



Highly sensitive troponin tests can diagnose a myocardial infarction within half an hour

Source: Prusek/shutterstock

Providing insights into new cardiac testing methods, Professor Stefan Holdenrieder, Director of the Institute of Laboratory Medicine at Munich's German Heart Centre, explained why biomarkers are a game changer in diagnostics.

**Interview: Daniela Zimmermann**

**Professor Holdenrieder:** 'Obviously the good news is that sensitivity, and thus the quality of biomarker tests for the early diagnosis of cardiac diseases, is constantly improving. Moreover, the change of marker levels and combinations of markers are increasingly used in diagnostics to obtain even more precise results.'

**Does this mean diagnostics is like a veritable orchestra with various instruments?**

'Correct. With regard to cardiac diseases new biomarkers, such as copeptin, are on the rise, complementing troponin since they provide results faster – an important factor particularly in the emergency room.'

**But troponin is here to stay?**

'Absolutely, particularly since today we have highly sensitive troponin tests that can diagnose a myocardial infarction within half an hour. The crucial advantage of highly sensitive tests is the fact that they measure even low values very precisely. Troponins take a while, until they increase significantly.'

'Before, a patient with symptomatic chest pain, but unsuspecting ECG and unsuspecting troponin values had to wait for about three hours until a new test showed the troponin changes. The new and highly sensitive tests can show changes after only an hour – if a myocardial infarction has happened.'

'This allows us to either intervene early or, if the values are unsuspecting, confirm that there was no cardiac event and we can send the patient home. This new type of test is faster and more precise. Equally important – with the help of troponins we can detect previous damage to the heart.'

**These highly sensitive tests are not yet available in Germany?**

Indeed. Having said that, many medium size labs are already equipped with the analytic tools required for these tests. Processing the tests is simple and not particularly expensive. Nevertheless, there are places where the tests cannot yet be applied, such as in your doctor's (GP's) surgery. Today, no POCT units are available that can use these highly sensitive tests. The development of such POCT tools will play a major role in the future.'

*Since troponin can be measured with such high precision, will other markers, such as copeptin, still be needed?*

'Yes, in the case of a disease we try to intervene as early as possible. There is still a gap between the onset of symptoms and detection of troponin, or rather the onset of the therapy. During this time gap there is a risk of the coronary vessels being obstructed. Copeptin can help us get through this phase because it's a pro-hormone, which, in a stress situation, is released by the hypophysis within minutes.'

'Obviously the stress can be triggered by a number of events, be it an accident, inflammation or infarction. Usually copeptin is already elevated when troponin is still unsuspecting. Thus copeptin gives us important time to prepare treatment. While the marker does not confirm the diagnosis myocardial infarction it does offer an important warning signal of a cardiac event. 'If, by the same token both copeptin and troponin values are unsuspecting, we can say with 99 percent likelihood that no myocardial infarction happened.'

**Where else can biomarkers be used?**

'In cardiology there are two reliable biomarkers that indicate cardiac insufficiency: the peptide BNP and the precursor fragment NT-proBNP. Both indicate the degree to which the heart muscle cells are stretched. Increased myocardial wall tension is a clear indicator of cardiac insufficiency. Increased markers are a serious alarm signal. However, for the initial diagnosis it is irrelevant which marker is being measured.'

BNP has a shorter half-life in the blood, thus the NT-proBNP value is more precise. With acute heart failure, though, both values are increased. Moreover, both values are used for risk assessment and follow-up. Since certain therapies affect BNP metabolism, NT-proBNP is the marker of choice to measure outcome: When NT-proBNP decreases, the therapy is effective. Further promising markers are in the pipeline, such as ST2, galectin-3 or GDF-15.'

**What role will biomarkers play in the future?**

'The potential of biomarkers is far

## Biomarkers are diagnostic game changers

Exposing activities in wayward hearts



With previous roles at the Institute for Clinical Chemistry and Clinical Pharmacology at Bonn University, and

the Institute for Clinical Chemistry at Munich University, today Professor Stefan Holdenrieder is the Director of the Institute of Laboratory Medicine at Munich's German Heart Centre. His research focus lies on the development and evaluation of new laboratory diagnostic biomarkers and technologies for cardiology, oncology, immunology and neurology, with an additional special focus on circulating nucleic acids and their genetic and epigenetic changes.

from exhausted. Currently a number of studies are investigating which biomarker categories can be used for which types of clinical issues. Generally speaking, biomarkers can play a role in genetics, epigenetics, with micro-RNAs or exosomes, lipids, proteins or as metabolomic markers, or any combi-

nation of biomarkers. There are many and various possibilities.

'We are charting new territory here and further exploring the potential will require large-scale studies and handling of huge data volumes.'

New diagnostic technologies open up new horizons with regard to under-

### DON'T MISS

#### MEDICA'S LABMED FORUM

• Tuesday, 14 Nov 2017  
11.00 – 11.10 a.m.

**Hot topics in cardiac diagnostics**  
Professor Stefan Holdenrieder  
Deutsches Herzzentrum  
München and Universität Bonn

standing the development of arteriosclerosis and cardiovascular disease. However, meticulous assessment of diagnostic findings is crucial to determine a suitable treatment that will help the patient.'



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POCT – clinical application, IT and technology

# Moving towards deeper diagnostics

Just two decades ago, even though promising, point-of-care testing (POCT) was only used in hospitals and surgeries by a small number of specialists. Today POCT is in use throughout healthcare. During the third POCT-Symposium initiated and directed by Professor Peter B. Luppá, from Rechts der Isar Hospital, at Munich's Technical University, EH asked him to forecast developments within the next decade.

**Looking to the future,** Professor Peter Luppá said: 'One clear trend is infectiology and, above all, molecular diagnostics for infectious agents. Another major topic, already intensively discussed, is the continuous measurement of metabolites. This not only includes glucose but also other parameters that must be continuously monitored on the intensive care ward.'

*The Munich symposium focused on nine subjects, which included point of care management for chronic diseases, and POCT in developing countries. 'Technical' topics included advanced POCT technologies and applications,*

*and Regulations and norms for POCT equipment. Is there a trend here?*

'The most important topic is clinical application. IT is important during the implementation of the clinical applications. Vice versa, we need the IT regulations to improve the availability of POCT for the users. The regulatory aspect is therefore very important so that the developers can assess what's possible; not everything that's being developed can be used immediately for patients.'

*Does this mean that new devices, procedures, solutions etc. should be developed in cooperation with the respective industries?*

'Yes. Any developments within the medical devices industry should occur in close cooperation, synchronously, so to speak, with the users, to verify the advantages of the technology and procedures. It is essential that the benefits and outcome for patients are taken into consideration and are clearly evident.'

*The two previous symposia (2012, 2014) were predominantly German events. This year saw greater internationalism – languages were German as well as*

*English, over three days, speakers from nine different countries held lectures, and the exhibition was also international. During the symposium, it became apparent that two speakers, Dr H. Stekel, from Linz in Austria, and Dr R. Fried, from Zurich, Switzerland, spoke about national issues when it came to regulatory requirements for POCT. Their respective contributions were entitled requirements for POCT in Switzerland, and ISO 22870 in Austrian Practice. Is there still considerable work to do in Europe on the development of unified standards, definitions and values etc.?*

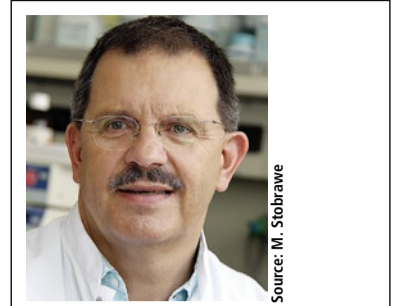
'Some European guidelines exist already. For example, the ISO 22870 is now not only used in all European countries but also worldwide. However, when it comes to the respective translation and implementation into national laws there can be inconsistencies. This is why we took a closer look at these two countries. We saw that the ring trials carried out for quality assurance, for instance, are organised on a national level, i.e. EU law is being converted into national law. In some other countries, such as France, we can see that the conversion is organised in a different way.

*Is there European or international*

*cooperation, for example working groups, commissions, or committees?*

'There are many active European and international committees in this field. It has become apparent that the Asian region needs to reposition itself, and we are working intensively on this. In the past, Asia has almost exclusively aligned itself with the FDA, based on the motto that whatever they approve automatically becomes licensed in Asia. But there has been a change here recently: both India and China, for instance, have now also developed analogue and national systems.

'International cooperation is in good shape. The ISO norms are an excellent example here as, once they have been introduced, a country cannot really opt out again. However, the



Professor Peter B. Luppá is head of the Central Laboratory and Blood Bank at the Rechts der Isar Hospital in Munich's Technical University in Germany. His main scientific interest lies in the regulation of steroid metabolism and biosensors, aiming to develop improved analytical-diagnostic procedures for autoimmune diseases. From this, POCT in the hospital developed as a further focus. He has published more than 125 contributions in international journals and is a co-editor of the first German specialist book on point-of-care testing (now in its 3<sup>rd</sup> edition).

## DON'T MISS

### MEDICA'S LABMED FORUM

● **Wednesday, 15 Nov 2017**  
**11.15 – 11.30 a.m.**

#### The lab comes to (and into) the patient

**Professor Peter B. Luppá**  
**Institut für Klinische Chemie und Pathobiochemie Klinikum rechts der Isar der TU München**

application is not compulsory, which means that national requirements can still be considered. In any case, it's beneficial that ISO norms are now used as a foundation worldwide. 'This trend is reinforced by the fact that the industry, which revolves only around a small number of manufacturers here, is not interested in national solo efforts.'

*During Medica, Professor Georg Hoffmann, from Trillium Verlag, will hold a four-day 'LabMed*

*Forum Medica'. On 15 November you will preside over the topic 'From point-of-care-testing to continuous monitoring'. Will this focus exclusively on POCT for diabetes?*

'Obviously the focus will be on diabetology, but we are not limiting ourselves and can also accommodate the interests of our participants. The event will be held for the first time and we are curious about how it will develop. Previously at Medica several working groups and symposia focused on POCT, when diagnostics still played an important part at this Düsseldorf-based event. That's why we will now observe developments and draw our conclusions.

'So, this time, we will mainly focus on continuous glucose monitoring. For other parameters that can be continuously monitored, such as lactate or other cardiac markers, the applications are still more straightforward.'



Courtesy of EKF

# Advancing lateral flow immunoassays

'Lateral flow immunoassays (LFIs) have evolved rapidly in the past 30 years, from the original crude and simple qualitative tests, to more complex multi-analyte and quantitative assays,' reports BBI Solutions, a firm that has been raising the performance of lateral flow tests with the development of technologies for next generation diagnostics.

#### Award-winning signal enhancement technology

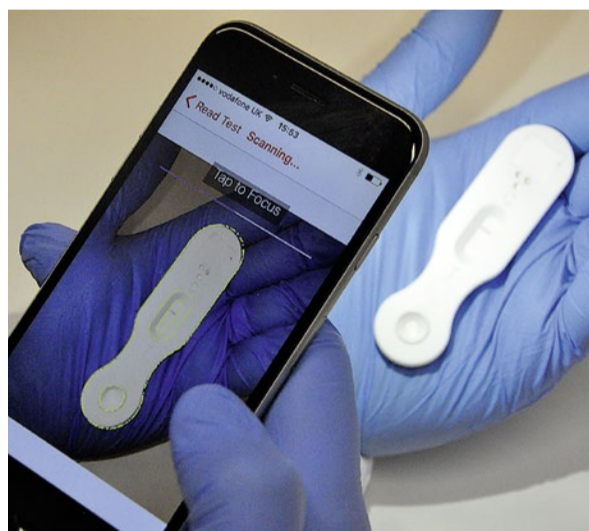
'Developments in component materials, antibody design, sample matrix handling and test fabrication have hugely expanded the potential of next generation diagnostics,' the firm points out. 'The launch of BBI

Solutions Morffi signal enhancement technology significantly boosts signal intensity and increases the limit of detection, up to ten-fold, to achieve a shorter time-to-result. This award-winning technology is helping BBI's customers to create the next generation of high performance lateral flow immunoassays.'

BBI Solutions is now poised to enhance its diagnostic capabilities for lateral flow testing with smartphone readers pioneered by Novarum DX, the report continues.

#### Revolutionising POCT

Lateral flow immunoassays are ideal for point-of-care testing (POCT), allowing a simple and visual inter-



pretation of results. However, the firm underlines, poor eyesight, inadequate lighting or human error can result in false positives or negatives and this establishes the need for a more reliable and accurate way to assess test results.

Acquired by BBI Group in 2016, Novarum set out to address this issue by harnessing the power of today's smartphone technology to revolutionise POCT and the interpretation of diagnostic results.

'Novarum works with diagnostic firms and pharmaceutical companies

to develop mobile medical apps specific to each POC test, using patented image-capture software to transform a patient's smartphone into an accurate test reader. Results can also be shared with healthcare professionals, safely and securely, enabling early diagnosis and empowering patients to manage conditions from their own home.'

#### Shaping the future of lateral flow

Combining full traceability and lab-quality results with advanced data

**Left: Image-capture software transforms a patient's smartphone into an accurate test reader**

**Lateral flow immunoassays have evolved rapidly in the past 30 years, from simple qualitative tests to more complex multi-analyte and quantitative assays**

sharing is expanding the potential of POC testing, and offers a future of improved, customercentred healthcare, supported by the smartphones we carry in our pockets. Developing this technology is the next step in BBI's commitment to helping customers to embrace the evolution of lateral flow immunoassays, and deliver solutions that enhance POC diagnostic testing.

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'We must act now – or we may run out of options'

# Antibiotics don't generate large profits

During our European Hospital interview with specialist in microbiology, virology and infection epidemiology Beniam Ghebremedhin MD, from the University Hospital Wuppertal, spoke about the impact of migration on infections, and ways to tackle the problem of multiresistant pathogens

'There is a lack of specialists in infectious diseases, for direct patient care on hospital wards as well as in the field of infectiology and diagnostics,' infections specialist Dr Beniam Ghebremedhin agreed. 'We are also short of specialists in infection prevention and control, along with microbiologists and virologists. In these times of multiresistant bacteria and large-scale microbial infections we should be promoting and supporting a new generation of specialists to strengthen research and diagnostics.'

This June, the EU published guidelines on dealing with antibiotics to help contain the spread of resistance. Could this help?

'The topic is of great importance as there are still many areas where anti-infectives are prescribed too quickly and not in a targeted manner. Due to time constraints in outpatient care for instance, antibiotics



Worldwide migration of viruses and bacteria is on the rise partly because taking holidays abroad and working on different continents has become the norm

are often prescribed so that patients can be treated as quickly as possible. However, Amoxicillin or Cefuroxim are the wrong drugs to treat viral infections. There should be much more emphasis on treating patients with more precision, and on adapting treatment to their individual risk factors.

'Apart from the EU guidelines, there are already other recommendations on how adequate treatment should commence, such as the "Tarragona Strategy". This is the basic concept for adequate, initial treatment of bacterial infections with antibiotics. It includes the recommendation that the patient should receive a systematic examination if there is a lack of relevant information, such as where the patient is

from and their local epidemiology (frequency of infections and resistance), because appropriate treatment cannot be given when these factors are not known. The focus should be on the dose, length of treatment and monitoring, along with the severity of the disease, all of which also requires as much information as possible about the patient. It is critical for the prognosis that adequate treatment commences without delay and with a high dose.'

At Medica 2017 you will focus on 'Emerging pathogens and multiresistance in the age of migration'. Why?

'Viruses and bacteria know no borders. Worldwide migration is very much on the increase, not only as waves of refugees but also because

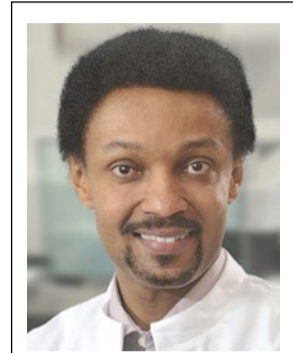
of open borders and changes in travel habits. Holidays abroad and working on different continents have become the norm. However, this also means that locally occurring infections no longer remain local.

A pathogen such as an influenza virus can quickly spread globally. Bacteria are carried from one country to another in suitcases. If we want to treat patients correctly we therefore need to know where they are from, which pathogens they could have brought with them, or which multiresistant pathogens they may have been exposed to. 'This is of particular importance in the case of multiresistant pathogens. In my lecture, I will talk about gram-negative bacteria such as Escherichia coli, Klebsiella pneumoniae or Acinetobacter baumannii, all of which have taken on greater significance. The latter in particular has made the headlines, in Kiel for instance and in Stuttgart at the beginning of this year.'

What can be done against multiresistant pathogens?

'This is a very important and also difficult question. Germany must definitely improve its procedures for infection prevention and detection. Infected patients need to be isolated earlier. In the Netherlands, the isolation of risk patients on admission is standard practice, in Germany; however, the capacities for isolation procedures are often insufficient. This is a strong point of criticism, as things are getting serious: the last weapons we can utilise in the fight against multiresistant pathogens are becoming ever blunter.

New anti-infectives are rarely approved and only have specific effects. Around thirty new substances are currently being examined in studies, but only four or five of those are likely to make it to the market. However, rather than multi-purpose weapons, these will be substances working against very specific pathogens only. Furthermore, resistance is developing much more quickly now.



Beniam Ghebremedhin MD is a Specialist in Microbiology, Virology and Infection Epidemiology at the University Hospital Wuppertal, Germany. He is also a member of the German Committee on Antimicrobial Susceptibility Testing (NAK), which is a national subdivision of the European Committee on Antimicrobial Susceptibility Testing (EUCAST).

Where some substances used to be effective for up to ten years, this is now wishful thinking.'

Is the pharmaceutical industry active in this area?

'Not as much as we'd like it to be; unlike cancer drugs, antibiotics don't generate large profits. Investment in studies is expensive, and treatment with antibiotics is not always comprehensive enough to regain the money invested.'

Another major problem: violation of hospital guidelines on infection prevention and control.

'Correct – and hand hygiene is critical here. This could help avoid a third of all transmissions of pathogens. Many places now have specially trained nurses who work in this field. Unfortunately, they have to fight obstinate colleagues on a daily basis. However, hygiene knows no hierarchy and a bacterium is not interested in chains of command. We must act now – otherwise we may well run out of options in the fight against multiresistance.'

## DON'T MISS

### MEDICA'S LABMED FORUM

● Thursday, 16 Nov 2017  
02.50 p.m. – 03.15 p.m.

Detection tools for carbapenemase-producing gram-negative bacteria  
Dr Beniam Ghebremedhin  
Universität Witten/Herdecke,  
HELIOS Universitätsklinikum  
Wuppertal



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Refined capillary blood collection

## Small tubes, great impact



The capillary blood collection system not only benefits geriatric patients, or those who need regular blood sampling, but also burns victims and others, including the youngest patients. All need a gentle approach. To that end, Austrian firm Greiner Bio-One

has developed and optimised its MiniCollect system.

### No more tubes and funnels

The cumbersome process of transferring the drop of blood using capillary

tubes or funnels is in the past, thanks to this system because the blood collection scoop is integrated into the wide tube opening. 'The sample comes into contact with the additive immediately,' the manufacturer reports. 'The caps are completely sealed, meet the highest standards and can easily be sent via pneumatic dispatch or other transport systems without losing any sample material.'

### Carrier tubes and combined filling volumes

The MiniCollect capillary blood collection system



**Greiner Bio-one is at Medica**  
Hall 03 / Stand F72

Innovative software, faster hardware and artificial intelligence in ultrasound

# Abundant ultrasound tech potential

Automation continues to conquer healthcare, including diagnostic imaging. Christian Kollmann, Assistant Professor at the Centre for Medical Physics and Biomedical Technology, Medical University Vienna, Austria, highlights innovative software, fast hardware and artificial intelligence in ultrasound – today and in the future

**Automated analyses** are already supporting the diagnostic work-up. In Doppler ultrasound, for example, flow speeds are automatically detected and in b-mode grey-scale optimisation attenuation effects in deeper tissues areas are automatically adjusted by specific algorithms: one mouse click provides an overall homogeneous and smooth image.

### Automatic compensation

Theoretically, constant velocity of ultrasound wave propagation is assumed; however, in reality velocity varies depending on the type of tissue, resulting in distortions and impaired resolution as can be seen inter alia in fatty tissue or large liquid-filled areas. Automatic adjustment of propagation above or below the theoretical value provides a solution to this problem. 'This feature, which is offered by some manufacturers, is very much like autofocus in a digital camera,' Kollmann explains. But beware: Despite the innovations, radiological experience is vital to be able to differentiate between software-induced artefacts and clinical findings.

### AI is still in the early stages

Quantification and classification of tissue types, for example to recognise and characterise tumours, Kollmann says, is one of the areas where artificial intelligence is showing potential.

'At this point, however, we are still in the research phase.'

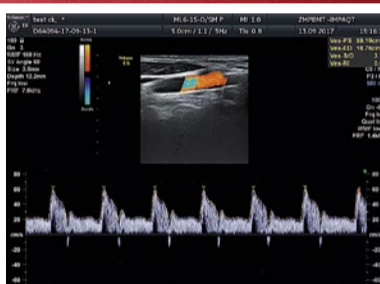
Quantification and segmentation of organs face one major challenge: the visualisation of multi-layer areas with many different types of tissue.



Wireless transducer (LA) being used in a training session on the recognition of artefacts (phantom). The real-time ultrasound images (b-mode) are transmitted via WiFi to a tablet (iPad/Android)

This complexity generates backscatter information leading to a wide variety of tissue parameters that need to be evaluated. Case in point: the abdomen. To be able to delineate and classify an organ unambiguously, the correct position data, dimensions and planes need to be determined. Moreover, echo amplitudes play a major role at tissue margins,' Kollmann explains.

Superfast 3-D visualisation has three requirements: high-resolution, multiplex matrix transducers, fast data processing (state-of-the-art chip technology) and precise segmentation algorithms. 'To be able to account for changes due to breath-



Example of automatic detection and evaluation of the flow curve with spectral Doppler

ing, several hundred if not thousands of frames per second are required in a plane,' Kollmann estimates. 'This opens entirely new diagnostic perspectives, also for Doppler.'

### Diagnostically valuable

Vector Velocity Imaging, an innovative diagnostic procedure, allows spatial and temporal 3-D visualisation of flow velocity. Complex blood

flow patterns can thus be measured and diagnosed independent of transducer orientation.

A vector arrow indicates the direction of individual erythrocytes in the blood in a vessel. Due to the very high frame rates movement patterns, such as turbulences, can be recognised within milliseconds. The diagnostic relevance of this capability is obvious: critical changes can be detected in early stages. Kollmann is positive that 'this technology will revolutionise ultrasound diagnostics and quantification in angiology and cardiology over the next five to ten years.'

### Multi-parameters for classification purposes

To classify different tissue types and tumours even more precisely, additional quantification parameters are needed. One of the earliest attempts to do so was spectral-based parametrisation, invented several years ago to evaluate fatty liver. Today, elastography is the technology of choice for quantification. In shear wave imaging shear wave velocity is measured providing an additional parameter for the tissue type.

Backscatter coefficient is another parameter, if it is available, adjusted for the propagation loss of the sound wave. Further parameters are being evaluated.

These multi-parameters are based on artificial intelligence algorithms and will allow the classification of tissue types. 'This is the way forward,' Kollmann believes. Combined, so-called hybrid procedures are also increasingly valuable: photoacoustics, for example, uses additional tissue parameters and today MRI-guided ultrasound is used for more than just uterine myoma interventions.

### US on mobile devices

New products link the wireless trans-



Christian Kollmann is Assistant Professor at the Centre for Medical Physics and Biomedical Technology at the Medical University Vienna, Austria. Having gained his doctorate in Technical Physics at Vienna's Technical University, between 1990 and 2017 Kollmann – whose focus is ultrasound in medicine – published more than 140 articles in professional journals and gave more than 200 presentations on ultrasound and biomedical techniques.

ducer to a tablet or smartphone via WiFi. These devices have enormous potential to teach and train physicians and sonographers, says Kollmann.

The app is downloaded to an iPhone or Android tablet and training, using a miniature transducer, can begin. But this is not a toy, Kollmann underlines:

'Actual patients should only to be used after instruction and in a controlled manner!' After all, ultrasound exams do add energy to the organism, a fact that has to be taken into consideration even if this energy is harmless.

Point-of-care use of mobile devices is conceivable in, for example, an ambulance, car or helicopter. Transmission speed, according to Kollmann, is no major issue for tablets and smartphones even if, as announced, colour and Doppler devices with higher frame rates will be available.

'This is entirely feasible using WiFi, as long as the signals are compressed,' he points out. 'The quality will no doubt be sufficient to visualise flow at the POC.'

'For centrifugation, the MiniCollect tubes can be inserted into a premium carrier tube using a simple rotational movement. When combined, the dimensions correspond to a standard 13 x 75 mm tube format and can easily be placed in a standard rack or standard centrifuge.'

Two easily visible filling marks on the tube provide greater flexibility for use. The new MiniCollect capillary blood collection system is on show here at Medica.

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Ultrasound device can now be smartphone size

# Emergency ultrasound training

Training is at the heart of the biggest annual fair in the world, thanks to the newly introduced Medica Academy sessions, i.e. full-day seminars that deal with practical questions, current techniques and advances in medicine. One of the hot topics tackled by the new format will be emergency ultrasound, with renowned experts such as Dr Wolfgang Heinz from Stuttgart giving hands-on training to use this modality.

Report: Méliande Rouger

In 2010 the German Society for Medical Ultrasound (DEGUM) introduced a curriculum on emergency ultrasound, a basic course for physicians and medical staff with little to none experience in the modality. Seven years later, the program has become a reference in Germany, and about 60 courses are delivered annually all across the country – this year including Medica. Dr Wolfgang Heinz is head of internal medicine at Clinic I, Karl-Olga

Hospital GmbH in Stuttgart, and is among the DEGUM course instructors. He chairs the seminar on Tuesday and invites every professional who has to deal with emergency patients to sign up, as ultrasound is central to emergency pathology diagnosis. 'Ultrasound is particularly useful in detecting and differentiating conditions that could easily be missed were it not performed. It is a great tool for emergency physicians. For example in patients who are short of breath, one can differentiate within seconds whether pleural effusions, pulmonary oedema or pneumothorax is the cause. In the pre-hospital setting, ultrasound also helps to bring patients with free intra-abdominal fluid after trauma to the appropriate hospital,' Heinz pointed out.

The course offers both theoretical and practical knowledge, and participants can immediately put in practice what they have learned, and to ask speakers questions.

'Participants train by performing examinations on each other and carrying out ultrasound-guided puncture using models. We teach them how to position the probe and share tips and useful content,' Heinz said.

The course adopts a practical approach and gives insight into protocols such as FAST, eFAST and FEEL, but also focus on various regions of the body – abdomen, thorax, etc.

Emergency ultrasound is a very specific field, therefore Heinz recom-



Dr Wolfgang Heinz giving hands-on training with ultrasound equipment



Prehospital ultrasound in rescue helicopter after trauma to rule out pneumothorax

mends physicians who are used to perform ultrasound examination in their daily practice to attend additional emergency training.

Ultrasound will often be key to support or question initial diagnosis, and the general rule is to see as much as possible. 'It's become our motto as emergency physicians: the more you see, the more you know,' Heinz said. You will definitely see more if you use ultrasound. It can give you core information and help you to use the right therapeutic approach because the diagnosis may be more accurate.'

According to Heinz, ultrasound is as mandatory as a laboratory test in an emergency patient – and it is the most available imaging modality across all specialties. 'You just need ultrasound when you meet the patient, and use it as an additional tool to broaden your diagnostic probability.'

Technology has prompted the widespread use of ultrasound in the emergency setting. Recent developments have squeezed the size of the equipment to smartphone dimensions – and often found ways to



Wolfgang Heinz MD is head of internal medicine at Karl-Olga-Krankenhaus GmbH in Stuttgart, Germany, where he worked since 2014. Beyond internal medicine, his interests include gastroenterology, diabetology, palliative care, infectious diseases, intensive care and emergency medicine and flight surgery. He is a DEGUM instructor for the Internal Medicine and Emergency Ultrasound level III course and a representative of the society's working group on emergency ultrasound.

insert it directly into a phone.

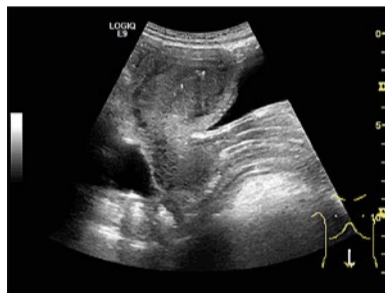
'Ultrasound devices are so mobile and small that you can bring them anywhere – on a helicopter, submarine, cruise ship, at home, on Mount Kilimanjaro... wherever you want and for any situation. The patient does not have to come to be scanned with a big machine, but we can bring the equipment to the patient,' he said.

Notably, the German Air Rescue (DRF Luftrettung in German) has equipped its helicopter fleet with ultrasound devices. Also, for the past three years, its teams of doctors and paramedics have received training through the DEGUM curriculum.

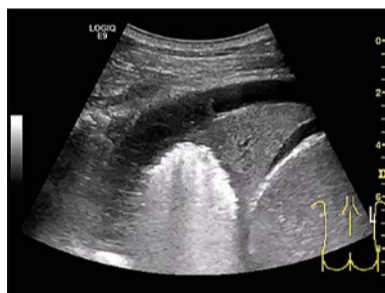
For Heinz, it's both challenging and motivating to teach such a wide variety of audiences. 'It makes a big difference to teach experienced doctors or paramedics. The latter usually don't have deeper knowledge of human anatomy, so I have to explain things a bit differently.'

The DEGUM syllabus is a two-day training designed for everyone using emergency ultrasound – these may be orthopaedic and trauma surgeons, anaesthesiologists who work within the ICU, internal doctors who work inside the emergency room, people who are underway as emergency physicians or part of a rescue team, paediatric doctors, and those in private practice.

At Medica, participants only receive the first of the two-day training, but may take the second day, which is entirely dedicated to echocardiography, on any other occasion, regardless of where or when.



Fluid in the Douglas space after trauma



Lung contusion after trauma

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Typical emergency situation in Germany

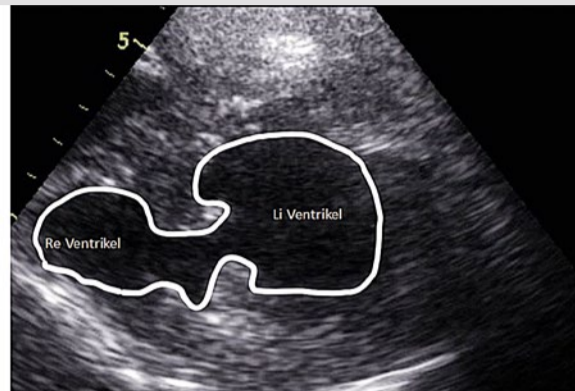
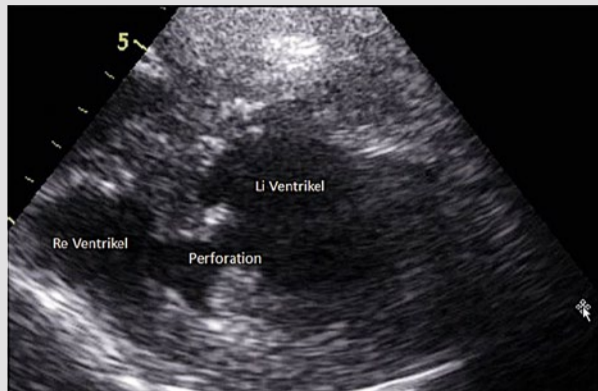


Doctors should be taught ultrasound basics when training

# Ultrasound can save lives

The hybrid operating theatre is among the most innovative developments in the surgical sector, Melanie Günther reports. 'The combination of interventional and minimally invasive surgical procedures is exciting for many clinical disciplines. The room design, intraoperative imaging techniques, as well as interdisciplinary collaboration, play a pivotal role in this.'

'Ultrasound plays a key role in diagnosis and monitoring of treatment in the A&E department,' emphasises Professor Joseph Osterwalder, Medical Director of the Cantonal Hospital in Appenzell, Switzerland. 'I cannot imagine emergency medicine without ultrasound.' At the time when the DEGUM, ÖGUM and SGUM outlined the importance of ultrasound in emergency medicine in their jointly developed guidelines this caused some raised eyebrows. 'But, we were pioneers in Europe,' emphasises Osterwalder. 'All the other countries are now following suit. In emergency situations, ultrasound can save lives.' Although we can ask patients ques-



tions, carry out manual examinations, take X-rays and do full blood counts, the human body is a black box. 'All these resources are comparatively imprecise. Ultrasound is a very valuable addition, as it provides certainty,' Osterwalder adds. Pneumonia for instance, or an intestinal obstruction, can be detected much earlier with an ultrasound scan than with an X-ray. For a patient with severe breathing difficulties, ultrasound can even be carried out during intubation and can help diagnose a potential central pulmonary embolism.

In patients with severe trauma ultrasound can localise the cause of internal bleeding. Even a pericardial tamponade, i.e. bleeding into the pericardium, can quickly be diagnosed. 'Before ultrasound it was only possible to assume such diagnosis,' the professor points out. 'With ultrasound however we can say within 30 seconds whether a patient has a pericardial tamponade, a pneumothorax, blood in the abdomen or the lungs.'

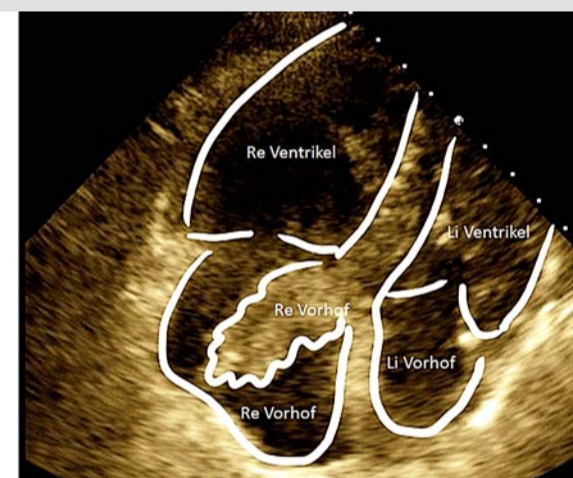
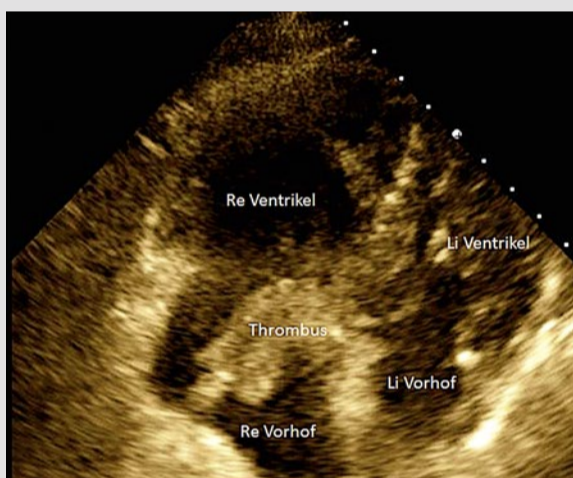
An ultrasound examination in A&E is different from a conventional ultrasound examination. First, it is a focused ultrasound, aimed exclusively at establishing the diagnosis relevant to the emergency situation. 'For instance, only the appendix is scanned in A&E when appendicitis is

**Patient with severe shock and unclear cause: Within 10 minutes, POCT-ultrasound confirms septal perforation (apical short-axis view), possibly days after unrecognised myocardial infarction. Fast transfer to the department of cardiac surgery – and the patient survives**

suspected. A potential small tumour in the adrenal glands is therefore unlikely to be detected,' Osterwalder explains. In A&E, the scan is also a POCT-ultrasound, i.e. carried out by the local examin-

ing doctor. Last, it is an interdisciplinary examination; with a trauma patient, several different medical disciplines will need to become involved: Is there fluid in the abdomen; fluid around the heart; fluid

**Female patient with severe dyspnoea and circulation problems; angio-CT was not possible under these circumstances. POCT-ultrasound (four chamber view) within the first few minutes shows an enlarged right ventricle and thrombus in the right atrium due to central pulmonary embolism. Fast transfer to intensive care ensures the patient's survival**



around the lungs? Is there air in the pleural space (pneumothorax)?

According to Osterwalder, the future lies in personalised ultrasound. This means a doctor carries his/her own ultrasound scanner in their coat pocket. 'Ultrasound will take over from the stethoscope,' he is convinced – not only in A&E but also in general practitioner (GP) surgeries and during hospital ward rounds.

Ultrasound transducers of manageable size are now available that can be connected wirelessly to a smartphone or an iPad via an app. 'There are products on the market already which only cost 2,000 Swiss Francs. Although the image quality they produce is not outstanding it is fairly good, and sufficient for triage,' he points out. For a patient with back or flank pain, it is easy to establish whether the aorta is enlarged or ruptured, or whether the renal pelvis is distended because of a kidney stone.

'In my view, all doctors should be taught the basics of ultrasound during their medical training,' Osterwalder believes. Germany, Austria and Switzerland still have a long way to go, but not the USA, where many medical faculties already teach anatomy with the help of handheld ultrasound transducers. 'We also have universities here in Switzerland, where students have already taken the initiative to introduce this,' Osterwalder explains, 'but the curricula do not yet attach enough importance to ultrasound anatomy.'



In April 2017, Swiss accident and emergency specialist **Professor Joseph Osterwalder MD FESEM MPH** became Medical Director of the Cantonal Hospital in Appenzell, Switzerland, following his leadership, since 1988, of the A&E Department at the Cantonal Hospital St. Gallen. He completed his habilitation in Geneva, and is now an emeritus professor of the University of Geneva. A member of numerous national and international associations, he has more than 250 publications to his name and runs DEGUM Level III training courses.

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### MEDICA ACADEMY

● Tuesday, 14 Nov 2017  
09.00 a.m. – 05.45 p.m.

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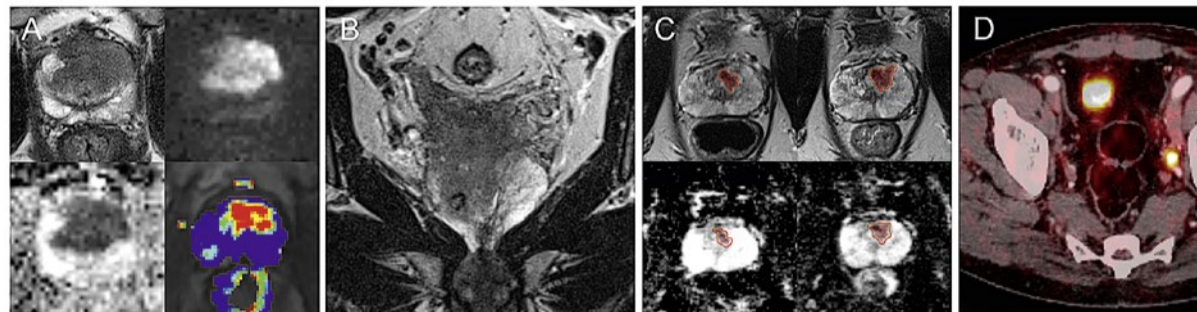
# MRI's role in prostate cancer diagnosis

Lars Schimmöller MD, associate professor of radiology at Düsseldorf University Hospital, will tackle current diagnosis of prostate cancer (PCa) and address tumour detection, staging, active surveillance and recurrence during the Medica Academy session on Imaging Update. He will also highlight how MRI helps improve biopsies and avoid unnecessary surgery in PCa.

Interview: Mélanie Rouger

Asked about the latest advances in PCa diagnosis, Professor Lars Schimmöller spoke of 'a remarkable change' – the increasing role of magnetic resonance imaging (MRI) in routine clinical diagnosis. 'In its updated guidelines, which will be published later this year, the German Society of Radiology notably insists on the importance of multiparametric MRI (mp-MRI) and MRI-guided biopsy for PCa diagnosis.'

'The new recommended technical approach is that mp-MRI can not only be used but also should be used in secondary PCa detection after negative transrectal ultrasound (TRUS)-guided biopsy and before inclusion of patients for active surveillance, similar to international guidelines. Moreover, the German preliminary recommendations for 2017 state that mp-MRI can be used for primary PCa detection as long as quality standards are fulfilled. Based on these requirements, urologists can and should perform targeted biopsies of MRI suspicious lesions, by using either the cognitive approach (fusion of MRI and US in mind) with TRUS or software-based MRI-US



A: Detection: Multiparametric MRI with T2-weighted image, ADC-map, high b-value image, and perfusion-map showing a large anterior prostate cancer in a patient with negative systematic biopsy

B: Staging: Extensive seminal vesicle invasion and lymph node metastases on a coronal T2-weighted turbo spin echo (TSE) MR-image

C: Active Surveillance: Tumour increase in size and aggressiveness (ADC-value decrease) in follow-up MRI in a patient with bioptic verified low-grad prostate cancer

D: Recurrence: PSMA-PET/CT with parailiac lymph node metastasis on the left side

fusion-guided biopsy approach.

'Five to ten years ago, the standard was to just measure prostate-specific antigen (PSA) value, carry out digital rectal examination, and then an ultrasound and US-guided systematic biopsy. The problem with systematic biopsy is that especially the anterior and apical parts of the prostate are not covered, and cancers missed or only partially captured with up to 50% false positive lower grade histology, so that you never know if higher-grade proportions of the tumour exist.'

'One of the big challenges in PCa is its biology. When you have multifocal tumour cells, which are quite common, it's hard to get the real imaging of where the index lesion is located. Performing an MRI-guided biopsy and an mp-MRI examination before biopsy to help prepare it enables it to hit a tumour with more precision. If you have quality mp-MRI, you can say with over 95% accuracy if there is clinical relevant cancer or not.'

'Also, if you carry out an MRI

examination before you do a biopsy, you may discover the reason for high PSA value. Sometimes it may just be prostate enlargement or an infection. So carrying out an MRI scan may also avoid performing unnecessary biopsies.'

'Another significant advance in PCa diagnostics has been the use of prostate specific membrane antigen (PSMA) as a relatively new tracer to check PCa recurrence.'

## Which diagnostic and imaging modalities do you use in PCa?

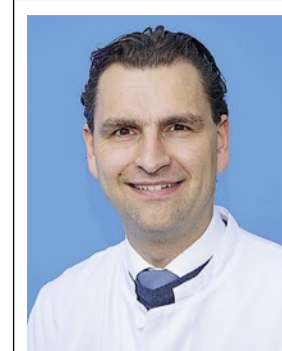
'The PSA determination is the basic diagnostic tool for PCa check-up, but PSA is specific to the prostate gland and not prostate cancer. An elevation of PSA does not have to be associated with PCa, but when you use it wisely, it is an easy and excellent test for a preselection.'

'The role of PSA screening has been extensively discussed, especially in over diagnosis and over treatment,

but trial results from large European studies have shown the relevance of this test. We are currently trying to figure out when it makes sense and in whom – in patients aged 40, 45, 50 or 55 years?'

'Ultrasound is the standard urologic imaging modality, but US has limitations in PCa detection. It is not so good for sensitivity or specificity, even combined with contrast agents. Currently none of these additional US-tools are recommended for primary PCa detection. US is primarily used to guide biopsy.'

'Computed tomography (CT) only makes sense in combination with PSMA-PET, e.g. for PCa recurrence, or it may be chosen for pre-operative staging. CT is easily available and gives you an idea of metastases of bone lesion or lymph node metastasis in patients with extensive disease. But lymph nodes imaging is challenging, because they are often very small. CT is mostly not good at differentiating whether they are tumours or not in



Lars Schimmöller MD is associate professor of radiology and head of the urology working group at Düsseldorf University Hospital, Germany. His research fields include multiparametric magnetic resonance imaging (MRI) of the prostate, image-guided prostate biopsy, hybrid imaging (e.g. PSMA-PET), urogenital radiology and cancer imaging.

the prostate setting.

'Mp-MRI is currently the best imaging tool for prostate cancer detection, especially clinical relevant PCa. Qualitative mp-MRI is extremely promising for active surveillance and furthermore it is good for local staging. It can also help in unclear cases or PCa recurrence.'

'PSMA-PET is the most promising imaging tool for PCa-recurrence and may be used for detection in unclear cases with high PCa suspicion. Combination of PSMA-PET with MRI might be very nice, but PET/MRI is rarely available and its clinical benefit remains to be demonstrated.'

## Screening programs in Germany

'The updated recommendation is that men of at least 45 years of age and a life expectancy of more than 10 years should be informed on the possible benefits and drawbacks of early-detection measures of prostate cancer like PSA determination.'

'We are performing a huge national prospective multicentre randomised trial on early PSA screening in young men. Currently we have over 30,000 patients enrolled. The study is called PROBASE and we try to assess if it makes sense to measure baseline PSA for risk-adapting PSA screening. Screening must help lower mortality. It only makes sense if you help people not to die or die later from that cancer.'

'PCa is most often a slow growing tumour, so that's why screening studies results need so long to show their value. You need at least 10 to 15 years approximately to show if a patient benefits from screening.'

## What are PCa imaging risks?

'Nationwide coverage of qualitative mp-MRI examinations and qualitative standardised reporting are two of the most important challenges in PCa imaging. Furthermore, the subsequent correct targeted biopsy is also a challenge for urologists and radiologists.'

'A further issue is that the biology of prostate tumours is often multifocal and/or heterogeneous in histology, and sometimes hard to differentiate from inflammation or atypical stromal hyperplasia. It is also complex to determine the possible metastatic clone with current technology. It's crucial to differentiate tumours that are life limiting from those who are not.'

'Mortality in PCa is often due to late cancer detection or inaccurate diagnosis. But most tumours are not life limiting or can be treated.'

'Radiation risk, as a general limitation or challenge in radiology, is not a problem, because these patients are usually not young and MRI, as the best imaging tool, does not use radiation.'

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The future of elastography rides on the shear wave

# Physicians gain a training centre

A practicing radiologist specialising in ultrasound, Pavlos Zoumpoulis MD PhD is also President and CEO of Diagnostic Echotomography, a day clinic based in Kifissia, Greece. The past President of the Hellenic Society of Ultrasound in Medicine and Biology spoke with our European Hospital team about his experiences with the next-generation in shear wave elastography on Mindray's Resona 7 platform.

**EH:** You are a leading advocate for elastography in ultrasound, calling it a revolution. What does that mean for you?

Pavlos Zoumpoulis: 'As a radiologist, I'm familiar with all the imaging modalities but, early on, I focused on ultrasound, believing it had an exciting future. It seems like every five years there are new, revolutionary applications and innovations. The newest chapter in this long history of innovation is shear wave elastography, though elastography already has a long history of its own.'

'The first technique was strain elastography using compression, which was useful for superficial organs such as the thyroid and the breast. Shear wave elastography brought a true innovation: a new technology that enabled us to apply this examination for tissue stiffness to more deeply situated organs, such as the liver, kidney,

**SWE Images produced in the Resona 7 showing various fibrosis stages of the liver (F0, F2, F3, F4)**

prostate, uterus, ovaries or pancreas. 'It also allows us to go beyond assessing tumours to evaluating diffused disease conditions. The most important application here is diagnosing liver fibrosis, the result of chronic liver disease. Shear wave elastography becomes an essential tool to study these conditions and, significantly, it can replace the need for other invasive examinations, such as needle biopsies.'

**In your practice, compression or strain elastography is now part of history?**

'Using the strain technique of elastography we could not reliably get quantifiable results. Shear wave technology brings us this capability. Now we can calculate tissue stiffness by measuring it in units of kilopascal (kPa). We've always known that cancerous tissue will be stiffer than the normal tissue in an organ. Now, by scanning with Shear wave elastography, we can discriminate normal tissue from cancerous tissue and reliably report the result in measures of kilopascal. The quantification in kilopascal helps us to determine accurately the level of tissue stiffness associated with diffused liver fibrosis.'

'I insist on the importance of reliability because, in the past, there have been problems with inter- and intra-observer variability of measurements using elastography. And this has been true for all the manufacturers, whether with a shear wave or a strain elastography capability. In our clinic we have been working with the Resona 7 for several months and it has proven to be highly reliable.'

**Can the elastography chapter be closed, or do you still see an exciting future here?**

'We are only at the beginning. With elastography we have already learned so much about disease in relation to tissue stiffness and we are going to discover even more, about the tissue characteristics, and content in fibrotic tissue or fat. 'Returning again to the liver, shear wave elastography has been widely adopted to assess diffused diseases, though there's work to do in stand-

ardising measures. Different scales of measurements have been developed to determine the level of stiffness according to the cause of the disease, whether Hepatitis B, Hepatitis C or Cirrhosis due to alcoholism.

'We have seen rapid advances for ultrasound in musculoskeletal exams. Muscles and tendons are superficial, so they are easily visualised with ultrasound. Therefore, we can now apply shear wave elastography because, unlike strain elastography, it does not rely on compressing tissues, which results in more reliable measures of the stiffness. This becomes very important in evaluating the disease condition, or even to assess whether any tumours we identify are malignant or benign.'

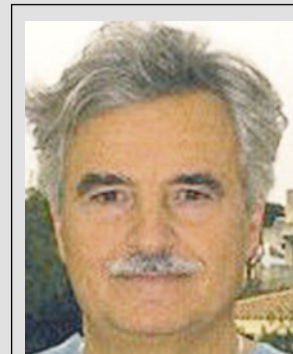
**What about paediatric diseases?**

'Unfortunately, there are chronic liver diseases that affect children. Yet, because children are smaller, fortunately it becomes easier to apply the benefits of shear wave elastography in examinations. Today we can reliably and non-invasively measure stiffness using ultrasound, rather than sending them for a liver biopsy procedure.

'We can also rely on these measures to grade the condition of the disease. The examination becomes even easier with the new technology, for the doctor, and especially for the patient who avoids both pain and complications because it's only an ultrasound exam.'

**You recently opened a training base at EchoMed Centre, in cooperation with Mindray. What has been your experience with this?**

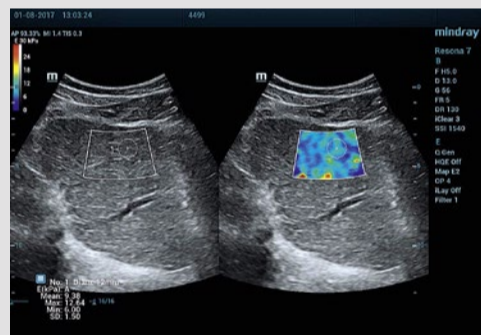
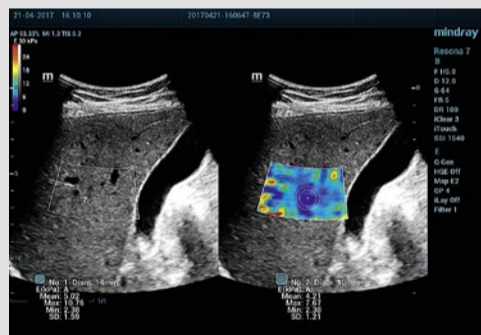
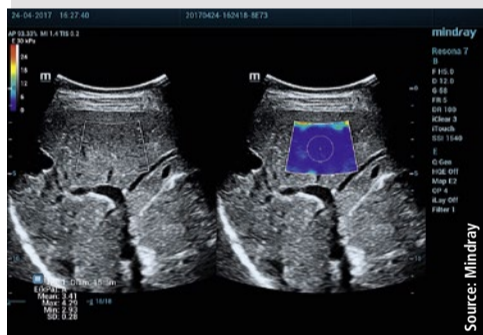
'Not every elastography application manufacturer has a commitment to training physicians. Mindray is one that



**Pavlos Zoumpoulis MD PhD** is practicing radiologist specialising in ultrasound as well as President and CEO of Diagnostic Echotomography, a day clinic based in Kifissia, Greece. As President of the Hellenic Society for Ultrasound in Medicine and Biology (HSUMB) he organized for the first time ever 2015 in Greece the EUROSON, the European Congress for Ultrasound.

does believe education goes hand-in-hand with its technology and that physicians need to understand how to apply the technologies as an essential step. For those with the skills and knowledge, the Resona 7 makes shear wave elastography easier to apply, but this is not to say that shear wave elastography is so simple anyone can do it.

'The program we offer is intensive, 18 hours of training covering theory and practice across all organs. It is also highly interactive. The participants come from all over the world – not only Europe, but Asia and North America as well. So far, I can tell you that much; it's international, intensive and very interactive.'



## DON'T MISS

### MEDICA ACADEMY

Monday, 13 Nov 2017  
09.45 a.m. – 10.30 a.m.

**Modern diagnostics of prostate carcinoma**  
Dr Lars Schimmöller,  
Universitätsklinikum Düsseldorf

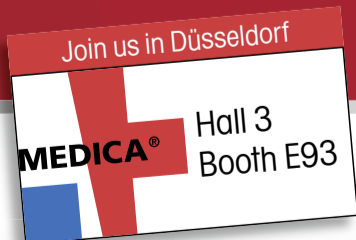
### Who should attend your talk at Medica?

'PCa is the most common cancer in men so most people will already have had contact with the disease. My talk is directed at those who are interested in PCa diagnostics update – medical doctors, technical assistants and product specialists. I will start with basics and then go more and more into detail.

'It will definitely be practical. I will share a lot of images from clinical cases. I will give a short introduction on PCa clinical background, epidemiology, PSA-screening, urologic diagnostics, and then go on to the radiology part, and share examples of where and how imaging can improve PCa diagnosis. 'I think it's a very interesting topic for Medica delegates, whether radiologists, other doctors, or professionals involved in medical technologies and products.'

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'It's popping up everywhere. Is this a good thing?'

# Bring your own ultrasound

Pocket ultrasound accelerates diagnosis at the point-of-care reducing the role of the radiologist, John Brosky observes



You can buy a pocket ultrasound probe online, download an app to your smart phone and start making your own diagnoses of joints and organs.

'It's popping up everywhere. But is this a good thing?' asked Michael Bachmann Nielsen, a radiologist at

the Rigshospitalet in Copenhagen, during a session dedicated to handheld ultrasound at the European Congress of Radiology (ECR).

Helmut Prosch, a radiologist with Medical University of Vienna, added that pocket probes are 'used by many, but understood by few. As radiolo-

gists we don't see the usefulness of these devices, yet we are surrounded by colleagues using them.'

The chairman of the special ECR session, Michel Claudon, from the University Hospital in Nancy, France, suggested: 'Our goal is not to stop people from buying, but to train them in how to use their device.'

## Quick answers to specific questions

Point of care ultrasound (POC) exams can quickly answer a specific clinical question, to send patients along care pathways rapidly. Examples of already established exams include focused assessment with sonography in trauma (FAST), bedside lung ultrasound in emergency (BLUE), and the focused echocardiography in emergency life support (FEEL).

The handheld portable ultrasound device segment is expected to be the fastest-growing niche in the overall ultrasound market, increasing at a 13.1% compound annual growth rate through 2022.

Enabling the trend toward pocket ultrasound is the wide acceptance in healthcare for bring-your-own-device (BYOD).

## Changes in device design

According to a study by IT network provider Cisco Systems Inc, based in San Jose, California, by 2013 some 88% of healthcare workers used their smart phones or tablets at work, with the tacit agreement of their institution.

This has led to a key shift among device design to throw out dedicated ultrasound viewers and enable scans to be viewed on personal BYO devices, which most often have a higher resolution of the image.

Bachmann Nielsen provided an overview of the leading devices used in the western world, noting he did not include the surge in such devices coming out of Asia.

## Device overview

The Vscan from GE Healthcare is one of the original devices in the segment, and the company holds the leading market share. The 14-ounce Vscan Extend is the latest version, introduced in 2016 with a five-inch touch screen for the dedicated viewer a permanently attached probe. The Vscan Extend offers, in a single handle, dual transducers, a phased or linear array enabling either shallow views of tissue or a deeper look into organs.

In 2014, Philips Healthcare introduced the Lumify smart-device ultrasound that is compatible with any handheld computer or phone running the Android operating system. The commercial USA launch came in 2015.

The BYOD approach offered by Philips includes a subscription model for \$199 per month for qualified healthcare professionals to scale their ultrasound solution to meet their needs without having to purchase imaging equipment. Pre-set exams in the app and three different probes enable use in acute and emergency care, internal medicine, or musculoskeletal exams for orthopaedics, sports medicine and podiatry, as well as rou-

tine medical office practice.

Clarius Mobile Health is riding the BYOD wave offering the first mobile ultrasound scanner with an application for both iOS and Android devices. At ECR the company was launching its commercialisation in the European Union of the handheld, wireless Clarius C3 and the Clarius L7 multipurpose ultrasound transducers that talk to the everyday technology onboard personal, off-the-shelf smart devices. 'We take advantage of the latest screen technology available on mobile devices, which has an appeal for radiologists with the high quality resolution and display,' said Neena Rahemtulla, the vice president for marketing.

Fujifilm SonoSite offers the iViz, a seven-inch tablet with two cabled transducers that stands out for its one-hand navigation of the touch screen and a superior 1900 by 1200 pixel image user interface, though it is hefty at 20 ounces.

Mobisante offers the Mobus SP1 System viewer that weighs less than 12 ounces as a dedicated system of transducer, cable and viewer, but also introduced the Mobus PE, that can run on any Windows-based device.



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Capturing precise colour and image detail in surgery

# The new MKC medical camera platform

A new MKC 4K Camera platform is on show at Medica this year. 'This includes a newly designed CCU to drive a 4K native 1-CMOS head, and additionally several different 4K and HD heads, such as the 3-CMOS 4K, 3-CMOS Full-HD and a unique 4-CMOS 4K camera head for ICG applications,' reports manufacturer Ikegami.

'The first camera in Ikegami's series of medical cameras based on the MKC 4K Camera platform is a 4K-native progressive-scan 1-CMOS model with an ultra-compact head designed to be operated from a remote CCU,' the firm explains. 'Features include ultra-high sensitivity, dynamic contrast correction, plus image correction. This marks the beginning of Ikegami's new cam-

era generation for microscopy and endoscopy in native 4K resolution.'

The CCU incorporates a completely new processing board with very compact measurements, requiring much smaller space in integrated solutions, the report continues. 'This board size reduction, combined with the ability to drive several different camera heads in 4K and Full HD resolution, makes Ikegami's new camera platform an ideal product for a variety of OEM applications.'

'In addition, the unique construction of the output boards allows maximal flexibility in the creation of OEM camera solutions based on

the MKC 4K camera platform. OEM designers have complete freedom to create either one universal CCU serving different heads, even in hot-plug configuration, or to serve several cameras with fixed heads. The new platform provides flexible choice of 4K monitors connectivity ahead of an industry standard for 4K output being defined.

'Besides known 4K outputs, such as 4xHD-SDI and HDMI 2.0, Ikegami's new MKC 4K camera platform also provides 4K output in 12G SDI. This signal format comes from the professional broadcast sector and allows 4K connection over a single coax



**Ikegami is at Medica**  
**Hall 10 / Stand B12**

# Virtual fracture clinic boosts patient care

A fracture clinic model being pioneered by a UK hospital is improving patient care and delivering significant cost savings for the NHS, Mark Nicholls reports

The **Virtual Fracture Clinic (VFC)** established by the Brighton and Sussex University Hospitals NHS Trust sees patients with broken bones or soft tissue injury supported through video links and self-management methods, rather than make additional journeys to hospital for face-to-face appointments with orthopaedic consultants.

The trust says the initiative also makes better use of consultant time by allowing specialists to focus more on their own areas of expertise.

The clinic was originally set up after orthopaedic consultant James Gibb became concerned that the existing model of care – where patients attending emergency departments with fractures were assessed and then booked in for a further appointment with an on-call orthopaedic consultant – was inefficient.

However, that meant they did not necessarily see the best person for their specific injury – a spinal specialist may be seeing someone with a broken toe, for example. 'It was a bit of a lottery,' said Lucy Cassidy, the trust's VFC project lead. 'Now, when a patient attends A&E, instead of being put on a list to see someone face to face, they are referred for a virtual consultation.'

'This consultation involves an

orthopaedic consultant looking through each case, and depending on the type of injury, the patient is placed on a self-management pathway and supported with rehab videos online. Or if they had an injury that needed to be seen, they would be booked into an appointment with the right specialist and receive the appropriate management.'

Patients have access to a rehab adviser within 72 hours of their injury, saving them having to come in to hospital with a generic fracture clinic consultant before being referred on.

The model is based on a virtual clinic in Glasgow, but has been taken a significant step further in Brighton by adding the physiotherapy component.

'Our service is now more streamlined and we find a large percentage of our patients can be self-managed, where they do not even need to come in for an appointment,' Cassidy added. 'We decided to design with a physiotherapy-led service because we found patients were not being given much information to self-manage injuries.'

The VFC has 27 rehab videos hosted on YouTube, presenting patients with six weeks' worth of rehab across various injuries. Giving patients the correct information at the outset of their treatment journey is helping to reduce long-term problems.

Brighton has 4,500 adult general fracture clinic cases and 3,000 wrist and hand injury patients a year with plans to expand to paediatric cases next year.

With the virtual appointment half the price of a £150 (170 euro) face-



The hospital has been collecting data to help manage referrals and ultimately to measure outcomes by coding every injury



The VFC has 27 rehab videos hosted on Youtube, helping patients to self-manage injuries

additional ward rounds for neck or femur fracture patients, while other hospitals have held additional clinics or helped increase theatre capacity. 'We are basically using the workforce to maximise their skills set rather than using them in a generic fracture clinic way.'

While there are clear staff resource benefits, putting figures on internal savings is more difficult, but it does mean less imaging, fewer registrars using clinics, reception staff time saved, and patient journeys down with carbon footprint reduced.

Current figures show that 57% of patients referred to the VFCs are discharged or placed on SOS appointments – where they are on

self-management but can regain contact for support – after first referral from A&E, compared to a previous discharge rate of approximately 40% in the traditional model.

The initiative has reduced outpatient appointments by 57%, saving the NHS more than £750,000 (€850,000), with 2,000 fewer patients having to visit the hospital a year.

Mrs Cassidy said patient satisfaction is up and, since January, the hospital has been collecting data to help manage referrals and ultimately to measure outcomes by coding every injury, to enable clinicians to look at the functional outcome for each injury and assess patient progress.



Lucy Cassidy is an advanced practice physiotherapist and leader of the Brighton and Sussex NHS Trust's Virtual Fracture Clinic project.

## grade

cable for long distances, without signal quality loss. This implementation confirms Ikegami as a leading company both in high-end broadcasting and medical video technologies,' the company reports.

Zeljko Romanic, Industrial & Medical Video Division Manager at Ikegami Electronics (Europe) GmbH pointed out: 'These new cameras are ideal for capturing the precise colour and image detail of surgical operations.' The MKC 4K camera platform is designed for easy setup by medical staff, allowing the entire system to operate automatically. Each camera head in the product series can be mounted on a lightweight support stand or boom. 'The combination of 4K UHD ultra-high resolution imaging and enhanced dynamic range display capabilities of our latest monitors greatly increases the quality threshold now possible in video signal reproduction.'

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# Down to earth devices **Virtual** with a

Augmented Reality in the operating

On sale now: a novel monitoring patch tried and tested in the International Space Station. John Brosky reports

Space missions are famous for driving innovation, from Mylar blankets to microchips. So when French scientists learned one of their compatriots would be aboard the Soyuz MS-03 spacecraft to reach the International Space Station (ISS), they gathered cutting edge technologies for him to carry into orbit.

On 17 November 2016 the European Space Agency (ESA) astronaut Thomas Pesquet was launched into space with NASA astronaut Peggy Whitson and Russian cosmonaut commander Oleg Novitsky for the six-month Proxima Mission.

Inside Pesquet's space gear were equipment and materials for two assignments, the Matiss project designed by the French National Centre for Space Studies (CNES), and the ESA's EveryWear program.

The EveryWear tablet computer serves as the data platform for two devices from BodyCap, a start-up based in Caen, France, which collaborated on a zero-gravity study of wearable technology with the CNES laboratory focusing on microgravity science and the Swiss Institute for Space Medicine and Physiology.

## Monitoring sensors

A sensor in the e-TACT patch worn by astronaut Pesquet combines activity tracking, skin temperature monitoring and body position detection; data is sent wirelessly in real time or stored on the device for subsequent analysis. The patch can be worn on any body area for some time, monitoring chronic diseases, sleep disorders and overweight people, for example.

'As there is no gravity in the ISS, the astronaut needs to be attached to the bed to avoid drifting around the capsule, which makes it difficult to sleep. What becomes important is an

ability to quantify movement during his sleep, as this is a very good indicator of sleep quality, a measure of whether he is truly sleeping or is restless,' explained Sébastien Moussay MD, a co-founder of BodyCap.

The other device from BodyCap is the Blood Pulse Wave sensor finger-worn device to detect changes in the blood pulse of the carotid artery when the astronaut presses his finger against his neck. This tonometer is being used as part of a study of modifications to astronaut Pesquet's cardiovascular system during long-term exposure to microgravity.

Without the resistance of gravity, Moussay said, the heart does not need to force blood flow to the brain and it progressively weakens, requiring a period of therapy for recovery once Pesquet returned to earth in May 2017.

The pulse wave sensor is a work-in-progress, Moussay pointed out,

but e-TACT is a CE-approved product with down-to-earth medical applications in programs for the obese and diabetic patients where physical activity is a vital measure, as well as for sleep labs. An example is patient compliance to prescribed physical therapy routines in the period following bariatric surgery.

Connected watches and other activity trackers popular with consumers do not make the grade with clinicians, he said.

'What's very important for doctors and medical staff is a measurement of metabolic change linked to activities such as walking and swimming. They are less interested in measuring hand movements of someone playing a video game, which is the data provided by connected watches,'

**Finger-worn Blood Pulse Wave sensor is a tonometer that checks on modifications to the cardiovascular system**



Moussay explained.

The Matiss project is a test of smart surfaces to resist bacterial colonisation inside the spacecraft with an eye on the future.

'If we are going to send people to Mars, we don't want them to get sick on the way, nor do we want them scrubbing and cleaning all the time,' said Guillaume Nonglaton, the project manager for the Matiss experiment at the Grenoble-based Leti research institute.

Housekeeping in the space station takes up an inordinate amount of the astronauts' time, which could be better spent performing their scientific mission.

## Keen housekeeping is a vital task

Astronaut Pesquet installed four plaques in spots regularly frequented by fellow astronauts, such as the kitchen area. Each plaque holds 20 different samples of hydrophobic materials that will be exposed to the air in order to come in contact with water droplets circulating within it, each possibly carrying bacteria.

The sample surfaces were each designed to repel the droplets so that they remain in the air and can be filtered, rather than being absorbed on a surface where they may take root.

Advanced materials developed for the experiment include a fluorinated thin layer, an organic silica and a biocompatible polymer, all chosen for their hydrophobicity, and ability to be manufactured on an industrial scale.

The materials also have practical benefits back on Earth for germ-free medical device surfaces and even elevator buttons.

Nonglaton: 'One never knows where the next good idea for practical applications will come from; perhaps this time it will come down from space.'



Report: Anja Behringer

**Medical Augmented Reality (AR)** assistance systems overlay information onto a surgeon's field of view. However this technology is complex and expensive. Therefore, the procedure must offer a big advantage compared to conventional treatment and diagnostic methods to qualify for standard use. The objective is a system that shows

Getting a grip on dermatology diagnostics

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'Three reflectors produce a well-blended and intense cone of light focusable through the automatic adjust-

ment of the light spot diameter. Its slim, practical and compact design makes it perfect for several uses.'

Ergonomical and easy to move and position the lamp suits the laminar flows of an operating room.

STARLED3 NX ENDO function also offers light for endoscopy and minimally invasive surgery, the company adds.

The entire system, including the I-SENSE control panel, has been designed for easy cleaning and sterilisation.

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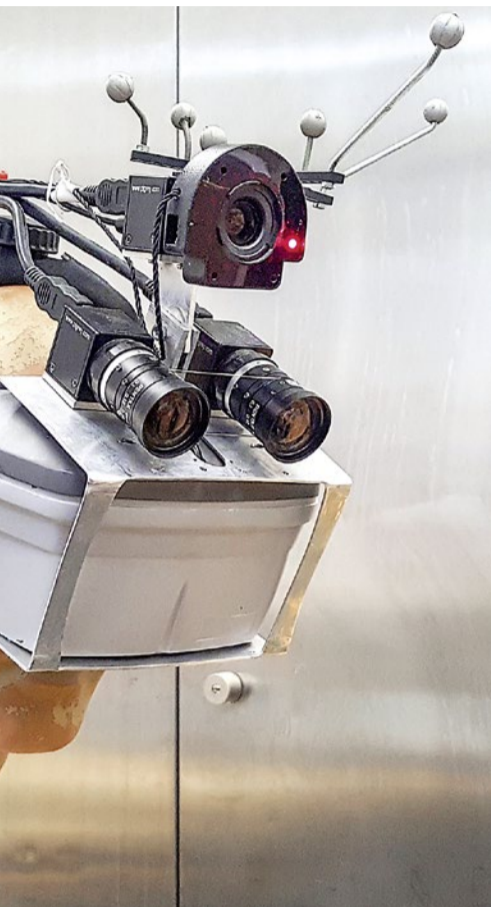
Special LED optics produce homogeneous, shadowless light



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theatre

# data merges real body



A head-mounted display used to develop prototypes for medical AR systems. The display has been developed in Munich – but is not conceived for use in the operating theatre (too many cables, too heavy)

a surgeon a 3-D image of inside the body plus instruments used during surgery – and not on an additional screen but with a direct view of the patient. For the system to improve matters

it must be easy to use, show relevant information and be easy to integrate into established workflow. Computer scientists merge existing and processed data with camera images of the real environment.

The C-arm, which with the help of AR lowers radiation exposure for patients by factor 40, has proved its value for some years. The challenges that medical technicians still faced three years ago, such as problems with imaging, reliable and precise tracking or issues around data preparation and visualisation have considerably reduced. Real-time imaging and visualisation are now so refined that AR systems can be utilised for an increasing number of applications.

During our interview, Dr Ulrich Eck, Senior Research Scientist for Computer Aided Medical Procedures and Augmented Reality at the Department of Informatics, Technical University of Munich, discussed some future applications.

'Minimally invasive procedures use endoscopes for imaging,' he began. 'The surgeon mainly operates with the help of images transmitted by the endoscope. As the image data is acquired and visualised electronically this type of platform is particularly suitable for the visualisation of additional information, such as pre-operative image data (CT/MRI/PET), or intra-operative image data (US/OCT).

### Data glasses for use in the operating theatre

'Planning data can also be visualised for interventions. One particular challenge is the provision of relevant information for the surgeon for every step,



In 2012, Ulrich Eck PhD began his Computer and Information Science studies at the University of South Australia. After gaining his doctorate in 2016, for his thesis 'Precise Co-Location of Haptic Devices in Visuo-Haptic Augmented Reality', he became a Senior Research Scientist at the Technical University of Munich. He manages research in the NARVIS laboratory at the Chair for Computer Aided Medical Procedures. His research interests include medical augmented reality, medical simulation, haptic simulators, computer vision and human/computer interaction.

at just the right time. The AR system must automatically detect in which phase the current procedure is.'

'The use of data glasses during surgery is an interesting concept, but there are still some unanswered questions, such as issues of ergonomics and sterilisation.

'The integration of data glasses also changes workflows – similar to the use of navigation systems. Effort and result must have a meaningful ratio, and it's not obvious which interventions are most suitable for this.

'In summary, there are currently no data glasses/HMD for use in the operating theatre which, along with technical criteria, such as screen resolution and contrast, system latency, precision and quality of visualisation, also meet the requirements for ergonomics (light, removable, comfortable, no cables) and operating theatre specific requirements (sterilisable, reusable, robust, cost efficient).

'The development of an HMD suitable for the operating theatre needs close cooperation between manufacturers of data glasses, researchers in augmented reality and medical experts. The first studies in this area are currently being carried out.'

Asked for which application we can expect the early implementation in the

operating theatre at a reasonable cost, Eck spoke of medical devices manufacturers who 'now have the first devices in their range which integrate the concept of the camera-augmented C-arm (CamC) developed in our department, into their products'.

### X-ray images projected onto the patient's body

'CamC is intended to help surgeons work faster, with more precision and with reduced radiation exposure for patients and staff.

'In future, we can expect augmented reality enhancements of products for specific types of application, such as in neuro-surgery.

The idea of projecting a patient's X-ray images onto their body during surgery makes sense even to lay people.

Eck explains the complexity: 'An X-ray image projects a 3-D space (the body) onto a 2-D plane. When an X-ray image is projected onto the body the spatial correlation between image content- and visualisation is no

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longer accurate, because it results in the impression that the information is located on the user's skin. Only when the projector projects from the perspective of the X-ray source and the user views the patient from this direction is all the information of an X-ray image visualised correctly. This is the idea that our CamC-system is based on, albeit with a screen and not a projector.'

Detailed 3-D reconstruction of the respective body region (static or dynamic) is an essential prerequisite for the correct projection of X-ray images onto the body. Only then can the image be projected without distortion.

'In simple cases,' computer specialist Eck concludes, 'projection of an X-ray image onto a body part, such as a flat hand, offers added value as the spatial correlation between the surface of the hand and the image corresponds well enough. We believe that, in most other cases, this type of projection does not deliver any noteworthy advantage.'

# f light



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Robotic-assisted visceral surgery

# The advantages are obvious

Report: Brigitte Dinkloh

The implementation of minimally invasive technology in the 1990s was a milestone for visceral surgery. A further chapter of innovation began about five years ago with advances in robotics, which were able to address certain technological shortcomings of minimally invasive surgery in the fields of optics, instrument technology and reconstruction.

If nothing else, pancreatic surgery has benefitted from these developments. 'It ranks amongst the most complex interventions in abdominal surgery and opens up an important perspective to be able to offer these complicated and very time consuming interventions, which have been carried out almost exclusively with conventional surgery, with an assistance system and minimal invasion,' explains Colin M Krüger MD, Dipl.oec, Senior Consultant at the Department for Surgery, Immanuel Hospital Rüdersdorf, near Berlin.

## A lower rate of complications

First studies and analyses confirm that the quality of organ removal and partial removal is more or less comparable for both procedures, but also that the rate of complications associated with the intervention is significantly lower for minimally invasive procedures than for open surgery. Therefore, minimally invasive surgery, whilst achieving the same surgical outcome, has clear advantages.

But, which patients and indications are suitable for robotic surgery? 'Basically, all patients who are operable and fulfil the surgical entry criteria,' Krüger responds. 'If the diagnosis confirms that a patient is likely to benefit from surgery, then this can also be done with minimally invasive procedures, or, in the best case, with robotic surgery, such as the da Vinci Surgical System.'

Krüger does not foresee a considerably better perspective for patients with pancreatic cancer as 70-80% of them are only diagnosed once the tumour has already spread and is considered inoperable.

However, there are other pancreatic diseases with a less negative prognosis, where surgical intervention is worthwhile. These include hormone producing tumours, as well as all types of chronic pancreatitis



Colin Krüger is establishing the first centre for robotic-assisted, visceral surgery in Rüdersdorf, near Berlin

such as those that may develop due to chronic alcohol abuse or as a result of autoimmune diseases, where the body tries to fight its own pancreatic tissue. The resulting inflammatory changes can cause jaundice, gastroparesis and, most importantly, chronic pain. This is an area of application for robot-assisted surgery.

## Improved optics and a higher degree of freedom

One essential advantage of the da Vinci Surgical System is the improved visibility over the operating area. 'Unlike conventional laparoscopy, which only offers 2-D visualisation, it facilitates 3-D HD visualisation in the same way as open surgery does. The surgical structures can be enlarged up to tenfold, which means more

precision during preparation,' the Berlin-based surgeon emphasises.

The same applies to handling, with much more freedom when guiding the instruments in the abdomen compared to conventional laparoscopic surgery. 'The instruments have up to seven degrees of freedom,' Krüger points out. 'When you work with double-joint technology the instruments carry out their own hand movements. This is the principle of the surgical robot – it controls the manipulators, and the hand movements carried out outside of the operating area are implemented 1:1 to the instrument working inside the abdomen. You sew externally, with the manipulator in your hands, and the robot sews with the needle, which you hold in the external nee-

dle holder, but inside the abdomen. This is brilliant.'

## More 'radicality'

A further advantage of robot-assisted surgery in oncology is immunofluorescence. These fluorescent dyes, injected by the anaesthetist, can stain the lymphoid tissue or other vessels and structures during surgery, either to protect them or remove them even more precisely with the respective radicality. The prescribed number of lymph nodes to be removed for certain types of tumour surgery can be significantly increased with the da Vinci system. 'During open surgery, the dyeing is very complex because there isn't normally a camera system available, which is why it's not usually done.'

'For a long time, it was quite controversial whether tumour surgery should actually be carried out with the minimally invasive procedure at all,' Krüger points out. 'There was always the claim that it is not sufficiently radical. However, this has been scientifically refuted. It obviously always depends on the expertise of the surgeon, but the procedure achieves at least the same, and sometimes even more radicality, and at the same time allows the patient to benefit from the advantages of minimally invasive surgery.'

## Costs and viability

Only a few patients in Germany currently benefit from robotics in pancreatic surgery. Last year, 43 surgical departments had access to one of the 87 systems currently available in that country. The number of departments for visceral surgery and centres that treat a noteworthy number of patients with robotics is considerably lower still; Krüger estimates it to be around 10-15 centres.

This can most probably be attributed to the increased costs of the procedure, which are €1,000-€1,500 higher than the costs of conventional surgery and therefore still not always viable, despite shorter in-patient stays. The discussion as to whether these systems are really required, or not, is still very heated and affected by jealousy. On the other hand, there are currently almost exclusively only studies that confirm the feasibility, and only very few studies that confirm a clinical advantage of robotics compared to

minimally invasive surgery. 'However, this is to be expected at the moment, as we require a critical number of users and data to confirm clinical superiority. Method studies are difficult to carry out anyway, and often only individual parameters are examined. We don't generally compare the minimally invasive procedure with robotics, so it is difficult to evaluate this,' he explains.

Krüger is establishing the first centre for robotic-assisted visceral surgery in Brandenburg, and plans to carry out his own studies. With gynaecological and urological colleagues he aims to achieve full capacity for the da Vinci-SI with around 500-600 interventions annually in one to two years' time.

Financial easing could occur from 2018/19 when large manufacturers will break the current monopoly held by Intuitive by releasing their own equipment, and when competition will regulate the prices for acquisition and maintenance. Krüger is sure that 'in five years' time the costs will settle down around the level of those currently expected for a complex laparoscopy'.



In April 2017, Dr Colin M Krüger MBA, Dipl.oec, became a senior consultant at the Department for Surgery at the Immanuel Hospital, Rüdersdorf, Germany, near Berlin since April 2017. Earlier, as a specialist for general, visceral and vascular surgery and emergency medicine at Vivantes GmbH, he also headed the visceral surgery programme for 'Robot-assisted, minimally invasive Surgery (Da Vinci)'. From October 2016, he was senior consultant at the Centre for Robotics and Minimally Invasive Surgery in the Department for Surgery, Vivantes Humboldt Hospital, Berlin. Krüger also holds a MBA in Health Economics, is a medical advisor at Intuitive Europe and is currently writing his habilitation at the University of Greifswald on the risk stratification in pancreatic surgery.

## Medica's Connected Healthcare Forum

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The forum takes place in hall 15 (Stand 15C24). The conference language is English.

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**Editorial team:** Wolfgang Behrends, Lena Petzold, Marcel Rasch  
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### Correspondents

**Austria:** Michael Kraßnitzer, Christian Prusznyski. **China:** Nat Whitney **France:** Jane MacDougall. **Germany:** Anja Behringer, Annette Bus, Walter Depner, Brigitte Dinkloh, Cornelia Wels-Maug, Holger Zorn. **Great**

**Britain:** Mark Nicholls. **Malta:** Moira Mizzi. **Spain:** Mélisande Rouger, Eduardo de la Sota. **The Netherlands:** Madeleine van de Wouw. **USA:** Cynthia E. Keen, i.t. Communications, Lisa Chamoff.

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Liane Kaiser,  
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### Representatives

**China & Hongkong:** Gavin Hua, Sun China Media Co, Ltd. Phone: +86-0755-81 324 036  
E-Mail: gavin\_hua@163.com

**Germany, Austria, Switzerland:**  
Ralf Mateblowski  
Phone: +49 6735 912 993,  
E-Mail: rm@european-hospital.com

Take a walk through the UK

# The United Kingdom's global platform



Presenting 120 UK companies over in Hall 16G, The Association of British Healthcare Industries (ABHI - [www.abhi.org.uk](http://www.abhi.org.uk)) is certainly highlighting the desire within this country to forge deeper, more sustainable trading relationships as the government navigates its departure from the European Union.

'The UK is open for business and is keen to forge global healthcare links,' said Paul Benton, Managing Director of International at ABHI. 'With 120 companies exhibiting, we are delighted that the UK Pavilion is at its capacity. The technology on show is a wonderful expression of what the industry has to offer in providing value-based healthcare solutions for patients across the globe.'

As the UK enters a new era for trade and business, the country's government has highlighted MedTech, and the broader Life Sciences sector, as having a critical role in its Industrial Strategy - to propel UK productivity once it leaves the EU.

MedTech is now worth over £17 billion to the country and is part of a £64 billion UK Life Sciences industry. A recent report, The Life Sciences Industrial Strategy, has been welcomed by senior government ministers and provides the framework for increased funding and support for the sector.

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As well as supporting UK export globally, ABHI are also keen to speak to international companies that want to do business within the UK. Their international membership has been set up to make it more accessible for global companies wishing to partner with their British counterparts.

### Meet the ABHI team at the UK Pavilion.

As the industry association for the medical technology sector in the

UK, the Association's mission is to champion the benefits and use of safe and effective medical technologies, to deliver high quality patient outcomes. With over 260 members, ABHI leads the advocacy of the industry to advance access to medical technology. Its membership includes some of the leading multinational businesses in the sector in the UK all the way through to small and medium-size enterprises (SMEs).

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## Medica's Tech Forum

The Tech Forum will be held for the eighth time this year. With alternating focal points experts will present technical, scientific, regulatory and political – in any case market-relevant – topics pertaining to the medical technology industry. The leading content-related industry associations SPECTARIS and ZVEI will discuss the German and the international market environment in the most varying ways, as well as the implementation of modern processes and methods in practice.

This year, particularly current challenges of the industry will be the focus of attention daily between 1.00 p.m. and 3.00 p.m. The European Medical Devices Regulation (MDR) and its consequences for the industry sector will be the main topic on Monday. On Tuesday, information on emerging Export Markets influenced by political decisions will be presented. On Wednesday, the midday block concentrates on the increasingly interdisciplinary complex Product Integration in the Operation Room. On the background of the general health digitalization, the controversial fields Data Protection and

Cyber Security form the forth conclusion forum on Thursday. More discussions on legal and economic topics such as In-vitro Diagnostics Regulation, the impact of Brexit, European patent law, plagiarism, compliance and medical technology, tenders ultrasound, guide reimbursement system, evaluation of medical operational methods and HTA Health Utility Measurement in Europe await visitors in the morning and afternoon.

**Challenges to the tech industry will be aired daily between 1 p.m and 3 p.m. in hall 12 (Stand 12E73 – 12F67).**

**The conference language alternates between German and English.**



- France, Italy, Spain: Eric Jund  
Phone: +33 493 58 77 43,  
E-Mail: [ej@european-hospital.com](mailto:ej@european-hospital.com)
- GB, Scandinavia, BeNeLux: Simon Kramer  
Phone/Fax: +31 180 6200 20  
E-Mail: [sk@european-hospital.com](mailto:sk@european-hospital.com)
- Israel: Hannah Wizer, International Media  
Dep. of El-Ron Adv. & PR Co., Ltd.,  
Phone: +972-3-6 955 367  
E-Mail: [hw@european-hospital.com](mailto:hw@european-hospital.com)
- South Korea: CH Park, MCI  
Phone: +82 2 730 1234,  
E-Mail: [mci@unitel.co.kr](mailto:mci@unitel.co.kr)
- Taiwan: Charles Yang, Phone: +886 4 232  
236 33, E-Mail: [medianet@ms13.hinet.net](mailto:medianet@ms13.hinet.net)
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International  
Phone: +1 301 869 66 10,  
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SONOSCAPE MEDICAL CORP.

Yizhe Building, Yuquan Road  
Shenzhen, 518051, China

Tel: 86-755-26722890

Fax: 86-755-26722850

E-mail: Market@sonoscape.net

www.sonoscape.net