



Chair of Medical Engineering  
Faculty of Mechanical Engineering

# Innovative Technology for Smart Therapy

## Director

Univ.-Prof. Dr.-Ing. Klaus Radermacher

## Vice Director

Dr.-Ing. Matías de la Fuente Klein

Helmholtz-Institute for Biomedical Engineering  
Pauwelsstr. 20, D-52074 Aachen

Phone: +49 (0) 241 80-23870 (Secretary)

+49 (0) 241 80-23873 (Office)

Fax: +49 (0) 241 80-22870

Email: [meditec@hia.rwth-aachen.de](mailto:meditec@hia.rwth-aachen.de)

Web : <http://www.meditec.hia.rwth-aachen.de>

## Staff

Al Hares, Ghaith, Dipl.-Ing. (SY)

Bisplinghoff, Stefan, Dipl.-Ing.

Benzenberg, Jan, Dipl.-Ing.

Benzko, Julia, Dipl.-Inform.

Chuembou Pekam, Fabrice, Dipl.-Ing.

Crets, Hans, CAD Technician

Dannenberg, Kirska, M.A.

Dell'Anna, Jasmin, Dipl.-Ing. (FH), M.Sc.

Dietz-Laursonn, Kristin, Dipl.-Phys.

Elfring, Robert, Dipl.-Ing., MBA

Eschweiler, Jörg, Dipl.-Ing. (FH), M.Sc.

Fieten, Lorenz, Dipl.-Ing.

Follmann, Axel, Dipl.-Ing.

Fuente Klein, Matias de la, Dr.-Ing.

(Team Leader Navigation and Robotics)

Fürtjes, Tobias, Dipl.-Ing. Dipl.-Wirt.Ing.

Goffin, Christine, Dipl.-Ing.

Hänisch, Christoph, Dipl.-Ing.

Harbor, Daniel, Dipl.-Ing.

Heger, Stefan, Dr.-Ing. (Team Leader Ultrasound)

Hübner, Moritz, Trainee

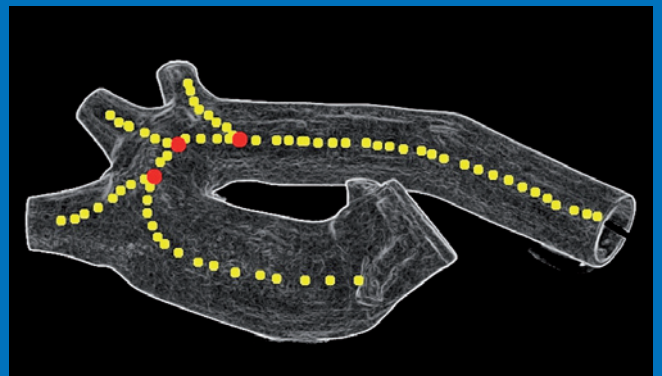
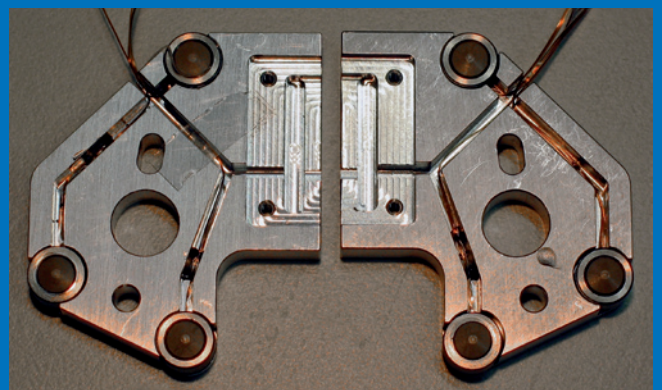
Ibach, Bastian, Dipl.-Ing.

Jansen-Troy, Arne, Dipl.-Ing. (FH), M.Sc.

Jansing, Johannes, Dipl.-Ing.

Janß, Armin, Dipl.-Ing.

Jeromin, Sabine, Dipl.-Ing.



Korff, Alexander, Dipl.-Ing.

(Team Leader Smart Instruments)

Kostykin, Leonid, Trainee

Lapa, Collins William, Trainee

Lauer, Wolfgang, Dr.-Ing. (Team Leader

Ergonomics and Risk Management)

Leucht, Gero, Math.-Tech. Assistant

Long, Yifei, Dipl.-Ing.

Marschollek, Björn, Dipl.-Inform.

Müller, Meiko, Dipl.-Inform.

Niesche, Annegret, Dipl.-Ing.

Niggemeyer, Martin, Dipl.-Ing.

Palm, Fabian, Trainee

Schmidt, Frauke, Dipl.-Ing. (FH), M.Sc.

(Team Leader Biomechanics)

Stockschläder-Krüger, Sabine, M.A.,

Team Management Assistant

Strake, Melanie, Dipl.-Math. (FH)

Vollborn, Thorsten, Dipl.-Ing.

## Introduction

The Chair of Medical Engineering (mediTEC) of the Faculty of Mechanical Engineering at RWTH Aachen University is engaged in basic research issues, as well as application-oriented aspects of computer assisted diagnosis, and engineering of model-guided therapy systems. For more than two decades our work has been focused especially on computer assisted personalized modeling, therapy planning and application. In this context our activities range from image, signal and information processing (with a special focus on ultrasound, apart from other modalities), to biomechanical modeling and simulation which represent an essential basis for computer assisted personalization of model-based therapy planning. To transfer the results of planning into therapy, surgical navigation and smart mechatronic instruments, devices and robotics, as well as medical shock wave technology, are addressed. Considering the increasing technical complexity of medical work systems, the integration and usability of medical systems and the related aspects of ergonomics and safety in medicine, are major topics of our research.

Actual projects in the domain of Orthopedic and Trauma Surgery, Neurosurgery, General Endoscopic Surgery, Cardiology, Interventional Radiology, Maxillofacial Surgery, Dental Therapy and Rehabilitation are ranging from feasibility studies (proof of concept) and system development to usability analyses and clinical field tests. Apart from the OrthoMIT project (minimal invasive orthopedic therapy; 7/2005-6/2011; 24 partners; 14.5 M€ overall funding by the German Federal Ministry of Education and Research - BMBF), the development of integrated surgical systems in the context of the smartOR project (smart medical IT networks for modular integrated OR; 4/2010 -3/2013; 6 partners; 2.8 M€ overall funding by the German Federal Ministry of Economics and Technology) has been the major project framework of our research activities. This also holds for the BMBF project IDA on the development of an intraoral ultrasound base micro-scanner (Medical Technology Innovation Award 2008). Further funds have been granted in the state of North Rhine-Westphalia and by the European Union as part of the European Regional Development Fund. Additionally, various new research grants related to basic research issues, as well as innovative application oriented concepts and industrial cooperations have been established. Also in 2011 we saw the market launch and the continuing successful market application of several products originally developed in our lab. Based on our long-standing research activities on ergonomics in medicine, we have established a portfolio of tools and methods for usability engineering of medical products. The HiFEM method and the related software tool mAIX-use for human error risk analysis (Walter Masing Award 2010 of the German Association for Quality (DGQ)) has been successfully applied in cooperation with an increasing number of industrial partners, receiving a very positive response.

## Immediate Cardiac Vitality Diagnosis Using Ultrasound-Based Strain Analysis

An exact differentiation between vital and non-vital myocardial tissues of patients with a restricted left ventricular ejection fraction is of great relevance for diagnostics and therapy in the field of coronary revascularization, since only vital myocardium benefits from a procedure such as angioplasty. Approximately 70% of all coronary angiographic examinations would allow performing immediate surgery if the location of vital and non-vital tissue was clearly known. However, even today additional MRI diagnostics are still necessary and lead to further intervention. Thus, the ability to determine the myocardial vitality mid-procedure would reduce cost and expedite treatment, which is of obvious great interest.

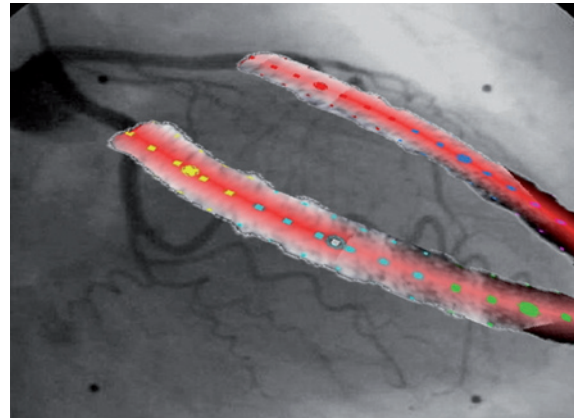


Fig. 1: Fusion of a 2D strain ultrasound analysis and a coronary angiography image.

The 2D strain analysis is an innovative echocardiographic method which enables precise statements about the myocardium deformation and its propagation. In validation studies one of our clinical partners was able to show a correlation between the deformation and the vitality of the tissue, as well as similar results compared to MRI diagnostics. Together with the Department of Cardiology, Pneumology, Angiology and Intensive Care (University Hospital Aachen), we are developing facilities for the fusion of 2D strain analysis data and X-ray based biplane coronary angiography data enabling an intra-procedural vitality diagnosis. This enables the determination of the correct spatial correspondence between stenosed coronary arteries and the myocardial segments. Using this approach, a decision about an intervention (PCI) could be made without incorporating the delays of MRI diagnostics.

## Personalized Musculoskeletal Modeling for Functional Surgical Planning

The personalized surgical treatment of pathological musculoskeletal deformities and related functional limitations requires customized morphological and functional models.

These models provide valuable information on morphology and function along with a better understanding of the pathology and an enhanced surgical planning in individual cases. These models can be customized based on patient-specific imaging data (e.g. MRI/CT). In the framework of several research projects model-based approaches for the segmentation and modeling of musculoskeletal structures are developed (Fig.2).

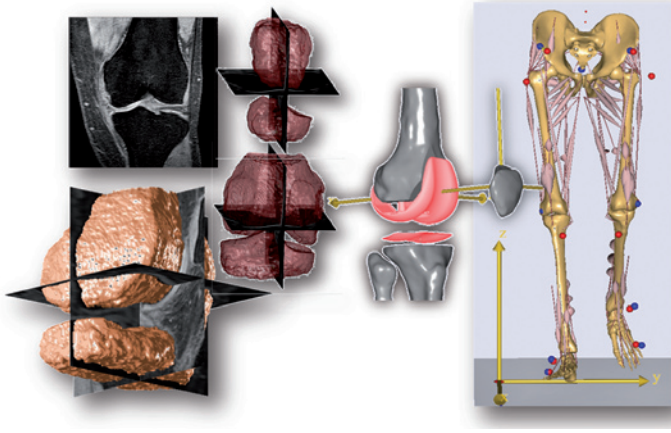


Fig. 2: Personalized morphologic and biomechanical modeling.

## Biomechanics of the Wrist

The study of wrist joint biomechanics is of great interest and importance to many researchers and also to clinical doctors. Kinematics of the wrist can be estimated by using different static imaging techniques such as MRI or CT. In cooperation with the Department of Plastic Surgery, Hand and Burns Surgery (University Hospital Aachen) we investigate wrist joint kinematics based on a miniaturized magnetic tracking system in combination with multi body simulations. Apart from model validation, these studies address the identification of appropriate parameters and strategies for surgical therapy planning.

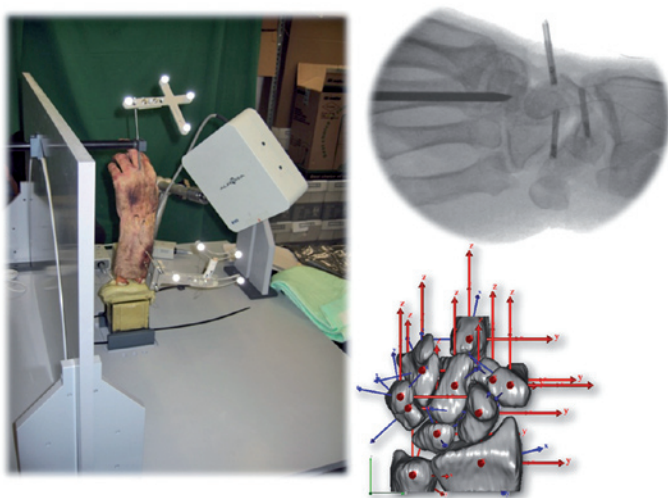


Fig. 3: Motion analysis and modeling of wrist joint bio-mechanics.

## SensoPaL – Sensor Integrated Patient Support

An ever increasing number of technical devices supports the patient treatment, but also congests the intervention room. The SensoPaL project aims to place helpful technology in the background and so the patient can be focused on. Therefore, patient support with integrated contactless ECG and tracking sensors for interventional therapy is being developed in co-operation with the Chair for Medical Information Technology (RWTH Aachen University). The intervention may begin the moment the patient is placed on the table. Capacitive ECG enables the diagnosis of heart activity even through clothes without fixing adhesive electrodes. The built in tracking equipment allows for easy and distortion corrected electromagnetic position tracking of flexible instruments within the body. The design allows for X-ray imaging to be free of interferences. SensoPaL was elected as “Project of the Month of December 2010” by the Ministry of Economic Affairs of the State of North Rhine-Westphalia.



Fig. 4: First prototype of the SensoPaL table.

## Impedance Controlled Surgical Instrumentation (ICOS)

Replacing the hip joint is one of the most successful surgeries in the field of endoprosthetics in Germany. However, after approximately 15-20 years a revision is necessary. For intraoperative real-time control of the femoral bone cement removal, the electrical impedance of bone, bone cement and soft tissues is analyzed. This real-time measurement data is used to control the MINARO mini-robot system in automated milling of the bone cement.

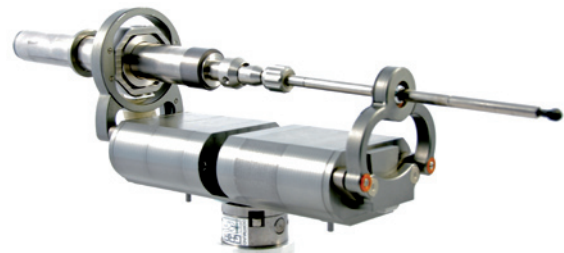


Fig. 5: MINARO - minirobot system for automatic bone cement removal.

## smartCUT – Synergistic Control of Cutting Tools

Synergistically controlled instruments can use sensor information to support surgeons during surgical interventions by automatically performing a part of the overall task. In craniotomy and re-sternotomy, sensor information can be used to preserve sensitive structures underneath the bone. Different concepts for synergistic operated surgical instruments for osteotomy and their integration based on different sensor modalities (optical and ultrasound) for the acquisition of the anatomic morphology have been implemented and tested. The general feasibility of a sensor-based automatic depth control of a freehand guided saw has been proven. Future research will deal with a combination of these different concepts to improve robustness and the evaluation of other sensing technologies.

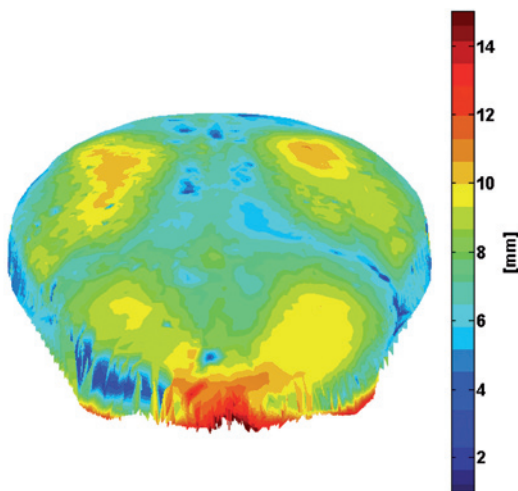


Fig. 6: Gradient of bone thickness on human skull.

## iShunt 201 I – A Mechatronic Shunt for the Treatment of Hydrocephalus



Fig. 7: Functional prototype of an extra-ventricular drainage system.

Hydrocephalus leads to pathologically high intracranial pressure due to a disturbed balance of cerebrospinal fluid (CSF), which can result in severe brain damage if left untreated. Conventional shunt designs can

lead to hydraulic mismanagement and cannot adapt to the patients' actual situation and physiology. Therefore, an intelligent shunt design is developed in cooperation with the Chair of Medical Information Technology (RWTH Aachen University), which controls the intracranial pressure

according to the vital signs of the patient. Our focus in this project is a conceptual approach and design of the valve and components.

## The genALIGN Navigation for Total Knee Arthroplasty

Preservation and recovery of the mechanical leg axis and well balanced ligaments are crucial for the outcome of knee replacement surgery. The genALIGN approach is based on intra-operative force-torque measurements. Optical or magnetic position tracking is no longer necessary. The alignment system measures the torques resulting from a deviation from the mechanical axis. A sensor-integrated tibial trial inlay determines the impact of ligament tensions on knee joint loads. The new revised alignment instrument (Fig. 8) incorporates a low cost force/torque sensor and an integrated microcontroller and display.

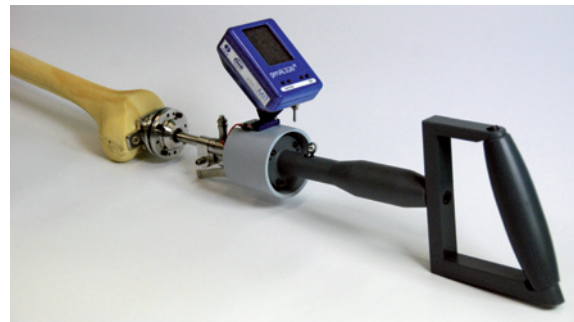


Fig. 8: New microcontroller based version of the genALIGN alignment device.

No additional computers are necessary in the OR. Moreover, the new sensor unit can be integrated in different tibial trial inlays.

## Noninvasive Diagnosis of Compartment Syndrome

In traumatology, the compartment syndrome is one of the most common complications during fracture healing with serious consequences for the patient. As of now, no objective non-invasive methods of diagnosis exist. We are developing new non-invasive approaches based on force sensor

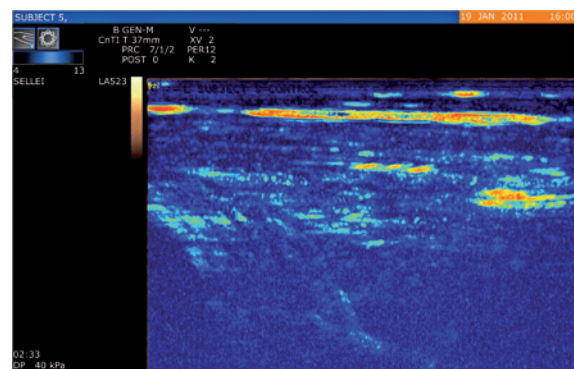


Fig. 9: Visualization of blood flow using contrast-enhanced ultrasound.

and ultrasound based measurements as well as contrast-enhanced ultrasound. By means of the latter, the distribution of a contrast agent within muscle tissue is analyzed, giving information on the micro perfusion and thus the inner pressure of the muscle.

## IDA – Intraoral Data Acquisition Using Ultrasound Micro-Scanning

Computer-integrated manufacturing of dental prostheses, such as crowns, bridges and inlays gains, is of increasing importance due to its high accuracy and time efficiency. One crucial step of the CAD/CAM process is the precise intraoral digitization of the tooth preparation. The objective of the interdisciplinary IDA-project is the development of an US based intraoral micro-scanner (Fig. 10), replacing the conventional casting process without the drawbacks of current optical scanners.

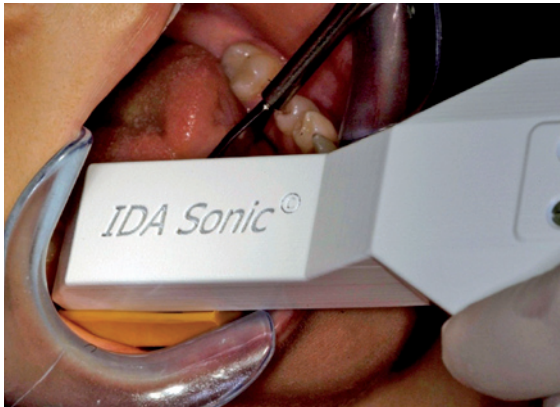


Fig. 10: Principal of intraoral ultrasound scanning with IDA Sonic prototype.

The IDA concept envisages the integration of a focused high frequency US transducer into a highly dynamic mechanical micro-scanner. First digitization results are shown in Fig. 11. The IDA-project is the winner of the “Medical Technology Innovation Award” (2008) granted by the Federal Ministry of Education and Research (BMBF).

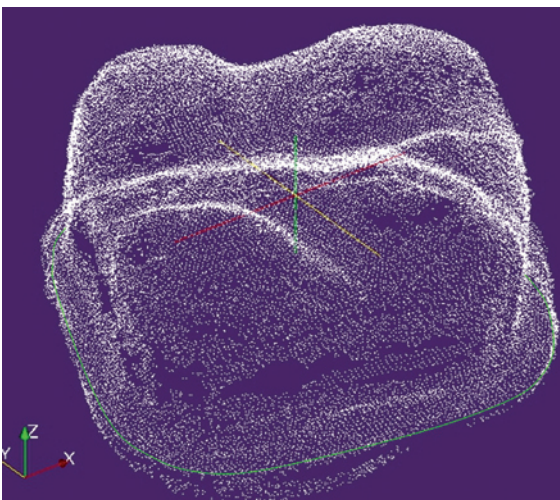


Fig. 11: High resolution ultrasound based digitization of a prepared molar.

## Smart Catheters for Interventional Radiology

Endovascular procedures allow for interventions that are often impossible in traditional surgery due to patients' general state of health. However, more complex interventions such as the placement of aortic prostheses or transjugular intrahepatic stent shunts require an exact navigation of vascular catheters.

Based on 2,5D and 3D image data, personalized therapy planning and sensor integrated catheters, a new approach towards a more accurate and reliable catheter handling is being developed. Primary phantom-based trials have already proven the feasibility of the concept and are to be continued *in-vivo* shortly.

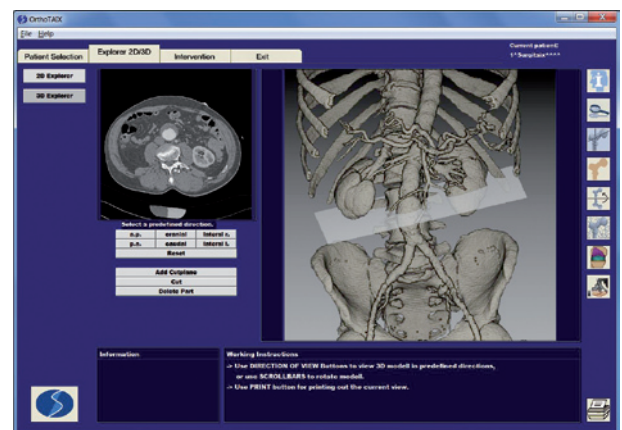


Fig. 12: Visualization of the navigation software.

## smartOR – Plug & Play in the OR

Communication beyond all boundaries: smartOR develops innovative communication and IT concepts for a flexible integration of medical systems. Its goal is to develop cross-vendor networkable medical devices based on non-proprietary standards and to enable effective risk management, as well as safe and efficient human-machine interaction. This especially pertains to the modular interconnection of image acquisition, computer-aided navigation, mechatronic instruments and monitoring. More focal points are the development of adequate concepts and solutions to improve the usability and thus the acceptance and the reliability of modular integrated workstations and operating rooms.



Fig. 13: Networking of medical devices through a switch in the smartOR network.

## Medical Shockwaves

Since 1988 medical shockwaves are applied for tissue regeneration mostly in the fields of orthopedics and dermatology. Despite the immense amount of experience gathered since, the link between the physical parameters of the shock wave,

the induced stress on the cells and the biological response is still unknown. To identify this relation, cell cultures and isolated rat hearts are treated with shock waves and the biological effects are being measured in co-operation with different medical and biological

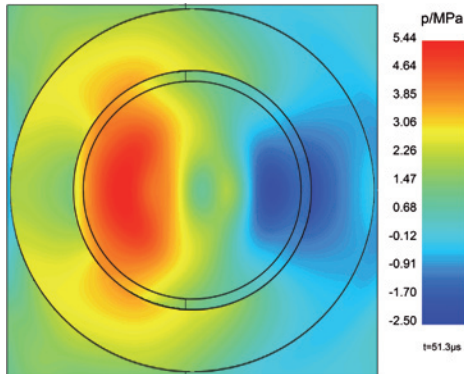


Fig. 14: FEM simulation of focused shockwaves.

partners of the University Hospital Aachen. Additionally to the biological evaluation, direct measurements of the pressure time history are performed with a fiber optic probe hydrophone. The results are used to validate FEM simulations of the experiments which offer the possibility to compute the shockwave induced stress and strain on the cells.

## Human-Centered Risk Analysis and Ergonomic Design

In order to increase usability and reliability of medical products, systematic usability engineering and risk management process are required during the complete development phase, according to international standards such as IEC 62366 and ISO 14971. The HiFEM method developed in our lab (Walter-Masing-Award 2010 of the German Society for Quality (DGQ)) uses formal, normative models to predict user-, interaction-, and system-behavior.

With the help of specific task categories and the integration of temporal relations, the state of process can be modeled. Based on different human error taxonomies, a systematic failure analysis is associated, in order to identify potential errors in human information processing and conflicts in the use of mental resources. The HiFEM method has been implemented in the mAIxuse risk analysis software tool and has been successfully evaluated with different industrial partners.

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## Selected Publications

- [1] Jeanette Mönch; Wolfgang Lauer; Bernhard Preim. Leitlinien für die Konzeption chirurgischer Ausbildungs- und Trainingssysteme - Zeitschrift für interaktive und kooperative Medien (i-com), Vol. 9, pp. 33-40, 2011.
- [2] M. C. Müller; P. Belei; M. De La Fuente; M. Strake; O. Weber; C. Burger; K. Radermacher; D. C. Wirtz. Evaluation of a fluoroscopy-based navigation system enabling a virtual radiation-free preview of X-ray images for placement of cannulated hip screws. A cadaver study. - Comput Aided Surg, Vol. 16, pp. 22-31, 2011.
- [3] Marcus C Müller; Peter Belei; Matias de la Fuente; Melanie Strake; Koroush Kabir; Oliver Weber; Christof Burger; Klaus Radermacher; Dieter C Wirtz. Evaluation eines 2-D-fluoroskopie-basierten Navigationssystems zur Implantation von Schenkelhalschrauben. Eine experimentelle Studie - Der Unfallchirurg, pp. 1-9, 2011.
- [4] Marcus C Müller; Peter Belei; Matias de la Fuente; Melanie Strake; Koroush Kabir; Oliver Weber; Klaus Radermacher; Dieter C Wirtz. Evaluation of a new computer-assisted surgical planning and navigation system based on two-dimensional fluoroscopy for insertion of a proximal femoral nail: an experimental study - J. Engineering in Medicine, Vol. 225, pp. 477-486, 2011.
- [5] Armin Janß, Wolfgang Lauer, Fabrice Chuembou Pekam, Klaus Radermacher: Using New Model Based Techniques for the User Interface Design of Medical Devices and Systems. In: Martina Ziefle, Carsten Röcker (eds.): Human-Centered Design of E-Health Technologies. Medical Information Science Reference, IGI Global, Hershey-New York, 2011, pp.234-252.

## Team

