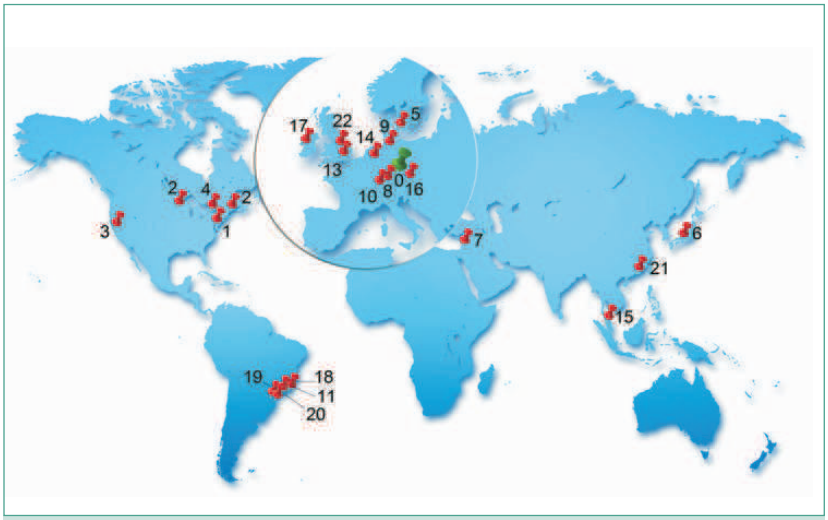

Fig. 3: *ZTarget areas of the consortium "3-D Imaging in Medicine"* ■

Fig. 4: *Dr Kurt Höller explaining the options of a stable horizon by rotation correction and image rectification for the use with flexible endoscopes* ■

of scientific facilities has to be assured.

By joining numerous sector-specific events of the corresponding research and technology landscape, interested partners abroad were given the opportunity to contact Erlangen research facilities and leading technology businesses during the campaign time span 2011 - 2013 *(fig. 3)*. Presentations took place on symposia and expert conferences as well as workshops, multiplier events, cooperation exchange panels, and lectures. The activities aimed mainly at scientists in academic and research facilities, deciders and developers from R&D orientated businesses, junior scientists, multipliers and investors.

Presentation of the science and business location, especially in the field of medical engineering, consistently caused great astonishment on trade fairs like the Biomed in Israel *(fig. 4)*, the Hospitalar in Brazil, the RSNA in the United States *(fig. 5)*, or the World Congress on Medical Physics and Biomedical Engineering in China. Thus, not only the research place of Germany benefitted from the lead of the Erlangen network, but also the Erlangen interconnection benefitted extremely by the political support of the BMBF in the international arena.

The outcome was a multitude of contract conclusions in the United States, Brazil, and China as well as numerous further contacts in Israel, Japan, and Russia. These laid the base for further close cooperation with international top organizations like the national elite university Peking University PKU (Beijing, China), the private elite university Johns Hopkins University JHU (Baltimore, USA) and the research organization CERTI (Florianopolis, Brazil). This not only comprises collegiate and scientific exchange, but also economic large-scale projects involving Erlangen partners like for instance in China or Brazil *(fig. 6)*.

As another outcome, a broad-based network with SMEs and research facilities was inititated by the company CiNNAMED GmbH that evolved from the international BMBF thematic campaign. It was founded following a suggestion by the project executing organization. According to that, the leadership fell to Dr Kurt Höller, Prof Joachim Hornegger, and Tobias Zobel who at the same time are the responsible persons of the Central Institute of Healthcare Engineering. CiNNAMED GmbH is already anchored in the structures of the Medical Valley EMN. Nature and purpose of the business is the communication of, the advice on, and the trading with products and services of every description in the fields of healthcare and biomedical engineering. Based thereupon, a network approach is being develo-

Fig. 5: *Dr Kurt Höller explaining the importance of the Medical Valley at the RSNA at Chicago to Dr Christian Brecht, Consul General of the Federal Republic of Germany* ■

Fig. 6: *Representatives of PKU, FAU, and Siemens signing contracts for a joint graduate program on healthcare engineering* ■

ped in order to implement the successful approaches already achieved on an international level up to now for and together with the participating SMEs. Thus in 2014 and beyond, the contacts to Brazil, China, and Russia as well as the US, Israel, and Japan are to be serviced and further activities are to be organized *(fig. 7)*. It's in evidence that the activities of the thematic campaign and its results provide further chances for cooperation and an increasing international visibility.

As the highlight of the thematic campaign, in February 2014 a 5-day conference series with the slogan "Germany - Partner for Medical Technology" or in short "MedtechPartners Conference" was organized at Erlangen under the patronage of BMBF state secretary Stefan Müller and in cooperation with BMBF, ZiMT, Medical Valley, and CiNNAMED GmbH. For the first time, industry and science got together in Germany's healthcare engineering center of excellence. Representatives of medical engineering associations, research facilities, and enterprises were invited to express and discuss their options and concerns about current and future challenges in the medical technology sector. This summit offered the exceptional opportunity to establish useful professional relations, to update oneself on the status quo of global research trends, and to get solid comprehension of the global cooperation development and its prospects. Manifold organizations used the conference series to present their activities and their results to the public.

Fig. 7: *Global targets of the CiNNAMED GmbH (in the rear) with company founders Dr. Kurt Höller, Prof Joachim Hornegger, and Tobias Zobel (in front, from right to left)* ■

Fig. 8: *Tobias Zobel reporting at the "Hospitalar" at Sao Paulo about innovation in medical engineering* ■

Moreover, further participants were able to profit by the arising synergies. In the course of a final panel discussion chaired by FAU vice president Prof Joachim Hornegger, well-respected, internationally esteemed lecturers like Prof Qiushi Ren (Biomedical Engineering Department of Peking University at Beijing, China) or Prof Russ Taylor (Johns Hopkins University at Baltimore, MD, USA) stressed the relevancy of intercontinental collaboration. By the successful conclusion of the thematic campaign, the beginning of a strategically persisting evolution of medical engineering in

Fig. 9: *Dr Kurt Höller giving a talk on funding for interdisciplinary innovations at the BMBF MedTechPartners Conference in 2014* ■

Germany and the world was initiated.

The second run of this highly effective event is going to take place on February 23-25, 2015 when leading national and international players in healthcare management and medical engineering will meet in the Medical Valley.

At the opening on February 23, information about the regional activities, projects, and partners of the Medical Valley EMN will be provided. In the course of an international day on February 24, particularly international co-operations and topics will be addressed, with a special focus on our initiative in the context of the Horizon2020 bidding "Healthy Living and Active Ageing" initiated by the EU as well as on current activities directed to Brazil, China, and Israel *(fig. 8)*. An evening event on February 23 provides the opportunity to strengthen partnership. Finally, all national associations and stakeholders are requested to use February 25 as the closure of the conference in order to integrate own workshops, annual meetings, and working groups into the agenda. The event will be topped by the updated version of the "Erlangen Declaration". It sums up recommendations of the scientific and economic community from a wide opinion forming process amongst associations, medium-sized businesses, and representatives of science, finance, and politics.

The concern becomes obvious: Innovation must furthermore be financially viable for small businesses in every start-up phase. ■

For further information see:
www.medtechpartners.de
www.cinnamed.de
www.zimt.fau.de
www.medical-valley-emn.de

About the author::

Kurt Hoeller studied Electrical Engineering at Friedrich-Alexander-Universitaet Erlangen-Nuernberg (FAU) with a diploma thesis on inertial sensors for navigation at the Fraunhofer Institute of Integrated Circuits IIS.
From 2005 to 2009, he was working on his dissertation on "Novel Techniques for Spatial Orientation in Natural Orifice Translumenal Endoscopic Surgery (NOTES)" in Computer Science at the Pattern Recognition Lab LME in Erlangen, the Research Group for Minimally Invasive Interdisciplinary Therapeutical Interventions MITI at TU Muenchen and the Computer-Integrated Surgical Systems and Technology Engineering Research Center CISST ERC at The Johns Hopkins University, USA. He earned his doctoral degree at the school of engineering at FAU and as an associated member at the TUM Graduate School of Information Science in Health (GSISH).
Since 2009, Kurt Hoeller is managing director of the Central Institute of Healthcare Engineering ZiMT at FAU Erlangen-Nuernberg. ZiMT supervises joint interdisciplinary research projects as well as the FAU Bachelor and Master programs in healthcare engineering. Dr Hoeller also coordinated the thematic campaign "3-D Imaging in Medicine - Cutting-Edge Research in Germany's Medical Valley" that was part of the international campaign "Germany – Land of Ideas" launched and supported by the Federal Ministry of Education and Research (BMBF).
By end of this campaign in 2013, he was founding CEO of the evolving university spin-off CiNNAMED GmbH that focuses on Communication, Consulting and Commerce especially in Biomedical Engineering projects. Dr Höller is also active in local politics as a municipal councilor and member of the supervisory board of Erlangen's municipal energy supplier.

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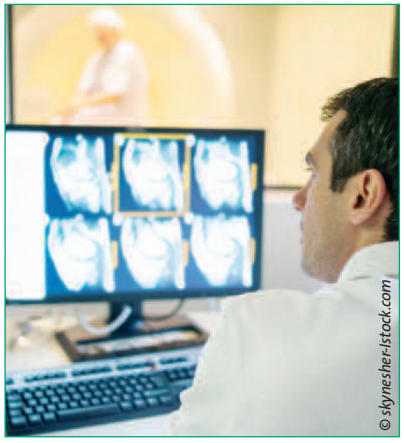
Medical technology needs safety

Receiving approval for medical devices and medical software might be a tedious, risky and not least cost-intensive process. For many years, imbus has been supporting renowned clients to efficiently overcome this obstacle – by consulting, training and providing services for development, quality assurance and test conforming to FDA and MPG regulations.



In the field of radiotherapy, imbus has been involved in the development of one of the market-leading products from the beginning. The highly qualified components (class IIa and IIb) of various suppliers have been brought into line with a uniform state-of-the-art. New components have been developed being economically reasonable and documented according to the verification and validation. To meet all regulatory requirements, the required standards were integrated in the development process and proven.

The Test*Bench* test management tool enabled collaboration across the locations around the globe. Due to the support in all testing phases of the system, the first radiotherapy system of its type could start operations in 2010.
Optimizing clinical work flows is of increasing importance for health care providers. In this context, imbus has optimized the use of a Radiology Information System (RIS) for a global medical technology company taking into consideration different approaches. Configurable profiles and different SW/HW configuration made it possible to receive information on the required use of hardware. The required hardware configurations could be determined for different utilization concepts of the manufacturer. This way, the objective of a projectable, efficient use of the application was achieved.
Also with respect to eye laser systems, high safety and quality standards play a decisive role. The approvals of a medical device are subject to high standards both for the US and European market. imbus supports renowned manufacturers of eye laser systems in the verification and validation process. Analogous to the process description according to IEC 62304, imbus consultants prepare comprehensive documentation of the test specifications, test reports and tracing documents. In economic terms and at the highest quality, imbus provides assistance in the process evaluation and optimization through extensive project reviews. The objective is a steady improvement of the project development.
imbus advises its clients on safety, basic requirements and documentation – always taking into consideration the quality of the end product. Verification and validation has to be practicable and projectable according to economic and quality criteria. ■

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Companion Diagnostics – the silver bullet for state-of-the-art medicine?

Patient-specific medicine, little more than a catchphrase for many years, is increasingly becoming a focus of care-centered discussions. For some time now, many epidemiological studies have examined the frequencies of diseases and the associated risk factors. One element that is new, however, is the more comprehensive and much more complex approach being adopted. An individual's health is determined not by a disease alone, but by the highly complicated interplay of many different influencing factors.

These include professional and social circumstances, health-impairing behaviors and a multitude of mental and physical functional disturbances and diseases. The Study of Health in Pomerania (SHIP) was initiated as a means of examining precisely these interrelationships in all their complexity. It examined the prevalence and incidence of common diseases affecting a relevant proportion of the population, e.g. cardiovascular diseases, diabetes mellitus, neurological diseases and the associated risk factors. The comprehensive data that was gathered generated knowledge offering significant potential for the refinement of patient-specific medicine. After all, the same disease does not have exactly the same characteristics in each individual patient. And patients with the same diagnoses often respond differently to treatment with the same medication. The reason is found in everyone's individual genetic make-up. Making medicine patient-specific calls for an analysis of these influencing factors and seeks tailored and thus especially effective options for both prevention and treatment, with minimal adverse effects. A precondition for successful treatment is, however, the ability to administer effective medications. This is where "Companion Diagnostics" comes into play. In simple terms, this involves tests to determine whether a specific medication will probably be effective – or not – for the patient in question. A distinction can be made in this regard between tests that are being developed for an existing treatment and those being brought onto the market in conjunction with a new medication.

HER-2 Testing: a drug administered for breast cancer, is given to the patient in question only if the HER2 test that is performed first shows that the response to the medication is likely to be positive ■

The HER2 test is an example of a companion diagnostic procedure that is already in use. Herceptin, a drug administered for breast cancer, is given to the patient in question only if the HER2 test that is performed first shows that the response to the medication is likely to be positive.

"Companion Diagnostics" is still considered a relatively new discipline, though one with huge potential. The use of companion diagnostics can avoid unnecessary costs and save valuable time. Treatment prognoses can also be improved and better treatment results obtained in the process. Both drug manufacturers and manufacturers in the area of laboratory diagnostics have already recognized this potential. Working in close partnership, they are developing new medications, e.g. for AIDS or cancer, and the associated tests in parallel. For the pharmaceutical industry, this implies radical changes: away from mass-produced drugs and toward tailored medications and tests. Indeed, in view of constantly rising health costs, there will be no other way to ensure their preparations are used more effectively.

It is not only the drug manufacturers, however, that face tough demands when it comes to enabling individually tailored treatment. Personalization also plays an increasingly important role in the area of medical products. Firstly, medical products are required to create the technical ability to provide patient-specific medicine as a direct combination of diagnostics and treatment in the first place. Secondly, the general objective of structuring medical treatment more effectively and with fewer adverse effects by adapting it to suit individual patients can also be applied to the design of medical devices, components and systems. This is the case in the area of imaging, for instance. Especially with magnetic resonance imaging (MRI) and positron emission tomography (PET), the contrast agents or radiopharmaceuticals are combined with specific biomarkers to identify the corresponding (patient-specific) target structures and improve the performance of the imaging processes (molecular imaging) in this way. The different imaging methods have differing properties and are used in accordance with the clinical issue in each individual case.

All of these innovations and developments offer major opportunities, although regulatory requirements, specifically in the area of companion diagnostics, have not yet been adapted to account for the latest developments. It is currently difficult to assign "companion diagnostics" in its entirety to either "pharmaceuticals" or "medical products" as a product group on the basis of the existing legislative provisions. This is also one of the reasons why renewed financing for tests that were developed for drugs that have already been registered is either being delayed or is not happening at all. At the moment it appears that "tandem solutions" offer the best opportunities. As has previously been mentioned, diagnostic and pharmaceutical manufacturers are working together in this case, at a very early stage, to develop drugs and the associated tests in parallel. In closing, it must be noted that companion diagnostics stands out as a component of patient-specific medicine on account of the positive effects obtained for all parties involved. Patients benefit from improved treatment options, health insurance companies benefit from reduced outgoings in the absence of ineffective drug treatments and adverse drug effects, and manufacturers enjoy new areas of activity. With regard to the regulatory requirements, all players seem motivated to continue driving the process of further refinement forward. In late April 2013, the German Ethics Council also provided recommendations as part of a statement on the future of genetic diagnostics regarding covering costs for companion diagnostics in healthcare, which shows the relative importance of this subject area. ■

Proven in research and clinical use, Biograph mMR brings a revolution in diagnostic imaging to life: state-of-the-art 3T MRI and cutting-edge molecular imaging, fully integrated as one, for simultaneous acquisition of whole-body MR and PET ■

The Siemens Healthcare Sector is one of the world's largest suppliers to the healthcare industry and a trendsetter in medical imaging, laboratory diagnostics, medical information technology and hearing aids. Siemens offers its customers products and solutions for the entire range of patient care from a single source - from prevention and early detection to diagnosis, and on to treatment and aftercare. By optimizing clinical workflows for the most common diseases, Siemens also makes healthcare faster, better and more cost-effective. Siemens Healthcare employs some 52,000 employees worldwide and operates around the world. In fiscal year 2013 (to September 30), the Sector posted revenue of 13.6 billion euros and profit of 2.0 billion euros.

For further information please visit: www.siemens.com/healthcare

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Cytotoxicity Testing of Medical Devices

One of the core requirements for the approval of medical devices on different global markets is a cytotoxicity test which represents the easiest method for the analysis of detrimental effects of substances on cells in vitro and allows a rapid and sensitive diagnosis of the biological reactivity of leachable or diffusable components of test materials. Several commonly used methods are presented and discussed below.

Tests on Extracts

Test items are extracted in cell culture medium in a defined surface/volume or weight/volume ratio for 4 to 72h depending on geometry, composition and clinical use of the product. Extracts are then subjected to freshly dispensed or preseeded cells and incubated for 24 to 72h. After treatment period, inhibition of cell growth can be evaluated qualitatively by visual inspection (Reactivity Grades 0-4, *Fig. 1A*) or using quantitative methods, such as protein staining (e.g. bicinchoninic acid, BCA) or enzyme activity assays (XTT or MTT, both are tetrazolium salts that are reduced to formazan by cellular dehydrogenases), where the intensity of the colour change is recorded by a photometer and serves as a measure for relative growth inhibition or viability of cells treated with test item extract in comparison to untreated controls. A reduction of cell growth or viability by more than 30% is considered as a cytotoxic result *(Fig. 1B, C)*. The colony forming ability (CFA) represents a further possibility for determination of cytotoxicity. Here, 100 cells are exposed to different concentrations of a test item extract for 7 to 9 days. Subsequently afterwards, the resulting cell colonies are stained and compared to untreated controls *(Fig.1D)*. Additionally, an IC50 of the extract can be determined. ■

Direct and Indirect Tests

For a direct cell contact test (DCC), small pieces of planar materials can be applied directly onto the cells for 24h. After removal of the test item, cytotoxic effects can be assessed by evaluation of inhibition zones of impaired cell growth surrounding the test item (Reactivity Grading) *(Fig. 2A)*. For indirect methods such as Agar Diffusion Test (ADT), cells are covered by a layer of agarose on which the test item or an extract is applied.
Diffusable cytotoxic leachables lead to decolorization of damaged Neutral Red-stained cells or even to cell lysis. Cytotoxicity is determined microscopically after an incubation period of 24 h *(Fig. 2B)*. ■

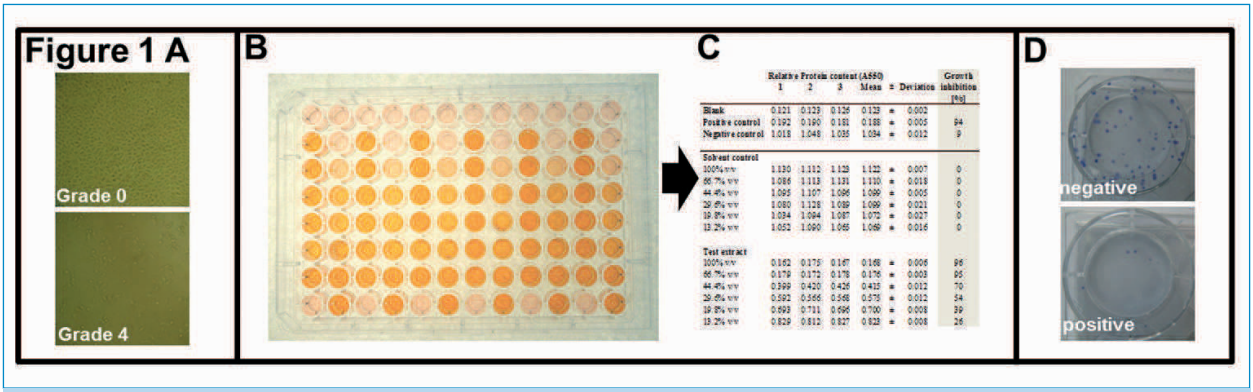

Fig. 1: *Biological endpoints when testing extracts of medical devices* ■

Cytotoxicity

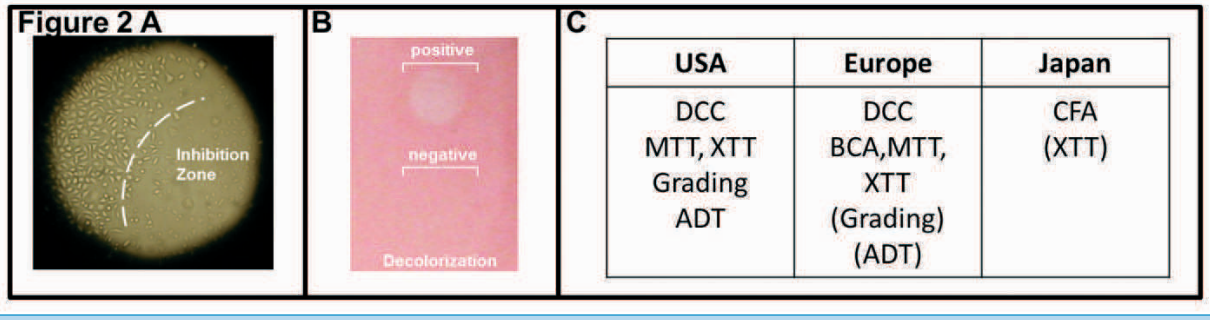

Fig. 2: *Biological endpoints of direct tests of medical devices. Acceptance of different test methods* ■

Acceptance and Conclusion

All methods have a different acceptance on the markets worldwide *(Fig 2C)*. According to ISO10993-5, European authorities prefer quantitative methods (BCA, MTT, XTT) over more qualitative ones (DCC, Grading, ADT), which are generally accepted by the US authorities according to USP<87>. CFA is a prerequisite for the Japanese market (according to MHLW notification from 2012).

Together with methods of chemical analysis (e.g. GC/MS-fingerprinting, ICP), cytotoxicity tests represent a powerful tool for root cause analysis identifying the hazardous potential of leachable substances from medical devices. ■

Geometry and clinical application of medical devices (here: stent) are relevant for test conditions ■

Testing of medical devices in the in vitro laboratory according to GLP ■

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On the move, stay connected with a doctor in your smartphone

Telemedical devices offer enormous chances in prevention as well as in therapy. They also provide a remarkable potential to reduce significant costs in the public health sector. In the context of an ageing society, especially mobile and user-friendly medical devices are of increasing importance. But despite the great progress made during recent years, patients, however, still have to be dependent on many different devices to obtain a consistent monitoring of essential medical parameters. This situation, because of both the complexity of conditions and mobility problems, is very unsatisfactory. This article describes a device which enables the simultaneous measurement, on the patient's finger, of blood pressure, temperature, the electrical conductivity of the skin, as well as pulse and oxygen saturation. The collected data can be accurately aligned via UMTS with an internet - based database, through which both the patient and the authorized medical staff can get insight into medically relevant parameters.

The western health care system is increasingly marked by a discrepancy between rising therapy costs and a decrease in quality [1]. One of the reasons is increasing life expectancy. This presents new challenges to the health care system, connected with high costs, especially concerning cardiovascular diseases [2] or diabetes [3]. In this context, the use of telemedicine offers a great potential for cost reductions together with a simultaneous increase in the quality of life of the patients. This is applicable for the prevention of these diseases, for the time during treatment and also for the treatment of chronic diseases.

Through telemedical support, the patient's compliance can be enhanced, which leads to a higher efficiency of the therapy [4, 5]. However, for consistent support, as in the case of cardiovascular diseases, patients must still go back to a multitude of different devices, as for each measurement parameter another measuring device is needed. These are usually: a blood pressure gauge, a balance, a blood glucose meter and an activity monitor, as for example, a step counter. At the same time, many patients, especially the elderly, express the wish to keep their individual mobility. By carrying along a multitude of devices in a measuring set case, this mobility will significantly be affected. Moreover there is also a danger of stigmatization while carrying out the measurements in public, as during a journey or at work. *Figure 1* illustrates the devices for the telemedical platform

Fig. 1: *Telemedical assistance system COMES® developed by the Heinz Nixdorf Chair for Medical Electronics.* ■

Fig. 2: *a) Telemedical All-in-One-Medical-Device with sensor cuff presented in the picture below, as it has been developed by the Heinz Nixdorf Chair for Medical Electronics in cooperation with the Research Group of Product Engineering of the Heinz Nixdorf Institute, University of Paderborn. Designed by the Department of Industrial Design of the Kunst Universität Linz, of Professor Axel Thallemer. b) Representation of the finger cuff with sensors at the inside, as it has been assembled within the device.* ■

COMES® developed at the Heinz Nixdorf Chair.

Furthermore, in order to enable the automatic data transmission into a database, the devices have to be connected with a communication unit, as for example a smartphone [6]. Thereby, not only the complex and partly different operation of the several devices, but also the use of a smartphone and the associated necessity of the application of it, are to be considered as critical. This condition does not fulfill at all the claim to have a preferably easy and intuitive handling, especially for the less technically-minded users.■

Development of an All-in-One Medical Device

The aim of the All-in-One-Medical-Device developed at the Heinz Nixdorf Chair for Medical Electronics is the integration of several essential medical sensors into a single, handy device combined with a communication unit. The All-in-One-Medical-Device enables the measurement of blood pressure, temperature, the electrical conductivity of the skin, as well as pulse and oxygen saturation, with one single device only. For this, the patient merely has to insert one finger into the provided sensor cuff and press the starting button. The following measurements, as well as the storage of the measured data in a central database, are fully automated. Additionally, a measurement strip for glucose can be put into the device. A scale is connected via Bluetooth whose measuring data will also be stored automatically into the database. The telemedical All-in-One Measuring Device is represented in *figure 2*.

The device is composed of two function blocks. The single sensors are connected by a microcontroller which records and preprocesses the data. There are available: a combined optical and oscillometric measurement for blood pressure, an optical measurement for oxygen saturation, a conductivity measurement by gold electrode structures on the inside of the finger cuff and a temperature sensor. For the measurement of glucose, the extraction of a drop of blood is needed; the measurement is made by an amperometric measuring method on a measure strip. As a second function block, an embedded android platform has been integrated. It offers both a user-friendly user interface and an automatic connection to the COMES® Internet Database, as well as an emergency call. The wireless transfer of the measured data via mobile internet, combined with the integrated lithium ion battery, allows the use of the device in everyday life, independently from the location of the user. The battery will be charged by a common micro USB plug as it is used for mobile phones. The connection of the two function blocks is realized by a USB interface, which provides both data interface and energy supply for the sensor system. *Figure 3* shows the two blocks, represented as a block diagram.

A large touch screen is located on the front side of the device where indications for use of the device as well as measurement results are shown. The user interface is intuitive to operate – this enables a large user group, especially older generations, to easily handle the device. The patient can choose between the "Easy View" and the "Expert View". The "Easy View" offers only a large button for starting

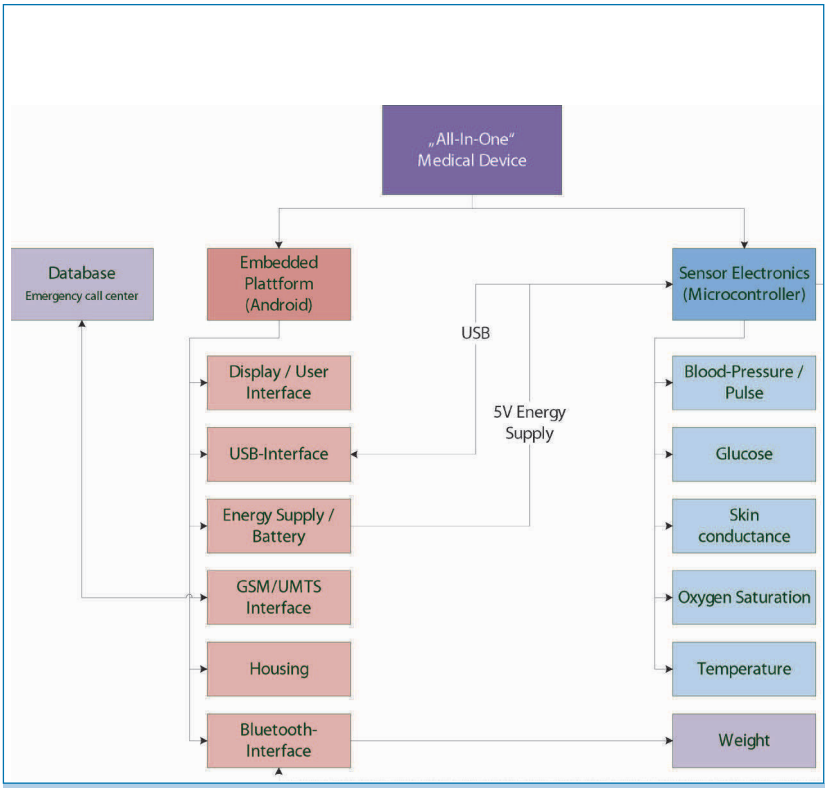

Fig. 3: *Technical design of the All-in-One device comprising of the android embedded platform and microcontroller.* ■

the measurement and displays the last measured values. There is also the possibility to create an automatic connection to an emergency center by means of an emergency call button. All the data stored in the database can be visualized through the "Expert View" in order to show the progress in therapy *(see figure 4)*. Furthermore, messages, for instance to the general practitioner, can be read and sent.

The housing of the device has been developed within a research project by the Research Group of Product Engineering of the Heinz Nixdorf Institute, University of Paderborn in cooperation with the Department of Industrial Design of the Kunst Universität Linz, of Professor Axel Thallemer. It is manufactured by Rapid-Prototyping. ■

Summary and Outlook

With its extensive functionality and its reduced dimensions, the All-in-One-Medical-Device follows the needs of the patient to keep unrestricted mobility. It weighs around 300g and is pocket sized. Through the combination of various medical sensors and a data transfer unit, the device is suitable for daily use both at home or away. Its easy and discrete measurement may also help to counteract feelings of stigmatization. As a further development of the system, we are currently working on a sensory fingering. This concept will offer the possibility to measure the parameters developed through the project presented above continually through a ring, which will be comfortably integrated in everyday life and connected to a smartphone [7]. That is why we have focused, during the current project, on a miniaturized and energy-saving development of all the sensors and data processing algorithms. ■

Acknowledgements

The research project described here was only made possible by the support of the Heinz Nixdorf Foundation in the course of the project „KOMPASS". We thank the Research Group of Product Engineering of the Heinz Nixdorf Institute, University of Paderborn under the leadership of Professor Gausemeier, for their excellent cooperation in this project. We also owe thanks to the company OMRON Deutschland GmbH for the providing of the blood pressure gauge. ■

Fig. 4: *Telemedical All-in-One-Medical-Device showing the "Expert View". [Developed by the Heinz Nixdorf Chair for Medical Electronics in cooperation with the Research Group of Product Engineering of the Heinz Nixdorf Institute, University of Paderborn. Designed by: Department of Industrial Design of the Kunst Universität Linz, of Professor Axel Thallemer.]* ■

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The Medical Technology Test and Demonstration Center METEAN

A Partner for Innovative Businesses

Innovations in medical technology will not only improve the quality of medical care, they also make an important contribution to the export success of German industry. To shorten the time to market launch, particularly the fulfillment of regulatory requirements is a key challenge in the transfer of research results into an approved medical device. In addition, there is often a lack of qualified staff and a lack of interdisciplinary knowledge transfer between actors involved in the value chain.

The Medical Technology Test and Demonstration Center METEAN was founded to reduce promptly these innovation obstacles and to allow minor, innovative companies and research consortia, the timely transfer of ideas and research results into product solutions.

The METEAN is operated by Fraunhofer IIS in close cooperation with the Friedrich-Alexander-University of Erlangen-Nuremberg and the University Hospital Erlangen since 2008 in the premises of the University Hospital. There, new medical solutions and devices are tested under the daily needs for safety, usability and interoperability in accordance with recognized standards.

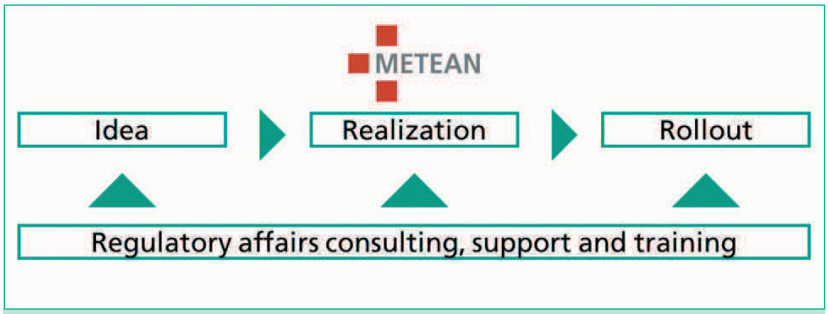

Fig. 1: Backbone concept of the Medical Test and Demonstration Center METEAN ■

The METEAN provides support services along the entire innovation cycle, i.e. on the precise nature of an idea to the marketing of an approved medical device. The METEAN service portfolio is ensured by an interdisciplinary team which enables optimal solutions for all aspects of innovation transfer to medical application – especially in medicine, engineering and business administration. The priorities of the current activities are the regulatory requirements for research and development, data ascertainment and the preparation and performance of validation and clinical studies. As part of the Fraunhofer IIS, the METEAN may also draw on all the expertise of the institute and of the Fraunhofer Society.

Cooperation with METEAN thus makes it especially possible for research consortia and small and medium-sized enterprises to overcome innovation obstacles and find ways through the jungle of legal, regulatory, economic and technical requirements and constraints. ■

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Sensor technologies by Fraunhofer IIS for mobile and comfortable training analysis

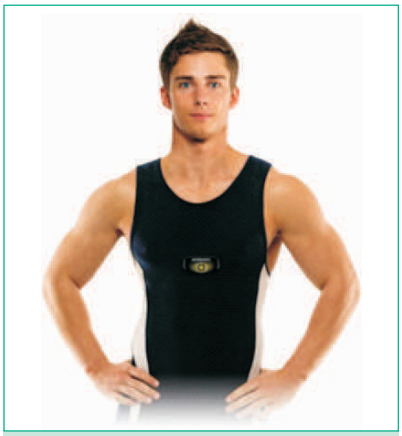
As a sport professional: did I perform an optimized training? Did I train at an appropriate level as an amateur? Does my daily schedule match a good work-life-balance or does stress push me to my limits?

Many people today ask the question for an optimized training and a balanced living. Sports professionals as well as amateurs and also managers seek for the same objective: How can I improve even better? The ambition for continuous optimization at present perks up in the web community „Quantified Self“ (www.quantifiedself.com) and is demonstrated in the steadily increasing number of so called „Wearables“. Portable sensor units for mobile applications are a crucial part in the loop of measurement, analysis and optimization. Sensor based data such as pulse or movement data provide relevant information on the own body, also identifying peaks of physical or mental stress. Based on these findings the appropriate measures for an optimized training or stress recovery can be derived.

FitnessSHIRT System by Fraunhofer IIS (Shirt, Electronics, Tablet) ■

ambiotex Tech-Unit as customer specific implementation of the FitnessSHIRT electronics ■

Fraunhofer IIS performs RnD activities on sensor technologies for the mobile acquisition of vital parameters as well as on the development of biosignal processing algorithms.



Product ambiotex with integrated sensor elements ■

The technological prototype „FitnessSHIRT“ supports the acquisition of a one-lead ECG, respiration activity and movement data in mobile application scenarios. Sensor elements integrated into a shirt gather the physiologic raw data and feature high comfort to the wearer. A detachable electronics processes the acquired data and calculates characteristic, numeric values, such as the heart rate, the breathing rate or the intensity of movements.

In order to further register and analyse stress conditions the physiological raw data ECG is processed for statistic indicators within HRV analysis (heart rate variability).

The FitnessSHIRT technology of Fraunhofer IIS is licenced by our commercial partner ambiotex GmbH and will be available as a product from automn 2014.

For various application scenarios – training optimization, stress analysis and relaxation exercises – a new product will be available, combining classic parameters like heart rate and activity, additionally providing breathing information and HRV analysis while featuring high comfort the wearer due to textile integration. ■

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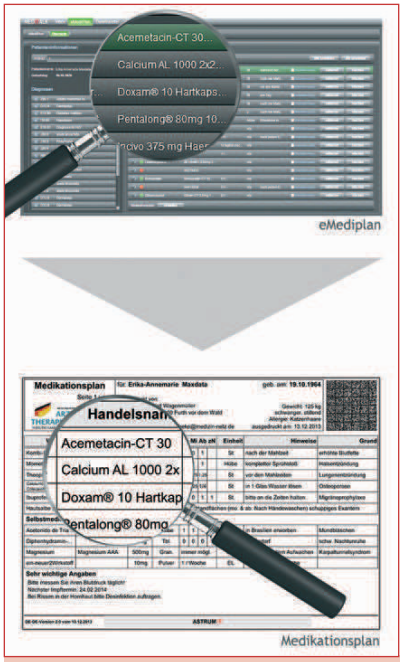
Electronic medication data transfer for optimal patient care

Adverse drug reactions are one of the most common causes of death worldwide: one in every ten hospitalisations and one in twelve hospital deaths are caused by medications. The frequently insufficient information sources available to treating physicians are one reason for this: either the medication plans or medical reports available are incomplete or the memory of the patient upon arrival in the hospital is unreliable. This inadequate information available to treating physicians exposes patients to unnecessary risks.

ASTRUM IT, a software company in Erlangen, Germany and a developer of products in the field of medical technology, has developed a solution to this problem. The idea of networking doctors' practices and hospitals for the communication of medication data has been implemented as part of „eMediPlan - cross-sector communication of medication data", a research project funded by the Bavarian State Ministry for Economics and Media, Energy and Technology. The system has already been implemented successfully thanks to productive cooperation with Fürth Hospital, the Ärztegenossenschaft Mittelfranken eG, the Department of Clinical Pharmacology and Clinical Toxicology at the Friedrich Alexander University Erlangen-Nuremberg and Hellmann Consult - Gesundheitsinformatik.

The eMediPlan IT system supports inter-sectoral networking among doctors in groups of medical practices and hospitals, permitting them to exchange the required information in the form of a standardised electronic medication plan. The goal is to improve the safety of drug treatments by reviewing the tolerability, rationale and necessity of the medications prescribed. This creates a valuable level of transparency for everyone involved.



With eMediPlan, everyone involved in the treatment process will have the same information. Photo: ASTRUM IT GmbH ■

As always, data protection is a topic of particularly critical concern when dealing with any system handling patient-related data. How secure is the data transmission? Are the rights of the patients assured? The creators of eMediPlan adhered strictly to the existing requirements for data privacy right from the development stages. The patients must provide their consent each time data is transmitted. Every transfer of data takes place via an encrypted connection which can be established only if both sides (sender and recipient) are using security certificates.

If the treating physicians have the required data at their disposal in eMediPlan, they are able to print out a federal harmonized medication list which can be provided to the patient.

After all, it is not only physicians and hospitals which are to use the system. In the near future, ASTRUM IT is planning to include additional partners in the transfer network, such as pharmacies, care homes and nursing services. Cooperation among different sectors will thus be strengthened further and the informal coverage of a patient's treatment process will become even more transparent. ■

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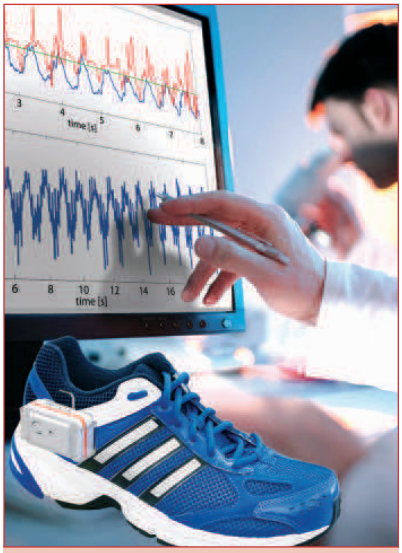
Automated gait analysis optimizes diagnostics and therapy monitoring

The high prevalence of movement disorders is reflected in the fact that they account for 20 percent of costs within the German health system (German Federal Statistical Office, 2008). They are caused by a disorder of the nervous system, such as Parkinson's disease, or of the musculoskeletal system, such as osteoarthritis. Because the ability to walk is in itself a gauge of mobility, patients feel strongly that an impaired gait impacts their quality of life. The gait remains a characteristic indicator of the stage and progression of a disease and so is utilised by the physician during the workup. The resultant diagnosis and the therapeutic decision-making are based solely on the physician's experience and subjective assessment. Accordingly, the assessment can differ from doctor to doctor.

Objective measurement methods with mobile devices could optimize diagnostics in this respect, as well as optimizing therapy monitoring. This requires a system which can measure defined gait parameters, display them and permit them to be modelled for the specific indication using assessment scales.

In eGaIT, ASTRUM IT is working with the Specialist Outpatient Clinic for Movement Disorders at Erlangen University Hospital and the Pattern Recognition Lab at Erlangen-Nuremberg University to develop a sensor system of this type for mobile and objective gait analysis. Inertial sensors in the patient's shoe record the gait pattern in standardised tests. These are used for the automatic calculation based on signal analysis of parameters such as stride length, speed, variability, angles, etc. All of the data collected are compiled using a secure online platform and made available to the therapist.



The shoe, which is fitted with a sensor, records the patient's gait. Photo: ASTRUM IT GmbH ■

eGaIT is being developed as part of a research project (2012-2014), funded by the Bavarian Research Foundation. To date, recordings have been taken for over 800 patients with neurological, orthopaedic and geriatric indications, as well as for healthy controls. Based on the gait parameters calculated, a definitive conclusion can be drawn regarding the stage of the disorder concerned and the course of the disease can be depicted clearly based on the calculations. A physician can also make the decision for a specific therapy on the basis of objective data. The right therapy for the patient can thus be identified more rapidly, demonstrating the success of a therapy becomes easier and the patients regain their quality of life earlier.

The online platform is designed for the conduct of multicentre studies, as a result of which eGaIT can also be used for privotal study to demonstrated the efficacy of medical devices and medications as a secondary outcome. The product launch is planned for 2015. eGaIT was awarded the 2014 City of Erlangen Prize for Medicine. ■

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We face challenges

The metropolitain area around Nuremberg has a very beautiful landscape and can refer to a long tradition in craftmanship as well as in industrial development. A great many of global market leaders is native to this region. This is what the proverb "Nürnberger Tand geht in alle Land!" means – "Goods from Nuremberg go to each country!

Today, it is medicine and medical devices which go to all countries. The area has advanced to a place of the highest density for companies of medical technology and manufactures of medical devices.

Nowadays and then, the basis therefore were entrepreneurial ability and skilled workers in order to adjust to changing circumstances and challenges. And not least, the colleges and universities around accelerated this tremendous development. We are also domiciled in this dynamic area and closely linked to its craft and industry.

Holzammer is a strong part of this region. Everyday, we are facing new challenges. In just under 12 months, a medical-technical global corporation developed together with us a complex medical-technical component, consisting of about 10 plastic parts with a single weight from 100 g up to 8 kgs plus dozens of single parts. All of them are assembled on a base plate made of stainless steel. This plate and the aluminium profiles have been designed by assistance of a sub-supplier. As the use of 3D-silicone gaskets was required, they were engineered together with the supplier.

But how can a time frame of only 12 months for the development be held, if you consider the manpower of several thousands of working hours? Here, in the first place, we must get to know our customers requirements and demands. A prerequisite therefore is the honest reflection of what each partner can do for the accomplishment of the project. We and our partner found both a positive answer to this issue.

In the beginning of the task is a common will to succeed in our aims. Essential is a constant exchange of data: starting with drawings, preparing 3-D-data, manufacture milled prototypes out of high grade plastic support blocks, modification and testing of these prototypes, making new prototypes with paint, construction of moulds for production of plastic parts, injection moulding of plastic parts – at the same time with completing the various tools, parallel development of main parts of stainless steel and aluminium profiles, proving the metal parts and adjustment after testing, overall proving the preproduction series, thereafter release for series production through customer, design of special packaging convenient for sea- and airfreight. All in all, a quality insuring attendance from the beginning on. An indispensable basis for this is a sense of responsibility of highest qualified employees (both from customer and supplier side).

The engagement of creative suppliers, a reliable delivery service ensuring a high-quality performance plus a commitment of all participants to a common goal, dedication to good work and a permanent checking of the entire workflow with regard to deadlines count as prerequisites.

Achieving these goals takes the integration of all efforts, ultramodern machinery and technical equipment, CAD and telecommunication systems. The involvement of external constructing engineers is a matter of course for us.

This is what we from Holzammer aim to live together with our suppliers! ■

HOLZAMMER
Kunststofftechnik

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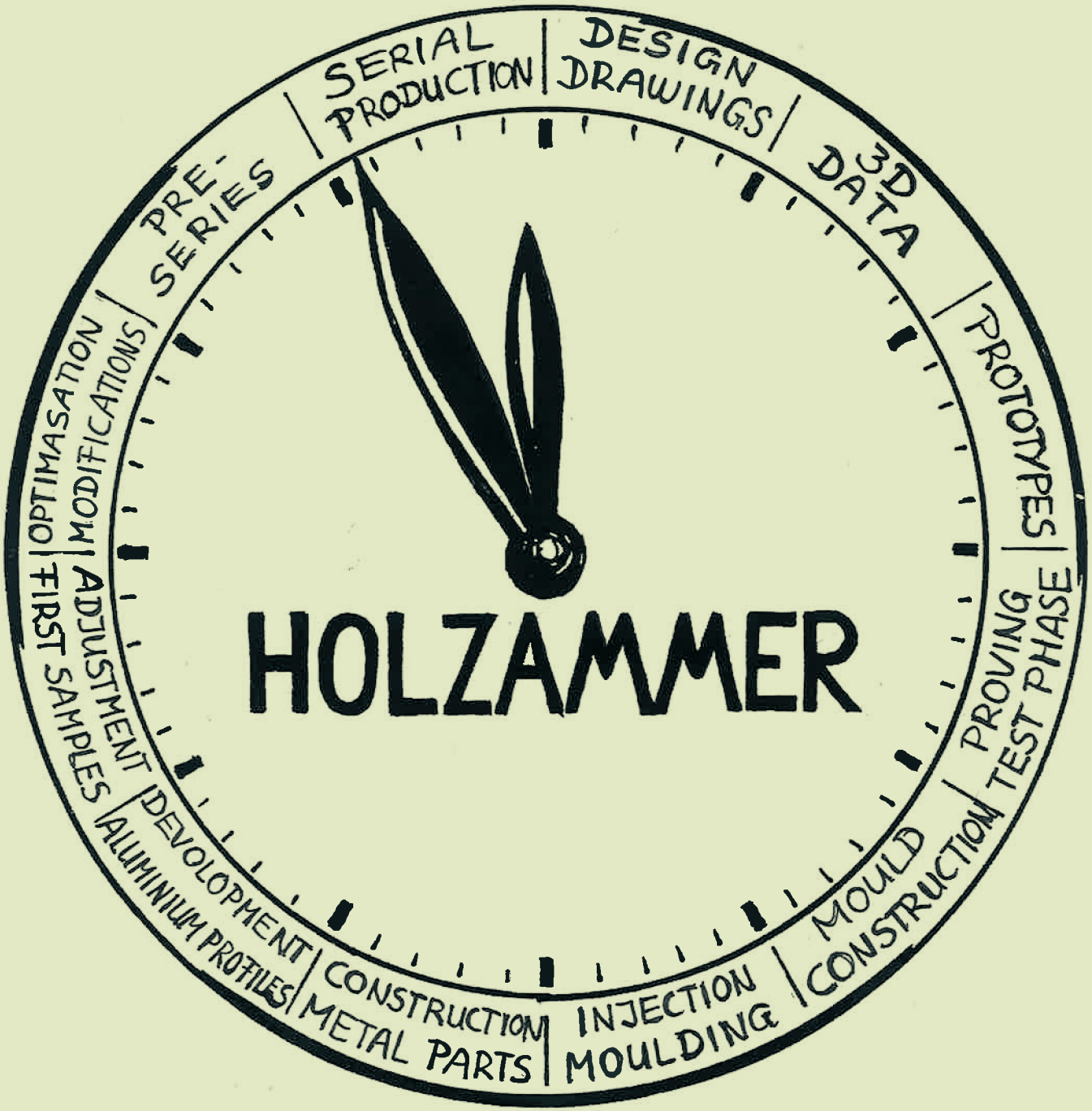

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Medical Engineering at OTH Amberg-Weiden

Since 2010, the Technical University of Applied Sciences Amberg-Weiden (OTH) has been building competencies in Medical Engineering: in the summer semester 2010, the first Bachelor program in medical engineering was started and thus began the first educational and research efforts in this area. In the winter semester 2014/2015, a medical engineering masters program will begin.

Additionally, high tech laboratory space for medical engineering was also implemented. Additionally to this, cooperative partnerships with regional institutions and medical engineering businesses were begun and are added to on a continual and active basis. For example, the Northern Oberpfalz Clinic PLC, a leader in health care, was integrated as a cooperation partner. Important industrial partners are Gerresheimer AG and Siemens AG Healthcare Sektor in Kemnath.

Primary goals of such collaborations are dynamic reciprocal contact and content exchange between partners which further a cooperative working relationship in the area of medical technology. This can take the form of support in teaching and training, the conducting of presentations, and the integration of contract partners in actual classes or seminars. This cooperation enables expert focus and scientific exchange in practice and theory which in turn creates multiple positive effects for both education and business in the field of medical engineering. Thus ensuring not only highly competent employees are educated regionally but also that these employees remain in the region with good long-term employment perspectives. A clearly mutually beneficial outcome. Quality improvement and efficiency in both goal oriented and need oriented patient care is also ensured due to close collaboration with clinic partners. New technologies, for example, can be tested hands-on in the OR and developed further.

An important contributing factor to the quality of a technical educational program is certainly dependent upon how current and how well a lab is appointed. Here also the OTH has high standards: in 1,100 m≤ of floor space with several modernly appointed and comprehensively specialized laboratories offering students excellent educational environments as well as applied research facilities. A class 7 clean room (according to ISO 16644-1) with an injection molding machine, an area designated for radiology and nuclear medicine and a complete teaching and research operation room are part of these facilities. Photos in the attachment will give you a better impression. More detailed information as well as video material you can find under the title Research and education tab on our website as well as information about the individual programs of study:

Laboratories:
http://www.oth-aw.de/einrichtungen/labore/labore_fakultaet_wirtschaftsingenieurwesen/labore_medizintechnik/

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X-Ray and Nuclear Imaging Laboratory ■

Teaching and Research Operating Room (OR) – Concept and Aims

Operative care is developing rapidly. New minimally invasive techniques and increased use of imaging are changing workplaces radically. The requirements in such rooms depend on clinical use and are very specific, especially when it comes to facilities and equipment. It is only with a comprehensive understanding of workflow, a careful and forward thinking and comprehensive planning with all involved, that a successful implementation of, for example, hybrid OR and modernly integrated OR are at all possible. As a result several new related issues will occur which can be explored in the Teaching and Research OR:

- Application and Use of Intraoperative Imaging
- Technologies, e.g: OR table and imaging and not least medical engineering and information technology (DIN 80001-1)
- Hygiene and air flow technology (DIN 1946/4 2008)
- Medical Technology Planning
- Ergonomic concerns and suitability of use
- Workflow and efficiency

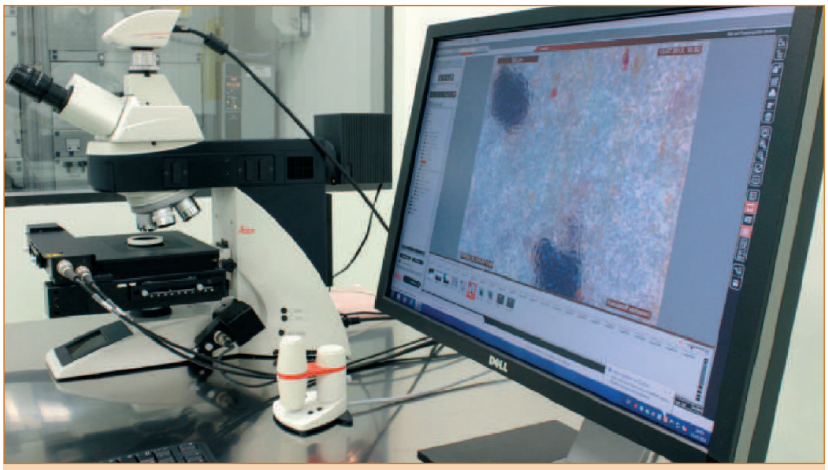
Demonstration in the Teaching and Research OR for students ■

Therefore a modern hightech Teaching and Research OR has been established at the Technical University of Applied Sciences (OTH) Amberg-Weiden. This OR includes the full functionality of a "real" clinical operating room including ventilation and air conditioning and is dedicated exclusively to teaching and research. The close connection to the Medical Engineering Program and the collaboration with regional clinical partners builds an excellent foundation for research and training. This setup enables comprehensive work on various aspects of systems integration and training of project engineers as well as service experts leading to the realization and implementation of ideas and visions of different users in an operating room. OTH Amberg-Weiden provides unique conditions to position itself as an innovative center in the Healthcare and Medical Engineering Industry. ■

The Technical University of Applied Sciences Amberg-Weiden operates a class 7 clean room in accordance with DIN EN ISO 14644-1.

Processes along the value added chain are carried out, in for example, component manufacture in injection molding, where the process from individual part handling to assembly is analyzed. One of many focuses is, among other things, particle generation.

Due to countless medical and pharmaceutical businesses located in close proximity to to the area, the OTH Amberg-Weiden boasts to be an application oriented education and development destination which actively supports the transfer



Microscopic Analysis in the Cleanroom ■

Cleanroom with injection molding machine (collaboration with Gerresheimer AG) ■

and exchange of expertise and best practices. Students receive both engineering and business competencies in clean room technology designed to meet growing and dynamic industry needs and requirements.

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Competence in laboratory and hospital construction

With over 6.000 successfully performed projects HT LABOR + HOSPITALTECHNIK AG is one of the world's leading project and manufacturing companies for room systems and their components in the field of laboratory and hospital construction.
Our experts are advising national and international customers and partners. Our projecting experience of 50 years and constant transfer of expertise create the basis for the successful execution of most diverse construction projects and their specific requirements.

To pursue the state-of-the-art trends and to carry on our own developments is of utmost importance to us. This is why we cooperate closely with the OTH Weiden-Amberg as a member of their Partner-Circle and manufacturer of their research OR. Thus we are able to develop our own products steadily according to the latest findings of medical technology. ■

Challenge OR Planning

The best possible treatment of the patient and the protection of the staff, due regard being given to economical aspects, are a core

Research OR at OTH-Amberg-Weiden ■

area of the planning process. Not only the investment level and the structural circumstances influence the OR design but also the workflow process of the operation mode.

Central to medical alteration are diagnostic systems, imaging procedures, data integration and documentation, all of which have a big impact on our new developments and system adjustments.

Furthermore the hygiene standards, climate regulations, radiation protection and the country-specific building regulations pose a challenge for every project.

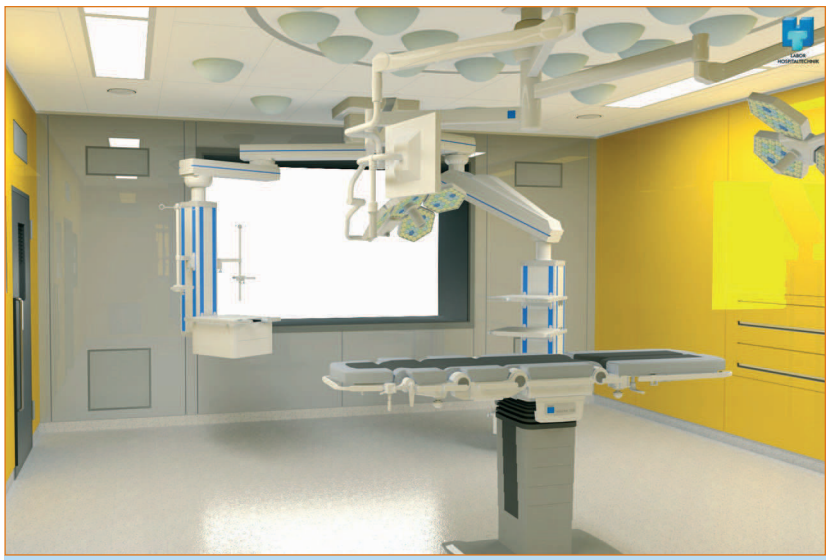
Already in the planning phase HT LABOR + HOSPITALTECHNIK operates as a consulting partner for architects, engineers and customers and therefore supports the highly technical coordination of all parties involved, which is essential for a successful venture. ■

Imagination – Highest Standards of 3D Visualization

Using the latest technology, we have the ability to reflect the ideas and designs of our clients photo-realistically.

Whole building complexes are created virtually on a PC and represent already in the planning phase a realistic image. In this way future users are actively involved in the planning process in order to create a optimized work environment.

With a well-performing construction-kit for functional and extensively equipped areas with demand on high quality regarding surface and function we facilitate the broad range of base estimates over outline and execution planning as well as budgeting and tender procedure to project monitoring and documentation. ■



3D Visualisation ■

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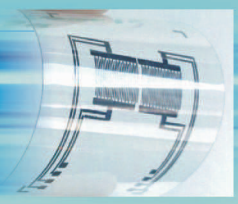

Sensors with Printed Polymers and Nano Materials for the use of Disposables in Diagnostics

Within the last years several sensor chips [1] for portable [2] and stationary [3] analytic devices have been developed by the Heinz Nixdorf Chair of Medical Electronics of the Technical University Munich (HNLME).
These devices cover a broad range of possible applications for environmental monitoring, lab diagnostics and medical testing for both, clinical and home settings. Together with our industrial partners we intend application in cancer treatment and for widespread diseases like diabetes, renal disease and bronchial asthma. ■

Cancer Prevention

In clinical cancer prevention, for instance, such measurements can be done in advance to therapy with small quantities of living tissue and with several drug candidates in order to find the best therapy for each individual patient and thus minimize side effects of chemotherapy. With this technique, vitalities of breast cancer cells *(Fig. 1)*, for instance, and the influence of a chemotherapeutic agent to these vitalities can be monitored.
We investigate these living biological systems in a relatively unaltered environment when compared to the conditions in the human body. Therefore cell culture and tissue culture shall be monitored in a physiological appropriate setting, as a whole. While, when examining single isolated cells instead – which may look as a facile approach for interpreting signals obtained – some information could be lost. Tumor cell sensitivity and tridimensional tissue architecture with intact relations to connective tissue are known to be interdependent when exposed to pharmacological treatment [4]. The cells interact and transfer their information to one another through several mechanisms [5], not yet accessible to direct monitoring or which have unclear relations. Therefore, we try not to specify global cell tissue vitality via a presence of specific messenger substances as so called "tumor markers", but by a monitoring of global parameters through our sensor chips. Such parameters influenced by cell metabolism are e.g. extra-cellular acidification or dissolved-oxygen consumption within the nutrient solution used. These variables are measured locally with pH and pO_2 sensors. The technological task for the creation of these sensors consists now in obtaining reliable data over a specific period using a miniaturized layout.
Due to their needs in long-term reliability and safety within the human body, implants are exceedingly demanding sensor devices. Once implanted, they need a stand-alone energy supply and provide sensor data with simple recalibration facility. These sensor data may be transferred to the outside through telemetry or directly trigger medication with a closed-loop actuator within the implant.
Sensors known up to now are not an entire match to all our needs and hence we do our own development of novel sensor materials. ■

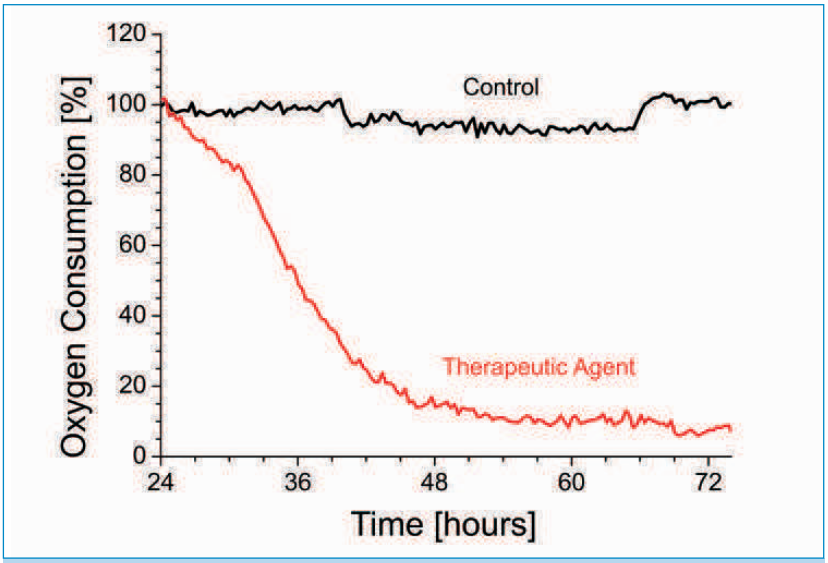

Fig. 1: *Vitality of breast cancer cells decreases after agent CAA (100 µmol/L) (red) is applied, when compared to untreated (black) assay. Dissolved oxygen consumption in cell culture media is measured by the sensor chips to score vitality* ■

Several Sensor Chips

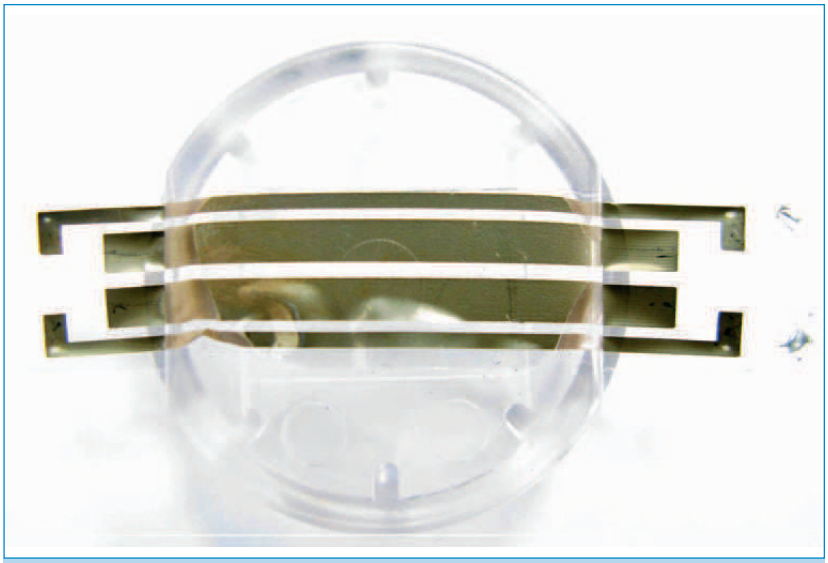

Fig. 2: *Model conductive path is encased with a transparent and biocompatible polymer by injection molding. Miniaturized sensors may be separated from other electronic parts with a fluid- and vapor- resistant feed-through. (Image by Erwin Quarder GmbH, Espelkamp)* ■

Biocompatibility

Physiological compatibility with living tissue is an ubiquitous task within the development of such sensors and devices.

This has to be taken into consideration in the selection of all the materials used.

A lot of common materials and production steps in electronics cannot be applied or have to be considerably modified. This imposes a critical interface between optical or electrochemical sensors in contact with biological material. Subsequent analog and digital signal electronics needs to be encapsulated from biological materials. One example for a hermetically sealed lead-through is given in *Fig. 2.* Here the biocompatible transparent polymer covers a conductive path. ■

Printed Devices

Within our research project „Printed Nanomaterials for Micro Sensor Technology" (PRINTS) we examine several printing technologies and polymeric materials for the applications mentioned above.

Emphasis is placed on inkjet printing with piezoelectric printers. Here tiny ink droplets of 20 pL volume are generated with high frequency from a 30 µm diameter glass nozzle *(Fig. 3)*. On the polymer surface these form single spots and can be combined to a line when drop spacing is accurate. Printing speed is in a range of 1 to 1000 mm/s according to the printer used and large areas can be printed with a multi-nozzle print head.

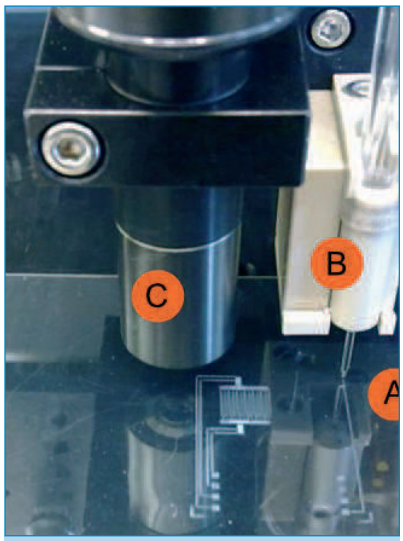

Fig. 3: *Inkjet printer print head made of glass (A) with piezo actuator (B) and process control camera (C). Printing onto a transparent PET film is conducted* ■

Pixel-accurate dosing of materials and the waste-avoiding additive process are decisive advantages of inkjet printing. The latter is crucial with some pretty costly materials like P3HT polymer [6] for pH sensing or with enzymes or specific antibodies, often prized several thousand euro per gram.

Printing parameters have to be optimized for each specific ink within the inkjet printing process, while layout adjustments for the sensor chips are easily done when compared to costs in conventional photolithographic technology. As no masks are needed, an especially advantageous feature in inkjet printing lies in the possibility to do all program changes directly by the PC operating the printer. ■

Isolating and Support by Polymers

In our field of research, disposable sensor chips are widely applicable for drinking water monitoring, or for autonomous tests done by a patient e.g. in case of diabetes.

Inkjet technology may provide convenient and inexpensive production of complete sensor chips for these purposes.

We have tested several biocompatible and transparent polymer films as support materials for our sensor chips as PET (polyethyleneterephthalate) and PI (polyimide). These are commercially available and may be furnished by inkjet printing or other additive techniques with conductive tracks as shown in *Fig. 4.* The same technology may be used to add further components like sensitive materials, thus avoiding machine set-up time.

Polymer solutions in organic solvents are processable by inkjet print-

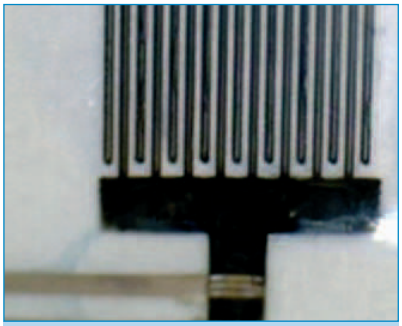

Fig. 4: *All-inkjet-printed interdigital electrode structure (IDES) with biocompatible carbon nano material (black) and metallic conducting path (tan) on a transparent polymer film support* ■

ing as well as mixtures of reactive components. The latter will form a polymer layer after inkjet printing.

As displayed in *Fig.5*, we could separate a crossing of two inkjet printed conductive paths by an isolating polymer layer printed in between. Such layers may also be used as a type of filter to block cross-sensitivity.

Photo resists can be applied by inkjet printing as well, the common UV hardening resist SU-8 tested in our work, however, is not well suited for printing and requires further research. ■

Printing Conductive Paths

The structure size is no limiting factor in our applications, but we need transparent support materials whenever our cell cultures shall be monitored with optical microscopy.

In some applications both, support and conductive path, shall form a flexible unit as shown in *Fig. 6*. That means their mechanical stability must be sufficient to function after having been deformed, as the conductive lines need to adhere to the support tightly not to break internally.

To print on polymer films we use nanomaterial carbon inks and different types of metal-containing inks. As this is purely additive, we may consider even those substrate foils which would lose their optical properties in photolithography or when being structured with laser ablation technique.

With inkjet or screen printing, a structure size of 20 – 100 µm can be achieved, which is fully sufficient for the production of our sensor chips. A conductive path made by inkjet-printed metallic inks has a 2–10-fold higher specific electrical resistance compared to the solid metal.

The practicability of inkjet printing is hitherto limited by commercial availability of inks with certified and constant properties.

While inks of tailor made sensitive materials are specific by nature, inkjet technology would benefit, if inks for standard tasks as conductive paths would be made available on a larger scale. ■

Polymers and Nanomaterials for Sensors

Both, electrochemical and optochemical sensors, are used within the development of our sensor chips. We use electrochemical impedance spectroscopy (EIS) with interdigital electrode structures (IDES). After cultivating living biological cells on these electrodes, an alternating voltage with alterable frequency is applied to obtain data related to cell vitality.

When the IDES are covered with some sensitive carbon nano materials or completely composed out of this material, the pH value can also be measured in aqueous media. We observed a change in impedance depending on a change of pH when low frequencies are used.

Those changes in pH value may also be caused locally by „active“ sensormaterials, depending on other parameters to be measured. In future work we will examine this model for facile diagnostics in case of diabetes and renal diseases.

We have already been using optochemical sensors provided by Presens GmbH, Regensburg, to measure the content of oxygen dissolved in our cell culture media as well as for pH value. These are composed of a fluorescent dye in a complex matrix of several polymers. With printing techniques we can apply these sensor dyes on transparent polymer support – all process steps needed can be implemented to our sensor chip manufacturing.

This yields reduced material usage and smaller sensors which can be precisely positioned. Further development of cell culture microwell plates by our industry partners will profit from this reduction in costs. ■

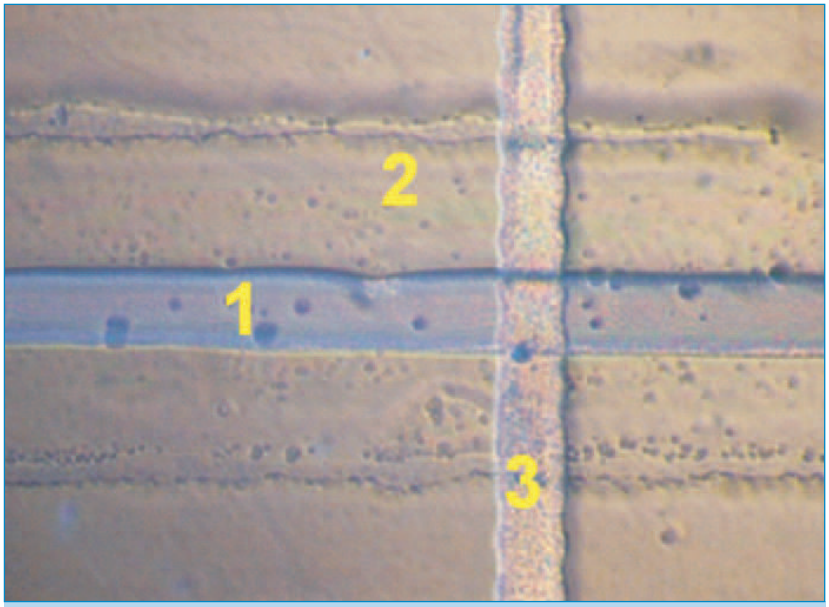

Fig. 5: *Isolation of conducting path crossing in an all- inkjet-printed specimen: Lower path (1) is covered by a polymer layer (2) and thereby isolated from path (3)* ■

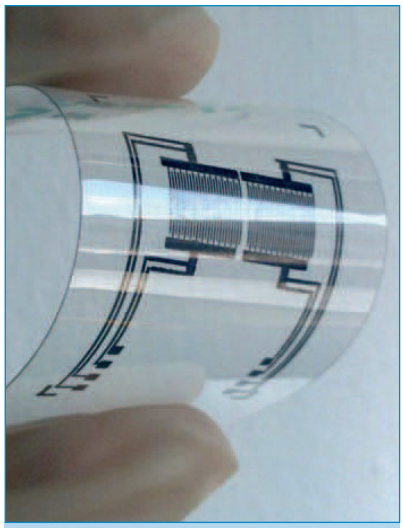

Fig. 6: *Inkjet printed electrode structures on a PET film remain intact and conductive even after repeated distortions* ■

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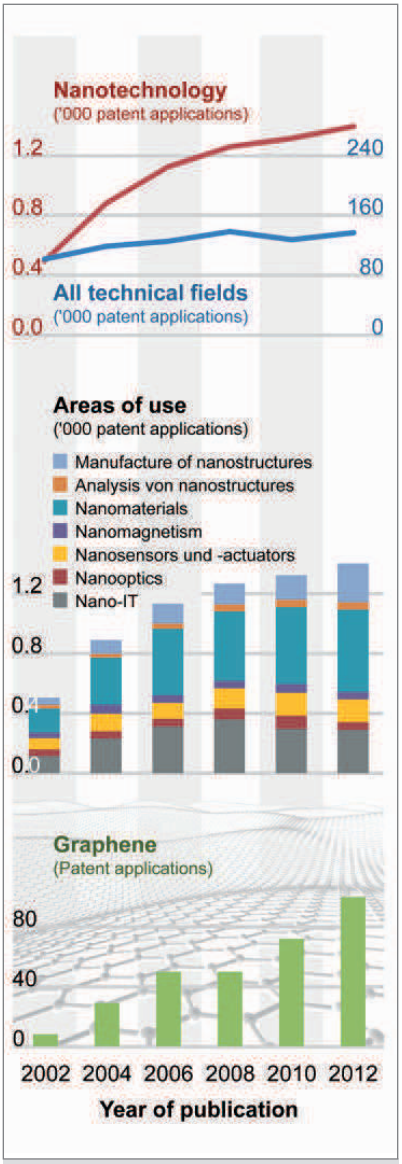
New rules in the race for nanotechnology patents

The competition for nanotechnology patents is hotting up. In this interview the Munich patent attorney Dr. Stefan Rolf Huebner explains why patent offices have so many problems with nanotechnology and what the pioneers in this young field of research have to do if they want to take advantage of the great opportunities offered by nanotechnology patents.

Nanotechnology has benefited from a good deal of investment in the past years. Does that translate into patent applications?
The number of patent applications in nanotechnology is increasing considerably faster than in other fields of technology. In particular, a sharp rise is currently observable in patent applications relating to graphene. This has sparked off a real race for patents.

What role does publicly funded research play in this development?
Roughly a third of the nanotechnology inventions we deal with originate from publicly funded laboratories, predominantly universities. Two thirds originate from companies – not only from large technology companies but also from young start-ups spawned by a university on the back of a promising idea.

Some people are warning that firms are monopolizing the foundations of nanotechnology with their patents and may thereby be hampering progress.
In some cases, perhaps. But it is in the nature of things that the pioneers of a new technical field make many fundamental discoveries that later prove very valuable to the whole field. Consider biotechnology, which was probably in more or less the same position in the 1980's as nanotechnology is today. At that time Mullis and colleagues discovered the PCR (editor's note: the polymerase chain reaction, for which the patents were sold to Hoffmann-La Roche for 300 million dollars). The best protection against becoming blocked by other companies' patents is to have a strong patent portfolio of one's own.



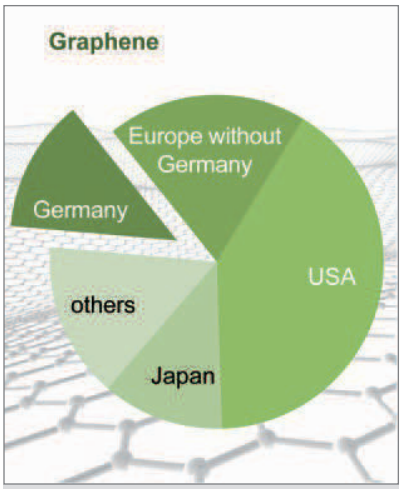
Patent applications newly published annually at the European Patent Office. Source: European Patent Office data, 2013 ■

What do patent applicants have to beware of in nanotechnology?
The greatest challenge facing patent applicants in nanotechnology is the fact that they often break new ground not only in technology but also in patent law.

What do you mean by that? Patent law is surely the same for all research disciplines.
Not at all. European patent law draws a distinction between, for instance, chemical substances and technical devices, a distinction which, incidentally, can quickly become absurd in nanotechnology: Is a nanorobot made up of a single macromolecule, a substance or a machine? But even more importantly, patent law only sets out the general principles; case

law develops these further for the individual technical fields. Let's take an example: According to the law it is only possible to patent something that the 'average person skilled in the art' does not already regard as obvious from the state of the art. But, you tell me, who exactly is an average person skilled in the art of nanotechnology? And what does he regard as obvious? In conventional mechanics, electrical engineering, chemistry, and so on, patent offices and courts have been answering such questions for many decades in numerous individual cases, and there is standard literature that analyses and systematizes this case law. In nanotechnology, on the other hand, there are only relatively few decisions so far. The field is still in its infancy.

So how can patent offices actually assess nanotechnology inventions?
In the absence of genuine nanotechnology case law, patent examiners try to find analogies to conventional technical fields which often fails. For example, reference is repeatedly made to the 'downsizing' argument, which is derived from mechanics and states that merely making an already known device smaller does not constitute an invention. That may well make sense in the case of a conventional technology. For example, it should be obvious to equip a tablet computer with a smaller screen if the market demands handier devices but the situation is very different with nanotechnology. The issue here is the new properties which materials can assume when shrunk to the nanoscale. Carbon in the form of graphene is an outstanding electrical conductor; nano-gold is a semiconductor. It's about the new possibilities offered by these new properties, and the ways of exploiting them. The old downsizing argument does not apply here. This is only one example, of course, but it shows that we need separate rules for nanotechnology.



Origin of the applicants of the European patent applications on graphene published in 2012.
Source: European Patent Office data, 2013 ■

What advice do you have for inventors until such rules come into existence?
To take advantage of this void and fill it with their own arguments – why their own concrete idea satisfies the patenting criteria very well, and why its particular implications justify a particularly broad protection. Those who exploit this opportunity, argue well and don't give up have the chance to achieve even more than in conventional technical fields.

Finally, what is it about nanotechnology that fascinates you?
I came across nanotechnology as a young graduate studying for a doctorate in biophysics. It has stayed with me ever since. What fascinates me as a patent attorney is that, more than virtually any other new technology that preceded it, nanotechnology questions established concepts of patent law. It is great fun rethinking these concepts from a nanotechnology perspective.

The interviewer was **Bernd Müller**.

Dr. Stefan Rolf Huebner *is one of the leading European experts in the field of nanotechnology patent law. The physicist and patent attorney advises and represents some of the most important companies and research establishments at the leading-edge of nanotechnology in Europe, Asia and the USA.* ■

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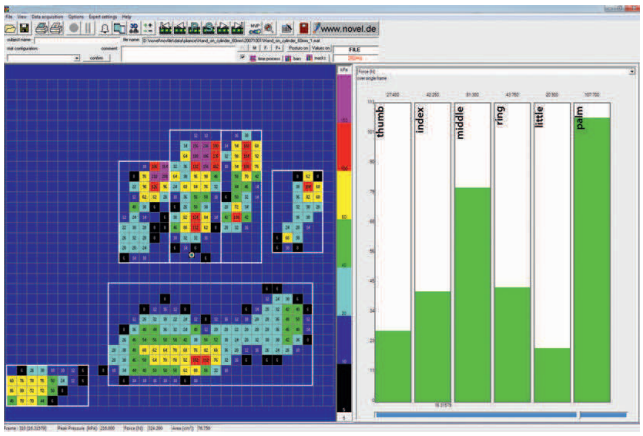
NEWS: Functional Hand Diagnostics



Manugraphy software depicting the forces exerted upon the different areas of the hand

The **manugraphy**® system newly developed by novel offers a key advantage over the conventional systems. Up to now, functional hand diagnostics could only quantify the total hand force, for example with a dynamometer. The new **manugraphy**® system is able to determine the gripping force of each single finger and even the phalanges, both in static and dynamic conditions.
On the basis of this detailed information, it is possible to achieve a truly objective biochemical analysis of the hand. Such an analysis provides important information for the physicians asked to give a medical report on the traumatic or degenerative alteration of a patient's hand. These reports may be used to assess a person's working capacity, a change of job, or even an early retirement.
manugraphy® is a further advancement of the measuring systems developed by novel GmbH in Munich. For over 25 years, novel's systems for foot diagnostics (pedography systems: pedar® and emed®) have been used successfully in hospitals and research laboratories world-wide.

Subject undergoing manugraphy analysis ■

The **manugraphy**® system is equipped with a biofeedback system for use in physiotherapy and rehabilitation. The patient is able to carry out different gripping exercises independently, and therapy results can be assessed and objectified.
In 2014, novel will once again be a co-organizer of the international Expert Scientific Meeting (ESM) in Cambridge, MA, USA. In doing so, novel aims to further promote biomechanics research into mechanical loading. Shortly before the World Congress of Biomechanics (6-11 July), in the first days of July, leading experts from science and research will meet in Boston to discuss the newest findings in basic and applied research. Themes to be discussed will include: in vivo loading on the joints and under the feet, dynamic loading during sports, and pressure distribution on the surfaces of seats, handles and tools, etc. ■

Relevant links:
www.esm2014.com
www.novel.de
www.manugraphy.com

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Novel Methods of Visualization in the Operating Room: Real-Time Tumor Identification for an Improved Therapy

Intraoperative imaging is becoming increasingly important for surgical interventions and represents one of the main sources of information in minimally invasive interventions for the surgeon. Exact differentiation between healthy and cancerous tissue as well as intraoperative visualization and localization of both blood vessels and tumors offer great potential in the removal of cancerous tumors in the bladder. The Institute of Micro Technology and Medical Device Technology (MiMed) at the Technical University of Munich is currently developing the Image Processing Unit (IPU), a new device allowing the surgeon to interactively utilize image processing technology in the course of surgery.

System Image Processing Unit

Image-guided surgery

Today image data in medicine is not only used for diagnostic analysis prior or after medical interventions but also intraoperatively in order to acquire information about the current operational area. Among such systems are miroscopes, endoscopes or ultrasound.

Endoscopes consist of a rigid or flexible tube, a light delivery system to illuminate the region of interest and a lens system transmitting the image to the viewer.

The first endoscope was developed by Philipp Bozzini about 200 years ago in present-day Germany. However, in contrast to conventional endoscopes, current systems are mostly used in combination with cameras enabling digital processing of the image data. These cameras deliver real-time high resolution images of the interior of the human body, which are presented to the surgeon on monitors.

Endoscopy is one crucial imaging method in various medical disciplines, as for example in applications in the gastro-intestinal system, ear-nose-throat (ENT) medicine, skull base surgery, neurosurgery or urology.

Because direct sight to the operational area is obstructed, in many minimally invasive interventions the surgeon is directly observing the video image displayed on a monitor. The video image is therefore the most important intraoperative source of information demanding both high color fidelity and accuracy with the original image.

Numerous algorithms are available that allow robust post-operative extraction of characteristics in medical image data. Such characteristics are, e.g. changes in color, highlighting of edges or measurements of surfaces and volumina. ■

Urinary bladder tumors and photo dynamical diagnostic

In many applications of medical imaging, not only one modality, but several imaging modalities are utilized, where each of them provides specific information. In early diagnosis of urinary bladder tumors, endoscopy is applied with both, a white light source and with a fluorescence light source as photodynamic diagnosis (PDD). During standard endoscopy with a white-light source characteristics such as blood vessels are clearly visible and can be used for orientation. Cancerous tumor tissue representing the region of interest can, in contrast, only be poorly distinguished. For that reason, fluorescence endoscopy is applied in addition to standard white light endoscopy. A comparison between both modalities is depicted in *Figure 1a and 1b)*. For the use of fluorescence endoscopy, the patient is administered a contrast medium that specifically binds to tumor tissue and re-emits light upon light excitation. Tumor tissue can thus be clearly distinguished from healthy tissue. However, problematic is, that both modalities can only be applied alternately by manual change over, and while utilizing one modality, the information of the other modality is not available. Simultaneous superimposition of both modalities could shorten intervention time and increase safety of the medical treatment,

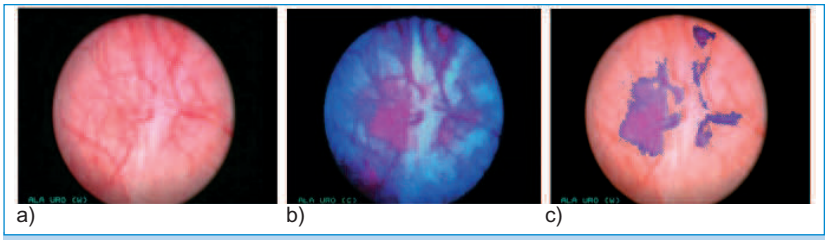

Fig. 1: *a) Recordings of the bladder with tumor tissue under white light endoscopy, b) as photodynamic diagnosis, c) superimposition of both modalities using the Image Processing Unit* ■

because both blood vessels for orientation and the cancerous tumor tissue are depicted together in the same image at the same time *(Figure 1c)*. ■

Image Processing Unit

To overcome the above described deficits, a new method for real time intraoperative video editing was investigated at the MiMed. The prototype Image Processing Unit (IPU) is specially designed for medical applications. For providing intraoperative image data, up to three imaging equipment (e.g. endoscope, ultrasound) can be connected to the system. Video outputs enable the connection of up to three monitors for better visualization in the OR *(see figure 2)*. To facilitate handling, the IPU is permanently installed on a clinical cart which provides an additional touch monitor for intuitive handling. Thus, the IPU can be placed and installed in the OR safely. The connection with the required imaging instruments for the operation as well as with the stationary monitors in the OR can be accomplished rapidly, due to the easily accessible video ports.

The system is controlled via a touch monitor. Video ports are visualized in nodes. Each node provides a preview window which shows the applied video. Thus, the video source connected is immediately visible for the user. For each connected monitor, a monitor node is displayed at the user interface. Intuitively - similar to the handling of smartphones and tablet PCs – one can drag the video from input nodes to monitor nodes. In this way, the current video is visualized in the preview window of the monitor node and the monitor connected at the same time. This property allows – inter alia - an easy exchange between the monitor displays in the OR.

Algorithms, extracting specific characteristics of the video data, are visualized in nodes, too. They also feature small preview windows. Due to these, the user has a direct visual feedback of the applied algorithms and the way they enrich the video data with information. In case of applying several algorithms successively, these features allow a visual control.

The simple drag and drop of preinstalled nodes allows medical personnel to find the ideal individual patient setting of parameters to enrich the video data with the required information. Adjustment, interconnection and combination

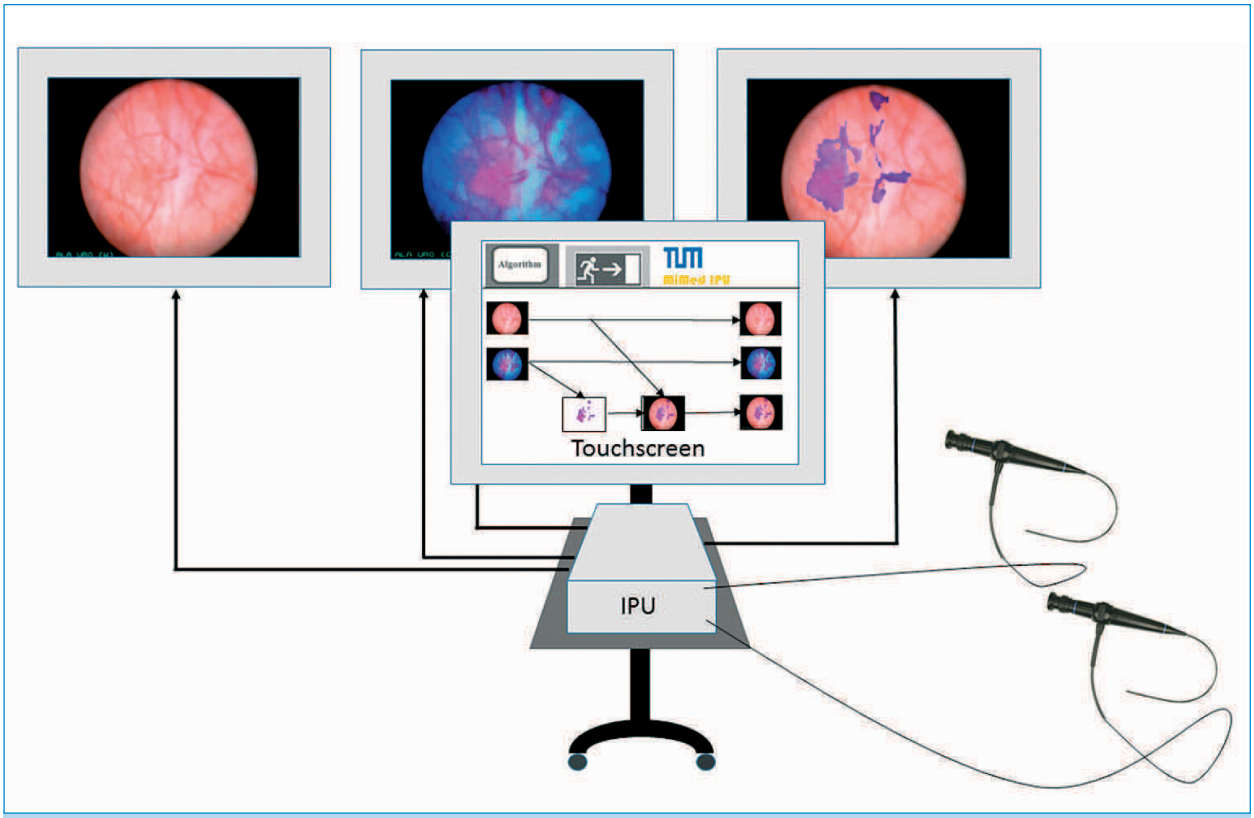

Fig. 2: *Schematic structure of the Image Processing Unit* ■

Fig. 3: *Structure of the Image Processing Unit in a test scenario under OP conditions* ■

of algorithms can be performed at runtime. In this way, e.g. the adjustment of algorithm properties can be performed without any discontinuation on the monitors.
The Image Processing Unit is characterized by the following features and therefore stands out from all known systems:

- It is the world's first system for intraoperative real-time image processing of colored HD images, providing several signal inputs at a time and an interconnection possibility to multiple signal outputs. The system has the following features:
- Up to three video signals can be processed simultaneously.
- Up to four monitors can be connected for visualization, one serving as a control input.
- The applied video image data can have a resolution up to 1080p (HDTV) in three color channels.
- It is operated via a touch monitor and parameters/settings can be adjusted at runtime without interrupting the main display.
- Each processing step, the video signal passes, is visualized in preview windows.
- Third party algorithms (Matlab, C, C++) can be included as long as they feature predefined interfaces.

The investigated system is the first system that solves the following disadvantages of the state of the art adequately and provides the following benefits:

- The system provides enriched image data of the region of interest during the operation without interruption of the displayed video on the monitor.
- The system's usability is simplified such that medical stuff without deeper programming experience can develop new nodes by interconnecting preinstalled algorithms. In particular, parameters of the algorithms can be selected and adjusted quickly and individually to the patient through the preview windows of each node.
- Own algorithms can be integrated easily. These can be implemented in different programming languages, as long as they feature the same application programming interface (API). ■

Conclusion and outlook

The assistance systems for real-time image processing, described in this article, point out the opportunities available in the fields of intraoperative imaging. In future it might be possible to provide and analyze 3D views of the region of interest during the operation.
The system is clinically evaluated regarding its ease of integration and workflow. New findings are incorporated and ensure a usable assistance system for real-time image processing.
In the next years, there will be more and more assistive functions, that will amend the features of already existing systems. In the future MiMed will continue to improve the possibilities of diagnostics and therapeutics through the use of modern technology and close collaboration with clinical partners. ■

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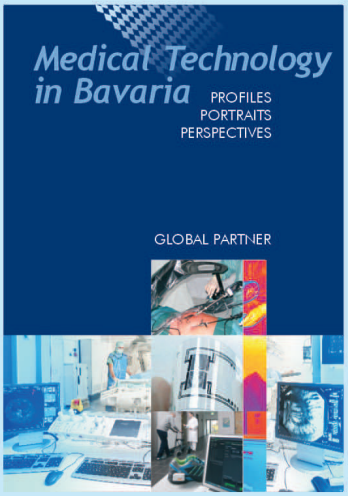

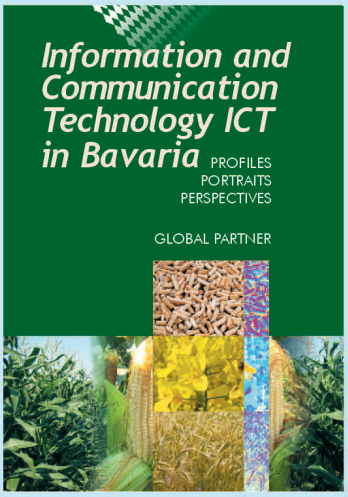

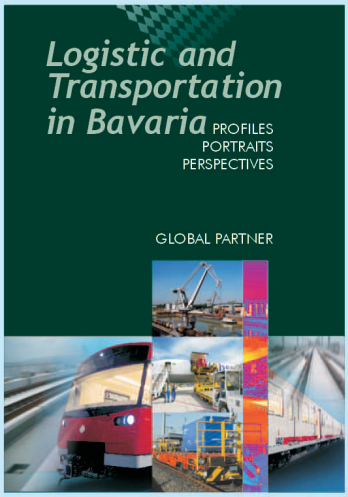

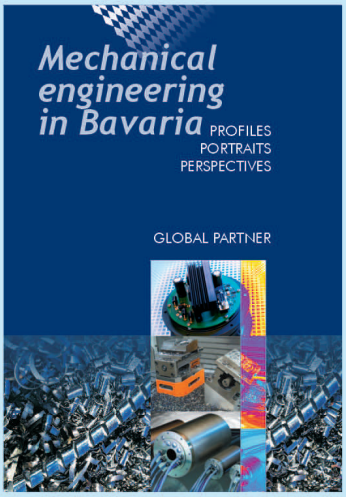

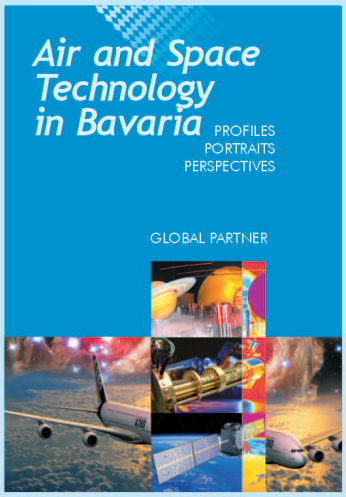

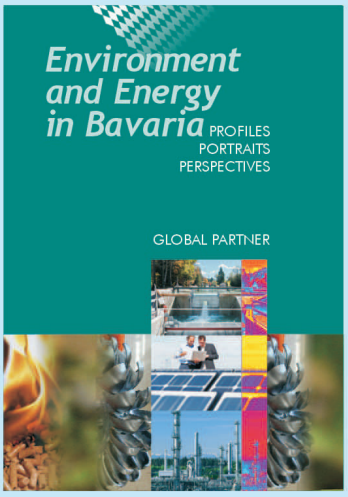

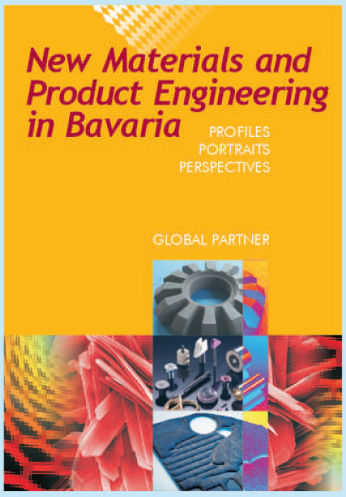

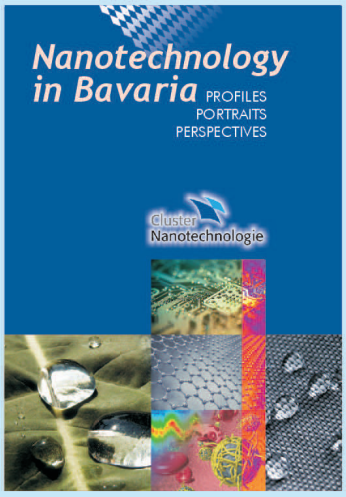

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