



1 Introduction

Next to a reliable flow measurement solution, bubble detection is an important feature in many applications within the medical field as well as within the bioprocessing industry.

For medical applications, the benefit of detecting bubbles within the tubing system as quickly as possible is clear, as it adds another layer of safety for patients and control for clinicians and medical staff and thus helps to prevent severe complications.

For applications within the bioprocessing industry such as chromatographies or filling processes, air-in-line can not only disrupt the process but, in the worst case, even damage the product. To avoid having to stop the running operation, the volume to become distorted during filling, or the system to falter because of an empty bag, implementing a bubble detection feature can achieve just that.

Our vast experience in medical flow measurement applications spans several decades and has turned us into an established and reliable solution partner for medical — and, in recent years, also bioprocessing — devices.

Fully integrable and highly customizable, the SonoTT™ FlowMeasurement System comprises two components:

- the SonoTT[™] SkyLark gold
 - → part of our range of flow measurement boards and designed for the integration into host systems



Figure 1: em-tec's integrated flow measurement solution

- and a compatible ultrasonic sensor.
 - → Our sensors are easy-to-use, easy-to-install,designed for long-term use, and available in a wide range of different sizes.

As 2-in-1 option, it can measure both the volumetric flow rates and detect bubbles at the same time. The gathered information is then sent to the respective host system and helps warn clinicians and process operators so they can act accordingly.

2 How it Works

2.1 The Measurement Principle: Transit Time Method

Non-invasive and without causing any additional shear stress for cells, our acoustic measurement principle uses the transit time method to determine the volumetric flow rate. By sending an ultrasound signal from one piezo ceramic to another, this method determines the transit time difference between the ultrasound signals. While two piezo ceramics are sufficient for the measurement principle to work, our ultrasonic sensors contain four, i.e. two pairs, for an even better accuracy. Based on the measured values, the volumetric flow rate can be calculated using a multi-step correlation method.

For more information and details regarding the transit time method, see our TechNote Issue #1 <u>"Transit Time Method"</u>.





2.2 Acoustic Coupling or RSS Value

One key aspect of the transit time difference method — or any ultrasound-based measurement principle is the signal quality which is represented by the acoustic coupling or RSS value (**R**eceived **S**ignal **S**trength). As air in line disrupts the ultrasound signal and therefore weakens it, there is a drop in the measured RSS value, which triggers a warning sent from the SonoTT[™] SkyLark gold to the host system. Here, it is important to note that the RSS value used to detect bubbles is an internal one that is updated more quickly and more frequently than the RSS value that is displayed on the host system. Due to this higher update rate, the internal RSS value is more sensitive and has a lower reaction time, ensuring that bubbles are detected and communicated as quickly as possible. As the RSS value indicates how strong the ultrasound signal that is sent through the flowing liquid is, the coupling should be as high as possible throughout the application.

To ensure a strong acoustic coupling,

- the sensor and tube must be compatible.
 - \rightarrow The tube must be the right size for the sensor and fit snugly into the flow channel without being crammed.
- the tube must be completely filled with liquid.
 - \rightarrow There should be no air bubbles inside the tube.

2.3 Using the Bubble Detection Feature

In order to effectively use the bubble detection feature, the RSS value during the application should always be ≥90 %. Once the value drops below a set limit, the SonoTT[™] SkyLark issues a warning to the host system. This warning is part of the data string that is—in general—issued in intervals of 100 ms (10 Hz).

It includes status and error information as well as information regarding the flow and RSS value. In case of a bubble, the reaction time of the board depends on the board variant that is used: the SonoTT[™] SkyLark gold with CAN interface or the SonoTT[™] SkyLark gold+ with RS232 interface.







2.3.1 **Bubble Detection via CAN Interface**

The SonoTT[™] SkyLark gold issues data strings in intervals of 100 ms, i.e. with an output rate of 10 Hz. This data string includes status and error information as well as information regarding the flow and the RSS value(s). If a bubble is present, i.e. if the internal RSS value falls below a set limit, the reaction time via the CAN interface is 3 ms.

The status and error information 0A01 is given out in little-endian format with the CAN ID 008. This lets the host system know that there is a bubble present. This information is issued 3 ms after the bubble was detected. The message stating the presence of a bubble is repeated another three times, i.e. four times



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in total. While the original detection of the bubble is issued with CAN ID 008, the subsequent messages are reported with CAN ID 300.



Please note: The graphic and the distances and time lines in it are not true to scale and serve illustrative purposes only.

Figure 4: Bubble Info SonoTT[™] SkyLark gold





008817F3010A009CBC 1 8 1 8 0 2 6 A 0 0 0 0 0 0 4 7 2 8 1 8 1 7 1 9 0 0 0 0 0 0 1 4

2 0 1

301

C O O O 30381A1A18000000CBB5

t 3 0 0 8 1 E F 3 0 0 0 0 0 0 9 4 7 2 A 1 6 5 2 6

B 6





2.3.2 Bubble Detection via RS-232 Interface

Just like the SonoTT[™] SkyLark gold, the SonoTT[™] SkyLark gold+ also issues data strings including status and error information in intervals of 100 ms (10 Hz).

Other than the SonoTT[™] SkyLark gold, however, the SonoTT[™] SkyLark gold+ does not deviate from this interval, i.e. it does not issue any warnings or error messages inbetween regular data string reportings. As a result, there is no set reaction time for the SonoTT[™] SkyLark gold+ as the time between the detection of the bubble and the error message being sent depends on when the bubble occurs within the interval of 100 ms (10 Hz) (i.e. the maximum time frame would be 100 ms).





Please note:

Due to the fact that the UART interface does not issue any status information inbetween regular data string reportings, the reaction time is slightly slower, i.e. the error information regarding bubbles is transmitted to the host system later than it is over the CAN interface.

The default sensitivity of the board is set to recognize bubbles with a diameter of ≥3 mm. While a recognition of bubbles with a diameter of <3 mm is possible, this needs to be preceded by an evaluation of the specific requirements and a testing and validation of the system, i.e. the host system, as a whole.





2.3.3 Sensitivity and Reaction Time of the SonoTT[™] SkyLark gold

The impact the output and reaction time of the different interfaces has on the application and the host system the board is integrated in can be illustrated by looking at the bubble speed at different flow rates. In addition to the speed at different flow rates, the table below also shows the size of the bubbles used during tests carried out at em-tec GmbH.

Please note:

- The test were carried out
 - \rightarrow under lab conditions
 - \rightarrow with water
 - \rightarrow with bubbles sized between 3 mm and 9 mm
 - \rightarrow for all sensor positions
- During these tests, the bubbles were detected and transmitted within 3 ms over the CAN interface.
- The sensitivity of the standard board is set to recognize bubbles \ge 3mm.
 - → While the sensitivity of the bubble detection feature can be configured (i.e. set to recognize bubbles
 ≤ 3mm) according to customer specifications, doing so needs to be preceeded by an evaluation of the specific requirements and a testing and validation of the whole system, i.e. the complete medical device.

| | 1/4" Tube (ID = 6.35 mm) | 3/8" Tube (ID = 9.53 mm) | | | · | | | | · | | |
|------------|-----------------------------|-----------------------------|------------------------------|--------------|--------------|--|---|-----------------------|--------------|---|--------------|
| flow rate* | bubble speed | | bubble size (diameter in mm) | | | | | | | | |
| [ml/min] | [cm/s] | | 3 | 4 | 5 | 6 | 6.35 | 7** | 8** | 9** | 9.53** |
| 250 | 13.1 | 5.8 | ✓ | \checkmark | ✓ | √ | ✓ | \checkmark | ✓ | Image: A start of the start of | \checkmark |
| 500 | 26.3 | 11.7 | ✓ | ✓ | ✓ | √ | ✓ | ✓ | ✓ | Image: A start of the start of | ✓ |
| 750 | 39.4 | 17.5 | ✓ | \checkmark | \checkmark | \checkmark | \checkmark | ✓ | \checkmark | \checkmark | \checkmark |
| 1 000 | 52.6 | 23 | ✓ | \checkmark | ✓ | \checkmark | Image: A start of the start of | ✓ | √ | ✓ | \checkmark |
| 3 000 | 157.7 | 70.1 | ✓ | \checkmark | ✓ | ~ | ✓ | ✓ | ✓ | Image: A start of the start of | ✓ |
| 5 000 | 262.9 | 116.9 | ✓ | ✓ | ✓ | Image: A second s | ✓ | ✓ | ✓ | Image: A start of the start of | ✓ |
| 8 000 | 420 | 187 | \checkmark | \checkmark | \checkmark | \checkmark | ✓ | \checkmark | \checkmark | \checkmark | \checkmark |
| 10 000 | 525 | 233.8 | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | ✓ | \checkmark |

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

** Only relevant for the 3/8" tube.





3 Benefits

Among the benefits of using em-tec's flow measurement solution is that users gain a fully harmonized system offering both a flow measurement and a bubble detection feature while only having to integrate one component: the 2-in-1 SonoTT[™] SkyLark gold. With a sensitivity of ≥3 mm bubble diameter, the SonoTT[™] SkyLark gold firmly establishes itself as high-level solution when it comes to integrated flow measurement functions and evaluation electronics within the medical field.

Moreover, the wide range of sizes the ultrasound sensors are available in and the fact that they are noninvasive, i.e. their position on the tube is not fixed, means that users retain a maximum of flexibility.

Additionally, the system, consisting of a flow measurement board and a compatible sensor, is highly customizable and therefore helps ensure a seamless integration into and data transfer to the host system.

All of our components come with full documentation regarding quality management and regulatory affairs and we are always happy to help with the integration into your system.

4 Contact

If you want to learn more about our customization process, you can download our <u>brochure</u> or watch our <u>video</u> where everything is explained in more detail.

If you want to learn more about the SonoTT[™] SkyLark gold, you can find the relevant information <u>in here</u> or on our <u>website</u>.

You can, of course, also always contact us directly:

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