6 Cover Story
In the Palm of your Hands
CUSTOM MOUNTING SOLUTIONS

Innovative specializes in custom product configuration and OEM development. Tap into our design and engineering resources for your technology mounting requirements.

Innovative has worked with such prestigious healthcare institutions and partners as: American Red Cross, Astra Zeneca, Beckman Coulter, Carstens, Childrens Hospital Los Angeles, Fresenius Medical Care, Jefferson University Hospitals, Lilly, Mayo Clinic, Siemens, Thermo Scientific, Vanderbilt University Medical Center.

Let us create a unique mounting solution for your medical equipment.
Why do many people have the best ideas while they take a shower? Simply because they allow thoughts to flow freely. By the way, that is basically what artificial intelligence does. Artificial Intelligence is one of the most important future topics. This is at least the result of a study the association VDE has executed in November 2018. Even though 41 percent of the questioned managers, research heads and university professors feel that European countries are well-positioned, the leading position is rooted in the USA (59%), China (39%) and Israel (31%) followed by Japan and South Korea (17% each). Only 3% of the individuals surveyed consider Germany as a trendsetter in this connection.

Why are other nations ahead of European countries like Germany?

A crucial factor are surely research funds. USA and China invest high amounts in research and development of artificial intelligence. An additional criterion are data records. After all, algorithms are going through a huge amount of data in order to reach a conclusion. Therefore, artificial intelligence and data analysis are a real dream team. At the same time, data privacy statements are likely to prevent pertinent development in Europe.

Of course, data security presents an important topic. The international market has established a particular confidence in safety products made in Germany. The very strict privacy policy benefits here. Consequently, this is the very point where we need to start to build up knowhow in order to make sure that European medical technics continue to be state of the art.
System Platform for Time-Pressure Dosing
If liquid media are to be precisely filled in small and varying amounts in medical or laboratory technology, time-pressure dosing is often a perfectly suited flexible method.

Complex and Flexible at the same Time
The company BGS BETA-GAM-MA-SERVICE GmbH & Co. KG, in short BGS, treats products with high-energy rays in order to convert them into a sterile state or to optimise the product characteristics.

The new Sharp, Authentic and Efficient
Richard Wolf GmbH raises image quality in endoscopy to a new level with pin-sharp 4K resolution technology.
FAULHABER drive systems

As pioneer and founder of a high-tech industry, FAULHABER is among the most innovative companies in Germany. For the new 1660 ... BHx series, the drive specialist once again fundamentally re-examined the physical principles of electromagnetic power generation and developed a drive which, in a market comparison, sets new standards: with respect to installation space and weight, the 1660 ... BHx series delivers values that were inconceivable just a short time ago – at higher speeds and with lower noise and heat development. This drive series is thereby predestined for medical handpieces with high power requirements in applications with limited installation space.

FOR. FRITZ FAULHABER GMBH & CO. KG
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IN THE PALM OF YOUR HANDS

It wasn’t all that long ago when handpieces for delicate one-handed tasks were supplied with an external drive source. The handpiece with integrated drive unit was simply too heavy to hold with one hand while at the same time moving the tool with a high degree of accuracy. So the motor was put in a box and the drive power was transmitted to the rotating tool via flexible shafts. One drawback was that the shafts had their own intrinsic weight, and their low flexibility dramatically limited the range of movement and power efficiency. And the same is true for the pneumatic variant, where the tool is operated with compressed air which results in more noise and less precise control. However, this variant is not feasible for medical applications to begin with.

Patients benefit from motor performance

The rapid development in motor technology in particular is the reason why such shaft-driven handpieces are nowadays only admired in technology museums. Today’s successors get their power from small electric motors that fit conveniently into common housings. Combined with the latest high performance batteries, they can even do without electrical lines. For use in the medical field, robotics, lab equipment or the watchmaking industry, the motor with a diameter of 16 millimetres has established itself as the standard. These drives have been used for many years, and they have proven themselves in the handpieces of various machineries.

For working comfortably, every gram of the handpiece a doctor needs to hold during treatment counts. Motion technology as small and as strong as possible is required at the same time.

But when a new standard is achieved, new requirements emerge once again. Advancements in medical science, such as for dental treatments or musculoskeletal operations, enable increasingly comprehensive treatment options. This may require very lengthy treatment, which can be highly taxing on the physician. Even the machines used are often required to work extremely hard during frequent use.

New knowledge, methods and systems now ensure that difficult root canal treatment procedures can today be performed successfully and with minimal discomfort for the patient. New powerful and lightweight hand tools using modern drive technology have made a significant contribution to this.

A powerful and robust high-performance motor that can work quietly and without disruptive vibration: The new 1660...BHx series from FAULHABER is setting new standards on this point, and it yields the greatest torque from this motor format compared to market competitors.

Electromagnetic principles rethought

FAULHABER has thus developed an entirely new, 2-pole, brushless 16-millimetre motor. The new 1660...BHT/BHS series demonstrates that a motor with this dimension can offer significantly more power than previous models. „We took a very fundamental approach to this question and re-examined the physical principles of electromagnetic power generation,“ explains product manager Silvio Taraborrelli. „The basis of these principles is the so-called Lorentz force, which arises from the interaction of magnetic field and flow of charge. This force is used in full when the wire of the coil is perpendicular to the magnetic field. With the traditional angled winding of...“
AMONG MORE THAN 800 INTERNATIONAL COMPANIES, ARE ALREADY ACTIVE IN THE FIELD OF DESIGN AND MANUFACTURING OF MEDICAL DEVICES.

THE MOST IMPORTANT MEDTEC GATHERING OF SWITZERLAND

AMONG MORE THAN 800 INTERNATIONAL COMPANIES, 365 ARE ALREADY ACTIVE IN THE FIELD OF DESIGN AND MANUFACTURING OF MEDICAL DEVICES.

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the coils, part of the Lorentz force is lost which is why we developed a new winding technology. With this so-called segment winding, we can now optimally align a large part of the wire. As a result, we get much more power with the same diameter, same amount of copper and same power consumption."

The new motor is available in two versions to accommodate different requirements. The 1660…BHT model – HT standing for „high torque“ – has been optimised with regard to the maximum continuous torque of 18.7 mNm, this version is also capable to deliver intermittent torque above 30 mNm for application requiring impulsive cycles. The 1660…BHS can achieve high-speed up to 100,000 revolutions per minute and is dedicated to applications where the motor is operating almost continuously or in handtools where the unit operates for extended period.

Load change and continuous operation

Besides these differing characteristics, the two variants of the motor offer similar benefits. These include, among other things, particularly quiet and practically vibration-free running, which facilitates handling the machine over a long period of time. Since a particularly large part of the energy used is converted into motion, heat dissipation is no problem either – the handpiece remains relatively cool for the most common application requirements. This is especially the case for intensive operation with short-term overload conditions. The rugged, small motors can easily handle both continuous or intermittent use scenarios, while they can process highly dynamic movement patterns at the same time.

The extremely flat speed-torque curve down to 95 rpm/mNm allows a very high motor performance, easy control and helps to avoid large speed drops under variable load conditions. One of the strengths of the new motor series is also the precisely adapted electronics. They are equipped as standard with digital Hall sensors and can therefore also be operated without an encoder. If this does not suffice, the motor can be combined with high-resolution incremental magnetic encoders.

Pre-loaded ball bearings ensure that the motors can easily withstand the radial and axial forces that the handpiece is subjected to. They are designed for an extremely long service life. The motor can work without and with gearhead. In the second case, numerous matching precision gearheads are available. Product manager Silvio Taraborrelli is convinced: „This motor relieves the hand holding the machine. This then offers more freedom for highly precise work."

Individually wrapped segments will be inserted overlapping. It is thus possible to fit in a huge amount of copper. The high copper content increases the performance of the motor.
Your partner in medical technology

Sphinx Tools Ltd. sets standards for optimum quality and security. As a partner and OEM manufacturer of high-quality instruments in the field of medical technology, we have acquired an extensive knowledge base. Our in-depth expertise is based on longstanding partnerships with leading international medical technology companies.

The cutting edge geometry technology from Sphinx Tools Ltd. guarantees low torque and thus a lower heat generation. The precisely ground and burrless instruments are extremely durable even under the most challenging conditions and can be sterilised over and over again. Our development department is a high-tech laboratory specialising in measurements to within a thousandth of a millimeter. We ensure that our customers can use their instruments with absolute precision and in the best interests of patient health.

Quality management system in compliance with
- DIN ISO 9001:2015
- FDA registration: 3010871687

Clean room
We are operable for cleaning and packaging in accordance with GMP (Good Manufacturing Practice) in our own clean room approved of category 8 ISO 14644-1

Products
- Surgical bone drills
- Cannulated instruments
- Thread cutters
- Schanz screws
- Wire drills
- Steinmann pins
- Dental drills
- Screwdrivers

Expertise
- Long-term partner in the medical technology sector as OEM manufacturer
- Support with the selection of materials and construction
- More than 100 years of machining expertise
- Know-how in the processing of high-quality materials
- High flexibility
- Complete supplier
- Optimal manufacturing solutions for small and large series production
- Delivery times according to customer’s request
bMotion is Bühler Motor’s new initiative for a completely innovative platform of DC motors, gearboxes, brakes and encoders, which fit perfectly together. bMotion exceptional compared to existing solutions on the market; but there is even more that makes bMotion a competitive solution.

bMotion is a highly modular and easy-to-combine drive platform consisting of countless predefined variants. Within this new product line are pre-validated and market specific combinations, now available to new and existing customers. With this new platform, Buehler Motor offers excellent application support and fixed lead times for samples, pre-series parts, and series parts. This process creates added value for the customer and makes bMotion a seamless customer service experience.

The customer already experiences benefits in the development phase. The advantage with bMotion our customers will get visibility into the wide spectrum of solutions. Different drives in a customer’s application can be selected from Bühler as a single source. Similarly, drive combinations for unique market requirements are also available. Overall, Bühler will cover the market requirements and application-specific needs of the customer. For instance, there are several combinations available for building doors which are tailored for low cogging and low back-drive-torque to protect the safety needs of our customers. Strong and environmentally-proofed solutions for farming are available, as well as, durable and quiet drives for medical applications. Undeniably, the flexibility of the drives is also appropriate for industrial applications in industrialization. Additionally, the platform offers cost savings in all applications where the lifetime of a BLDC motor is not required.

Furthermore the main benefit for our customers is the drive solution does not need not to be developed customer specific but the solution can be configured to each customer’s requirements (configure-to-order). This decreases our customer’s development and implementation timing as well as their costs. The expedited development does not mean a sacrifice in quality. Bühler Motor offers superior support over the complete product life cycle; also, we are very aware that the development phase is essential to the success of the customer’s project. Even though standardization is a part of the new platform, customizations are always possible. Lastly, it does not matter what customization is required e.g. windings, pinions as well as special shaft length, EMC suppression and temperature sensors are all customizable.

To cover the increased need for predictive maintenance, temperature sensors are available for condition monitoring. To offer such flexibility paired with fixed lead times, Bühler Motor implemented new processes to realize this goal for new and existing customers. Likewise, Bühler completely changed over to a digital order management system, which allows for fast, efficient processing of orders, and creates a production environment that is resourceful. This way lot sizes down to 200 pieces can be handled.

In addition, this advanced manufacturing concept includes full traceability of materials, process values, and motor performance data. Moreover, it incorporates the Bühler Motor Quality Management philosophy. To summarize, the customer benefits of Bühler Motor’s new bMotion drive platform can be done very succinctly. Our customer benefits include but are not limited to the following: technical excellence, defined, short delivery times and competitive prices combined with exceptional customer service throughout the entire product life cycle. Unquestionably, our benefits add value to the customer and optimizes their total-cost-of-ownership.

ENEMAC Maschinentechnik GmbH offers a new product line, the distance coupling EWLC. Even in difficult areas, such as medicine technology, long distant shafts have to be connected often. Distance couplings have been created in order to avoid complex and cost-intensive design work for necessary intermediate bearing arrangements. The distance coupling EWLC, with an overall length of up to 3 m, has a length-variable intermediate pipe made of stainless steel A2 or A4, which is adapted according to customer’s requirements. This pipe is connected with two metal bearings and application-specific needs of the customer. For instance, there are several combinations available for building doors which are tailored for low cogging and low back-drive-torque to protect the safety needs of our customers. Strong and environmentally-proofed solutions for farming are available, as well as, durable and quiet drives for medical applications. Undeniably, the flexibility of the drives is also appropriate for industrial applications in industrialization. Additionally, the platform offers cost savings in all applications where the lifetime of a BLDC motor is not required.

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www.buehlermotor.com

www.enemac.de
MORE SECURE LIQUID COOLING

CPC (Colder Products Company), maker of quick disconnects (QDs) designed specifically for liquid cooling use, has enhanced its LQ Series with easier to connect, more robust non-spill connectors for high-performance computing and data center applications.

“As HPC manufacturers and data center operators continue to migrate to liquid cooling for their equipment, we hear concerns about quick disconnects as a potential point of vulnerability in liquid cooling systems,” says Dennis Downs, business manager, liquid cooling. “By working with tech customers, CPC has developed quick disconnects specifically for liquid cooling applications. Our LQ Series couplings are leak free, durable enough to withstand both years of use and corrosive fluids, and easy to use in tight spaces.”

CPC’s well-known LQ2, LQ4 and LQ6 Series quick disconnects now all feature unique swivel configurations and an integrated thumb latch for easy, one-handed operation in confined spaces like the server racks of large data centers.

In addition to the swivel joints, CPC reduced the force-to-connect by more than 20 percent. The robust LQ4 and LQ6 QDs also can handle twice the original side load force and feature a 38% higher burst pressure rating than before, offering additional protection from rough handling or use.

All LQ Series quick disconnects also feature a multilobed seal for redundant protection against leakage and lasting shape retention during extended periods of connection. Multilobe seals provide greater sealing efficiency than standard O-rings while requiring less force to connect. The non-spill design allows disconnection under pressure without leaks—a critically important factor in protecting electronics from exposure to fluid and enabling hot swapping of equipment.

The upgraded LQ4 and LQ6 Series quick disconnects join the LQ2 Series, the highest-flow capacity 1/8-inch connector in the liquid cooling industry. LQ2 Series connectors offer a 22 percent better flow coefficient than other 1/8-inch connectors. Higher flow capacities reduce pressure drops by an average of 34 percent, optimizing liquid cooling system performance.

“Couplings and QDs borrowed from other industries can result in suboptimal performance,” said Downs. “Because the CPC LQ Series QDs were designed for liquid cooling specifically, they are compatible with liquid cooling solutions and resistant to valve corrosion. They’re also tested to 10,000 cycles—double that of some other connectors—so manufacturers and operators can use the LQ Series with confidence.”

www.cpcworldwide.com
Dunkermotoren offers with the modular construction kit highest flexibility for customers. That it is possible to receive drives from one source.

**Design Meets Highest Functionality**

Friday evening - in the busy hustle and bustle of afterwork traffic, everyone just wants to get home from work as quickly as possible in order to finally start the weekend with the family. This is also the case at a main intersection, where the traffic light is actually set to red. Actually.

University Hospital Emergency Room 7:35 p.m.: Traffic accident with an injured person. After the drive with the ambulance, it goes directly into the operating room. Blessing in disguise applies to the patient, who is admitted to hospital with only a few complicated bone fractures instead of life-threatening injuries. Due to his body mass index over 30, the patient is transferred to bariatric surgery. This is aimed at the treatment of overweight patients. In order to meet the increased requirements in this area, the operating rooms in bariatric surgery are specially equipped. Particular importance is attached to the robustness of the devices and the relief of personnel during manual activities. The company Getinge offers requirement-oriented solutions. 175 years of experience in the development of operating tables are reflected in these products. One of these newly developed products is the Maquet Meera operating table. It is a mobile operating table as a further development of the already established products Maquet Alphastar PRO and Maquet Betastar. During the development, Getinge incorporated the advantages of the predecessor models into the Maquet Meera product. Maquet Meera combines highest patient comfort, user friendliness and economy.

The mobile operating table doesn’t only convince by its stability and extreme mobility, but also by its design. The Maquet Meera is one of the winners of the famous if label. It won the if DESIGN AWARD 2016 in the category Medicine / Healthcare. For 60 years, the if Design Award has been considered one of the world’s most influential industrial design awards. With a maximum patient weight of 250 kg and a total load capacity of 454 kg, the operating table offers full stability and mobility. Getinge is focusing on an integrated travel drive for the implementation of mobility. To move the table, it is raised electrically. The four double castors allow the operating table maximum mobility in every direction. In combination with the sensor drive, the table with integrated travel drive can be moved precisely and steplessly - forwards and backwards. In the narrow
corridors of an operating wing, Maquet Meera offers users ergonomic and safe patient transport. Sensor Drive creates safety in the operating theatre and relieves the hospital staff because the table no longer has to be moved manually. By retracting the castors, the electrical detection sets the operating table foot completely on the ground.

The central component of the sensor drive is a motor solution from Dunkermotoren. As a manufacturer of electrical drive technology, Dunkermotoren distinguishes itself by its modular construction system. In a specification, the customer defines the requirements with regard to installation space, speed and torque for the application. With the modular system, Dunkermotoren has the option of implementing a customer-specific and economically attractive motor solution when selecting the right motor, gearbox, encoder and brake. At Getinge and the mobile drive unit, Dunkermotoren is going one step further now. Dunkermotoren becomes a system supplier who has optimized and further developed the complete drive unit together with Getinge.

The drive consists of a brushed motor GR 63 and a worm gear SG 80, a roll, springs, cylinder and other mechanical parts.

In addition to the drive combinatorics of the GR 63, a brush type DC motor and the SG 80 a worm gearbox as the basis, the scope of supplying the complete system also includes the assembly of the roller, springs, cylinders and other mechanical components. Nevertheless, the design authority of the entire assembly is still at Getinge.

The challenge in this drive unit project was to meet the increased requirements of the medical market. Such a project can only be realized with a partnership-based and cross-company cooperation with regard to qualification and validation within the various areas of responsibility. The requirement for supplier optimization in the medical market can be implemented with the expansion to a system supplier. For Getinge, the motivation is reducing the supplier base and shortening the supply chain. This significantly reduces the involved effort in supplier management for the OEM. In order to evolve from a component supplier to a system supplier, some organizational, process and production-related adjustments are necessary. Dunkermotoren has gladly accepted and implemented this challenge.

The development of Dunkermotoren to a system supplier is a completely new practical experience and knowledge. To date, the motor manufacturer has only had an insight into the technical requirements of the application. By expanding the scope of supply, Dunkermotoren can now incorporate the design and selection of the drive into the overall system at an early stage. In addition, the interface between the drive and the application can be optimized. Another positive aspect is also direct communication between the individual departments and the customer and supplier. This allows the development a reduced time of new and product optimizations to be implemented more quickly.

First positive experiences with the implementation of a project as a system supplier could be gained with the operating table Maquet Meera. Further projects are currently being implemented with well-known customers in the medical technology sector. Previously, the supplier’s focus was more on the selection of the drive in relation to the application. This has now changed with the stronger integration into the customer’s overall system. The additional information on the Maquet Meera product has led to a wider perspective and thus a better understanding of the needs of users and patients. The accident patient from obesity surgery was optimally treated with the product Maquet Meera. The flexible travel drive was an important support. As a system supplier, Dunkermotoren was also able to make a small contribution to the patient’s recovery. In the field of medical technology, Dunkermotoren has established itself in numerous fields of applications. With its existing product portfolio of brushless and brushed DC motors, AC motors and linear systems that can be combined with gearboxes, brakes and encoders, the motor manufacturer offers customer specific solutions. In addition to operating tables, MRT/CT applications, laboratory applications, pumps, X-ray applications and rehabilitation equipment are among the main applications.

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Marsi Bionics develops exoskeletons for children. Because young people are still growing, developing this type of exoskeleton is a great challenge for the skills of engineers.

A Great Leap for Little Legs

We’ve all seen them in action films, comics, and computer games: exoskeletons that give people unimagined powers and equip them with all kinds of technical tricks. Devices that support people’s motor systems do not just exist in the realm of fiction – although the real-life exemplars are not quite as spectacular as their Hollywood counterparts. They are made largely for people suffering from paralysis or muscular dystrophy.

One of the obstacles is that these technically sophisticated exoskeletons are very expensive. Whether they will eventually make wheelchairs obsolete in years or decades remains to be seen.

Because exoskeletons are usually rigid constructions that move only in the joints, they are predominantly used by adults. There is no risk that the exoskeleton will stop being a good fit. But it’s another story with children. An exoskeleton that fits a six-year old like a glove may be much too small by the time the child turns seven. An additional complication for people with muscular dystrophy is that their muscle mass decreases over time – another factor to which exoskeletons should ideally be able to respond.

This is precisely where Marsi Bionics comes in. The Spanish company was created in 2013 as a spin-off from the Centre for Automation and Robotics (CAR), a joint venture of the Spanish National Research Council CSIC, and the Technical University in Madrid. In addition to exoskeletons for adults, the product portfolio of Marsi Bionics also includes two pediatric exoskeletons called Atlas 2020 and Atlas 2030, which can be used by children from 3 years up who are suffering from a neuromuscular disease. The exoskeleton weighs 14 kilograms and can be adapted to various leg lengths and hip widths, so that it also fits teenagers up to about 14 years of age.

Mobility is retained

As a therapy device, the exoskeleton doesn’t only help children walk but can also counteract the progressive loss of mobility – a symptom of spinal muscular atrophy.
This is where another special feature of the Atlas 2030 comes into play. The exoskeleton takes advantage of the fact that children with spinal muscular atrophy are not completely paralyzed but are able to move their legs to a certain extent. The Atlas 2030 has sensors that detect weak leg movements and respond immediately to provide support. As a result, the child is able to control the exoskeleton directly with the legs.

"Atlas 2030 is an upgrade of Atlas 2020", explains Elena García, initiator and co-founder of Marsi Bionics. "The main difference is that Atlas 2020 is intended for the use in hospitals for gait training and rehabilitation, while Atlas 2030 is designed for use in private homes as an integral part of the patient’s everyday life. Both devices are ready for industrial production and will be made available commercially once they have received their CE certification marks. Until then, Atlas 2020 will continue to be used in hospitals for clinical research."

"EC flat motors provide the best power-to-weight and power-to-volume ratio", explains Elena García. "This is a variable of paramount importance, as gait exoskeletons require high power but a very low weight and volume. This is an aspect that still needs improvement."

Author: Adrian Venetz, maxon motor Switzerland, Editor

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Accurate Low Flow Pumps

The Watson-Marlow 400ST/RX pumps have been used for over five years in numerous ClampArt® devices and have achieved more than 100,000 hours of operation – still without a single pump failure.

Profil Institut für Stoffwechselforschung GmbH is a world-leading contract research institute that specialises in performing clinical trials on new diabetes medication. One of its core areas is the study of glucose clamps – complex procedures that determine the properties of newly developed insulin preparations.

After administering the blood sugar-lowering medication to a patient, a small amount of blood is continually taken over a period of up to 48 hours in order to analyse the blood sugar level minute-by-minute. Until recently, such tests had to be conducted manually, making them labour intensive and subject to problems such as inaccuracies and human error.

ClampArt is Profil’s automated glucose clamp solution. After entering a target blood sugar level known as the clamp level, ClampArt is able to control and maintain this level by administering glucose automatically. Needless to say, the method of pumping such small amounts of fluid both precisely and at very low flow rates was one of the main engineering challenges to overcome.

Selection dilemma

“The selection of a suitable pump was a big factor in the development of ClampArt,” confirms Sascha Heckermann, managing director of Profil. “Initially we experimented with several different pumps that proved unsuitable. The main problem was that glucose clamps operate with very low flow rates of only 7.5 ml/h and consequently with tube diameters of only 0.4 mm.”

None of the pumps tested originally by Profil could provide the precision needed at such low flow rates. Furthermore, the tubes could not withstand the constant, high contact pressure. That is, until the institute made an enquiry with Watson-Marlow.

Watson-Marlow recommended using its 400 series OEM pumps, which have been designed for flow rates of just 0.2 µl/min up to 2 l/min. When combined with a wide selection of pumpheads and control units, pump solutions can be configured to suit specific customer requirements.

Trio of pumps

In ClampArt, a total of three Watson-Marlow 400ST/RX pumps are deployed. The first supplies the body with a sodium chloride and heparin mixture to prevent the blood from clotting, while the second „sensor“ pump continually takes a small amount of blood from the patient. This is pumped into a mixing chamber by the third pump, where it is mixed with a hemolysis buffer and transported to the measuring unit so that the glucose concentration can be measured.

The Profil Institut für Stoffwechselforschung GmbH [institute for metabolic research] is using Watson-Marlow OEM pump technology in a newly developed medical device designed to automatically measure and control blood sugar levels in patients suffering from diabetes.
The solution involved minor customisation in that the small tube diameter of 0.4 mm meant the gap between the pump-head rollers and the track was too big. As a result, Watson-Marlow increased the roller sizes in the pumphead, making the gap the ideal size for the tubes used. This solved the problem of high contact pressure and offered the additional benefit of greater tube life.

**Successful outcome**

"Watson-Marlow gave us expert advice during the development process," confirms Sascha Heckermann. "We are very satisfied with our specially designed pump model because it supplies the low flow rates we require with the highest degree of precision."

As glucose clamps can last up to 48 hours, the pumps must work reliably. Furthermore, test patients usually remain at Profil overnight, so the pumps need to operate as quietly as possible. The pumps can also be programmed and controlled individually by means of a separate control line, while in terms of safety they operate at only 12-60V and stop automatically whenever the cover is lifted. This made it easier to obtain CE certification for ClampArt.

"After several years of research and development we have created, with ClampArt, an analysis instrument that is ready to go into production. As far as we know, there are no rival products with comparable performance in either Europe or the USA," concludes Sascha Heckermann.

"Meanwhile, a total of 28 ClampArt® devices are being used, each uses three Watson-Marlow 400ST/RX pumps*," says Sascha Heckermann. "We are absolutely impressed by the pump’s reliability. After five years and more than 100,000 operating hours, there was not a single pump failure. And not once, we had to replace a single pumphead."

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**Magnetic Self-Mating Connectors**

Magnetic connectors of Rosenberger – with self-locating and self-locking function – are ideally suited for medical and hospital environment applications: e.g. patient monitoring, communication and nurse call systems, bedside entertainment and surgical equipment such as surgical helmets and protection.

**Product features**

- Easy and fast connecting
- High number of mating cycles > 10,000
- Break-away function prevents damages by unintended disconnections
- Shock and vibration proof
- Current 500 mA up to 40 A

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www.med-eng.de
MED Components Fluidics

If liquid media are to be precisely filled in small and varying amounts in medical or laboratory technology, time-pressure dosing is often a perfectly suited flexible method.

System Platform for Time-Pressure Dosing

In contrast to mechanical pumps, there are no mechanical parts to interrupt the flow of the medium, contamination through wear particles is not a matter of concern and variable quantities can be dosed at high levels of reproducibility. Based on the principle of time-pressure dosing, Bürkert (see info box) has developed a system platform with a time-pressure dosing head (Image 1) at its core that can be quickly adapted to individual requirements. The fluid specialist provides support at every stage, from design, project planning and development all the way to final assembly and testing. In accordance with an agreed and binding time line, the overall dosing solution is supplied to users as a fully tested and certified compact unit that is ready for connection. Bürkert takes care of the complete fluid management system - from medium input to the dosing point.

Precise, fast and flexible

With time-pressure dosing, the medium is conveyed from a pressure tank (Image 2) through a valve to the dispensing needle. The tank pressure and, if required, the temperature of the medium are precisely controlled, while other process parameters, such as product viscosity, are monitored and flow resistance taken into account. The valve controls the flow of the medium by either opening or closing the stream of flow for a defined amount of time per switching cycle. High dosing speed is combined with outstanding dosing accuracy while maintaining a high level of reproducibility and repeatability. The dosing process remains flexible as delivery quantities can be varied at any time thanks to time and pressure parameters. There are no limits to what the system can do within a wide range of dosing volume from a few µl to several ml. Time-pressure dosing enables highly uniform dosing, which is very important, for example, when filling blister packs as it helps to prevent splashes that could cause problems later on when sealing the packs. The upstream fluid management system allows dosing to continue even while the pressure tank is being refilled.

Ready for Industry 4.0

Data transfer with the dosing system takes place via the device platform EDIP (efficient device integration platform), which enables intelligent networking of all electronic Bürkert devices. Integrated communication in the plant is then possible via any bus system and the course is set in terms of Industry 4.0. For example, if a tank needs to be filled, order processes...
can be initiated automatically. Pressure, temperature, filter conditions, flow and much more can also be monitored remotely, maintenance cycles are customisable and cleaning of the system is also possible automatically, minimising downtime.

Various applications

The fields of application for time-pressure dosing are broad. Examples of potential uses include filling machines in medical technology, in laboratory analysis, in pharmaceutical manufacturing, in food technology and also in the consumer sector, for example when moist or disinfectant wipes are produced.

CONTACT

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Edmund Optics –
From Design to Prototype to Volume Production

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- Trustful partner for various industries, institutions, institutes, and universities
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Edmund Optics® (EO) is a leading global manufacturer and distributor of precision optics, optical assemblies and imaging components with headquarters in the USA and manufacturing facilities in the US, Asia and Europe and sales representatives around the globe. With a portfolio of more than 30.100 products, EO has the world’s largest inventory of optical components for immediate delivery and offers products, standard or customized, in small quantities but also in volume for various industries. With a global team of experts in optical design and manufacturing, EO is ready to support your next project – from prototyping all the way to serial production. You can reach us via phone +49 (0)6131 5700-0 or by email sales@edmundoptics.de. Please also ask for our latest catalog, we are happy to send it to you, just contact us!
MED Components | Tubes

Performed since ancient times, a tracheotomy is a surgical procedure during which an opening is made into the trachea through the soft tissues of the neck. Also known as a tracheostomy, this opening into the windpipe becomes necessary, e.g. when the swallowing reflex is impaired or long-term ventilation is necessary after accidents or operations, during radiation treatment of the head or neck, larynx palsy or full removal of the larynx (laryngectomy).

These procedures lead to the loss of the function of the upper airways such as filtering, warming and moistening breathing air through to voice loss and extreme limitations in terms of the senses of smell and taste. Tracheostomy tubes and speaking aids are absolutely essential and for which the professional industry offers an extensive range of ultra-modern tubes and aids optimally tailored to the respective demands and requirements of each individual patient, which are distinctive in terms of function, material, design and accessories – in line with defined requirement profiles.

Most tube wearers can benefit from tracheal tubes made from lightweight, soft plastic material as these lead to less irritation of the sensitive tracheal mucus membranes and less mechanical irritation of the tracheostoma, but also because metal tubes may not be inserted during radiotherapy. Reflections on the tracheostomy tubes could prevent the calculated radiation dose from being applied or they can cause uncontrolled radiation exposure through to burns of healthy tissue.

As in many areas of medical technology, most plastic-based tracheostomy tubes are manufactured from PVC. But criticism of this material is not letting up and an increasing number of customers are requesting solutions which are free of PVC and plasticizers from manufacturers of medical technology.

This request leads to the material group of thermoplastic elastomers (TPE), such as the PROVAMED® TPE from Actega DS, whose good processability makes them ideal for all conventional injection-molding and extrusion plants but also on account of their very low emissions, reusability and cost effectiveness. Furthermore, they can be sterilized, are conformant with the FDA, ISO and USP classes, and display very good sealing and adhesion properties. Features which are helpful or even necessary when it comes to manufacturing tracheostomy tubes.

Tracheostomy tubes are typically manufactured in extrusion or injection-molding processes. Their material properties need to be adapted accordingly. Extrusion requires exact setting of the material flow properties to the processing method while injection-molding offers the possibility of manufacturing the tracheostomy tubes and neck flange in a single step. Multi-component injection-molding enables economic manufacturing of multiple components such as a connector made from a thermoplastic and the soft components made using TPE. This is particularly applicable when the material’s adhesion properties need to comply with the connector material, thereby requiring optimization. PROVAMED® TPE display perfect adhesion to polystyrene and ABS.

Another area of focus is represented by solvent bondability. Micro-tubes are often inserted through the neck flange, e.g. in the case of transporting air to the cuff (inflatable sleeve at the lower end of the endotracheal tube or a tracheostomy tube for sealing the space between the tube and the tracheal wall) or for optional secretion removal, whereby the micro-tubes need to be bonded to the outer tubes. Conventional solvents are used for this. Here, too, an excellent solution has been found for the PROVAMED® portfolio. One which has been examined in an extensive range of tests featuring frequently used solvents.

Manufacture and printing (this printing capability also needs to be considered when developing the plastic material) are followed by sterilization, usually with E10 or Gamma. TPE can display their particular advantages as only minimal changes in terms of mechanics and optics can be ascertained after sterilization, even after 50 kGy Gamma sterilization.

While metal tubes are offered with thin walls which are rigid and have a comparably large inner volume, silicone and plastic tubes featuring thicker walls minimally limit inner volume and are distinguished by a high degree of wearing comfort and lighter weight.

While metal or plastics, TPE or PVC - an increasing number of customers are requesting material solutions which are free of PVC and plasticizers.

According to the German Federal Statistical Office, 55000 tracheotomies and 1,300 laryngectomies are carried out annually therefore 40000 patients receive tracheostoma care provided by specialized homecare experts.

TPE for Tracheostomy Tubes

www.actega.com/ds
congatec AG

congatec AG has its head office in Deggendorf, Germany and is a leading supplier of industrial computer modules using the standard form factors COM Express, Qseven and SMARC as well as single board computers and embedded design services. congatec’s products can be used in a variety of industries and applications, such as industrial automation, medical, entertainment, transportation, telecommunication, test & measurement and point-of-sale. Core knowledge and technical know-how includes unique extended BIOS features as well as comprehensive driver and board support packages. Following the design-in phase, customers are given support via extensive product lifecycle management. The company’s products are manufactured by specialist service providers in accordance with modern quality standards.

Since the company’s inception in December 2004, congatec AG has established itself as a globally recognized expert and reliable partner for embedded computer-on-modules solutions, coupled with excellent service and support. We have secured second ranking worldwide in our market segment thanks to our clear focus.

congatec’s Computer-on-Module platforms with their widely scalable computing and graphics performance enable the creation of application-ready, widely usable products. The quality and durability of the modules, in combination with their excellent EMI characteristics reduce cost of development, service and certification.

congatec is represented with more than 240 employees at eight branch offices on four continents in Taiwan, Japan, China, USA, Australia, Czech Republic, United Kingdom and France.

This consistent expansion together with our strong partner network secures close customer relationships on a worldwide base. We continue to focus on efficiency enhancement through optimizing processes and structures in the future. Through close co-operation with our technology partners Intel, AMD and NXP, congatec continues to prove its leading position in technology and product innovations. In addition to our successful Computer-On-Modules products, we also offer Single Board Computers and embedded Design Services to fulfill the special requirements for our customers.

Services to Speed Up the Design Process:
- Design Guides with In-depth Best Practice Solutions
- Reference Schematics as High Level Starting Point for Own Designs
- Component Selection based on Functionality, Cost, Availability, ...
- Signal Integrity Simulation to allow for Layout Improvements
- Schematic Review to Identify Problems Early
- Layout Review and Best Practice Advice
- BIOS/UEFI/Firmware Customization
- Bring-Up Support to Bring Life to the First Prototypes Quickly

Validation Phase Services:
- Signal Integrity Compliance Measurements up to 36 GHz
- Optimized Cooling Solutions featuring Heat Pipes and Vapor Chambers
- Handling of Manufacturing and Logistics Requirements
- Engineering Support to Optimize the Design to Meet EMC Requirements
- MTBF Reliability Calculations

“We simplify the use of embedded technology.” This is the congatec commitment. It’s not just the products – it’s also the people at congatec which work hard to perform this promise. congatec is the right partner when it comes to embedded computing solutions.

www.congatec.com
Aluminium profile enclosures are used in many different industries. Through their enclosure design they have numerous positive characteristics, such as durability, enormous stability, good heat dissipation and electrical conductivity. With the new SMART-TERMINAL, OKW Gehäusesysteme offers an elegant, flexible and robust aluminium profile enclosure in its standard product programme. A uniform profile cross-section with variable length design as well as matching accessories allow a flexible variety of applications as a table-top, desk-top or wall-mounted enclosure.

Robustness and elegance

The SMART-TERMINAL range of enclosures has a robust enclosure body made of anodised, polished aluminium. The enclosures consist of a C-shaped base profile, a bottom profile as well as end caps. The material selected for the basic body of the SMART-TERMINAL makes it particularly scratch and impact-resistant. It also offers optimum heat dissipation. The top part includes a recessed area to protect membrane keypads/ decor foils and flat lateral interface surfaces. There is sufficient space here for operating elements, switches or displays. In order to close the enclosure from below, the flat bottom profile is fixed using 6 stainless steel Torx screws. Protection from splashing and dust has also been provided. The assembly kit contains not only the screws but also a round-cord seal as well as sealing rings. On the open profile sides, the SMART-TERMINALs are closed with covers made of high-quality UV-resistant ASA+PC-FR material in the colour lava.

Sophisticated extruded aluminium enclosures for central control units

This design provides particularly good accessibility during installation and assembly work. For the covers there are separate designer seals made of TPV material in the colours volcano or green (RAL 6016). Interfaces such as plugs and connections are also possible through the plastic parts. These have a recessed interface level and also conceal the connections. Alternatively, mechanical processing of the aluminium body is possible, as it offers enough room, for example, for cable bushings or for USB connectors and SD cards.
Choosing the right fluid connector and the right connector partner.

At CPC we know that fluid connectors need to be considered early in the process in order to fulfill product performance and patient safety objectives.

Because the connector is usually the user’s primary interface with the device, it plays a key role in the overall perception of the design. Reliable, well-designed connectors from CPC make medical devices easy-to-use and enhance overall customer satisfaction.

**Cleaner, faster, and safer.**

CPC quick disconnect couplings make medical device connections cleaner, faster and most important, safer. Whether your application calls for non-valved or non-spill, low flow or high flow, reusable or disposable, our broad range of standard (including a complete line of small-bore connections, fittings, and luers) and custom-engineered components can meet your every specification.

**Cold/Compression Therapy**

**Dialysis**

**IVD**

**Patient Monitoring**

**Surgical**

**Extracorporeal Treatments**

**Aesthetic Medicine**

**And more**

**About CPC**

CPC has more than 400 employees, with operations in St. Paul, MN, Germany and China; sales offices in ten countries and more than 200 distributor partners around the globe. CPC has engineered and produced highly tested standard and custom solutions to meet fluid handling challenges worldwide.

Ideal for display/touch solutions

The complete enclosures are available with profiles in the dimensions of 170 x 50 mm (width x height) and in the profile lengths of 160 mm, 200 mm and 240 mm. With the covers, the length of each version increases by 42 mm. The sizes were designed for standard display and touch solutions from 4.3" up to a maximum of 8". The 200 mm SMART-TERMINAL, for example, is ideal for a 7", touch solution, as there is a border here of approx. 15 mm around the recess for gluing. The inside of the enclosure has several mounting options on 2 assembly levels. The displays and PCBs can thus be optionally mounted face up or face down. In addition, the bottom part has two grooves for attaching accessories.

Optional accessories are ideal for rounding off the range of enclosures. For example, optimum operation is guaranteed by an enclosure canting kit in landscape format. Thanks to the 12° inclination, data can easily be processed and analysed. The kit contains two plastic brackets and is simply pushed into the existing groove in the bottom profile and automatically fixed in place by the side covers. The black non-slip enclosure feet included with the enclosure canting kit ensure safe use as a desk-top version.

A wide variety of possible applications

However, a solution for wall mounting is also guaranteed. In this case, the enclosure can simply be installed in landscape format with the optional wall suspension element, which includes a wall bracket as well as a tongue and anti-slip pads. The wall suspension element is simply screwed. Anti-slip pads are then glued on to prevent the enclosure from being pushed to the side.

The SMART-TERMINAL is hung onto the wall suspension element, the tongue on the lower rear side of the enclosure is hoo-
ked into the centre and secured by a screw. The housing is now correctly fixed in place and hangs flat against the wall. As alternatives to the covers made of plastic, aluminium panels are available to close the sides of the enclosures. The panel is mounted on the body of the enclosure using 4 screws. In this version with end plates, the three profile lengths are each 4 mm longer (42 mm with plastic end covers). With a set of square-head nuts, which is also available, PCB and mounting plates can be attached to the bottom profile with M3 screws. The square-head nuts can be positioned anywhere within the T-grooves provided. The existing range of accessories makes the SMART-TERMINAL into a versatile table-top, desk-top or wall-mounted enclosure.

Individual finishing

In order to allow the SMART-TERMINAL to meet customer-specific requirements, there are different processing and finishing technologies to choose from. Since we have our own Service Center, the enclosures can be modified to your liking. The options include, among other things, mechanical machining for interfaces, individual lettering and printing, or the manufacture and installation of digital printing foils. If you wish an individual design, the designer seals and covers can, on request, be produced in a different colour. Customer-specific profile lengths are also possible.

Product advantages in brief:

+ 3 basic enclosures in the profile lengths 160, 200 and 240 mm (overall enclosure length with end covers + 42 mm), width 170 mm, height 50 mm.
+ Covers in lava (similar to anthracite) moulded in high-quality ASA+PC-FR plastic.
+ Designer seals made of TPV material in volcano or green.
+ Recessed area in top for the installation/ protection of displays, membrane keypads, operating elements.
+ Optional accessories: wall suspension element, case canting kit, set of square-head nuts for PCB mounting.
+ Individual profile lengths to customer specification.

THE ADVANTAGE OF PROFILE ENCLOSURES: THE LENGTHS ARE VARIABLE

OKW extruded aluminium enclosures are used particularly as high-quality enclosure solutions for demanding applications. Choose the enclosure whose design and size meets your own special requirements. The extruded aluminium profiles are available in special lengths on request.

All extruded aluminium enclosures offer a high degree of stability and good heat dissipation, as well as a high-quality appearance thanks to a matt anodised finish in conjunction with attractive end element plastic parts plastic end panels.
Maintenance-free low cost linear systems with predictable service life are used in medical technology for the benefit of the patients.

Lubrication-free Linear Guides

Special requirements are placed on individual components in medical technology. Be it the suitability of materials for cleaning in an autoclave or the minimum installation space of functional elements in laboratory equipment. With the drylin linear guides, the motion plastics specialist igus offers lubrication-free and maintenance-free systems for just such requirements. Whether anti-magnetic, extremely compact and robust - the high performance values and the variable application possibilities of modern linear guides from igus lead to ever new innovations. Whether anti-magnetic, extremely compact and robust - the high performance values and the variable application possibilities of modern linear guides from igus lead to ever new innovations. Whether anti-magnetic, extremely compact and robust - the high performance values and the variable application possibilities of modern linear guides from igus lead to ever new innovations. Whether anti-magnetic, extremely compact and robust - the high performance values and the variable application possibilities of modern linear guides from igus lead to ever new innovations.

In linear technology, as with all bearings, a distinction is made between two types according to the principle of action: the plain bearings and the roller bearings. The latter are often named after the main representative of their group, the ball bearings. Thanks to the innovative iglidur high-performance plastics, plain bearings today offer the possibility of being able to do without lubrication completely. Therefore, they are particularly suitable for applications in medical technology, as contamination is avoided by using the iglidur plain bearings. Sliding elements and running partners made of tribo-plastics exhibit optimum wear and friction properties. In contrast to metallic bearings, which are susceptible to corrosion and must be constantly oiled or greased, plastic bearings are universally applicable. They are equally resistant to moisture and heat. Equipped with polymer plain bearings, applications in medical technology benefit from the high, online calculable service life and the very low friction coefficients of plastics. Costly downtime due to maintenance or failure of the devices is eliminated.

Solid lubricants make plain bearings lubrication-free

One of the main reasons for the wide range of possible uses of igus products is the thermoplastic material iglidur, which provides the stable matrix as a base in the plain bearings. Reinforcement fibres are usually embedded in this to increase the compressive strength. In addition, there are solid lubricants, which are situated in tiny chambers millions of times. As soon as the bearing or shaft starts to move, each of them lubricates its immediate environment on the surface. Thus there is no lubrication that can be pushed away under load, which is one of the major differences to traditional recirculating ball bearings. The drylin linear systems mounted with liners offer design advantages over competing products. For example, only igus offers sliding elements with integrated dirt channels, which push away the dirt.
particles from the slide-way and conduct them through the bearing. Thus there is no pressure build-up in front of the bearing. In case of extreme dirt accumulation and increased wear, the liners can be replaced easily and cost-effectively.

Linear plain bearings predestined for sensitive applications

Due to their range of services, maintenance-free and lubrication-free linear plain bearings from the igus' drylin range are already used in numerous medical technology applications. „Complete linear and lead screw units are used in hygienically sensitive areas, such as in already installed devices for in-vitro diagnostics and guarantee a clean and safe drive, which allows even high speeds with minimal noise,“ says Ulf Hottung, industry manager for medical technology at igus. For example, the low profile guide system drylin N is widely used in medical assistance and X-ray systems. A new curved drylin W rail, which is based on the drylin W modular system from igus, offers developers in medical technology the freedom to implement different radii. In the product range, igus also supplies dryspin high helix lead screws made of non-magnetic, coated aluminium. Their use is particularly useful in applications in the field of MRI systems, as well as in operating table accessories, which must be easy to move by hand and must be easy to clean.

Stainless steel as a hygienic solution for medical technology

The company igus offers a selection of its linear systems in its range in aluminium as well as stainless steel. Under the name of drylin SHT, the motion plastics specialist offers lead screw linear units for very precise and silent adjustments whilst also being robust. To expand its range, igus is now also offering an option made of stainless steel. From the lead screw modules shafts and carriages up to the shaft end supports, all existing components are entirely made of 316 stainless steel. The moving parts are mounted using tribo-optimised plastics. For example, users can choose between the heat-resistant problem solver iglidur X and the food-grade material iglidur A180 for use in pharmaceutical technology. Stainless steel offers the advantage that it is corrosion-resistant and permanently resistant to chemicals such as disinfectants and cleaning agents, yet withstands mechanical stresses. The smooth surface of stainless steel also ensures that no bacteria settle in the material. In addition, it is easy to clean and thus meets the highest hygienic standards.

Variety made easy with the drylin SHT online configurator

The new lead screw module is available in four different installation sizes. For the thread, users can choose between self-locking trapezoidal and high-speed high helix thread. „To keep an overview of all these options and to find the best combination in every case, customers can now access the new drylin SHT configurator,“ explains Stefan Niermann, head of the drylin linear and drive technology business unit at igus. „The handy online tool cuts short the selection, configuration and ordering of the lead screw module to a few mouse clicks.“

Stainless steel offers the advantage that it is corrosion-resistant and permanently resistant to chemicals such as disinfectants and cleaning agents, yet withstands mechanical stresses. The smooth surface of stainless steel also ensures that no bacteria settle in the material. In addition, it is easy to clean and thus meets the highest hygienic standards.

With the new drylin SHT configurator, customers can configure their individual lead screw modules in just a few steps, and receive among other things a 3D view, a dimensioned technical PDF drawing, and a 3D CAD model.

After the selection, users receive an exact documentation of their selection as well as a 3D view of their configured lead screw module and are shown the price and delivery time directly before they are forwarded to the shopping-basket. For tougher environments of medical technology, igus is currently developing a version of the drylin SHT-ES made from extremely corrosion-free and acid-resistant V4A.
Radiologists confirm that more realistic and detailed images would help to improve their work. Their daily task is to compare images on workstations with mostly three to six monitors, looking for anomalies in order to make a diagnosis. Radiology displays therefore significantly influence the quality and efficiency of care. Recent developments have made new breakthrough solutions possible, such as Barco’s largest diagnostic display form factor. It impresses with an extremely high resolution and its size more or less equals a radiologist’s natural field of vision, so no additional monitors are needed. The concept of using a single display for all image data is suitable for all reading environments – from standard X-rays to digital mammograms.

Greater productivity and ergonomics

The new display provides a 33-inch screen and 12 megapixel resolution. Removing the need for multiple single-function displays, the system can render high-quality grayscale images as well as calibrated color and fused modalities – including 2D/3D and static/dynamic imaging features. Thanks to the extremely bright display even the smallest details are highlighted, which supports a particularly accurate diagnosis.

Professional AMD graphics inside

Barco uses AMD graphics technology for its powerful single-monitor solution. The Coronis Uniti® diagnostic system includes an AMD FirePro™ graphics unit with a custom Barco driver to provide an impressive 30-bit color depth, which yields four times more shades per color channel (red, green, and blue) than conventional 8-bit technology. As a result, displays can render colors much more realistically; images can reflect reality more accurately; diagnostics can be accelerated and diagnostic errors avoided even better. The professional AMD FirePro graphics cards make it possible to efficiently render even compute-intensive tasks, including 3D imaging. This is because they integrate professional graphics units that provide ultra-high geometry performance and smooth handling of complex models.

One for all

The Coronis Uniti is the first diagnostic display that can be used for both PACS (picture archiving and communication system) and breast imaging for mammograms. It eliminates all the usual multi-display configurations. It also solves the problem of doctors having to switch to another workstation to view other exam results. Thanks to its high brightness, radiologists can even use the display as a light box to view and compare older analog X-ray film. In the past, radiologists first had to place the images on a wall-mounted X-ray film viewer, study them and then go back to compare them to the current digital X-ray image on the monitor. With the Coronis Uniti, radiolo-
gists can now attach the film to the display for a direct comparison, which both improves ergonomics and makes the workflow more efficient.

**Further ergonomic benefits**

The „one for all“ monitor approach also yields ergonomic benefits that protect doctors’ eyes and necks. Looking from one monitor to another to view different medical image types and formats doesn’t adversely affect workplace ergonomics or eyes as such. However, if the monitors are positioned in such a way that the head looks sideways in one direction for an extended period of time, rather than directing the gaze straight ahead, this can cause stiffening in the neck. What is more, doctors can focus better and work more efficiently when everything is displayed on one monitor. This prevents fatigue from concentrating on repeated movements that are irrelevant to the actual diagnosis and can have a distracting effect.

**Spotlight on doctors’ needs**

For radiologists to achieve even more accurate results, they need specific functionalities that enable them to do their job better. For this purpose, Barco has also addressed some image visualization issues that the company identified during discussions with doctors and from observing the day-to-day clinical environment. The outcome was the development of the SpotView™ diagnostic function. When activated, nearly the entire display is dimmed, except for a specific area where the pixels are brightened and the contrast is increased to reveal more detail. For many medical specialists, this fulfills another wish they have had for decades: A clear view of the diagnostic situation without clouding other image information.

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- Intelligent PowerSharing
- Battery start function
- Integrated reboot function
- Interfaces USB, RS232, I²C
- Open-frame version **UPSI**
- DIN-Rail version **UPSI-D**

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Large diagnostic displays with extremely high resolutions use a radiologist’s full field of vision and can replace installations with multiple monitors.
Accurate Targeting with Stereotactic Ablation

For non-resectable tumors in the liver and other organs, percutaneous tumor ablation can be an option to consider. An ablation probe is placed through the skin in the tumor and tumor cells are locally destroyed by heating, cooling, radiation or electrical pulses. It has been shown that these treatments prolong the survival of patients compared to chemotherapy. However, clinical studies also show a large variance in the treatment outcomes achieved and the resulting benefit for patients. Therefore, although percutaneous ablation has been available for years, it has not been fully established in clinical treatment guidelines and is not currently available to all patients who may benefit.

The challenges to achieve reliable tumor ablation lie in the exact positioning of ablation instruments and in the controlled release of energy to destroy a target area (tumor + safety margin). In clinical practice, needles are currently placed under ultrasound and computer tomography (CT) imaging. This allows to control the needle position, but offers only limited possibilities for needle planning and guidance. Interventional navigation systems allow the planned needle path and treatment area to be planned prior to surgery, and needle placement to be performed using instrument guidance. Clinical studies show that this workflow is designed to achieve a higher positioning accuracy and that planning reduces the duration of the procedure. The energy output during ablation is planned on the basis of the manufacturer’s specifications for the various ablation systems. However, as the currently achieved treatment areas can vary greatly due to tissue properties and cooling effects by blood vessels, ablation control during the procedure and, if necessary, post-ablation is required. Image fusion solutions enable a comparison between the tumor area before the procedure and the ablation zone achieved and can thus be used to assess the quality of the treatment.

With CAS-One IR, CAScination has developed an interventional navigation system for ablation treatment that addresses the challenges described above in order to enable more reliable tumor ablations. The aim is to establish tumor ablation as a safe and efficient treatment method for irresectable tumors. CAS-One IR supports interventional radiology in all steps from treatment planning to needle placement, treatment control, post ablation and documentation of the intervention. The navigation system is based on a stereo optical camera which can determine the position of instruments and optical markers on the patient. The markers on the patient are used to compare the patient’s position with the image data recorded during the procedure. In addition, the markers record the patient’s respiratory movement, as this leads to internal organ movement, which influences the accuracy of the navigation. During the procedure, the physician uses a touch screen to create a treatment plan for the needle path, target area and the intended treatment zone in 2D and 3D and to optimize possible treatment options (Fig. 1).

After planning, needle placement is performed using a stereotactic navigation system and an aiming device. The navigation software calculates the planned needle position relative to the patient and assists the physician in aligning the aiming device with the needle path. The needle is then positioned with the aiming device and under breathing control using optical markers. In order to exclude any needle bending and organ movement during needle placement, a control image is taken and

Figure 1: Set up of the CAS-One IR navigation system in the intervention room and intervention planning on the touch screen by the physician.
superimposed with the planned needle path. Once the exact needle placement has been confirmed, ablation is being performed and another control image is taken. By merging the second control image with the image before the intervention, the treatment area can be displayed in relation to the tumor. This allows a treatment control during the intervention (Fig. 2).

After the procedure, the navigation system can be used to create treatment documentation and make it available to referring physicians and patients alike. CAScination’s stereotactic tumor ablation is currently in use in 30 centers in Europe and India and over 2000 patients have been treated with the solution. Current developments include the treatment of complex tumors, difficult-to-reach sites and larger areas that are difficult to treat with conventional ablation. Stereotactic ablation has shown in certain indications that treatment results are equivalent to surgery but they can be achieved with a shorter and significantly less invasive procedure. As a result, patients recover faster and valuable resources in hospitals and healthcare systems can be preserved.

The CAScination AG team is working on the application of stereotactic navigation and robotic precision surgery for other areas of application and aims to treat patients more reliably, gently and efficiently in various areas using minimally invasive procedures.

Figure 2: Result of image fusion after ablation treatment. The treatment zone achieved is shown in the CT image as a dark grey area. By means of image fusion the tumor of the preoperative image is displayed in red, the desired ablation zone is shown in orange. The physician can see, that a sufficiently large treatment zone has been achieved.

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Cameras for the OR

To date, camera systems in the OR have mainly been used for documentation and training purposes. But thanks to the latest technologies, their field of application is constantly developing – culminating into a turning point in medicine: Artificial intelligence (AI). This means computer-aided systems which can derive precise information about the patient’s status and suggest treatment options – and thus assist physicians in decision-making. The prerequisite for this are ultra-high resolution images.

For this reason, SIMEON Medical, a solution provider for hospitals with a focus on operating and examination rooms, has developed the groundbreaking Sim.CAM camera system – and is the world’s first supplier of a medical 4K camera solution.

“In general, the interaction and networking of products, processes and systems are becoming more and more important in the operating room,” says Tobias Mager, Head of Product Management at SIMEON Medical. “We want to stay abreast of future trends with our manufacturing technologies and product developments. For instance, our HD and 4K cameras for the OR can be integrated into any current OR LED light from the SIMEON HighLine or Business-Line series. This way, we form the basis for the future support of systems with artificial intelligence which evaluate high-resolution images to and in diagnosis or treatment decisions.”

All camera functions, such as 20x optical and 12x digital zoom, image alignment (>360°, mechanical and electronic) are flexibly and independently adjustable directly on the wall control unit or using a remote control. The camera’s visual data are easy to integrate into any hospital information management system by way of a standard interface to the IT system. SIMEON cameras can be linked to any AI or vision support suppliers and thus offer maximum flexibility.

Far-sighted development

The requirements for OR cameras in medicine are very strict. In addition to user-friendliness and reliability, hospitals place great value on sustainable investments and durable devices. “We pay special attention to integration and retrofitability when we develop new products,” reports Mager. For instance, since the beginning of 2018 every OR LED light from the medical technology company out of Tuttlingen, Germany, is ca-
mera-ready. This means that the lights can be retrofitted and upgraded without great effort – for instance, with the latest 4K-wireless camera generation, which is available as of 2019.

User-friendliness and flexible operation

The intuitive and safe handling of devices is an important factor in the OR. After all, the OR personnel has to be able to act quickly in hectic situations or emergencies. That’s why SIMEON Medical pays special attention to user-friendliness when developing OR accessories – including with its cameras. Safety is only guaranteed if everyone can use the camera safely and intuitively. So all cameras have the same operating functions to ensure clear, uniform and above all intuitive operation. This also means that the same remote control / wall control unit can be used in each case.

Development also focused on flexible and intuitive operability which enables both manual and electronic image alignment. This makes SIMEON Medical the only manufacturer whose cameras can be turned and rotated both mechanically as well as electronically. This is made possible by the camera’s unique design. The camera is in a moveable housing with a sterile handle for manual rotation and is very easy to turn without force. At the same time, the camera has an electronic operation option: An electric motor in the camera enables rotation via remote control or wall control unit.

Secure data transmission

SIMEON uses camera modules from the world market leader Sony for its medical cameras. Like with the Sim.CAM 4K wireless, data is transmitted by way of an algorithm for sending and receiving data specially developed by SIMEON. The image material is transferred by radio at 60 gigahertz from the camera to the receiver, for instance on a monitor. The camera is operated and controlled via remote control with infrared. Moreover, the cameras can also send to multiple recipients, as long as they are coupled to one another: for instance, multiple monitors or receiver devices within the OR which forward the signal to the hospital’s network. Image data can be transferred over a distance of approx. 20 to 25 meters. The algorithm also ensures absolute data security, since the data can only be transmitted between the coupled transmitter and its receivers. In times of heightened data protection, this is an extremely important criterion.

Camera technology in medicine will also be continuing to develop over the coming years. It is already technically possible to produce 8K cameras, and their use in the field of medicine is being researched. 8K cameras also mean much larger data volumes which require suitable medical monitors, recorders, etc... SIMEON Medical has already aimed its innovation and development process at new trends such as digitalization and artificial intelligence. For instance, the Sim.CAM 4K wireless supplies the necessary image quality and data transmission for diagnostic procedures which use artificial intelligence in order to provide diagnostic and treatment support in coordination with natural human intelligence. A standard interface for digital communication does not yet exist in general, however. That’s why SIMEON Medical is participating in the OR.NET initiative. The aim of the project is the development of strategies for a manufacturer-independent, real-time, dynamic networking of medical devices in the operating room.

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Bioelectronic Medicine - Promises and Challenges

Bioelectronic micro implants are already being used for a wide variety of clinical applications. The devices which are sometimes only a few millimeters in size can electrically stimulate the nervous system locally via microscopically small electrodes and thus can be used to treat for example chronic pain, migraine or depression.

Retina Implant AG in Reutlingen develops sub retinal implants that partially restore functional vision to patients suffering from retinal degeneration and blindness. This is achieved with a tiny microchip implanted under the retina, similar to a camera. Although the implant cannot enable colour vision, grey scales are nevertheless distinguishable and help with orientation by recognizing contours. This gives patients back some freedom and thus quality of life.

A research consortium consisting of four institutes of the Baden-Württemberg Innovation Alliance (innBW), with the Natural and Medical Sciences Institute (NMI) in Reutlingen, the Hahn-Schickard Institutes in Villingen-Schwenningen and Stuttgart and the Institute for Microelectronics in Stuttgart (IMS CHIPS), is focusing on the widespread disease of diabetes. In the current project „innBW Implant“ electrical stimulation of the pancreas is applied using foil-based flexible electrodes to technically restore the control loop between the blood sugar level and insulin secretion which is disturbed in diabetes patients. This technology would ultimately make the administration of drugs redundant.

These so-called „electroceuticals“, in distinction to chemically active pharmaceuticals, can potentially replace pharmaceutical drugs without side effects through targeted stimulation of the peripheral nervous system. They are increasingly becoming a serious treatment alternative with regard to the challenges of an ageing population and the associated increase in chronic diseases.
At the University of Freiburg, in particular in Prof. Dr. Thomas Stieglitz’ group for Biomedical Microtechnology at the Department of Microsystems Engineering (IMTEK), intensive research is carried out on these topics as well. This has already led to the establishment of several successful companies. As one of them CorTec GmbH is developing a novel responsive brain pacemaker technology. The high channel closed loop system CorTec Brain Interchange is able to measure brain activity and influence it individually by electrical stimulation. This technology can be used, for example, for epilepsy, brain tumors and paralysis.

About a quarter of Germans suffer from high blood pressure. Many patients do not achieve a permanent reduction in their blood pressure despite medication. Researchers around the world are therefore looking for alternative treatment methods for this widespread disease. neuroloop GmbH, also a spin-off of the IMTEK and the University Hospital Freiburg, developed the neurostimulator „Baroloop“ for this purpose. A novel thin-film electrode is implanted around the vagus nerve and causes it to report excessively high blood pressure values to the brain. Through this „trick“ the patient’s blood pressure is reduced. A recently published study by “brand eins Wissen and Statista“ lists both Retina Implant and CorTec among the 16 companies that receive the „Innovator 2018“ label in the medical technology sector. This illustrates the enormous innovative strength of this well-connected region in southwestern Germany.

The federal state, the federal government and the European Union are well aware of the versatile opportunities that these technologies offer, as there are numerous and highly endowed funding programs set up to provide support. Nevertheless, so far only a few products have reached the market. There are many reasons for this. First of all, there are only a few funding possibilities for bringing these technologies and products from the research stage into clinical testing, once they have reached a certain degree of maturity. Private venture capital is heavily needed here, but, unlike in the USA, it is not sufficiently available in Europe. Additionally last year the regulations for the approval of medical devices in the EU were considerably tightened by the new Medical Devices Regulation (MDR). This leads to great uncertainty, especially for small companies, as the approval procedure will become even more time-consuming and cost-intensive than before. At the same time, the hurdle to obtaining reimbursement for such high-tech products from the health insurance funds is extremely high. Many expensive clinical studies are required in order to clearly prove the effectiveness of the therapy. Of course, all this serves the safety of the patients, but for many patients it prolongs their suffering without adequate alternative therapies.

The expert group on „Intelligent Implants“ of microTEC Südwest e.V. has set itself the goal of tackling these hurdles together. Here, a network of companies and institutes with proven expertise in the development, manufacturing and marketing of active implants and components has come together to expand its technological leadership in Europe. The members and guests of this expert group meet on a regular basis for exchange and discussions and to initiate collaborative projects. This group is organized by microTEC Südwest, the professional association and leading-edge cluster for microsystems technology in Freiburg, which was awarded as one of 15 so called leading-edge clusters in Germany. Guests are always welcome to join the group and convince themselves of the added value.

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OLEDs are weak in light, short-lived and unreliable – these are common prejudices against this technology. This may be true of about displays made 15 years ago, but the technology has evolved since then.

Don't be Afraid of OLED!

Since large-area OLED displays can be manufactured efficiently and are commercially available, this technology has also moved into the consciousness of electronics market customers.

What does OLED mean? The abbreviation stands for „Organic Light Emitting Device“. „Organic“ refers to the materials that contribute to the function of the display - they are materials of organic chemistry. In contrast, TFTs are based on semiconductor materials of inorganic chemistry. In the following, the generic term „LCD“ will stand for all liquid crystal technologies. In addition, only passive displays are considered, i.e. those where the picture element switches by applying a voltage alone and where a transistor is not involved as an active component, as is the case with TFFs.

Basic differences to LCD

LCDs act as a valve for existing light, which usually comes from a light source behind the display. The transparency of all layers is well below 10%, which means that 90% of the light is lost. Figure 1 shows a comparison of the typical parameters of two equivalent modules in OLED and TFT technology.

OLED and LCD compared

OLEDs do not require a backlight and are therefore thinner than LCDs. While the power consumption for LCD is mainly determined by the backlight and is constant, in OLED only the actively illuminating picture elements consume power. OLEDs have a wide viewing angle of almost 180° with no colour deviation or loss of contrast. OLEDs with their luminous materials achieve a large colour gamut (see Figure 2). Their contrast is very high, since in dark areas no background illuminated by the backlight shines through. The technology allows a wide temperature range.

Implementations

Only „low end“ applications require segmented displays. The most versatile applications are offered by OLED dot matrix displays. They are available in various (monochrome) colours such as yellow, green, blue-green, orange, white, red and blue. If two dyes are applied next to each other on the same substrate, two screen areas with different colours can be displayed using the „Area Colour“ effect.

Figure 3 shows monochrome displays in different colour designs, clockwise from top left green, yellow, orange, blue-green and white in the centre.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>OLED WiseChip UG-2828GDEDF11</th>
<th>TFT Startek KD014QTBND01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>1.54“ full colour, 128 × 128</td>
<td>1.44“ full colour, 128 × 128</td>
</tr>
<tr>
<td>Power Consumption</td>
<td>Total −300 mW (90 cd/m²)</td>
<td>Total −68 mW (140 cd/m²)</td>
</tr>
<tr>
<td>50% Checker Board Logic</td>
<td>2.8 Y × 240 µA = 0.57 mW</td>
<td>3.3 Y × 1.2 mA = 3.96 mW</td>
</tr>
<tr>
<td>Display</td>
<td>13 V × 23.3 mA = 300 mW</td>
<td>Backlight 3.2 V × 20 mA = 64 mW</td>
</tr>
<tr>
<td>Contrast</td>
<td>10,000:1</td>
<td>700:1</td>
</tr>
<tr>
<td>Viewing Angle° (LRUD)</td>
<td>180 all around</td>
<td>60/60/30/60</td>
</tr>
<tr>
<td>Temperature Te°</td>
<td>−40...+70°C</td>
<td>−40...+70°C</td>
</tr>
</tbody>
</table>

Figure 1: Comparison of OLED and TFT specifications

Figure 2: Comparison of OLED and TFT colour spaces
If you arrange three basic colours in strip form as with TFT, you get a colour display that can display thousands of different colour tones by combining them.

Are OLED dark?

When studying a data sheet, it is noticeable that the indicated brightness is rather low compared to TFT: depending on the colour, it lies between 80 and 150 cd/m². To conclude from this that OLEDs are difficult to read is not correct: the readability depends on the contrast, i.e. the ratio between light (pixel switched on) and dark (background). The background of OLEDs is very dark, because no backlight shines through from behind. Unlike TFT, OLEDs do not need a polarizing filter for their function, but they can increase contrast by eliminating reflections from the incident light. Absolutely high brightness is not necessary for reading. Examples include sports watches with heart rate monitors that can also be read outdoors at high brightness levels.
Life expectancy

The service life of OLEDs is defined in the same way as that of TFTs: it describes the time that elapses before the initial brightness drops to 50%. With TFT the brightness of the LED backlight decreases, with OLED the display itself. During operation, the service life depends on various factors, especially temperature and brightness. Depending on the colour emitted, luminous materials have different lifetimes, from blue with 30,000 hours to yellow with 150,000 hours. Environmental influences are independent of the operation and limit the storage life span. Humidity and oxygen react chemically with the organic materials. They are well controllable by the design of the encapsulation of the cell and have only a minor role.

Undesired Display Effects

The effect of (differential) aging of individual pixels by operation is known under various terms: Burn in, image sticking, persistence or ghosting. The human eye recognizes differences in brightness quite well. Therefore, the GUI designer should ensure that all pixels of a display are switched on for approximately the same time and avoid static image contents. In some applications this is not possible, so other strategies have to be followed. „Screen savers“ are suitable if the display content does not have to be read permanently. The protection is effective if the user does not actively work with the display, e.g. with status displays, energy meters or measuring devices. The original image content is reactivated by pressing a key, touching a button or values are changed.

OLEDs are used wherever a small display with not too much information content is needed. Small medical devices, especially portable ones, are predestined for this. Seniors who monitor glucose or blood pressure themselves prefer clear, high-contrast displays. The low-power technology enables a long service life without charging or battery replacement. Oxygen therapy devices, defibrillators and electro-medical devices also benefit from OLEDs, as do devices for medical or biochemical laboratories, as they can be read from all sides thanks to an all-round viewing angle.

Technology outlook

The manufacturers of OLEDs are working on the further development of their technology. Driven by their use in consumer devices, future display generations will be refined: in the first step, substrate glasses will become thinner, contours do not necessarily have to be rectangular, and through optimized production, the edges of the display can be slimmer. In the next generation, flexible substrates are available that enable 2D curved surfaces or bendable displays. Applications include „wearable“ displays that can be integrated on the body or clothing.

A further step is the optimization of optical properties. So far, OLED layers offer only a limited transparency of a few 10%. Future materials will enable a significantly increased light transmission, which will pave the way for new applications. Head-up displays or spectacles for augmented reality, but also optical measuring instruments such as magnifying glasses with crosshairs or rulers, are in the pipeline.

In the age of the Internet of Things, where every device collects, bundles and sends data to the cloud, interaction with sensors does not necessarily focus on local visualization, because this takes place where the data is aggregated and filtered according to certain criteria. This reduces the complexity of the local display. Despite of this, the demand for small-format displays is growing, because each sensor must be set up and parameterized - e.g. its IP address and measuring range, wants to transmit local messages - e.g. to request maintenance or to display the battery status, or wants to transmit a trend.

OLEDs are particularly suitable for this because they have low power consumption, high contrast and are easy to control even by low-power CPUs. With their bright colours, they can be easily integrated into many devices, from design-driven coffee machines to portable blood pressure monitors. The potential of the technology has not yet been exhausted, and further developments make the displays even more attractive.
SONOTEC presents SONOFLOW CO.56 for combined flow measurement & air bubble detection

As medical devices replace important body functions, provide patients with necessary nutrients and drugs and therewith deal with human lives, technical requirements are specifically high and reliable functioning of all utilized equipment must be guaranteed at any time. When controlling fluid circulation in human medical applications, combining flow measurement and air bubble detection is a significant advantage.

SONOTEC has developed the SONOFLOW CO.56 sensor series, which combines flow measurement and air bubble detection in one compact unit. The integrated electronics and the option to operate up to 12 sensors with only one control unit guarantees the world’s smallest footprint for an OEM flow- and bubble detector to use in medical devices. The ultrasonic sensors quickly perform bi-directional, non-invasive flow detection for measuring the flow velocities of liquids, such as water or blood, in tubing. Simultaneously, the sensors detect air bubbles as small as 1/3 of the inner diameter of the tube. Top medical technology manufacturers already rely on this game-changing technology and have implemented the control and monitoring unit for instantaneous flow and bubble detection into their machines. One of the industry leading companies developing and manufacturing heart-lung equipment has integrated the hybrid sensor solution into their recently launched machines. The main aspect of the manufacturer to trust in the SONOFLOW CO.56 sensor series is its small design and its option for multipoint measurement. Thus, five of the smart sensors have been easily applied to the customers’ new console. The sensors themselves operate to measure flow rates on different shunts going to the body and simultaneously detect air bubbles to ensure patient safety at any time. Finally, the sensors give feedback on the real flow compared to the theoretical flow of the pump.


The SONOCHECK air bubble sensors incorporate intelligent ultrasonic transmission technology and innovative safety concepts to provide maximum sensor reliability. A selection of the SONOCHECK sensors recently met the tightened regulatory EMC requirements of the IEC 60601-1-2 standard (4th edition). Those non-invasive bubble sensors are ready to be integrated into the latest generation of medical technology products. Next to the products of the SONOCHECK family, SONOTEC offers sensors of the SONFLOW CO.55 V2.0 series. The non-invasive flow sensors are made of different materials (e.g. aluminum, stainless steel, plastics), are applicable for a wide range of tubing diameters and materials and are simply clamped on the tube with the flowing medium. This way the fluid will not be contaminated by the sensor housing. The sensor, in turn, does not have to be sterilized. Therefore, the SONOFLOW sensors are specifically suited for applications with strict hygienic requirements.

SONOTEC – 20 years experience in non-invasive flow measurement & air bubble detection

With its focus on non-invasive flow measurement and air bubble detection, SONOTEC has been an appreciated and reliable component and solution provider for highly sophisticated medical devices for decades. Over a long period of successfully implemented projects, the Germany-based ultrasound specialist – certified to ISO 9001 and EN ISO 13485 – has gained an excellent reputation among manufacturers of dialysis and transfusion devices, heart-lung machines, medical pumps and diagnostic systems. The intensive guidance from a very early stage in the product development process, support in verification, prototyping and its expertise in certification processes gives the company a lasting competitive edge.

The hybrid sensor SONOFLOW CO.56 combines flow measurement and air bubble detection in one compact unit.
Richard Wolf GmbH raises image quality in endoscopy to a new level with Pin sharp 4K resolution technology.

The new Sharp, Authentic and Efficient

The optimally tailored system components ensure image reproduction that matches the natural state of the image, at the same time operates energy efficient, and is ergonomic and compact.

4K entails a resolution of at least 3840 x 2160 pixels and this represents a fourfold increase compared with the existing HD standard. In order to get this pixel power on the road, Richard Wolf with its long tradition of innovation has strategically bundled all of its in-house expertise: telescope, light, signal processing and the latest production technology melded into one system, providing a solution from a single source.

Optical systems and light cables: Optimum match guaranteed

The new sharp begins with the completely new telescopes developed in-house for the rigid 10 millimeter and 5.5 millimeter endoscopes. This generates a homogeneous, illuminated image with sharp margins. Specially doped glass material is used for the lenses to minimize any optical errors.

The transmission of light plays an important role in implementing the new sharp. Light power keeps pace with the increase in resolution. The latest light cables combined with powerful LED light sources are precisely tailored to the requirements of the new camera system and therefore a perfect match for ENDOCAM Logic 4K.

Lower power consumption reduces development of heat

The new compact is manifested in the ergonomically shaped camera head with reduced dimensions and weight. Richard Wolf uses a new generative method here in order to manufacture the metallic camera casing utilizing a 3D printing process. The result is that the camera head is a comfortable fit in the user’s hand and it is also tangibly lighter. The stainless-steel material can be autoclaved and is ideal for chemical sterilization procedures. It is therefore classified as sterile and may be used without the need for any additional covers.

Richard Wolf reaches a new level of efficiency as a result of the reduced power consumption in various areas. The LED technology demonstrates significant savings over the previous gas discharge lamps. At the same time, the company has succeeded in using more powerful and very efficient electronic components in the camera head. It consumes around 30 percent less electricity and this is demonstrated in a significantly lower development of heat.

Precise image of reality with visualization of the invisible

The advantages of the system from a single source are displayed throughout the whole image chain and by the handling of...
the 4K signal that convert to the new authentic. Cables, connectors and controllers are consequently designed so that the significantly expanded data volume is free of loss. This increases the failsafe performance and the faithful visualization of the original image – very much the new authenticity.

At the same time, Richard Wolf GmbH has the experience and the ability to generate additional benefits from the surveyed data. Special visualization processes improve tissue differentiation, illuminate critical areas of an image, and clearly visualize structures situated in bright but overexposed regions.

Be flexible and modular

The ENDOCAM Logic 4K camera controller is designed as a flexible platform that is also capable of handling all application parts of the whole ENDOCAM Logic HD family including HD camera heads, pendual camera heads as well as flexible sensor endoscopes. Furthermore, all available telescopes can be used, which makes it easy to switch to the new standard and start the 4K journey step by step.
What Engineers need to know about Big Data and Small Wearable Sensor Devices

Healthcare Gets Digital

Data has always been a pillar of the medical profession. Because of the highly-regulated nature of healthcare, new drugs and treatment therapies are never approved without an abundance of empirical evidence gained through clinical trials. Even medical device improvements rely heavily on data gleaned from how they performed with actual patients. Over the last decade, the utilization of Big Data has been incorporated into virtually every industry. Businesses are able to be more efficient and make more informed decisions in everything from forecasting to operations to customer behavior.

The “Big Data Era” already takes place across the healthcare profession. To harness its power for improving people’s health, improved sensor and coating technologies are necessary to deliver continuous reliable data. This data provides a new way for everyone from pharmaceutical companies to device manufacturers to care providers, to monitor the outcomes of their treatment on patient health and to better guide care decisions.

Thanks to innovations in the wearable activity tracker field, 24/7 remote monitoring and “virtual health management” is now a reality for an increasing number of conditions. Wearable devices for diagnostic and therapeutic use are going through the same rapid “growth spurt.” Like the entire medical device industry, wearable sensors and devices are becoming more advanced and sophisticated, offering more functionalities with each successive device generation. As medical practitioners harness the enormous possibilities of wearable medical sensors to more closely track a wide variety of conditions, there will be a significant increase in data capture and two-way data communications. To unlock the potential of wearable devices to provide effective, non-invasive treatment options for patients, the data volume/signal strength challenge has to be addressed. Like the use of Big Data in other industries, continuous data is useless unless you can reliably capture it, transmit it, process it and turn it into an actionable solution.

For wearable devices, there is a bottleneck at the tissue-electrode interface that limits the ability to get a continuous, high quality signal from the body. Skin, fat, and bony tissues dampen and limit bio-electrical signals from being detected easily from outside the body. They add noise, reduce signal amplitude, and make spatial localization very difficult. Invasive technologies can provide much better signal quality than most external electrodes, but demand surgery or another invasive procedure.

There are medical technologies for external use in clinical settings that provide high quality electrical signals for short amounts of time (hours/days) but demand laborious setups and preparation. Typically, these rely on wet gel-based electrodes which tend to dry out over time and can cause skin irritation and rashes. For example, EEG applications can require...
multi-hour setups, the use of gel conductivity enhancers in the hair, and potential skin abrasion. Physical activity trackers can provide continuous data for years, but the transmitted data is not sufficient for medical analysis. So far, the marriage of technologies that are comfortable, easy to use, and continuously collect high quality data has been elusive.

One of the ways that Heraeus is addressing this issue is with the use of its Tecticoat™ line of dry electrode materials. Tecticoat is a polymer-based, electrically-conductive material that can be applied to a variety of substrates (including soft molded plastics and rubber, 3D printed parts, fabric and textiles) to create comfortable, high-signal quality dry electrodes for monitoring cardiac, neural, muscular, or other signals from the body.

Tecticoat provides a low and stable contact impedance with the skin which is key for consistent performance and high signal quality. By improving the quality and amplitude of signals leaving the body, less filtering and signal processing is required. This allows for lower power devices, faster device response, the ability to record from more locations simultaneously and improved spatial resolution. This is similar to how Amplicoat™, our conducting polymer coating for use inside the body, improves signal quality and allows for vastly improved electrophysiological mapping with higher spatial resolution for better localization and treatment in real-time. Additionally, Tecticoat can be used to make dry electrodes for therapeutic electrical stimulation of the body for different neural and rehabilitation applications such as providing motor function to paralyzed patients by electrically stimulating their limbs. The use of the dry Tecticoat electrodes improves usability of the device, reduces setup time dramatically by eliminating the need for gel conductivity enhancers and makes the device more robust for long-term use. Big Data and high-performing wearable devices will play a major role in healthcare. Over 5 million people are using remote monitoring devices worldwide, and that number will continue to increase. The ability to continuously monitor and treat patients in real-time, 24/7, will make patient care more convenient, responsive and effective. But patient data cannot be monitored and transported on the existing roadway; medical technology engineers need an “information superhighway” to ensure the incredible volumes of two-way data that need to travel between the patient and the care provider.
If you want to use the latest high-performance, high-graphics processor technology without fan cooling, modular designs based on VITA’s Rugged COM Express standard are your first choice.

A Standard for Fanless High-End Medical Systems

All embedded electronics designs are subject to hard limiting factors depending on the required computing power and the area of application. One such factor is the maximum permissible dissipation. New CPU series, such as the AMD Ryzen Embedded V1000 series or the 8th generation of Intel Core processors, have a TDP (Thermal Design Power) between 12 and 56 watts. If developers want to exploit their full potential on a COMExpress-module, they are above a critical TDP limit for fanless designs. Under those circumstances, conventional COM Express designs can only be realized with active cooling concepts. Many developers are therefore under the conception that fanless designs are only possible up to a maximum of 25 watts. However, to be able to conform to the highest hygiene standards, imaging systems with high-resolution screens and high-performance graphics also require completely fanless and hermetically sealed housings above this limit. Only in that case can they withstand extensive and regular cleaning with all the disinfectants commonly used in everyday hospital life to not become a breeding ground for hospital germs that would be released into the environment through integrated fans.

Rugged COM Express has been designed to meet these needs, leveraging completely fanless heat dissipation even above the 50 watt limit – perfect for the development of medical systems based on the AMD Ryzen Embedded V1000 processor family, which can scale up to 54 watts. The foundation for this is standardization.

COMs offer many advantages

- COMs (Computer-on-Modules) combine the ready availability of CPU modules (COTS products) with the flexibility of full custom designs
- Buying in the complex parts of the circuit technology (CPU, memory, core voltage regulator) lowers development costs significantly (about 50%)
- The exchangeability of COMs provides easy retrofit and scaling options even across different processor architectures and vendors
- Safety-critical applications with long product development and lifecycles and high certification requirements benefit from easy upgradeability with new standardized modules
- When replacing the computer unit of a certified end system, re-certification in modular systems is largely limited to the part of the system that is related to the new module

COM Express is leading

The leading standard among Computer-on-Modules is COM Express. Specified by the PCI Industrial Computer Manufacturers Group, PICMG for short, it is hard to imagine the embedded world without it – from ultra-compact low-power designs based on single/dual or quad core ARM or Intel Atom CPUs to high-performance computers in basic format based on server CPUs with 16 or more cores. With the large number of manufacturers of COMs, carrier boards and development kits, COM Express has the most comprehensive ecosystem in the Computer-on-Module world. The wide distribution ensures a balanced price/performance ratio for products and services as well as the long-term availability of the standard, as it is supported by many companies.

Equipped with the AMD Ryzen Embedded processor, the CB71C from MEN Mikro Elektronik is currently the most powerful Rugged COM Express design.
When it needs to be rugged

Some applications demand a highly rugged computing system. Since the COM Express specification doesn’t consider harmful influences, such as mechanical shock, strong vibration, rapid temperature fluctuations, moisture or electromagnetic radiation, it was expanded to include the Rugged COM Express specification (VITA 59). On the basis of VITA 59 it is possible to realize high-performance Rugged COM Express (RCE) modules with completely fanless cooling at a TDP of more than 50 watts.

Rugged COM Express

Based on the COM Express standard, RCE modules provide everything that COM Express modules offer. The VITA 59 specification extends the printed circuit board (PCB) of the modules with additional side wings for embedding in a standardized aluminum frame (CCA) to establish optimal thermal connection. This precisely specified frame ensures that the hot spots (CPU, memory and voltage transformers) are cooled. In addition, heat is dissipated via the PCB towards the frame. From there, any waste heat can be transported by conduction directly to the surrounding housing to be then dissipated by convection to the environment via cooling fins. These measures lower the assembly’s thermal resistance to the housing. Compared to a standard COM Express heat sink, this can reduce temperature rises of electronic components by up to 5°C. The lower thermal load on the components leads to lower failure rates thereby improving the reliability of RCE modules over traditional COM Express designs. Since the entire concept has been standardized by VITA, RCEs are fully manufacturer-independent as well as future-proof, and it is possible to change a module together with its standardized aluminum frame at any time.

Better protected

RCE modules are more robust in other respects, too. The aluminum housing means they are well shielded and highly immune to electromagnetic radiation. Additionally, the modules come with a protective varnish as standard. This conformal coating offers effective protection against environmental influences such as dust, moisture or even chemicals. The VITA 59 standard has its origins in the railway sector. However, modules in this standard are also developed and produced by manufacturers such as MEN Mikro Elektronik for medical applications. Railway sector conformity makes the modules also a perfect computing platform for emergency services. Because the frame is firmly screwed to the carrier board, particularly high resistance to mechanical shocks and vibration is ensured. Amplitudes of up to 5G for vibration and even up to 50G for shocks are realistic, making the modules even suitable for off-road driving conditions.

Author: Maximilian Kolpak, Product Solution Manager MEN Mikro Elektronik
Wearables, miniature computers which are worn as clothes or accessories and include integrated sensors, attract increasing attention on the market.

Sensors Widen Potential for Wearable Devices

With environmental sensing, these devices can also be made aware of their environment. The latest sensors are able to measure relative humidity and temperature (RH/T), light and pressure to enable devices and their users to understand their ambient condition and what is going on around them. The main advantages of these sensors are that they are very energy efficient, do not require lots of computation power and are becoming smaller and smaller. Hence, they are ideal for wearables and offer a broad range of potentially valuable applications.

Personalized Ambient Conditions

The integration of temperature and humidity sensors into wearable devices allows measurement not only of the ambient conditions but also the user’s physiological information, such as skin temperature or sweating rate. This can give a better understanding and interpretation of achieved performance (e.g. disturbed sleep in hot weather, slower running in high humidity) and is the basis for a variety of potential new applications. This information can also be used in a connected home (smart home) to automatically control the indoor climate. If skin temperature and sweat rate is shared with a climate system, the room ambience can be optimized to personal preferences without the need for human intervention.

This is particularly relevant if a user is sleeping and is not aware of unhealthy or uncomfortable conditions. In addition to increased comfort, energy is consumed only when needed, leading to cost savings.
Tracking ambient conditions is also useful for other applications. Depending on the temperature and dryness of the environment, a wearable device could provide useful skincare tips. Our skin is highly sensitive and an understanding about exposure could be used in cosmetics to recommend the right product for the right skin and exposure.

But it’s not only the beauty industry that can enhance its products to satisfy customers – the healthcare market would also benefit. People with respiratory diseases need a climate adjusted to their condition. A bad indoor climate can increase the risk of illness – asthma, mites and mold infestation are just a few of RH/T-dependent health risk factors. By tracking the ambient condition with a wearable device, distinct patterns will emerge and abnormal or risky conditions will trigger the adjustment of heating, ventilation, air-conditioning or humidifiers.

In the near future, spectacles, watches, articles of clothing and other items will have the ability to sense temperature and humidity, making it possible to integrate the measurement of our environment into every facet of our lives. This will help us to get a better understanding of our environment and the ambient condition in the space we live in. As a result, processes in daily lives could be optimized, energy consumptions minimized, money saved and comfort and health could be improved.

Integration and Sensor Fusion

Integrating ambient sensors into wearable devices like Smartwatches is a non-trivial undertaking. This is especially true for ambient temperature sensors and all measures dependent on ambient temperature such as humidity. Temperature sensors built in a wearable or mobile device face three major challenges.

First, the electronic components in the tightly packed device generate heat and influence the sensor reading. This effect gets even worse as the heat dissipation of the different components is highly load dependent and therefore is changing all the time. Second, the sensor readings are influenced by the heat of the skin.

Third, the device has a certain thermal mass which results in a slow thermal response. Similar to the fact that a hot cup of coffee needs about 30 minutes to cool down to room temperature, a smart watch or phone needs about 30 minutes to adopt to temperature changes.

There are multiple measures to mitigate or even eliminate this obstacle. One of the most crucial parts is the placement of the sensors. It is important that they are very well decoupled from the main device-internal heat sources and the human skin.

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The placement of the sensor is highly device specific and has to be well considered for every product independently.

An ideal sensor placement, however, is not enough as a complete decoupling is most likely not feasible. To compensate for the remaining influences, the influence factors have to be monitored and their impact on the temperature reading has to be determined. For example to compensate for the body heat, an additional sensor can be placed closely to the skin. A heat-propagation model can then be applied to estimate how big the temperature gain of the body heat on the sensor is. This information allows for compensation. This environmental sensor fusion software called Sensirion Engine is already actively used in several smart phones enabling accurate ambient temperature and humidity sensing. Further the Sensirion Engine allows to speed up the response of the temperature and humidity signal to ambient changes far beyond the physical limits. Which is necessary as no user wants to wait up to 30 minutes to get accurate readings.

Combining all these approaches allow wearable devices an accurate measurement of ambient temperature and humidity by providing an experience users expect from wearable devices.

Sensor Packaging Innovation

Implementation of such a system is possible only with innovative technology in both hardware and software. The hardware in question is currently one of the smallest humidity and temperature sensors available. It has been developed by the Swiss high-tech company Sensirion specifically for devices where space is limited, and it is optimized for the requirements of the consumer electronics industry. This innovative product combines minimal size with maximum performance to define the latest generation of humidity and temperature sensors. The SHTW2 is Sensirion’s 2nd generation WLCSP (wafer-level chip-scale package) humidity sensor, offering a complete digital humidity and temperature sensor system in a package so tiny that it fits into virtually any application. The SHTW2 comes in a flip chip package, which is an established technology and represents one of the simplest and smallest possible ways of packaging for a semiconductor chip. The supply voltage of 1.8 volts and the low power consumption of just 2 µW at 1 measurement per second provide an optimal base for the use of the sensor in small, wearable devices.

The company provides not only the sensor but also the accompanying software, ensuring a significant time reduction in obtaining accurate readings after a change in ambient conditions. The tiny SHTW2 sensor extends the range of possible applications; for example, as a basis for physiological signals, such as skin temperature and sweat rate, where tailored algorithms are required. Sensirion has created the space for new ideas - now it is up to wearable providers and app developers to take the next step.

HIGHER VOLTAGES FOR INDUSTRIAL APPLICATIONS

Mouser Electronics is now stocking the MAXM17552 compact step-down DC-DC power module from Maxim Integrated. Offering an ultra-small power source to drive high-voltage industrial and consumer applications, the micro system-level IC (uSLIC) module provides a wide input voltage range for medical devices. The Maxim MAXM17552 module, available from Mouser Electronics, is part of Maxim’s Himalaya series of voltage regulator ICs and power modules, which enable cooler, smaller, and simpler power supply solutions. The MAXM17552 module operates over a wide input-voltage range of 4 V to 60 V and delivers up to 100 mA output current over an adjustable output voltage from 0.9 V to 5.5 V. The module integrates a synchronous wide-input Himalaya buck regulator with built-in FETs, compensation and other functions with an integrated shielded inductor in a miniscule 2.6 mm × 3.0 mm × 1.5 mm package. The module uses peak-current-mode control architecture, operates in pulse-width modulation (PWM) mode, and offers a soft-start feature to reduce input inrush current. Compliant to CISPR 22 (EN 5022) Class B and JEDEC certified, the MAXM17552 power module delivers increased energy efficiency, shock and vibration tolerance, high temperature operation, and electromagnetic interference (EMI) compliance.
RECOM introduces new medical-grade DC/DC modules in a power range from 15W to 30W, which can be easily integrated in medical designs due to their compact case size and full medical certifications. The enhanced properties make these modules ideal for medical-grade applications as they excel in reinforced isolation of 5kVAC, low leakage current, while offering extra wide 4:1 input voltage ranges.

**MEDICAL DC/DC CONVERTERS PROVIDE 2 x MOPP**

The reliable REM15-W, REM20-W and REM30-W series are DC/DC converters, which offer well balanced specifications for critical medical applications including a 60601-1 3rd Ed. certification. They feature 5kVAC reinforced isolation rated at 250VAC working voltage, 8mm creepage and clearance and low 2µA leakage currents, despite the compact case sizes of only 1.6'x1' and 2'x1'. At the same time they guarantee far-reaching compatibility with their extra-wide 4:1 input voltage range. The high efficiency of up to 90% means they can operate reliably in harsh environments from extreme temperatures from -40°C up to 105°C at natural convection. Their single output options range from 5V up to 24V and dual outputs offer either 5V, 12V or 15V with low output ripple and zero-load operation. To underline the high reliability, RECOM grants a 5-year warranty for these modules.

**FANLESS 1000W MODULAR POWER SUPPLY**

The CoolX1000, a fanless 1000W modular power supply, is packaged in a compact 6.5 x 10 x 1U U-channel design, the CoolX1000 provides up to 1000W without any requirement for fan or base plate cooling, eliminating acoustic noise detrimental to scientific and medical applications, as well as applications sensitive to vibration or where fan cooling is not available. The CoolX1000 also offers increased flexibility by allowing system designers to monitor and control power supply performance – essential for staving off process disruption – via analog or digital communications (PMBus™). The series will offer two base models: the CX10S, which is certified to IEC60950 2nd edition for industrial applications, as well as the upcoming IEC62368-1 standard; and the CX10M, which carries IEC60601-1 3rd edition and IEC60601-1-2 4th edition (EMC) for medical applications. Both models can be populated with up to six CoolMods, providing up to 12 isolated DC outputs ranging from 2.5V to 58.0V. Outputs can be configured to the required set point voltages and connected in parallel of the series for higher output current and/or higher output voltages. Typical applications that the CoolX1000 supports include clinical diagnostic equipment, medical lasers, dialysis equipment, radiological imaging, surgical robotics and clinical chemistry.
Combating Unilateral Facial Paralysis

The NI platform accelerated the development of our first facial pacing prototype system. Our achievements would not have been possible with alternative technologies.

The problem: Addressing unilateral facial paralysis by creating a measurement and control system for facial pacing, which measures facial movements from the healthy side of the face and uses functional electrical stimulation to simultaneously reanimate the paralysed side.

The solution: Using myRIO combined with custom electronics to measure multiple channels of surface EMG, process the acquired signals, and produce stimulation waveforms to activate facial muscles with the low-latency and reliability required for this novel medical system.

Unilateral Facial Paralysis and Facial Pacing

Unilateral facial paralysis is a condition in which one side of the face is either partially or totally disabled due to paralysis of the facial nerve. There are a number of possible causes for the paralysis, including Bell’s palsy and physical trauma. Unilateral facial paralysis is fairly common. Its most common and idiopathic form alone reportedly affects approximately one in every 60–70 persons. The paralysis affects daily activities such as blinking, eating, drinking, and social interaction. Problems with blinking can cause dryness of the eye and even loss of vision. A drooping mouth corner can make eating and drinking difficult. Smiling and other socially-important facial expressions become distorted. People suffering from paralysis may have concerns related to their appearance and may feel like they cannot fully express themselves. The goal of the treatment of facial paralysis is regaining lost functions to overcome the negative impact they have on the quality of life.

Permanent forms of the paralysis can be treated surgically. However, surgery involves risks, is expensive, and regaining lost functions is not guaranteed. In reality, some nerve repair surgery techniques have reported success rates as low as 20 percent.

Prosthetic technology is another approach to regain lost facial functions. Functional electrical stimulation can be used to activate facial muscles for reanimation. Facial pacing describes the act of reanimating the disabled side of the face based on the simultaneous measurement of the healthy side. For example, a smile detected on the healthy side of the face can be replicated on the disabled side using electrical stimulation. This type of pacing can provide a short-term solution to regain facial control while awaiting surgery or, in the case of temporary paralysis, while waiting for the paralysis to heal. For short-term facial pacing, we can use wearable devices that carry out measurement and stimulation via electrodes placed on the face.
skin. In the future, prosthetic technology could be an effective alternative to costly repair surgeries whose success is never guaranteed. Miniaturized, implantable devices would be less obtrusive and more suitable for continuous use. An effective facial pacing system has strict computational demands. Aside from fulfilling common medical device requirements, pacing requires determinism and true parallelism to achieve synchronous facial expressions. An acceptable delay between the sides of the face (detected versus stimulated movement) is tens of milliseconds.

Research Goals and Current Status

Our research focuses on developing transcutaneous facial pacing beyond the state-of-the-art. Current limitations include difficulties in activating the targeted muscles, difficulties in producing varying levels of muscle contraction, and problems related to the comfort of the stimulation. In order to study how these issues could be solved, we needed a research prototype system that allows us to fully customize the processing, from measurement to stimulation.

Currently, we have designed and constructed a prototype system that we are using for clinical trials under the supervision of the National Supervisory Authority for Welfare and Health (Valvira) in Finland. We have already carried out clinical trials at the local hospital to study the excitability of facial muscles of both healthy participants and patients with unilateral facial paralysis. We also have our first implementation of pacing for reanimating eye blinks. We are developing our system further to continue with more experimental research and clinical trials.

Developing the Facial Pacing Research Prototype

Our original idea was to make our own custom device with amplifiers for the measurement and stimulation, and combine it with a laptop to carry out the required processing. However,
the connectivity to the computer would have created a bottleneck, leading to unacceptable processing delays. NI reconfigurable I/O (RIO) platform represented an ideal solution, offering reliable, deterministic computational power, whilst simplifying the integration of our custom electronics to form our facial pacing prototype system (Rantanen et al. 2016). Our device currently has four EMG measurement amplifiers with appropriate gain and bandwidth. Our four stimulation amplifiers produce constant-current signals to varying loads with ±48 mA maximum amplitude, and nominal maximum voltage of 100 V. The amplifier bandwidths allow arbitrary waveforms to be produced.

We chose the NI myRIO device as the embedded controller. We used it to measure the signals from the EMG amplifiers, carry out real-time processing on the data streams, and generate the signals for the stimulation amplifiers. A custom LabVIEW application, running on a standard laptop, wirelessly connects to the myRIO to provide a graphical user interface (GUI) and data logging. The GUI is required for configuring the processing and stimulation parameters, providing real-time visualisation of the signals, and setting-up the data logging. However, we use the myRIO integrated FPGA for time-critical tasks. Generation of accurate square wave stimulation pulses with pulse widths less than a millisecond wouldn’t be possible without an FPGA program running at tens of kilohertz. We also currently sample and process the EMG signals in the FPGA because a high sampling frequency allows fast detection of the onset of muscle activity from the background noise.

The myRIO greatly simplified the design of our prototype system, allowing us to implement a vast amount of functionality on a single device—from analog and digital I/O, to customized signal processing, to wireless connectivity. We use analog I/O to measure signals and to read UI buttons and the status indicators of our stimulation amplifiers. The built-in wireless connectivity of the myRIO was important because we designed the prototype system to be a medical-grade device. Physically connecting it to a computer would have caused safety concerns. Choosing myRIO as the system controller was also a future-proof design choice. NI RIO architecture helps us easily reuse all of our current software IP, whilst upgrading from myRIO to a higher-end processing target (such as Single-Board RIO) with larger FPGA capacity, if required in the future.

**Conclusion**

The NI platform accelerated the development of our first facial pacing prototype system. We achieved more than would have been possible using alternative technologies. We can take advantage of the extensive programmability of the prototype to develop facial pacing further, helping us discover more specific requirements for designing dedicated, wearable, lightweight devices in the future.

**Authors:**

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Petr Veselý (St. Anne’s University Hospital Brno)
Trends like artificial intelligence (AI), neural networks, cloud computing, machine learning, deep learning, wearables, and Internet of Things (IoT) are defining a new technological era.

The Imminent Digital Health Revolution

While one cannot be blamed for thinking this might be more hype than substance, the changes emerging from these trends are quite real. The traditional healthcare system has enormous amounts of patient data (medical records, images, videos, and ICU signals) that is being used for predictive analytics systems that learn and detect trends that improve patient care. Besides collecting medical data at the point-of-care (at hospitals and clinics), engineers and scientists can now acquire, store, and work with large amounts of data from wearable medical devices in ways that weren’t conceivable even 10 years ago.

With all this data, though, comes the very real challenge of transforming it into actionable insights. Often, this involves applying some of the latest analytics to your data to develop an innovative product or service that positively affects patient outcomes and delivers commercial growth. Beyond that, getting your product or service approved and out to the market quickly is another significant challenge. A key enabler of success in overcoming these challenges are engineering software tools, like MATLAB, that let medical device engineers and researchers prototype and implement advanced algorithms, analyze large amounts of varied types of data quickly and effectively, and develop/deploy new machine learning models without coding them from scratch.

How the Landscape Looks like

To better understand this big data challenge, you can view this emerging landscape using two different perspectives: the IoT system framework along with the infrastructure enabling it to be possible, and the data analytics (machine learning) framework, which focuses on the smart algorithms that helps physicians and patients make more informed, data-driven decisions.

The IoT System View

The first framework that helps us characterize digital health is the IoT system framework. An IoT framework typically has three main elements:

1) Edge node(s)
2) A gateway or a cloud aggregator
3) A back-end data analytics engine operating on the aggregated data for trend analysis, anomaly detection, etc.

Edge nodes typically collect raw physiological health data through various sensors. Wearable fitness devices as well as some proprietary FDA-regulated devices, such as blood glucose sensors and ECG monitors, are examples of edge nodes in an IoT system. Data collected from the edge nodes needs to be processed to extract meaningful information from it.

With the right signal or image processing algorithms running on the sensor data streamed from the edge nodes, signal features can be extracted and transmitted to a cloud in a way that reduces bandwidth requirements and improves power efficiencies of these wearables that leads to reduced device size and longer times between recharges. The feature extraction algorithms may be run locally on the low-power embedded processor, which allows processed or compressed information to be sent to the cloud periodically, and then aggregated for a single patient or across a population of patients on the cloud. Predictive analytics can be run on the larger data collected across patients and time to provide patients and physicians with real-time reports.

Identifying the right combination of the algorithms for preprocessing and feature extraction is a critical step in this workflow and can determine the effectiveness of the final predictive analytics solution. It can also be difficult and time-consuming to figure out the right partitioning of algorithms without the right engineering and algorithm prototyping tools as seen through Respiri’s process for creating a digital asthma measurement device. By developing the respiratory monitoring algorithms using advanced signal and image processing techniques, Respiri was able to produce a device that measures the severity of asthma by analyzing chest sound from breathing. The device then sends the processed data to the patient (or the parent of the pediatric pa-
tient) and the physician, so actions can be taken depending on the severity.

**Data Analytics View**

The second framework that helps us understand this landscape is the machine learning algorithms that adds intelligence into this entire system and helps transform data into actionable insights. Smart algorithms built using machine learning techniques enable the extraction of meaningful information from large amounts of text data, signals, images, and videos to automate and accelerate diagnostic capabilities.

A machine learning algorithm has three primary components:

1) Preprocessing of data
2) Feature extraction
3) Developing a predictive model that is trained to learn the features from a training set

The training of the model is typically done on large amounts of historical data recorded over long periods of time using well established computational approaches. The trained model can then be applied on new, untested data to provide predictions on various parameters acting as an advanced diagnostic aid for the physician and/or patients.

In Respini’s case, a handheld device is used to collect and preprocess audio signals that are sent via Bluetooth to the patient’s phone. A smart algorithm built in MATLAB and implemented on a smartphone app using C-code generation analyzes the spectral image using computer vision techniques and calculates a wheeze rate which quantifies the severity of wheezing. This information is then sent to the cloud from the smartphone for further aggregation and for sharing the patient’s wheezing trends with physicians.

Being able to prototype signal processing algorithms, while quickly exploring machine learning models and rapidly implement them on a target platform through C-code generation technologies is helping companies accelerate the development of such complex medical device products.

In today’s world, where data-driven analytics is pushing the boundaries of what’s possible, digital health will help move healthcare regimes toward personalized medicine. It’s quite likely that in the foreseeable future, both preventative and therapeutic care will be driven by predictive analytics collected from wearables and shared on smartphones and personal devices. This technology will allow for a better understanding of a patient’s health and a more effective diagnosis of a wide range of human physiological conditions leading to a healthier society.

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Security controls, i.e. measures to increase the security of a product, are defined by regulatory documents.

How to Ward off Cyber Attacks

Within the US-Administration – e.g. Department of Defense, Homeland Security, Department of Veterans Affairs, Food and Drug Administration, National Electrical Association – documents have been developed which define measures to increase the security of a product. For example the NEMA standard HN 1-2013: “Manufacturer Disclosure Statement for Medical Device Security” MDS, the standard SP 800-53A “Assessing Security and Privacy Controls in Federal Information Systems and Organizations Building Effective Assessment Plans” or SP 800-53 “Security and Privacy Controls for Federal Information Systems and Organizations” by the NIST.

Deriving from Europe the ETSI TR 103 305-1 V2.1.1 “Critical Security Controls for Effective Cyber Defence” could be mentioned. These publications are supplemented by non-binding documents like “Common Weakness Enumeration”, “Common Criteria”, “CIS Critical Security Controls” and many more.

These documents state requirements as

- is the product capable of encoding patients’ data?
- how can be ensured that such data cannot be manipulated when sent?
- does the operation system run on the latest patch level, how is it being installed and how do you ensure that unwanted third-party-software will not be installed on the product?
- “Off-the-Shelf-Software” is on the latest patch-level.
- minimal administrative rights.
- exclusively necessary services, users, shares and ports are installed.
- no booting of removable storage devices.
- limitation of network traffic to trusted IPs.
- two-factor-authentification for administrative users. An audit-trail is established which can be archived and signed digitally.
- personal data on USB data carriers have to be encoded.
- training of developers.
- identification of duly authorized representatives for Incident Response Management.

All of these documents have in common that lists of security aspects can be derived from them. Such lists of security aspects are being developed during the design-phase of a product and have to be reviewed after all significant modifications. These modifications can either be internal (the product itself is modified) or external (the software applied receives a security relevant patch). The review of security requirements does not end with the release but has to be extended to the entire life cycle of the product.

The challenge consists in defining for every single element on the list the value and the consequence of this requirement on the product. In case a network connection cannot be established it will be annoying for the service operator and can hopefully be avoided by means of removable storage devices while such a blackout will be harmful to a web application.

<table>
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<tr>
<th>Probability</th>
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<td>rarely</td>
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[Consequence]

[Probability]
Secondly, the probability of such an occurrence has to be defined. Here the spying on passwords through the Meltdown/Spectre-leak is to serve as an example. It is being attempted to read the storage of another process as well as of the operating system via this gap. Actually the probability is real whenever the product is in use.

Still, preconditions to successfully carry out such a hack are very high. Generally, the normal user should not at all be able to open the command-shell and the system should be protected by a whitelist. So the probability of a successful cyber attack is smaller than expected at first sight. As a third step it is to be evaluated how high the effort is to close the security leak. Meltdown/Spectre can only be closed externally, but measures to impede the attack are recommended and practicable.

The Risk and Threat Analysis consists of at least these three steps. They form a matrix of security characteristics for the product. For big-sized products the use of tool support is recommended. But that’s another story…

The steps described can only guarantee passive security. They apply to general security aspects, to lists derived from the documents mentioned above or to security relevant defaults detected previously, like patchdays by software producers. Errors within the own product are thereby not taken into account. Active security can only be found after product specific tests.

Only static code analysis, fuzzing and penetration tests can guarantee active security. Again, another story to be told…

One final point: The OWASP Testing Guide 4 already stated that while the space of time between the discovery of an endangerment and its patch stays the same, the time for active exploitation is reduced. Consequently, there is an increased necessity to execute the steps of risk-analysis described above and for a continuous application of security testing to the product.

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**SQUARE CONTROL CENTRE**

OKW’s new PROTEC enclosures have a modern and highly attractive square design with soft contours. As a result, these wall-mount and table-top housings are ideal for modern electronics applications, both indoors and outdoors. The enclosures have an inclination angle of 20° which considered ergonomically ideal for operating terminals and for reading off data.

A recessed operating area for integrating membrane keyboards, operating elements and touch systems has been provided in the square top cover. The top cover is screwed to the bottom part at the back with stainless steel Torx screws, and the entire screwed connection is thus hidden from view. The range of accessories for the enclosure series includes matching sheet aluminium holders, which allows hidden, secure wall mounting. As can be expected from OKW, the PROTEC enclosures can also be modified according to the individual requirements of the customer, for example with printing, mechanical machining for interfaces/displays, painting, EMC coating on the inner side of the enclosure and much more. The PROTEC-series is made of high-quality V0 material in off-white (RAL 9002). The electronics compartment can be sealed up to protection class IP 65 by means of an accessory sealing kit — this is particularly useful for tough applications, for example in the smart factory / IIoT, central control units, surveillance systems and access and security controls in industrial environments or outdoors. However, the PROTEC can also be used in many other sectors: for data acquisition systems, data systems engineering, measuring and control engineering as well as medical technology and in health care.
Integrating Protection in Medical Device Software

Like smartphones revolutionized the cellphone, modern medical devices are a breed of their own, making development more efficient, shortening the time-to-market, and enabling new business models like pay-per-use payments.

As medical devices have learned to communicate, the medical world is benefitting from greater efficiency, but it also has to account for a greater risk of manipulation from the outside. Device settings and parameters might be tampered with, and the number of security incidents and hacker attacks has risen considerably in hospitals everywhere. Protections are in order that cover all connected devices in the field. And this is not limited to their hardware or software; the sensitive patient data used and produced by the machines needs to be kept confidential and safe from manipulation.

For medical technology enterprises, product piracy is also a pressing concern, as much invaluable know-how is invested in their X-ray or MRI scanners, dental technology instruments, or even smaller devices like infusion pumps or mobile patient monitors. The backbone of these devices – the embedded software and the know-how of their makers – can and should be protected.

Preventative Protections for Software and Data

Medical technology can be protected most effectively by solutions that offer copy, know-how, and integrity protection alongside flexible licensing capabilities. Whether it is about diagnostics PC software or embedded applications in high-tech medical devices – the first target for attackers and the first line of defense is the software and the data generated or used by it, be it operating setting or actual patient files.

Encrypting Software and Know-how

To protect the know-how invested in such software, the application is encrypted before delivery, either as a whole or in individual functional blocks. All legitimate users are given the rights and licenses with the keys required to use the functions they have paid for. The type of user right (single user license, network license, or temporary license) can be defined by product management. Wibu-Systems CodeMeter Protection Suite empowers device makers to encrypt and protect their software in this way, using modern and robust algorithms like the Advanced Encryption Standard (AES) for symmetrical and Elliptic Curve Cryptography (ECC) for asymmetrical operations like software encryption and signatures.

The device functions contained in the separate protected blocks can be activated with the right license and key to allow...
add-on features – even after the original sale of the product. One pleasant side-effect is the positive impact it has on the production process, as fewer models with different feature sets need to be produced, kept on stock, and delivered to the customer. On top of the great IP protection, this technology creates a plethora of opportunities for lowering production costs and creating new business models. CodeMeter lives up to the requirements of both the traditional PC universe and the new embedded world, with special flavors of the technology now available for modular and resource-efficient embedded applications. Particular attention has been paid to account for the real-time capabilities and the limited memory and processing power of embedded systems.

**CodeMeter Technology – Scalable and Consistent across all Platforms**

No solution could be called ideal unless it offers a perfectly tailored implementation of the protection technology for each platform. At the same time, the tools and license models and formats must be compatible across the board. With all cleverly targeted optimizations, the solution has to stay consistent. The same API has to be used everywhere, and only the specific functional range should be adjusted to reflect the available resources.

**Secure Key Storage**

In strict compliance with Kerckhoffs’ Principle, the encryption processes used by CodeMeter are public knowledge – the keys alone are the only secret. This means that the keys need to be safely stashed away in a particularly robust storage place. The best such protection can be offered by hardware key storage with integrated encryption, i.e. smart card chips that can withstand even side-channel attacks (Differential Power Analysis, DPA). The keys never need to leave their secure home, and all important cryptographic operations can be executed on the secure hardware as well. An alternative option is offered by encrypted license files that are bound to the devices in question with an unique and tamper-proof fingerprint (e.g. the device’s serial number).

**Custom Maintenance and Pay-per-Use Models**

On top of protecting their devices, the technology enables medical device makers to track and bill the use of their products reliably and flexibly, to offer add-on features on the after-sales market, or to allow temporary demo functions that give the users a taste of their device’s capabilities. The quality standards of consumables can be maintained by integrating special counters in the licenses that count down until a set threshold value is reached. The user would then be notified that new supplies need to be ordered, or the order could even be initiated automatically. Once the purchase has been made, the counter is reset. Such licenses for add-on functions, for consuma-
Centralized license admin with CodeMeter License Central

Encryption and Signatures against Snooping and Tampering

The law is clear on how patient data should be treated; it is now up to the makers and users of medical devices to see that it is implemented. Patient data is encrypted to protect its confidentiality and signed to guarantee that it has not been manipulated and has indeed come from the right, legitimate device.

Licenses under Central Control

The CodeMeter License Central license management system makes it easier to create, manage, and distribute rights and licenses and helps product managers develop attractive and secure products. The processes are fully integrated and easy to use: orders are created in one of the usual ERP or CRM systems, and an automation interface notifies the license management system to create a license. Device makers can even tap into new revenue streams by allowing their users to activate additional device features later through a dedicated app-store-like portal. Pay-per-use or subscription models are managed just as easily. All the manufacturers need to do is balance the security, comfort, and benefits for the user to design an attractive and successful offering.
Medical device development has become increasingly complex. High-performance mobile processors, lab-on-a-chip devices and the expansion of wireless networks, are just a few reasons why functionality of individual medical devices is continuously increasing. As a result, the use of software in medical devices and the number of electronic components within them is constantly growing. Only by adopting new methods in product development, the continued development of high-quality products is possible, maintaining a fast pace of production while keeping them compliant with strict regulatory and safety requirements.

The multitude of technological innovations increases competition between manufacturers of medical devices, which leads to ever shorter product cycles. Nevertheless, one of the key tasks of the manufacturers is to ensure the quality of medical software and devices. Software bugs in the medical industry, can result in an adverse event, leading to considerable financial losses and worse even, loss of human life. In order to keep up with the high rate of innovation, while still meeting the stringent requirements for medical devices, manufacturers need to adapt their product and software development methods. The use of agile software development methods in medical software development helps to shorten time-to-market, while still complying with regulatory requirements.

**Traditional development methodology**

Most manufacturers traditionally used the waterfall model for medical software development. The waterfall model, also referred to as a linear-sequential life cycle model, is commonly perceived as the most straightforward way to comply with regulatory requirements. Following this methodology, all requirements are first stated, checked and then approved by the stakeholders. Only then does implementation begin. When implementation is completed, verification and validation follows.

The waterfall model is still applicable in certain cases. However, in reality, requirements can rarely be fully specified at the beginning and seldom remain the same throughout the development process. When a product is mostly customer-oriented, changes to the requirements are to be expected during its development. Methods such as agile software development help bring more flexibility to projects. The question is: can they meet regulatory requirements?

The IEC 62304 standard specifies the life cycle requirements for the development of medical software and software within medical devices. It specifies the processes, activities and tasks which need to be performed in order to make the software comply with.

**Benefits of agile methodology**

Agile methodology breaks a project up into several iterations. Rather than starting with obtaining a full set of requirements, the project team composes a high-level set of core features and decides which of these features can be implemented in the first iteration. The remaining features are implemented in the subsequent iterations according to their priority.

If the product is highly customer-oriented, the short-term planning and development cycles facilitate regular alignment with the feedback from the users. This allows changes to the project to be made more easily, as well as any overall course corrections if needed.
Keeping in compliance

The IEC 62304 aims to ensure that the general requirements for medical software development are met and that the prescribed processes are carried out in a controlled manner. For the software development process, the V-model is prescribed. It defines the activities that need to be carried out and documented in order to produce the software in accordance with regulatory requirements.

There is a misconception that the activities in the V-model need to be sequential. One activity does not need to be completed before the next is started. The V-model describes the dependency between activities, not their sequence. Because of this an agile methodology can be adopted for medical software development, while still ensuring compliance with IEC 62304 requirements.

IEC 62304 does not specify which software development life cycle model must be used. The choice of what software development life cycle model to use is left to the manufacturer, as IEC 62304 only defines the set of activities required. Mandatory milestones, such as reconciling requirements with functionality and verifying the inputs and outputs of the activities, ensure compliance is achieved.

Variety unlimited: VariCoat Wire Coating Solutions

Plastic-coated wires, braids and fibers fulfill a wide range of medical purposes. They can be used as guides in minimally-invasive surgery or as signal-transmitting electrodes for neuro-stimulation, for example.

With VariCoat, the medical technology manufacturer RAUMEDIC has developed a single-step process that makes it possible to uniformly coat wires, braids and fibers with a large number of high-temperature polymers, technical polymers and standard polymers. Instead of being applied layer by layer, polyamides (PA) and materials like PTFE, FEP, amorphous PEEK and PUR are directly extruded onto the substrate in a single processing step. The possible wall thicknesses range from 0.01 mm to 1.0 mm (0.0004" to 0.0399”).

RAUMEDIC produces the coated wires, braids and fibers exclusively under controlled clean room conditions of ISO Class 7. As a result, contamination by germs and particles is kept extremely low from the very beginning. In addition, the products can be further processed immediately afterward because no subsequent cleaning procedure is required.

About RAUMEDIC

Human health is at the core of RAUMEDIC Group’s business. The company specializes in processing medical-grade thermoplastic polymers and silicones at five production sites in Germany and the United States.
Agile software development according IEC 62304

Developing complex medical devices is a challenging task. With new customer-oriented products, where changes to the requirements happen during development, traditional development methods turn out to be inefficient. Agile methodology proves to be the better solution, because of its many iterative, short planning and development cycles. It facilitates regular alignment with customer feedback and allows course corrections more efficiently than traditional development methods.

Agile software development can be used in compliance with IEC 62304 requirements. To meet the central requirements of IEC 62304, it is important to properly organize the software development processes within the company. The agile approach helps development keep within schedule, lowers costs and allows the manufacturer to put the product on the market faster than it would be possible if he used the traditional waterfall approach.

Helpful tools for software development

Continuous iterations, where work items (requirements, software design, code, etc.) change and evolve, put pressure on development teams to keep documentation consistent and up-to-date. Application Lifecycle Management (ALM) tools are invaluable means for maintaining traceability, which help manage changes in requirements, architecture, design, implementation as well as testing. The versatility of ALM tools makes them indispensable in achieving compliance with regulatory requirements.

ALM tools can provide functionalities that support project management, requirements management, development, issue tracking, testing and quality assurance (QA) as well as risk management and configuration management. Generating arbitrary trackers for tracking individual tasks and work items is possible with ALM tools. Establishing dependencies allows for comprehensive monitoring of changes and their traceability. When work items change, the change is reflected in all dependent items. Additionally, ALM tools manage the approval process for work items as well as their documentation. An integrated development environment, source control tools, document management tools and collaboration tools are among the other common software development tools that are also required.

Additional information

A Comtrade Digital Services white paper provides detailed information about agile software development in the medical industry:

https://content.comtradedigital.com/agile-software-development-medical-devices

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Complex and Flexible at the Same Time

The company BGS, established in 1981 and headquartered in Wiehl near Cologne, covers two major areas of activity: Radiation sterilisation and refinement of materials. With its other branches in Saal an der Donau and Bruchsal, the radiation specialist is represented at three locations in Germany. In an interview with our editorial team, Dr. Andreas Ostrowicki, Managing Director of BGS, provides more details.

MED: Dr. Ostrowicki, just recently, a new gamma radiation plant went officially into operation in Bruchsal. With an annual capacity of 80,000 pallets loaded with medical products, the plant is one of the largest of its kind worldwide. BGS has invested about 15 million euros in the construction of the new plant. In addition to the financial expenditure, the company had to implement extensive permit requirements – a huge investment and high costs for a medium-sized enterprise with currently 170 employees. What were the key factors of taking this step?

Dr. Ostrowicki: Only a few companies are active in the business of radiation sterilisation. The plants are equipped with complex and sophisticated technology and besides a high investment, they also require extensive capacities. Therefore, it makes no sense for individual companies to build their own plant. On the contrary, it is common practice to outsource this process. At the same time, customers benefit from the comprehensive advice of our experts, for example with regard to regulatory requirements, questions on materials and logistic processes. In addition, the market for medical technology has been growing for some years now at an annual rate of 3 to 6 percent, depending on the field of application. In Germany however, there has been little investment in the areas of radiation sterilisation, bioburden reduction & disinfection over the past 20 years, which is why a significant shortage of capacities prevails in the European market.

MED: Which advantages does the location in Bruchsal offer?

Dr. Ostrowicki: The medical device industry is very strongly represented in Baden-Württemberg, which almost automatically resulted in choosing Bruchsal. The location is also characterised by its excellent logistical connection to the medical device markets in neighbouring countries. Incidentally, the transportation of many products is oftentimes routed via logistics centres in Germany, and the stopover in Bruchsal is more or less situated en route to the final destination.

MED: BGS offers radiation cross-linking and radiation sterilisation services. What are the characteristics of the processes?

Dr. Ostrowicki: Radiation cross-linking triggers chemical reactions in plastics, which modify polymers. Radiation cross-linking gives commodity plastics and technical plastics the mechanical, thermal and chemical properties of high-performance plastics. Usually, standard polymers melt or wear away at medium to high temperatures or the material is affected by chemicals. The refinement of materials provides plastics with new and high-quality properties for their use.
Radiation sterilisation, on the other hand, is used for applications that require a high level of hygiene or sterility. For example, in the field of biotechnology or when materials are processed in the clean room, up to highly sensitive medical devices such as endoprostheses or implants. Gamma and beta rays are used for this purpose. The main difference between both processes lies in the penetration capabilities for materials and their speed. Gamma rays have a high penetration depth and a relatively low dose rate. In this way, complete pallets can be sterilised in a few hours. As a result, the procedure makes it possible to market products without waiting times after they have been treated with the correct radiation dose.

However, beta rays have a high dose rate and a reduced penetration depth. E-Beam is a particle radiation with accelerated electrons where the mass of the electrons is virtually accelerated to the speed of light. This method provides the same results as the gamma irradiation. However, the penetration depth is limited in the case of particle radiation since the irradiated material absorbs the electrons more readily. Therefore, the cardboard boxes loaded on a pallet are irradiated in layers, whereas the irradiation is completed in only a few seconds. This way, and under optimal conditions, a full truckload can be sterilised in a few hours.

MED: Are there any other limitations?

Dr. Ostrowicki: The operational step of particle radiation is not suitable as soon as homogenous penetration is no longer possible due to the density. Metal components or inappropriately arranged packaging must therefore be considered separately. Products with integrated electronic components are not suited for any radiation, because the radiation may result in a transformation of semi-conductor properties and consequently impair their functionality. Nevertheless, a broad selection of materials has been specifically optimised for radiation sterilisation in the meantime. These also include materials with very transparent properties such as COP polymers.

MED: On what basis do you specify the parameters for the radiation treatment and how do you examine the sterility level?

Dr. Ostrowicki: The spectrum of pathogenic microorganisms generated during production is determined in a sophisticated qualification process and the radiation dose is adjusted accordingly. Besides the materials to be sterilised, the parameters such as the extent of transport packaging, packing scheme and sterile barrier of a product are also taken into account. The reproducible sterilisation processes can be finally examined with statistical methods as well as through random tests.

MED: Which processes are used for which products?

Dr. Ostrowicki: Generally, our radiation sterilisation covers the entire spectrum of single use materials through to risk class 3. However, we operate in a competitive environment. Typically, the customer has the choice between the often used radiation treatment and the sterilisation with ethylene oxide gas (EtO). The treatment with ethylene oxide is suggested, for example, in the case of products made from plastics, which react to the radiation by embrittlement or other changes. Principally, both methods are qualified in this regard, as the radiation treatment and the sterilisation with ethylene oxide gas (EtO) complement each other. If products have complicated geometries or large surfaces, radiation sterilisation provides significant advantages over EtO. Moreover, the irradiation with electrons enables a considerably faster completion of the process. In this way, the sterilisation treatment with beta irradiation can be carried out within seconds.

On the other hand, the gamma irradiation process will take about two to four hours. However, the sterilisation with ethyle-
ne oxide requires a relatively long dwell time of several days, as the desorption of the gas must be allowed by the material.

MED: Are there any other factors that have to be taken into account?

Dr. Ostrowicki: Compared to gamma irradiation, the sterilisation with ethylene oxide and the irradiation with electrons is slightly less expensive. A fact that is optimally already considered when the products and their packaging are developed. However, the sterilisation with gas involves some disadvantages, because chemical residues may build up on the surface of sterilised products. For products with areas that are difficult to access, such as tubes or closed cavities, it is therefore mandatory to perform the work by using the residue-free radiation sterilisation. By applying this method no radioactivity is ultimately generated, but rather chemical processes are exclusively triggered. Since there is a wide range of products and materials in the medical device sector, consultation on a case-by-case basis is almost always necessary.

MED: Dr. Ostrowicki, thank you very much for your interesting explanations.

Interview conducted by Carola Tesche

ODU: The best connection between technology and medicine

In the world of modern medicine, new possibilities are arising at lightning speed – with demands on the respective technology increasing just as quickly. And, just like existing applications, each and every innovation must guarantee the highest level of security along with a wide range of benefits.

ODU has been providing time-tested connector technology and innovative customized solutions for decades now. Leading medical technology manufacturers know they can count on our expertise as a globally active partner – because when it comes to interfaces for medical applications, we know exactly what we are talking about. ODU products offer consistent failure protection and the dependable transmission of signals, power, data, and media such as air, liquids or even light waves.

They are also the perfect solution for a variety of applications in the daily medical environment: highly functional, robust technology ideally suited to high-hygiene environments and heavy-duty use – but always user-friendly and easy to operate.

Upon request, ODU is able to meet the high quality requirements of the EN ISO 13485 international standard as well as the IEC 60601 series of technical standards for the medical field. We strive to provide all our customers with a solid foundation for an ideal partnership. Check out our whitepaper at www.odu-connectors.com

ODU is your dependable partner for future-focused medical technology with perfect connections – for diagnostics, treatment, hybrid operating rooms and patient monitoring.

Company Profile

BGS is represented at three locations in Germany. The picture shows the company Headquarters in Wihl, close to Gummersbach/Köln.
In-line laser marking is the process of choice for the permanent marking of tubing without adding any ink or material to the extrusion.

In-line Laser Marking of Silicone Tubing

Performed in-line with the extrusion process, not as a secondary procedure, laser marking is cost efficient, flexible, reliable, and proven to be safe.

The industry drives the market for printing and marking technologies as many pharmaceutical companies now require full lot traceability down to the component level. Popular marking methods include pad printing, rotary printing, and silk screening; these methods all require the addition of ink as a print medium. This often brings up questions about the biocompatibility of various inks. Additionally, the application methods, particularly uncontained printing applications like screen printing, can be in conflict with cleanroom manufacturing processes. Inks need time to dry and are therefore applied in secondary batch processes with a minimum dry time. If the ink is not dry the printed information can be illegible and other products in contact with the ink may become contaminated. Batch processing, performed as a secondary operation, poses the risk for potentially mixing up products with another batch which corrupts the purpose of lot traceability.

In order to overcome these issues, Freudenberg Medical has implemented an innovative solution for laser marking silicone tubing without adding any downstream processes. With the Freudenberg method, silicone tubing is laser marked, on-the-fly, in parallel to the extrusion process. An ERP system provides the information to be printed on the tube; it is transferred directly to the printer via barcode. The digital transfer of information eliminates human error and avoids mixing products or applying the wrong information. With each work order, data is electronically transferred to the laser system and the focus point of the laser is adjusted to the specifications of the extruded product. The letter size is set in accordance with the tubing’s outer diameter and markings are only applied to the surface of the outer diameter. The in-line printing process will adjust automatically to the production speed without putting any additional constraints on the extrusion line speed; this is a significant benefit. This process can be used over a wide range of diameters and is very flexible in terms of applying frequently changing characters. Print data can include any information required from article or material number to lot number and production date.

A Superior Solution

In-line laser marking is superior to silk screening and pad printing processes, which require additional material applied to the tube and therefore additional validation processes. Ink can rub off or smear if it does not dry properly and risks occur if the wrong type of ink is used. With laser marking, no ink, pigment, material, or media is added to the extrusion. In addition, no additives or byproducts are used to facilitate laser marking so there is no danger of cleanroom contamination by ink or colors. Laser marks are achieved through a photochemical reaction on the outer layer of the tube, near the surface; the inner diameter does not see any alteration. The result is a durable mark which cannot be wiped or rubbed off. Extensive testing has been made to fine tune the wavelength of the laser in order to achieve the best results and provide clear letters and no burn marks.
The Test Results

Freudenberg engineers have conducted research on both laser marked and non-marked silicone tubing using tensile strength tests and cytotoxic residue tests and have determined there to be no significant change in the mechanical properties of the silicone tubing. To test the presence of possible cytotoxic residue related to the laser marking process, samples of both laser marked and non-marked tubes were sent to a certified contract research organization. The results indicated that the test materials did not release substances in cytotoxic concentrations during a constant 24 hour contact period. For the complete test results please contact a Business Development representative.

The end result proves laser marking to be a cost effective, reliable, and fail safe procedure for the permanent marking of silicone tubing when full lot traceability down to the component level is required.

Higher Voltages for Industrial Applications

Mouser Electronics is now stocking the MAXM17552 compact step-down DC-DC power module from Maxim Integrated. Offering an ultra-small power source to drive high-voltage industrial and consumer applications, the micro system-level IC (uSLIC) module provides a wide input voltage range for factory automation and medical.

The Maxim MAXM17552 module, available from Mouser Electronics, is part of Maxim’s Himalaya series of voltage regulator ICs and power modules, which enable cooler, smaller, and simpler power supply solutions. The MAXM17552 module operates over a wide input-voltage range of 4 V to 60 V and delivers up to 100 mA output current over an adjustable output voltage from 0.9 V to 5.5 V. The module integrates a synchronous wide-input Himalaya buck regulator with built-in FETs, compensation and other functions with an integrated shielded inductor in a minuscule 2.6 mm × 3.0 mm × 1.5 mm package. The module uses peak-current-mode control architecture, operates in pulse-width modulation (PWM) mode, and offers a soft-start feature to reduce input inrush current.

Compliant to CISPR 22 (EN 5022) Class B and JEDEC certified, the MAXM17552 power module delivers increased energy efficiency, shock and vibration tolerance, high temperature operation, and electromagnetic interference (EMI) compliance. The devices boast an ambient operating temperature range of minus 40 to 125 degrees Celsius and are guarded by hiccup overcurrent protection and overtemperature protection. Ideal for space-constrained applications in small enclosures, the modules offer a power solution to support industrial sensors, motor encoders, building control, 4mA to 20mA current-loop powered sensors, and low dropout (LDO) regulator replacement.

www.mouser.com

Visit us: Intec, Leipzig – Halle 2 Stand C06 / LogiMAT – Halle 3 Stand D21

www.med-eng.de
Preproduction Run and Series Production

Samples, Prototypes, Preproduction Run and Series Production – in that respect, the manufacturing of samples and prototypes and the preproduction run are seen as the start of the home stretch for developers and product managers. However, up until the first sample production, all uncertainties must be taken into consideration and the troubleshooting must be largely completed. Developers can identify the last adjustments to the prototypes that are needed through control loops.

Prototype and sample manufacturing

To produce in a successful and resource-friendly way, detailed qualifications and comprehensive tests to ensure later production quality must be performed and passed. These qualifications and tests comprise several phases and begin during the sample and prototype manufacturing. DATA MODUL has their own specialist department at the production site in Weiurersheim which takes care of the manufacturing of fully functional prototypes and the production of the subsequent preproduction run.

Both, prototypes which are produced in near-serial processes, and the initial samples are manufactured in small quantities in partly non-standardized procedures. Here, all manufacturing-related documentation, such as, for example assembly instructions, is created during the process and the parts lists are checked.

In the field of medicine, there is the “Device Master Record” and ”Device History Record”. Both are essential elements when it comes to the manufacturing of ISO 13485 products. Numerous functions of the end product can be demonstrated with samples. The manufacturing is done on the basis of the previously created parts lists. This results in the production of product samples which are used for demonstration purposes and for the performance of preliminary tests of panel and touch functionalities. The parts manufactured using a Rapid Prototyping Procedure, such as 3D printing procedures according to the requirements of modelling and CAD software, provide important information about function and fit accuracy. At this point the product becomes reality for the first time.

Feedback from the customer is requested

For the further process, feedback is now requested and needed from the customer. The basic evaluation of the prototypes

The production of medical operating devices is subject to the strictest checks. The path to final series production can be shortened with expertise and a suitable selection of components, but it will always involve diverse, partially specified process steps.
usually takes place in the early stages of the product development for straightforward adjustments. The later in the development process modifications have to be implemented, the more time-consuming and expensive the product development will be. Even more so if highly specialized products such as devices for medical applications are concerned.

In critical medical areas, the Change Management, in particular the Engineering Change Request (ECR) plays an important role. For this reason, digital models/prototypes are increasingly simulated. To master the so-called Frontloading, corresponding competences, know-how and high-performance software are required.

In all project phases, the knowledge acquired either flows directly back into the development or is used for the later series planning. Unplanned changes to the display unit can at this stage be implemented without any significant effect on the later series.

Here, the production start date has a very high priority. Especially for complex medical projects, the manufacturing, scheduling, production planning and purchasing are involved right from the beginning. This ensures that steps to improve production can directly be integrated in the process.

Qualification and certification for products

The latest point in time to perform the tests (temperature, EMC), certifications and qualifications planned for the series is during the preproduction run. However, in most
cases it is worth testing any critical requirements earlier on with the prototypes.

Thanks to the internal release process, optimal implementation of the customers’ specific requirements is possible. Additionally, an initial sample test report (ISTR), which must always be created in agreement with the customer can be added. In this ISTR, it will once again be checked if all of the customer’s relevant parameters have been fulfilled.

DATA MODUL has their own department for qualifications. This department is responsible for all internal qualification and all external certifications phases. In here, stress tests, temperature and climate tests and parts of the device safety testing are carried out. Cable-related malfunctions can be qualified in-house. With the new EMC chamber, important findings from the pre-measurements can be integrated into the product.

With medical projects specific parameters, such as strict medical hygiene regulations must be taken into consideration. Amongst other things this includes residue-free cleaning of the device (e.g. Wipe disinfection). Any gaps in the device housing must either be so narrow that no fluids or contamination can run in or settle in the space, or so wide that it can be cleaned easily at any time. In order to optimally fulfill functional requirements such as this with current design specifications, the gap must either be filled with suitable materials or a gap optimization must be performed: For this, construction experience with various materials and the corresponding manufacturing equipment is required.

After any necessary adjustments are made, this ensures a perfect set-up for the later procedures in the series. The manufactured prototypes are often used for product introductions and presentations to the public (at trade fairs, exhibitions). The feedback generated by the customers there has a significant influence on the product development. If an adjustment must be made, all adjustment requirements are compiled in an Engineering Change Request for example. All contracting parties must then agree to a possible modification of the product / a deviation from the original product description. The following must be described: modification creator, product version, modifications and the expected optimizations, the reasons for the modification, costs and all other schedule sequences and expenditure of time.

Preproduction run and second qualification

The preproduction run refers to the production process between prototype manufacturing and series production. With the preproduction run, like the prototypes, an approval process will be carried out. This represents an additional control loop. The preproduction run products will be produced under series conditions. Therefore, these devices will fulfill all basic requirements and will be used for the customer qualification. The customer approval for the series production will finally be issued with the preproduction run samples. All manufacturing instructions, assembly steps and instructions are created at this point. In the preproduction run, the specific parameters, such as size accuracy / surfaces / functions / features are all tested again and the manufacturing procedure is tested and optimized (press fitting). Paint testing and possible optimizations are done now and the optimal equipping of the light corners with LEDs (LED intensity, illumination quality), as well as the ground connection and potential (Grounding Concept) are tested and finalized. At the same time, the preproduction run is certified and undergoes tests such as EMC, stress, temperature.

Series production & forecast

When all iterative processes are completed, series production begins. A medical monitor / HMI, like any other device, is made up of many individual parts that follow their own production specifications. From a commercial point of view, the machine costs for a series part should only have a very small effect on the price which, most of the time, can be guaranteed through having minimum purchase quantities.

For an effective forecast planning, the determination of costs and the definition of the manufacturing lot sizes, the customer and developer must conclude the framework agreement with preparation of the requests early. In doing so the quantity planning for the parts used can be taken into consideration during the design phase.

Author: Thomas Wolfmüller, Product Manager
DATA MODUL AG
There are about five million amputees of the upper extremities. Thanks to modern medical technology, myoelectric arm prostheses can restore many basic hand functions, worldwide.

3D Printing Changes Prosthetics

Complex high-tech prostheses are not only expensive. It often took months to fabricate the right prosthesis individually. 3D printing is the next evolutionary step in prosthetics and offers unexpected new opportunities, especially for people in developing countries or war zones. The British start-up Open Bionics has developed bionic hand prostheses that can not only be customized in the shortest time possible, but are also affordable and can be produced locally anywhere in the world with a 3D printer.

Cost-saver 3D printing

3D printing has established itself in many different medical fields. The additive manufacturing process in particular revolutionizes the field of prosthetics. Exoprostheses in particular can be adapted to the patient’s specific requirements more quickly and at a significantly lower cost with 3D printers. Founder and CEO of Open Bionics Joel Gibbard wants to make myoelectric prosthodontics technology affordable for a larger number of patients while shortening the time it takes to fit and fabricate the wearers, and many amputees around the world do not have access to expensive functional arm prostheses. The costs are usually around €30,000 and can be up to €120,000 in individual cases. Open Bionics’ bionic arm prostheses, on the other hand, can be produced with a 3D printer for €1,200.

Time saver 3D printed prostheses

Conventional techniques often require half a year to complete the final fitting of the prosthesis. Using 3D printing techniqu-
es, such as those used by Open Bionic in development and production, prostheses can be fabricated quickly and accurately. The 3D scanning of the arm stump takes only about two minutes and 3D modelling software then creates the prosthetic model for the hand and socket. The patient receives a customized myoelectric arm prosthesis within two days. Children and adolescents in particular, who usually need two prostheses per year due to their growth, benefit from the fast and precise manufacturing process.

**3D printing process**

Not all 3D printing methods and 3D printers meet the requirements of prosthetics. The hardware requirements of the printer are important, but the Slicer software is crucial. A slicer divides 3D designs into many thin layers, which are then printed layer by layer. Open Bionics relies on the Fused Deposition Modeling (FDM) method. Here, individual layers are applied with heated and melted materials. With Ultimaker’s 3D printers and the slicing software Cura, for example, layers of up to 0.02 millimetres can be applied. For the wearer, these are no longer noticeable. The pressure of a complex component, such as the fingers and joints of Open Bionics’ hand, takes several hours and often runs overnight. In order to ensure that printing does not stop, or quality losses occur, the job must be optimally configured and the hardware must be precisely controlled. The different plastic filaments behave differently in the printing process. Criteria such as layer thickness and weight of the applied material also influence the printing process and must be optimally controlled. The software must therefore recognize the materials and configure the orders accordingly.

**Common materials and less components**

In order to reduce the complexity of the arm prosthesis and simplify assembly, Open Bionics has developed a design with few components. All fingers including the joints are printed in one operation. One hand consists of only four printed parts, using only two filaments. The filament PLA is used for the pressure of the little moving parts of the hand, such as the back of the hand. The soft flexible prosthetic fingers are made of Ninjaflex, an elastic and flexible TPU.

**Principle of myoelectric prostheses**

The myoelectric system is only suitable for prostheses of the upper extremities and is state-of-the-art here. Electrodes on the musculature of the upper arm transmit electrical signals, which are generated by the wearer by tensioning certain muscles. A microprocessor in the artificial hand controls the movements in real time. The wearer can move every finger individually and with different power and speed.

**Open Bionics Developer Community**

Engineers and developers are invited to join the Open Bionics Developer Community. The community sees itself as a research and test platform for the further development of bionic hands in prosthetics and robotics. Various designs, construction plans and building instructions for bionic arm prostheses are available for download on the platform. Each hand is designed in such a way that anyone interested in robotics or prosthetics can build it for further development or for their own test purposes or adapt it to their own requirements. Various components such as sensors, actuators, EMG electrodes or specially coated fingertips for more grips are available from the Open Bionics shop. The settings for 3D printing of the mechanical parts with Ultimaker printers are described in detail in the accompanying tutorial. The slicing software Cura is available as freeware.

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EFFICIENT USE OF PCBs

New Possibilities thanks to CleanCut Technology

The new Managing Director ElectronicsQuipment, Benjamin Kligenberg, has only been in his new position at LPKF Laser & Electronics since October. However, he is far from unfamiliar with the company as he was employed at the headquarters in Garbsen from 2000 to 2009. Now, after nine years, he has returned - and is convinced of the many new developments and innovative technologies. He was particularly impressed by the CleanCut technology, which sets a new standard for fast and clean PCB depaneling using lasers.

LPKF has achieved a further breakthrough with its innovative CleanCut technology and has significantly improved speed and cleanliness which are the two most important parameters for depaneling. The use of Clean-Cut avoids any discoloration at the cutting edges that can occur during conventional laser processing. In addition, laser processing speeds of previously unknown dimensions can be achieved. This is groundbreaking in the field of depaneling and offers both PCB manufacturers and EMS service providers an unprecedented degree of efficiency with the highest cutting quality - and thus also new possibilities for PCB design.

At electronica, we will present this technology live for the first time with our PicoLine 3000 ci laser system, which was specially developed for integration into fully automated production lines at EMS service providers. High quality printed circuit boards are processed with this system in a very gentle way. The user can now build even more compact and utilize printed circuit board surfaces up to the edges. Thanks to software-defined cutting paths and extensive geometrical freedom, it is possible to work out developments faster and more flexibly - and to implement new geometries.

The results improve the reliability of the subsequent circuits. The process safety ensures that the printed circuit boards also meet the high-quality requirements of the automotive industry and medical technology.

The fact that additional cleaning processes after laser cutting are superfluous offers considerable savings in terms of process flow and material costs.

I think LPKF’s PicoLine systems have opened up great opportunities for PCB production and depanelization at the end of the assembly lines and offer new options for various fields of technology.

www.lpkf.de

Microscope photo of a cutting edge: Smooth surface, fast cut. With PicoLine systems, common PCB materials can be processed cleanly and residue-free in the shortest possible time.

„Laser technology has numerous advantages over mechanical cutting processes when it comes to PCB processing and particularly depaneling: extremely low material stress due to quasi contact-free cutting, minimal edges to the cutting areas, no milling dust, largely free geometries and flexible design due to digital data processing. In industrial applications, where minimum size, maximum functional density and high cutting quality without chipping are required for printed circuit boards, laser technology is a must.

The LPKF PicoLine 3000 ci laser system is ideally suited for depaneling in production lines. It produces clean PCB cut edges in a short process time.

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