

SENSOR PERFORMANCE INSIGHTS

MEDICAL DEVICES ISSUE | VOL. 1



SENSOR PERFORMANCE INSIGHTS

Medical Devices Issue

The global medtech market has shown strong performance for several years. With the improving economy encouraging more consumers to seek medical care, an ageing population, as well as an increase in technological advancements in the market, the segment faces a robust growth path ahead. Market researcher Evaluate Ltd. forecasts a compound annual growth rate (CAGR) of 5.6%, reaching USD 595 billion in sales by 2024.

With the first issue of **Sensor Performance Insights**, we want you to take a journey with us getting a deep insight in new sensor developments, giving modern medical device developments an innovative boost.

Enjoy reading
Your editorial team

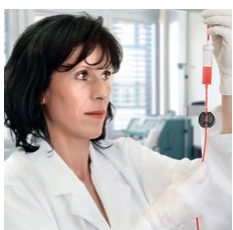
Combined FlowBubble Measurement



**SONOFLOW CO.56 Pro FlowBubble Sensor
successfully designed into heart-lung machines**

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Air Bubble & Blood Leak Detectors



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for hemodialysis**

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Combined FlowBubble Measurement

SONOFLOW CO.56 Pro FlowBubble Sensors successfully designed into heart-lung machines



Cardiopulmonary bypass (CPB) is a method that temporarily takes over the function of the heart and lungs during surgery, maintaining the human blood and oxygen circulation. The CPB pump, often also named as heart-lung machine (HLM), deals with human lives. Hence, technical requirements are specifically high. A reliable operation of all utilized equipment must be guaranteed at all times. For that reason, combining flow measurement and air bubble detection constitutes a significant safety and comfort feature.

As the heart-lung machine takes over the function of the heart and the lungs, it technically imitates the heart as a „pump“ and the gas exchange of the lungs. The HLM operates two main circuits: the venous circuit and the arterial circuit with additional feed

lines. The venous circuit is fed by venous blood originating from the right ventricle of the patient's heart drained into the venous reservoir, where it is processed and smoothly pumped back into the aorta of the human body.

A medical device full of high-grade technologies

The arterial pump takes over the full or partial pumping performance of the heart when required. The pump, which is fed by the venous reservoir and directly connected to an extracorporeal oxygenator, is the main pump of the HLM; all other pumps and components of the HLM are subordinated to it. All stored alarms regulate or stop the main pump and its associated components if required. The extracorporeal oxygenator is an artificial device that substitutes for human

lungs by delivering oxygen to, and extracting carbon dioxide from, venous blood. The tubing system of the heart-lung machine consists of PVC and silicone tubes, cannulas, and shunts which are used in different sizes. The heart of an HLM, however, is the console with integrated control unit and emergency batteries. Heart-lung machines are available as modular systems that each hospital can assemble according to its specific requirements and needs.

„This launch takes FlowBubble sensors to a new level. The SONOFLOW CO.56 Pro sensors are technologically leading in the global field of competition. The non-invasive devices captivate through their compact design and integrated electronics, and can be mounted freely suspended.“

Melanie Schmidt,
Business Unit Director Non-invasive Fluid Monitoring

Different sensors monitor, support, and protect vital human functions

Pressure Sensors

... continuously measure and document the pressure within the tubing system. If certain pressure limits are reached, an alarm signal is triggered. This ensures that the HLM does not pump the blood back into the patient's vascular system at too high a pressure.

Level Sensors

... are utilized to monitor changes in fluid or blood volume in the venous reservoir of the heart-lung machine.

Bubble Detectors

... are key to patient safety. They are required to be clamped on the arterial line right after the arterial filter to protect against massive air embolism. The bubble sensors automatically warn and deactivate the arterial pump.

However, there are further options to place bubble detectors within the HLM circuit. The venous reservoir represents the first critical position where air can get into the circuit. Therefore, a reasonable location to apply the bubble sensor is between the venous reservoir and the arterial pump. Even to place a bubble sensor between the oxygenator and arterial line filter allows for trapping and purging air if necessary. The ideal and safest set-up would be to have multiple bubble sensors.

Flow Sensors

... are also a main component in HLM's. In order to not only detect air bubbles but also to effectively manage them, using shunts to connect the arterial circuit line and the venous reservoir in the tubing set-up is a critical point.

When air is detected, the arterial line is promptly closed by the arterio-venous shunt while the detected air is directly eliminated to the venous reservoir. When no more air is spotted, the shunt automatically re-opens the tubing to again feed the arterial line going straight into the human body.

For this reason, flow rates passing the shunt need to be continuously compared to the flows generated by the arterial pump, monitored and controlled over the time the HLM is running. Ultrasonic flow sensors accomplish this task failure-free and reliably.

SONOFLOW CO.56 Pro sensors combining flow measurement and air bubble detection

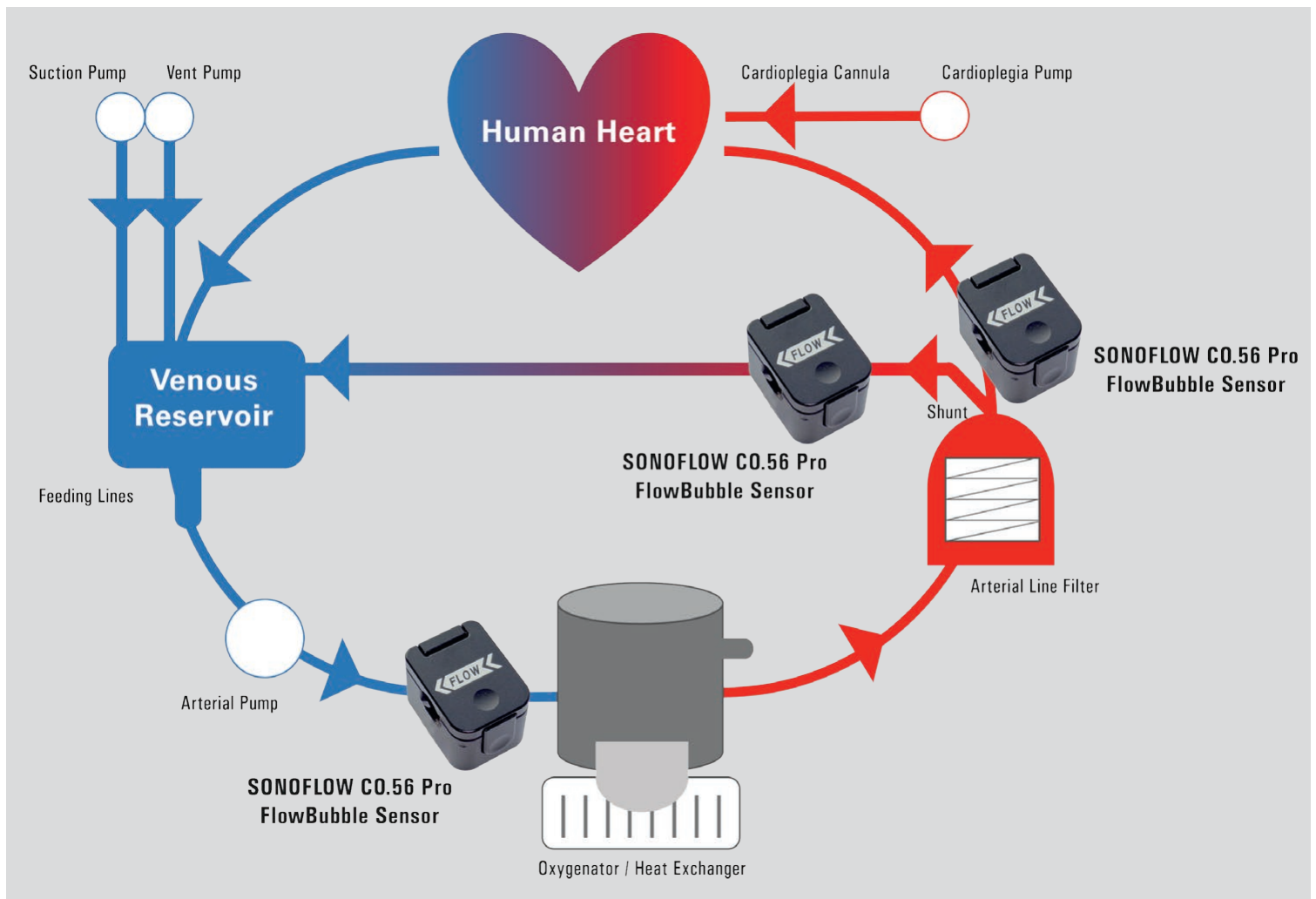
As both bubble detectors and flow sensors are elementary safety elements in heart-lung machines, SONOTEC has developed the SONOFLOW CO.56 Pro ultrasonic sensor series, which combines both flow measurement and air bubble detection of liquids in one compact unit. The integrated electronics and option to operate up to twelve independent sensors with only one control unit guarantees the world's smallest footprint for an OEM flow and bubble detector to be used in HLMS.

The non-invasive ultrasonic sensors operate without any media contact, they quickly perform bi-directional flow readings, and can be easily clamped free-hanging on the tubing. The accuracy of the SONOFLOW CO.56 Pro is up to two percent and the repeatability is as low as one percent, depending on where the sensor is mounted and which kind of liquid is actually measured. In addition to the measurement of flow conditions, the sensor is able to detect air bubbles as small as one third of the inner diameter of the tube.

SONOFLOW CO.56 Pro sensors successfully designed into heart-lung machines

Top medtech companies already rely on this game-changing technology and have implemented the control and monitoring unit for instantaneous flow and bubble detection into their equipment. One of the industry's leading companies developing and manufacturing HLMs has integrated the hybrid sensor solution into its recently launched device. The main reason for the manufacturer to trust in the SONOFLOW CO.56 Pro sensor series is the small electronic footprint and the option for multipoint measurement: Five of the smart sensors with different tubing channels have been applied to the

customer's newly developed console. The onboard electronics and its options for data processing make connecting the sensors an easy game. The built-in microcontroller guarantees to control all processes while data is transferred via the RS485-interface. The sensors themselves measure flow rates on different tubes and shunts leading to the body or back into the venous circuit of the heart-lung-machine. Simultaneously, they detect air bubbles accidentally caused. Finally, the non-invasive ultrasonic sensors give feedback on the real flow compared to the theoretical flow of the pump.



Simplified illustration of a heart-lung machine:
Implementation of SONOFLOW CO.56 Pro FlowBubble Sensors into cardiopulmonary bypass (SONOTEC GmbH)

Air Bubble & Blood Leak Detectors

Innovative air bubble and blood leak sensors for hemodialysis



Hemodialysis is an essential and routine medical treatment for which safety has become a clinical priority. As every step carries the risk of human error and/or hardware failure, the process requires a chain of interventions. Dialysis machines are essentially composed of pumps, screens, and alarms that allow safe proportioning of dialysate and blood circulation. Therefore, the device combines a variety of sensors for the monitoring of pressure, flow, and liquid level as well as for detecting leaks and air in tubing systems.

As an extracorporeal circuit, the dialysis machine substitutes a kidney's function during treatment. The patient's blood is redirected from the intracorporeal to the extracorporeal circuit. The actual diffusion between blood and dialysis fluid is processed in the dialyzer in which a biocompatible polymer membrane separates the two fluids from each other. Finally, toxins and/or water are removed from the blood through the membrane, or filter, as the membrane is often named.

During the process of blood transfer from the human body to the dialysis machine and back, as well as during membrane diffusion itself, there are numerous critical parameters to be monitored and controlled. For patient safety reasons, blood circulation is continuously observed with regard to the presence of air bubbles as they may result in life-threatening air embolisms. Membrane defects in the dialyzer, in turn, can accidentally cause blood loss through the separated dialysate. For this reason, the dialysate discharge tube is constantly monitored for blood leaks.



Non-invasive SONOCHECK ABD air bubble sensors used in hemodialysis

SONOCHECK ABD air bubble sensors are widely used in dialysis machines for hemodialysis. They are applied for fast and safe air bubble detection in the venous path of the extracorporeal blood circulation. By squeezing the tube into the measuring channel of the sensor, simple tube handling is guaranteed. This enables dry coupling with no need for any additional closing mechanisms. The sophisticated sensor design also ensures easy single-handed operation and a smooth cleaning process. The sensor itself is integrated into the front panel of the machine and acts as the last safety component before returning the blood to the patient.



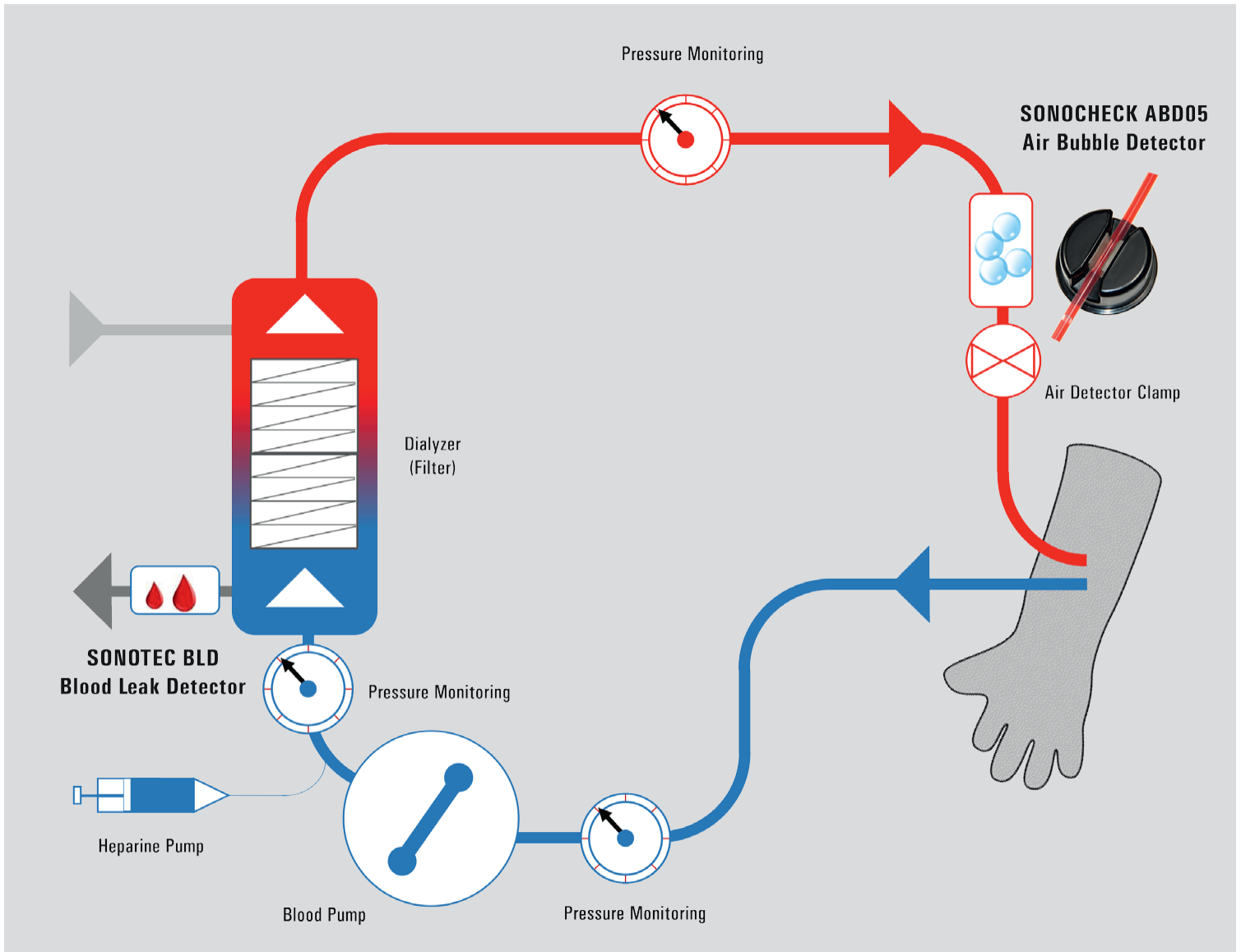
Based on quality regulations requiring overall patient safety, a simple and intuitive handling as well as a faultless operation at any time, SONOTEC engineers have developed the sophisticated SONOCHECK ABD05 sensor family. The sensor detects air bubbles reliably, but ignores harmless microbubbles. An additional optional optical sensor module acts as an initialization switch to start the actual dialysis treatment after the rinsing process.

Since the acoustic transmission through the tube strongly depends on ambient conditions during treatment, the sensor is programmed to constantly adapt to these changes without compromising patient safety. Bubbles are reliably detected from a certain predefined size onwards, with no influences caused by the tube setting, ambient humidity, temperature change, or a potential tubing shift. The built-in microcontroller allows smart and dynamic adaptation of the ultrasonic properties to ensure reproducible results. A patented algorithm dynamically adjusts the sensor to guarantee constant bubble sensitivity. Thus, the sensor does not need to be calibrated.

Within the SONOCHECK ABD05 security architecture, redundancy has been deemed unnecessary since all components meet the high requirements of "fail safe" and run extensive self-check routines during operation. "Fail safe" ensures that there is no need for the machine to actively trigger bubble simulations. This allows the sensor to keep performing without technically caused interruptions and to react to error messages in less than 0.2 seconds. For this purpose, the sensor periodically sends measured values as status reports

as well as predefined messages for bubble activity and error codes as alarm settings. With its unique safety concept, the SONOCHECK ABD05 has been implemented by numerous medical device

manufacturers and is verified by their renowned regulatory authorities. Today, the sensor is used worldwide in all major medical technology markets.



Simplified illustration of a dialysis process:
Implementation of SONOCHECK ABD05 Air Bubble Sensor & SONOTEC BLD into a hemodialysis machine (SONOTEC GmbH)



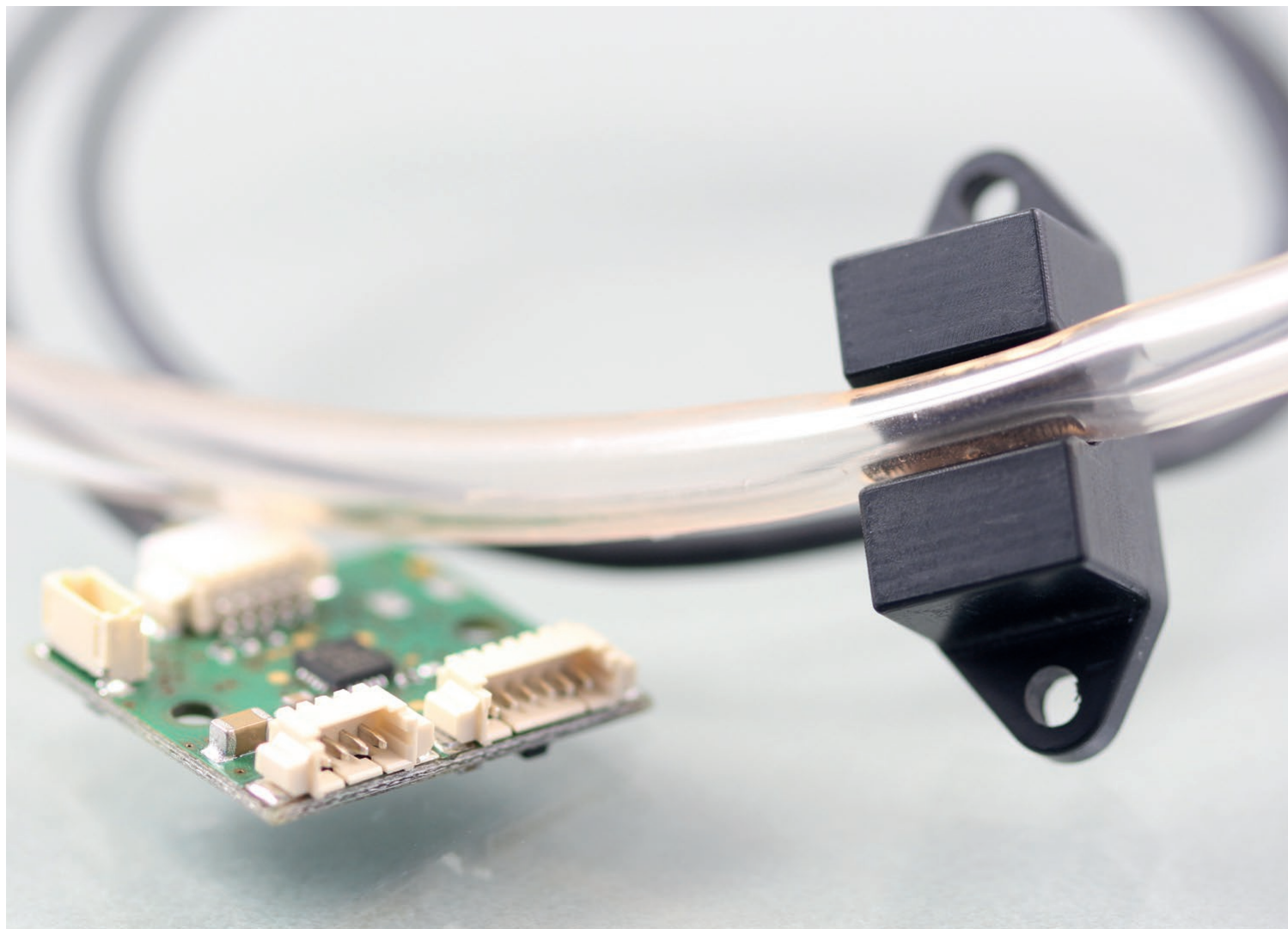
SONOTEC blood leak sensors detect the smallest traces of blood in dialysis fluids and prevent extracorporeal blood loss

An undetected membrane rupture in the dialyzer can lead to unwanted blood loss of the patient during dialysis treatment. For this reason, the discharged dialysate is continuously examined for blood traces. This task is performed by panchromatic optical blood leak sensors that non-invasively detect for red colorations in the dialysate.

With a wavelength adapted to the transmittance of blood, the SONOTEC BLD sensor meets the international standard IEC 60601-2-16:2012 for electronic medical devices.

The sensor reliably detects 0.04 percent of blood in an isotonic saline solution. If the sensor identifies blood in the dialysate, an error message is triggered on suspicion of membrane defects. Depending on treatment progression, either the blood pump is stopped, the venous clamp activated, or the ultrafiltration rate (UF rate) is reduced to a minimum.

BLD | Blood Leak Detector
Optical clamp-on sensor for contactless detection of smallest traces of blood (SONOTEC GmbH)



SONOTEC – with over 20 years of experience in developing ultrasonic sensor systems in medical technology

As developer and manufacturer of ultrasonic sensors and expert for the implementation of sensors for bubble detection and fluid monitoring in medical devices, SONOTEC has made a name for itself, gaining worldwide industry reputation over the last two decades. With the ISO 13485 certification standard, the company meets the highest requirements for a comprehensive quality management system to design and manufacture medical products.

Over a long period of successfully completed projects, SONOTEC has gained an excellent reputation among manufacturers of dialysis and transfusion devices, heart-lung machines, blood separators, medical pumps, and diagnostic systems. The intensive guidance from a very early stage in the product development process, prototyping, support in verification, and its expertise in certification processes gives SONOTEC a lasting competitive edge.





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Non-invasive Flow Measurement & Bubble Detection

Ultrasonic Sensors for the Medtech, Biotech and Semiconductor Industry



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The background of the slide is a blurred photograph of a heart-lung machine (ECMO) circuit. In the foreground, a red SONOFLOW CO.56 Pro flow sensor is attached to a clear plastic tube. The sensor has a small black display screen at the top and a white arrow pointing to the left with the brand name 'SONOFLOW' and model 'CO.56 Pro' printed on it. The overall scene is brightly lit, with a soft glow around the sensor.

SONOFLOW CO.56 Pro

in Heart-Lung Machines

Freely suspended

Non-invasive design

Small footprint/lightweight

High bubble sensitivity

Integrated electronics