Medical Technology in Bavaria

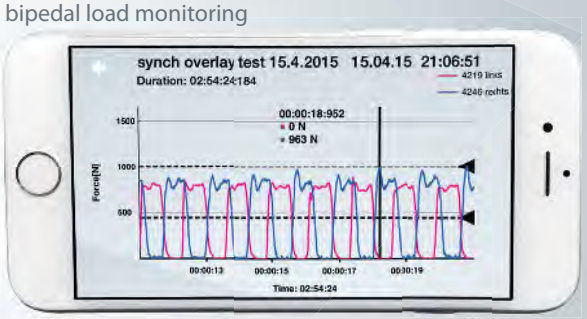
PROFILES
PORTRAITS
PERSPECTIVES

GLOBAL PARTNER

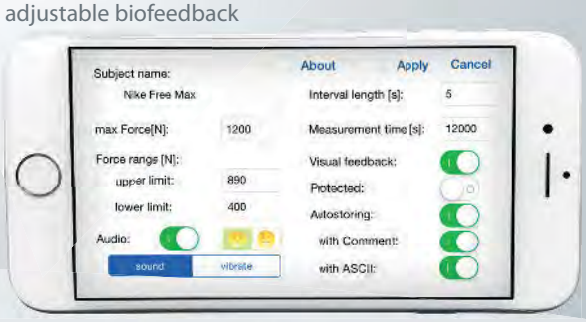
pedoped®.de

Mobile force measuring insole displays on mobile devices. Designed for load monitoring in orthopaedics, sports, biomechanics, and rehabilitation.

bipedal load monitoring



adjustable biofeedback



novel is the world leader in accurate systems for load distribution measurement.

art science

All systems from novel operate with high quality, calibrated sensors and provide reliable and reproducible results.

novel gmbh • Ismaninger Str. 51 • 81675 Munich, Germany • tel +49 (0)89-417767-0 • fax +49 (0)89-417767-99 • email: novel@novel.de

novel.de

Editorial

New concepts and findings for diagnosis and therapy

Nanotechnology promises a broad range of applications for treating cancer and other diseases.

Successes are reflected in an inter-disciplinary research approach by medical professionals, biologists and pharmacists, along with chemists, engineers and physicists.

„Personalised medicine“ is already a hot topic and will continue to gain importance in the future. Sensors are used, for example, to measure the reaction of cells to medicines or harmful substances.

This publication contains exciting topics such as start-up companies, product and user ergonomics, safe packaging solutions, new study programmes in medical technology and much more. Expert answers to complicated questions:

- What opportunities does the Innovation Research Lab (IRL) offer for realising new ideas?
- Why are communication standards so important in medicine?
- What does „iMob“ mean for age-appropriate products and solutions?
- How can time and money be saved by reusable sterilisation containers?

In addition to the sophisticated „world of medical technology“, the fascination with money and patents play a key role and enrich the view of entrepreneurial activity (see pages 60-82).

Walter Fürst, Managing Director

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

Masthead:

Publisher:	media mind GmbH & Co. KG Hans-Bunte-Str. 5 80992 Munich/Germany Phone: +49(0)89/23 55 57-3 Telefax: +49(0)89/23 55 57-47 ISDN (MAC): +49(0)89/23 55 57-59 E-mail: mail@media-mind.info www.media-mind.info
Managing director:	Walter Fürst, Jürgen Bauernschmitt
Design + DTP:	Jürgen Bauernschmitt
Prepress:	media mind GmbH & Co. KG
Responsible editor:	Ilse Schallwegg
Published annually:	1 x annually
Printed by:	Druckerei Frischmann, Amberg

Table of contents

We face challenges

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

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

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

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

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

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

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

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

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

HOLZAMMER
Kunststofftechnik

Author:

Hans Holzammer, Managing Director

HOLZAMMER
Kunststofftechnik GmbH
Am Ursprung 9
92369 Sengenthal/Germany
Phone: 0 91 81 / 2 95-0
Fax: 0 91 81 / 2 95-34
E-Mail: kontakt@holzammer.de
www.holzammer.de

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

Cluster of excellence Medical Valley EMN

The Medical Valley European Metropolitan Region of Nuremberg (EMN) is a leading international cluster in the field of medical technology. Here highly specialised research institutions are active together with internationally leading companies and at the same time many growing companies as well. The latter cooperate closely with world renowned institutions of health research in the cluster to join together to find solutions for the challenges of healthcare, today and tomorrow. How extraordinary this cluster is was emphasised in January 2010 by its appointment as top national cluster by the Federal Ministry for Training and Research (BMBF).

Functioning since 2007 as cluster management organisation has been Medical Valley EMN.V, a consortium with currently 175 members from business, science, healthcare, networks and politics. Central tasks of cluster management are further development, coordination and marketing of the cluster. We measure our success and the relevant central issues:

- Will we succeed in stimulating new ideas, projects and startups?
- Are we recruiting R&D grants for innovative projects?
- Do our services catalyse the commercialisation of ideas?
- Do our operations promote cross-sector and trans-disciplinary exchange?
- Do we reinforce exchanges inside the cluster; are we improving the culture of cooperation?
- Do we promote creative minds?

Medical Valley EMN supports internationalisation – explicitly into the lead markets of the US, Brazil and China ■

- Do we support the internationalisation of our partners?

Our services help you in commercialising your ideas. The things we offer include recruitment of support grants and counselling, promotion of startup founders, identification and brokering of clinical partners, market certification and reimbursement, strategic requirements analysis and commercial health evaluation, open innovation as well as international market access. In order to provide you with comprehensive support, we integrate established specialists and experts in the cluster according to the one-stop-shop principle.

Tangible select operations on our part have been, and currently are, global coordination of the top-rate BMBF cluster (45 R&D projects with a total project volume of over € 80 million), management of the "Franconia Model Region for Digital Healthcare business" (over € 8 million in total project volumes focusing on "Optimisation of the medication process"), management of the ZIM cooperation networks "InnoPlanT.NET" and "Healthcare IT" and putting the project, "Science2Market," likewise subsidised by the Bavarian Ministry of the Economy, into practice. In addition, Medical Valley is an associated partner of the top-flight European consortium "EIT Health," currently one of the largest health research programmes worldwide operating in the framework of Horizon 2020. ■

Contact the Cluster

At the Medical Valley EMN top-rate cluster, research institutions, internationally renowned companies as well as healthcare providers set standards in the field of medical technology. ■

MEDICAL VALLEY
Europäische Metropolregion Nürnberg

Contact:

Jörg Trinkwalter

Medical Valley EMN e.V.

Hemkestr. 91
91052 Erlangen
Phone: +49 9131 5302-863
E-Mail:
joerg.trinkwalter@medical-valley-emn.de
www.medical-valley-emn.de

A word of welcome

Medical technology remains a growth market. The worldwide potential for innovations in healthcare business that assist in making care more effective and efficient is immense. This means products for diagnostics and therapy as well as optimisation of treatment processes.

Innovations are also crucial for the field of prevention. The recognition of diseases at an earlier stage enhances the chances of cure and reduces the required expenses. Particularly effective are measures that help one remain healthy. That affects the lifestyle and nutrition fields. Here is where "social innovations" are needed in order to motivate the public to exercise more and to eat healthy foods. Motion is a very effective and efficient medication.

Databases are increasingly coming into being which in empirical form contain much information about health and progression of diseases in time. By evaluating these databases knowledge is generated that can be crucial for the treatment of patients. For this, "big data" approaches must be developed further with determination.

Innovations for health frequently stimulate concerns whether health is not becoming too expensive and that we cannot afford to be healthy. In actual fact, the innovations referred to can precisely make contributions to keeping health financially feasible.

The handling of all these issues makes trans-disciplinary work necessary. That is, structures must be created like the cluster Medical Valley European Metropolitan Region of Nuremberg which link up different disciplines, including business, and facilitate efficient cooperation. The public only benefits from all the outstanding research results achieved by scientists if they lead to products and services. Commercialisation skills are of great importance.

Prof. Dr.-Ing. Erich R. Reinhardt

Managing Director of
Medical Valley EMN e.V.

Health region Mainfranken

Gesundheitsregion mainfranken

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

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

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

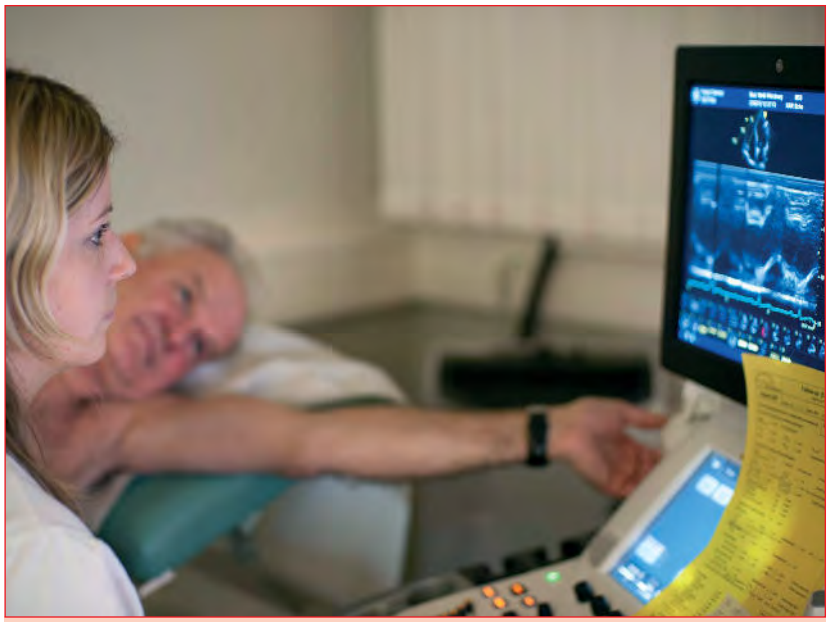
Region Mainfranken GmbH/Hub ■

Region Mainfranken GmbH/Hub ■

Top biomedicine research

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

The Rudolf-Virchow Centre for Experimental Biomedicine, the DFG



Region Mainfranken GmbH/Hub ■

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

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

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

World-leading medical technology

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

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

Health region faces up to the competition

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

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

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

IGZ Würzburg

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

RSG in Bad Kissingen

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

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

Contact:

Theresia Oettle-Schnell

Project director

Region Mainfranken GmbH

Ludwigstraße 10½, 97070 Würzburg
Phone: 0931-452652-12
Fax: 0931-452652-20
info@mainfranken.org
www.mainfranken.org

Network for Innovations

Forum MedTech Pharma

A unique platform for business contacts and knowledge exchange

Newest information on technologies, markets and trends

More than 600 members from 16 countries

Congress and Exhibition

MEDIZIN INNOVATIV
MedTech Pharma 2016

June 15 - 16, 2016
NürnbergConvention Center

www.medtech-pharma.de

Nanomedicine – The SEON-Concept

Nanotechnology promises a broad spectrum of applications for medical imaging and molecular diagnosis, as well as improved and targeted treatments for patients. However, the implementation of nanotechnology-based methods for the treatment of cancer or other diseases requires an interdisciplinary approach combining the expertise of health professionals, biologists, pharmacists, chemists, engineers and physicists.

Superparamagnetic iron oxide nanoparticles (SPIONs) deserve a close attention, as they can be utilized both for diagnostic imaging and for therapeutic approaches as drug carriers. Currently, SPIONs are used for magnetic cell separation in vitro and as contrast agents for MRI and for a new imaging modality called "Magnetic Particle Imaging" (MPI), which is at present under development. But above this, SPIONs offer the unique possibility of combining drug delivery and diagnostic imaging, serving as so-called "theranostics". From the drug delivery point of view, SPIONs are of high interest for the individual treatment of solid tumors, because they can be used for magnetic accumulation of drugs in the tumor region. Additionally, they can be used for local hyperthermia via alternating magnetic fields and after treatment their local distribution can be monitored by MRI.

A promising drug delivery approach utilizing SPIONs is Magnetic Drug Targeting (MDT), which enables the targeted local accumulation of chemotherapeutics for the locoregional treatment of cancer. Using this new treatment concept, the Section of Experimental Oncology and Nanomedicine (SEON) already showed very promising preclinical results in an animal tumor model *(Fig. 1)*.

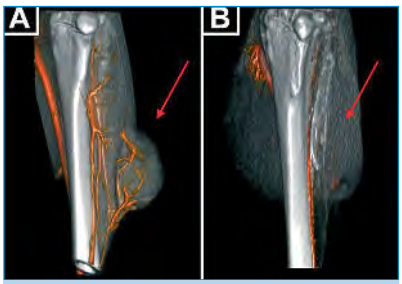


Fig. 1: *Tumor remissions were achieved in 30 % of the treated animals within 7 to 11 weeks after a single application of 5% to 10% of a usual single systemic dose of chemotherapy. A) VX2-tumor at the hind limb of a rabbit before the treatment. B) Hind limb of the same rabbit 11 weeks after the treatment – the tumor shows a complete remission. Image: SEON* ■

The declared aim of SEON is to translate the effective therapeutic treatment by MDT into a clinically used therapy. To achieve this goal, a multitude of different requirements have to be fulfilled. Among those, a highly reproducible and standardized production process of the nanoparticles is one of the prerequisites. Additionally, standardized physicochemical characterization, nanotoxicological evaluation as well as ex vivo and in vitro models, which simulate in vivo conditions, are crucial. By these tests, the necessary parameters (e.g. magnetic field strength and gradient, nanoparticle concentration and drug dose etc.) are identified to enable successful preclinical animal studies. The results of these studies are the basic requirement before starting the GMP-compliant production of the drug-loaded nanoparticles and their approval by the responsible authorities.

Additionally, the cooperation with physicists and engineers is crucial for the successful implementation of a suitable technical application environment in a clinical setting and for the noninvasive evaluation of the particle distribution in the tumor region after the treatment.

The Section of Experimental Oncology and Nanomedicine, which is located at the University Hospital Erlangen, Germany, addresses these fields of research with a special focus on targeted drug delivery by using magnetic nanoparticles and external magnetic fields. The aim of this work is to improve the treatment of solid tumors and metastases by reducing the side effects of cancer therapy. This therapy holds the promise of improved outcomes in cancer patients and an improved quality of life during and after the treatment. ■

Further information can be found at: *http://www.hno-klinik.uk-erlangen.de/seon-nanomedizin/*

Contact:
Professor Dr. med. Christoph Alexiou
HNO-Klinik Erlangen, Sektion für Experimentelle Onkologie und Nanomedizin (SEON)
Else Kröner-Fresenius-Stiftungsprofessur
Phone: 09131 85-33142
E-Mail: seon@uk-erlangen.de

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 healthcare and thus constantly increase the efficiency and quality of medical care. All of the players involved with healthcare 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. ■

Every two years 150 representatives from the medtech and pharma sector come together to meet at the B2B Event "Partnering for MedTech & Pharma" ■

Areas of thematic focus and projects

Within its theme-based networks, the association focuses in symposia and expert conferences on biomaterials, diagnostics, clinical trials, minimal invasive medicine, 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 areas

The medtech- and pharma community will meet again from June 15-16, 2016 at the international congress Medizin Innovativ - MedTech Pharma in Nuremberg. The event takes place for the fifth time and gathers nearly 1000 participants and 120 exhibitors ■

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 seventeen years since it was founded, the Forum MedTech Pharma has welcomed about 20,000 delegates at 200 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, medical imaging, biomaterials, minimally-invasive technologies, pharmaceuticals, diagnostics and clinical testing, regulatory affairs, markets and products, education and training*

Congress Medizin Innovativ – MedTech Pharma 2016

June 15 – 16, 2016
Nuremberg
Convention Center

The international congress "Medizin Innovativ – MedTech Pharma 2016" is adressing researchers, developers, manufacturers, suppliers, service providers and clinical users of the medical and pharmaceutical sector. With nearly 1,000 participants, the congress has become one of the most important meeting points for the health sector in Germany in recent years.
Combining a series of lectures on scientific-technical and operational market-related topics with a large exhibition with over 100 exhibitors, the congress provides ideal conditions to connect participants from various disciplines. The variety of participants from company representatives to scientists and clinical users has been a unique feature from the beginning of the congress.
The two intensive and highly efficient days of the "Medizin Innovativ" congress give international participants the opportunity to acquire new knowledge and expand their contact network, giving them a competitive edge in the global market.

- *65 High Level Lectures in Parallel Sessions*
- *Congress Language: German and English (all lectures will be translated simultaneously)*
- *120 Exhibitors*
- *Scientific Poster Exhibition*
- *International Delegations*
- *Job Wall*
- *Evening Reception at the Nuremberg Imperial Castle*

Author:
Marlene Klemm

Forum MedTech Pharma e.V.
Vorsitzender des Vorstands
Prof. Dr. Michael Nerlich

Office:
bayern innovativ

Gewerbemuseumsplatz 2
90403 Nürnberg/Germany
Phone: +49 911 - 20671 330
Fax: +49 911 - 20671 788
info@medtech-pharma.de
www.medtech-pharma.de

BAYERN INTERNATIONAL
Competence for International Business

EASY ACCESS TO ECONOMIC PARTNERS IN BAVARIA

YOUR KEY TO BAVARIA

Exclusively available at Bayern International, the database "Key Technologies in Bavaria" comes free of charge and offers valuable insights into more than 14.500 companies.

Visit www.keytobavaria.com to obtain the regularly updated information of all 22 industries.

Questions? KeyTech Hotline*: +49 (0) 180 5 949260
Mon to Thu 9 am to 5 pm, Fri 9 am to 3 pm

* (14 cents per min. for calls from Germany; fees for international calls subject to your local provider)

Bavarian Ministry of Economic Affairs and Media, Energy and Technology

Looks different. Is different.

New stereo microscope family for optical visual inspection

Vision ENGINEERING

Ergonomic Advantage

The product and user ergonomics become more and more important for the industrial optical microscopy. Especially in inspection, control and rework as well as long-term operations on the microscope as usally in a lot of industrial areas in quality, R&D, manufacturing and laboratories, the user should have a relaxed posture in front of the system and increase the efficiency considerably. This will be particularly achieved with the new Lynx EVO stereo microscope. ■

Eyepiece-less Technology

The highlight of Vision Engineering's Lynx EVO stereo microscope is for sure the patented Dynascope technology which offers the user advanced ergonomics by removing the need for restrictive eyepieces. That means the user can sit in a comfortable position in front of the microscope and perform his work in an ergonomic posture, which can sometimes be for long periods of time.

An increased efficiency and productivity depands especially on microscope ergonomics. There is critical link between operator ergonomics and increased productivity, efficiency and ultimately improved quality. The Dynascope technology which is integrated in the stereo microscope head allows almost a fatigue-free viewing without loosing image brilliance and contrast.

Although the eyepiece-less advantage of Lynx EVO stems from stunning 3D (stereo) imaging, the real brilliance of the patented design is the simplicity of operation.

Superior imaging combined with unrivalled ergonomics promotes simple hand-eye co-ordination, critical for precision inspection tasks, re-work, repair and other manipulation activities. Operators can maintain the highest levels of performance, even across an entire shift.

Benefitting from a high optical specification, the 10:1 zoom ratio with long working distances provides users the ability to inspect up to 120x magnification (6x – 60x standard), ideal for a wide range of applications.

Lynx EVO is available in a range of configurations, designed for use in different environments, from laboratories and medical device clean rooms, through to production, or manufacturing inspection. Accessories include HD image capture. ■

360° rotating viewer

The amazing 360° rotating viewer for Lynx EVO is the ultimate inspection accessory, permitting a full 360° rotating view of the subject (at an angle of 34°). Operators can simply switch between rotating and a conventional direct view for ultimate flexibility. The rotation provides enhanced observation for many applications, including electronics, mechanical, medical and plastics components. ■

The new Lynx EVO stereo microscope in the flexible multi-axis bench stand version ■

Author:

Stefan Summer
Central Europe Marketing Manager

Vision Engineering Ltd.
Anton-Pendele-Str. 3, 82275 Emmering
T: +49 (0)8141 401670
F: +49 (0)8141 4016755
info@visioneng.de
www.visioneng.de

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 ■

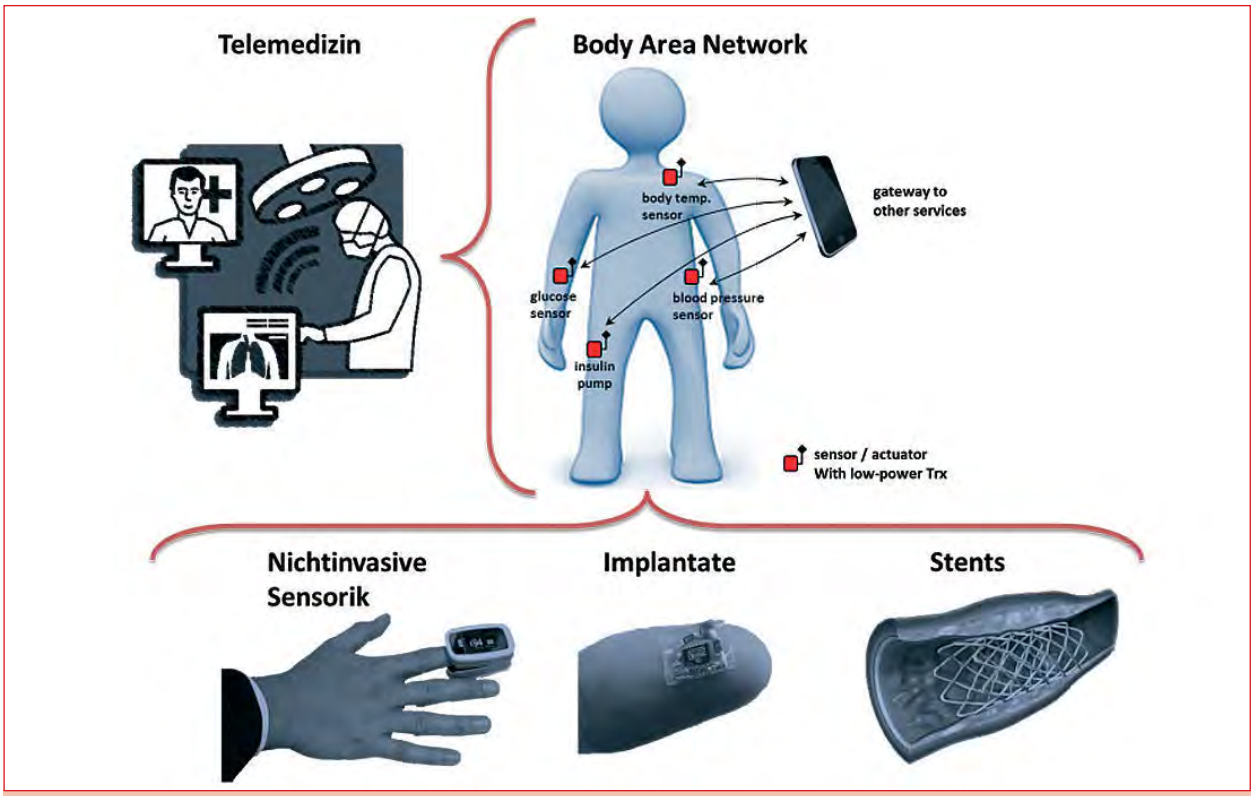
Another exciting development project was the support for multimorbid patients in the home-care-area. senetics implemented both patient-orientated application studies and usability testings of the product with patients as well as with medical staff.

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. ■

senetics healthcare group GmbH & Co. KG

Authors:

Rico Brendtke, Michael Wiehl
Wolfgang Sening

senetics healthcare group GmbH & Co.KG

Henkestrasse 91, 91052 Erlangen
Phone: +49 9131 - 9 201 201
Fax: +49 9131 - 9 201 202
E-mail:
wolfgang.sening@senetics.de
www.senetics.de
www.nezumed.de

Cytotoxicity tests on medical devices: endpoints in comparison

The test for cytotoxicity is the most important in vitro basic test in evaluating the biological safety of medical devices according to ISO 10993. In this process, the reaction of mammalian cells on potential toxic substances which leach out of the medical device are examined. Qualitative (microscopic) or quantitative (biochemical) evaluation methods can be used to determine the cytotoxic effect. Eurofins BioPharma Product Testing Munich has validated quantitative and qualitative methods which allows a direct comparison of all of the endpoints.

Safety evaluation of medical devices

Cell-based methods play an increasingly important role in the safety evaluation of medical devices since they are quick to perform, inexpensive and repeatable as often as desired as opposed to *in vivo* studies. Moreover, they can avoid unnecessary animal suffering. Biocompatible materials or cytotoxic contaminants during production can thus be screened already within the development process of the medical device. In moreover, cytotoxicity tests are regarded as especially sensitive, since the medical device itself or an extract are given directly onto the cells lacking natural barriers (such as skin) or detoxification systems (liver, kidneys).

While the cell morphology and density are evaluated in the microscopic examination, endpoints of biochemical cytotoxicity tests are often cell viability (XTT, MTT tests) or protein quantification assays (BCA assay). In the viability tests, XTT (2,3,-Bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide) dye is reduced by enzymes (dehydrogenases) of living cells which can be quantified photometrically. When using bicinchoninic acid (BCA) staining, the total amount of protein is determined after the dead cells have been removed from the test system, which likewise leads to a measurable colorimetric change in colour.

Fig. 1: *Preparation of cells and extracts in 96well test setup* ■

For comparison between the microscopic evaluation and the biochemical endpoints XTT and BCA, monolayers treated with dilutions of a test solution containing varying concentrations of the cell toxic chemical dimethylsulfoxide (DMSO) were incubated at 37°C for three days. Afterwards, the cells were evaluated microscopically (grading scores according to ISO 10993-5). Then, the cell viability (XTT) and the growth inhibition (BCA) were determined. Results for treated and untreated cells were compared for calculation of relative cell viability or growth inhibition, that ideally add up to 100% cells in total.

Fig. 2: *Biochemical staining methods for determination of cytotoxicity* ■

Using this correlation, the XTT results were transformed into BCA-compatible data to facilitate comparison between both end-

Test solution [%]	ISO 10993-5 [% dead cells]	Determined grading score	BCA [%]*	XTT [%]*	Comparison Grading with BCA/XTT
100.0	> 70	4	94±2	98±1	comparable
66.7	> 70	4	79±3	83±3	comparable
44.4	≤ 70	3	67±2	69±2	comparable
29.6	≤ 70	3	53±3	49±2	comparable
19.8	≤ 50	2	40±2	34±3	comparable
13.2	≤ 20	1	29±2	23±3	comparable to a limited extent

*Growth inhibition

Table 1: *Quantitative and qualitative endpoints are comparable* ■

points. The mean values from nine independent experiments show a good correlation between XTT and BCA data, proving, that both methods are comparable *(Figure 3)*. However, slight deviations were observed at low concentrations of test solution (lower cytotoxicity). A comparison between the quantitative methods and the qualitative microscopic evaluation is depicted in *Table 1*. Column 2 shows the ISO 10993-5 standards to evaluate the microscopic grading scores. Data obtained with quantitative methods corresponded well to the grading scores determined microscopically (Table 1, Columns 3 – 5) with only minor deviations between the three endpoints in the 13.2% test solution. ■

XTT vs. BCA method

Depending on the type of medical device or the different registration markets, the choice of evaluation method can play an important role. The XTT endpoint for instance is often required for approval on the US-market. However, medical devices that are liquid and intensively coloured or medical devices showing reducing properties can interfere with XTT staining. In this case, the BCA test represents an alternative. Conversely, for protein-containing medical devices the BCA method is applicable only to a certain extent so that using XTT may be advisable. We were able to demonstrate that both types of assays are equally suitable and provide comparable robust results. Microscopic evaluation is often seen as subjective since the judgement directly depends on the analyst. The data presented by Eurofins BioPharma Product Testing Munich demonstrates that qualified personnel lead to equal results in microscopic evaluation as in the quantitative evaluation. While the acceptance criterion for a passed test using microscopic evaluation allows a maximum of 50% dead cells (Grading Score 2), a threshold of 30% growth inhibition is defined for the quantitative evaluation procedure. Hence, according to ISO 10993-5, the quantitative determination shall be preferred. Nevertheless, a microscopic evaluation should be performed in addition, to identify any possible false positive or false negative results of the quantitative endpoints.■

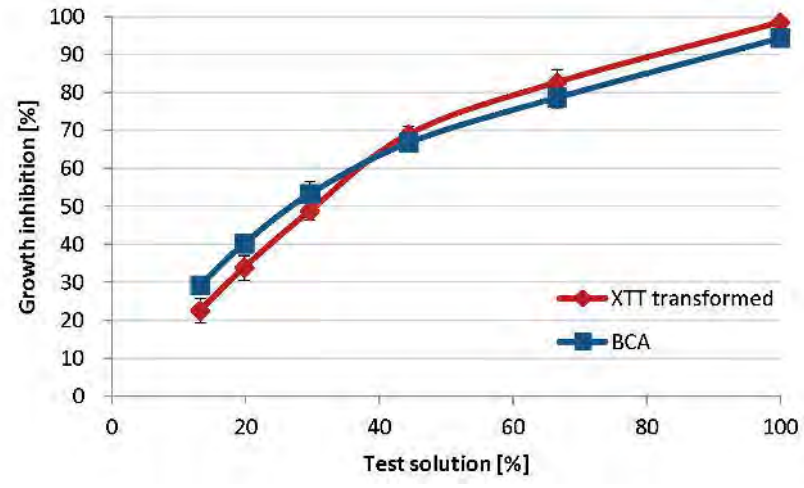


Fig. 3: *Cell viability (XTT) and protein quantification (BCA) assay are comparable. Cellular monolayers were treated with varying concentrations of DMSO and then stained using XTT and BCA. The XTT results were transformed. Test solution: 2:3 dilutions of 7.5% v/v DMSO in cell culture medium* ■

[1] Roehm, N.W., An improved colorimetric assay for cell proliferation and viabilty utilizing the tetrazolium salt XTT. J. Immunol Meth., 142, 257 – 265

[2] Smith, P.K., et al: 1985, „Measurement of Protein Using Bicinchoninic Acid.„ Analytical Biochemistry 150, 76 – 85

Author:
Dr. Benjamin Hoy
Study Director in vitro Pharmacology & Toxicology

Eurofins BioPharma Product Testing Munich GmbH
Behringstraße 6-8, D-82152 Planegg
Phone: +49 89 899 650-0
Fax: +49 89 899 650-11
E-Mail: info-munich@eurofins.com
www.eurofins.com/pharma-services

A new standard in the operating theatre

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

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

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

Joystick ■

SOLOASSIST II ■

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

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

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

About AKTORmed GmbH:

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

AKTORmed™
ROBOTIC SURGERY

Contact:
Robert Geiger
AKTORmed GmbH

Borsigstraße 13
93092 Barbing/Germany
Phone: +49 (0) 9401 9320-110
Fax: +49 (0) 9401 9320-115
E-mail: info@aktormed.com

MULTIVAC: Reliable Packaging Solutions for the Life Science and Healthcare Industry

In 1968 MULTIVAC launched its first packaging solution for sterile medical products onto the market. What at that time began as an offshoot to the core business of food packaging solutions, is today a highly specialised business unit, which develops solutions for the automated packaging to GMP standards of medical items, pharmaceuticals and biotech products. ■

Packaging solutions from MULTIVAC – flexible, modular, intelligent

Changing regulations, shorter life cycles for products and the transition to just-in-time production have resulted in ever smaller batch sizes in the medical industry and pharmaceutical sector. At the same time, the industry is developing ever more complex and sensitive products and applications, which in some cases are even tailored to individual patients. Many products are also having to be packed in ever smaller batches in order to be able to meet regional and statutory specifications. These trends require packaging machines to be capable of being converted quickly and easily to other pack formats or materials, so that short set-up times can be achieved.

For these applications MULTIVAC provides flexible and customer-specific packaging solutions, which are characterised by their modular construction. This means that new components, such as identification and inspection solutions, can be integrated very easily.

So that there can be strict compliance with the statutory requirements within the sector, MULTIVAC offers a wide range of innovative packaging solutions, such as for example the MULTIVAC Clean Design™.

This machine concept is specially designed for the demands of the life science and healthcare industry, and it takes into consideration aspects of the packaging machine such as process reliability, ease of cleaning, cleanroom compatibility and compliance with requirements on cleanliness. ■

The portfolio includes a GMP-compliant packaging machine in the MULTIVAC Clean Design™ ■

One area in which MULTIVAC specializes is the packaging of sterile medical supplies and pharmaceutical products ■

MULTIVAC is a leading provider worldwide of packaging solutions: in addition to thermoforming packaging machines, its portfolio includes traysealers, chamber machines, chamber belt machines, labellers, quality control systems and automation solutions as well as turnkey lines. The MULTIVAC Group has over 4,500 employees worldwide, with about 1,600 based at the headquarters in Wolfertschwenden. With more than 70 subsidiaries, the Group is represented on all continents.

Contact:

MULTIVAC Sepp Haggenmüller GmbH & Co. KG

Bahnhofstr. 4
D-87787 Wolfertschwenden
Phone: +49(0)8334/6010
Fax: +49(0)8334/601-199
E-mail: muwo@multivac.de

MedTech made by Venturetec

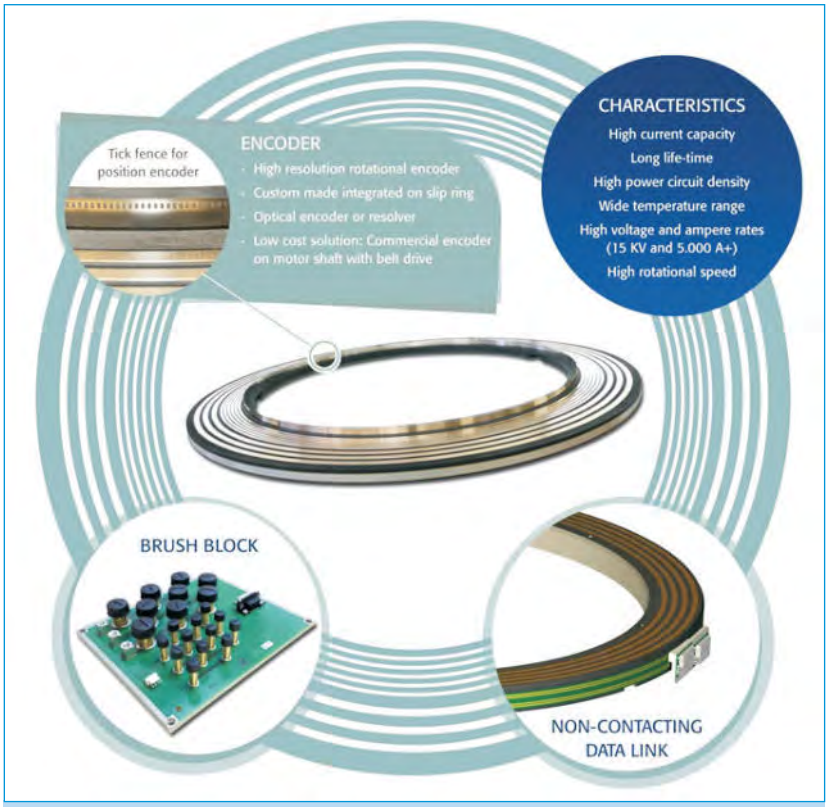
Venturetec Mechatronics is a specialist in the development and production of slip rings, rotary joints, components and complex systems for the high-tech industry.
As a well-known partner to the high-tech industry with locations in Germany, Sweden, and the United States, Venturetec Mechatronics supports leading companies in the areas of medical technologies, industry automation, aerospace and surveillance. As a systems supplier we integrate the entire mechatronic spectrum including the fields of mechanics, electronics, and optics. Systems are in place to monitor and track your order from inception to completion. Within this system we combine our competencies associated with development, production, integration, and testing.

Slip rings for CT scanners and nuclear medical devices

Electrical and optical rotary joints in the area of medical technology are commonly used in CT scanners. With regard to the interface, slip ring systems with a free inner diameter of up to 1500 mm are required.

CT scanners require the slip ring to transmit up to 150 KW of power for the x-ray source, and at the same time transmit data rates up to 10 Gbit/s without loss for the detector. The power for the X-ray source can be transferred by contacting or non-contacting slip ring solutions.

If contacting transmission is used, the type of rings and brushes are selected depending on the customer requirement. These refer mostly to the relevant parameters of "data rates", "frequency", "bus systems", and "performance". In addition, topics such as executing speed and durability of the ring/brush combination play a dominant role. Other important factors are the interface and the prevailing environmental conditions. The brush and contact material has to withstand a lapse of more than 10.000 km without system failures.



Venturetec Mechatronics' slip ring system for CT scanners ■

The customer requirements vary depending on their desired market and can be divided into two segments "low-cost" and "high-end". In the low-cost segment the basic functions are performed at an optimal price performance ratio.

Slip rings for high-end scanners usually have to guarantee the highest data rates for images (> 10

Gbit /s), high transmission power (150 to 200 kW) and contactless Control Links (bidirectional GigaBit Ethernet) at high speeds (> 20 m / s rotational speed).
In both types of systems a bit error Failure rate > 10^{-12} for the image data links is required. ■

Contactless transmission solutions: Capactive link and GigaFluo™

The Capacitive Link technology (capacitive route) is currently used in many different applications for electrical slip rings. Venturetec Mechatronics is able to transmit data rates of > 5 Gb/s per channel.
The newly developed "Any rate system" of Venturetec Mechatronics provides data rates of 1.25 Gbit/s to 3.125 Gb/s. The system operates using a constant-emitting structure, transmitter electronics, receiver antenna, and receiver-electronics over the specified "Any rate" bandwidth.
Venturetec Mechatronics also develops and integrates the contactless passive optical solution GigaFluo™. This technology offers a unique approach for data transmission in medical technologies.
High data rates are contactless and transmitted through fluorescent colors doped polymer fiber by a laser diode with "Side Illumination".
This passive transmission technology already meets the new IEC standards for medical technology regarding e-Mission and / or I-Mission.
Stable and smooth data rates of 1.25 Gbit/s can be achieved with this approach.
Since the polymer fibers have a diameter of only 1.0 mm, the data rate can be increased by simply adding parallel lying fibers. Tolerances of up to 10.0 mm have no influence on the stability of the overall system. ■

Venturetec Mechatronics' components and systems for CT scanners ■

System components for CT gantries

In addition to the rotating transmission systems, Venturetec Mechatronics also manufactures components and systems for CT gantry. Examples include frame structures, drives, shaft and bearing mounts, collimator boxes, laser indicators and more. ■

Breast CT

On behalf of and in collaboration with our valued customer CT Imaging, we currently manufacture the high-resolution chest computed tomography "Breast CT". For this advanced new technology, Venturetec Mechatronics is responsible for the entire production of the complete system (for additional information please see www.ct-imaging.de).

Breast CT of CT Imaging ■

From Nov. 29th to Dec. 04th 2015 the two companies, Venturetec Mechatronics and Ct Imaging will present our systems in the field of medical technology at RSNA 2015 in Chicago.
We will be happy to arrange an appointment with you at our joint booth. ■

Contact:

Ville Dollhofer
Business Development / Marketing Manager

Venturetec Mechatronics GmbH
Füssener Straße 20-24, 87600 Kaufbeuren
Phone: 08141-82960-14
E-Mail: marketing@venturetec.de
www.venturetec.de

GAUDLITZ – a full service supplier

Products for the highest quality requirements

The company GAUDLITZ GmbH which is headquartered in Coburg, with subsidiaries in China and the Czech Republic, can look back on more than 75 years of experience in the production of high precision plastic parts and tools. GAUDLITZ successfully faces the growing requirements in the area of thermoplastic and thermoset injection molding. In our tool shop in Coburg, we manufacture tools and inserts with very high standards in tolerances for the subsequent serial production in-house.

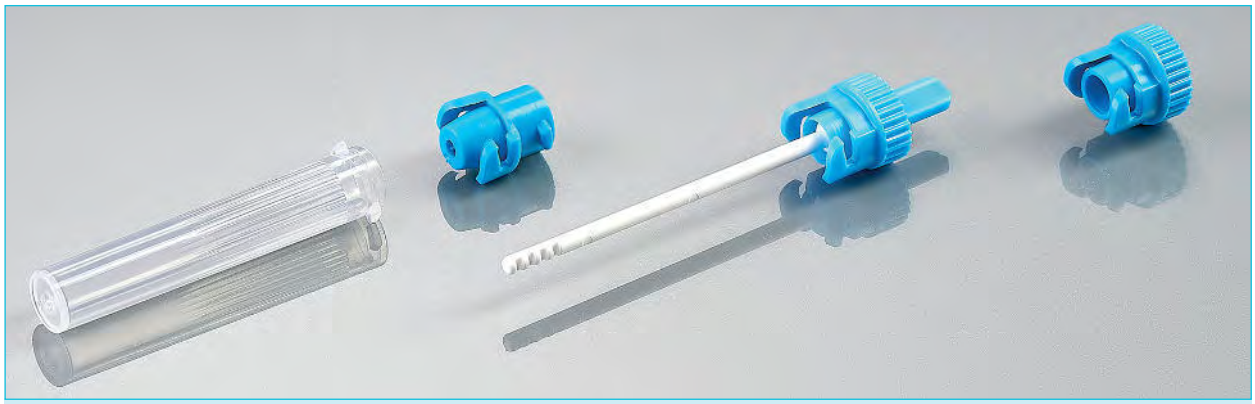
With 570 employees worldwide and about 150 injection molding machines - as well as the usage of modern technologies and production machines - GAUDLITZ has been, since the very first day a synonym for quality and customer satisfaction in the sectors automotive, industry, and medical technology. We view a high degree of quality as a basic requirement for the long-term success of a product and of a company. We as GAUDLITZ have been taking on this challenge for decades.

Particular requirements notably apply to products from the area of medical technology: GAUDLITZ meets these standards – no matter if e.g. certificates or clean room production (class 8) – for small plastic-components in the area of dialysis, up to housing elements for blood sugar devices. ■

Core competences

To our range of services, there are among others: 2K-plastic injection molding, thermoplastic production (e. g. PEEK, LCP,

simplix components are available in a variety of colors or color combinations. Thus, an individual adaption of different test procedures, or respectively, the branding in the company colors of the customer is realizable ■



simplix is an easy to use, highly functional, reliable and safe system to absorb laboratory samples. All components of the system can be closed leak-proof and can be colored based on the customer's desires ■

PPS) and thermoset processing, fully automated insert molding as well as the finishing of individual parts and the complete assembly of systems.

We implement new technologies (e.g. 2K with caoutchouc) together with our customer. It is self-evident that we are certified after all vital certificates (ISO 9001, ISO 14001, ISO TS 16949, ISO 13485, and ISO 50001).

We already differentiate ourselves from our competitors during the research and development phase, in particular through our technical consultation; wether it be during the selection of the right materials for a product, the coordination of the part geometry as well as the mold-flow analysis. Together with the customer, we develop and produce high quality technical components along the value chain, in order to meet the required product life cycle demands. ■

Simplix

In October 2010 our sales team reported the first time about our patented, own developed, sample preparation system – recently known under the name of "simplix". With simplix we realized a significant reduction of the processing time during the preparation process in laboratories and as a result generate cost advantages for our clients. Clinical studies have identified a time advantage of one minute per sample at the same quality of the test results, in comparison to available products of other manufacturers. The millionfold sales of simplix to well-known customers underlines these results.

Only together with our customers we can be successful. This is why we already start working closely together with them during the development of the plastic based products and modules, in order to implement the technically best as well as cost-optimized solution for their demands. As a full service supplier with a specialized tool shop and a broad range of components in the area of plastics manufacturing, we convert the concrete task of our customer into a successful product. We also see ourselves as a partner for start-up-companies and are open for their future oriented ideas. With our experience we can, practically oriented, already assist in the early stages of the development up until the market-ready solution and serial production.

You can receive more information under *www.gaudlitz.de* or under *info@gaudlitz.de.*

We would be delighted to welcome you soon to our newly designed website and proudly present you at this point our new logo. ■

GAUDLITZ®
PLASTIC
TECHNOLOGIES

The production of the components of simplix as well as the filling procedure takes place in our clean room class 8 ■

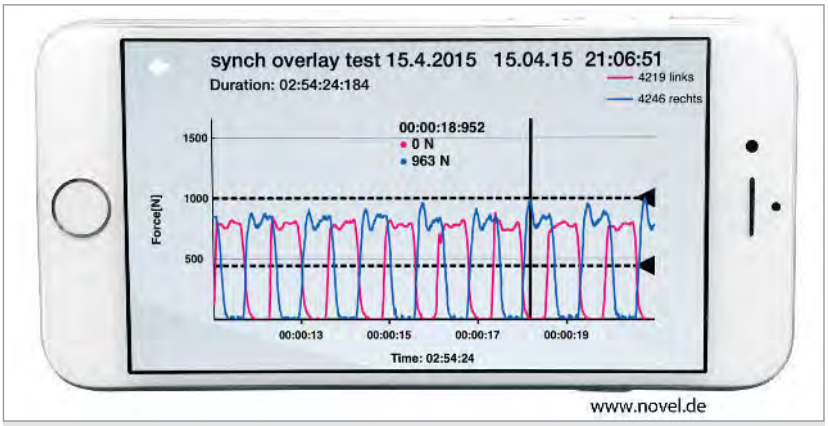
Contact:

Dominic Schauber
Sales Management Medical and Industry

GAUDLITZ GmbH

Callenberger Str. 42
D-96450 Coburg
Post office box: 17 43
96407 Coburg
Phone: +49(0) 95 61/ 648 - 0
Telefax: +49(0) 95 61 / 648 - 648
E-Mail: info@gaudlitz.de

pedoped®
The innovation for monitoring body load



pedoped® iPhone app display ■

With the new pedoped® technology developed by novel it is now possible to accurately measure the normal ground reaction force under the feet statically or dynamically.

The ground reaction force supports the body during standing, walking, or running. When the body is in motion, this force can reach a multiple of the body weight.

The pedoped® sensor insole accurately measures the load under the foot independent from which part of the foot is loaded (heel, whole foot or only the toes). pedoped® precisely measures the normal ground reaction force.

The new pedoped® technology includes a matchbox sized electronics and communicates wirelessly with a smartphone via Bluetooth®. The data is transmitted real-time to the smartphone. The user receives instantaneous biofeedback about load of the feet via sound or vibration. Several smartphone apps will be available, each tailored to the specific application such as load monitoring after implanting artificial joints, measuring of balance and stability of gait, comparison of ground reaction force in sport biomechanics, assessment of foot function with footwear, improvement of running technique, as well as other applications.

pedoped® insole with electronics ■

pedoped® is a further advancement of the measuring systems developed by novel GmbH in Munich. For over 30 years, novel's systems for foot diagnostics (pedography systems: pedar® and emed®) have been used successfully in research laboratories, athletic footwear companies, hospitals and in orthopedic departments across the globe. novel's product family is completed by the pliance® systems that monitor the load on all body surfaces during sitting, lying down, gripping, and under prosthetics. The manugraphy® system was developed for functional hand diagnostics.

As novel aims to push investigations of mechanical load on surfaces of the human body, the company regularly participates in major conferences related to orthopedics, biomechanics and sports. In the field of Diabetic Footcare the novel systems are said to be the gold standard for early detection of foot ulceration that are caused by high local pressure under the foot.

The international Expert Scientific Meeting (ESM), biennially sponsored by novel, assembles leading experts from load distribution science to present and discuss the latest findings in basic and applied research. ■

www.novel.de, www.pedoped.de
www.emed.de, www.pedar.de
www.pliance.de,
www.manugraphy.de

Contact:
novel gmbh
Ismaninger Str. 51
81675 Munich, Germany
Phone: +49 (0) 89 4177 67-0
Fax: +49 (0) 89 4177 67-99
E-mail: novel@novel.de
www.novel.de

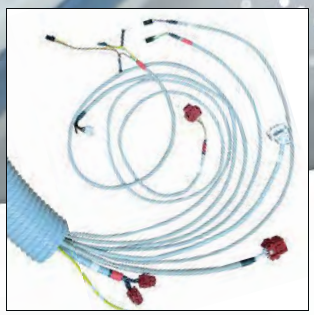
www.leoni-healthcare.com

Get connected

with innovative cable solutions for your application

customised cables with optimised surfaces

autoclavable systems for endoscopy applications



ready-to-install system solutions for medical devices

Are reliable transmission, lasting flexibility, easy handling and maximum patient safety the attributes you want in your medical device or system? As a systems supplier, LEONI supports development work and provides innovative cable solutions for your specific application.

Find out more …

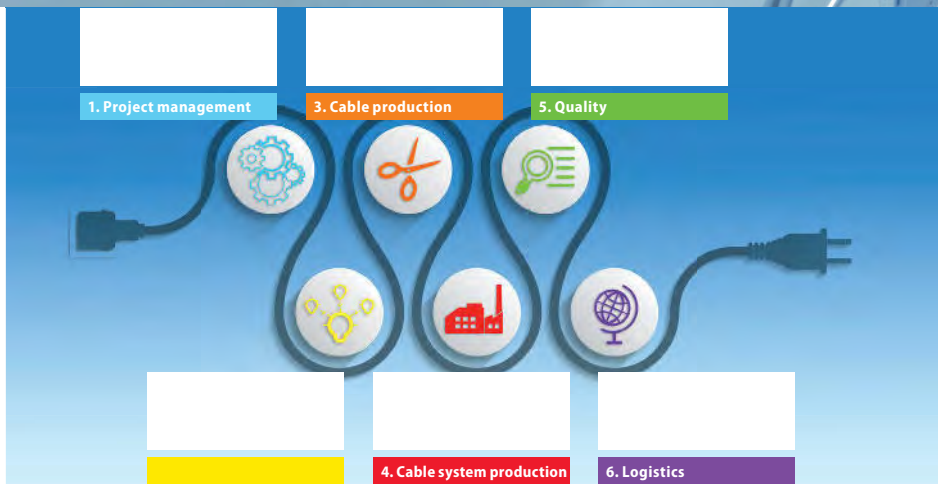
LEONI

Business Unit Healthcare · healthcare@leoni.com

LEONI – Business Unit Healthcare

Cabling with a system

This is how innovatively systems supplier LEONI supports the specific requirements of medical technology >>



LEONI's extensive portfolio of products and services ranges from engineering during the development phase to production of customised cable solutions and through to individual, worldwide logistics concepts.

>> Meeting the objective with know-how and creative solutions

Having in the early years built an extensive range of special cables for medical devices based on existing know-how and specialist production methods, LEONI started its assembly business for this market at the beginning of the 90s. Over the years LEONI established itself as a systems supplier by developing many innovative ways to optimise cable components. Business Unit Healthcare now regards itself as a systems partner for tailor-made and ready-to-install cable solutions that gets involved with its customers' products as early as the development phase – a range of service that has by now convinced most of the major medical technology OEMs.

LEONI is able to supply everything associated with wiring from within its own company and is also exceptionally well positioned with respect to quality assurance as well as certification to national and international standards. In addition to its self-conception as a systems provider, the strength of Business Unit Healthcare lies in an extensive portfolio that is virtually unique in the medical technology sector. This includes:

>> Cable systems unsusceptible to disruption

By being involved in the process of developing a device at such an early stage, LEONI can specify the cable systems with the integrated components in the best possible way and minimise interference on the wiring. LEONI provides copper and fiber-based cable solutions for use in radiation-intensive applications whose attenuation remains virtually constant even when exposed to high radiation.

>> Permanently mobile subsystems

Ready-to-install cable routing systems by LEONI support the long-term mobility of medical devices. Fitted with an ideally integrated cable reservoir or spring return system, they can reduce the tensile force

Medical technology applications are especially varied – LEONI provides wiring optimised for both medical devices and near-patient applications.

on individual cables. The systems fulfil both national and international standards, and LEONI can draw on more than 700 UL AWM styles.

>> Space-saving cable

LEONI hybrid cables are custom made to individual requirements and can contain various conductors to provide reliable power, signal, data and light transfer as well as media hoses. The core diameter and thereby the overall size of the cable is reduced by means of LEONIzell® skin-foam-skin extrusion. LEONI furthermore supplies highly miniaturised cables with single-core diameters of up to 50 AWG.

>> Optimised cable surfaces

LEONI gives not only its biocompatible silicone cables such optimised properties as lastingly improved gliding properties, which are maintained even after numerous autoclave cycles.

In addition, an acid-based technology gives plastic surfaces a germ-killing effect. With antimicrobial cables, LEONI can contribute to reducing the risk of infection in hospitals.

>> Tested quality

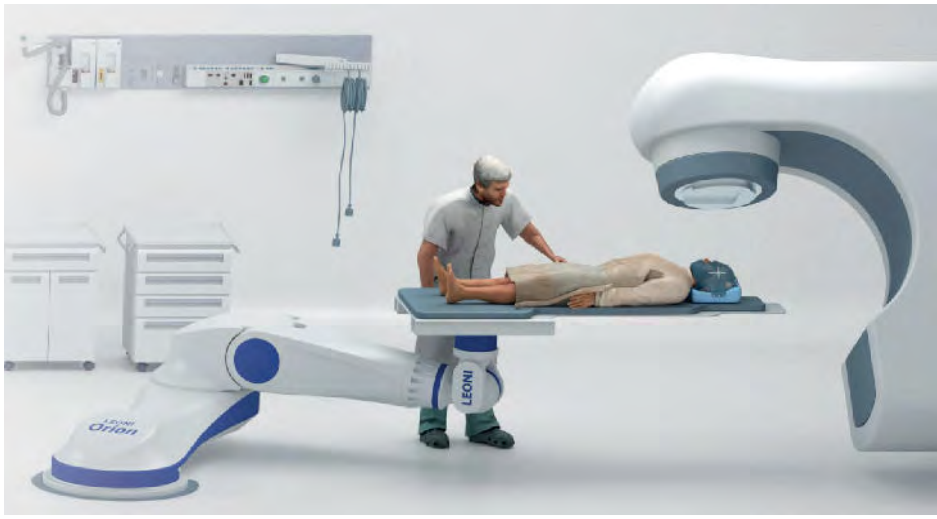
Our bulk cable is made to high standards of quality and is thoroughly tested both during production and thereafter. Every single cable system is meticulously tested before it is supplied. Depending on customer requirements, we apply dedicated testing and measurement methods and tests in accordance with national and international standards. >>

The portfolio ranges from bulk cable to complex systems.

LEONI

>> LEONI has developed an intuitive and high-precision patient positioning system.

Based on its many years of close contact with cancer treatment centres and integration of radiation systems, LEONI has recognised the major demand of the medical sector to apply its comprehensive experience as well as its highly reliable and proven industrial products and solutions to patient positioning: LEONI ORION.



The LEONI ORION patient positioning system is currently undergoing the FDA 510(k) approval process and is therefore not yet available for sale. Planned launch >> 2015.

The system's centrepiece is an intuitively operable software solution, which ensures that all software and hardware components like the robot and the 3D camera system with real-time control work perfectly together. Complemented with cobotics technology, i.e. translation of the therapist's manual guidance into the robot's movement to achieve easy patient positioning, LEONI ORION constitutes an unprecedented standard in radiotherapy.

Benefits: The system has dynamic position control with six degrees of freedom and accuracy of less than one millimetre. The integrated tool changer for the patient table reduces the cycle time per patient significantly. The system is furthermore flexible and easy to operate.

>> Global presence

Detailed contact information regarding our international locations can be found at: **www.leoni-healthcare.com >> Sales**

- ***Technical competence centre***
  Friesoythe, Germany
- ***"LEONI ORION" competence centre***
  Chartres, France
- ***Production and distribution locations***
  Friesoythe, Germany
  Georgensgmuend, Germany
  Halver, Germany
  Roth, Germany
  Stará Turá, Slovakia
  Kitchener, Canada
  Changzhou, China

Vice President Business Unit Healthcare
Siemen-Jannes Meinders >>

"*As a systems supplier* we support the manufacturers of medical devices and systems as early as the development process, designing the best possible cabling for their products or supplying individual components – from a small jumper wire through to ready-to-install subsystems.

As a cables specialist we have a comprehensive range of dedicated technologies and materials that optimise our cables for use in a device or near a patient. We therefore in essence do not have any solution that we supply again in identical form. We are represented worldwide – currently strongly so in Europe and Asia and with a focus on North America."

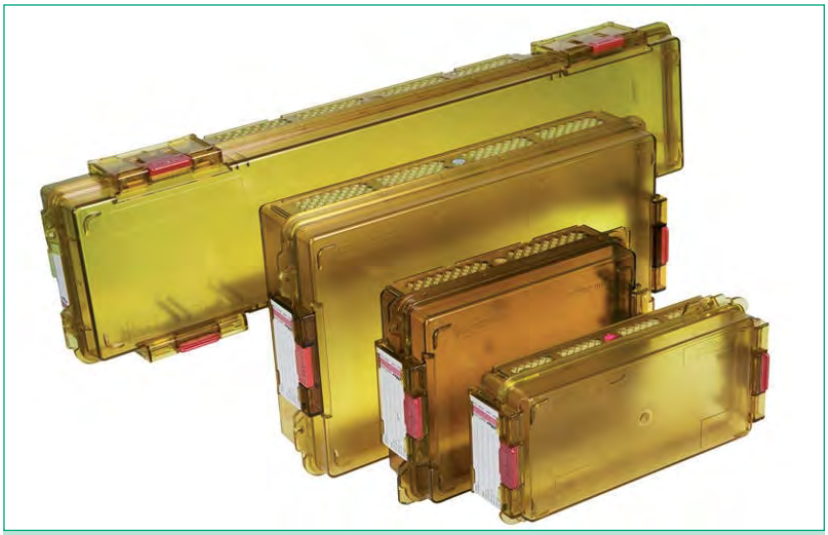
Contact >>
LEONI Special Cables GmbH
Business Unit Healthcare
Eschstrasse 1 · D-26169 Friesoythe
Germany

Phone: +49 (0)4491-291-5040
Fax: +49 (0)4491-291-5041
E-mail: healthcare@leoni.com
www.leoni-healthcare.com

All in one: the reusable sterilization, transport and storage container

Save time and money with re-usable sterilisation-container

The polySteribox® from Ritter Medical for sterilization of instruments, storage and transportation of sterile goods is a secure solution in line with the requirements of validated processes affecting sterile goods. The polySteribox® is available in four different and compatible standardized sizes (SH, M, L and XL) which are suitable for all current sterilization automats. It is produced out of a transparent, dimensionally stable and high temperature resistant (up to 150 °C) material. The polySteribox® is therefore suitable for autoclave vacuum sterilization up to 134°C, depending on the sterilization method recommended by relevant authorities such as the Robert Koch Institute in Germany. In addition, it can be used for plasma sterilization (STERRAD®) as well as for gas sterilization (formaldehyde and ethylene oxide) at a maximum of 65 °C. Lid and bottom close hermetically and include a built-in bacteria barrier.



Polysteribox in 4 sizes: SH, M, L and XL ■

Ritter Medical offers two kinds of PTFE filter sets: a permanent lifetime filter or an annual filter which needs to be changed once a year. The patented interlocking system is compatible within all different models and prevents from accidental opening of the box. The boxes are space-saving and easy to stack, therefore they are well-suited for storage of sterile goods. ■

Loading an autoclave with 6 polysteribox SH ■

Contact:
Ritter GmbH
Kaufbeurer Straße 55
86830 Schwabmünchen
Phone:08232/5003-0
Fax: 08232/5003-48

Medical Engineering at the Ostbayerische Technische Hochschule (OTH) Amberg-Weiden: The Success Story Continues!

The OTH Amberg-Weiden has established a proven track record in medical engineering over the past 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) *(see Fig. 1)*.

Against this background, an Institute for Medical Engineering (IfMZ) with its registered seat in Weiden was founded under the auspices of the Dean, Prof. Dr. Franz Magerl, and Prof. Dr. Clemens Bulitta, who also serves as the Institute's director. The new institute's goal is to expand application-oriented projects in the field of medical engineering and to intensify the network of partners from industry, such as hospitals or manufacturers of medical technology.

The IfMZ is a scientific research institute of the Ostbayerische Technische Hochschule (OTH) Amberg-Weiden and serves as a central interface to connect all university-related activities between research, teaching and industry in the field of medical technology.

With its team of professors, scientists and engineers from different areas of specialisation, the Institute can draw on a broad range of competencies in the fields of medicine, molecular biology and technology.

Fig. 1. *The building of the Weiden Technology Campus (WTC)* ■

In close cooperation with trans-regional and inter-regional partners, the IfMZ interlinks applied medical-technical research with the nuts-and-bolts education of highly qualified specialists for the promising field of medical technology. In this context, the Institute cooperates with various businesses from the medical-technical industry; with hospitals, medical practices as well as external research institutes. Special emphasis is placed on the redevelopment and advancement of diagnostic and therapy systems as well as on the optimisation of medical examination procedures.

The IfMZ's research activities involve imaging systems as well as software and hardware components. Further core activities include the areas of hygiene, clean-room technology and microbiology. For these activities, the IfMZ has excellent equipment and laboratory facilities at its disposal, thus ensuring outstanding conditions for both teaching and application-oriented research.

The IfMz's activities regarding practical education and research-related projects are concentrated in the Weiden Technology Campus (WTC). Most of the special laboratories are located on the ground floor of the building, which is opposite the new lecture hall *(see Fig. 1 and 2)*. The main building of the Faculty of Industrial Engineering accommodates the laboratories for Electrical Engineering, Medical Electronics and Biosignals as well as the laboratory for Materials Science I. The latter is equipped with two CT systems and an electron microscope and serves to support research activities and teaching in the area of imaging.

The professors of the Medical Engineering programme are in

Fig. 2: *Diagnostic Laboratory* ■

Fig. 3. *Biophysics Laboratory* ■

charge of the different laboratories, which offer research facilities for student projects as well as for current topics in R&D. The laboratories are also used by graduate students to conduct complex measurements under predefined conditions within the scope of their final papers. They are also made available to our partners from industry: Research problems that cannot be addressed by them during day-to-day operations might as well be carried out in our laboratories under realistic conditions.

Our research focuses on the areas of hygiene and medical technology; simulation and computer-aided engineering; dental technology and clean-room manufacturing. ■

Our Master's Programme in Medical Engineering – a Master of Science Degree in Three Semesters

Some may ask themselves, "I have finished my Bachelor's degree; now what?" There is no general answer to this question; individual circumstances have to be taken into account. However, an exciting opportunity has arisen in Weiden: In the winter semester 2014/2015, the OTH Amberg Weiden and the OTH Regensburg set up a joint Master's programme in Medical Engineering with the main emphasis on "Technologies and Systems", which is available to graduates of Bachelor's programmes in Medical Engineering, Medical Informatics or Medical Physics. The goal of this programme is to equip students with the skills and qualifications required to hold an executive position in an internationally operating medical engineering or pharmacy company with various fields of activity, such as research, development, production or services. The scope of work involves, for example, development and innovation management; system development and medical engineering development; IT and imaging systems; research and development in medical engineering; simulation-based development processes; diagnostics; or process and quality management. Graduates are qualified to assume responsibility within their group or organisation, to provide guidance for mastering complex tasks

Fig. 4. *Electronic Laboratory – Brain Computer Interface* ■

Fig. 5. *Materials Science Laboratory* ■

Fig. 6. *A Glimpse into the Master's programme in Medical Engineering* ■

and to specifically foster the professional development of the team members. A further qualification of a Master's in Medical Engineering involves both application and research oriented tasks and projects. The skills acquired in this degree programme enable the graduates to assume complex tasks and managerial functions and may provide a basis for participation in a consecutive cooperative doctorate programme or for a position in a scientific institution.

The excellent research facilities in the area of medical engineering at the OTH form an essential prerequisite for the transfer and application of expert knowledge in the fields of new technologies and medical systems. This particularly includes the laboratory for nuclear medicine, the hybrid operating theatre, the in-vitro diagnostic laboratory, the biomechanical laboratory and the industrial clean room.

Within two semesters of full-time study, students gain in-depth insight into innovative topic areas. A multitude of term papers, laboratory projects, presentations and field trips open up opportunities for the participants to enhance both their knowledge and their personal skills as well as to expand their personal network by establishing contacts with numerous partners from industry.

The third semester is intended for preparing the master's thesis. This arrangement enables students to complete their thesis far away from the University, for example at an international location of an industrial company.

Against this backdrop, a decision in favour of the Master's programme at the OTH Amberg-Weiden should be easy. Industrial enterprises are looking for highly-skilled employees willing to assume complex tasks and managerial functions - this programme provides all the necessary contents. ■

Technology and Science Network Upper Palatinate (TWO) – a Factor of Success

The Free State of Bavaria provides funding for the Technology and Science Network Upper Palatinate (TWO), a joint project of the OTH Amberg-Weiden and the OTH Regensburg. This network includes the strategic field of medical engineering, which is provided with funds for professorships and research assistants, as well as with investment capital for laboratory equipment for the Medical Engineering Department in Weiden. ■

Further Information

Institute for Medical Engineering:
http://www.oth-aw.de/einrichtungen/institut_fuer_medizintechnik/ueber_das_ifmz/

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

Studies and course programme:
Bachelor: http://www.oth-aw.de/studium/bachelorstudiengaenge/medizintechnik/allgemein/
Master: http://www.oth-aw.de/studium/masterstudiengaenge/medizintechnik/allgemein/

Contact:

Prof. Clemens Bulitta, MD
Director, Institute for Medical Engineering
Director of the Bachelor's programme in Medical Engineering. Subject area: Diagnostic Systems and Medical Engineering Management

Ostbayerische Technische Hochschule (OTH) Amberg-Weiden
Hetzenrichter Weg 15
92637 Weiden i. d. OPf.
Fon : +49 961 382-1620
Fax.: +49 961 382-2620
Mail: c.bulitta@oth-aw.de
www.oth-aw.de
www.ifmz-weiden.de

Prof. Burkhard Stolz
Director of the Master's programme in Medical Engineering
Subject area: Technical Development of Diagnostic Systems and Microsystems

Ostbayerische Technische Hochschule (OTH) Amberg-Weiden
Hetzenrichter Weg 15
92637 Weiden i. d. OPf.
Fon : +49 961 382-1609
Fax.: +49 961 382-2609
Mail: b.stolz@oth-aw.de
www.oth-aw.de
www.ifmz-weiden.de

SIEMENS

More healthcare stories with happier endings.

Siemens technology is helping to give families the answers they need, when they need them.

When someone becomes seriously ill, the story of his or her life changes. So does the story of the people who unselfishly care for them every day. Parents. Siblings. Children. Doctors. Their story becomes one of support. Perseverance. And hope that it ends with the best possible outcome. Today, Siemens is strengthening that hope. With a host of new and innovative technologies like the Biograph mMR scanner, healthcare professionals around the globe are combating illness more efficiently and effectively. Offering patients and caregivers a greater chance to end their story with a "happily ever after". Every day we're working with the world to create answers that will last for years to come.

A91CC-9304-A1-7600

Room for creative ideas at the Central Institute of Healthcare Engineering

„Innovation Research Lab (IRL)“ at Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU)

Upon completing their studies, many students dream of either founding their own startup company, becoming an entrepreneur, or making a difference through new developments in a well-established company. While there are various ways to achieve personal goals, a more direct and guided path will always prove to be more efficient. Every company is driven by the urge for new innovative products. Therefore, it relies on a strong R&D-department in order to stick out in today's competitive market. Innovation also means to implement change in the right areas through new perspectives. Young students with unbiased minds need the opportunity to learn and gain experience through practical training. The Innovation Research Lab provides a creative environment for the implementation and development of new ideas and concepts. The topics originate from the students themselves or are suggested by different industry partners, researchers or third parties.

The IRL is led by Sultan Haider, the founder and head of the Innovation Think Tank and Key-Expert within Siemens Healthcare. The main driving factor for success comes from the remarkable variety of disciplinary backgrounds of the participating students; interdisciplinary collaboration is the driving force of innovation. The wide spectrum of expertise includes but is not limited to: design, liberal arts, economics and a multitude of engineering sciences.

Students are developing their innovative creativity in the new IRL rooms ■

These different viewpoints combined produce diverse ideas and prototypes with various applications for industry and research areas. The IRL is always looking for any interested partners for collaboration in supporting the new lab.

The Innovation Research Lab is the most recent lab at FAU. “We are happy that we were able to commit Mr. Sultan Haider to run the IRL within our university“, says Prof. Dr.-Ing. Joachim Hornegger, president of FAU. Mr. Sultan Haider has already been giving several lectures at FAU on the topic of Innovation Management and now has the possibility to expand his academic program to contribute to his network of worldwide experts. ■

Structure and integration of the IRL

IRL is located at Medical Valley Center in Erlangen and belongs to the Central Institute for Healthcare Engineering (ZiMT) serving as a

Sultan Haider, head of Innovation Think Tank, Siemens Healthcare GmbH, and initiator of IRL, in discussion with participating students ■

structural interface between scientific research, training and industry in the field of medical engineering. This project perfectly underlines one of ZiMT's core objectives as an initiator of interregional and international scientific research in the Medical Engineering sector.

Dr.-Ing. Kurt Höller, Managing Director of ZIMT, emphasizes the characteristic feature of the IRL and the courses, which are offered in its context: "Here, technical challenges, as well as questions that come from synergies between technology, production, marketing, usability and societal acceptance, are solved in multicultural and interdisciplinary teams".

„On the one hand this develops the competences of the participants in intercultural communications with representatives of different fields of study, e.g. engineering with humanities. On the other hand, these courses teach that an innovative solution will take more than a view from a technical perspective", says Dr Rudolf Kötter, CEO of the Center for Applied Ethics and Science Communication (ZIEW). ZIEW offers seminars on key qualifications from different faculties and departments at the FAU and therefore has a close tie to the IRL. A board of students takes care of: organization of the lab, management of the internal and external communication, coordination of the management of projects and finances as well as administration of the internal training. ■

Involvement of the students

The participants of any offered course at IRL work in teams on different topics and projects within the following areas: hospitals and medical devices of the future, 3D printed applications in medicine, applications of camera and mobile systems, optimization of clinical workflows, medical devices for children, green innovations, sports medicine, orthopedic implants, physiotherapy, homecare systems, next-generation IT, elderly care, etc.

The IRL cover a range of projects from research based on futuristic developments all the way to current challenges and problems for the implementation of research relevant topics. The opportunity to work on different projects within their own field of study as well as within interdisciplinary teams is provided to the participants. During the course, the students can decide independently how to implement their ideas. For this purpose, the IRL Lab in the Medical Valley Center in Erlangen is available, offering not only different facilities to realize prototypes but also support from various scientists and experts of industry and research. Moreover industry designers provide support for the visualization of complex correlations to make the content accessible and understandable to everybody. Additionally, students are encouraged to design

The president of FAU Prof. Joachim Hornegger (center) with his managing directors of ZiMT Dr Kurt Höller (left) and Tobias Zobel (right), supported the IRL with space at ZiMT to organize the lab ■

3D printed prototypes to support and explain forward-looking concepts for healthcare by applied realization and evaluation. ■

IRL Exhibition 2015

As motivation, the students have the opportunity to participate at the annual Innovation Research Lab Exhibition (IRLE). It took place for the first time on September 3rd, 2015 at the Medical Valley Center. The top 20 projects from the IRL teams and other international students are presented and awarded. Among others, Prof. Dr.-Ing. Joachim Hornegger, president of the Friedrich-Alexander-Universität Erlangen-Nürnberg, and Dr. Peter Molnar, CEO of CV within Siemens Healthcare GmbH were present in 2015 to participate as part of the guest jury to determine the three best projects of the semester.

The winners receive the "FAU-Siemens Award" and prize money. Furthermore, they have the chance to participate in a three- or six-month-fellowship at the Innovation Think Tank within Siemens Healthcare in Germany, Turkey, China or India.

The collaboration between IRL and FAU at ZiMT provides opportunities for students to develop fundamental training through real-world applications and their own initiatives.

It would be desirable that not only Siemens Healthcare and other established partners give input, but also that small and middle-sized companies use this pool of engaged and creative students for solutions to current challenges. The Medical Valley Center offers a perfect environment for students to realize their own ideas and potentially gear them towards the development of a small start-up.

This offer is available for any student, whether they have a medical, engineering, humanities, sciences or economics background. Together they can develop innovative ideas for several groups of interest such as university, public services, or industry. ■

http://www.zimt.fau.de/innovation-research-lab/

E-mail: *irl@fau.de*

About the author:

Kurt Hoeller studied Electrical Engineering and achieved his doctoral degree at the Pattern Recognition Lab, FAU Erlangen-Nuernberg, TUM Graduate School of Information Science in Health (GSISH), Munich, and Johns Hopkins University (JHU), USA. Since 2009, Kurt Hoeller is the founding managing director of the Central Institute of Healthcare Engineering (ZiMT) at FAU Erlangen-Nuernberg. ZiMT supervises joint interdisciplinary research projects with more than 75 associated professors as well as the FAU Bachelor and Master programs in healthcare engineering with more than 800 students. Dr Hoeller also coordinated the thematic campaign "3-D Imaging in Medicine - Cutting-Edge Research in Germany's Medical Valley" that was part of the international campaign "Germany – Land of Ideas" launched and supported by the Federal Ministry of Education and Research (BMBF). By end of this campaign in 2013, he was founding CEO of the evolving university spin-off CiNNAMED GmbH that focuses on Communication, Consulting and Commerce especially in Biomedical Engineering projects. Dr Hoeller is also active in local politics as a municipal councilor and member of the supervisory board of Erlangen,s municipal energy supplier. Since 2015, he is spokesperson of the German Academic Core Partners and universities within the European Institute of Innovation and Technology for Health (EIT Health).

Contact:
Dr.-Ing. Kurt Höller, MBA
CiNNAMED GmbH, Henkestraße 91, D-91054 Erlangen, Phone: +49 9131 974991, Fax: +49 9131 974992, hoeller@cinnamed.de

ITD GmbH presents the new product line rm-port

rm-port pivot arms – new support arm systems for patient monitoring

Modern electro-medical applications require innovative mounting systems. The secure mounting of monitors or other equipment, intuitive positioning, quick installation and compliance with the hygiene requirements, has to thereby be ensured.

The support arm system rm-port of the new product generation of the ITD GmbH, fully meets these demands. The "rapid-mounting" (s. Fig.) allows easy installation as well as subsequent installations of the equipment to given hospital infrastructures. In addition to the seamlessly easy securing, the handling of the attached devices is also very convenient. The new rm-port no longer needs to be readjusted or fixed manually. This generation of the pivot arms is already set to the optimal adjustment force, whereby a secure, precise and effort-free positioning of even heavy monitors can be made effortlessly. rm-port support arms are of course also designed to accommodate diverse cables. The cables are accurately laid and latched in the inner cable duct with a click-&-slide cover. In addition to the many technical advantages, the rm-port also convinces on account of its contemporary design and concomitantly fulfils the hygiene requirements in hospitals. This is confirmed by a hygiene certificate.

A special service for users is offered by online tools, such as the Productfinder and the Online-Configurator on the website of the ITD GmbH. This provides the users with an easier orientation of the wide variety of product variants and thereby enables the users to configure optimal customised product solutions for themselves in a few minutes.

As a manufacturer of stationary and mobile equipment carriers, the ITD GmbH has established itself since 1995 as one of the leading companies in Europe and disposes over a global sales network. The company offers modular standard products as well as professionally competent advice and customised system solutions for medical equipment carriers. All ITD equipment carriers are medical products of the class 1 and therefore meet the requirements according to DIN 60601-1 as well as the Directive 93/42 EEC. The ITD GmbH is of course certified according to ISO EN 13485. ■

Contact:

ITD GmbH
Grünwalder Weg 13a
82008 Unterhaching
Germany
Phone.: +49 89 61 44 25 0
Fax: +49 89 61 44 25 20
Web: www.itd-cart.com
E-Mail: marketing@itd-cart.com

Personalized medicine: The benefits of electronic systems

All humans are the same, yet different. Our faces are a good example: We all have eyes, a nose and a mouth – but our appearances differ. This also applies to our cells and tissues. In all of us, they follow the same functional principle, but in cell metabolism there may be subtle differences from one individual to the next. This can have serious consequences in terms of medical therapy. A drug that is very beneficial to one patient may be less effective in others. Hence it will take only a few years for a single drug, used as a standard therapy for all patients suffering from a particular condition, to become outdated – for the good of the patients. Meanwhile, what is called "personalized medicine" has become the latest trend, and will gain in importance in the future: treatments customized to the individual patient.

Sensor systems instead of genetics

This said, how can we determine what makes the cells of a certain individual tick? In the past, scientists attempted to do this by studying a patient's genetic make-up, but discovered that the possibilities were somewhat limited by the confines of molecular biology. At Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik (HNLME) of Technische Universität München, however, we have recently developed sensors that enable cells to be monitored. Some of these sensors can be used to measure the reaction of cells to drugs and also to harmful substances. Sample cells taken from a patient are grown directly on the sensor chip, leading to intergrowth of the tissue with the electronic components.

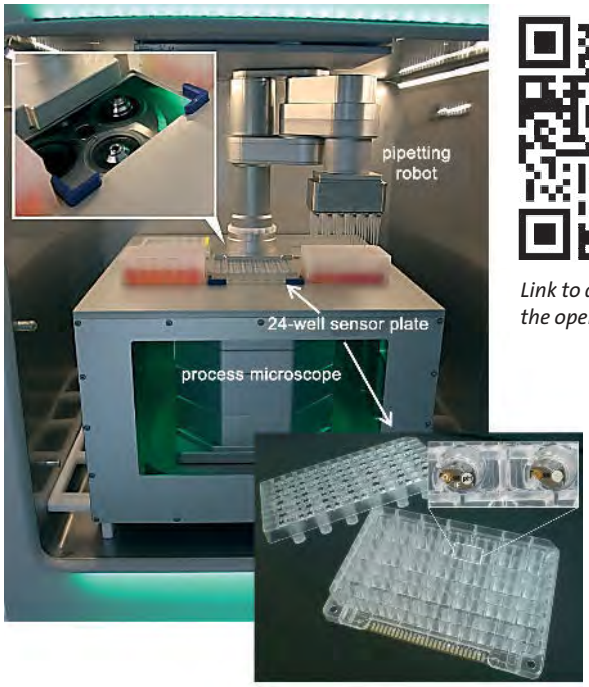
A small reaction chamber for introducing substances (e.g. the drugs to be tested) is located above the sensor. Different parameters (oxygen concentration, pH, electrical signals) in the cell environment can be measured with these "lab-on-chip" systems. The results thus obtained can be used to ascertain whether the cells tolerate the substance and to assess their subsequent vitality. This is a very effective way of testing active substances – potentially rendering certain animal experiments superfluous.■

Fig. 1: *A wide range of sensor chips has been developed (and produced using silicon, glass, ceramics and printing technologies) at HNLME for use in bioanalysis* ■

Gentle cancer therapies

With personalized therapy it is necessary to go one step further. The aim is not only to measure the effect of a drug on the cells of a patient, but also to examine different concentrations of an active substance and possibly even active substance combinations. This means that large series of measurements must be taken in a short period of time. To this end, we have created the "Intelligent Microplate Reader" (IMR), a fully automated analysis platform. Biosensors are placed on the bases of microtiter plates – each of the 24 wells of a plate contains a multiparametric sensor on which cells can grow, e.g. tumor tissue taken from a patient. Thanks to a sophisticated fluidics system, the cells can be supplied with a constantly renewed culture medium. In a single operation, the fully automated pipetting robot of the IMR permits 24 different active substances or 24 different concentrations of an active substance to be added to the 24 wells.

In this way, quick measurements can be taken to determine which dose of which chemotherapeutic agent or which drug combination is best able to destroy the tumor cells in a particular patient. This could aid in the selection and precise adaptation of therapy for an individual patient – one which would be more effective and at the same time less onerous than conventional cancer therapies. With most cancers, only about



Link to a video showing the operation of the IMR

Fig. 2: *"Intelligent Microplate Reader" (IMR) analysis platform with pipetting robot, sensor plate and process microscope for automated imaging. Bottom right: Sensor plate with integrated microfluidics and sensor systems; each of the 24 wells has a sensor for measuring the pH, the dissolved oxygen concentration and impedance.* ■

20 % of patients respond well to conventional chemotherapeutic agents, but all suffer the burden of severe side effects.
In the future, this situation could be improved by means of IMR. ■

Implant with drug reservoir

More effective therapeutic strategies would in fact be those in which an implant releases the drug directly where it is needed – in the case of a tumor this would be within the tumor itself or at least in the adjacent tissue. This would make sense, since by far the greatest amount of a drug administered orally or intravenously does not travel further than the liver or kidneys. Our team at Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik has been working on such "intelligent implants" for quite some time – and has already developed a number of prototypes. The resulting implant would hardly be any larger than the size of a sugar cube and hold a small battery for the supply of energy, a miniaturized electronic system, a radio unit, and a small drug reservoir.

We plan to use a battery that can be recharged externally, requiring the patient to occasionally place a coil on the part of the body where the implant is located.
Such an active implant could be placed within the body in the area of the tumor. The sensors on its outer surface permit the oxygen saturation in the tissue to be measured, transmitting the results to a receiver outside the body.
With many solid tumors, decreasing oxygen saturation values are an indication of increased growth. If this is the case, the implant would inject a chemotherapeutic agent from its drug reservoir directly into the tumor or supply oxygen to the tissue. There is nothing worse for a tumor cell than molecular oxygen. A circuit comprising automated measure-

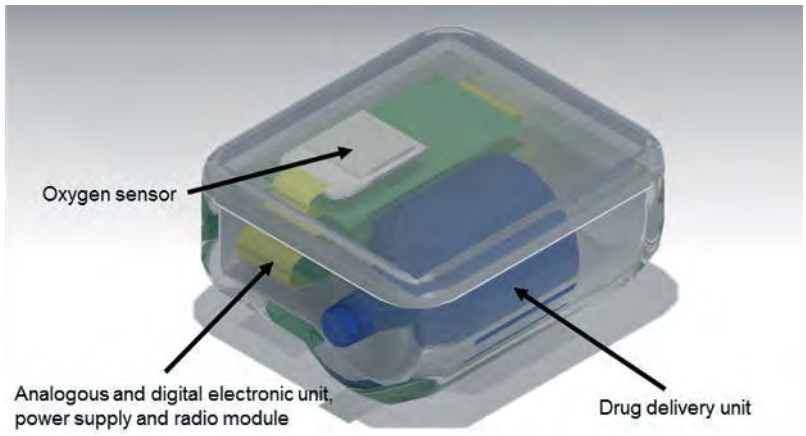


Fig. 3: *Concept of an implant the size of a sugar cube, comprising a collapsible electronic unit, a sensor chip on its outer surface, and an integrated drug pump* ■

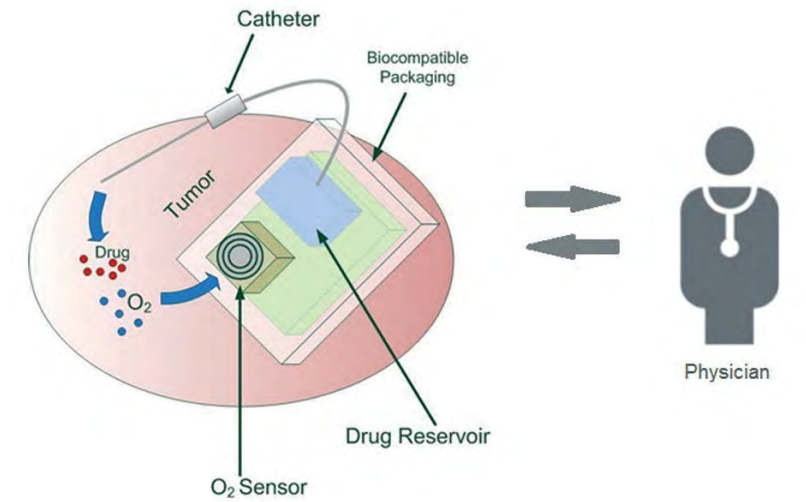


Fig. 4: *Concept of a closed-loop system (with implant) for cancer therapy* ■

ments and diagnoses as well as controlled therapy would thus be created – what experts call a "closed-loop system".
This would already offer a high degree of personalization and enable patients to undergo therapy without having to stay in hospital; it would be much more effective and would involve fewer side effects than conventional therapy. ■

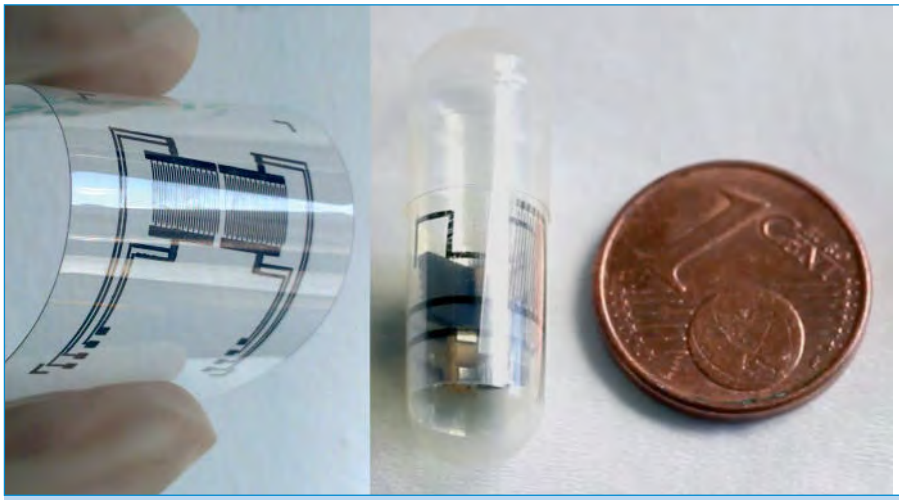
Intelligent nano pill

The same applies to our current project, the "intelligent nano pill" – a form of implant that can be swallowed. It consists of a plastic foil onto which sensors, called nanoparticle sensors, are applied by means of inkjet printing, an effective yet inexpensive process. The sensor foils can be rolled and formed into small, edible capsules that also contain microelectronic chips, a battery and a radio unit – all in miniature. The sensors on the outer surface of the foil could then detect and attach itself to a bleeding stomach ulcer, for instance. Subsequently, the nano pill could monitor the ulcer, wirelessly send the data to an external receiver and potentially also release active substances – again, precisely at the target site, i.e. the ulcer, without causing the patient discomfort. ■

Fig. 6: *a) All-in-one telemedical device as developed by Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik, Technische Universität München, in collaboration with the Fachgruppe Produktentstehung, Heinz Nixdorf Institut, Universität Paderborn. Design: Abteilung für Industrial Design, Kunstuniversität Linz, Prof. Axel Thallemer; b) Sensor sleeve, detailed view* ■

All-in-one medical device

It is not only in drug discovery and oncology, but also in other healthcare segments where scientists are pursuing personalized medicine. In the future, patients suffering from cardiovascular diseases will be able to monitor their vital signs independently. This is another area where our experience with sensor systems has proved beneficial.
We have developed an all-in-one medical device for taking daily measurements of parameters such as blood pressure, heart rate, oxygenation of the blood and hydration, simply by slipping a finger into the integrated sleeve that contains a variety of sensors. Blood glucose can be measured with a drop of blood and a test strip.
The device uses mobile radio services to automatically transmit all the measurements to a database – this is facilitated by the COMES® telemedical system developed in recent years. The treating physician can access the data of his/her patients at all times and will be alerted immediately about abnormal values so that all the necessary steps can be taken.
COMES® also sends automated warning messages to the patient depending on the measurements taken, and offers personalized advice. Initial studies have reported a positive response from patients with cardiovascular diseases, who felt safer and at the same time more independent thanks to the constant monitoring provided by the system. Obviously, personalized medicine using new



Link to a video showing the production of the nano pill

Fig. 5: *Sensor made of nanoparticles applied to plastic foil by inkjet printing (left). The foil is then equipped with electronic components and rolled to form a nano pill (right)* ■

Fig. 7: *The overall COMES® concept: Cognitive Medizinische Systeme (Cognitive Medical Systems) as an intelligent telemedical assistance system, accompanying the user everywhere, in all walks of life* ■

electronic systems gives them peace of mind. ■

Acknowledgements

We would like to express our gratitude to the Heinz Nixdorf Stiftung for supporting our projects and research for so many years. ■

Literature

Wolf B, Brischwein M, Grothe H, Stepper C, Ressler J, Weyh T: „Lab-on-a-chip systems for cellular assays." In: G. Urban (ed.) BioMEMS Series: Microsystems (2006), 16, pp. 269–308. Springer Verlag, Dordrecht (NL), 2006. ISBN-10:0-387-28731-0, ISBN-13:978-0-387-28731-7.

Mzoughi N, Neumann B, Grothe H, Wolf B: "Sensorik Chemo/Bio. Inkjet printed electrodes on PET substrate for biosensing applications", Biomedizinische Technik/Biomedical Engineering, Band 56, Heft s1, Seiten 1–12, ISSN 0013-5585, DOI: 10.1515/BMT.2011.844, September 2011

Kleinhans R, Brischwein M, Wang P, Becker B, Demmel F, Schwarzenberger T, Zottmann M, Niendorf A, Wolf B: „Sensor-Based Cell and Tissue Screening for Personalized Cancer Chemotherapy". Medical and Biological Engineering and Computing, (2012) 50, 117–126

Clauss J, Becker S, Sattler M, Wolf B, „In vivo Diagnostik mit intelligenten Implantaten", In: Wolf B (Hg.): Bioelektronische Diagnose- und Therapiesysteme. m3: microelectronic meets medicine. 1. Aufl. 2012, Aachen: Shaker Verlag, S. 237–246. ISBN: 978-3-8440-0831-9.

Brischwein M, Scarpa G, Grothe H, Wolf B, Thalhammer S.: "Toward printable lab-on-a-chip technologies for cell analytics" in: Biological and Medical Sensor Technologies, Kryzysztof Iniewski, ed. CRC press 2012, p. 125-148, Print ISBN: 978-1-4398-8267-2, eBook ISBN: 978-1-4665-5257-9

Wolf B, Spittler T, Herzog K, Clauss J, Friedrich P, Scholz A: „COMES® – Cognitive Medizinische Systeme für Diagnose und Therapie". Duesberg, F. (ed): e-Health 2014 Informations- und Kommunikationstechnologien im Gesundheitswesen. Solingen/Mittweida, medical future verlag, 2013, 254-262.

Wolf P, Brischwein M, Kleinhans R, Demmel F, Schwarzenberger T, Pfister C, Wolf B: "Automated platform for sensor-based monitoring and controlled assays of living cells and tissues". Biosensors and Bioelectronics (2013), 50, 111-117

Clauss J, Herzog K, Wolf P: „Sensorgestützte regionale Tumortherapie". Meditronic-Journal, 2/2014, 14-16.

Demmel F, Brischwein M, Wolf P, Huber F, Pfister C, Wolf B: "Nutrient depletion and metabolic profiles in breast carcinoma cell lines measured with a label-free platform". Physiological Measurement (2015), 36, 1367-1381

Contact:

Univ.-Prof. Dr. rer. nat. Bernhard Wolf

Dipl.-Biol. Christian Scholze

Technische Universität München
Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik

Theresienstr. 90 / Gebäude N3
80333 München
Phone 089 / 28922948
www.lme.ei.tum.de
E-Mail: wolf@tum.de;
christian.scholze@tum.de

Panoramic endoscopy of the bladder

Cystoscopy is the term for a medical examination of the urinary bladder in order to detect tissue changes early enough and if needed, to carry out treatment. The procedure involves the insertion of a rigid or flexible endoscope through the patient's urinary tract and into the bladder to inspect the tissue structure. Although these minimally invasive procedures alleviate patient discomfort, they harbor challenges for the attending physician.

Because the endoscope provides the physician a limited field of view (so-called "keyhole perspective"), it is difficult to determine if the bladder wall has been completely examined. In order to obtain a complete scan of the bladder, the endoscope has to be pivoted and moved by the user,, forcing the physician to form a composite picture in his own mind. Digital image processing techniques make it possible use the acquired image data stream from an endoscopic examination to create a panoramic view for the physician. The Endorama© software developed by the Fraunhofer Institute for Integrated Circuits IIS in Erlangen generates a composite picture from a series of successive acquired images by searching for distinctive and correlating points in the images and then calculating an overall view. Although panoramic images are a standard feature of conventional digital cameras and can also be created with smartphone apps as an example, they present a challenge with endoscopic images.

Panorama of the bladder wall, the white line indicates the endoscope motion ■

Endoscopic images typically have more distortion, a lower resolution and a comparatively low contrast due to the uneven lighting conditions. And because the tissue structures in the bladder are not very pronounced, the challenge is finding distinct points of correspondence that can be used to merge the overlapping images into a composite picture. To compensate for these conditions, in a first step the Endorama© software removes the optical distortion and balances the shadows that result from the irregular lighting. Various calculation processes then merge the images together. While one process looks for image characteristics such as vascular structures on the bladder wall, another arranges the images in the proper order. The software also relies on mathematical models to account for the geometry of the bladder. To provide the attending physician a direct impression of the expanded field of view and thus visual feedback regarding the completeness of the examination, the possibility exists to generate a panorama view during the examination; in effect in real-time.

The physician can see the entire area of the bladder that has been examined at a glance. The software displays the camera's current image in the middle of the monitor. If the panorama image shows a gap or a "hole" at a certain point, the physician knows that this area still has to be examined. After the examination has been completed, the digital panorama can be placed in the patient's file in the form of an interactive overview image in order to document the results of the exam. Such panorama images can also serve to verify the completeness of the examination, which creates new opportunities for assuring the quality of cystoscopic examinations. Compared to conventional documentation that relies on video sequences and single images, with panorama images the completeness of the examination can be documented at a glance, thus saving valuable time. The Endorama software has meanwhile been successfully tested using a phantom bladder made from plexiglass, with video sequences during regular bladder examinations and also with a phantom pig's bladder. ■

Contact:

PD Dr.-Ing.-habil. Thomas Wittenberg

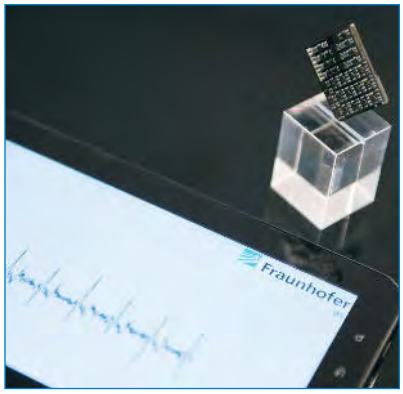
Fraunhofer-Institute for Integrated Circuits IIS
Department of Image Processing and Medical Engineering

Am Wolfsmantel 33, 90158 Erlangen
phone: 09131 / 776-7330
mail:thomas.wittenberg@iis.fraunhofer.de

Medical Technology Communication Standards – Opportunities and Obstacles

When the question of the advantages of communication standards for the medical industry is raised, the most common response is „cost efficiencies“, followed closely by „quality assurance“. Although both terms belong in the plus column of opportunities, the consistent utilization of communication standards in medical systems is far removed from reality. What can this be traced to? Without question, the primary causes are related to technical heterogeneity and government structures in the health care sector. Different operating and hardware systems, a lack of network infrastructures, application software from various manufacturers and countless data formats, structures and models with different semantics are hampering end-to-end interoperability and quickly thwart any efforts to standardize. Nevertheless, for specific fields of application there do exist some established communication standards that have proven their value for many years already. Most notably is the set of so-called Health Level 7 (HL7) international standards that focus primarily on the exchange of patient and health care services data, as well as diagnostic results. Despite the fact that HL7 has been around for 30 years, it still has limitations such as no plug-and-play functionality since the processing of HL7 messages is not part of the standard, which leaves it up to the application developer.

As a rule, even systems that use the same version of the standard



cannot communicate with one another without further modifications. This puzzling development occurs in many other medical communication standards. The question then is: why even bother standardizing?

The answer is as simple as it is inadequate: without standardization, it would no longer be possible to manage the complexity involved in the development of communication standards. On the other hand, a standardized specification can only describe a limited sub-system. The concrete implementation is still application-specific.

Even POCT1-A, a standard that describes communications between so-called point-of-care testing devices and which is viewed as an extension of HL7, is unclear in many of the details. This leaves too much room for interpretation, which is what standardization is actually meant to prevent. That leads to divergent implementations and incompatible systems.

In summary, there is no denying that communication standards for medical systems create one major advantage: when developing medical system software, uniform interfaces allow companies to concentrate on their core expertise and avoid having to deal with the details of data exchange. The selection of the suitable standard is determined mainly by the respective application software.

When the decision is made to go with an existing standard, one thing must be kept in mind however: there is little chance it will function properly without being modified.

Using its reference implementations, Fraunhofer IIS offers libraries tailored to the customer's requirements in addition to services such as the systematic testing and integration of existing standards. Fraunhofer IIS participates in the ISO, CEN, HL7 and DIN standards committees and through the Fraunhofer Ambient Assisted Living (AAL) Alliance is also a member of the Continua Health Alliance. ■

Contact:

Matthias Struck

Fraunhofer-Institute for Integrated Circuits IIS

Department of Image Processing and Medical Engineering

Am Wolfsmantel 33
90158 Erlangen
phone: 09131 / 776-7345
mail: matthias.struck@iis.fraunhofer.de

„iMob“ – A mechatronic AAL project of the CoKeTT Zentrum at Hochschule Kempten in cooperation with Technische Universität München

CoKeTT is the first AAL application center at Hochschule Kempten in the Gesundheitsregion Allgäu, the Alpine region in southwestern Germany offering a wide variety of spas and health resorts, sports and leisure activities. It is an application, test and training center, or living lab, for products and solutions tailored to specific age groups, where the main aim is to develop and test mechatronic-telematic healthcare systems for all generations.

CoKeTT, founded in the autumn of 2011, is a joint project with the Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik of Technische Universität München and stands for "COMES® Kempten Test- und Trainingszentrum".

Ambient Assisted Living (AAL) is a field of research that focuses on problems and solutions related to demographic change. Technical assistance systems offer people with a physical handicap help in their everyday activities and enable the elderly to continue living at home for as long as possible. To this end, all spheres of life, such as working, living, health, mobility and social interaction, are taken into account. ■

The "iMob" project

In their joint "iMob" project, the Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik and the CoKeTT application center of Hochschule Kempten aims to develop a new assistance system in the form of a novel wheelchair for people with limited mobility.

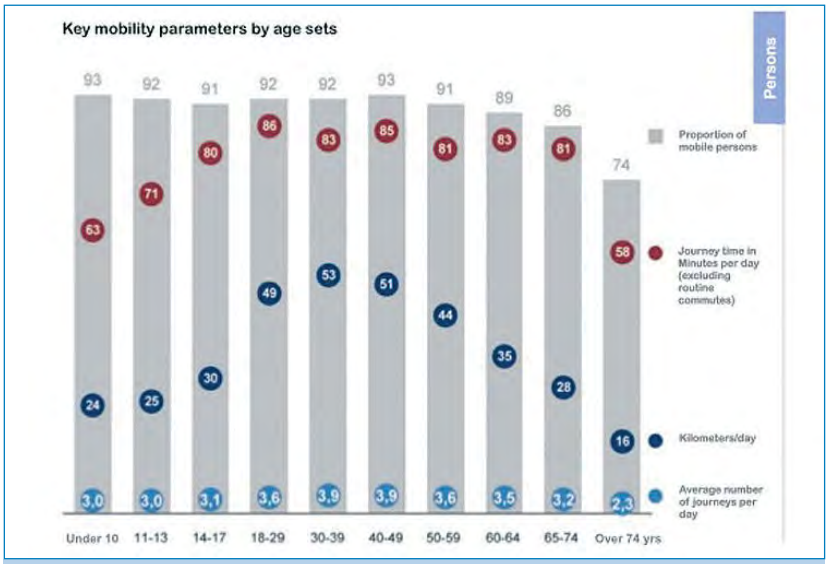


Fig. 1: *Key mobility data classified by age sets [2]* ■

The project name "iMob" is an acronym, standing for "intelligent mobility", and the project abides by the motto "unlimited mobility for all ages at all times". The assistance system is based on a highly maneuverable wheelchair with which even obstacles such as stairs can be overcome unaided [1].

1. Background

The growing population of seniors in many countries worldwide due to higher life expectancies and a simultaneous drop in birth rates has given rise to a new way of thinking and transformation in all spheres of everyday life, the economy, and society as a whole. One of the most essential areas in all of this is mobility, particularly during retirement when many people feel they should be traveling the world and doing all the things they never managed to do during their working lives [2].

Figure 1 illustrates a decrease in the average mobility data for people aged over 74 years: time, distance, number of journeys. According to the results from the study Mobilität in Deutschland [3], however, these individuals do not leave their homes often: over two thirds of their journeys are made for shopping and private purposes, a pattern that becomes increasingly important with age. *Figure 2* illustrates the relative increase in the journeys made for private purposes by those older than 68 years. The older we become, the more important are our daily chores and shopping trips, with increased age correlating to a shorter average distance.

The study also revealed that the elderly tend to travel more by car whereas among the younger

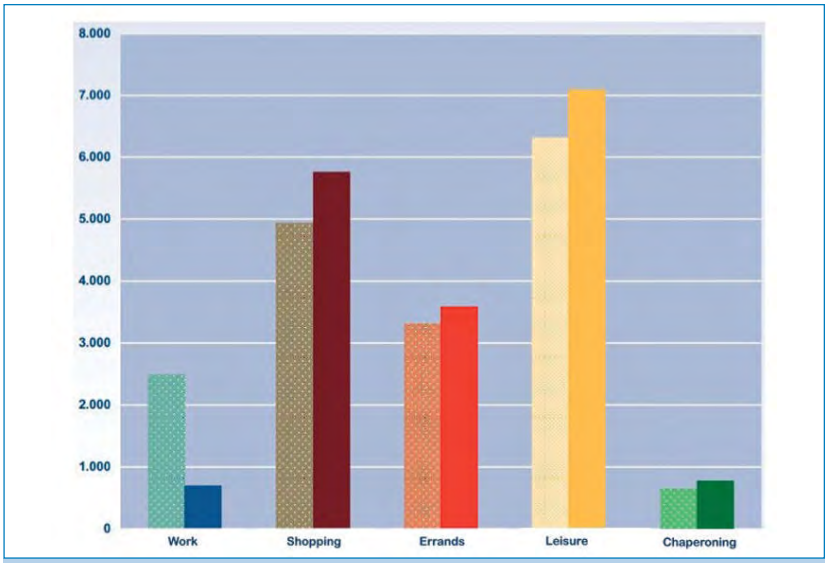


Fig. 2: *Age cohort born 1940-44 and distances traveled classified by purpose, including commercial traffic, given as thousands per day for the years 2002 (left column) and 2008 (right) [2]* ■

population, especially in urban areas, the use of automobiles is decreasing. At the same time, the use of local public transport is decreasing among the elderly, since older seniors cover 38% of all distances on foot, meaning that walking has become the second most important mode of transport. It was also found that senior singles are less mobile than their peers who live in a household of two or more people.

1.1 Old-age mobility

In our aging society, mobility is a vital, basic need that is closely linked to quality of life. To limit this basic need would mean to deprive people of the possibility to maintain their social contacts and independence, which in turn would have psychological and social consequences [5].

According to Schlag [2] mobility is an important way to prevent age-related degeneration and in many seniors it can even be beneficial to health. The fact that maintaining the daily routine and running errands are all the more important in old age can be seen from the distances illustrated in *Figure 2*. If a person's daily routine is disrupted due to limited mobility, this has a massive impact on social integration and also on the quality of life.

1.2 The elderly in the driver's seat

According to MID 2008 [3], elderly people who have enjoyed unlimited use of their own car throughout their lives and who are still mentally capable of doing so, will wish to maintain this standard of living. For the "new elderly", having their own automobile is a symbol of activity, prosperity and independence [4]. Although they are not responsible for the majority of car accidents at present, an increase in incidents involving over 75-year-olds has been noted in recent years [2]. According to Schlag [2], three quarters of all accidents are caused by seniors at junctions and crossings when they fail to comply with the traffic rules. An analysis of police data in the Bonn area revealed that among drivers over 65 years of age maneuvers such as U-turns and reversing are the second most common cause of accidents *(see Figure 3)*.

High speed, or physical or mental disorders, on the other hand, account for a small percentage only [5]. Schlag [2] states that the following psycho-physical developments in old age have a direct impact on the ability to drive: Impaired vision, a diminished ability to multi-task and a reduced selective attention, which easily leads to distraction, slower decisions and/or responses, reduced physical mobility and resistance to physical and mental stress.

With the aid of the driver assistance systems that are already available, the elderly can maintain their mobility. Technical aids such as parking assist systems, head-up displays, traffic monitoring with radar and laser scanners, automated braking maneuvers, tactile, acoustic and optical alarms, can compensate for age-related functional limitations.

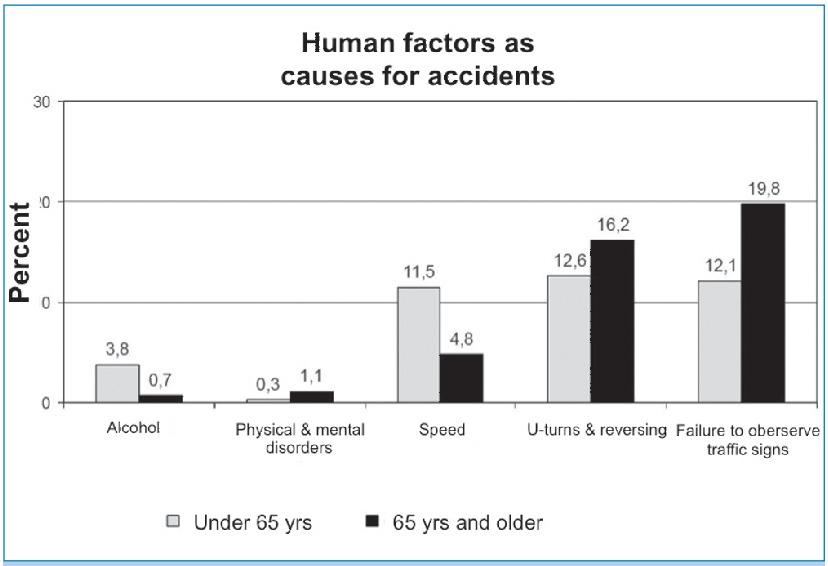


Fig. 3: *Analysis of the human factors as causes for road accidents in the Bonn area, Germany [3]* ■

The study conducted by Schlag [2] further shows that seniors tend to compensate for the age-related loss of sensory, cognitive and motor skills in everyday activities: the more experience an elderly person has of road traffic, the lower the risk of an accident. ■

2. The situation

With increasing age and diverse health issues, many people find it increasingly difficult to walk and thus become dependent on others for help. Possible causes include stroke, sarcopenia, degenerative joint disease and other conditions affecting the joints or bones.

Technical solutions are already available for those who nevertheless wish to remain independent and mobile with as little support from others as possible. Rollators are practical walking aids, for instance, while mobility scooters can be used for longer distances. Depending on the model, these electrically driven single-seat vehicles have a maximum speed of 6 to 15 km/h, and in some cases do not require a driving license. Mobility scooters are recommended for individuals who have great difficulty walking and need assistance when leaving the home [6].

When it comes to electric wheelchairs, there are two categories: those for indoors and those for outdoors. Models for outdoor use are usually sturdier, heavier and larger, and are designed to cover longer distances at a higher speed, whereas indoor models need to be very compact and easy to maneuver. Wheelchairs are generally recommended for individuals who have lost their ability to walk or at least have great difficulty walking. As described above, for many seniors the automobile becomes all the more important with increasing age and having to give up driving signifies a tremendous loss of mobility and freedom.

Experience shows that older seniors who have driven a car all their lives and still are mentally capable of driving, are not willing to swap their car for a mobility scooter or electric wheelchair, despite the fact that they could then travel shorter distances such as for buying groceries. This may be due to the unwillingness to let go of a habit, or because they believe a car is more comfortable and convenient, or simply that it allows them to travel longer distances. If an elderly person can no longer walk unaided but could drive a car that is equipped with adequate assistance systems, additional technologies will be required. Another obstacle to be tackled by anyone in a wheelchair are steps and staircases that cannot be overcome without help. ■

3. The solution - approaches and implementation

To date there are no products on the market that offer adequate solutions. In this project, we have therefore analyzed and discussed new approaches to solving these issues. The main focus is on a completely autonomous technical aid that offers the user mobility without being dependent on others. Looking at the individual products offered by various companies, it is clear that only a combination of these options can deliver a holistic solution. A completely autonomous solution is all the more important for single seniors in helping them to remain socially integrated.

The combination of a stair-climbing wheelchair and a vehicle integration concept which eliminates the difficulty and strain of transferring from wheelchair to car, offers a solution for the present and future driving generation aged 75+. With this car-wheelchair combination, the user does not expect his or her electric wheelchair to reach high speeds and long distances. Here, the focus is more on a design that offers easy maneuverability, both indoors and also over shorter distances outdoors. Furthermore, it is imperative that such a system offers easy and intuitive handling and a reliable stair-climbing mechanism. Today's built-in driver assistance systems and those still in the planning phase already make a valuable contribution to the safety of seniors. However, the more complex they become, the more difficult they will be to use. Therefore, such systems should also be simple to use and offer all the assistance required in particular by the elderly.

3.1 Chassis with stair-climbing function

Excellent maneuverability is achieved with a Segway-like chassis design which enables the wheelchair to move on one axle and one pair of wheels only. To achieve this, each wheel is driven by a separate motor. Based on the principle of the inverse pendulum, these motors are dynamically

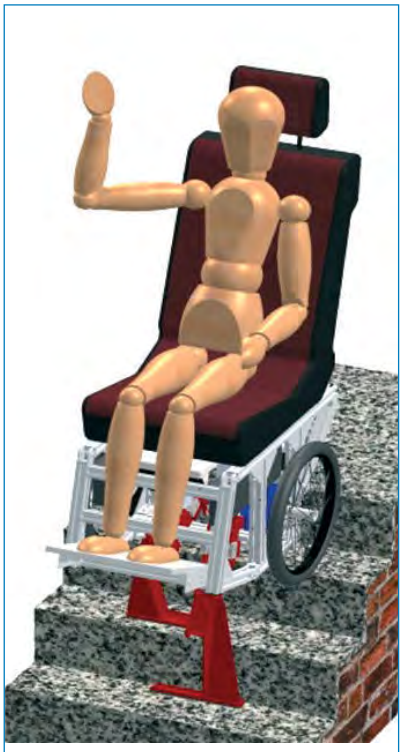


Fig 4: *Climbing stairs with the iMob wheelchair* ■

Fig. 5: *iMob wheelchair from different angles* ■

actuated in order to always keep the center of gravity precisely above the wheel axle. *Figures 4 and 5* illustrate the design from different angles.

In stair-climbing mode, two fold-out legs which each consist of an upper and lower leg just like that of a human limb are located between the wheels. These legs push the wheelchair up or down the stairs as shown in *Figure 6*. A 3D camera system combined with an intelligent control algorithm specifies the correct leg position for each step [7].

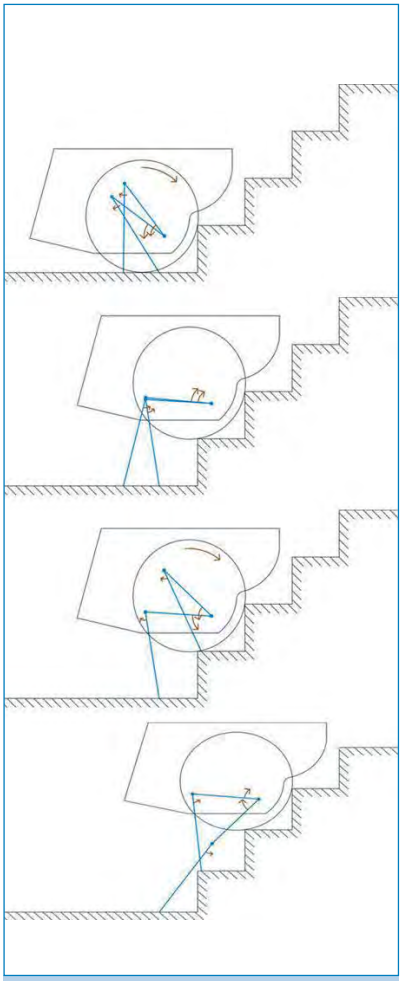


Fig. 6: *Climbing mechanism of the iMob wheelchair* ■

3.2 Production vehicle interface

To travel longer distances in comfort, the iMob wheelchair is equipped with interfaces that can be easily integrated into a production vehicle.

The automotive integration system is based on a modified version of the seat transfer system produced by Autoadapt. It features a pivoting mechanism that transfers the driver, while in the driver's seat, out of the car and onto the wheelchair chassis. With the original system, another person is always needed to place the chassis by the driver's door, and fold and stow it in the trunk, respectively.

An additional feature of this system developed during the proj ect is the ability of the wheelchair chassis to unfold and drive autonomously from the trunk to the driver's door and return after use. The automated stowing process is illustrated in *Figure 7*. Thus, the elderly driver-'s dream of independent mobility becomes a reality. ■

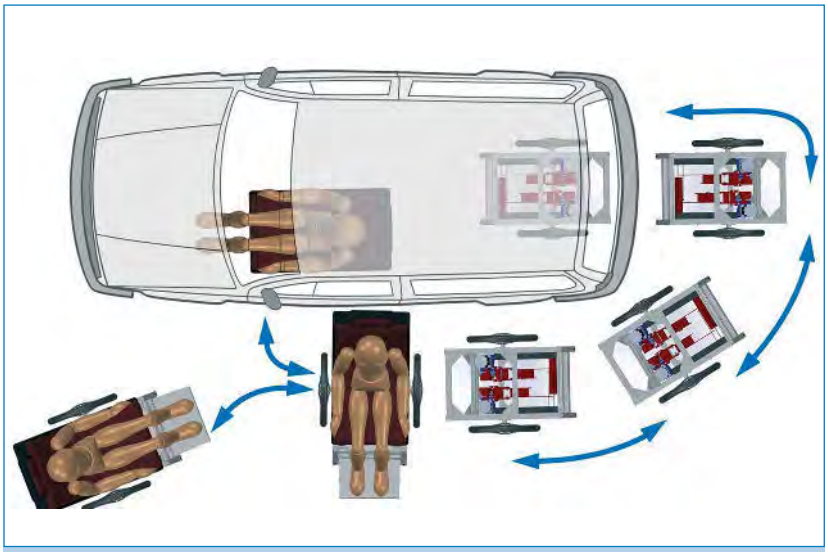


Fig.7: *Concept of the vehicle interface for the iMob wheelchair* ■

Acknowledgements

We would like to express our gratitude to the Hochschule Kempten for funding our project and to the Heinz Nixdorf Stiftung for partly funding it from the KOMPASS project. ■

References

[1] Häcker, M.:
Barrierefreiheit in der Stadt der Zukunft am Beispiel von iMob:
VDE Kongress 2014,
20/21.10.2014 Frankfurt am Main

[2] Schlag, B.:
Sichere Mobilität im Alter?
DVR-Presseseminar -
Raum für alle!?,
Dresden 2008

[3] Mobilität in Deutschland 2008, publ. by the Bundesministerium für Verkehr, Bau und Stadtentwicklung, Bonn and Berlin 2010

[4] Zauner, P., Wolf, B. [Ed.]: Der Autofahrer der Generation Plus, Cuvillier Verlag Göttingen, 2007

[5] Pottgießer, S., Kleinemas, U., Dohmes, K., Spiegel, L., Schädlich, M., Rudinger, G., Profile von Senioren mit Autounfällen, Zentrum für Alternskulturen at Universität Bonn, Mensch und Sicherheit, 2012

[6] Herner, S., Rollstühle: So findet man das richtige Modell. [Online], Available: http://senioren-ratgeber.de [last visited on Nov. 21, 2012].

[7] Häcker, M.: New mobility concepts for disabled and elderly people: IEEE Third International Conference on Consumer Electronics - Berlin (ICCE-Berlin) 2013.

Contact details:

Prof. Dr.-Ing. Petra Friedrich

Hochschule Kempten
CoKeTT Zentrum

Bahnhofstraße 61
87435 Kempten (Allgäu)
Tel: 0831 2523 9256
Fax: 0831 2523 197
E-Mail: petra.friedrich@hs-kempten.de
www.hochschule-kempten.de
www.cokett.info

Univ.-Prof. Dr. rer. nat. Bernhard Wolf

Heinz Nixdorf-Lehrstuhl für Medizinische Elektronik
Technische Universität München

Theresienstraße 90, Building N3
80333 Munich
Tel: 089/ 289 22947
Fax: 089/ 289 22950
E-Mail: wolf@tum.de
www.lme.ei.tum.de

M.Sc. Michael Hinderer

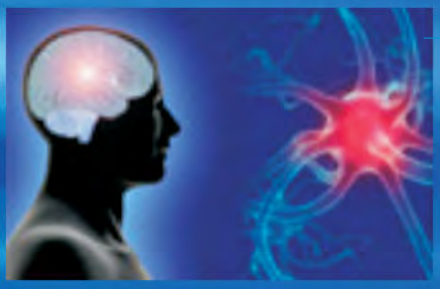
Hochschule Kempten
CoKeTT Zentrum

Bahnhofstraße 61
87435 Kempten (Allgäu)
Tel: 0831 2523 9300
Fax: 0831 2523 197
E-Mail: michael.hinderer@tum.de
www.hochschule-kempten.de
www.cokett.info

Prof. Dr. phil. Klaus Bengler

Lehrstuhl für Ergonomie
Technische Universität München

Boltzmannstraße 15
885747 Garching
Tel: 089/ 289 15400
Fax: 089/ 289 15389
E-Mail: bengler@lfe.mw.tum.de
www.lfe.mw.tum.de



Sensor-based gait analysis in Parkinson's disease

Medical-technical applications in the treatment of chronic movement disorders

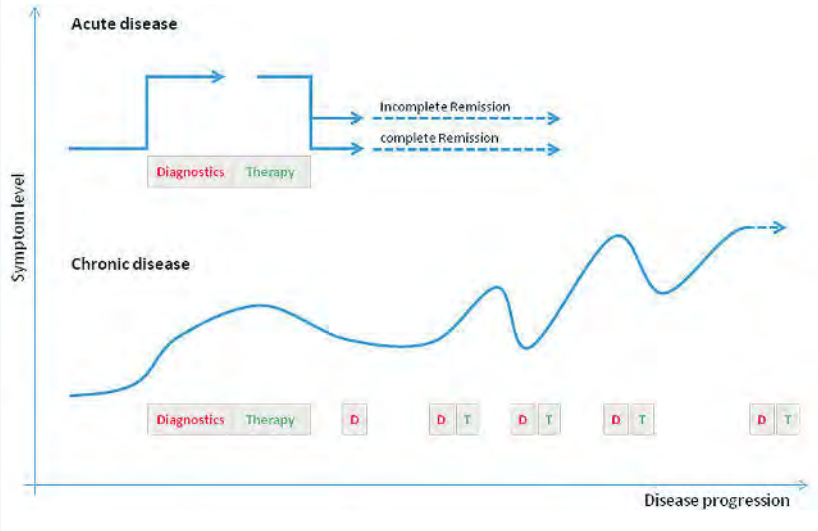
Recent developments of modern technology using wearable/body-worn sensors are increasing in our daily lives. Smartphone, bracelets, watches, or pulse measurement belts are now available as consumer products monitoring the health and sport activities in manifold design. This progress and the commercialization of the relevant technologies are the driving force to apply modern sensor systems also in the diagnosis and treatment of a broad range of diseases. In medicine, sensors provide objective and comparable surrogate markers of clinical intervention and complement the traditional examination strategies that depend on the experience and availability of the physician. In addition, sensor can generate objective information on the patients symptoms and wellbeing, independent of the doctor visits, and thereby provide telemedical home-monitoring approaches in everyday life of the patient.

In contrast to activity monitoring concepts of wearable sensors in fitness and health, two fundamentally different conditions in the application under medical conditions are to be considered: During activity monitoring in healthy subjects, a non-restricted body function has to be assumed, in fact, it is typically excluded by the manufacture to use activity monitor systems under disease conditions. Assuming normal body function the sensor can measure and correlate activity to fitness and training concepts. In addition, medical device regulations do not apply to the respective sensor system in respect to medical privacy, patients' data ownership rights, and product and application specific quality criteria. Therefore, the scientific development and validation, as well as the requirements for the placing sensor systems as medical products on the market in this fast-paced world of technological development are much more complex. Nevertheless, due to the possibility of medical application in continuous diagnostic, e.g. monitoring concepts, wearable sensors will fundamentally change the healthcare concepts for diagnosis and treatment of chronic diseases in the near future.

Albeit the patients' needs are substantially different the classic care concepts of today's health care system remain largely similar for acute and chronic diseases. Diagnostic and treatment of out- or inpatients includes the assessment of clinical information, symptoms, and patients history as presented by the patients' using various diagnostic procedures aiming to find the right diagnose and to initiate treatment. For acute diseases, this paradigm works very well, since it makes very costly diagnostic procedures clinically as well as economically efficient. The best therapy is initiated with the goal to (at least partially) restore the impaired body function specific for the disease of the patient. In chronic diseases, this procedure also results in the process of finding the right diagnose, however, the care concept for the subsequent chronic phase of these disease is facing several crucial challenges: A) Chronic diseases require constant therapy monitoring. B) The selected therapy is mostly symptomatic in several chronic diseases, thus requiring continuous observation of progression or aggravation of the diseases' symptoms. C) Importantly, during the chronic phase of these diseases the requirements to medical care are highly predictable, since the characteristics of potential progression, additional symp-

toms, and therapeutic adjustments are known over the course of chronic diseases, but can only be presented to the doctor during the patient visits. The typical scenario of these visits is that the patient has either unchanged conditions (e.g. the appointment would not have been necessary), or he experienced changes in symptoms that would have required an even earlier adjustment of treatment paradigm. Thus, a major need of nowadays health care systems is to monitor changes of symptoms or related limitations constantly in patients under at home conditions. Wearable sensor systems are able to meet these needs. They can provide a simple and inexpensive measure allowing to quantify therapeutic effects, detect early signs of progression or non-respsonder to treatment allowing to change therapy regimes, as therapy monitoring. In this respect, they can support therapeutic decisions or necessary treatment adjustments in the future even before the next scheduled doctor's appointment.

A frequent and typical chronic disease with progressive course and need for almost constant control of symptoms and treatment is the Parkinson syndrome. It is the most common neurodegenerative movement disorder with about 4.1 million people affected worldwide an estimated 250,000 to 280,000 patients in Germany (German Parkinson Society). Due to increasing life expectancy, environmental and industrialization factors a region dependent doubling of its prevalence is estimated by 2030. In most patients the disease is diagnosed at an age between 55 and 65 years. In Parkinson's disease the progressive dysfunction and loss of specific nerve cells in the brain leads to a constant increasing disabilities by the typical motor symptoms, e.g. tremor (shaking), rigor (muscle stiffness), bradykinesia (slowness), and postural instability (impaired postural reflexes). The resulting movement and gait impairments are well known to the general public. They also serve as clinical target symptoms defining the diagnosis for the attending neurologist. The symptomatic therapy aims to improve the movement and thus to minimize the resulting restriction of quality of life for the patient. The effect of the chosen therapy is assessed by the attending neurologist during the next visit of the patient at the doctor's office. As the disease progresses these control visits have to be constantly repeated. With increasing progression several symptoms cannot be completely reduced anymore by drugs and require additional therapeutic strategies. In addition, gait impairment and other symptoms become considerably variable during the course of a day – an advanced stage of the disease that is referred to as motorfluctuating phase. Information on the changes of motor symptoms mainly relies on historical description of the patient to the doctor and is not validated by continuous objective data. Therefore, the aim of wearable sensor systems is to recognize symptoms, or their deterioration at an early stage enabling to adjust and optimize the therapy as fast as possible.



Requirements for diagnostical workup:
Acute diseases require rapid and intensive diagnostics to identify the disease and initiate the treatment leading to immediate (optimally complete) remission of symptoms and recovery of the patient. Chronic diseases require constant diagnostics and therapy adjustment ■

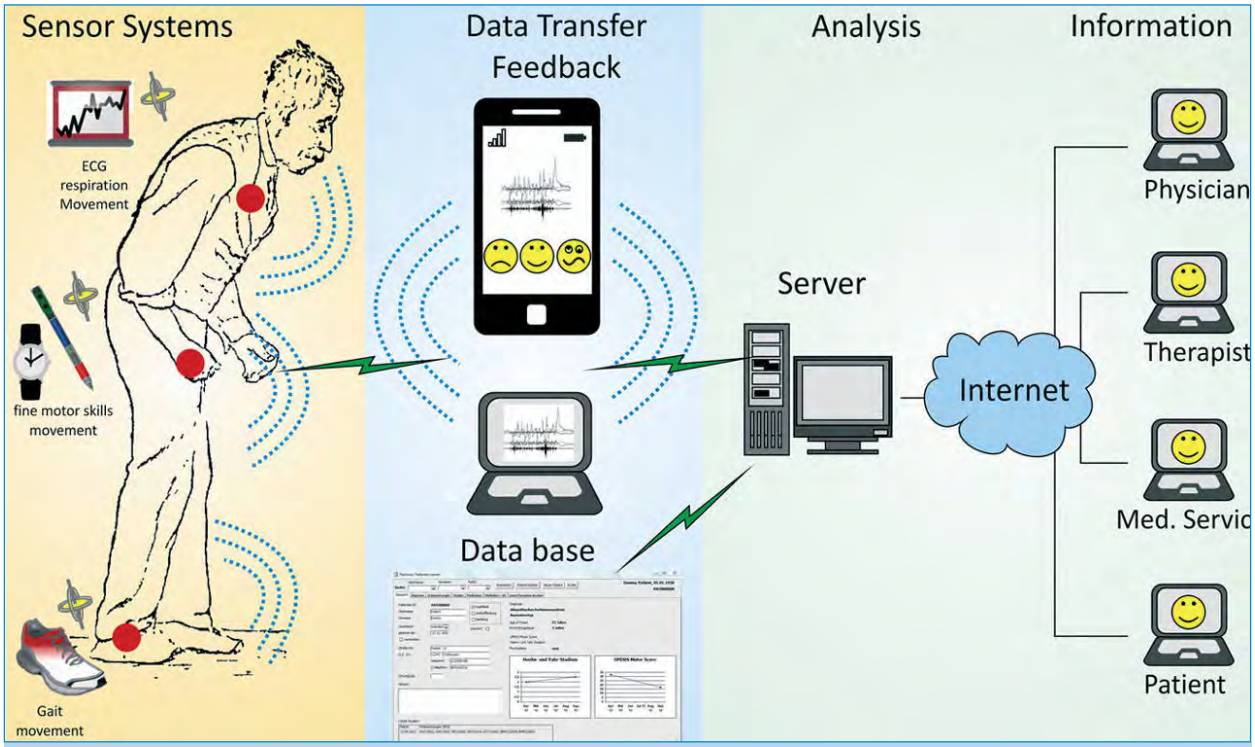
In the Medical Valley European Metropolitan Area Nürnberg, our consortium at the Friedrich-Alexander University of Erlangen-Nuremberg (FAU) consisting of the Department of Molecular Neurology, University Hospital Erlangen, the Pattern Recognition Laboratory, and the industrial partner ASTRUM IT GmbH developed a mobile gait analysis system that is easy to handle for doctors and patients and provides objective and complementary parameter for the movement impairment of patients with Parkinson syndrome. The project was launched in a direct co-operation between medical, technical and industrial partners promoted by the Bavarian Research Foundation. It has received the medical-technical price in health care of the city of Erlangen in 2014, and the Bavarian Innovation Award eHealth in 2015. Since 2014 it is also a new

flagship project of the Emerging Field Initiative (EFIMoves) of the FAU. Our goal is to support the medical care of patients with movement disorders by instrumented movement analysis using wearable motion sensors. The classic diagnosis of movement disorders relies on the clinical examination by the movement disorder specialist. Therefore, this subjective assessment depends on the experience of the attending neurologist and the medical evaluation differs from doctor to doctor thereby limiting its comparability. Thus, our newly developed sensor-based movement analysis system helps to objectively capture changes of gait impairment in Parkinson syndrome.

The recently developed study system for sensor-based gait analysis – eGaIT: „embedded Gait Analysis Using Intelligent Technology“ - consists of inertial sensors attached to the shoe which measure acceleration (accelerometer) and angular velocity (gyroscope) during distinct walking sequences. Mathematical algorithms using signal analysis and pattern recognition methods compute spatio-temporal gait parameters such as stride length, velocity, foot angles and clearance. These objective gait parameters that are assessed independent of the subjective judgment of the physician characterize movement impairment of patients and complementary support therapeutic decisions. eGaIT was validated in cooperation with the geriatric hospital (Waldkrankenhaus Erlangen) in geriatric patients with different gait impairments associated with increased risk of falling. Until now, the analysis of standardized walking sequences of more than 800 patients and controls with different movement disorders clearly support that objective gait parameters can be used characterize the diagnose, the stage of the disease, and the effect of treatment. Instrumented movement analysis has the potential to be performed in „mobile“ movement laboratories in the everyday care of patients thereby complementing the regular medical examination in out and inpatient units for movement disorders. In addition to the one-stage sensor-based gait analysis during the diagnostic workup our current research aims to transfer the findings from controlled instrumented gait analysis to continuous monitoring concepts into everyday life of the patient. In advanced Parkinson's disease, it is a particular challenge to optimally adapt the time and dose of medication throughout the day for the individual patient. This is necessary because the level of motor impairment changes during the course of a day. Rapid changes from drug-induced hypermobility to phases with severely impaired movement are substantially limiting the quality of life. Here, the adjustment of the medication represents a major challenge to the continuous treatment of this chronic disease, since the therapeutic decisions rely purely on the subjective impression of the patient and his historical information. Here, subjective and incomplete patient diaries provide only little objective information. A continuous and objective gait analysis could therefore supported complementary and objective information for the treatment of Parkinson patients. In the future, instrumented movement monitoring concepts will lead to earlier detection of aggravation of the disease and rapid identification of responder and non-responder to initiated therapies. Our results suggest that eGaIT can also be used to monitor the so-called „invasive therapies“ in advanced Parkinson's disease, where continuous drug pumps or deep brain stimulation concepts are applied successfully treating the motor impairment of patients. This leads to a more rapid increase in the quality of life for the patient, and thus a higher efficiency in health care.

Our experience and findings during the scientific and industrial development of eGaIT clearly

eGaIT – Embedded Gait Analysis using IT:
eGaIT was been developed by the Department of Molecular Neurolgy (PD Klucken, Prof. Winkler), the Pattern Recognition Lab (Prof. Eskofier), and the industrial partner Astrum IT GmbH. The study system enables automated and mobile gait analysis. Motion sensor record movement signals to a tablet PC or smart phone from distinct movement tests. Gait parameters are computed on the server and results are provided to the physician or patient ■



Sensor-based Home-Monitoring concepts:
A variety of sensor systems are adapted to the specific symptoms of patients and measure respective body functions, classify distinct impairments and monitor therapeutic effects or progression of diseases. Sensor-based parameters complement aditional information on the patient and results are provided to physicians, medical services, or the individual patient ■

shown that sensor-based movement analysis approaches reaching high biomechanical resolution need to be adjusted to the particular symptom and disease. In future, modular sensor systems will be selected and applied to effectively monitor different body functions providing therapy-relevant information for the individual patient and the treating physician. This information can also be used to provide objective evidence for therapy efficacy using objective, reproducible, and comparable data. These concepts will allow to validated therapeutic targets in health care, ultimately leading to a greater benefit for the patient due to better and faster therapy adjustments. Both, the adaptation and further development of technical solutions, as well as the ethical and legal definitions of appropriate platforms, patient privacy rights, and medical data protection require further research. Using the example of Parkinson's disease eGaIT can provide objective parameters on human gait as a measure for motor impairment and mobility.

The eGaIT system is currently further developed for its application in other neurological diseases, e.g. Multiple sclerosis, but also musculo-skeletal movement impairments. In particular, ager-elated chronic and multifactorial gait impairments require constant nursing and medical care. It is the most important patients' need to rapidly adapt the various therapies for successful treatment, and to prevent secondary comorbidity and serious complications.

Developments in medical technology can provide complementary information on the medical status of patients across the distinct sectors of care from cost-effective and easy to use solutions. Long-term and continuous therapy monitoring or telemedical applications will support patient care and significantly change the treatment processes sustainably. ■

Informations:
www.egait.de

Literature:
Barth, et al., Sensors, 15: 6419-6440. 2015
Rampp, et al. IEEE Trans Biomed Eng, 62: 1089-1097. 2015
Klucken, et al., PLoS One, 8: e56956. 2013
Klucken, et al., Neurologie & Rehabilitation 19: 69-76. 2013
Klucken, et al., Nervenarzt, 82: 1604-1611. 2011

Author:

Priv. Doz. Dr. med. Jochen Klucken
Stellv. Leiter, Oberarzt

Abteilung für Molekulare Neurologie, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität (FAU)

Schwabachanlage 6
91054 Erlangen/Germany
Phone: +49 9131 85 39324
Fax: +49 9131 85 34672
E-mail: jochen.klucken@uk-erlangen.de

Patents

IP rights for the protection of medical technologies

Medical technology is a relatively small, but very innovative and fast-growing branch of German industry. Alongside some big companies, the creative backbone of this branch is formed by about 1.500 small- and midsize companies. In 2014 the export quota reached an international top position of 70 %. Intellectual property (IP) rights are essential to secure and strengthen this economic-scientific success, and new developments (products, their use, processes) should regularly be assessed as to whether IP rights could be secured. ■

German medical technology in international top position

As regards patents and the relative share of world trade, Germany holds position 2 behind the USA. Research enterprises in the field of medical technology reinvest, on the average, about 9 % of their turnover in research and development; in comparison, the highly innovative chemical industry reinvests about 5 % in research and development, and the processing industry about 3.8 % in total (BV-Med Annual report 2015). This innovative capacity is reflected in the filing figures of European and German patent applications. ■

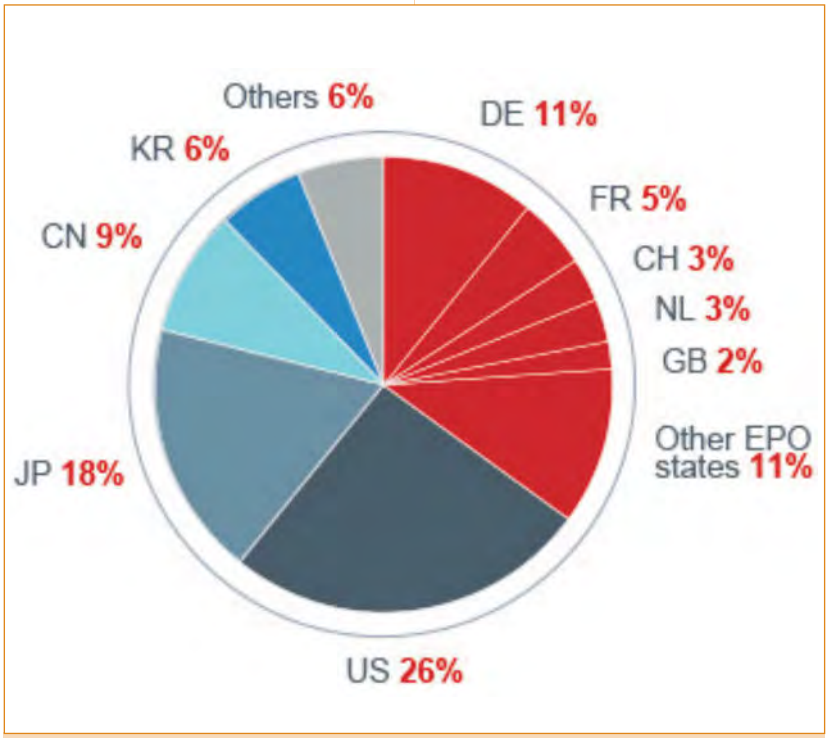
European Patent Applications according to the countries of origin[1]

In 2014 the number of European patent applications rose to 274,174 which is a plus of 3.1 % in comparison to the previous year. Medical technology again holds the leading position with 11,124 filed European patent applications, followed by electrical devices (10,944) and digital communication (10,018). Most of the applications originate from USA, Japan, Germany, China and South Korea. In Europe, the number of applications from Germany are followed by applications from France, The Netherlands and Switzerland, as well as the UK, as shown in the following graph from the European Patent Office (EPO). ■

Also the German Patent- and Trademark Office (GPTO) registered an increase of 3.7 % in the numbers of patent applications in the field of medical technology, as well as an increase of 2.1 % in the filing of trademarks. ■

Which IP rights are suitable?

Patents and utility models are technical IP rights which protect the technical embodiment. Trademarks and designs are non-technical IP rights, where designs protect the 2- and 3-dimensional form of a product and a trade-



[1] *Direct, first European filings as well as European filings after PCT (http://www.epo.org/about-us/annual-reports-statistics/statistics/filings_de.html)* ■

mark allows for the assignment of a product or service to an enterprise or, as the case may be, "brands" the enterprise.

Patents provide a protection term of 20 years, utility models 10 years, registered designs 25 years, non-registered designs 3 years, and trademarks 10 years, whereby the protection term of a trademark can be extended endlessly by payment of a renewal fee. In principle, any invention which is novel, inventive and industrially applicable can be protected by a patent or utility model which is novel, inventive and industrially applicable. It has to be taken into account that treatment of the human or animal body is excluded from patent or utility model protection in many countries or regions, including the EPO and GPTO, to ensure that the treatment of humans and animals is not hindered or even prevented by patent or utility model protection. In addition, under German utility model law, the protection of processes in general is excluded. ■

Combination of IP rights increase protection

The different aspects of a product or process can be protected by different IP rights, whereby the safeguarding of an invention can be increased and the possibilities to defend an invention against copying competitors ("me-too products") can be optimized. For example, the technical embodiments of an invention can be protected by one or more patents and/or utility models, the form of a medicinal product by a design, and the product name by a trademark. Designs and trademarks are often particularly effective in acting against "me-too products" since the assessment of their infringement is, in general, easier than of a technical IP right. "Me-too products" also primarily attempt to copy the product form and make use of the trademark and, to a much lesser extent, copy the technical quality. Accordingly, trademarks and designs are particularly suitable for forming the basis for quick enforceable legal means such as border seizure or preliminary injunctions to avoid "me-too products" accessing the market or to remove them early from the market. This is highly important for medicinal products as "me-too products" of low quality may lead to health risks and have to be removed from the market quickly so as to avoid the original product being removed from the market due to a negative reputation created by the lower quality "me-too product". ■

Observing third party rights

All the above mentioned IP rights provide the owner of the right to prohibit third parties from copying the form, the trademark, or the technical embodiment of an invention during the time the IP right is in force. In the case of patents or utility models, a protected product or process cannot be produced, brought onto the market or used by third parties without the consent of the IP right owner. Consequently, it is possible for the IP right owner to block the market for competitors and to generate sales by licensing out the IP right(s).

However, a granted or registered IP right does not provide the IP right owner the guarantee that the protected subject matter can be realized and brought onto the market without infringing an older third party IP right where the scope of protection may comprise the later more specific invention. Therefore, it is advisable to conduct a "freedom-to-operate" analysis early and before the launch of the product and/or process on the market. If the analysis does not identify relevant third party rights, nothing stands in the way for the launch; if the analysis identifies potentially relevant third party rights, early considerations should be undertaken to modify the product and/or process so as to delimit it from and avoid infringement of the older IP right. ■

Conclusion

The safeguarding of innovations by IP rights plays a particularly important role in the field of medical technology. The IP strategy should be harmonized with the innovation- and company strategy and follow a sensible budget plan to attain maximal success for the enterprise. ■

V.O.
Patents & Trademarks

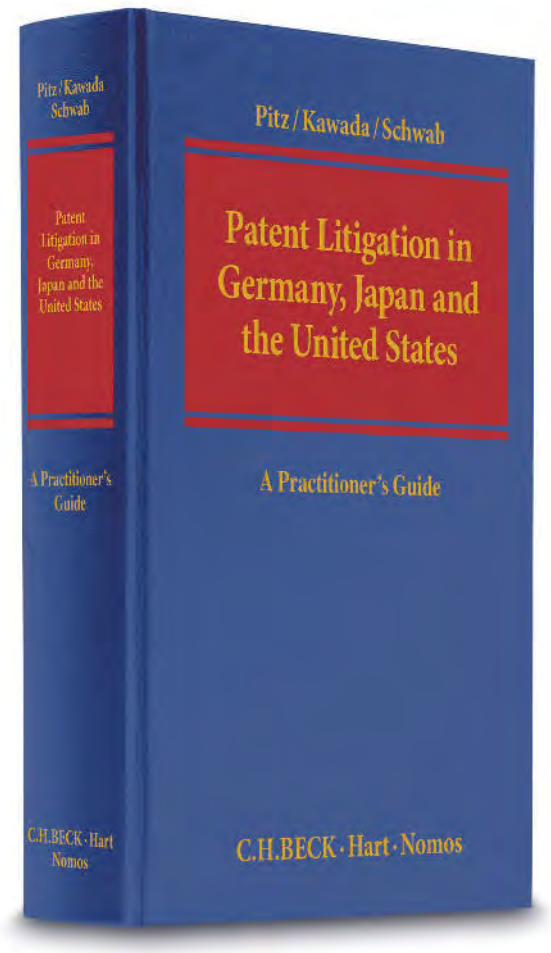
Author:

Dr. Bettina Hermann

V.O. Patentanwälte

Rindermarkt 5
80331 München/Germany
Phone: +49 89 890636936
E-mail: b.hermann@vo.eu
www.vo.eu

Patent litigation – Best practice in Germany, Japan and the United States.



Pitz/Kawada/Schwab
Patent Litigation in Germany, Japan and the United States
Hardback
207 pp, 2015
€ 190,–
ISBN 978-3-406-65075-8

More informationen:
www.beck-shop.de/bakdzd

Patent litigation proceedings

are of utmost importance in order to guarantee powerful enforcement of patent rights. An efficient litigation procedures is the litmus test for the acceptance and the working of a patent system. Practitioners with a multinational focus on patent disputes will have to be aware of the specific legal conditions in the various countries.

The book

provides a comparative overview on patent law and patent litigation proceedings in Germany/Europe, Japan and the United States. The systematic presentation of the legal systems including comprehensive references reveals differences and similarities and provides guidance for successful litigation.

Content

- Survey
- Matter of infringement
- Fact finding
- Claims of patent holder and objections of the infringer
- Pre-procedural matters
- Infringement proceedings
- Procedural principles

Authors

Dr Johann Pitz, attorney at law and patent litigator, Vossius & Partner, Munich, **Atsushi Kawada,** attorney at law and patent attorney, Tokyo, and **Jeffrey A. Schwab,** patent attorney specialising in IP litigation, licensing, ADR, and advertising law, New York.

IP Protection Strategies for Medicinal Products

The trade with counterfeit products continues to boom. In its annual report on EU customs enforcement of intellectual property rights of July 31, 2014, the European Commission informs that in the year 2013 the customs authorities in the EU have detained almost 36 million goods suspected of infringing an IPR. The medical technology sector which in the year 2013 alone was responsible for more than 10,000 patent applications does not escape such unfair competition. According to the German Medical Technology Association, 8% of the medical technology products sold worldwide are counterfeits. A large number of these products find their way over the external border of the EU and are afterwards exhibited at one of the numerous large medical technology trade fairs, such as the MEDICA, most of them taking place in Germany.

Thus, trade fairs are often the scene of patent and trademark disputes. Here - from the point of view of the IP right holder - the fast and effective enforcement of IPRs already prior to or during a trade fair is of particular importance. Further issues of interest are strategies for preventing a legal dispute and an effective defense in the case of a legal action.

For IP right holders, trade fairs are the best opportunity to obtain an overview of competitors' products already at an early stage, often even prior to the relevant market entry, and to investigate them for possible IPR infringements. It is seldom that easy to get to know the competitors' products and innovations and to clarify relevant infringement issues, for example with respect to specific product features or the distribution channels in Germany, and in this way to already collect evidence for later court proceedings.

If the IP right holder knows that potentially infringing products of a competitor will be exhibited at a trade fair, he has basically three options, namely:

- to send a warning letter
- to apply for a preliminary injunction
- to request a border seizure

A warning letter is a serious and final demand to the competitor to cease and desist from committing a particular act (e.g. from offering a specific product). In the warning letter, a term will be set within which the competitor has to submit a declaration that he will in future desist from committing the acts objected to. Failing which he is threatened with legal proceedings. It may also be considered to serve a legal action during the trade fair in order to avoid delays that would ensue from a service abroad. If the warning letter is justified, the competitor regularly has to bear the fees of the lawyer handling the warning letter.

The option of applying for a preliminary injunction against counterfeiters is of particular relevance prior to or during a trade fair, because if the application is successful it is possible to surprise the competitor, without prior warning, with an injunction title. Consequently, ideally it will be possible to enjoin the competitor already prior to or during the trade fair from exhibiting and offering infringing products.

With regard to infringing goods from EU countries, the IPR holder can file an application for a border seizure with the competent customs department.

In contrast to what is suggested by the term border seizure, the effectivity of an application for a border seizure action does not end at the external border of the EU. Rather, the German Customs Investigation Office has the right to seize infringing goods at any place within the European Union and thus also at a trade fair.

Where there is a risk of a legal action for infringement of a patent or trade mark, it can be crucial to prepare for possible attacks by the IPR holder already before the trade fair so as to be in a position to quickly take counter measures. Primarily the following options exist:

- obtaining a "freedom-to-operate opinion"
- license negotiations
- deposition of protective letters

In the case of a so-called "freedom-to-operate opinion", specialized attorneys will analyze the product portpolio intended to be exhibited and promoted at the trade fair with a view to IPR infringements already prior to the trade fair. They will point out possibilities to circumvent relevant IPRs or even to destroy them. Thus, the risk of an infringement suit can be minimized. Of particular interest to researching and innovative medical technological companies is the experimental use exemption under patent law, which offers scope for research in the area of patented technologies.

If it is already known that a competitor considers one's own products to infringe his IPRs and if an IPR infringement cannot be rejected out-of-hand it is advisable to enter into licensing negotations with the competitor already prior to or even during the trade fair in order to prevent a surprise attack at the trade fair.

Where there is reason to fear that competitors will apply for a preliminary injunction against one's own company, the deposition of a protective letter at the relevant courts is an option. It is the object of such a protective letter to prevent the grant of a preliminary injunction. For this purpose, the potential respondents will argue that the requirements for the grant of a preliminary injunction are not met and that the potential respondent must in any case be heard before a decision about the injunction claim is taken.

Expert advice by specialized patent attorneys and attorneys-at-law guarantees an effective use of legal instruments with respect to trade fair activities. Especially in view of the question of whether in the individual case the mere exhibition of a product at a trade fair can be considered as constituting an infringing act against which the IPR holder can take action, which continues to be controversial in particular due to the so-called "Keksstangen" Decision of the Federal Supreme Court, it seems to be indispensible to have specialists analyze the individual case. In any case, it is advisable to have a good look at one's own IPRs and also at relevant IPRs of others already before a trade fair, in order to avoid missing opportunities, to minimize risks, and to be prepared for the worst case of being taken to court for an alleged IPR infringement. ■

VOSSIUS & PARTNER

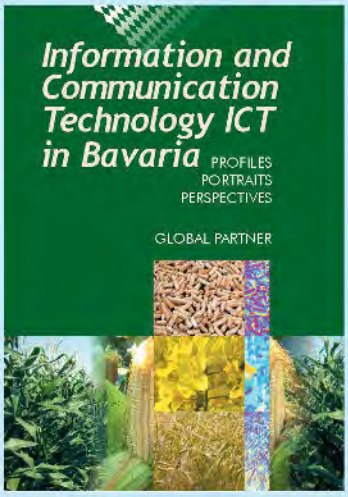
Author:

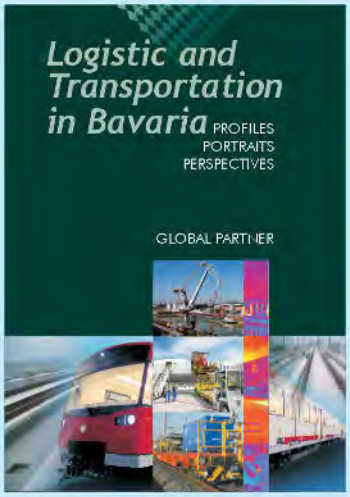
Dr. Johann Pitz

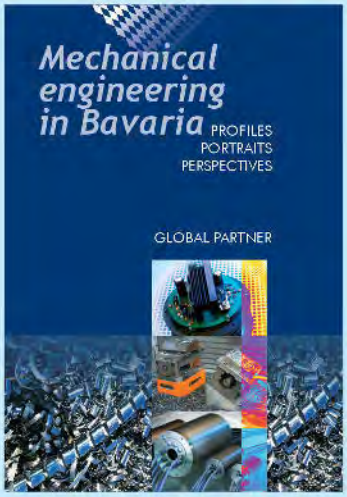
Attorney-at-Law
Patent Disputes and Patent Litigation

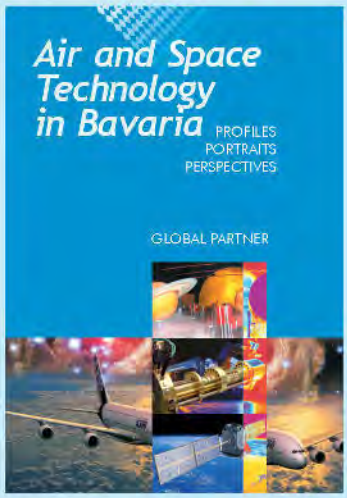
Vossius & Partner
Siebertstr. 3
81675 München/Germany
Phone +49 89 41304-0
Fax +49 89 41304-430
E-mail: pitz@vossiusandpartner.com
www.vossiusandpartner.com

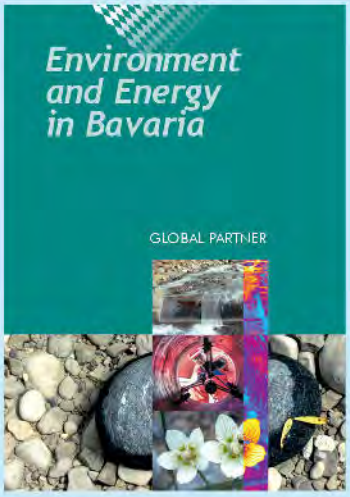
Magazines
Future Technologies in Bavaria

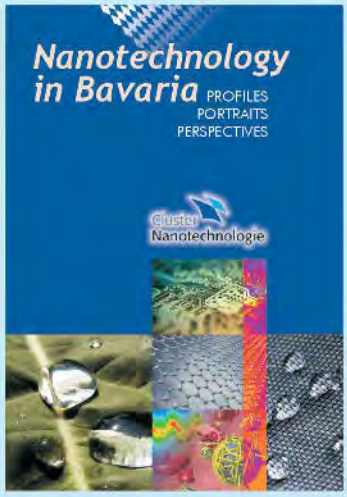






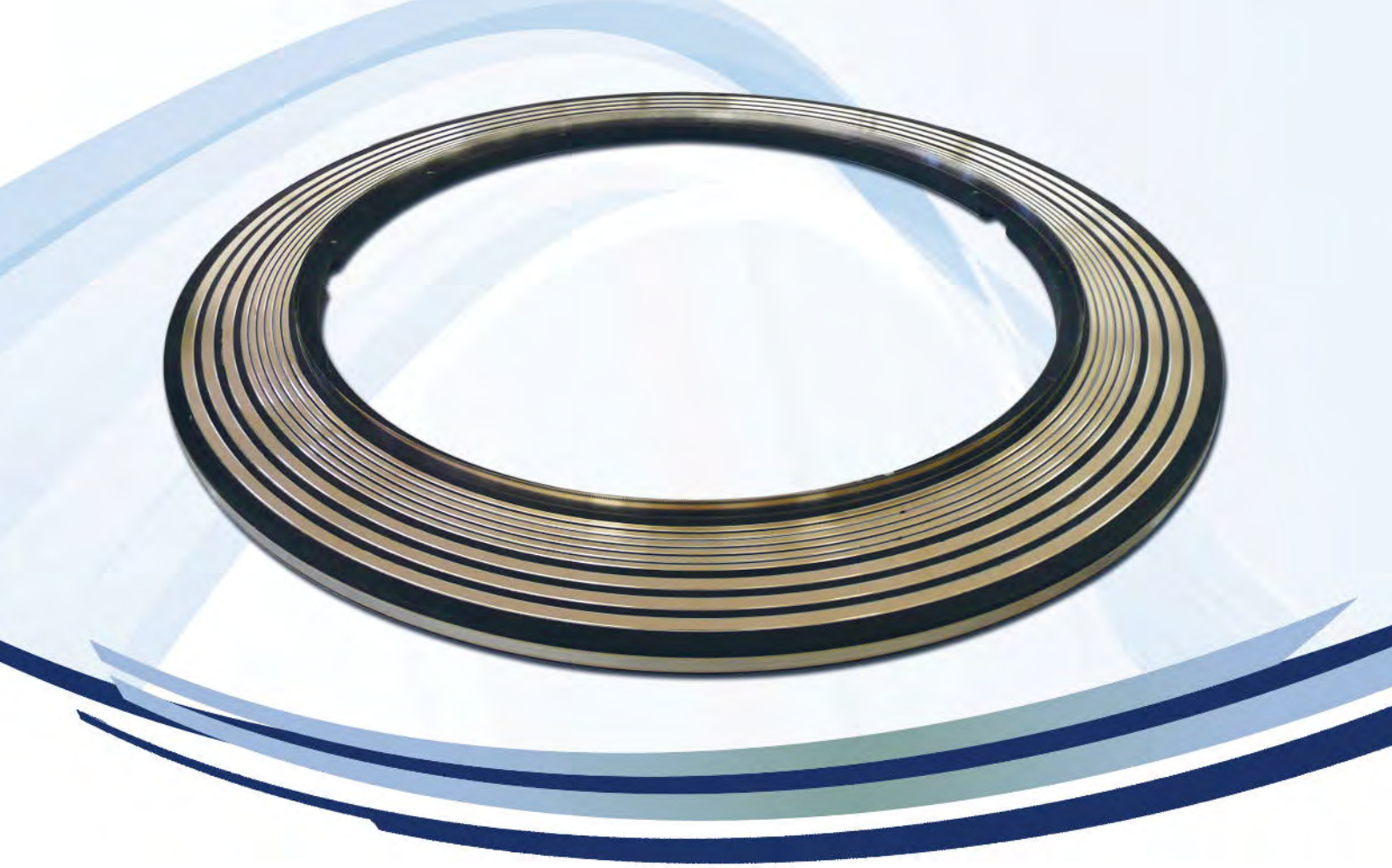






media mind

Hans-Bunte-Str. 5 · 80992 München · Tel.: 089-23 55 57-3 · Fax: 089-23 55 57-47
E-mail: mail@media-mind.info



venturetec
mechatronics

Venturetec Mechatronics

Experts in medical technology

As a reliable partner of the med-tech industry, Venturetec Mechatronics develops and supplies a wide range of systems and components with a continuously growing portfolio:

- Slip rings and components for CT-systems as well as nuclear medicine systems and devices
- Sub systems for a large number of medical applications such as C-bows and further analysis devices
- Mechanical components and structural parts
- Order production of complete mechatronic systems

www.venturetec.de