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Case study

Stop – you have reached your destination

Ultrasound-guided navigation for the placement of needles and cannulas

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At eZono, a multicultural team of experts from various disciplines develops innovative solutions for ultrasound-guided medical procedures. The eZono®4000 is an ultrasonic navigation device for the placement of needles, cannulas and other invasive medical devices. In developing the product, eZono's main aim was to address the practical challenges of everyday clinical life. The result is a battery-powered, portable instrument that enables doctors to easily integrate sonography into their workflow, even if they are no ultrasound experts. The technological concept of the device is based on a completely new way of making a needle and its journey through the body visible. The intelligence of the ultrasound navigation system is provided by the conga-BAF, a COM Express module from congatec AG. This module is based on the AMD Embedded G-Series APU and is well suited for battery operation, because the conga-BAF requires just a few watts of power despite providing high computing power and excellent image processing performance.

Straight to the point of pain and back

Invasive procedures are common in operating theatres, intensive care units, emergency rooms or diagnostics. Doctors use them to inject drugs such as painkillers and anaesthetics, or to take synovial fluid, blood or tissue samples. These procedures are simply indispensable for medical diagnosis and treatment.

During an invasive procedure, a needle or other sharp instrument pierces the skin and enters deep into the body tissue. It needs to travel past nerves, vessels and other internal body parts to reach the often minute target area. But how can the needle get to a deep lying vein or the precise pain point? Even if the needle only penetrates the body a few centimetres, 'flying blind' through the body is risky with possible side effects ranging from bruising to a stroke.

The risk of injury is reduced if the needle's path past vessels, nerves and tendons is planned in advance and made visible. Navigated procedures are more successful and safer for the patient. They are recommended by national health organizations, such as the National Institute for Health and Care Excellence (NICE) or the Society of Cardiovascular Anesthesiologists. Successful treatment means faster recovery and greater patient satisfaction. As a result, patients leave the hospital sooner with less complications, leading to cost savings.

Better imaging thanks to ultrasound

Ultrasound has been used in diagnostic tests for a long time. There is hardly any baby whose size or position has not been determined by ultrasound. In general, this technology is perceived as safe. The exposure to contrast agents or radiation that occurs with other imaging techniques is eliminated. During an ultrasound check, a transducer moves back and forth or rotates over the skin. It sends ultrasonic waves into the body and receives the reflected signals. These vary

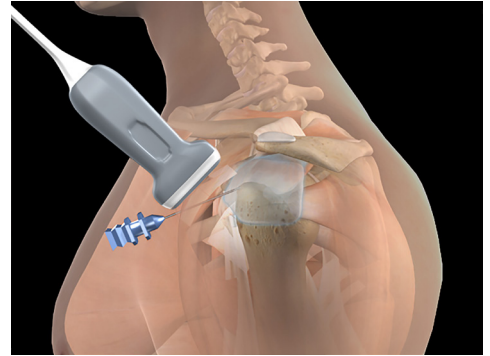


Ultrasound-guided navigation with eZono in action

depending on the structure of the targeted tissue. From these signals, a 2D image (plane) showing vessels, organs, structures and fluids is generated. Sounds easy? Unfortunately, it's not always been plain sailing. In the past, astronomical prices and high training costs formed a barrier to the use of ultrasound-assisted technologies in the clinical setting.

Staying on course with coordination and skill

Ultrasound-guided procedures are complex and require a high degree of coordination and skill from the operator. While one hand sounds out the target area, the other hand drives the needle through the tissue. The success depends on the clinician's skill and experience. The inexperienced find it difficult to track the needle with the help of the ultrasound image, and they run the risk of inserting the needle past its target point.



Presentation of ultrasound-guided procedure

A 2D journey through the 3D maze

One of the challenges for the navigation system is that the needle is mapped in a 2D image plane as it makes its way through the 3D tissue. Traditionally, there are two approaches – the in-plane vs the out-of-plane method.

In-plane

With the in-plane approach, the needle moves parallel to the ultrasound beam. In other words, the angle between the needle and the plane is 0 degrees. The needle is visualized as a line. If the needle diverges from its parallel route or if it revolves along the axis, this is not visible in the picture. As a result, it is easy to underestimate the depth of penetration. The in-plane approach is therefore of limited use for deeper lying targets.

Out-of-plane

With the out-of-plane approach, a portion of the beam is deflected at an angle. This ensures that it is possible to track the needle even as it penetrates deeper into the tissue. While an angled beam makes it easier to visualize the needle, it remains difficult to assess the exact needle position. What exactly does the dot in the ultrasound image represent? Is it the tip of the needle or the point where the needle meets the ultrasound plane? Therefore, some procedures use modified needles with built-in sensors. These special needles are often thicker and manufacturer-specific. Proprietary needles limit clinicians in their choice of needle gauge, length and bevel type. Another disadvantage of some special needles lies in the fact that they need to be manually disconnected from the sensor after reaching their target position in order to connect the syringe or injection tube. This may cause the needle to deviate from its original and optimal position, increasing the risk of injury in tricky procedures. Another option are needle guides that fix the needle's direction and angle. The downside is a limited freedom of movement for the practitioner.

Exploring new ways

The traditional methods of using 2D imaging to find a 3D route requires great experience, skill and coordination from the clinician. Until he masters this art, the risks remaining for the patient

are not trivial and a lot of training is needed. And because proprietary needle systems restrict the choice of the appropriate instrument, eZono has followed a different route.

A long wish list

The interdisciplinary eZono team analysed the concerns and needs of hospital staff. Their ideal device needed to be compact and portable. It also had to be capable of battery-operation in case there was no power outlet nearby. In point-of-care diagnostics the devices are often used at the bedside or in consulting rooms. Here, the wish for a device that is easy to operate and can be used without much training was particularly strong. A device that provides reliable information about the position and depth of the needle. A device that eases the workload while using familiar syringes and instruments. All this without the need to use additional plug-ins or extension modules. Plus a device that increases safety, both for the patient and for the inexperienced operator. The result was a completely new approach to ultrasound-guided navigation.

Magnetic route planning

eZono has evolved the idea of needle visualization. Instead of special needles with built-in sensors, the eZono®4000 uses magnetized standard needles. Most standard needles contain enough metal for them to be magnetized sufficiently. The magnetization process is simple: The needle is briefly placed into a small sterile plastic cup with two built-in magnets.

Adaptive needle detection automatically calibrates the eZono®4000 system for the selected needle. The transducer incorporates a needle tracking system which collects the position data of the magnetized needle and measures the signal strength of the reflected sound waves. The measured values are then converted into 3D data with the help of elaborate algorithms. In addition to tracking the needle's path through the tissue, the depth of insertion is visualized. Again, this needs complex algorithms to turn the raw measurement data of the hardware into a meaningful image in real time. The required graphics and computing power were among the reasons why eZono opted for the cong-a-BAF module from congatec.

Visibility from any angle

As the needle moves through the tissue, the patented needle guidance technology eZGuide™ FreePlane Navigation visualizes its direction and the location of the tip of the needle relative to the imaging plane in real time. The operator can clearly see where the needle is and when it has reached the target area. Coloured indicators in the ultrasound image further facilitate needle guidance. A target corridor indicates whether the needle is on the right track. This makes precise needle positioning possible, both for the in-plane and out-of-plane approach.

Wishes fulfilled

Deep interdisciplinary insight into everyday medical practice led to the development of the eZono®4000.

Compact and portable

Weighing in at 4.7 kg, the eZono®4000 meets the wish for a small, portable device. It is reminiscent of a tablet PC.



The portable eZono®4000

Point-of-care diagnostics at the bedside or in practice rooms

The device can be mounted on a trolley or placed freestanding on any surface, supported by its rear stand. Accessories such as quick release VESA mounts or special trolleys are available.

Battery operation

To enable use on the move, the device comes with a battery. In battery mode, the device can operate for approximately 2.5 hours; this is long enough to carry out several consecutive procedures without recharging the battery. The compute-intensive graphics applications of the eZono®4000 require high-performance processors while battery operation needs low power consumption. Both software and hardware are therefore optimized for energy efficiency – another reason why the conga-BAF-module was selected. It contains an energy-efficient yet powerful processor of the AMD Embedded G-Series APU platform.

Workload

The eZono®4000 is operated via a multi-touch 12.1-inch display. Users are familiar with this type of interface from their tablets and smartphones. There are a lot of soft keys to control important functions and settings. The display shows brilliantly sharp images. Even when lighting conditions are poor, which is a common issue in point-of-care applications, the images are clear to see in all 256 shades of grey. The device boots up in less than 20 seconds from standby mode, and even a full start up takes barely a minute. Preparation of the standard needles with the magnetizing cup is simple, sterile and quick. The sealed surfaces of the eZono®4000 can be disinfected efficiently. Easy cleaning and the use of standard needles have a positive impact on the cost-of-ownership.

Short learning curve

Educational Cue Cards provide information and help for any kind of procedure. This integrated training method bridges the gap between teaching and practical clinical application. It covers the basics of ultrasound examinations, vascular access, local anaesthesia, rescue blocks, musculoskeletal system disorders, pain management and many other topics. The Cue Cards can be expanded with new, customer-specific topics.

Reliable information about the position and depth of the needle

Adaptive needle tracking and a selection of display modes facilitate assessment. The position of the needle tip can be correctly identified both with the in-plane and out-of-plane method.



Various display modes help the clinician

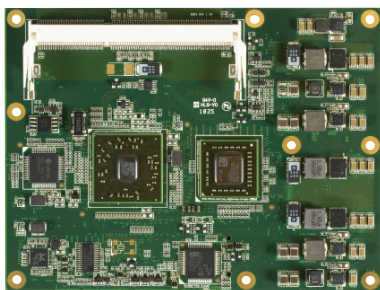
Benefits of a COM Express solution

Modern specialist medical devices like the eZono®4000 require a high-performance computer, yet the computer in such a device is only the means to an end. The real know-how lies in the medical technical application. Designing a processor board is a complex job and a draw on own resources that would be better used for application specific tasks. When using Computer-on-Modules (COMs), the computer part is available off-the-shelf so the focus can shift back to the core competencies. COM Express is one of the leading module standards and is supported by many module manufacturers. In addition to the processor, a COM module also contains the entire periphery and supply. The COM module is a full-fledged computer

which is mounted onto a custom carrier board that contains the application-specific properties. This approach provides several advantages. The crucial know-how remains in-house while computer specialists such as Congatec or other COM vendors develop and manufacture the ready-made, pre-integrated modules. Commercial challenges, such as product discontinuations or new processor generations, are easier to handle when using COM modules. The use of standard modules guarantees long-term device availability; it also saves time and money because tested, proven and certified components in industrial quality are readily available.

A clever brain thanks to the conga-BAF COM Express module

eZono selected the conga-BAF COM Express module from Congatec's product range because it provides an ideal mix of computing performance, graphics features and power efficiency. The low power draw allows battery operation and the unit also functions well without fan cooling. Thanks to its characteristics, the entire unit can be housed in a fully enclosed casing which



Various display modes help the clinician

is easy to clean and disinfect. This is an important point when it comes to meeting the strict hygiene requirements of the medical environment. To deliver the complex tasks of needle navigation and visualization, high computing power and excellent graphics were an absolute must. The conga-BAF module ticks these boxes. It is based on the AMD Embedded G-Series APU platform. This space-saving and power-efficient two-chip platform includes a powerful multicore processor along with a graphics unit that already offers the functionality of a dedicated graphics card at the chip level. This high level of integration also provides the basis for the

powerful image processing and quick visualization provided by the eZono[®]4000. With the APU architecture, certain computing tasks can be outsourced to the integrated graphics unit to relieve the CPU. This results in latency-free operation and display. Using standardized graphics libraries such as OpenGL and OpenCL[™], it is possible to outsource compute-intensive image processing algorithms to the graphics unit for user-friendly presentation. The conga-BAF is therefore the ideal platform for the eZono[®]4000 or similar compact, mobile devices with advanced graphics.

eZono and congatec

It was love at first sight between the two young companies. Both founded in 2004, they started working closely with each other right from the beginning. Back then eZono used the conga-945 module. The rules applying in medical technology are stricter than in most industries. To meet the regulations regarding electromagnetic radiation, Congatec expanded its BIOS following a suggestion from eZono. It was now possible to configure the module's clock system specifically for reduced EMI emissions and as a result of their intensive cooperation, both companies had improved their product. The partnership remains strong until today. The current eZono[®]4000 is powered by the conga-BAF. Its extremely high graphics performance, computing power and energy efficiency made the conga-BAF the first choice. Another advantage is the module's long-term availability of about ten years.

eZono chooses congatec

“Whenever we use new COM modules, we will continue to go with congatec. The chemistry between our companies works, congatec’s support is outstanding, the products meet our requirements and the price is fair. So why change?”

Quote: Manuel Berrocal, Development Manager

Conclusion

In invasive medical procedures, ultrasound-guided navigation increases patient safety because the used imaging technology lowers the risk of complications. The eZono®4000 increases the efficiency of the treatment because interventions can be carried out faster and more easily. The eZono®4000 meets the practical needs of the medical staff. The training effort is low and clinicians with little experience in ultrasound technology master this navigation technique safely after a short training period. The use of standard needles pays off twice: First, these are proven, familiar instruments; and second, their ready availability translates into a clear cost advantage. The eZono®4000 has already proven itself in practice. The treatment is faster, first attempt success rates are higher, and the incidence of artery injuries is lower than with straight landmark-based procedures. Key features such as battery operation and improved graphical representation were realized with congatec’s conga-BAF COM Express Module with the AMD Embedded G-Series APU.

About eZono

Founded in 2004, eZono helps clinicians to integrate ultrasound technology into their daily work. The eZono®4000 was specifically developed to address real-life challenges at the point of care. This led to ground-breaking improvements in procedural ultrasound guidance.



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