Safe sterilisation of medical devices

SOLSTEO is a designer, manufacturer, installer and maintainer of EO sterilisation equipment. Ethylene oxide (EO) sterilisation is the most common industrial sterilisation technique for medical devices. A leading European player in this space, SOLSTEO has partnered with Picarro. Through this partnership, the companies will provide customers throughout Europe, the Middle East and Africa, as well as South-East Asia with a one-stop-shop for market-leading Ethylene Oxide (EO) gas concentration analysers and high-performance EO sterilisation equipment. EO is an important chemical used for the sterilisation of medical equipment and a common ingredient in the industrial production of other compounds. Known to have mutagenic properties even at low concentrations, there are major concerns about the effects of long-term exposure on humans, and regulatory bodies worldwide are re-evaluating exposure limits, as Jean-Baptiste Bonnet, Technical Director at SOLSTEO, explains. "With Picarro we can offer sterilisers that are safe and in compliance with regulation now and in the future."

> SOLSTEO was co-founded by Mr. Bonnet in Paris, in February 2014. It was spun off from CristalDoc, a software developer which later began supplying spare parts and small peripheral equipment for EO sterilisation. "But as demand grew strongly it became necessary to set up a separate, dedicated company for the design and supply of complete machines," Mr. Bonnet explains.

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SOLSTEO today serves the global medical industry, with customers device

including device manufacturers and EO sterilisation service providers in Europe, the Middle East, North Africa, and South East Asia. The company's clear development strategy is based on networking and partnering with experts in EO sterilisation field worldwide. "We are strong believers in this extended enterprise model that make customers benefit from the best of both worlds: engineering & software innovations with SOLSTEO, and our partners' expertise such as manufacturing know-how with

our boiler maker," says Mr. Bonnet. "All SOLSTEO machines are 100% manufactured in France with a strong customer-centric approach. an uncompromised priority on quality in mechanical design, in software engineering and in the manufacturing processes and documentation."

Key differentiators of SOLSTEO's machines in his view include the SOLSTEO software package, and the unique features they provide. He highlights the SMART-RECORDING feature: this is a PLC-embedded data buffer that secure 100% recording of cycle data in whichever situation, even when a power or network failures. "Our SCADA system eliminates the risk of incomplete cycle reports." SOLSTEO machines also exclusively feature IQ-SIM software tools reproducing the physical parameters of an EO steriliser. "These function like a flight simulator, enabling 95% software validation prior to installation in the machine." As SOLSTEO software is developed with web-type industrial applications (e.g.





Microsoft SQL), they can connect and be integrated with other systems in a factory, SAP or other ERP systems for example.

Mr. Bonnet was instrumental in making SOLSTEO's recently announced partnership with Picarro happen. Picarro has developed a gas analyser family capable of measuring parts-pertrillion (ppt) levels of EO (C, H, O) in real time (less than 2 seconds), and without the need for chromatographic separation or pre-concentration. These analysers enable services providers, regulators, and industrial users of EO medical sterilisation such as companies, to accurately and effortlessly measure and monitor EO. With this technology, customers can adapt to changing regulations, protect the health of workers and the environment by minimising exposure, monitoring how the system performs and tracking down what part works below standards so that the responsible part can be replaced or fixed before it's too late.

"It is becoming necessary to detect trace gases at much lower concentrations that we used to, at much lower concentrations that present-day-technologies have been designed for," Mr. Bonnet explains. "A

fact of our industry is that EO can be a dangerous component if it isn't handled with care. As we design and build EO sterilisers we feel it's our corporate responsibility to provide users with the means to accurately measure the residual emissions of our equipment, going beyond the regulatory requirements."

SOLSTEO had been looking for a technology capable of detecting and characterising EO at low levels in a factory environment. "We read an article on CRDS (Cavity Ring-Down Spectrometer) analyser by Picarro in early 2020. We contacted them and we immediately understood that CRDS technology was THE technology the industry had been waiting for," says Mr. Bonnet

Within the terms of their partnership agreement, SOLSTEO will serve as the one-stop-shop for Picarro in Europe and other parts in the world, he adds. "We have hands-on experience with EO sterilisation so we bring our own perspective, gained from user feedback. We also are the information provider for customers, providing technical advice, selling Picarro analysers, installing them on site and providing maintenance services and technical assistance. We can leverage our own network of EO

sterilisation stakeholders to promote Picarro's technology and its actual applications in the field."

Interested parties are welcome at SOLSTEO for a product demonstration, he points out. "We are happy to share our knowledge with customers and help them get ready for new, upcoming changes in the regulatory landscape. Last but not least, our commitment to our Corporate and Social responsibility is something we take seriously. We want to design sterilisers that are safe to operate and that limit our environmental footprint by controlling and reducing EO emissions, which can only be done with the right tools."



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