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Faculty of Mechanical Engineering

Engineering Science and Innovation for better Health Care

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Introduction

The mission of the Chair of Medical Engineering (mediTEC) of the RWTH Aachen University is to provide an active link between interdisciplinary basic sciences and application-oriented engineering research and development of innovative solutions for a better health care. Focus areas of our research are:

- Ultrasound & Shockwaves
- Biomechanical Modelling & Simulation
- Image & Model Guided Surgery
- Mechatronics & Robotics
- Integration, Usability & Risk Engineering

Apart from international publications and a practical transfer and implementation of scientific findings, the education of our students from different disciplines and specialties is a major objective. In addition to basic research grants, industrial cooperations, corresponding to about 50% of our annual turn-over, represent an important complementary application-oriented pillar of our work for the transfer of our research and developments into clinical applications.
In 2021 the pandemic situation continued to challenge our team regarding teaching as well as research activities. Especially our novice students and younger colleagues, even not knowing "normal" live and cooperative work, suffer from the ongoing demanding boundary conditions. However, based on established networks and our long lasting cooperation with partners from research, industry and clinics, we have been able to succeed in creating fertile ground for diverse ongoing as well as new activities in research and teaching.
This annual report summarizes some examples of our project work.

Selected Projects

Impact of spinal stenosis on CSF hydrodynamics

The impact of spinal stenosis on cerebrospinal fluid (CSF) dynamics is still unclear. In particular, the correlation with the disease normal pressure hydrocephalus (NPH), respectively with its pathogenesis is vague. Therefore, we experimentally investigated the influence of varying degrees of stenosis in the cervical region on CSF hydrodynamics with respect to NPH. An in vitro model of the craniospinal CSF dynamics, developed in our lab, was used. The stenoses were located in the C6 region. The hydrodynamic cross-sectional area varied in seven measurements from no stenosis to total blockage to simulate different degrees of stenosis. Intracranial pressure (ICP), spinal flow and cranial and spinal compliances were measured. The results show an increase of the ICP amplitude and an accompanying decrease in overall compliance. Increased ICP amplitudes and a decreased craniospinal compliance are typical characteristics of NPH patients. Nevertheless, it is not clear whether a spinal stenosis favors the development of NPH. Therefore, clinical studies will be conducted to determine the prevalence and severity of spinal canal stenoses in NPH patients.

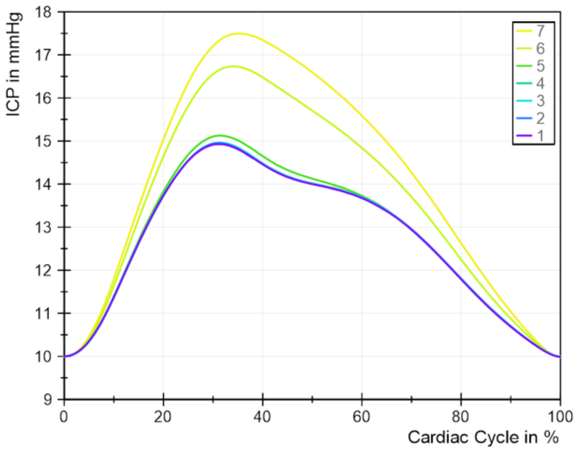

Fig. 1: ICP measurements with increasing cervical stenosis from 1 (no stenosis) to 7 (full blockage).

Patient-specific biomechanics of the knee

In vivo native knee kinematics are of relevance for different clinical applications. The measurement however is time consuming and not part of the clinical routine. Further drawbacks are exposure to radiation or inaccuracies of non-invasive measurement methods. An attractive alternative for the prediction of individual knee kinematics are patient-specific simulation models. Previously, a multi-body simulation model of TKA was developed and validated. The existing model was used as a basis for the derivation of a native knee simulation model. Validation and sensitivity studies were performed in order to assess the prediction accuracy of the model for specific settings.

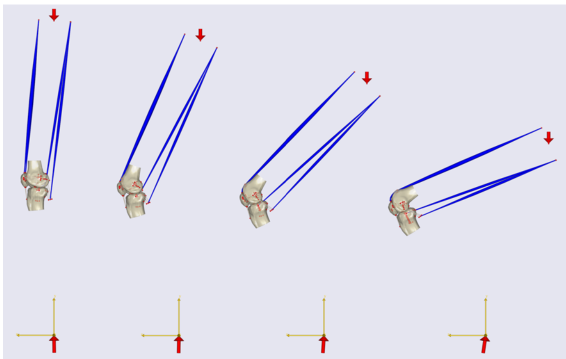

Fig. 2: Patient-specific simulation model for different degrees of knee flexion.

Robotic Bin Picking of Surgical Instruments

Usage of robots for the reprocessing of surgical instruments can reduce risk by avoiding manual interaction of humans with contaminated instruments, as well as avoiding nosocomial infections through standardised and reproducible process control. An important prerequisite for enabling the robot to reach into a tray with contaminated instruments and identify gripping positions is automated instrument detection by means of computer vision. To solve this problem a basic set of instruments, which make up more than 60% of the reprocessed instruments, have been analysed.

With the help of a camera designed for bin-picking metallic objects, point clouds can be captured, which are evaluated by an algorithm based on RANSAC. Because the robot first removes the instruments on top, the tray is divided into levels based on the depth information in order to reduce the computational effort and to improve the detection accuracy by filtering out occluded instruments.

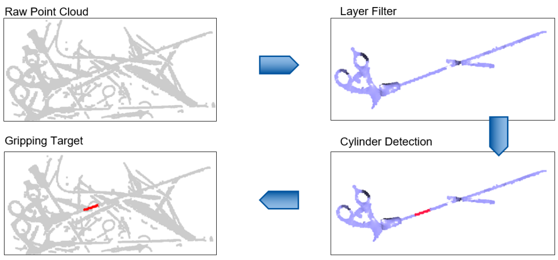

Fig. 3: Identification of gripping targets in unordered instrument tray by applying Layer Filter to reduce clutter

Reference architecture for surgical robot design

Surgical robots have different modular layouts. Modules are often difficult or impossible to identify. In order to make different systems comparable with each other, reference functions can be defined by which each robotic system can be functionally described. These reference functions can be specified for an application scenario. For instance, the reference function “move tool in volume” can be specified to “move burr in a volume of 30x50x10 mm³” to specify the size of a required implant bed in unicondylar knee arthroplasty. Consequently, we have developed a reference system architecture in which not only reference functions but also potential technical and human-based solution principles are collected and linked. Using property-based modularization methods, robots can be systematically modularized by matching properties of solution principles with module drivers and requirements.

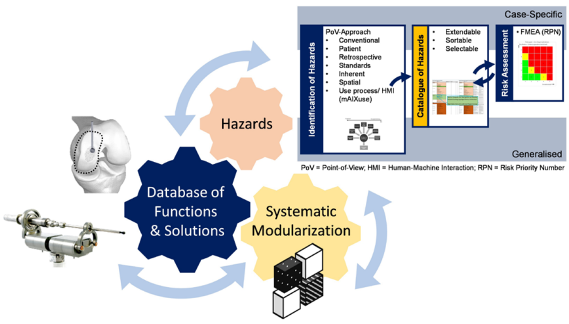

Fig. 4: Reference system architecture: a fundamental part of systematic modularization of surgical robots.

3D robotic ultrasound

For diagnosis and treatment planning in orthopedics, e.g. total knee arthroplasty, 3D imaging is often required. Today’s standard for 3D image acquisition is CT or MRI. Both techniques cause high costs and CT emits harming radiation in addition. In contrast, ultrasound is commonly available at chairside, comes at low costs and does not expose the patient to radiation. Interpretation of ultrasound images however is a difficult task, in particular for volumetric images. Sonographer require years of experience to reliably detect the bone surface. Fast and precise diagnostics, e.g. of cruciate ligament rupture or periimplantitis, thus depends on automatic processing. We investigate the potential of robotic ultrasound scanning.
For image acquisition the robot moves along the region of interest while a contact force between the skin and the probe must be maintained. Challenges include robot control strategies as well as image processing for an accurate bone segmentation.
Latest research involves customized machine learning architectures for leveraging the spatial information: The transformer architecture, originally developed for natural language processing tasks, proofs to be a promising alternative to the convolutional neural network.

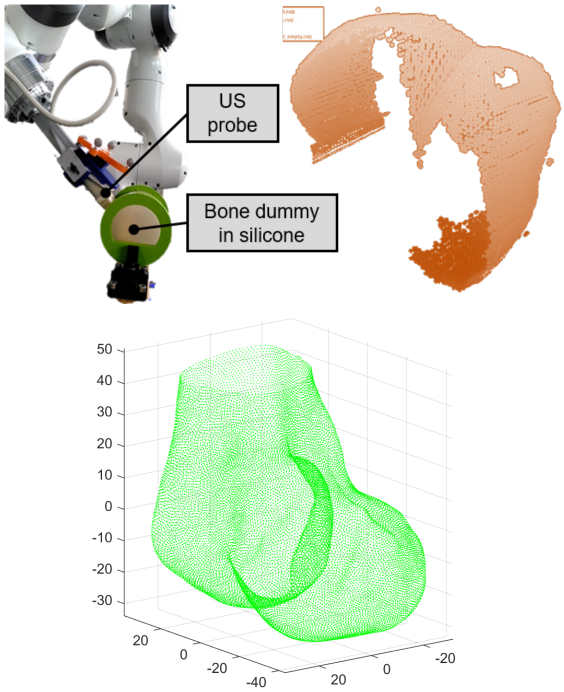

Fig. 5: Scanning of bone dummy (top/left), initial 3D reconstruction of scanned bone dummy regions (top/right), fully automatic reconstruction of a distal femur bone from ultrasound (bottom): Image slices were segmented by a vision transformer architecture, the segmented partial 3D bone surface was completed using a statistical shape model (SSM).

US based navigation on the wrist

For minimally invasive fixation of scaphoid fractures, a navigated approach based on ultrasound images represents a cost-efficient and non-invasive alternative as compared to fluoroscopy, while at the same time addressing the problem of 3-dimensional screw placement based on projective 2-dimensional imaging. We propose a machine learning based two-stage approach that tackles the tasks of image segmentation and point cloud registration individually, achieving a full automation and a significant reduction of processing time. For this purpose, state-of-the-art architectures are employed and trained on in-vitro and in-vivo datasets created at our institute.

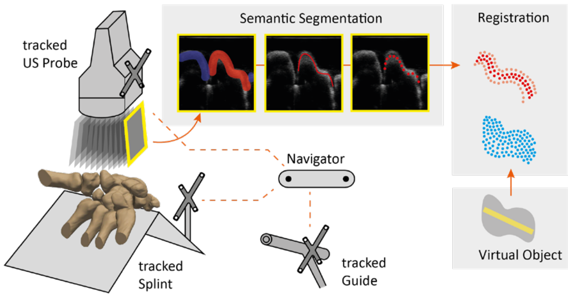

Fig. 6: Procedure for the ultrasound-based intra-operative registration of pre-operative planning data for percutaneous scaphoid fixation

Modelling cooperative surgical robotics

Surgery consists of complex sensorimotor tasks with multiple degrees of freedom. Complete automation like in industrial applications is generally impractical due to the unstructured and highly variable nature of surgical tasks. However, cooperative robotics can support surgeons by providing planning dependent (e.g. virtual fixtures) and planning independent (e.g. tremor filter) assistance functions. Thereby, different types of cooperative robotic systems (handheld, hands-on, telemanipulated) provide different scopes of assistance functions. Based on prior user centered studies, model based analysis of cooperative robotic assistances in the surgical context have been conducted on a process, a task, and a control level (Figure 7). Model architectures and relevant parameters were identified and evaluated in known applications. Modelling human robot cooperation and characteristic scenarios enables an systematic approach towards optimized surgical robotics regarding usability and risk management.

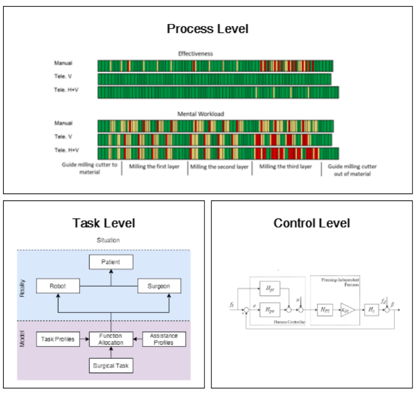

Fig. 7: Modelling Cooperative Assistance Functions on Process, Task and Control Level

A handheld robot for bone milling tasks

Current surgical robotic systems consist either of a large serial arm, resulting in higher risks due to their high inertia and no inherent limitations of the working space, or they are bone-mounted, adding substantial additional task steps to the surgical workflow.

To overcome these disadvantages, a robot was developed that has a handy and lightweight design and can be easily held by the surgeon. No rigid fixation to the bone or a cart is necessary. For the comfort of the surgeon, a support unit can be optionally added. A high-speed tracking camera together with a realtime control system ensures the accurate positioning of the milling tool, while automatically compensating for movements of the surgeon or the patient's bone.

After the manipulator has been pre-positioned and activated by the surgeon, the milling tool is automatically moved by the robotic system along a previously planned trajectory. In case of any unforeseen event, the manipulator can be stopped at any time or, since it is a handheld device, just being withdrawn from the surgical site by the operator.

Milling out cavities e.g. for unicompartmental knee arthroplasty, the position and orientation of the cavity according to plan and a smooth surface are essential. First results in cortical bone phantom material show high accuracy with a mean error of 0.13 mm. Only at the edges of the cavity, where milling direction is changed, higher deviations of up to 0.7 mm occur.

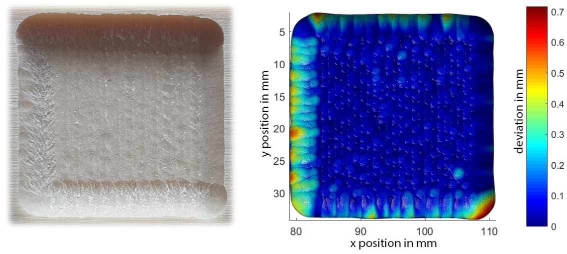

Fig. 8: Milled standard test cavity and accuracy evaluation

Control of critical devices in open OR networks

Medical devices in the operating room (OR) must be able to provide their functions reliably and on their own at all times. However, sharing information and control capabilities across the OR network with other devices enables added benefits regarding patient safety and ergonomics. For example, a wireless multi-purpose footswitch can drastically reduce the amount of switches and cables placed at the feet of the surgeon. The switch triggers different devices based on the current state of the operation. However, critical equipment such as burrs, saws or electrocautery tools (Fig. 9) impose strong safety requirements on the data exchange paths in the OR network with real time control. However, isolating critical real-time traffic from low-priority traffic accordingly is not a trivial task, especially since the device ensemble and architecture may change when devices are added or removed even during an ongoing operation. The automatic network configuration must succeed without any intervention by clinical staff.

In this context, we develop new models for the self-description of medical devices and automatic provisioning of network resources based on device profiles. These developments lay the groundwork to integrate critical medical devices more securely and seamlessly into an ever-growing operating room ensemble, including novel technologies such as 5G private networks and surgical robotics.

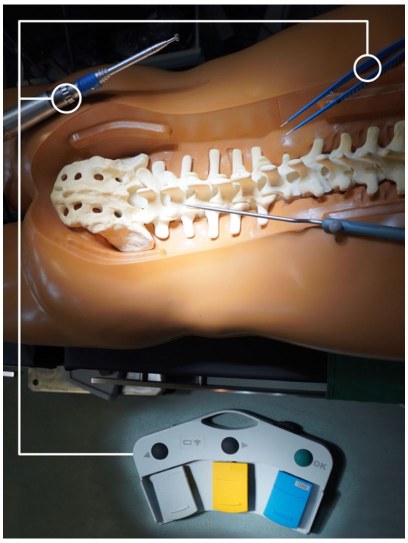

Fig. 9: Critical devices such as a medical burr or electrocautery tweezers may be controlled by the same foot pedal depending on the current workflow step

Process Optimization and Context Management in the open networked operating room (PriMed)

There are more than 17 million surgeries per year in German hospitals, and an operating room (OR) is very expensive to maintain. Therefore, a high utilization of the OR is highly desirable. Today, optimization often takes place on device-level, but not enough on process or management level. Existing medical devices are able to detect if and how they are currently being used or not. In the EFRE funded PriMed project, process optimization is achieved by integration open networking based on service oriented device connectivity (SDC), according to the international standard ISO IEEE 11073 SDC, into medical devices, as well as Standard Operating Procedures (SOPs).

Fig. 10: PriMed SDC Workstation on the DMEA booth

A combination of those can determine the actual phase of a surgical intervention. Phone calls, just to ask how far a surgical procedure is, will become unnecessary, if the context information is automatically transmitted to the OR-Management. Furthermore, context and device data such as patient status, current medications, allergies, and supplemented medications can be used for automated documentation during the intervention. Those features are integrated into central surgical, anesthetic and OR management workstations (Fig. 10).

Hybrid test bench for radial shock waves

Radial shock wave therapy is used for different therapeutic indications. In order to assess the effect on the treated tissue, it is important to know the parameters of the sound field. However, it is difficult to measure the pressure curves, especially at high pulse repetition rates. The whole sound field can be characterised using a wet test bench, but the process is cumbersome and cavitation is likely to occur at high pulse repetition rates. This effect is avoided using a dry test bench where the measurement position is limited to a single spot. Therefore, a hybrid test bench was developed combining the dry bench's device mounting and coupling with a small water basin. The ballistic device was coupled to the basin filled with degassed ultrapure water using a latex membrane covered with ultrasound gel. The contact pressure was applied with a spring. A fibre optic pressure hydrophone was used for the sound field measurements. The pressure curves of every 10th shot were measured on the beam axis 1mm from the membrane. The device was analysed at different driving pressures and pulse repetition rates.
The test setup enables an easy handling and reproducible results at all pulse repetition rates. The ballistic device provides constant peak pressures over different frequencies. The small water basin has the advantage that the water quality is easy to control and the measuring process is fast and uncomplicated. Cavitation suppression requires a clean water basin filled with degassed ultrapure water kept at a constant, low temperature. The hybrid test bench can be used to easily study shock wave parameters of ballistic devices at high repetition rates

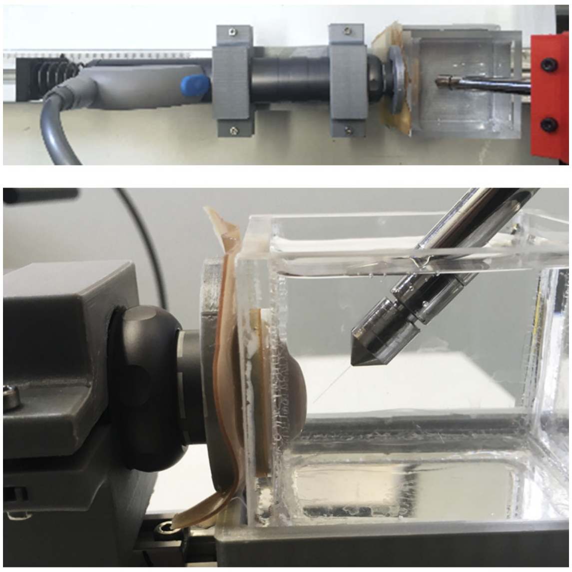

Fig. 11: In-vitro test setup for sound filed measurements of ballistic pressure wave devices.

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- the German Ministry of Health (BMG)
- the German Research Foundation (DFG)
- the European Union, the European Regional Development Fund (EFRE), the Ministry of Innovation, Science, Research and Technology and the Ministry of Economic Affairs North-Rhine-Westphalia

*Note: In this report, we can only provide a short overview of selected activities. For further information on the related projects, our cooperating partners, funding agencies and sponsors, please visit our website www.meditec.rwth-aachen.de or contact us directly.

Selected Publications

[1] M. Asseln, S.A.G.A. Grothues & K. Radermacher: Relationship between the form and function of implant design in total knee replacement. Journal of Biomechanics, 2021, 119, pp. 110296

[2] A. Benninghaus, L. Stellmann, U. Kehler & K. Radermacher: In vitro investigation of the influence of cervical spinal canal stenosis on CSF hydrodynamics. Abstracts from Hydrocephalus 2021: The Thirteenth Meeting of the International Society for Hydrocephalus and Cerebrospinal Fluid Disorders, Fluids and barriers of the CNS, 18(60), 2021

[3] P. Broessner, B. Hohlmann & K. Radermacher: Ultrasound-based Navigation of Scaphoid Fracture Surgery. In: C. Palm, T.M. Deserno, H. Handels, A. Maier, K. Maier-Hein & T. Tolxdorff (ed.): Bildverarbeitung für die Medizin 2021, Springer, 2021, pp. 28-33

[4] P. Brößner, B. Hohlmann, K. Welle & K. Radermacher: Validation of Automated Ultrasound-based Registration for Navigated Scaphoid Fixation: Evaluation of registration performance regarding simulated screw placement. Current Directions in Biomedical Engineering, 7(1), 2021, pp. 116-120

[5] S. Drobinsky, T. Lindemann, P. Schleer & K. Radermacher: Usability of Haptic Volumetric Assistance for Surgical Navigation Tasks. Current Directions in Biomedical Engineering, 7(1), 2021, pp. 11-16

[6] M.C.M. Fischer, P. Damm, J. Habor & K. Radermacher: Effect of the underlying cadaver data and patient-specific adaptation of the femur and pelvis on the prediction of the hip joint force estimated using static models. Journal of Biomechanics, 2021, Onlinefirst, pp. 110526

[7] M. Gatz, S. Schweda, M. Betsch, T. Dirrichs, M. de la Fuente, N. Reinhardt & V. Quack: Line- and Point-Focused Extracorporeal Shock Wave Therapy for Achilles Tendinopathy: A Placebo-Controlled RCT Study. Sports Health: A Multidisciplinary Approach, 2021, 13(5), pp. 511-518

[8] S.A.G.A. Grothues & K. Radermacher: Variation of the Three-Dimensional Femoral J-Curve in the Native Knee. Journal of Personalized Medicine, 2021, 11(7), pp. 592

[9] J. Habor, M.C.M. Fischer, K. Tokunaga, M. Okamoto & K. Radermacher: The Patient-Specific Combined Target Zone for Morpho-Functional Planning of Total Hip Arthroplasty. Journal of Personalized Medicine, 2021, 11(8), pp. 817

[10] J. Heibeyn, P. Gödde, P. Görtz, A. Janß & K. Radermacher: Ermittlung von Leistungsfaktoren im Rahmen der Instrumentenaufbereitung zur gezielten Workflowunterstützung. Zentralsterilisation Abstractheft 25 Jahre DGSV e.V. - 24. Fachkongress der Aufbereitung von Medizinprodukten, 29, 2021, pp. 7-9

[11] J. Heibeyn, N. König, N. Domnik, M. Schweizer, M. Kinzius, A. Janß & K. Radermacher: Design and Evaluation of a Novel Instrument Gripper for Handling of Surgical Instruments. Current Directions in Biomedical Engineering, 2021, 7(1), pp. 1-5

[12] B. Hohlmann, P. Brößner, K. Welle & K. Radermacher: Segmentation of the Scaphoid Bone in Ultrasound Images: A comparison of two machine learning architectures for in-vivo segmentation. Current Directions in Biomedical Engineering, 7(1), 2021, pp. 76-80

[13] L. Phlippen, M. Vossel, M. de la Fuente & K. Radermacher: Development and evaluation of a straightforward method to identify the elastic structure of a lightweight robot. 2021 European Control Conference (ECC), 2021, pp. 1925-1930

[14] N. Reinhardt, T. Dick, L. Lang, K. Radermacher & M. de la Fuente: Hybrid test bench for high repetition rate radial shock wave measurement. Current Directions in Biomedical Engineering, 2021, 7(2), pp. 395-398

[15] P. Schleer, M. Vossel, L. Heckmann, S. Drobinsky, L. Theisgen, M. de la Fuente & K. Radermacher: Usability of cooperative surgical telemanipulation for bone milling tasks. International Journal of Computer Assisted Radiology and Surgery (IJCARS), 2021, 16(2), pp. 311-322

[16] R.M. Sellei, U. Warkotsch, P. Kobbe, C.D. Weber, N. Reinhardt, M. de la Fuente, K. Radermacher & F. Hildebrand: Non-invasive and reliable assessment of compartment elasticity by pressure related ultrasound: An in-vitro study. Injury, 2021, 52(4), pp. 724-730

[17] M. Verjans, L. Phlippen, Z. Li, P. Schleer & K. Radermacher: Semi-automated stair climbing of a wheel hub-based patient transportation aid for emergency medical services. at - Automatisierungstechnik, 2021, 69(6), pp. 550-561

[18] M. Verjans, L. Phlippen, K. Radermacher, M. Kinzius, M. Eichenbrenner & D. Struck: SEBARES: Ein neuartiges Konzept für den Patiententransport. Rettungsdienst, 2021, 44(2), pp. 18-22

[19] M. Verjans, P. Schleer, M. Kinzius, P. Krumholz, L. Phlippen, S. Drobinsky & K. Radermacher: Evaluation of a novel stair-climbing transportation aid for emergency medical services. Biomedical Engineering / Biomedizinische Technik, 2021, 66(3), pp. 323-333

[20] M. Vossel, M. Müller, A. Niesche, L. Theisgen, K. Radermacher & M. de la Fuente: MINARO HD: control and evaluation of a handheld, highly dynamic surgical robot. International Journal of Computer Assisted Radiology and Surgery, 2021, 16, pp. 467–474

The mediTEC team