





For more than 30 years, em-tec has made a steadfast commitment to the development and manufacture of customer-specific products and solutions that help optimize non-invasive flow measurement in medical and bioprocess engineering, particularly in regard to heart-lung machines and extracorporeal membrane oxygenation.

em-tec has established itself as a highly respected global participant in the field of cardio technology based on its experience, innovation, competence and reliability.

em-tec products are known worldwide and used for flow measurement applications in medical devices.

According to the edicts of the ISO 13485 standard, em-tec acts as both a legal manufacturer and OEM supplier.

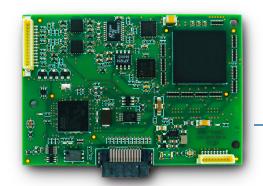


Configurable em-tec Components for Your Flow Measurement

On a hand-in-hand basis, we develop a customized system that is in tune with your unique and specific needs. We offer cutting-edge electronic and sensoric components that enable a non-invasive flow measurement function to be seamlessly integrated into existing devices – most commonly in the development of class III medical devices.

Combine our base components for your reliable and fully customized solution for an integrated flow measurement function in extracorporeal tubing systems of life-sustaining applications such as ECMOs, CPB/HLMs, dialysis machines, organ perfusion and ventricular assist device (VAD) systems, etc.



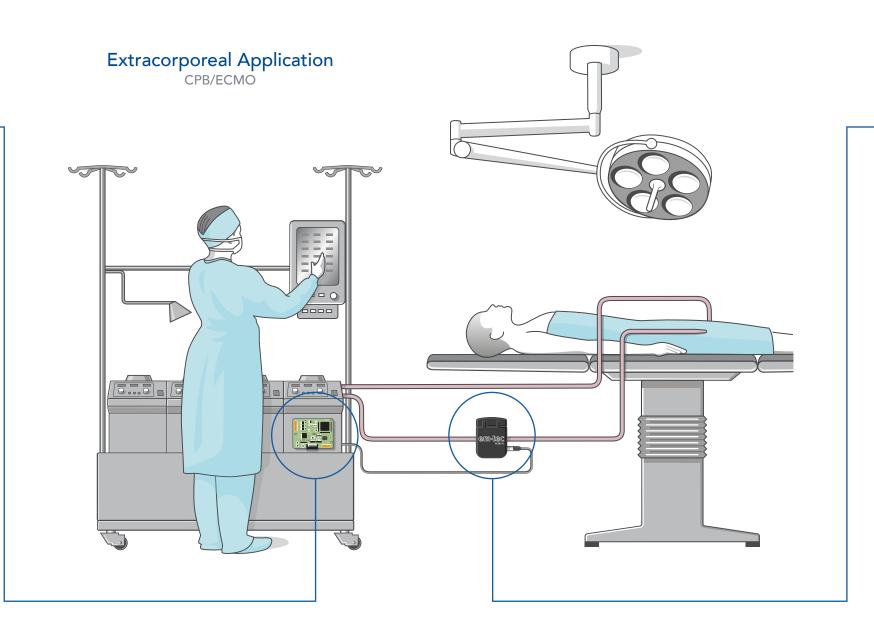


SonoTT[™] SkyLark Series*

Evaluation Electronic

- Universally integrable evaluation electronic according to standard IEC 60601
- Extended error log provides optimal risk analysis and troubleshooting for more control and safety during the operation of flow measurement processes
- Small frame size
- Bubble detection feature
- Clear function overview
- Customer-specific output rates and interfaces (CAN or RS-232)
- Class C software built to IEC 62304 specs suitable for use with class III medical devices
- Complete documentation for regulatory integration to enable clients' device MDR certification
- Option to use several boards at once for the measurement on multiple flow channels







SonoTT[™] Clamp-On SL

Corresponding Sensor

- Together with the SonoTT™ SkyLark the sensor forms a unit for the integrated flow measurement in existing extracorporeal tubing systems
- Non-invasive operation based on acoustic measurement method
- Simple click-fastening for an easy and hygienic attachment to the tubing
- Waterproof: easy to clean and disinfect for long-term use
- Available for all commonly used medical tube sizes and materials
- Fully configurable according to specific customer requirements:
- Individual lid print
- Plug type
- Cable length
- Mounting feature
- Calibration parameters

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Turning Your Vision into a Customized Solution

Are you looking for a flow measurement function for your critical medical device, but aren't quite sure how to turn it into reality? Ask us! Our tried-and-true CustomizationProcess is built on our strong portfolio of products and components and high-level customer service. Integrate our SonoTT™ Components into your medical device – tailored to your specific needs. Let's work together – step by step from initial request to serial production.



REQUEST AND REQUIREMENT PROFILE

- · Customer request is received
- Customer request is evaluated by our engineers
- A product manager is assigned as point person for all future communications
- · NDA is created and signed

- Based on your requirements, we configure the base components
- First prototype is created
- Prototype is shipped to you (2-4 weeks)

PROTOTYPE MANUFACTURING AND DELIVERY





PROTOTYPE TESTING

- The prototype is tested at your facility
- We provide support and consultation throughout the entire testing phase, including QM&RA

 After the testing phase, changes and adjustments are defined and communicated

DEFINITION OF CUSTOMIZATION SCALE





CHANGES AND PILOT SERIES

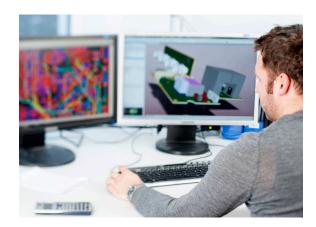
- Necessary changes or adjustments are finalized
- Approval procedure for the pilot series initiated
- Completion of OEM contract and delivery agreement
- Approved pilot series is transferred into our serial production process
- Completed system is delivered to you according to the agreement

SERIAL PRODUCTION



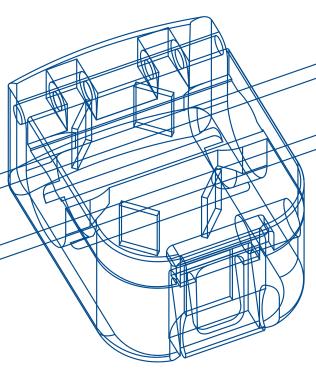
Our role in the process does not have to end with product delivery. Additional services such as obsolescence management and continuous-improvement management are available throughout the collaboration process.





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



For more details, please don't hesitate to contact us. We are excited to help!

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Where Innovation Flows

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