SonoTT™ Components

FLOW MEASUREMENT & BUBBLE DETECTION FOR MEDICAL DEVICES

PSG a DOVER company

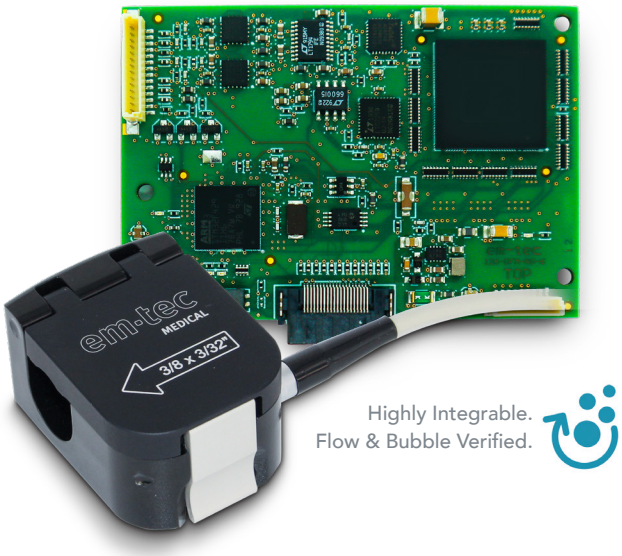
em·tec MEDICAL

Where Innovation Flows

SonoTT™ Components. Highly Integrable. Flow & Bubble Verified.

Introducing the Newest Member of the SonoTT™ Components:

Designed to be integrated into medical devices, the new SonoTT™ SkyLark gold comes with advanced features to provide a high level of customization, more convenience, and increased safety – especially with its new bubble detection feature to measure and detect two critical parameters: flow & bubble.



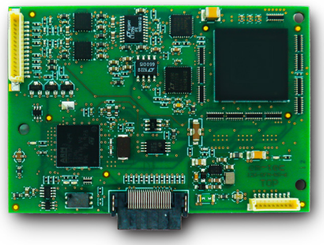
Features and Benefits

- 2-in-1: flow measurement and bubble detection
- Customizable according to customer requirements
- Designed to meet IEC 60601-1 standards
- Full integration support from initial request to serial production

SonoTT™ Components. Highly Integrable. Flow & Bubble Verified.

Integration Into Medical Devices

SonoTT™ components are to be integrated into medical devices such as HLM or ECMOs. To ensure the flow measurement and monitoring function, you need to combine the SonoTT™ SkyLark evaluation electronic with a corresponding SonoTT™ Clamp-On SL sensor. Available in different configurations, the SonoTT™ SkyLark can be adjusted to customer specifications regarding output rates, interfaces, or bubble sensitivity. The sensor can be customized to specific requirements such as cable length, lid print, or flow range.



SonoTT™ SkyLark Series*

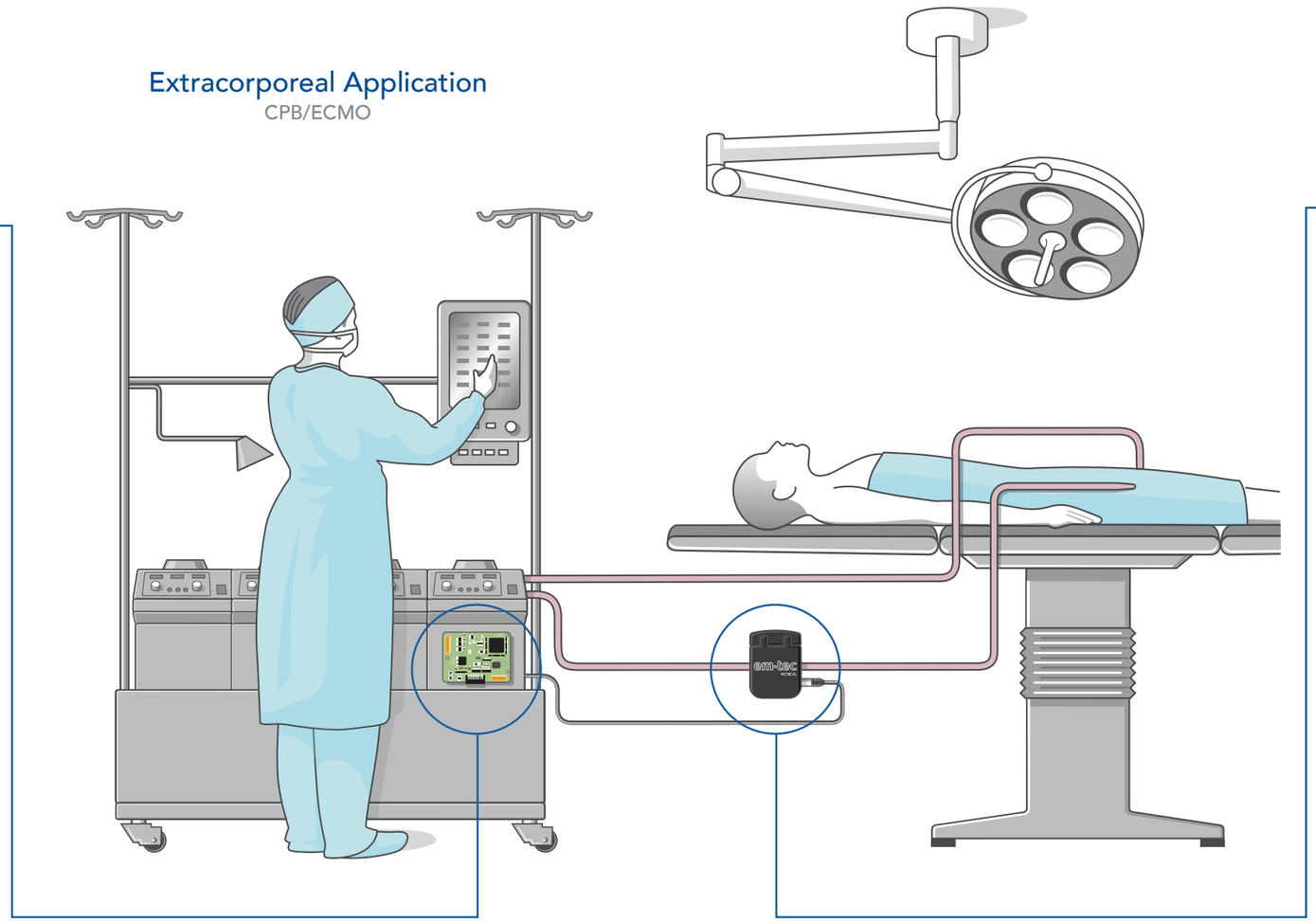
Evaluation Electronic

- Bubble detection feature
- Integrable evaluation electronic according to IEC 60601-1
- Extended error log for optimal risk analysis and efficient troubleshooting
- Available with CAN, UART (TTL), and RS-232 interface
- Customizable in regard to interface and output rate
- As OEM board: Class C software according to IEC 62304 and suitable for class III medical devices
- Compatible with full range of SonoTT™ Clamp-On SL sensors

* Please note: The SonoTT™ SkyLark is for integration into a medical device and thus not an independent medical device.

Extracorporeal Application

CPB/ECMO



SonoTT™ Clamp-On SL

Corresponding Sensor

- Sensor for the non-invasive flow measurement of liquids
- Simple click-fastening for easy and hygienic attachment
- For use on flexible tubing (e.g. PVC or silicone)
- Adjusted and calibrated according to customer specifications
- Small footprint
- Low weight for hanging installations
- Waterproof: easy to clean and disinfect for long-term use

Flow Verified

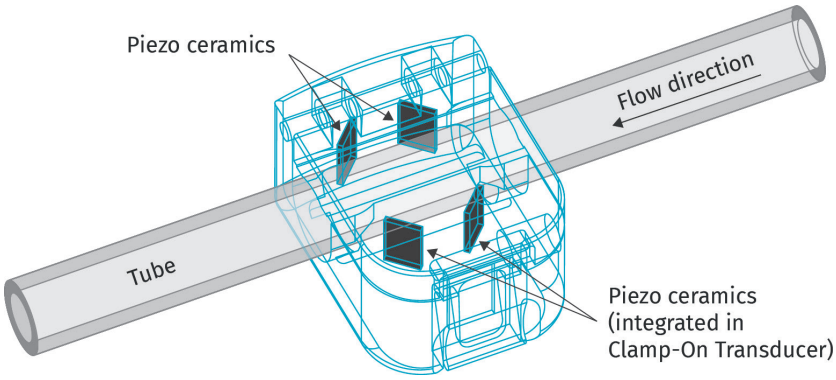
SonoTT™ components measure and evaluate (SonoTT™ SkyLark) volumetric flow rates based on an acoustic measurement principle.

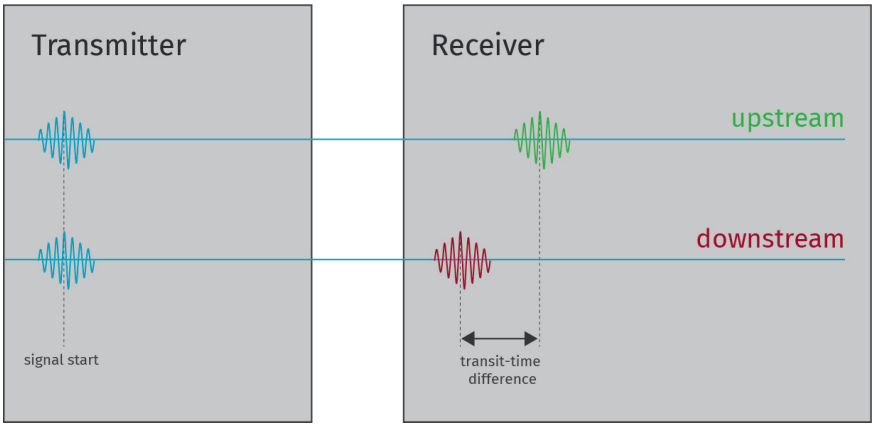
This principle prevents direct contact to the medium within a tubing system and determines the flow rate by sending and receiving ultrasonic signals with and against the flow direction while measuring the transit time difference between them.

Downstream =
Signals are sent along the flow direction and volume flow of medium.

Upstream =
Signals are sent against the flow direction and volume flow of medium.

Transit time difference =
The difference in the transit time of downstream and upstream signals proportional to the volumetric flow rate.





SonoTT™ Components. Highly Integrable. Flow & Bubble Verified.

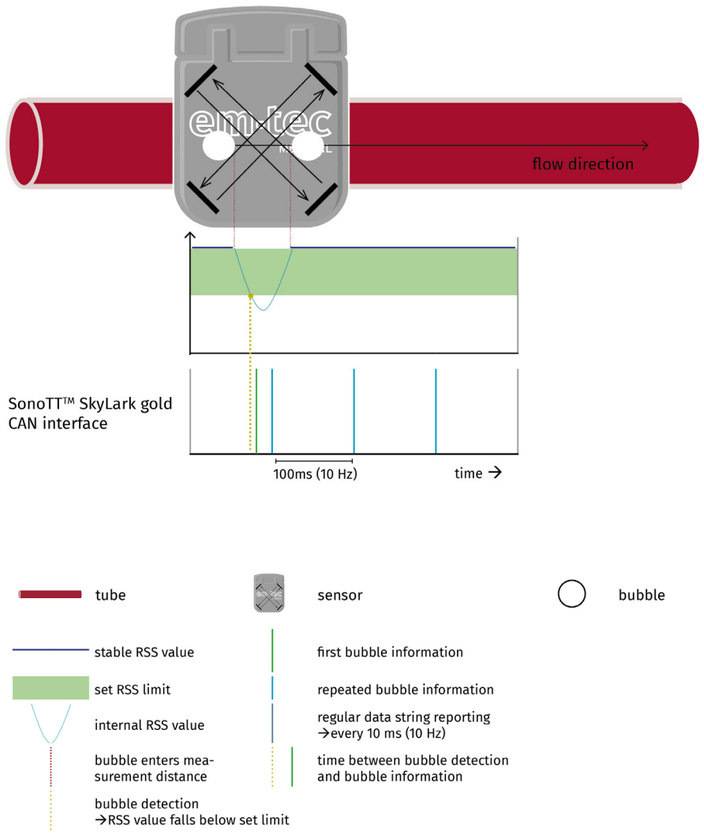
Bubble Verified

The measurement principle described to the right enables the detection of air inside a tube.

One important factor for this is the signal strength, which is defined by the acoustic coupling, also referred to as RSS (Received Signal Strength) value*. Bubbles directly impact the RSS value since it decreases if the ultrasound signals comes up against air inside the tube.

Once this happens, the new SonoTT™ SkyLark gold issues a warning to the host system.

Its bubble detection feature recognizes bubbles with a diameter of 3 mm or more. The reaction time of the CAN interface is 0.003 s**.



* For a strong acoustic coupling, it is important that the sensor and the tube are compatible and that the tube is completely filled with liquid.
** A customer-specific configuration of the bubble sensitivity (i.e. of the recognized bubble size) is possible after an evaluation of specific requirements and the testing of the entire system.

Bubble Detection – Sensitivity

The sensitivity of the standard board is set to recognize bubbles with a diameter of ≥ 3 mm.

The tests carried out by em-tec took place:

- Under lab conditions
- With water
- With bubble sizes between 3 mm and 9 mm
- For all sensor positions
- With tubes of an inner diameter (ID) of 1/4" and 3/8"

	1/4" Tube (ID = 6.35 mm)	3/8" Tube (ID = 9.53 mm)					
FLOW RATE* [ml/min]	BUBBLE SPEED [cm/s]	BUBBLE SPEED [cm/s]	BUBBLE SIZE (DIAMETER)				
			3 mm	4 mm	5 mm	6 mm	6,35 mm
250	13.1	5.8	✓	✓	✓	✓	✓
500	26.3	11.7	✓	✓	✓	✓	✓
750	39.4	17.5	✓	✓	✓	✓	✓
1,000	52.6	23	✓	✓	✓	✓	✓
3,000	157.7	70.1	✓	✓	✓	✓	✓
5,000	262.9	116.9	✓	✓	✓	✓	✓
8,000	420	187	✓	✓	✓	✓	✓
10,000	525	233.8	✓	✓	✓	✓	✓

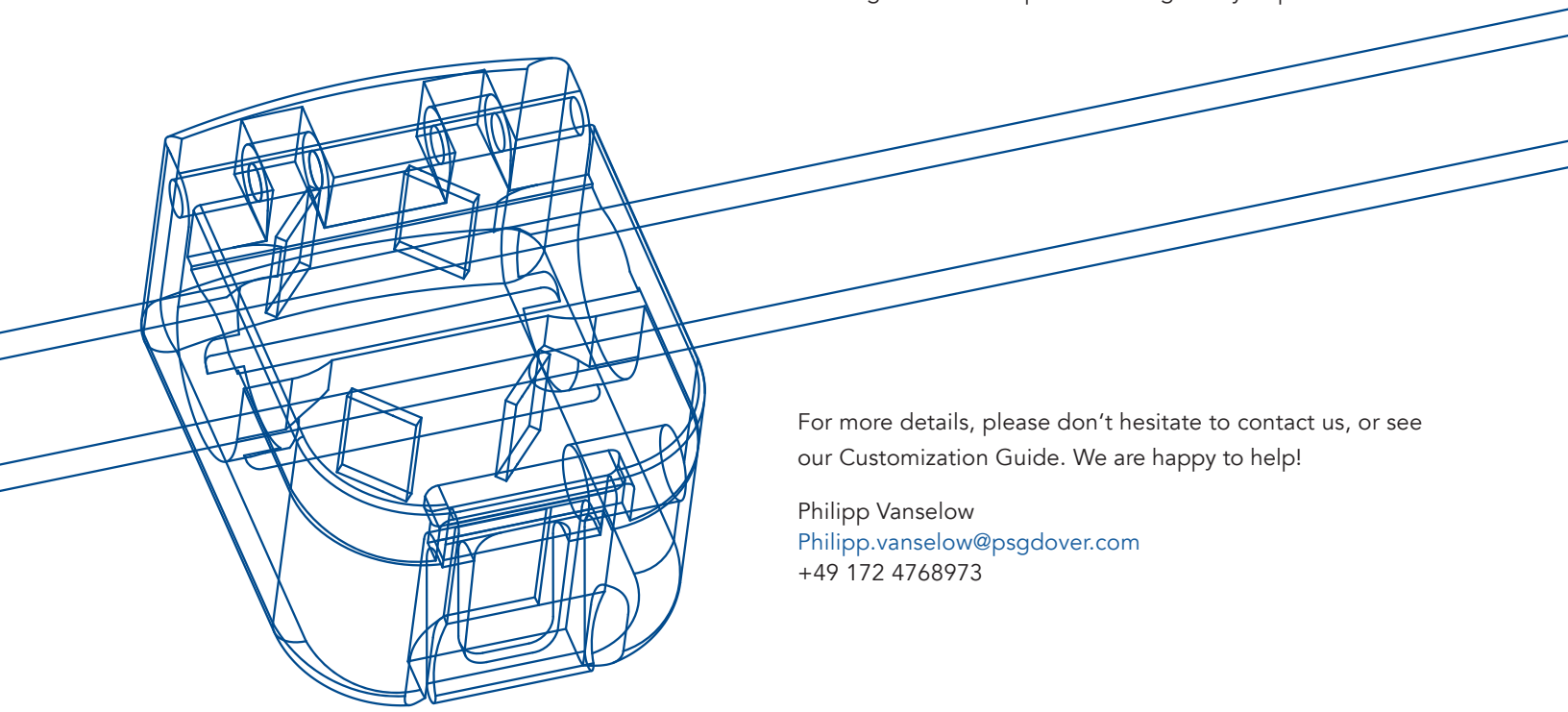
* The flow rates are examples only. The flow range (i.e. Qmin and Qmax) depends on the sensor and the tube used.

Please keep in mind that while the sensitivity of the bubble detection feature can be configured (i.e. set to recognize bubbles ≤ 3 mm) according to customer specifications, doing so needs to be preceded by an evaluation of the specific requirements and a testing of the whole system.

Harnessing the Full Power of Collaboration

Benefit From Our Experience and Versatility for Your Success

- Expert on non-invasive flow measurement solutions in medical applications for over 30 years
- Trusted and long-term partner for many well-known players in the medical market
- ISO 13485 certified quality management system
- Legal manufacturer of own medical product lines
- Tried-and-true process to customize our base components to fit into your system – from initial design to final development – meeting all customer-specific and regulatory requirements.



For more details, please don't hesitate to contact us, or see our Customization Guide. We are happy to help!

Philipp Vanselow
Philipp.vanselow@psgdover.com
+49 172 4768973

em·tec
MEDICAL

em-tec GmbH
Lerchenberg 20
86923 Finning, Germany
P: +49 8806 9236 0
F: +49 8806 9236 50
E: em-tec-info@psgdover.com
www.em-tec.com

PSG
a DOVER company

Where Innovation Flows

D 126-714 SonoTT™ Skylark Gold en-V2.0 | EMT-20005-C-02

Authorized PSG® Partner: