PRISMA

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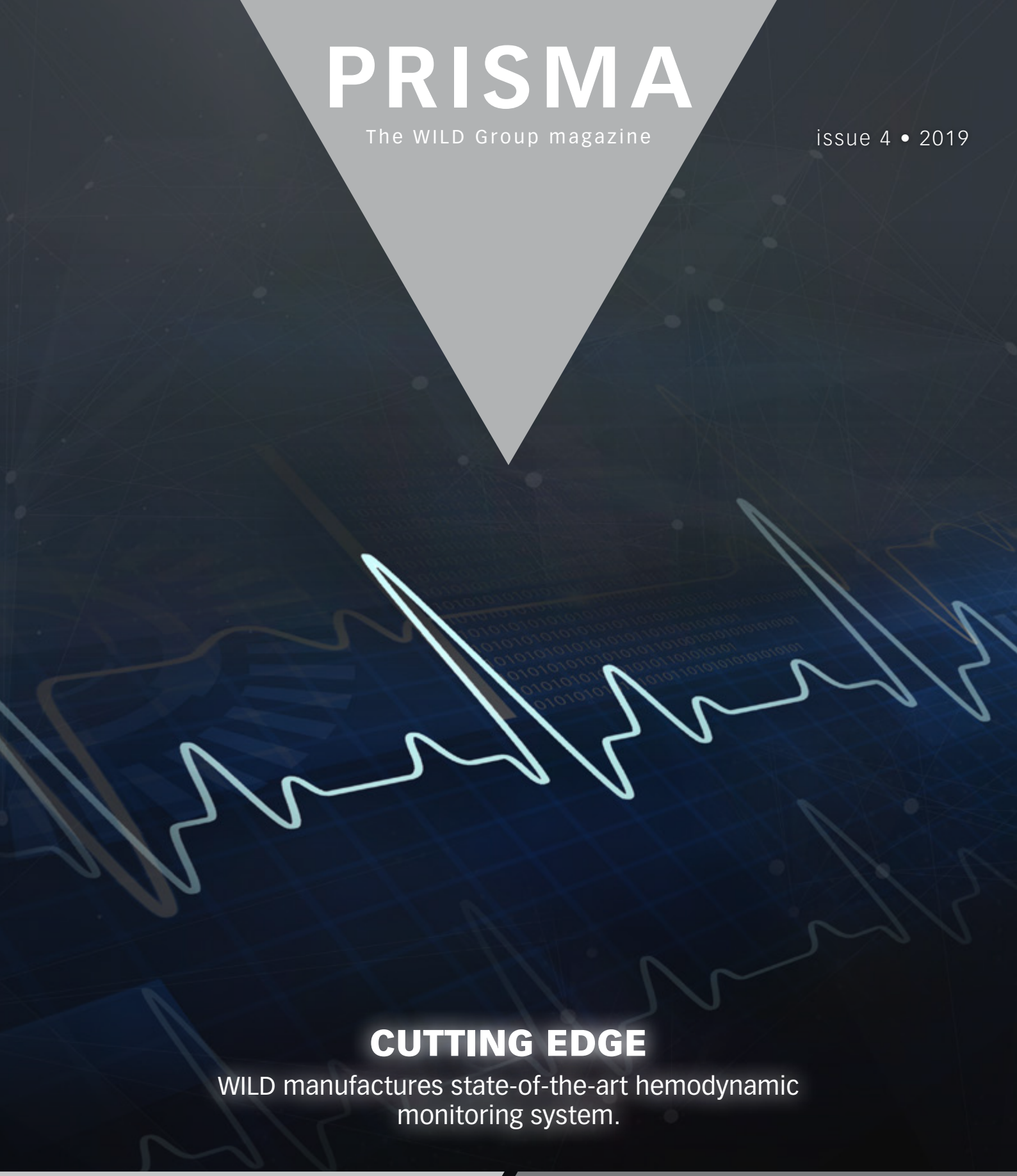

CUTTING EDGE

WILD manufactures state-of-the-art hemodynamic monitoring system.

WILD

PHOTONIC

Life cycle engineering helps relaunch the HRT 3 RCM worldwide.

Photonic intensifies cooperation with 3D endoscope manufacturer.

Latest FDA audit confirms WILD's top quality standards.

Wolfgang Warum
Managing Director CTO WILD Group

A RAW PASSION FOR MEDICAL TECHNOLOGY!

"Bundled know-how for your products." True to this principle, we will once again be participating in this year's COMPAMED together with our partners from the WIN Network. This time, WILD and Photonic will be joined at the trade fair stand by Alphagate and Insion, two equally innovative and renowned companies.

The current issue of PRISMA explains how together we form a knowledge hub which acts as an enabler for varied yet always pioneering and exciting solutions in medical technology. It provides a first insight into the latest developments from the areas of medical & life sciences and lighting technology.

The latest example is NICCI, a state-of-the-art extended hemodynamic monitoring system. Pulsion Medical Systems recently tasked us with the complete production of the device, something we are delighted with. The report on page 6 describes how we contributed to the return of the Heidelberg-Retina Tomograph 3 CRM with our professional life cycle engineering, complete with validation. Photonic is also pleased to announce that it is intensifying its cooperation with Blazejewski MEDI-TECH and will be supporting the German 3D endoscope manufacturer with innovative light solutions. Moreover, I am proud to announce the results of our FDA inspection one the back page.

We would be pleased to arrange a personal meeting for you with our experts at this year's COMPAMED. For more answers to the industry's challenges, come and visit us at Stand J19, Hall 8a.

Wolfgang Warum

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↗PRODUCTION

BECAUSE EVERY PULSE COUNTS.

▼WILD

WILD is the production partner for a new type of extended hemodynamic monitoring system.

In everyday practice, hemodynamic monitoring represents one of the most important parameters in patient monitoring. Not every procedure, however, requires continuous extended monitoring with arterial access. Around 80% of patients are monitored using a non-continuous blood pressure cuff. This, however, brings with it the risk of missing dangerous drops in blood pressure. **Continuous non-invasive arterial pressure (CNAP)** is a technology that allows for non-invasive hemodynamic monitoring of this patient group in particular. Every heartbeat is measured at the finger artery, just as other necessary parameters, e.g. those required for fluid management.

Pulsion Medical Systems, a leading manufacturer of hemodynamic monitoring products worldwide, is now introducing NICCI, the next decisive development step towards non-invasive, continuous blood pressure and cardiac output monitoring. What is new about this system is that, for the first time, the control unit has been designed to resemble a computer mouse. "In addition, we have implemented our typical disposable concept. Especially in the operating theatre and intensive care environment, where cross-contamination and infections are particularly relevant, we can thus make a significant contribution to curbing these", explains Clemens Brühl, Head of Product Management at Pulsion Medical Systems.

NICCI is primarily used when an arterial line is not indicated, not feasible or not conclusive enough. The ergonomic mouse is comfortably positioned directly on two fingers of the patient. Three available sensor sizes ensure a good fit. Within just 2 or 3 minutes, the physician or nurse receives the first important cardiovascular measurements such as blood pressure and cardiac index, as well as other parameters indicating whether the patient requires fluids. Thanks to its design and intelligent user interface, this innovative monitoring system can be easily integrated into the clinical workflow.

Systems partner WILD has been producing NICCI since early 2019 and has also been assigned with the transition into serial production. "By this time, development had already been completed. Nevertheless, our team provides support with production-relevant topics and contributes significant input, especially on process FMEA and validation. Know-how for future version and evolution stages also comes from the WIN partner network", says Project Manager Dieter Trampusch. One of the biggest challenges in manufacturing is the high-precision adjustment work, which requires a great deal of instinct and a lot of technical understanding. During pilot production and zero series production, contract manufacturer WILD was already able to furnish proof of its ability to provide both.

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FROM PRECISION MANUFACTURER TO STRATEGIC PARTNER.

▼WILD

Take time and listen. Pick up speed once implementation starts. And boldly chart new courses. CEO Josef Hackl and CTO Wolfgang Warum explain in an interview how the WILD Group has succeeded in becoming a serious contender in medical technology.

WILD has held pole position as contract manufacturer in the medical technology market for almost 50 years. How do you manage to keep the pace at a such high level for such a long time?

Wolfgang Warum: "We are never satisfied with what has been achieved, we always look towards the future. For instance, the fact that we recently passed the FDA audit without any ‚observations' is not an invitation for us to stand still, but instead motivates us to reach the next level. Thanks to this fundamental approach, the WILD Group has been able to develop from an initial precision manufacturer to a consultant and expert in the development and process validation of complex products."

> **We are never satisfied with what has been achieved, we always look towards the future,**
> *says Wolfgang Warum.*

Josef Hackl: "It has also been important to shape the individual companies of the Group into a complementary system with homogeneous processes. Moreover, the WIN partner network gives us a real technological edge."

The market is growing rapidly and innovation is abundant in different areas. How do you know you are backing the right horse?

Warum: "This is only possible if we broaden our horizons and precisely monitor new technologies that are now emerging. We analyse such trends as part of our Technology Roadmap. By focusing on selected target segments, we specifically build up application and industry expertise, which is important in

order to understand the requirements relating to current products. We listen very carefully to our customers and constantly react to changing demands. In addition, the close collaboration with external experts as part of the WIN partner network broadens our perspective and allows for true innovation leaps."

Don't the tremendous bandwidth of technologies and the profound specialisation contradict each other?

Warum: "No. The WILD Group's USP is precisely this combination. We bring together state-of-the-art knowledge in optics, mechanics, electronics and software. We developed the term ‚optomechatronics', which best expresses this uniqueness."

Why do you think demand for contract manufacturers in medical technology is growing and how do you see things developing in the future?

Hackl: "For today's medical technology manufacturers, it is quicker and more economically efficient to enter at a know-how level which is as high as possible with the help of a systems partner than to build everything from scratch themselves. In our volatile business world, the demand for partners in development and manufacturing will continue to grow. After all, implementing every trend in your own ranks entails significant risks. In addition, a short time to market has a significant impact on the success of a product. This is why you need solid partners who can show you the way forward."

Have the increasing regulatory requirements intensified this trend?

Warum: "Absolutely. Especially small and medium-sized enterprises benefit from not having to develop all manufacturing processes and their evaluation and validation in-house, and instead from being able to resort to established players like the WILD Group. In addition, it makes sense to keep internally developed products stable through external process validation, so as to avoid any future recall campaigns."

Hackl: "Regulatory systems pose barriers to entry, especially for newcomers in the medical technology sector and regrettably they also slow down the speed of innovation because they require a very high level of organisation. As partners, we can provide massive support to our customers in this respect."

WILD maintains long-standing partnerships with many customers. Why are the requirements today different from the past?

Warum: "The drastic changes in the regulatory regime in Europe alone is causing uncertainty among many companies. We see ourselves as a kind of sparring partner for our customers. This already makes the bond stronger and more intensive."

Hackl: "At the same time, medical technology products are becoming smarter and more connected. Despite a higher level of complexity, they offer better usability. To achieve that, it is becoming increasingly important for a contract manufacturer to become involved in a customer project already during the development phase. Our development expertise, further boosted by the WIN partner network, has been given completely new status as a result."

> **"For today's medical technology manufacturers, it is quicker and more economically efficient to enter at a know-how level which is as high as possible with the help of a systems partner than to build everything from scratch themselves,**
> *explains Josef Hackl.*

↗ DEVELOPMENT ↗ PRODUCTION

RETURN OF THE HRT 3 RCM IN OPHTHALMOLOGY.

WILD

WILD's professional life cycle engineering, complete with validation, is readying the Heidelberg Retina Tomograph 3 RCM for the world market again.

The Heidelberg Retina Tomograph 3 with the Rostock Cornea Module (HRT 3 RCM) offers unique, high-resolution en-face scans of the individual layers and structures of the cornea. Despite the great demand in the international market, Heidelberg Engineering had to temporarily withdraw the HRT 3 RCM from the market due to updates introduced in medical technology standards. The device is now available again thanks to the intensive collaboration with WILD.

> **"We were able to draw from this pool of experience for the relaunch, which brought us significant benefits, also with regard to parts procurement and the redesign of the head-and-chin rest,** *explains Damien Kerschbaum.*

The systems partner has been manufacturing the corneal microscope for over a decade, subjecting it to continuous life cycle engineering. "We were able to draw from this pool of experience for the relaunch, which brought us significant benefits, also with regard to parts procurement and the redesign of the head-and-chin rest", WILD Project Manager Damien Kerschbaum explains.

The biggest challenge: time scheduling

"Thanks in particular to the cooperation with WILD, we were able to relaunch the HRT3 RCM in just a very short time. Especially the experience, flexibility, transparent communication and reliability of the systems partner guaranteed that we could commit to a very tight schedule", says Peter Buttgereit, Technical Project Lead at Heidelberg Engineering. "Among other things, the outstanding know-how in procurement, documentation and production came into play, as well as quality assurance that included complex function and safety tests during production in compliance with international and special HE standards." WILD is currently in charge of the manufacturing of the HRT3 device, including the specific head-and-chin rest, the camera and the optical block.

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↗ PRODUCTION

TOGETHER WE'RE FASTER.

PHOTONIC

Photonic recently began supporting German 3D endoscope maker Blazejewski MEDI-TECH with its innovative light solutions.

Especially in medical technology, trustworthy partnerships are a meaningful and common practice. They are frequently established for the development of new products, where close cooperation can help cut costs and reduce time to market. Photonic and Blazejewski MEDI-TECH, too, recently decided to combine their skills.
"Photonic is an exciting partner for us because it possesses in-depth expertise in light coupling in endoscopy camera systems and offers a broad range of LED laser modules in various brightness levels and different light qualities", stresses CEO Reinhold Blazejewski.

In a first stage, Photonic adapted its F5000M light module exactly to customer requirements for a 2D endoscope used in spinal surgery and neurosurgical interventions. "More specifically, the latter had to be fitted together with the camera controller in the same casing, despite the limited space available. Other requirements included maintenance-free operation throughout the product's envisaged life cycle and as little power dissipation as possible", says Stefan Zotter, Head of Research & Development at Photonic.

"Another specification was that the fibre optic light guides and the electrical cable had to share the same inlet tube so that the cable could be connected to the controller using a hybrid connector."

In the future, Photonic's specially adapted light modules may also be used in 3D endoscopy. Although minimally invasive endoscopic interventions are daily business, they still remain a challenge for surgeons. Their field of vision is severely limited during surgery and they often struggle with orientation and navigation issues.
To alleviate both, Blazejewski MEDI-TECH has developed the BMTvision® endoscope system which provides stereoscopic imaging and thus a greater sense of depth.
"Stereoscopic vision is created by projecting the images on the sensors from slightly offset angles.
The control unit processes this information for display on a 3D monitor. Polarised 3D glasses then provide surgeons with images that give them a significantly better sense of depth and make it much easier to navigate", explains Blazejewski MEDI-TECH's CTO Volkmar Freystein.

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↗ INTERNAL

THE FDA AUDIT WAS A SUCCESS.

WILD

The US authority attests that WILD meets the highest quality standards.

The guidelines of the Good Manufacturing Practice (GMP) are strict. The US Food and Drug Administration (FDA) was accordingly thorough in its recent audit of WILD GmbH. The auditors inspected the production and quality assurance systems for 2 days, focusing in particular on assembly, complaint management and management processes. The positive result of the audit: "No observations".

> **"The audit demonstrates our high level in process development and our distinct competencies in manufacturing and quality assurance,**
> *says Emmerich Kriegl.*

For Head of Quality Management Emmerich Kriegl, the successful FDA audit is the consequence of WILD's commitment to quality. "The audit demonstrates our high level in process development and our distinct competencies in manufacturing and quality assurance", says Kriegl. "In order to cooperate with the authorities in a targeted manner, you above all need a competent team to act swiftly and reliably while accompanying and supporting the staff." Therefore, WILD put together a specific project team to prepare for the audit, in which Emmerich Kriegl himself, Markus Lippe, Martin Haubitz, Lukas Gruze and Wolfgang Pischounig played a crucial role. As part of the preparation, they meticulously reviewed the processes and evidence and continuously performed simulation audits, so-called mock inspections.

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The WILD Group
The WILD Group is comprised of the WILD brands which are established in Völkermarkt, Wernberg and Trnava/Slovakia, as well as Vienna-based Photonic. The Group's 451 highly qualified staff members are always the first choice when precision and reliability are a must and when innovations are called for.