Medical Technology in Bavaria

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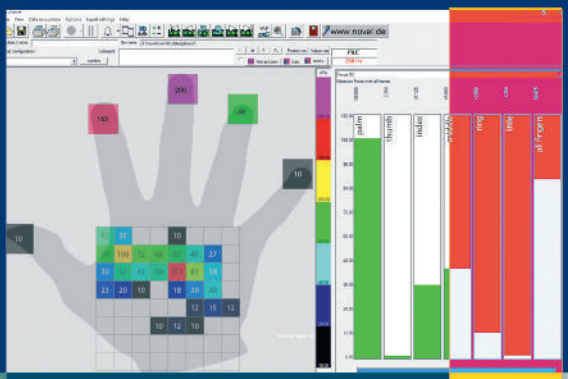

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art science

Editorial

Standard 4.0 – Medical Technology on the Test Stand!

The age of 4.0 has taken hold in nearly all areas of life and with them medical technology as well.

New paths for diagnostics and treatment are now appearing and making revolutionary changes, making never-before-seen treatments possible. What sounds futuristic today can be already be reality today.

You can find exciting articles i.a. with information about the topic 4.0 and healthcare in the appendix:

- What options does the leading edge cluster Medical Valley offer in terms of research facilities and support for start-up-companies?
- Why is "Made in Bavaria" such a success story in exports?
- How can the Project INSYDE help with the development of an intelligent care system?
- Where are technologies from the aerospace field used in medical technology?
- What regulatory perspectives does software provide as a medical product?
- Medicine 4.0 – the way to a healthcare system ready to meet the future?

How can medical devices from different manufacturers be made real-time capable and networkable?

- What new legal provisions for medical products take effect at the European level?

Learn "first hand" knowledge and insight from research, development and application!

Walter Fürst, Managing Director

This publication can also be found on the internet at www.media-mind.info

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Table of contents

bayern innovativ

SOLUTIONS.
FOR THE FUTURE.

Bayern Innovativ GmbH promotes an open exchange across industries and technologies and supports small and medium enterprises in their innovation process. It connects potential partners from industry and science in five focal areas:

www.bayern-innovativ.de

) digitalisation.

) energy.

) health.

) material.

) mobility.

Bayerisches Staatsministerium für
Wirtschaft und Medien, Energie und Technologie

Greetings!

The global potential for innovation in the healthcare sector is immense Innovation will help to make care more effective and efficient. „Big Data“ will certainty hold great leverage in this process.

„Big Data“ approaches require large, representative databases (Omics, images ...), contains wich a lot of information about health and progression of diseases. However, in their digital form these databases implicitly describe a large amount of medical know-how that could be made available for worldwide use. Additionally, rapid development and dissemination is leading to so-called mobile „quantified self“ devices or „wearables“ (watches, fitness bracelets, T-shirts, monitors for diabetics, etc. with integrated sensors and interfaces to mobile phones as well as cloud-based databases), through which even people themselves continuously ‚feed‘ data via appropriate health applications into their electronic medical records. Through analyzing these databases and combining data knowledge can be generated that would be crucial to the prevention and treatment of patients. These „Big Data“ concepts must be developed. In particular, methods for the semantically annotated integration of various heterogeneous databases have to be established.

The theme „Big Data“ plays a central role in the development of the so-called „Precision Medicine“, which will allow treatments specifically tailored to the individual patient. For example, drugs are often prescribed for the treatment of tumor diseases. For another group it has no effect, whereas for a third group mainly negative effects arise. It is to be expected that through „Big Data“ approaches, one could predict whether the drug selected to treat the patient would have the desired positive effect, due to more information available about the patient and especially from comparable patients considered in the therapy selection. This would be an enormous improvement for the treatment of tumor patients and would additionally avoid the expensive administration of drugs to many patients that do not have a chance of producing the desired therapeutic effects. In very general terms, „Big Data“, in combination with molecular medical treatment, helps to develop a better understanding of disease and health at a cellular and molecular level.

The processing of all these issues requires transdisciplinary work between science and industry. The platform Digital Medicine/ Health within the Center for Digitization Bavaria is structured to make this possible in the future. Additionally, privacy regulations have to ensure that the benefits associated with the topic „Big Data“ can actually be used for patients. Data protection must also provide opportunities and should not be used solely for the avoidance of malpractice.

Prof. Dr.-Ing. Erich R. Reinhardt

Executive Chairman
Medical Valley EMN e.V.

Forum MedTech Pharma – Network for Innovations in Health Care

With more than 600 members, the Forum MedTech Pharma is one of the leading cooperation networks in Europe. By offering a broad portfolio of network activities, it supports research institutes, companies, clinics and other actors within the health care market: Individual consulting, expert talks and conferences about technological developments are supporting members to select knowledge and to scout trends. Expertise in regulatory affairs, intellectual property rights and market access as well as several further education courses about medical technology are also offered by Forum MedTech Pharma.

In the further development of innovations, cooperation agreements are an important factor for giving companies and research institutions a competitive edge over their rivals. It was on this background that the Forum MedTech Pharma e.V. was founded by the Bavarian State Government back in 1998. Since that, the association acts as a hub between science, business and research.
The Forum MedTech Pharma focuses on the identification of skills and potentials in the fields of business and science. The aim is to initiate innovations in health care and thus constantly increase the efficiency and quality of medical care. All of the players involved with health care are integrated into this process: Research and development, production, clinical applications as well as cost bearers and self-administration. Bayern Innovativ GmbH operates the Forum MedTech Pharma via a business management contract, which is now unique in Germany in terms of bringing together potential cooperation partners. ■

Forum MedTech Pharma offers a unique network for all actors in the health care sector in Europe. Individual consulting and special offers for members are part of the broad range of the organisations profile. ■

Areas of thematic focus and projects

Within its theme-based networks, the association focuses in symposia and expert conferences on mobile & digital health, medical equipment, biomaterials, diagnostics, health telematics, hospitals & clinical trials and the health care system. Regulation-related areas, however, such as approvals or market access, for example in the USA, China, India and Arabia, are also discussed by experts in workshops.
The circle from scientific principles to marketing is therefore closed – an important feat in an industry with the highest proportion of exports in Germany. Accompanying trade exhibitions, as well as the association stand at MEDICA, offer small and medium-sized companies especially the opportunity to present their innovations in a targeted manner. Further

The medtech community will meet again from June 21-22, 2017 at the international congress MedTech Summit in Nuremberg.
For the first time the event takes place in cooperation with MT-CONNECT, the new fair on medical technology ■

areas of focus for the network activity include the field of education and training in medical technology.
From 2011-2013 Forum MedTech Pharma supported the national strategy process 'Innovations in Medical technology', initiated by the federal government. At the moment, the network is engaged in the setup of the BMBF-webpage www.medizintechnologie.de.

The network

With about 600 members, the Forum MedTech Pharma is one of the leading cooperation networks in Europe. Its member structure – 68% companies, 10% research institutes, 9% hospitals, 4% law firms and lawyers and 4% associations and insurance funds – reflects the heterogeneous nature of medicine and healthcare. Along with Germany, the association has members in ten other European countries, as well as in the USA, Japan, India, China and Hong Kong. In the eighteen years since it was founded, the Forum MedTech Pharma has welcomed about 22,000 delegates at 230 of its own expert conferences. The speakers of that conferences support the activities of the Forum MedTech Pharma free of charge with their expertise – just like the entire board of management, chaired by Professor Michael Nerlich. ■

Forum MedTech Pharma e.V.

- *Independent network for innovations in medicine*
- *600 members from business, science and the healthcare sector from 16 countries*
- *Focal areas, including electronics & IT, mobile & digital health, medical equipment, biomaterials, diagnostics and clinical testing, regulatory affairs, markets and products, education and training*

MedTech Summit
Congress and Partnering

21 and 22 June 2017

Platform for Trends and Technology
With more than 1,000 participants, the international MedTech Summit congress is one of the most important conventions of the health industry and has established as a key event in Europe since 2008.
Developments in the fields of Medical Technologies, Diagnostics, Digitization and Mobile Health have been among the core items of the congress programme for many years. Besides technological contents, the congress increasingly also focuses on the fields of Innovation Management, Regulatory Affairs or Strategic Partnerships.

In Cooperation with MT-CONNECT
Besides lectures on technology trends in the congress area, discussion forums and short lectures will be part of MT-CONNECT. The new fair on medical technology will address market topics for funding and financing as well as reimbursement.

Cross-linked in an optimal way
The partnering event enables efficient B2B networking between all participants of the MedTech Summit as well as exhibitors and visitors of MT-Connect.
Select your discussion and business partners online using company profiles and interests, and arrange on-site targeted talks in the meeting area.

www.medtech-summit.de

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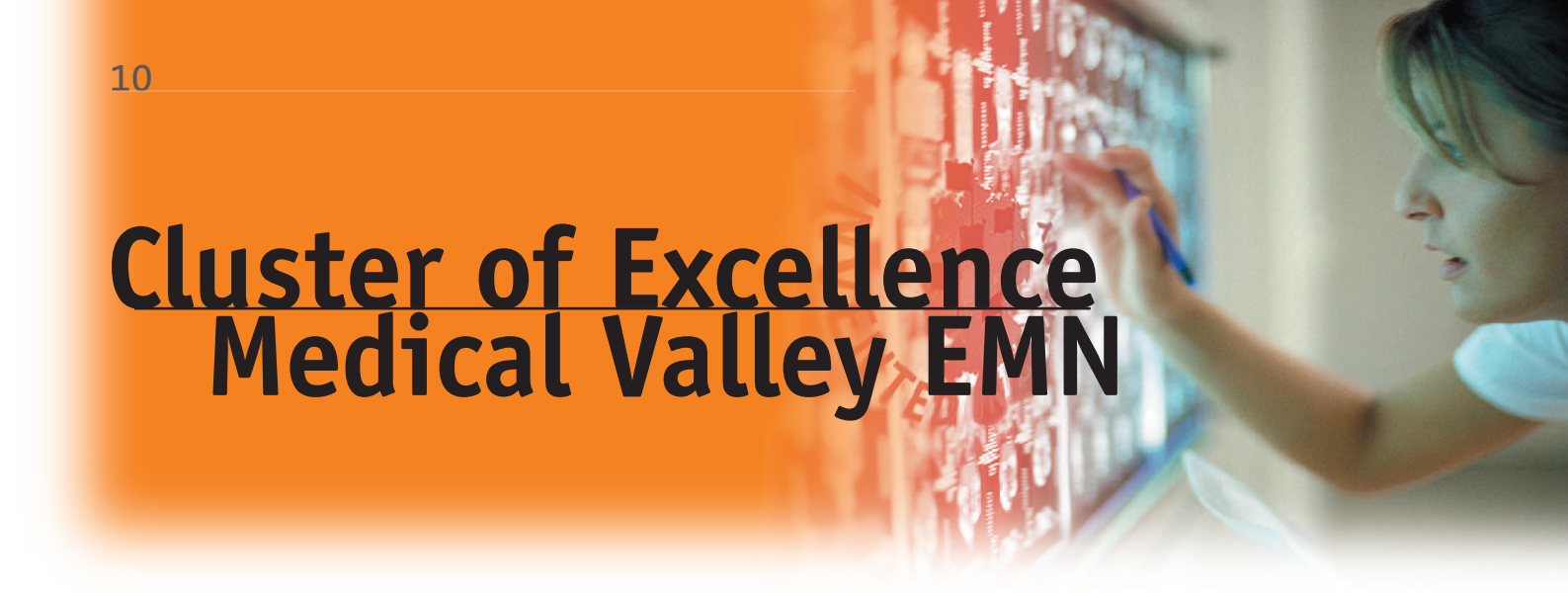

Cluster of Excellence Medical Valley EMN

The Medical Valley European Metropolitan Region Nuremberg (EMN) is a leading international cluster in medical technology. Here, there are not only highly specialized leading international research institutions, but also many emerging companies. They work closely with world-renowned health research facilities in the cluster in order to find solutions to the challenges of healthcare of today and tomorrow.

The cluster is so outstanding that in January 2010 it was nominated as national Cluster of Excellence by the Federal Ministry of Education and Research (BMBF).

Since 2007 Medical Valley EMN e. V. operates as a uniting cluster management organization. It currently has more than 190 members from industrial, science, healthcare, network and political sectors. The key tasks of cluster management are the development, coordination and marketing of the cluster. We measure our success by asking these fundamental questions:

- Are we able to stimulate new ideas, projects, and foundations?
- Do we obtain R&D funding for innovative projects?
- Do our services catalyze the innovation of ideas?

Medical Valley Center Forchheim – new innovation center opened Q3/2016 ■

- Do our activities promote the cross-sectoral and transdisciplinary exchange of knowledge?
- Do we strengthen exchange in the cluster and improve cultural cooperation?
- Do we promote creative minds?
- Do we support the internationalization of our partners?

Our services help the commercialization of your ideas. Our offerings include funding-procurement and consulting, foundation support, identification and exchange of clinical partners, regulatory approval and reimbursement, strategic needs assessment and health economics evaluation, open innovation as well as international market access. To provide you with comprehensive support, we incorporate established specialists and experts within the cluster through the „One-Stop-Shop“ principle. Our current specifically-selected activities include the operation of innovation centers in Erlangen and Forchheim, the coordination of the Bavarian Cluster's medical technology (in cooperation with Forum MedTech Pharma), the conducting of the Medical Valley Awards (prize for research teams in pre-foundation phases) and the coordination of the platform „Digital medical / Health“ within the Center for Digitalization Bavaria. ■

MEDICAL VALLEY
Europäische Metropolregion Nürnberg

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Activoris is the German medical device specialist, building up on decades of management experience in the medtech and pharma industry. No matter if you are looking for a manufacturing partner or if you need strategic advice. We take a holistic view on product concepts and put your innovative idea into perspective. We support our clients in setting-up and executing their projects. Due to our management experience of successful fund rai-

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Example: Cerbomed „Nemos“

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For almost 10 years, Chimaera GmbH has specialized in the development of innovative software solutions for medical image processing and machine learning applications. Founded in 2007 as spin-off from the Pattern Recognition Lab at the University of Erlangen-Nuremberg, Germany, the company has consistently extended its core technologies.

Chimaera is a certified manufacturer of medical software in the EU and the USA since 2013. Located in the heart of the Medical Valley, Erlangen, Germany, the company provides business-to-business software services for healthcare companies, as well as customized software for physicians and medical experts in the fields of radiology, oncology and preclinical imaging.

The company offers key technologies for image registration, image segmentation and image understanding, which are required for various medical applications. Chimaera offers these technologies both as OEM algorithm libraries, as well as customized extensions for established medical workstations.

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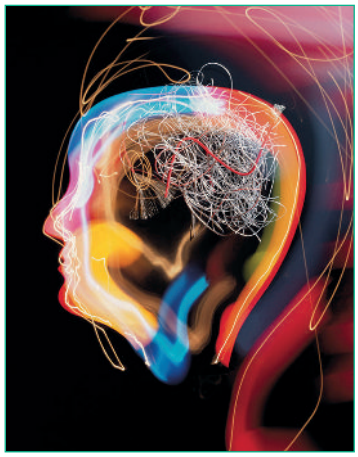

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The Institute of Photonic Technologies of the Friedrich-Alexander University of Erlangen-Nürnberg focuses in research on the application of light and lasers in industry and medicine. In the area of medical engineering, the institute in collaboration with the university hospital, is investigating a wide range of optical methods for fundamental research and clinical applications. These include

research on approaches for the determination of tissue optical properties, the investigation of optical tissue differentiation techniques with the aim to build a smart laser scalpel with a feedback system as well as the use of multispectral endoscopy to identify tumors in the upper intestinal tract.

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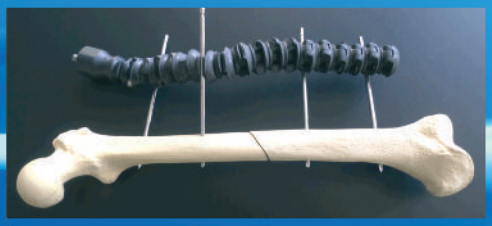

StartUp Company nice!innovations develops new external fixator system „snakeFX“

For decades „external fixation“ performed an outstanding service, as it stabilized fractures in the seriously injured, open fractures and severe joint fractures. For all „external fixation“ systems, four to six bone pins are screwed through the skin into the bone. There is an external holding device (the actual „external fixation“) attached on to the bone pins. Very often, this is what is called the „trauma fixation“, and after a few days or weeks, it is then removed if the general condition of the patient has stabilized. The fracture is then definitively stabilized through the means of plate and screws or intramedullary nails. However, the assembly of „external fixation“ systems currently on the market is enormously time-consuming, error-prone, and can only be reliably implemented by experienced trauma surgeons. Some of the material, as well as „technical“, requirements are often not guaranteed due to the situational or site-related circumstances, and the handling of this fundamentally simple technique in the rush of an emergency situation can often have a limited function. Complications are therefore often inevitable.

The technical invention „snake-FX“ from the Erlangen StartUp company nice!innovations GmbH fundamentally revolutionizes „external fixation“ and its use in orthopedic and accident surgery! It is a completely conceptually new and already well-developed product that is enormously clever, incomparably fast and incredibly simple, and thereby enables a mistake-forgiving stabilization of fractures through an unprecedented „snake“ principle.

A „snakeFX“ consists of 10 - 20 elements that are each constructed from two half-shells. The half-shell above is convex and the half-shell below is concave. The stringing together of 10-20 such elements (depending on the stabilized bone) creates a snake-shaped structure with elements that can be tilted approximately 15° in all directions. These „snakes“ can thus assume virtually any required shape: C-shape, S-shape, wave, etc. The bone pins are screwed into the bone in the same way as in the traditional systems; they are clipped in between the two half-shells and so neither disturbs the placement of the elements nor their stability. Finally, a high-strength tractive member runs in the center of the elements. It primarily provides a certain pretension for the basic stability of the attachment of the „snakeFX“. After the installation of the „snakeFX“, the central tractive element is then tightened and the elements are pressed against each other, which together have two functions: the „snake“ is stabilized due to friction and the half-shells are pressed on the bone pins. This one-step rapid fixation technology therefore enables both the fixation of the „FixEx„ to the bone pins and the stabilization of the „FixEx„ in one single step! The traditional external fixation systems, both of these were done in connection with time-consuming and error-prone assembly operations.

Currently, nice!innovations GmbH is developing snakeFX for series prototypes. For this purpose, more than € 260,000 was collected through www.aescuvest.de by a crowd-funding campaign. Subsequently, nice!innovations GmbH is searching for strategic partners interested in commercializing the product. If you are interested, please contact us. ■

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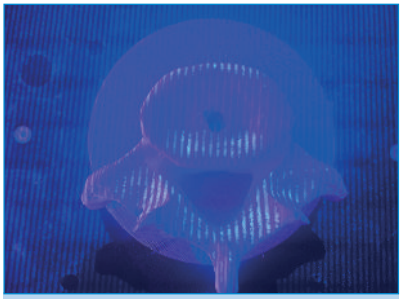
Optical measurement in the field of medicine

Assuring the target geometry specifically for implants

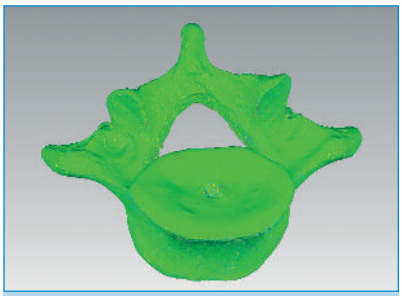
Any objectives can be scanned and measured three-dimensional ■

There are many quality requirements for implants and surgical instruments in the medical field. To reduce tremendous geometric errors, it requires high precision and completely reliable equipment for testing. Optical measurement assures comprehensive recording and examination of the geometry and surface of implants, surgical instruments and further application cases in medical technology. The prerequisites are a large personnel competence of the measurement and special equipment for a professional recording and the analysis of data.



A structural sample is projected on the object to gather the surface with a camera ■

Over 20 years, Descam 3D Technologies has specialized in measurement of medical technology. Therefore, our customers rely on us for their suitable implants preparation and high-precision quality assurance. We measure the object by projecting a sample structure on the work piece. A camera detects the reflective radiation of the object. The result is a three-dimensional cloud diagram. Every single point is comparable with a tactile measurement point. On the basis of the large number of points, a high-precision and three-dimensional image of the implants is created.



The target and current geometry are consist on the complete surface with a tolerance of 0,01 mm ■

The optical measurement enables a precise recording of the entire current geometry of the three-dimensional object. Specialized software enables the detection of defects, which are significant evaluated. On the basis of a 3D false color image, detected geometric defects or variations of specific dimensions of holes, radii or adaption points are immediately visible.

Descam 3D Technologies GmbH is an innovative company and a part of the Autision Group, and are a very interested in new challenges around the medical field of technology. In this case, we are also active in R & D projects. If you have any questions or measurement tasks, you will find further information of our numerous possibilities of our measurement services at www.descam.de

■ Autision Group combines several strong partners with competences in surface inspection, measuring technology and robotics from a single source. The name Autision stands for automation of surface inspection and measuring technology – Automation and Vision. ■

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Made in Bavaria

This year Bayern International is celebrating its 20th anniversary promoting exports under the slogan of "Exploring new markets – around the world in 20 years" and is a key player in the promotion of Bavarian exports. With around 100 projects per year, we support Bavarian companies to explore and tap into new markets.
As a central element in the health sector, medical technology represents a significant growth market – throughout the world and in Bavaria. Bavaria is well positioned in this environment.

10 good reasons for Bavaria

Bavaria offers...

1. Innovation & tradition – Small and medium family-run companies in Bavaria carry out research and development alongside large corporations. Global players in medical technology and the pharmaceutical industry are at home in Bavaria. Some 250 predominantly medium-sized businesses go to show that innovative technology isn't just reserved for the "big boys".

2. Quality & productivity – Bavaria accounts for more than 60% of the entire production of electromedical devices and 30% of the entire production of medical technology in Germany. Bavarian products are in strong demand internationally: The export rate of the Bavarian medical technology industry is around 70%.

3. Research & investment – The Free State of Bavaria has invested some € 80 million in life sciences in recent years. Innovative entrepreneurs and scientists are funded right from the start by the Free State of Bavaria, e.g. with start-up centres and innovation centres specifically equipped for medical technology.

4. Networks that work – As part of its cluster policy, the Bavarian State Government supports network-building between university research and business to the tune of €50 million.

5. Top class medical-clinical infrastructure – 400 authorized hospitals for acute care, 48,000 doctors, 10,000 dentists and 341 occupational or rehabilitation facilities. The Free State Bavaria combines these "hard" location factors in a unique way with a healthy and intact nature, which makes the stay in Bavaria for patients as pleasant as possible.

6. Recovery & well-being – 53 exclusive health spas and health resorts in Bavaria enable rehabilitation and relaxation with gentle treatment methods.

7. A home for patients – The first-rate treatment and understanding care provided in Bavaria by internationally renowned doctors and specialists in all divisions offer an unprecedented network of medical care, tailored specially to the needs of guests from other countries.

8. Shopping & experience – "Live and let live" is the motto of Bavarian conviviality. Bavarian food is a gourmet's delight whilst the cultural scene offers endless leisure opportunities – from Alpine sports to luxury shopping facilities and visits to museums, galleries and opera houses.

9. Pure nature – With superb mountains right at the doorstep, a magnificent low mountain range just around the corner and fairytale-like rivers and lakes nearby, surrounded by forests. Historic cities with original Bavarian charm and cosmopolitan flair at the same time. - In harmony with the environment.

10. International airports – Two modern, international airports in Munich and Nuremberg are global turntables which pave an easy, safe and smooth way into Bavaria for visitors, patients and investors alike.

Meet Bavarian companies at the following international trade fairs:

- Arab Health, January *2017, Dubai/United Arab Emirates*
- Medical Japan, *February 2017, Osaka/Japan*
- Australian Healthcare Week, *March 2017, Sydney/Australia*
- EgyMedica, *April 2017, Cairo/Egypt*
- Iran Health, *May 2017, Tehran/Iran*
- CMEF - China Medical Equipment Fair, *May 2017, Shanghai/China*
- FIME, August 2017, *Miami/USA*
- Medical Fair Thailand, *September 2017, Bangkok/Thailand*
- MessePlus- Trip to Yangon/Myanmar in conjunction with Medical Fair *Thailand*
- Hospital Expo Jakarta, *October 2017, Jakarta/Indonesia*
- MedicAll Mumbai, *October 2017, Mumbai/India*

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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.

Region Mainfranken GmbH/Hub ■

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. ■

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

Region Mainfranken GmbH/Hub ■

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.

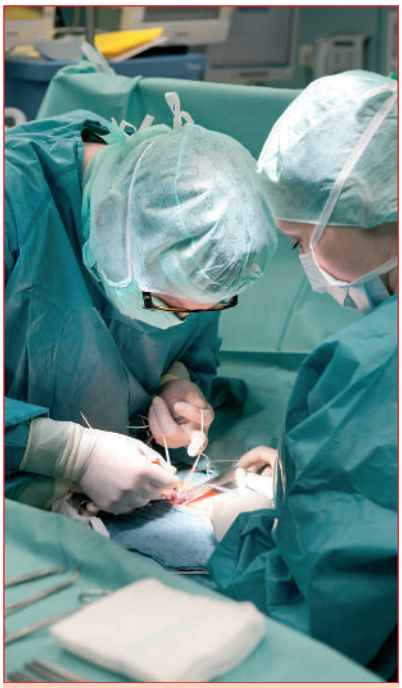
Locally, there are state-of-the-art *Founder and Innovation Centres* available, specially designed for the needs of those starting up medical and biotech companies:

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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Medical Valley offers future oriented solutions for an optimized healthcare system

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.

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.

The extraordinary concentration of companies as well as research and development organisations within the Medical Valley EMN is also proven by the numbers of employees. About 127,000 persons could be assigned to this competence field in the year 2014. With a share of 9.2 Procent of all employees of the Metropolitan Region, about each eleventh worker is connected to the competence field "Medicine and Healthcare". 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 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). Since 2012 the EMN offers - as model region for the digital health industry - solutions for cross-sectoral communication of "medication data", "personalized medicine in the childhood" and "mobile supply file in the rural area".

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

"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

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 ■

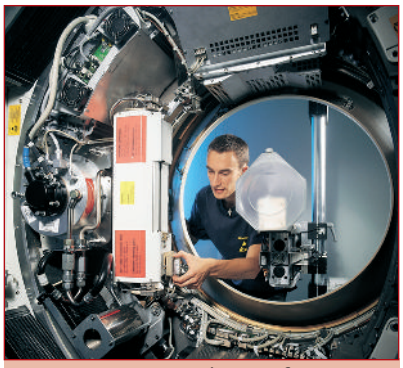
the local economy and academia, and to use the potential of new technologies to increase the efficiency of the health system. The varied initiatives of regional players and the support of the Bavarian state government led to the completion in 2003 of a start-up centre, the "Innovation Centre for Medical 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.
Moreover the new start-up center in Forchheim created an additional offer for companies with focus on Healthcare IT.
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.

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 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". (more than 60 %)
Together with the Forum MedTech Pharma e. V. the Medical Valley EMN e. V. manages the bavarian cluster „medical technology" until 2019. Another strong signal for the medicine site is the planned displacement of the Bavarian State Ministry for Health and Care from Munich to Nuremberg. ■

Solutions for optimal and efficient healthcare from the Medical Valley EMN

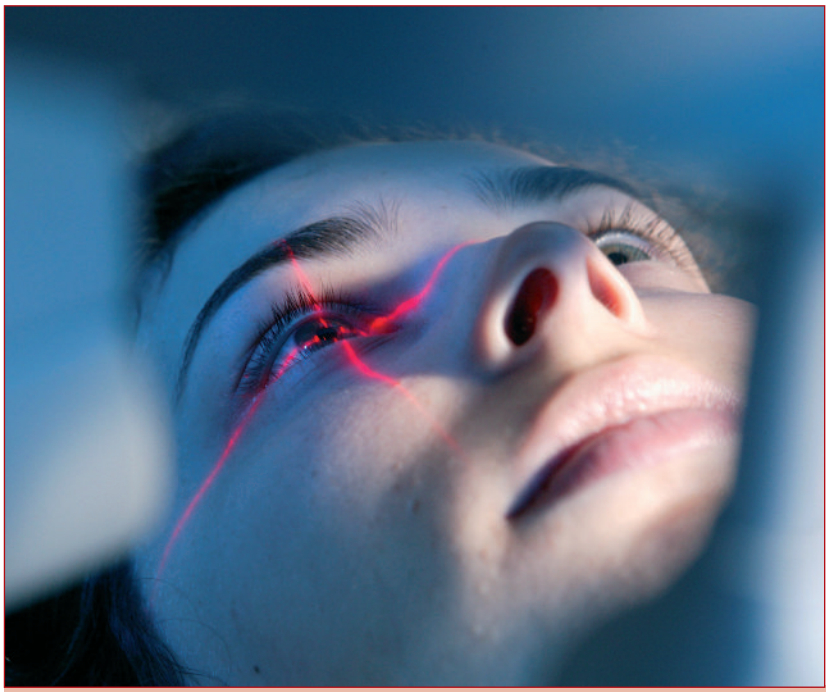
Innovative medical technology is firmly rooted in our region. The interdisciplinary technologies of mechatronics, microsystem technology, optics, photonics, nanotechnology and biotechnology, concentrated in the EMN, contribute scientific know-how to medical technology. Biomedicine and bioinformatics 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;



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 ■

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).

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.



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) ■

Examples of companies and their highly innovative products

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. In the year 2014 the company was winner of the Innovation Award Bavaria. 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), **Bio-Gate 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,

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

systems and equipment, **Siemens Healthineers GmbH** 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 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. ■

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Medical Engineering in Erlangen – in the heart of Europe

Erlangen is located in the excellence cluster in the Medical Valley of the Nuremberg Metropolitan Region (EMN) and benefits from being in the world wide leading center in the field of medical engineering. For years, Erlangen has stuck out through its numerous initiatives in promoting/strengthening regional networks and intensifying international cooperation. The Federal Ministry of Education and Research's excellence cluster grant was awarded to the Medical Valley (EMN) in 2010 leading the cluster to be part of a campaign by the Federal Ministry of Education and Research the following year to promote Germany´s Medical Engineering location. The initiative focuses on „3-D Imaging in Medicine". The inclusion of Erlangen in this campaign was brought on by the initiative of the Central Institute of Healthcare Engineering (ZiMT) of the Friedrich-Alexander-University Erlangen-Nuremberg (FAU) by the then managing director Dr. Kurt Höller. On the recommendation of Federal Ministry of Education and Research, the company CiNNAMED GmbH was founded to continue the initiative's work and to maintain its network. CiNNAMED is substantially involved in the internationalization process of the Medical Valley EMN and serves as a contact for medical engineering companies regarding foreign markets. The Central Institute of Healthcare Engineering ZiMT in its function as a coordinating platform for medical engineering between the university, clinics and industry was also in charge of organizing the most recent achievement for Erlangen: since December, Germany has become the headquarters of the European Institute of Technology and Innovation for Health (EIT Health) while Erlangen has been participating from the very beginning. This initiative was formed as a part of the EU's Horizon 2020 program and will provide billions in funds for the next 10 years. It's goals are to structurally standardize the European health sector and to support entrepreneurial actions that centers on prevention measurements and health promotion for all European citizens. The German association, which accounts for 4 partners located in Erlangen, was able to position itself as one of six European management headquarters next to Spain, France, the UK/Ireland, Scandinavia and Belgium / Netherlands. Under the guide of ZiMT, FAU was admitted to EIT Health next to only three other German universities, and now forms a strong representation of the Erlangen location in the European consortium with Siemens, Medical Valley EMN and Fraunhofer IIS. EIT Health regards itself as a supporter of translational projects which should enter the phases of marketing to the pharmaceutical industry and clinical application after its development. Projects supported by EIT Health operate within the three sectors of technology development & research, education & teaching and innovation & entrepreneurship. The implementation of the EIT Health funding line at FAU and the University Hospital Erlangen is conducted since January 2016 by the new managing director of ZiMT, Dr. Simone Reiprich. An information event was held in March 2016 as a

Fig. 1: *Dr. Simone Reiprich presents ZiMT and the Medical Valley structure to young researchers at the EIT Health Summer School in Barcelona* ■

Fig. 2: *Young researchers present their innovations and prototypes at the Innovation Research Lab Exhibition IRLE in front of an expert jury from FAU and Siemens. The managing directors of ZiMT, Tobias Zobel (top center) and Dr. Simone Reiprich (top right), FAU president Prof. Joachim Hornegger (top right), Director of Business Creation of EIT Health Dr. Kurt Höller (top right) and Sultan Haider (bottom), founder of the Siemens Innovation Think Tank during the award ceremony* ■

starting point, at which more than 60 participant of FAU, the University Hospital and external parties were given an overview of the basic structure of EIT Health and the funding opportunities. In the first year of working with EIT Health it was already possible to realize different projects. During the innovation project „P3 stroke" the Chair of Pattern Recognition of FAU, the Neurological Clinic of the University Hospital and Siemens Healthineers are preparing a cooperation to develop a hybrid device that combines magnetic resonance imaging and angiography in order to improve the diagnosis and interventional treatment of strokes. ZiMT participated in one of the EIT Health Campus programs by organizing a summer school with the European partners Trinity College Dublin und IESE Business School Barcelona centering on „Innovation and Business Creation in Health" *(fig. 1)*. Students and researchers from FAU could submit innovative project ideas from the field of Medical Engineering that where further developed up to the creation of a business plan with professional help during a one week in Dublin and one week in Barcelona.

Among the international students, FAU's students also participated in acting out the projects until its spin-off.

One group was therefore able to move a sensor developed at FAU for measuring heart parameters and its corresponding app one step closer to its market entry.

The close cooperation of ZiMT and Medical Valley EMN forms the crucial basis to encourage industrial partners and SMEs from the Medical Valley to form spin-offs with outstandingly trained experts from FAU and to interlace with the European network provided by EIT Health. In addition to the financial support by EIT Health, the access to this European network of cooperation partners and potential investors gives a substantial advantage within the global competition. To continue advancing new ideas, ZiMT and Medical Valley EMN will host a Design Thinking Workshop organized by Openlab from Stockholm within the EIT Health framework. Opening up university activities to being more interdisciplinary and international and promoting more interaction with users will ease the way for graduates into the job market. ZiMT acts a coordinating unit to interlace the various offers in the region. Projects, for example, that were developed within the Innovation Research Lab (IRL) can become part of the EIT Health funding. The IRL is a ZiMT testing and development laboratory sponsored by Siemens Healthineers where students are provided material and devices to develop medical engineering innovations.

The annual highlight of the IRL is an exhibition held in the Medical Valley Center at which project ideas and prototypes are presented to an expert jury *(fig. 2)*. The best ideas do not only receive a financial award but also qualify for applying to the EIT Health funding. This exhibition depicts perfectly how the excellently established cooperation of FAU, Siemens Healthineers and Medical Valley EMN unfolds and how it creates the groundwork for ZiMT to coordinate the securing of partnerships between Erlangen and European consortia like EIT Health. ■

ZiMT
ZENTRALINSTITUT FÜR MEDIZINTECHNIK

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senetics - Intelligent service for innovative medical technology

Challenge, product innovation and regulatory affairs

Innovation and competence

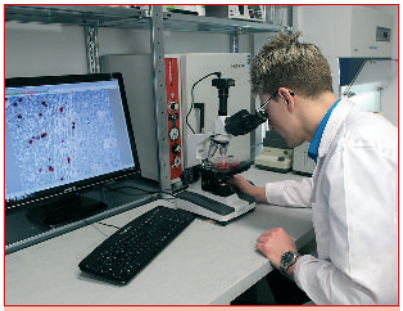
Success in medical technology is defined through innovative strength, cooperation ability, knowledge and an excellent network. Especially the increasing complexity of the medical technology and its varied regularities-requires strong cooperation abilities not only within medical technology but with the pharmaceutical industry as well. The senetics healthcare group GmbH & Co KG is specialized in the field of cooperative project management. Our departments work closely together as to cope with special needs of clients and projects in order to solve given tasks reliably.

From the idea to the product

The way, which an idea needs to walk along in order to be transformed into a product successfully, has many sights. From the development towards the validation of a technology and the examination of biological safety, regulatory aspects, as well as the collection of relevant clinic data, many facets have to be taken into account. Hence, interdisciplinary competences are really important for a successful realization of a product development.

Developmental competence in the interdisciplinary field

The development of a medical product is composed of many related sub-processes, which need to be merged. This enables to transfer a project idea into a product. In former projects, senetics was able to successfully develop an innovative therapy device which was created for pain relief. senetics took over the conception, CAD-realization as well as material analysis and selection.



Microscopic evaluation of biofilms on medical devices at the senetics laboratories ■

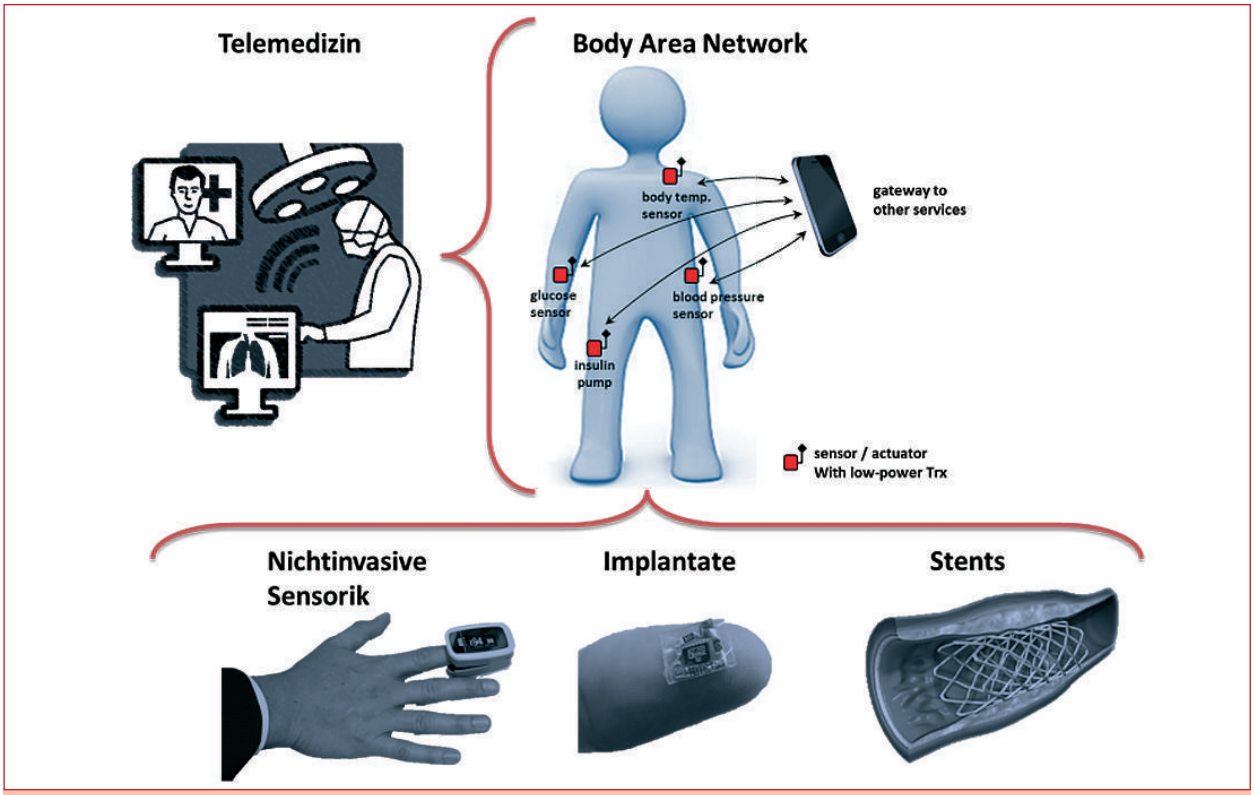
Another exciting development project was the support for multimorbid patients in the home-care-area. senetics implemented both patient-orientated application studies and usability testings of the product with patients as well as with medical staff.

Sensor technology body area network

Currently, we develop a new type of a sensor system, in cooperation with the work of notable partners, which has the function of targeting and processing vital parameters, located in a wireless area body network (WBAN). We are always looking for interested partners in that field of action. User analyses are helpful to work out requirements of a novel sensor network. A feasibility study is supporting the decision, whether the technology is practical useful or not. A market analysis makes it easier to target groups and work out a specification sheet. Further, already the development of the prototype should include major requirements of the product as to classify the medical device depending on the functional principle and pave the way towards certification.

Biological validation and usability testing

Our mechanical and electronical testing department warranties to proof both functional and safety aspects as to point out potential risk factors at the human-machine-interface considering ethical, legal and social implications in order to create a maximum user acceptance. This is important to guarantee the safety of the user in all cases. An unoptimized product design may cause the development of biofilms with microbial contamination for instance. Approximately 80% of care-associated infections are related to biofilms. Hence, testing of potential functional and usability risks are addressed using risk management according to ISO 14971 such as in system and process FMEAs. The aim of risk assessment is to develop of medical devices and equipment as safe as possible. Additionally several aspects have to be implemented. This



Schematic setup of a wireless area body network that is developed by senetics. Noninvasive sensor systems and implants are combined as to monitor vital parameters at different body areas. The recorded informations are then transduced via novel communication systems to responsible monitoring stations and smart phones ■

contains the proof of biological safety according to ISO 10993, which is an essential step within the certification process. This is important as material and technology has to be evaluated in the context of the interacting method and tissue. This testing steps are applied on the final product, however it is highly recommended to validate several parts in earlier project stages as well.

Regarding the reduction, replacement and refinement guidelines the number of animal testing has to be reduced as much as possible. This is not only important for drug testing but for medical devices as well. Therefore model systems, that mimic the in vivo situation, can be applied. For non-invasive vital parameter monitoring within a WBAN, the principles of tissue engineering will help further. Three dimensional skin equivalents can be named as role models. Those systems mimic the in vivo appearing structured skin and can already be applied for cytotoxicity testing of medical devices. Risks such as biofouling and inflammatory reactions can easily be investigated without the need of using animals such as rodents. Another positive aspect is the fact that those systems are based on human cells and therefore have a better predictability compared to animal testing of novel materials for instance.

From the idea towards the development and certification

Our R&D services work as an interface between technical engineering and biomedical expertise. This serves as big advantage in the development of novel devices compared to competitors. Additionally senetics offers regulatory know-how and is therefore able to take all relevant aspects into account to take ideas to products. A major point within the validation of innovative technologies is the production of relevant clinical data in order to proof the functionality. Together with other partners such as from our network for innovative suppliers in medical technology (NeZuMed) or the network for carbon fiber reinforced materials (CarboMedTech) we serve as a One-Stop-Shop starting from application and functionality analysis, working out essential requirements towards the development of norm compliant documentation and the support of distributors. Our team of experts is happy to support you with any problem that has to be solved. ■

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Enhancing regional know-how, seizing global opportunities

The excellent competence in the field of medical engineering that is accumulated by the Medical Valley of the Nuremberg Metropolitan Region (EMN) and Friedrich-Alexander-University Erlangen-Nuremberg (FAU) is now well known across the Metropolitan Region´s boarders. Cooperation inquiries from around the world prove the cluster's international importance within key technologies of medical engineering, for example electronic and microsystems technology, information and communications technology, device engineering and prosthetics, optical technologies and new materials.

The unique infrastructure and composition of members of business, science and the health service sector offers ideal conditions to develop ideas on the spot and evolve them into marketable products or services.

The increasing importance of globalizing the value chain requires the Medical Valley to establish an even tighter cooperation with international partners from science and business. To seize the opportunities that result from this challenge the Federal Ministry of Education and Research introduced the „Internationalization of leading-edge clusters" funding initiative. New incentives are set in motion to build strategy-driven, international partnerships creating new and accessible know-how by concentrating complementary expertise.

Expert presentation of Tobias Zobel at the e-Health Forum during the Hospitalar 2016 in Sao Paulo regarding the Medical Valley and the digitalization of the health care system ■

The primary goal of the internationalization strategy of the excellence cluster Medical Valley (EMN) is to further develop the already existing strategic partnerships with Hong Kong (Hub China), Rio Grande do Sul (Hub Brazil) and Boston Area (Hub USA) into an international innovation system within the global growth market of medical engineering/ health economy. The focus lies on generating international solutions for global challenges of tomorrow's health care service. This global innovation system should provide German SMEs substantially significant potential for growth in future key markets. Crucial tasks in the design phase are the development of a mutual innovation fund, the support of start-ups by encouraging the entrepreneurship culture, the development of an accelerator program with services for market access and intellectual property support, the establishment of inter-

(from left to right) Tobias Zobel, managing director of ZiMT, José Fortunati, mayor of Porto Alegre, Prof. Erich Reinhardt, chairman of Medical Valley EMN, José Ivo Sartori, governor of Rio Grande do Sul, Dr. Kurt Höller, business creation director of EIT Health, and the president of the national bank Badesul, Susana Kakuta during the signing of a treaty between the Medical Valley and the state of Rio Grande do Sul ■

national communities of practice, as well as the preparation of future R&D projects.

Apart from the partnerships with well-known technology countries like the United States and China, Brazil offers new possibilities to benefit from its so far untapped resources and somewhat underrated know-how. The chosen region in the south of the country excels through its dynamic entre-preneurship culture, above-average equipped hospitals and excellent universities that are increasing the number of their industrial partnerships. Various technology parks are offering ideal conditions for startups and SMEs for office or production spaces. A tenant also enjoys access to services that ease the daily bureaucratic life in Brazil. Tobias Zobel is the driving force behind the cooperation with the state of Rio Grande do Sul and entertains a close dialogue with the Brazilian state government to offer tax saving systems for newly arriving companies and to eliminate the majority of bureaucratic obstacles.

In spite of Brazil's momentarily difficult political and economic situation, the country's health spending is constant and stable (8% of GDP) and its middle class with access to public health service financed mainly through taxes is growing. The necessity of overcoming great distances in thinly populated areas offers innovative ideas from the field of medical engineering the possibility to explore new applications that couldn´t be envisioned in the densely populated Germany. The legal requirements obligating companies to invest in research and development result in attractive business plans for partnerships with accredited research facilities and universities.

These requirements and the momentarily favorable exchange rate offer innovative companies the possibility to invest in new projects and partnerships. For the Brazilian research landscape, Germany and the Medical Valley EMN, whose companies hold an excellent position within the international competition are the reference region in the field of medicine and technology. Our goal is to further strengthen our preceding reputation. The Medical Valley EMN and CiNNAMED GmbH offer competent contacts for members of science and business seeking to enter international markets and research landscapes. ■

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INSYDE

Intelligent Care System for Pressure Ulcer Prevention and Treatment

The quality of life of bedridden patients who cannot be sufficiently mobilized, or whose position cannot be changed frequently enough, gradually declines. Often after only a short period, these patients develop a decubitus ulcer, a painful pressure sore on their skin. Around 400,000 people in Germany suffer from this condition annually.

In an effort to help these patients, the project INSYDE is developing an intelligent care system. A simultaneous aim of the project is to support nursing staff and family caregivers, on whom the moving of bedridden patients places a serious physical and mental burden, as well as a great time demand.

To avoid the occurrence of decubitus ulcers and to treat already existing pressure sores, INSYDE is developing an intelligent and adaptive mattress which identifies the patient's current lying position and suggests a new position to relieve pressure. Once cleared by a professional or a family caregiver, the shift in the patient's position is automatically initiated by actuators. Like the sensors measuring the pressure distribution, these are embedded in the mattress. Information on the repositioning and the pressure distribution created in the process will be shown on a display attached to the bed. Finally, this information will be automatically added to existing care documentation.

The solution approach of INSYDE's intelligent care system for the prevention and treatment of pressure ulcers is unique up to now. What sets it apart, in particular, is its closed functional chain and its automated care documentation.

It significantly improves the quality of care for bedridden patients, as the mobilization of patients helps both to prevent decubitus and to heal existing pressure ulcers. ■

Consortium

- Ergo-Tec GmbH, Wilhelmsdorf (Project coordination)
- LBU Systemhaus AG, Amtzell
- Gesellschaft für Biomechanik Münster mbH
- DRK Soziale Dienste Baden-Baden gGmbH
- Friedrich-Alexander University Erlangen-Nürnberg, Institute for Biomedicine of Aging
- Fraunhofer Institute for Integrated Circuits IIS, Erlangen

Jointly with these partners, the Department of Image Processing and Medical Engineering of the Fraunhofer Institute for Integrated Circuits IIS is conducting research on this project, which is sponsored by the German Federal Ministry of Education and Research in the framework of the funding program "Assistierte Pflege von morgen – ambulante technische Unterstützung und Vernetzung von Patienten, Angehörigen und Pflegekräften" (Assisted care tomorrow – ambulant technical support and networking of patients, relatives, and caregivers).

The Department of Image Processing and Medical Engineering offers further solutions in the areas of medical image processing, computer-aided diagnostics (CAD), vital sign sensors, biosignal processing, and medical communication, and is certified by a quality management system (QMS) in accordance with ISO 13485. ■

GEFÖRDERT VOM

Bundesministerium für Bildung und Forschung

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Fraunhofer Institute for Integrated Circuits IIS

METEAN – the Medical Technology Test and Application Center as a partner for innovative companies

Innovations in medical technology not only improve the quality of medical treatment, but also make an important contribution to the export success of German industry. In translating research results into an approved medical product, the fulfillment of regulatory requirements poses a decisive challenge to shortening the time until market launch. Additionally, there is often a lack both of personnel with the necessary interdisciplinary qualifications, and of sufficient knowledge transfer between the actors in the value chain. METEAN, the Medical Technology Test and Application Center, was founded in order to remove these obstacles to innovation, and to allow smaller, innovative companies and research consortia to more quickly transfer ideas and research results into product solutions. METEAN is operated by Fraunhofer IIS in close cooperation with the Friedrich-Alexander University of Erlangen-Nuremberg and the University Hospital Erlangen. It is located in the hospital's facilities.

New medical technology solutions and devices are tested pursuant to recognized standards for

their safety, usability, and interoperability under conditions of routine use.

METEAN offers support services to accompany the entire innovation process – from the substantiation of an idea through to marketing of the approved medical device.

The METEAN service portfolio is provided by an interdisciplinary team, enabling optimal solutions for all aspects of the transfer of innovations into medical application. Current activities focus on regulatory requirements during research and development, measurement data collection, and clinical observation studies, as well as the preparation and conduct of validations and clinical trials. Moreover, as an organization of Fraunhofer IIS, METEAN can draw on the full expertise of the institute and the Fraunhofer-Gesellschaft.

In collaboration with METEAN, companies can clear hurdles and find an efficient path through the thicket of legal, regulatory, economic, and technical requirements and constraints. ■

METEAN

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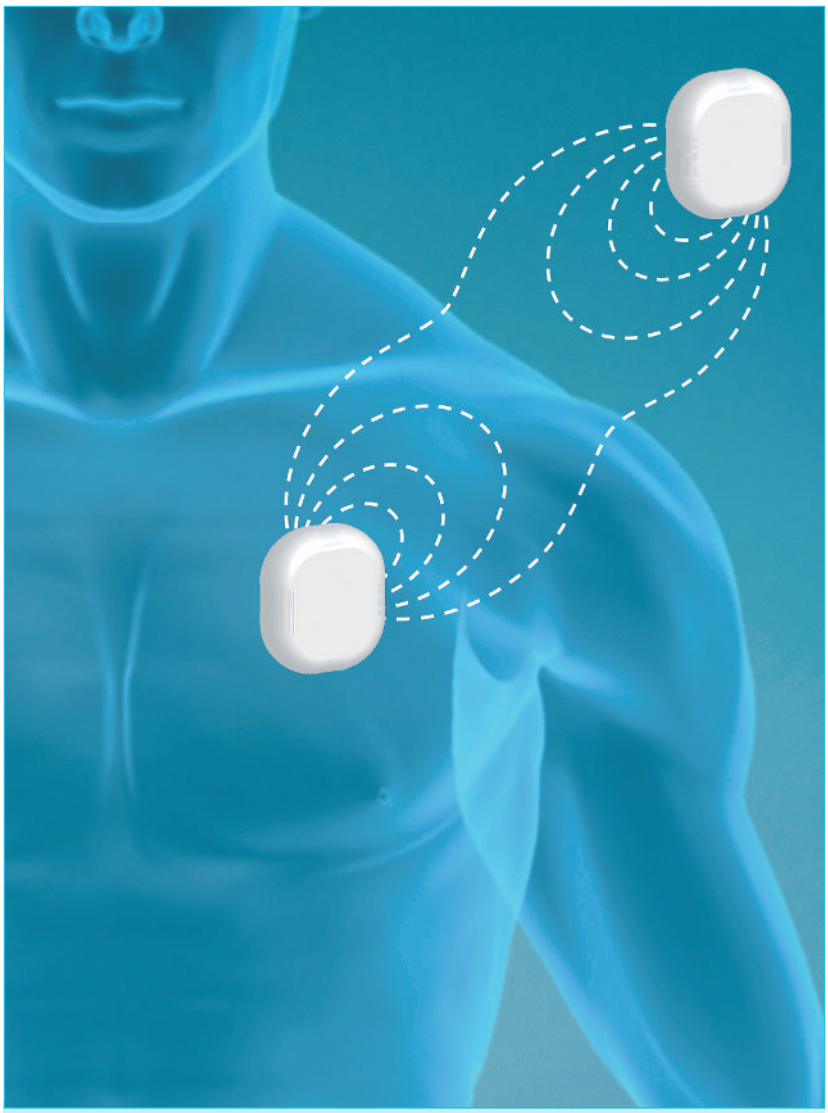
Technologies from aviation and space travel are being used in medical engineering

Dualis is developing wireless energy and data transmission systems along with innovative pumping systems for active implants.

Battery and wire are familar terms that everyone can handle, in most situations anyway. When it comes to active implants however, a case can be made for dispensing with an incision and cable passage through the skin, and also for considering alternative energy supplies.

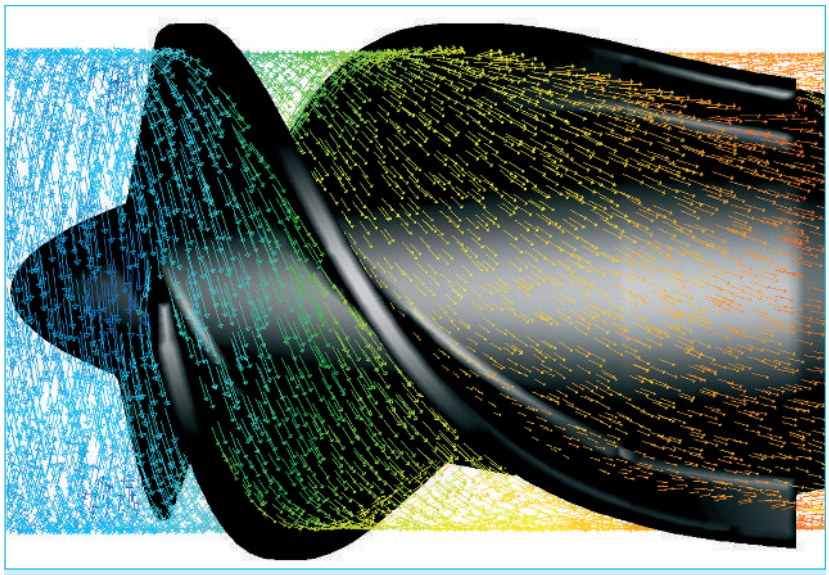
Engineers and physicians at Dualis MedTech GmbH have been considering this issue for years. The answer they have come up with is the MedBase® platform. This makes it possible to transfer wireless energy from a few microwatts up to about 30 watts, which makes the platform attractive for supplying numerous medical devices and also implants. The range of applications is very wide and includes artificial heart systems, drug pumps, myoelectric prostheses and external defibrillators.

MedBase® utilizes the principle of resonant inductive coupling to transfer energy wirelessly. Various secure RF communication techniques are used to control the system telemetrically, depending on the application. Because the platform has a modular design, it can be adapted to different products or integrated into them. Inductive charging of an implanted battery is also feasible with MedBase®. The energy platform is very tolerant toward horizontal and vertical displacement of the transmitter and receiver coil. That is particularly critical for use in implants, because the coupling elements are always moving both inside and outside the body and cannot be precisely aligned. The implanted system heats up only slightly so that the maximum limit of 2 degrees is not exceeded in the process. ■



Schematic representation of a transmitter and receiver coil through which wireless energy and data are transferred into the human body ■

DUALIS MedTech GmbH



Rotor geometry, optimized through simulation, of an implanted blood pump that is characterized by maximum efficiency and minimal damage to the blood components ■

Dualis MedTech GmbH is also involved in pump development

The body is full of fluids that perform a very wide range of tasks, from blood, which is responsible for transporting gases and nutrients back and forth, to saliva, gastric juice, urine and various stationary fluids such as the eye's aqueous humor. To transport these fluids and establish static pressures, the body uses mechanisms that can have serious consequences for people if they fail.

Dualis MedTech GmbH is involved with a wide range of pump technologies that use technical solutions to make it possible to support, or if necessary fully replace the function of fluid transport and establishment of the required pressures in or on the body.

With the technology transfer of the German Aerospace Center (DLR) artificial heart, a CAREFLOW cooperation project for developing an implantable blood pump promoted by the Federal Ministry of Education and Research (BMBF) and various customer-driven blood pump projects, Dualis is moving in arguably the most technically demanding field of pumping systems in medical engineering. In the process, Dualis MedTech GmbH uses state-of-the-art fluid simulation techniques to pump the sensitive medium of blood as gently as possible and at the same time meet the requirements for size and efficiency. With implantable blood pumps especially, which typically stay in the body for several years, both the fluid dynamics and positioning of turbines in contact with the blood are a major challenge. On the one hand, the positioning used must satisfy the mechanical requirements in the aggressive medium of blood, and on the other, the blood must be neither mechanically nor thermally damaged. Magnetic positioning systems that keep the rotor free-floating in its housing and thus free from wear are being developed by Dualis for this. Another advantage of this non-contact storage technique, especially for use in blood pumps, is that the blood can optimally flow around the rotor, thus significantly reducing the formation and accumulation of thrombi.

Along with the blood pumps that establish flow rates of more than 5L/min and pressures up to 500 mmHg (combined with oxygenators for oxygen enrichment), Dualis MedTech GmbH is also developing systems that must offer a much lower volume flow rate and thus also turn out to be much smaller in size. So the interdisciplinary team consisting of medical, mechanical, electrical and software engineers is working on miniaturized pump systems to regulate intraocular pressure and pump urine and other body fluids.

Dualis is a young innovative medical engineering company that has specialized in technologies for active implants. Engineers and a heart surgeon founded Dualis MedTech GmbH in 2006 as a spin-off from the German Aerospace Center (DLR). The company is both a development contractor and supplier of its own technologies.

As a development partner, Dualis tailors technologies to specific customer requirements. From the initial idea to a product ready for serial production, Dualis offers an extensive range of services and has EN ISO 13485 certification. ■

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Medical Engineering at the University of Applied Sciences (OTH) Amberg-Weiden: Profiling with innovative concepts in research and teaching

Innovative Learning Centers (ILO) for applied research and teaching

The OTH Amberg-Weiden has developed proven expertise in medical engineering in recent years: In summer 2010, the Bachelor's programme in Medical Engineering started operations, and a consecutive Master's programme has been on offer since winter 2014/2015. Currently, there are 170 students enrolled in the two programmes. In addition, roughly 1,100 square metres of high-tech laboratory space have been set up at the Weiden Technology Campus (WTC). For applied research and teaching in medical engineering, close collaboration and exchange with clinical users in a hospital set-up and industry partners is of a critical success factor. Innovations develop through exchange, debate, and creativity. The concept of Innovative Learning Centers (ILO) that has been developed and implemented at OTH Amberg-Weiden provide the best conditions for this approach. The innovative approach and concept create a novel culture of learning. Various contacts with businesses and local authorities allow taking advantage of the existing infrastructure thereby creating a unique place of learning where in decentralized centers students and teachers create a dynamic environment for research and education, while simultaneously highlighting the presence of the university in the region. For the medical engineering study programmes, the first ILOs have already been established. Since a collaboration with the clinical users of medical technology is particularly important, a research and teaching a cooperation with clinical partners in the Northern Upper Palatinate was established.

The Weiden Technology Campus (WTC) ■

The Kliniken Nordoberpfalz AG (The Clinic Group of the Northern Upper Palatinate, PLC) provides healthcare services in the Northern Upper Palatinate with seven acute care hospitals, a clinic for geriatric rehabilitation and a clinic for orthopedic rehabilitation. In addition, in 2010, the central training academy, NEW LIFE, which provides further education and training for nursing staff as well as for clinical and non-clinical training and education, was opened. The driver of progress and innovation in healthcare delivery in this region is embodied in the flagship hospital in Weiden.

The Klinikum St. Marien Amberg (Clinic St. Marien, Amberg) is a hospital of care level II with 574 beds and 14 clinical departments. The comprehensive portfolio of clinical care covers all aspects of modern basic and specialized medical services. The affiliated health center, St. Marien, provides outpatient and consulting services. As an academic teaching hospital of the University of Erlangen-Nuremberg and the University of Regensburg, the Klinikum St. Marien is actively engaged in medical education.

The Innovative Learning Center (ILO) is the framework for the collaboration driving the expansion and institutionalization of existing and future network and project activities. The objective is to

foster and promote professional exchange between clinical application, research and education. Thus, the challenge of demographic change in rural areas, where an aging society is associated with an increasing need for medical services and nursing care can be effectively met. The Innovative Learning Center serves as the platform for cooperative projects between the hospital partners and the OTH Amberg-Weiden in Weiden. The activities involve many professors, employees and students. These cooperative efforts thus represent an important contribution to create a network of the major players in the health region of the Upper Palatinate.

A corresponding Innovative Learning Center was established with Siemens Healthineers at their manufacturing plant in Kemnath in the Upper Palatinate. Focus of the cooperation are the areas of medical engineering and mechatronics. There is a broad spectrum of activities established covering student projects, field trips, internships as well as bachelor and master theses. Furthermore, several applied research projects are currently in preparation addressing challenges and topics in manufacturing, logistics, and mechatronic aspects of medical engineering.

Healthcare and Medical Engineering Campus Oberpfalz at the OTH Amberg-Weiden

This project is based in the Faculty of Industrial Engineering and in the degree programme in Medical Engineering at OTH Amberg-Weiden. It pursues the goal of strengthening the healthcare industry and Medical Engineering in the Upper Palatinate. It is funded by the State of Bavaria under the Northern Bavarian Funding Initiative. It serves as economic and structural driver for the region through institutionalizing and sustaining ongoing projects and

The University of Applied Sciences Amberg-Weiden (OTH), Weiden Campus ■

activities in healthcare and in the regional medical engineering industry. To this end, research and education in medical engineering were expanded in order to promote innovation and to strengthen regional competencies. Technology transfer and start-up support are provided to establish competitive businesses in the medical engineering industry as well as to create additional jobs. Further activities include projects on quality and efficiency improvements in healthcare delivery through innovative technologies and services. This also includes new concepts to meet the demands of demographic change. Activities include e.g.:

- The focused education and training programmes covering the special requirements of the healthcare and medical engineering industry
- Applied research and technology transfer in cooperation with partners from science (also OTH Regensburg), the OTH Technology Campus, industry and the regional healthcare providers including hospitals and manufacturers of medical equipment in Eastern Bavaria
- The establishment of an incubator/accelerator environment for new technologies and services and start-up assistance in the field of medical engineering and healthcare industry
- The creation of an institutionalized network of the regional players in healthcare and medical engineering .

The comprehensive and institutionalized networking of stakeholders and decision-makers in the healthcare and medical engineering industry of the Upper Palatinate is the key strategic success factor for the viable and sustainable implementation of Campus initiative. This approach allows the region to position itself as a role model for a healthcare region at the highest level. This is particularly important to manage the impact of demographic change (i.e. the aging society with an increasing need of technical support for patient care whether in outpatient, inpatient or home care settings), and to cope with the growing shortage of skilled professionals in healthcare and nursing. ■

Further Information:

Institute for Medical Engineering:
http://www.ifmz-weiden

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

Education Programmes:
Bachelor:
http://www.oth-aw.de/studium/bachelorstudiengaenge/medizintechnik/allgemein/

Master:
http://www.oth-aw.de/studium/masterstudiengaenge/medizintechnik/allgemein/

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Medicine 4.0 – Electronics and digitalisation pave the way to a sustainable healthcare system

Digital networking has heralded a new era that could be termed "Era 4.0". First there was "Industry 4.0", which seemed to mark a new industrial revolution – signifying how humans, machines and products can be interconnected with the aid of Internet technologies. Meanwhile this revolutionary spirit has spread to almost all areas of our daily life: Work 4.0, Family 4.0, Career 4.0, University 4.0 – a list that could go on and on. In years to come, there will also be fundamental changes in medicine: Digital networking of patients, doctors, hospitals, rehabilitation centres, pharmacies and health insurers will enable faster, easier and cheaper management of therapies. At the same time, digital technologies will bring about completely new options for the prophylaxis, diagnosis and treatment of diseases which from today's perspective seem relatively futuristic. We are at the threshold of "Medicine 4.0".

Telemedicine on the rise

This new era of medical technology will also change many of the customary processes in our healthcare system. One example is telemedical applications, which will transform the doctor-patient relationship: In future, patients will not only be the recipients of medical care, but will also play an active role in the diagnostic and therapeutic process. Patients will in any case become more and more familiar with collecting their own health data, as is already the case with smart watches. However, these are not certified and therefore not suitable as medical devices. At any rate, there is no doubt about the fact that telemedicine will play an ever important role in healthcare. Predominantly in rural areas, telemedicine will be the only means of maintaining comprehensive medical coverage for the entire population. Telemedicine will also enable costs to be reduced, another factor that is becoming more and more important. ■

Technology improves the quality of life

Aside from these aspects, added value to patients should always be prioritised, with digital technologies above all helping to improve their quality of life. This is exactly what we had intended with the All-in-One telemedical device *(Fig. 1)* developed at the Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik of Technische Universität München in recent years. The first studies conducted to test the device in patients with cardiovascular disease have shown that patients have a greater sense of independence and mobility, at the same time as feeling safer and assured of better care. The patient simply slips a finger into a special sensor sleeve in the All-in-One device *(Fig. 2)*. The device then automatically measures the patient's blood pressure, heart rate, body temperature, oxygen saturation in the blood and hydration level. A sensor located at the side of the device can be used to apply a drop of blood for glucose measurement. The device is small, robust and mobile, and can be taken wherever the patient goes.

The vital parameters are measured several times a day, and the data are sent via an integrated

Fig. 1: *All-in-One medical device with integrated sensor sleeve (right)* ■

Fig. 2: *All-in-one medical device. Left: To collect the relevant vital data, the patient simply slips a finger into the measurement sleeve in the lower part of the device and presses the "Start" button. Right: After a short while the data appear on the display and, if the patient so wishes, may be transmitted to the COMES® telemedical platform via mobile radio* ■

smartphone to an intelligent assistance system connected to a medical expert centre. Both doctor and patient have access to the data at all times and are therefore always informed about the patient's health. If the measured values are critical, the patient's doctor will be alerted for the purpose of intervention, if necessary – if the patient's doctor is not available, doctors at the expert centre can contact the patient or make an emergency call. An example of such an intelligent system is our COMES® *(Fig. 3)* telemedicine platform. It is currently under trial and has recently been tested by a number of rehabilitation clinics. We are currently working on a new version of the All-in-One device to make it much smaller and more stylish. It will then easily fit in a jacket pocket and can be used anywhere, whether in a café, on a walk, on holiday or at home. The patient can thus remain active and will be less constrained by the disease – a clear plus when it comes to quality of life. ■

No more grinding of the teeth

Electronics and digitalisation can bring about substantial improvements not only for patients suffering from cardiovascular diseases but also for many other conditions. Consequently, telemedical systems like COMES®, when combined with special spirometers, can assist asthma patients during their recovery or motivate obese individuals to lose weight – another area in which we have already tested the COMES® system. We have developed an intelligent tooth splint for patients with bruxism that can help detect the reason for the abnormal habit of teeth grinding. The splint contains a small sensor that records the teeth grinding activity. Radio transmission is then used to send the data to a receiver unit at the bedside or in the patient's pocket. It is also possible to automatically process this data using a telemedicine platform like COMES®. Tests have shown that many patients only grind their teeth if they are under stress at work or in their personal life. Feedback systems, for example with a vibration unit placed under the pillow, can even help these patients to rid themselves of their bruxism.

Stair-climbing wheelchair

Nursing is another field in which new electronic developments will soon open up new possibilities. In Asia, service robots are already widely used, and it is merely a matter of time until they are also introduced in Europe to help nurses with the care of the elderly. Even today, digital technologies and systems can facilitate many supportive and nursing tasks. It is also conceivable that, in the future,

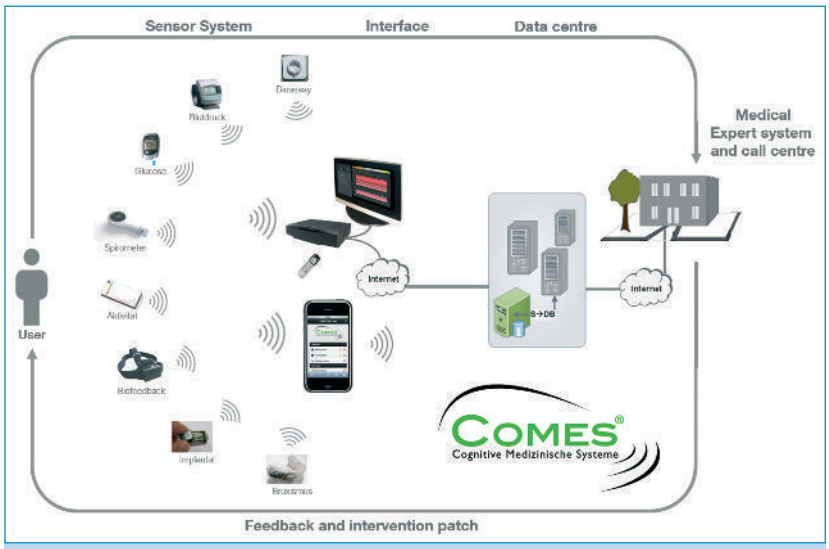

Fig. 3: *Overall COMES® concept: Cognitive Medical Systems (Cognitive Medizinische Systeme) with intelligent assistance devices that can be used anywhere, in all walks of life (Comes = Latin for "companion")* ■

Fig. 4: *Left: Intelligent tooth splint with battery (1), sensor unit (2) and antenna (3). Right: Receiver for acquiring data and relaying biofeedback (vibration or acoustic signals)* ■

the elderly will increasingly use intelligent assistance systems to retain their autonomy and mobility, only requiring nursing at a very old age or when they become seriously ill. A group at Technische Universität München in collaboration with Hochschule Kempten has developed a mobility system called "AssistMobil", an example of such an intelligent assistance system. It can travel autonomously over short and medium distances and is even able to overcome obstacles such as stairs. It has interfaces that allow for easy integration into a standard car. The core element of this system is a seat that can be used both inside the car to replace the driver's seat and outside, mounted on a wheelchair unit.

If the user travels only short or medium distances, the universal seat is placed on a Segway-like chassis to form a bionic wheelchair. Motion is achieved by balancing only on one axle, i.e. using only one pair of wheels. Each of the wheels is controlled by its own electric motor; the motors hold the centre of gravity of the wheelchair precisely over the wheel axle *(Fig. 5)*. The result is a wheelchair that is extremely manoeuvrable and easy to control. If the ultrasound sensors in the chassis detect a step, the wheelchair changes into stair-climbing mode: Two auxiliary wheels emerge from the chassis and the wheelchair is reversed towards the stairs until the two main wheels come into contact with the first step. Two foldable legs, each consisting of an upper and a lower part similar to the human thigh and lower leg, then extend outwards. Each of the legs uses two electric motors to push the wheelchair up to the next step, before successively moving onto each of the next steps. In this way, the wheelchair is able to ascend the stairs step by step *(Fig. 6)*. If the user wishes to get into a car, the wheelchair can be manoeuvred into position at the open driver's door. We have taken the seat transfer system produced by the Autoadapt company and modified it slightly. The seat can be unmounted from the wheelchair and swivelled into the car to act as the driver's seat. The wheelchair chassis is then transported automatically to the rear of the car and stowed in the boot. On arriving at the desired destination, the chassis is automatically unloaded and returns to the driver's door for the driver to again be transferred to the wheelchair. Thus, the user can move about on a daily basis completely unaided, from getting up in the morning to going to bed in the evening, whilst sitting on the same seat. If the user wishes to stand up occasionally for particular activities, the wheelchair will automatically move into a specified position and change to stationary mode, e.g. when connected to its battery charging station. The user thus benefits from maximum flexibility since the electronically controlled AssistMobil offers independent mobility throughout the day. ■

Fig. 5: *Model of the "AssistMobil" system. On even ground, the bionic wheelchair is balanced on two large wheels, with the additional legs needed for climbing the stairs (yellow) folded back into the chassis* ■

Ready for series production

However, there are still issues with the exemplary results from the collaborative research projects we have conducted in recent years which are described in this article: Much valuable time is lost before such innovations can be marketed and authorised, and before they may be prescribed by doctors and used by patients. Too often, political and economic interests, and the demands of various organisations, associations and lobbyists, can delay the introduction of new medical technologies. However, it would be of great advantage to the entire healthcare sector and above all to patients themselves if we were to accelerate the journey towards Medicine 4.0. Hence, we will continue working on the

Fig 6: *AssistMobil in stair-climbing mode: The two legs (yellow) push the wheelchair from step to step. Scan the QR code (right) to watch a video of a model of the stair-climbing wheelchair in action* ■

research projects discussed here and certain other projects at our Steinbeis-Transferzentrum Medizinische Elektronik und Lab on Chip-Systeme – thereby paving the way for products to go into series production. We would therefore very much welcome the support of suitable collaborative partners.

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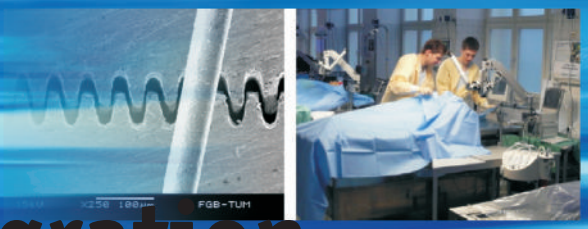

Open Real-time Integration of Medical Devices in the Operating Room

Interoperability of medical devices has been a central topic in medical research for years. While the number of medical devices and their computational intelligence have increased continuously, the lack of appropriate communication standards and a strict regulatory framework impede a cross-manufacturer interoperation of medical devices.
The MiMed institute at Technical University of Munich has conducted intensive research on modular, open real-time interconnection of medical devices over the past 3 years. The results show that through open communication of medical devices, numerous new and innovative applications can be made available to the user: For instance an automatic, real-time power control for active instruments on the basis of intelligent sensor data, such that damages to structures at risk can be avoided.

Modern Operating rooms and Their Equipment

The increased use of minimally invasive procedures and the therefore necessary equipment, promote the constant growth in quantity of medical devices in the operating room (OR). Three out of five of the most common (formerly open surgeries) interventions are now performed endoscopically and therefore require an endoscopy tower with monitor, camera control, cold light source, video documentation, suction pump, insufflator, HF unit and now and then an ultrasonic dissector. Depending on the type of surgery further complex devices are used. Neurosurgical interventions (~750.000 interventions p.a.) often require a microscope, intraoperative ultrasound, a surgical laser, ultrasonic ablation, an irrigation pump and a Drill. Computer-aided assistance systems like medical navigation systems provide the surgeon with additional information in real-time. Such navigation systems can localize and track instruments and anatomical structures with submillimeter accuracy and visualize their movements with respect to preoperatively taken CT or MRI image data sets of the patient.

Traditionally manufacturers equip their devices with specific, proprietary communication interfaces and sell them in small compounds (i.e. foot switch – HF unit). To meet the demand for intelligent, networked data exchange of medical devices, leading medical companies offer so called integrated operating rooms, which offer the possibility to view and adjust device parameters and data and to distribute patient demographic data.

These manufacturer specific solutions are monolithic in two different ways: On the one hand, they impede cross-manufacturer interoperability from the technical point of view; on the other hand the manufacturer has full knowledge of the system's composition, so that he can configure and certify the system all together.

A standard for communication, covering cross-manufacturer communication between medical devices and accessories and being accepted by the market, does not yet exist today. ■

Deficitis of incompatible device interfaces

In the medical domain, many intelligent functionalities base on inter-device communication. These include a central configuration of devices through touch panels in the sterile area, a sensor based control of active instruments or an overlay of device and patient parameters in intraoperative image data. To enable the implementation of such functionalities, it is necessary that all devices support the same communication protocol.

As such open communication standard does not exist today, the user is left with only two possibilities: He can either spare the additional functionality or he is bound to one single vendor, when investing in an integrated operating room. ■

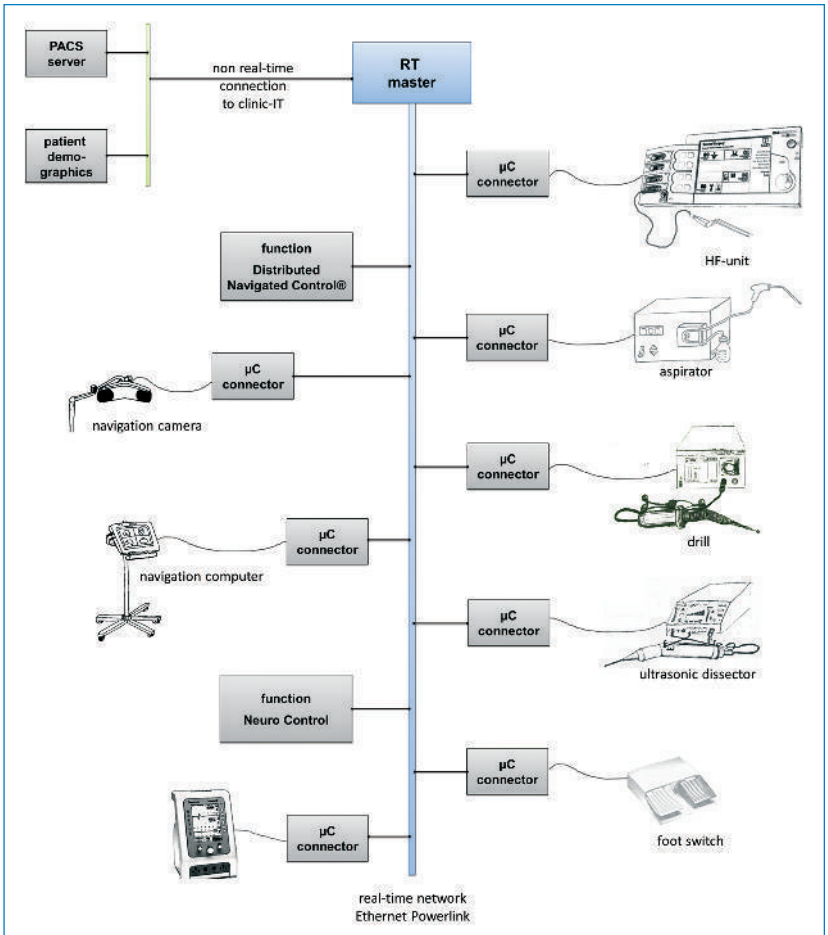

Fig. 1: *Devices are connected to the real-time network via so called connectors. A central RT master provides guaranteed real-time transportation of the right data to the right receiver* ■

Approach and use cases

Within the project "OR.Net – Secure and dynamic networking in operating room and hospital" (funded by the Federal Ministry of Education and Research – BMBF), the MiMed institute has developed and implemented a standard for inter device communication in the medical domain. TU Munich thereby focused on the real-time capabilities of the network *(see architecture in Figure 1)*. Existing devices and their legacy interfaces are connected to the network via so called connectors. A central master *(Figure 2)* controls the data flow in the network and ensures the guarantee of real-time data delivery. These real-time guarantees are required, when data has to be transported and processed within restricted time limits – hence they are particularly needed for the control of invasive instruments, which are in direct contact with the patient. Use cases, in which novel assistance functions can be achieved through a networking of components, are shown in the following. At the end of the OR.NET project a real-time demonstrator, to serve as a reference implementation, has been realized. It exemplarily demonstrates some of the use case and was introduced to representatives of industry, research and clinic in March 2016.

1.1 Sensor Based Control: Navigated Control and Neuro Control

In many surgical interventions, the surgeon is faced with the challenge to protect healthy neurological structures. Example interventions that expose danger to neurological structures are the implantation of cochlea implants (nervus facialis), the resection of brain tumors (nervus facialis, vestibulocochlearis) as well as a surgical removal of the thyroid gland (nervus laryngeus recurrens).

On the market there are various sensor based systems (for example optical navigation systems or nerve monitors) that assist the surgeon in keeping sensitive structures intact. Optical navigation systems measure the position of instruments relative to the patient. They consist of a stereo camera, a navigation computer and so called localizers. Localizers are a set of reflecting marker spheres mounted on the instruments in a specific geometry. Infrared light flashes from the camera are reflected by these makers and are thus visible to the camera. The

Fig. 2: *Connector for the navigation computer. A display shows status information of the device and the network* ■

Fig. 3: *Central master of the real-time integrated operating room, developed at MiMed* ■

maker's positions can be measured from the stereo images, captured by the camera at submillimeter accuracy. The measured data can then be used to calculate and visualize the instrument's positions relative to the patient *(see Fig. 3)*.

In a preoperative planning phase, position data of critical structures such as nerves can be segmented within the patient's image data. In combination with the navigation system this information can be used during the intervention to stop active instruments such as a surgical drill before nerve structures are damaged. This procedure has been patented by Prof. Dr. Tim Lüth in 2001 under the name Navigated Control. In the OR.NET project this technique was extended and applied for several active instruments simultaneously based on an open network architecture, for the first time.

A similar procedure, called Neuro Control, can be realized using a nerve monitor: A stimulation electrode of a nerve monitor is integrated into an active instrument and continuously sends stimulation pulses. Whenever the instrument gets too close to a neurological structure, a nerve response to the stimulation pulses can be detected and the instrument – i.e. an ultrasonic dissector – can be deactivated to prevent damages to the nerve. This approach disburdens the surgeon, shortens the duration of the intervention and increases the patient's safety.

1.2 Extending the Field of View: Merging Navigation Data

The so called line-of-sight problem is a well-known challenge of optical navigation systems. If patient or instruments are obstructed or outside the viewing angle of the camera, the navigated intervention is interrupted and can only continue after the camera's view on all required instruments is cleared. A situation quite likely to occur during surgery, for example when the surgeon moves instruments out of the camera's view or occludes the camera with his body. It also happens that the camera has to be moved for a nurse to have better access to the patient. This means, the surgical team has to accept limitations in its available workspace when using navigation systems.

However, the line-of-sight issue can be mitigated with the help of additional navigation cameras viewing the situs from different angles. In this way, other cameras can take over when patient or instruments are occluded for one camera. To include multiple cameras into a navigation system, the navigation data from all cameras need to be merged together. In addition to merging

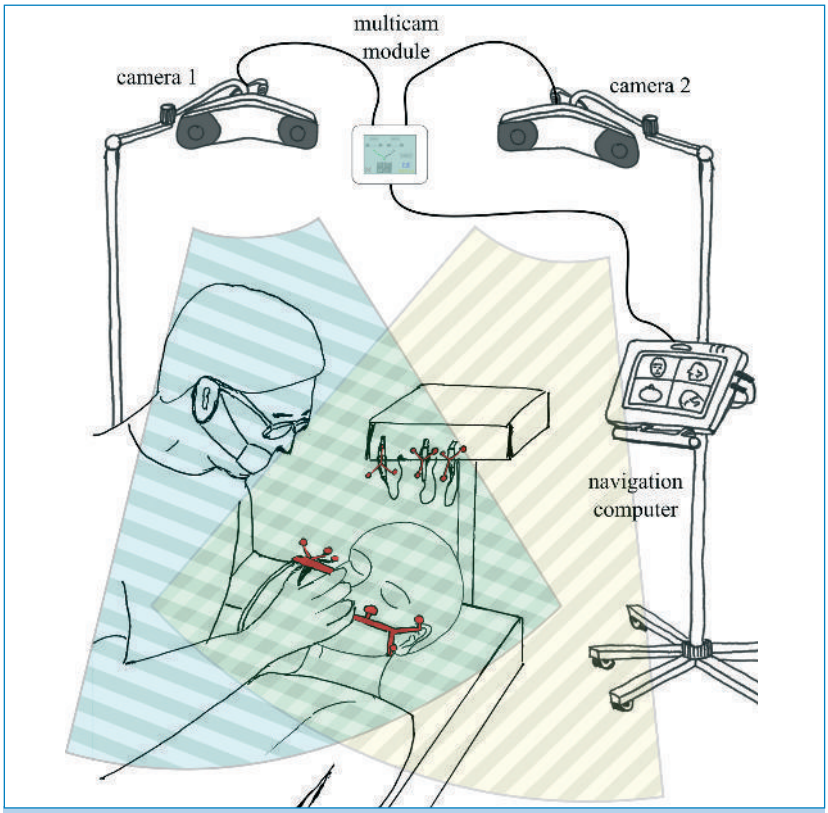

Fig. 4: *The data of two stereo measurement cameras are merged together and forwarded to the navigation computer* ■

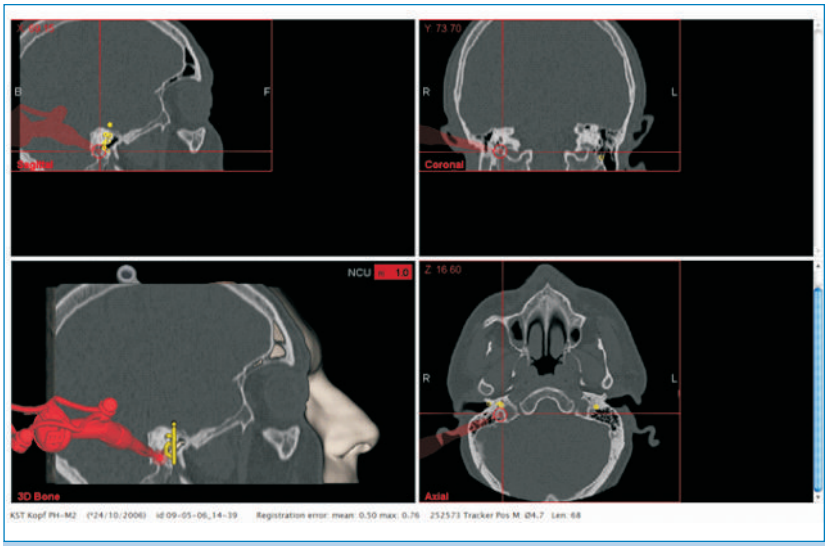

Abb. 5: *Screenshot of a medical navigation system in a neurosurgical intervention. A drill is colored red as a warning, because it is in very close distance to a yellow colored nerve structure* ■

navigation data from multiple optical tracking systems, this method also allows to combine different types of navigation systems. For example optical tracking can be supported by electromagnetic tracking when the type of intervention prevents a direct view on the instruments.
MiMed has developed a module connecting multiple optical navigation cameras and merging the navigation data for parallel camera use. It was developed for a dental use-case, as illustrated in *Fig. 4.*

1.3 Reducing Wires: Networked Footswitch

High-tech disciplines, like neurosurgery, require a great number of medical devices. While the control pedals of these devices are very similar in terms of appearance and function, their interfaces are incompatible and each medical device comes with its on foot pedal. Therefore, a variety of pedals can be found below the OR table, leading to dangerous tripping hazards or ambiguity errors.
To mitigate this problem, a system for networked pedal control of medical devices via a real time network was developed at MiMed. This allows a variety of medical devices to be controlled from a single networked foot switch, reducing the amount of cables below the OR table. The desired medical device can be selected via touchscreen and then controlled by a single foot switch, regardless of the device's manufacturer.

Conclusion

The above-mentioned use cases show the potential of an open, real-time capable, communication standard. Overcoming proprietary standards means more freedom for the clinic operator in terms of medical device vendors and the possibility to upgrade an existing network of medical devices with new functionality, such as Navigated Control or Neuro Control. Especially small medical device manufacturers can benefit from a common, open real time communication standard as they are excluded from todays integrated operating rooms, which use proprietary communication technology of the respective manufacturer.
Additional research will have to focus on regulatory challenges, as today's certification processes pose several challenges for distributed networked medical devices and necessary tools to support clinic operators with legal matters do not yet exist. Therefore, the MiMed chair which is ISO 13485 certified, works on methods to support the certification process as well as the operation of a clinical real time network in terms of regulatory matters.

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EIT Health ACCELERATOR

The business creation tool of one of the largest healthcare initiatives worldwide

EIT Health

EIT Health is one of the largest healthcare initiatives worldwide. Its goal is to sustainably advance the foundations of healthcare and thus promote the future conditions for healthier living and the well-being of people across Europe. EIT Health leverages the expertise of more than 135 leading organisations spanning key areas of healthcare, such as Pharma, MedTech, Payers, Research Institutions and Universities. Chosen by the European Institute of Innovation and Technology (EIT) to form EIT Health as one of its five "Knowledge and Innovation Communities" (KICs), the consortium offers best-in-class research capabilities, higher education and business expertise. With a budget of € 2 billion provided by Horizon2020 over the next decade, EIT Health will purposefully invest in Europe's best entrepreneurial talents and creative minds, to foster the development and commercialisation of smart product and service solutions in the health sector that can address the challenges imposed by demographic change and ageing societies.

International Headquarters in Munich

With the official opening of the new headquarters in Munich on 3 May, 2016, EIT Health reached a major milestone in its young history *(Figure 1+2)*. CEO Sylvie Bove was delighted to welcome more than 150 prominent guests – mainly from the numerous partner organisations – for a great celebration in Munich *(Figure 3+4)*. Among the special guests of the evening, the presence of Martine Reicherts, Director General for Education and Culture (DG EAC) of the European Commission, showed the relevance of EIT Health within the European community and its connection to what exists already. Ilse Aigner, Bavarian Minister of Economic Affairs and Media, Energy and Technology, underlined the organisation's important contribution to shaping future healthcare. Without the immense support of the Bavarian ministry of economics, which convinced the international organisation to locate its headquarters in Munich by supporting it with €500,000 per year, EIT Health's powerful and independent management would not be possible. For its part, the free state of Bavaria benefits a great deal from hosting this international hotspot, which attracts numerous decision makers in BioTech and MedTech for international meetings every day. Furthermore, a number of very strong partners – like Roche Diagnostics GmbH (Penzberg), Siemens Healthcare GmbH (Erlangen), TU München (Munich), FAU Erlangen-Nürnberg (Erlangen), Fraunhofer IIS (Erlangen), BioM (Munich) and Medical Valley EMN (Erlangen) – have their headquarters or locations in Bavaria. They can use EIT Health as a platform and catalyst to cooperate with world-leading institutions in the network – like Philips, GE, Sanofi, Pfizer, Merck, Essilor, Procter & Gamble, Nestlé, IBM, Oxford, Cambridge, Imperial College, ETH Zurich, EPFL, UPMC, Karolinska, KTH, KU Leuven and IESE Business School – as well as the other German core partners: Abbvie, UCB, SAP, Profil, Heidelberg University, RWTH Aachen and Max Planck Society.

Fig. 1+2: *EIT Health Headquarters Location (right image © Design Offices GmbH 2016)*


Fig. 3+4: *Inauguration with Ricardo Rueda, Associate Director at Abbott Nutrition, Martine Reicherts, Director-General for Education and Culture of the European Commission, Sylvie Bove, CEO EIT Health, Ilse Aigner, Bavarian Minister of Economic Affairs and Media, Energy and Technology, Koenraad Debackere, chairman of the EIT Health supervisory board.* ■

The regional structure of EIT Health extends across the whole of Europe. With its headquarters in Munich (Germany), EIT Health has established six Co-Location Centres (CLCs) in London (UK/Ireland), Stockholm (Scandinavia), Barcelona (Spain), Paris (France), Mannheim and Heidelberg (Germany/Switzerland – financially supported by the Federal State of Baden-Württemberg with €500,000 per year) and Rotterdam (Belgium/Netherlands), which have been operational since October 2015. All six CLCs are defined by the EU Innovation Scorecard as high innovation performers and all locations provide a shared physical space, with access to laboratories, test beds, offices and seminar rooms, that will promote close cooperation. Moreover, a seventh consortium named "InnoStars" integrates the innovative regions in Hungary, Poland, Portugal, Croatia, Italy and Wales *(Figure 5)*.

EIT Health is a strong, diverse and balanced partnership of best-in-class organisations in education, research, technology, business creation and corporate and social innovation. The partnership is uniquely positioned in terms of its critical mass, breadth, capability and commitment to promote health in Europe. The commercialisation of new products and services will lead to improvements for quality of life and the sustainability of healthcare systems, while EIT Health's educational programmes nurture talents and train the workforce of tomorrow. EIT Health has identified three main challenges: promoting healthy living, supporting active ageing and improving healthcare.

Entrepreneurship in Healthcare

EIT Health has been set up to tackle the European healthcare challenges that accompany developments such as an ageing population, a downward trend in birth rates and increased life expectancy. To provide Europe with new opportunities and resources, we will promote entrepreneurship and foster innovation through the entrepreneurial spirit. EIT Health therefore believes that one critical factor of its success is its Business Creation strategy. This is why it has set up the ACCELERATOR, its Business Creation pillar.

Entrepreneurship skills empower healthcare professionals to turn interdisciplinary ideas into action in a highly regulated market. These skills include creativity, innovation, risk-taking, and the ability to plan and manage projects in order to achieve objectives. But entrepreneurship also depends on the surrounding ecosystem: It requires an environment with direct market access, potential customers including patients and medical doctors, mentors and market coaches, investors and funding organisations.

Europe's economic growth is supported by a strong healthcare sector, which depends on the market's ability to sustain the development of enterprises. Entrepreneurship creates new companies, opens up new markets, and nurtures new skills. But unlike most other markets, strict regulation and huge barriers for reimbursement in the healthcare field make it nearly impossible to set up a successful business without external support. The European Commission's objective is to encourage people to become entrepreneurs and also make it easier for them to set up and grow their businesses. Innovation by entrepreneurs who are able to think out of the box is more important in healthcare, but also riskier and harder than in any other field.

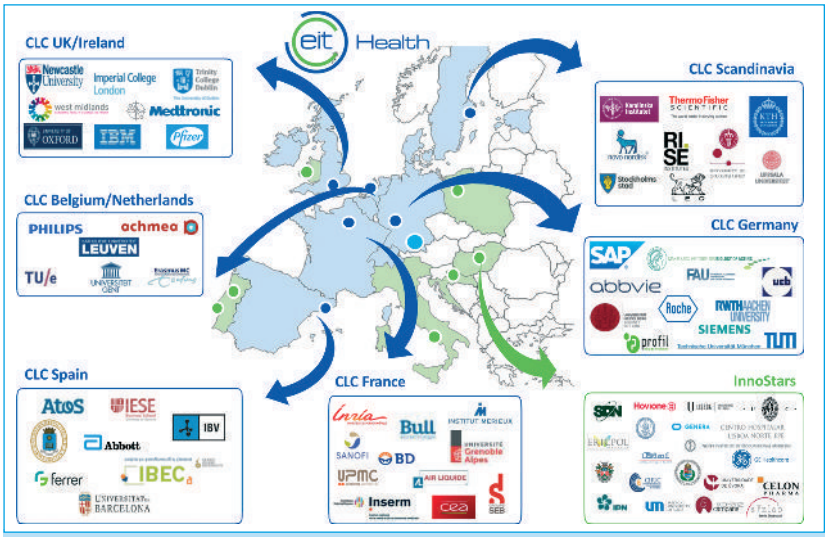

Fig. 5: *EIT Health Core Partners and Co-Location Centres (CLC)* ■

Joining Forces for the EIT Health ACCELERATOR

With this challenge in mind, EIT Health ACCELERATOR is putting all its efforts into supporting start-ups and business creation in

the field of healthy living and active ageing, to encourage disruptive innovations and out-of-the-box solutions in these areas. EIT Health creates an ecosystem where interdisciplinary innovation for healthcare can thrive. It gathers the best and brightest health industry entrepreneurs, and provides them with the support, skills and services that they need to get their ideas off the ground and into the very unique healthcare market. Health innovation through entrepreneurship and education is key to citizen-centred well-being and healthcare. This innovation can be achieved only if we are able to unite the strongest innovators and leaders in all major healthcare disciplines. To this end, EIT Health puts its focus on building a sustainable and globally recognised community of trust with strong organisational leadership. The overall goal is ensuring that Europe's best incubators and accelerators with links to the healthcare market will see EIT Health as the partner of choice to incubate new companies and to set up acceleration programmes.

Support for Start-Ups and SMEs

ACCELERATOR focuses on entrepreneurship and innovation in health by setting up a whole supply chain based on the EIT Health partners' excellent and unique portfolio. This effort is made possible by the strong community of trust to which all EIT Health partners belong. Based on these excellent partners, EIT Health ACCELERATOR offers strong programmes for business in Europe. From Incubation via Validation to Scaling, all entrepreneurs and start-ups will get the best support in the European setting. In only a few years' time, the Business Creation Core Group – which consists of the leading TTOs, cluster managers and investment experts distributed over all CLCs and InnoStars – has developed a strong portfolio

Fig. 6: *EIT Health ACCELERATOR Industry Ideation Meeting* ■

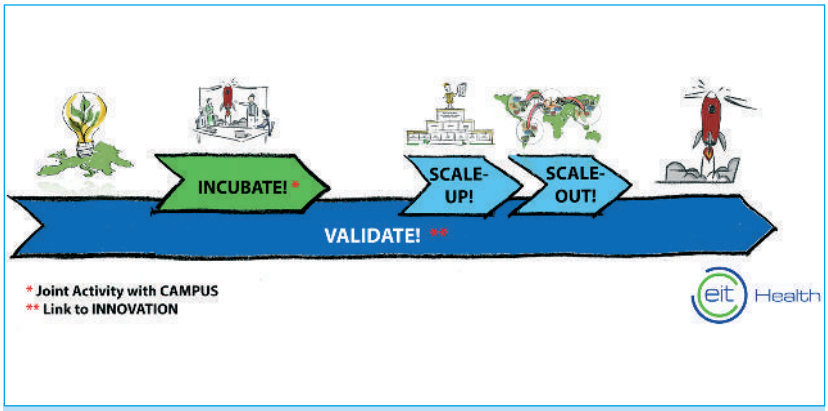

Fig. 7: *EIT Health ACCELERATOR Supply Chain 2017* ■

of activities, which it offers to entrepreneurs through the EIT Health ACCELERATOR.

Using the Market Power of our Global Players

Global players in the MedTech and BioTech industries recognise that innovation through entrepreneurship is a key driver, for the market and also for their own ability to innovate.

For instance in the Industry Ideation Meeting in Munich *(Figure 6)* industry leaders committed to contributing to entrepreneurship with mentors, corporate funds and access to their research facilities. In the future, industry partners will benefit from ACCELERATOR activities too. One major goal, therefore, was to understand and explain how the industry can benefit from the ACCELERATOR when it comes to developing their own intrapreneurship schemes. With the benfit of a wide-ranging portfolio *(Figure 7)*, the ACCELERATOR will support business creation as well as corporate growth.

INCUBATE! ACTIVITY LINE

ACCELERATOR's INCUBATE! activity line *(Figure 8)* aims to bring together entrepreneurs, start-ups, SMEs and intrapreneurs, as well as investors keen to learn about opportunities in the health industry.

The activities included in the INCUBATE! activity line are strongly connected to the EIT Health CAMPUS, which is EIT Health's education pillar. Students could, for example, take part in one of the summer schools organised by CAMPUS and then further develop their business idea within the ACCELERATOR programmes, such as the eight-week Launchlab, the Local Training programmes or the Intrapreneur Lab.

Connections between entrepreneurs are extremely valuable and weighty. Entrepreneurs learn the most from other entrepreneurs and from mentors who have entrepreneurial experience. When

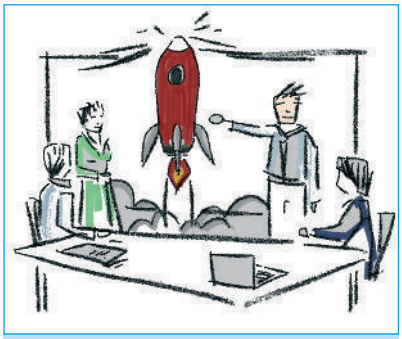

Fig. 8: *EIT Health ACCELERATOR INCUBATE! activity line (Grafic: Ulrike Höller)* ■

it comes to the aims and activities that connect entrepreneurs, intrapreneurs, experts and investors, the initiatives that compose the INCUBATE! activity line have real synergy.

VALIDATE!

The VALIDATE! activity line *(Figure 9)* aims to support start-ups, entrepreneurs and SMEs in the validation-related aspects of health-tech innovation, business creation, and product or service commercialisation.

More than in any other business, when it comes to healthcare, clinical trials and studies – of children, elderly, disabled people, or any other target group of European citizens – are mandatory for a significant market reach. With a strong focus on validation aspects, VALIDATE! covers not only the evaluation-validation phase of a digital health or MedTech product development, but all possible validation activities throughout the whole value chain (e.g. validation of an idea, a proof of concept, a prototype, a developed product, etc.) The VALIDATE! activity line provides all participants of ACCELERATOR and CAMPUS activities and INNOVATION PIs with a central database containing relevant resources, such as: Living Labs, health technology assessments, clinical validation labs, population cohorts and biorepositories, experts, and specific knowledge (i.e. funding and reimbursement schemes). VALIDATE! will also offer a gateway to other EU networks whose resources are connected (i.e. reference sites for active and healthy ageing). This platform is intended to be a single entry point for all relevant stakeholders (start-ups, entrepreneurs and SMEs) who are looking for support to validate an idea or product in the various phases of the value chain.

The need for such domain-specific support is especially high in the healthcare sector, as health start-ups need to overcome a set of market entry barriers, such as specific health regulations, reimbursement schemes, privacy legislation, user validation and the need for clinical-/interoperable/economic validation of their products. Scientists, doctors, entrepreneurs and engineers need to come together and combine their knowledge, in order to create products that improve the quality of life of Europe's citizens.

SCALE!

ACCELERATOR's SCALE! activity line *(Figure 10+11)* aims to support start-ups and SMEs seeking to grow their already existing businesses to the "next" level. In the end, the SCALE! activities should have a high impact on the participating start-ups and SMEs, in order to increase turnover and jobs.

Start-ups and SMEs must answer challenges in the scale process, such as:

- How do I find the right private investors to grow my business?
- Which easy-to-apply grant can bring my product to the next maturity stage?
- What internationalisation strategy fits for my company?

The SCALE! activity line is especially open to start-ups and SMEs that have already taken part in the activities included in the INCUBATE! and VALIDATE! activity lines, so that they can complete their successful Business Creation journey with the EIT Health ACCELERATOR, either by gaining visibility within their home market or by expanding to different markets all over the world. An applicant who has developed a business plan in one of the INCUBATE! activities could, for example, take part in the annual Business Plan Competition, Crowdfunding, Go Global programmes or the Investors' Network, either to get further funding to boost his or her

Fig. 9: *EIT Health ACCELERATOR VALIDATE! activity line (Grafic: Ulrike Höller)* ■

company or to establish valuable contacts. The great news about this portfolio is that it supports any stage of the Business Creation process. With the help of EIT Health's ACCELERATOR, a single business idea can turn into a start-up, becoming a successful company in any desired market worldwide.

How to benefit from our EIT Health ACCELERATOR Programme

The ACCELERATOR is not only open to entrepreneurs and start-ups, but also to micro SMEs (small companies with less than 50 employees). Many stakeholders within the European Health Economy ecosystem will benefit from our ACCELERATOR activities, the interdisciplinary portfolio, the competitive selection processes and the international network:

- Start-ups, SMEs and large companies benefit from new forms of cooperation within the healthcare industry, and from European research and innovation infrastructure.
- They have increased access to the international market and to public and private funding, and

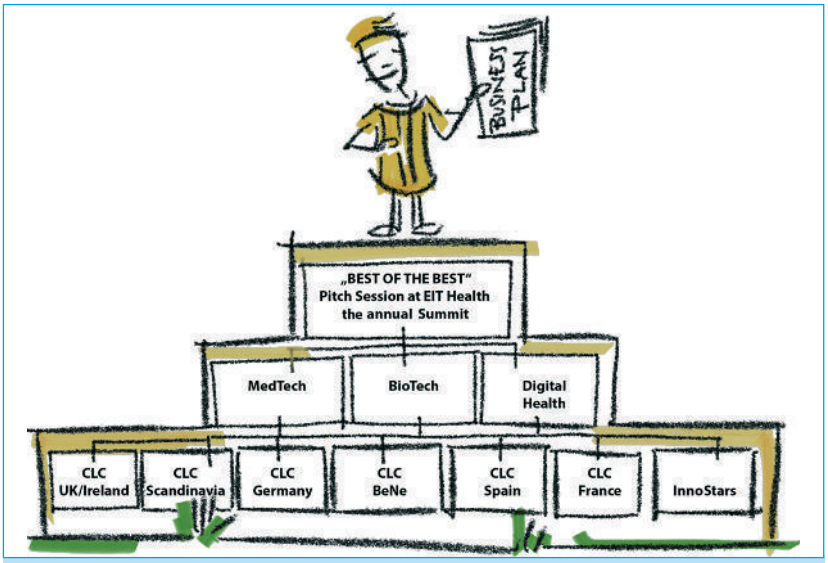

Fig. 10: *EIT Health ACCELERATOR SCALE-UP! activity line (Grafic: Ulrike Höller)* ■

they have access to co-creation environments and living labs.

- Institutional and private investors, Business Angels and Venture Capitalists get early access to the most innovative entrepreneurs with the brightest ideas.

To be part of the ACCELERATOR and to apply for its programmes, it's not necessary to be an official EIT Health partner. It is sufficient to come along with just a recommendation or reference letter of one of our partners.

If you are interested in our EIT Health programmes, please have a look at www.eithealth.eu or get in touch with our CLC Business Creation managers, who will act as a single point of entry to all EIT Health activities for start-ups in their region. These managers offer a first consultancy with regard to their home market, and also access to whole European network. To find the local contact person, you can also simply write an email to the European director, via kurt.hoeller@eithealth.eu.

Dr.-Ing. Kurt Höller, MBA is EIT Health's Director of Business Creation. He attained his Doctorate of Engineering at the FAU Erlangen-Nuremberg in a medical engineering research topic, with stations at the Fraunhofer IIS, "Klinikum rechts der Isar" and TU Munich as well as the Johns Hopkins University in Maryland, USA.
After that he went on to earn an MBA with focus on Entrepreneurship at Deggendorf Institute of Technology (THD) with study sections at the Santa Clara University in Silicon Valley.
Besides his position as founding member and managing director of the Central Institute of Healthcare Engineering (ZIMT) at Friedrich-Alexander-University (FAU) from 2009-2015, he was involved in the foundation of several start-ups as stakeholder and CEO/CFO.

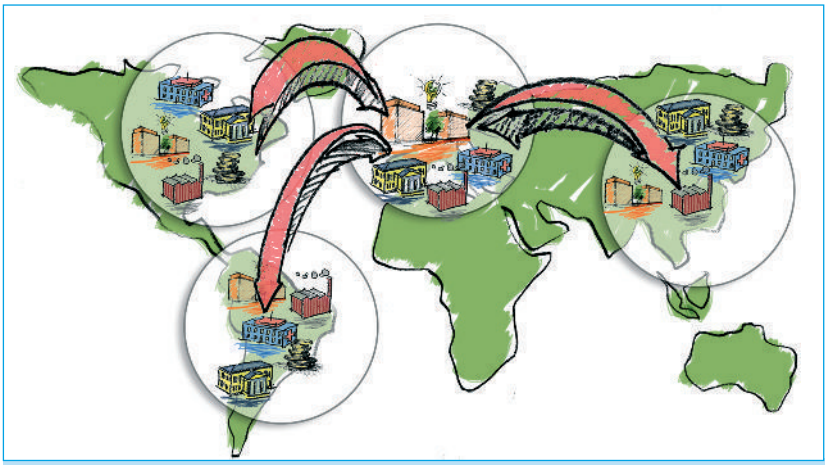

Fig. 11: *EIT Health ACCELERATOR SCALE-OUT! activity line (Grafic: Medical Valley EMN e.V., Ulrike Höller)* ■

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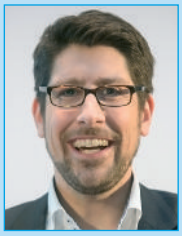

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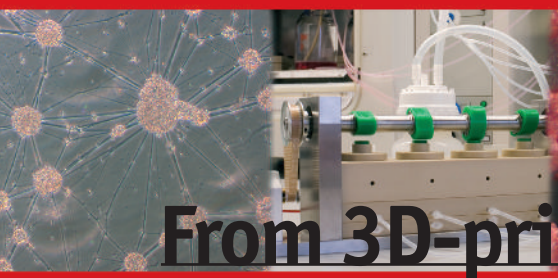
EIT Health is supported by the EIT, a body of the European Union

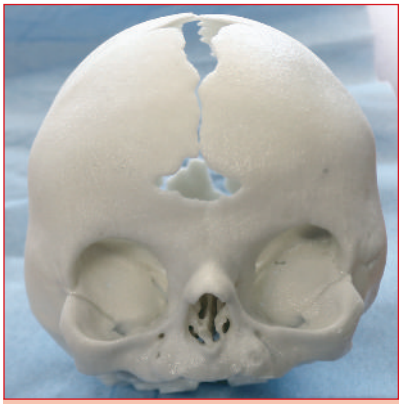


From 3D-printed Scaffolds to in vitro tissue culture – modern medical technology in Upper Franconia at the Friedrich-Baur BioMed Center in Bayreuth

The Friedrich-Baur BioMed Center in Bayreuth is a non-profit organization that promotes the development and realization of medical innovations in of Upper Franconia, giving the region a medical center for research and development. The Orthopedic Clinic and Polyclinic Großhadern of the LMU, headed by Prof. Jansson, is an important clinical partner. The FB BioMed Center has active contacts with further medics and medical professionals all over Germany and the world. ■

A step into the future – the next generation Rapid Prototyping

3D printing has always been a focus of our development. Competence in Rapid Prototyping reaches back as far as 2003 with the participation in Bavarian pioneer projects, meanwhile we work on refinement and integration into clinical routine. Highly precise models of complicated bone deformations are created from imaging data and printed with a material that feels and can be worked on just like real bone. They help solve intricate cases of infant skull defects, where ingenious operational methods are planned. They make it possible to exchange interesting cases between international experts in medical seminars. Dispense plotting technique is expanded to process a wide range of materials, crossing the borders of traditional 3D printing. In powder bed printing, we use proprietary resorbable ceramic powder-mixtures to print custom-made bone substitute material – sturdy implants with individual geometry and optimized pores and surfaces for secure biological integration. The implants can bear screws at any chosen position and even be reshaped during operation by the surgeon.



Our 3D-printed bone models are used for operational planning, technique improvements and training workshops, as they are uniquely precise and can be worked on like real bone ■

Based on the longstanding experience with processing 3D data and printing with various rapid prototyping techniques, the Friedrich-Baur BioMed Center gGmbH is now working on expanding classical printing techniques to stretch the limits – integrating robotics, modifying the building platform, using different extrusion methods… This enables us to develop new solutions for additive manufacturing. Here, we are always looking for interested partners to open new horizons. ■

Material development and biological research in one institute

The FB BioMed Center has an innovative concept: engineering sciences, with material and process development, are integrated with a cell lab in a hybrid construct. In the biological labs, we do more than just testing materials for their biocompatibility. Tissue culture systems, which include tumor cultures in three dimensional polysaccharide carriers, combine with high-tech bioreactors and biosensors constructed in our institute to form the base for substance evaluation, physiological effects and novel biomaterials. A special project is the standardized in vitro characterization of bone implants including induced osteoblasts, osteoclasts (resorption) in co-culture and vascularization assays as a complete substitute for animal testing, sponsored by the swiss foundation AnimalFreeResearch. The Invitro-BoneSpec system gives you a cost-effective, precise and reproducible investigation set for the suitability of novel bone implant or substitute materials. ■

Friedrich-Baur BioMed Center

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Software as a medical device – regulatory perspectives

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The reform of the EU law on medical devices is just around the corner. It will substantially increase the regulatory burden on manufacturers. This also applies for software. It is nothing new that software for medical and diagnostic purposes can be classified as a medical device and therefore has to be CE-certified. For integrated software this is normally done together with the device.
But what happens if the control software is not connected to the equipment? And what about independent software? Because of the uncertain legal situation, the answers of legal experts to these and similar questions are everything and the resulting legal uncertainty is challenging for the innovative climate of MedTech 4.0. Unfortunately, it is not going to improve with this reform.

The main hurdle

The biggest mistake of the EU legislator is the classification rule 10a. It is, from the perspective of most observers, a rather surprising result of the trialogue negotiations and reads as follows:
"Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, is in class IIa, except if such decisions have an impact that may directly or indirectly cause:

- the death or an irreversible deterioration of the state of health, in which case it is in class III;
- a serious deterioration of the state of health or a surgical intervention, in which case it is in class IIb.

Software intended to monitor physiological processes is in class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, in which case it is in class IIb.
All other software is in class I."

Scope of application

The wording of rule 10a itself suggests that any type of software is covered. However, according to the materials pertaining to the law, the Union legislator only wants this rule to prevent a misclassification of independent software. Integrated software or control software is thus not covered.
Even software which is separate from the medical device but necessary to operate it according to its designated purpose is not subject to rule 10a. This is because such software is not "independent of any other device" within the meaning of the sub-rule which was added to the third rule of application. It can therefore not be "classified in its own right". This applies for example to decoupled control software or software that updates integrated software.

Points of criticism

AMost worrying is the specification that even software whose only function is to support diagnostic or therapeutic decisions that can indirectly lead to death, an irreversible or serious deterioration of the state of health or a surgical intervention is assigned to class IIb or III. The result of this is that even a mere diagnosis software can be classified as a class IIb product if a possible false negative result of its diagnosis can, due to omitted therapy, seriously deteriorate the state of health. A simple software for recording and transmitting increased temperature would therefore be class III because death due to malfunction could never be excluded.
Furthermore, the relationship between sentence 1 and 2 of rule 10a is unclear. Because patient monitoring by definition aims at providing information concerning the condition of patients, the

sub-rule of sentence 1 applies to software with control functionality as well. However for classification every relevant classification rule has to be taken into account. This means according to the principle of allocation to the highest class that if the requirements of sentence 1 are met, a control software can be classified as a class III product although that is exactly what sentence 2 tries to prevent.

Besides, due to the wide coverage of sentence 1, sentence 3 tends to be futile. Because of this, the Medical Device Regulation (MDR) will probably cause a major surge in demand at the designated bodies for software that was previously often categorized as class I. Furthermore, it is unclear if rule 10a is an exclusive special regulation for independent software or if other classification rules have to be taken into account as well.

Summary

Overall, the Union legislator would have done better to orient themselves on the specific recommendations of the International Medical Device Regulators Forum (IMDRF). Technically they would have been obliged to do so.

Qualification

Another controversial issue that was insufficiently answered by the Union legislator is under which circumstances software can be classified as a medical device in the first place. In recital 18a of the planned Medical Device Regulation it is laid down that:

"It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is qualified as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being application is not a medical device. The qualification of software, either as device or accessory, is independent of its location or type of interconnection between the software and a device."

The first thing standing out here is that the recital contains a categorization that is similar to a definition. Typically, recitals should only point out what thoughts led to the adoption of the legal act. Moreover, the framing of legal definitions in recitals appears even more questionable since the MDR draft contains numerous legal definitions.

Sentence 1 of recital 18a offers essentially nothing new. A real innovation is only the signal, put out as a complementary alternative in half sentence 2, towards the necessary differentiation between health apps that are to be qualified as medical devices on one side and lifestyle apps on the other side. The resulting gain in distinction should be very limited but this deliberately performed negative delimitation will be paid due regard when it comes to the qualification of health-related apps as medical devices.

Contrary to sentence 1 of the recital, sentence 2 has no predecessor. At first glance its only statement is that software can theoretically be classified as an accessory – a point that is still denied by some German legal scholars. Furthermore, sentence 2 seems to emphasize the function-related categorization of sentence 1. Apparently, the qualification of a medical device as software is supposed to be neither dependent from whether the software is in the device or outside, for example in a cloud, nor shall the quality of the connection between software and device (W-LAN etc.) play a role. However, sentence 2 only partially reflects the regulatory objective of the Union legislator. According to the intention of its Belgic authors, the provision was supposed to fulfil the typical function of a recital, namely to explain why the software-related application rule was implemented. The idea that a product's qualification (as a medical or non-medical device) determines its classification (as medical device) appears to be plainly flawed.

Conclusion

As sentence 2 of the recital is infected with a categorical mistake, it should not be used to broaden the normative leeway for the qualification of software as medical device.

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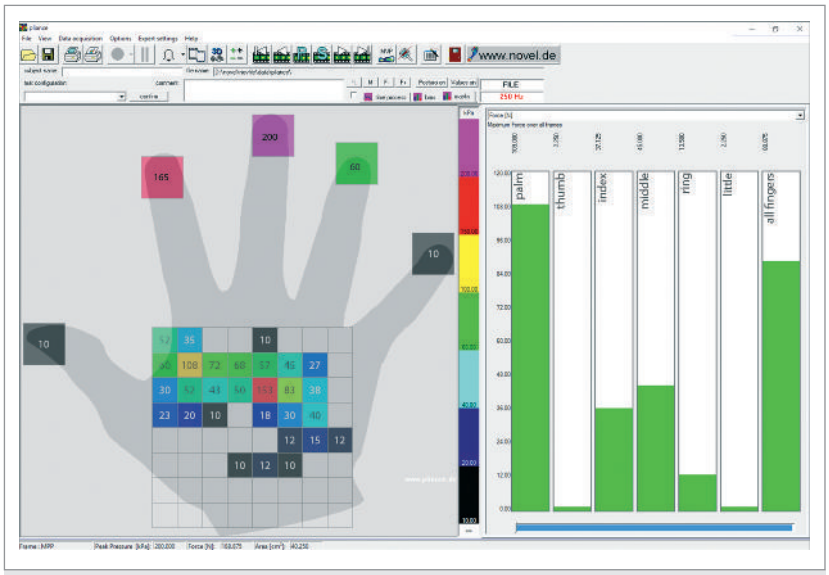
A new innovation from novel – the pliance® glove system



Screen display pliance®glove ■

Despite the progression of technology, many tasks in the workplace and in daily living must be performed with the hands. Furthermore, it remains a challenge to quantify the manner in which hands are being used and with what level of intensity. These measurements are very important; especially if a task requires repetitive motion, is exhausting, or requires high precision.

The ability to measure force distribution across the hand provides a perfect basis for the monitoring of hand forces during routine tasks, for the improvement of working conditions, and for the development of optimized hand tools.

The pliance® glove system offers state-of-the-art technology for force distribution measurement of the hand. The system consists of flexible and elastic measuring sensors, a multi-channel analyser, a calibration device, and a software package for Windows PC.

pliance® force sensor glove ■

As is the case for all physical measuring systems, the most important part is the sensor technology. Just like all novel systems, the pliance® glove system is based on calibrated, accurate, and reliable capacitive sensors. The individual sensor elements are elastic and arranged in a matrix which conforms well to three-dimensional shapes.

The pliance® glove sensors are a combination of five to twelve finger sensors and one palm sensor. All critical hand surfaces are covered and the grip force of the hand can be measured. The unique design of the sensors conforms to the shape of the hand allowing various handgrips to be tested in different situations.

The pliance® glove system is primarily designed for measuring force distribution across the hand while using manufacturing and production tools. These measurements may be used to reduce stress on the hand either by providing ergonomic assessment and feedback during the occupational activities or by providing critical data for modifying and improving the standard working process and redesigning the tools.

The system may also be used in physical therapy practice for assessing manipulations or for hand rehabilitation. Furthermore, it is useful for research in biomechanics and orthopaedics.

The pliance® glove system is an advancement of the company novel in Munich, Germany, whose measurement systems are already successfully used in clinics and research labs as well as in industry worldwide. ■

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Revision of the EU rules for medical devices

At present, the Commission is in the process of revising the EU legislation on medical devices. The products affected by this legislation cover a wide range, from simple adhesive plasters to cardiac pacemakers. Especially products such as the latter are becoming ever more sophisticated, which consequently also affects their error rate. The new EU regulations mainly aim at more patient safety by strengthening the rules for placing devices on the market and reinforcing surveillance once they are available.

Finally, in recent years faulty medicinal products have received negative publicity. For example, in the year 2010 it became known that a manufacturer used low-quality industrial grade silicone for breast implants. This has caused severe health damage to several thousand women worldwide. Likewise, deficient artificial hips of a manufacturer caused emergency surgery in thousands of cases.

On 26 September 2012, the Commission therefore presented two draft regulations which have been intensively discussed within the European institutions. Since 15 June 2016, the most recent consolidated versions have been available, which must still be approved by the Council of the European Union at ministers' level. One draft regulation relates to medical devices and will apply three years after publication; the other relates to in vitro diagnostic medical devices and will apply five years after publication.

In contrast to the current European regulations, these new regulations will have direct effect in the Member States of the European Union and therefore do not require implementation into the national legal systems. With them, uniform provisions will in future apply in the European Union instead of partly differing regulations in the 28 Member States as at present.

The safety level of medical devices under substantive law is comparable to pharmaceutical law and thus ensures sufficient patient protection. However, there are large differences with regard to the process of how a medical device is placed on the market. Contrary to the marketing authorization proceedings for pharmaceuticals which take several years, no official permit or regulatory approval is required for the placing on the market of medical devices and in vitro diagnostic medical devices. Medical devices must merely bear a "CE label". However, this "CE label" is not awarded by a public body but by the manufacturer himself. Thus, the manufacturer himself assesses compliance with the basic requirements, possibly controlled by a so-called "notified body". However, these "notified bodies" are private companies that are not supported by the state. Moreover, the extent of the duties of the "notified bodies" has so far not been sufficiently clarified. Thus, the "CE label" does not certify that a product is safe, and therefore is not a quality certificate. The "CE label" is thus unbureaucratic and fast, but questionable as regards monitoring the compliance with the prescribed safety level.

In spite of the just mentioned concerns regarding the launch of medical products, according to the new draft regulations there will not be a central regulatory approval for high-risk medical devices in future either - contrary to what has been demanded by, e.g., the German health insurance companies. However, as summarized in the following, with the new draft regulations mainly the existing regulations for the market introduction of medical

devices will be strengthened and the follow-up surveillance and control be improved.
As is already the case with other medical devices, in future in vitro diagnostic medical devices will be classified in four risk categories. The classification of these products in the categories A, B, C and D is dependent on their intended use and the risks associated therewith. Products of Class D hold the highest risk, products of Class A the lowest. The requirements that can be imposed on the manufacturer differ depending on the classification of the products. Moreover, the classification determines the requirements for clinicial investigations and clinical evidence as well as for market surveillance.

In future, the above mentioned „notified bodies“, as independent assessment bodies, will be allowed to carry out unannounced factory inspections. In view of the fact that these “notified bodies” are private enterprises, the monitoring rights of the national authorities are strengthened. Moreover, the ”notified bodies” will in future have to show that their personnel is qualified to assess medical products.

Furthermore, every company will be required to appoint a person in charge of ensuring compliance with the legal regulations. This person will have to show his/her qualification.

According to the new draft regulations, for the purpose of traceability of the medical devices put on the market, each product must be fitted with a Unique Device Identification (UDI). Said UDI must be affixed to the product label. Moreover, the UDI will be electronically registered with the health facilities and economic operators. Furthermore, the UDI will be registered in the already existing European data bank on medical devices (Eudamed). This database will be considerably extended, both with regard to content and accessibility.

In addition, there will be an „implant card“. This card contains information allowing the clear identification of the device, including the already mentioned Unique Device Identification. In case of complications, this card will enable patients and healthcare professionals to identify at any time the exact product that has been implanted.

Furthermore, especially for high-risk products, manufacturers of medical devices will in future have to provide stricter clinical evidence with respect to the safety and effectivity of their products.

Within the European institutions, the required professional guidance in case of DNA tests was controversially discussed. In the resulting compromise it was merely regulated that the Member States have to sufficiently inform the patients about the consequences of such tests.

The Member States will remain responsible for deciding the extent of this professional guidance. Furthermore, the reprocessing of medical devices designed for single use was a major concern. Here again, according to the final draft regulations, the responsibility for this question will remain with the Member States.

Undoubtedly, these new draft regulations will lead to more patient safety. However, the “big breakthrough” - the regulation of the requirement of a regulatory approval process for medical devices like in the case of pharmaceutical products – did not occur. ■

[1] Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 of 26.9.2012 (COM(2012) 542 final) and Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices of 26.9.2012 (COM(2012) 541 final).

[2] In English downloadable under : http://www.consilium.europa.eu/en/press/press-releases/2016/06/15-medical-devices/.

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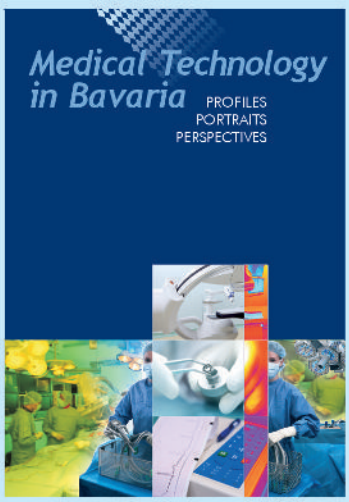

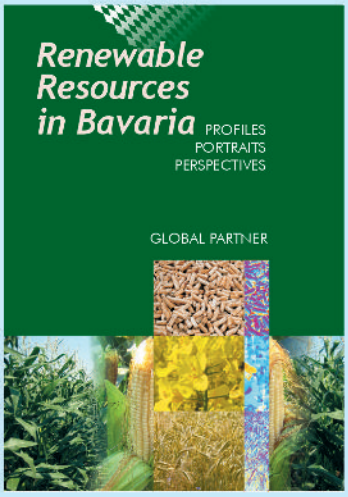

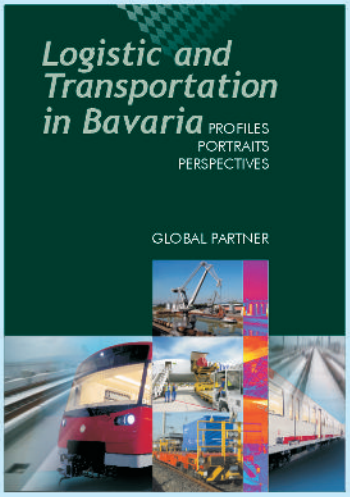

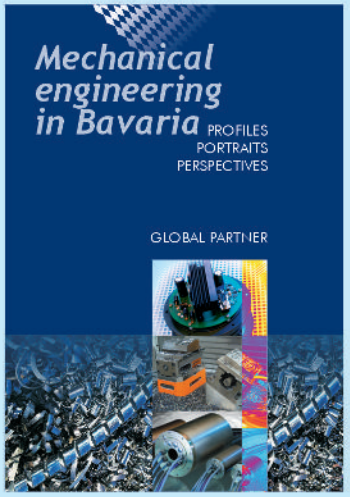

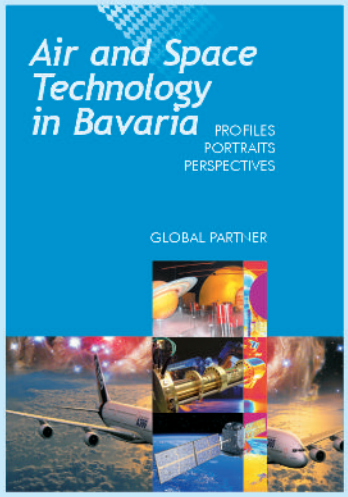

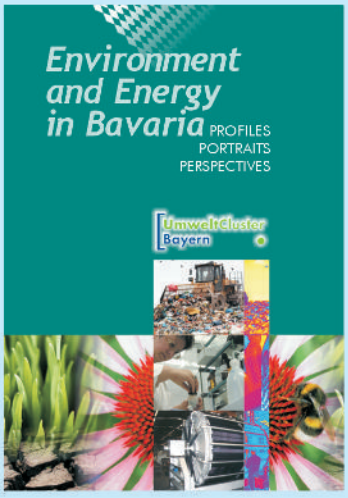

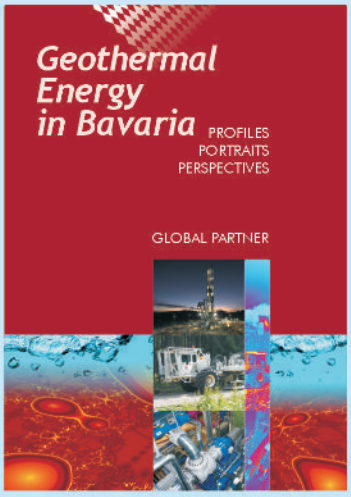

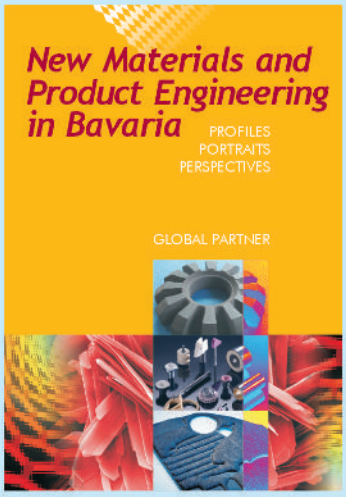

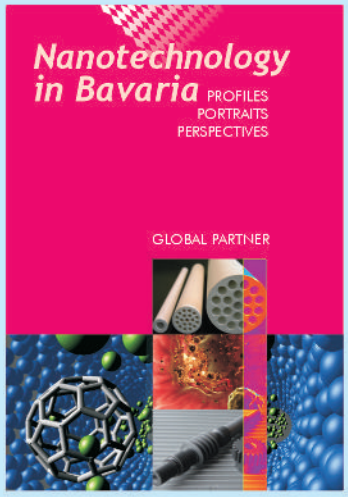

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