1 Customized Integrated Flow Measurement System

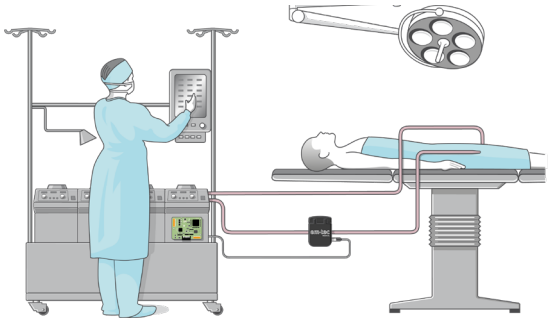

Figure 1: SonoTT™ FlowMeasurement System

Flow measurement is an important part of many medical applications where blood flow plays a role. This is, for instance, the case in heart-lung machines or ECMO devices, dialysis machines, etc. where monitoring the blood flow provides additional information regarding the patient's condition, the efficiency of the treatment and/or application, and helps prevent or detect any anomalies or possible risks as early as possible. Our fully integrable flow measurement solution consists of two components, the non-invasive SonoTT™ Clamp-On SL, a flow sensor that is available for all commonly used tube sizes, and evaluation electronics, i.e. a board within the SonoTT™ SkyLark Series. The boards are fully integrable, and the sensors are designed for the use on extracorporeal, flexible tubing systems.

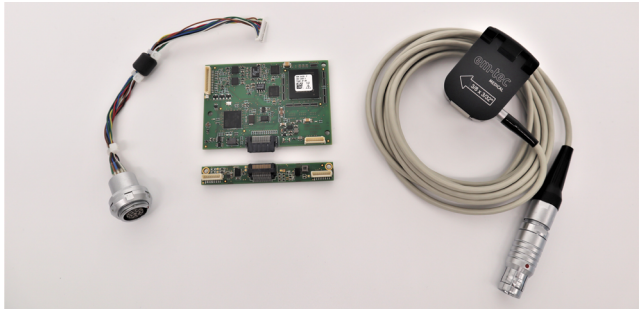

Figure 2: SonoTT™ FlowMeasurement System—components

1.1 Flow Measurement Board

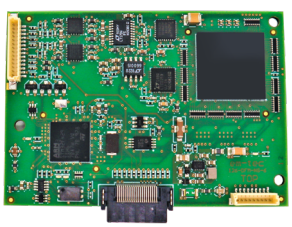

Figure 3:
SonoTT™ SkyLark Variant

The SonoTT™ SkyLark Series is our range of flow measurement boards. They are universally integrable and comply to the requirements of the IEC 60601 standard.

The software is a Class C software built to comply with the specifications of IEC 62304, making the flow measurement boards suitable for the integration into class III medical devices. With their small frame size, the electronics do not take up much space within the device while the extended error log provides optimal risk analysis and troubleshooting and consequently add another layer of control and safety to the respective process and application. All board variants are MDR-ready and we are always happy to support regarding integration and documentation alike.

1.2 Flow Sensor

For a complete and functioning flow measurement system, the evaluation electronics are used in combination with a SonoTT™ Clamp-On SL, our range of non-invasive flow measurement sensors.

Figure 4:
SonoTT™ Clamp-On SL variant

Based on an acoustic measurement method, the transit time principle, the sensors can be fastened to flexible tubing systems via a simple click-fastening. They are waterproof for easy disinfection and available for all commonly used medical tube sizes and materials.

2 Customization

In order to ensure a seamless integration into the respective host system, the SonoTT™ FlowMeasurement System is fully customizable, meaning both the flow measurement board and the sensor(s) can be adjusted according to the needs and requirements of your device and application. To find the best possible solution for each individual host system, we have a customization process in place that allows for a comprehensive customization of the components and a thorough testing at customer-site.

2.1 Request and Requirements

The first step is the customer request and the customer-specific requirements, i.e. what is the intended use of the overall host system, what standards must be taken into account, and what should the communication between flow measurement electronics and host system look like.

Another important factor are the general application parameters, such as

- medium type
- medium temperature
- tube size
- tube material
- flow range (Qmin and Qmax)

These parameters are relevant since they impact the ultrasound signal which is sent through the measurement section and which serves as basis for the determination of the volumetric flow rate. For the highest possible accuracy, our sensors are individually calibrated for those specific parameters.

Here, you can learn more about our measurement method, the transit time principle, and find additional information regarding the adjustment and calibration of our flow sensors.

2.2 Sample

After reviewing your parameters and requirements, you are sent a flow measurement board sample or prototype. The SonoTT™ SkyLark Series comprises several variants that differ regarding output rate, interface, or additional features. Additional descriptions and information can be found here, but the following chapters will provide a very brief overview.

2.2.1 Overview SonoTT™ SkyLark Series

Variant	SonoTT™ SkyLark one	SonoTT™ SkyLark one+	SonoTT™ SkyLark silver	SonoTT™ SkyLark gold	SonoTT™ SkyLark gold+
UART TTL/RS 232	TTL	RS-232	x	x	RS-232
UART Output Rate	10 Hz	10 Hz	-	-	10 Hz
UART Baud Rate	38 400 baud	115 200 baud	-	-	115 200 baud
CAN	✓	x	✓	✓	x
CAN Output Rate	10 Hz	-	output string 1: 1 Hz output string 2: 1 000 Hz	10 Hz	-
CAN Baud Rate	500 kBaud	-	1 000 kBaud	500 kBaud	-
Bubble Detection	x	x	x	✓	✓

2.2.2 Sample or Prototype

For testing purposes, we provide you with a board and a flow sensor. In case the parameters and default settings of our standard boards fit your application, you are sent the board variant that best fits your application while a compatible flow sensor is adjusted and calibrated for your specific application. If your parameters differ from those of our standard board variants, we create a prototype for you, again, in combination with a compatible flow sensor.

2.2.3 ID Allocation Flow Measurement Board

When ordering a standard variant of our SonoTT™ SkyLark Series, you receive the standard em-tec ID for the respective flow measurement board. If you order and receive a customer-specific flow measurement board, we generate a new and customer-specific ID.
Please be aware that if you need any changes and adjustment made on the board, this will mean that we are creating a prototype with a new and customer-specific ID.

2.2.4 ID Allocation Flow Sensor

For the sensor, the process is the same as for the flow measurement boards, meaning that as soon as you need any adjustments and/or changes made to the standard product—e.g. a customer-specific lid print, cable-length and/or calibration—we generate a new and customer-specific ID.

2.2.5 Sensor Type Allocation

Both our flow measurement electronics and our flow sensors contain information regarding the sensor type. The sensor type, which is a number, must be the same for the flow board and the flow sensor in order for them to be used together. This safety feature ensures that only components that are meant to be and designed as system can be paired, thus preventing the flow sensor to work with a system and/or device it is not meant for. This is particularly important if the sensor is not permanently fixed within the system and/or device it is part of.

Consequently, it is important to keep in mind that if you order and receive a standard product from our portfolio for your initial testing purposes, the sensor type stored onto both board and sensor might differ from the sensor type of your customer-specific components.

Please also note that for the sensor, only one sensor type can be stored, the board, in contrast, can contain several sensor types and thus be paired with several different sensors should that be required.

2.2.6 Sensor Plug Customization

Next to the sensor type, the plug can be customized as well. Just like the sensor type, a customized sensor plug represents a safety feature as it prevents the sensor from being plugged into a system and/or device it is not meant for. In this case, customization is possible in regard to the plug coding, i.e. the orientation of the plug and thus the pins and the corresponding socket.

2.3 Testing

Once you've received the components, you can start testing at your site. While the test setup and procedure largely depend on your processes and requirements, we provide full support and consultation throughout the entire testing phase—both from a technical as well as a regulatory side. Key aspects that should be taken into account during this stage are:

2.3.1 EMC

As the flow measurement electronics within the SonoTT™ SkyLark Series are unprotected flow boards, i.e. components only, they do not come with any integrated protection against outside disturbances, making electromagnetic compatibility the responsibility of the system integrator.

Consequently, even during testing, the overall setup of the final device and system should be considered to ensure that the electronics are protected from electromagnetic disturbances and outside frequencies. For more details, see chapter 3.

2.3.2 Communication

Another integral aspect when it comes to the integration of our flow measurement solution is its communication with the host system. Within the SonoTT™ SkyLark Series, there are three different interfaces, i.e. types of communication, available:

- **UART TTL**

  UART TTL, short for **U**niversally **A**synchronous **R**eceiver/**T**ransmitter **T**ransistor-**T**ransistor **L**ogic) describes a form of serial input/output where bits are transmitted one at a time at a specified data rate. This communication type always takes place between 0 V and Vcc, in our case the latter is set to 3.3 V. Consequently, Vcc, or 3.3 V represent a logic high, i.e. '1', whereas 0 V represents a logic low, i.e. '0'.

  Advantages of UART TTL:
  The UART TTL communication operates on the voltage range of microcontrollers and is therefore easy to pair.

- **RS-232**

  Within UART communication, RS-232 refers to the **R**ecommended **S**tandard **232**, which is a telecommunications standard. As is the case for UART TTL, bits are transmitted one at a time at a pre-set baud rate, with or without parity and/or stop bits. Other than with UART TTL, however, the voltages of the RS-232 communication are more extreme, a logic high, i.e. '1', being represented by negative voltages between -3 V and -15 V and positive voltages between 3 V and 15 V representing a logic low, i.e. '0'.

  Advantages of RS-232
  Due to the bigger voltage difference, RS-232 communication is less susceptible to noise or interferences, meaning the signal can travel longer (physical) distances while still providing valid and reliable data.

- **CAN**

  Short for **C**ontroller **A**rea **N**etwork, a CAN bus enables the serial communication between several CAN devices. It uses serial binary interchange to pass information from transmitter to receiver within a data frame. Data frames contain 0 to 8 bytes. Similar to UART TTL and RS-232, the speed of the data transmission depends on the set baud and output rate of the CAN bus.

  Advantages of CAN Interface
  The CAN Interface comes with several integrated safety features (e.g. use of swap/filling bits, message counter, little-endian format, etc.), meaning the data is well-protected and robust against outside interferences. It also transmits data relatively fast which can be a benefit if the bubble detection feature is used or if a speedy data transfer by the flow measurement board is critical.

For more details on the different communication types, check out our TechNote "Interface Overview of the SonoTT™ SkyLark Series".

2.4 Final Changes and Pilot Series

After all relevant tests were carried out, any changed and adjustments that need to be made are defined and communicated. If necessary, a new ID is allocated, and the sensor type is defined (see previous chapters). Once this is done and changes and adjustments have been finalized the approval process for the pilot series is started. This usually goes hand in hand with completing an OEM contract and a delivery agreement.

2.5 Serial Production

With the final approval, your system, i.e. your customized flow measurement board and flow sensor, enters the serial production and is delivered to you according to your orders and/or the signed delivery agreement.
Of course, we remain available for any additional support you might need and are happy to help at any time should your requirements change.

3 Integration

When it comes to the integration of our flow measurement function, there are a few key aspects to keep in mind in order to ensure a smooth operation of the overall system and/or device.

3.1 Housing

Ideally, the flow measurement board is mounted

- inside a metal case
- onto a metal plate if a case is not possible.
- using metalized screws
- without any tension

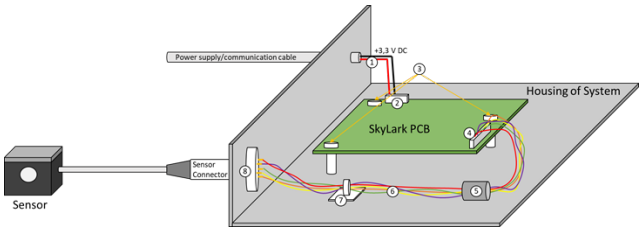

Figure 5: Schematic example for flow board housing

In addition, the housing should have a defined potential, such as a connection to earth potential.

Please note:
Ensuring the flow board is grounded is essential when it comes to protecting the data transfer and communication from interferences.

3.2 Wiring

When it comes to wiring, there are a few key factors to consider in order to keep the risk of electromagnetic disturbances to a minimum and to protect the integrity of the flow measurement values.

- Cables should never be crossed.
- Cables should never run across the flow measurement board.
- If possible, use twisted pair cables.

3.3 Power Supply

For the boards of the SonoTT™ SkyLark Series to function reliably, they must receive a continuous and stable power supply of 3.3 V.

- The power must be provided via three individual pins
  → Either via the 40-pin Samtec or the 9-pin JST connector.
- Each pin must be supplied with a minimum of 300 mA to adequately power the flow measurement board.

Please be aware that the power source must deliver slightly more than the indicated 3.3 V to compensate for any power loss that might take place as it travels through the wiring.

3.4 Zero Flow Adjustment

To provide the highest possible accuracy of measurement values, a zero flow adjustment should be carried out before each new measurement.

To do so,

- the tube the flow sensor is clamped around must be filled with liquid, but the liquid must not move
- there must be no air within the tube

The zero flow adjustment ensures that no initial offset is carried into the measurement and affecting, i.e. distorting, the flow measurement values.

Consequently, the zero flow adjustment function should be part of and designed into the overall host system. This can either mean that the overall system carries out a zero flow adjustment automatically or it can mean that users can manually carry out the zero flow adjustment, e.g. via a button on the device or within the user interface.

4 Conclusion

Given the amount of customization options and the complexity connected to integrating a PCB into a host system, early and open communication is the basis of a successful integration and a seamless functioning of the overall host system. Ensuring a correct connection and communication of the board to the host system from the start prevents issues down the road such as electromagnetic compatibility (EMC), susceptability to disturbances, etc. Another point to keep in mind, and one that should be targeted early on, is the regulatory integration. Depending on your overall system/device and the position our integrated flow measurement solution assumes within your process and application, the regulatory requirements might differ. While both the SonoTT™ SkyLark Series and the SonoTT™ Clamp-On SL range are MDR-ready and fully documented, this is a subject area that should not be left too long as to not cause any delays and/or regulatory inconsistencies.

5 Contact

If there are any questions concerning the information in this document, please do not hesitate to contact em-tec GmbH.

You can reach us at:

em-tec GmbH
Lerchenberg 20
86923 Finning
GERMANY

Phone: +49 8806 9236 0
Fax: +49 8806 9236 50
E-Mail: em-tec-info@psgdover.com
Internet: psgdover.com/em-tec