



Ready

Meet the new solution for flow measurement within biotech and the latest innovation within the PSG Biotech product range: the BioProTT™ FlowSU System.

Suitable for both upstream and downstream processes, the in-line flow measurement system consists of a reusable transmitter, the BioProTT™ FlowSU System, and a single-use flow sensor, the BioProTT™ FlowSU Sensor.



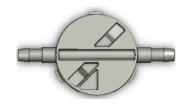


Figure 1: BioProTT™ FlowSU System (left) multi-use part; (right) single-use part

With its easy integration, smart connection to a host system or pump, and high accuracy of 2%, the low maintenance system represents the ideal flow measurement solution for a wide range of applications.

2 **Connect:** We've Listened, We've Innovated, We've Solved Your Pain Points

As a 2-in-1 in-line flow measurement solution, the BioProTT™ FlowSU System adds both flow measurement and air-in-line detection to applications within the biopharma and bioprocessing sector. Among those applications are, for example, buffer and media preparation setups, centrifugation, depth filtration, chromatography, (tangential flow) filtrations, or filling processes.

2.1 Space

One common issue when it comes to building skids or designing process setups is space, or rather the lack thereof. Ideally, everything that is needed for a smooth, uninterrupted process flow fits into one compact skid to ensure a comparatively small footprint while also being neat and organized to ensure an easy handling. When integrating the BioProTT™ FlowSU System, the the multi-use transmitter is mounted directly to the skid. With dimension of only 135 mm x 135 mm, the BioProTT™ FlowSU System is not only rather small, but it also comes with only one cable located at the back of

the device. As a result, the system does not take up much space and does not add to the total number of cables, helping the overall skid to retain a clearly arranged design. The compact size also means that there is very little hold-up volume and that the available space can be used as efficiently as possible. This is also reinforced through the

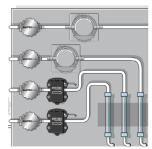


Figure 2: BioProTT™ FlowSU System on skid (example only)

option of an on-site adjustment (see 2.6) as this also makes a reduction of the distances within the tubing set possible.

2.2 Standardization

Another common difficulty customers within the bioprocessing and biopharma sector face are long lead times as well as the complexity of the individual parts that then form an overall application setup. To enable a quick and uncomplicated order process, the BioProTT™ FlowSU Sensors do no longer need an individual calibration but come with a standard calibration that fits the majority of biopharma applications, thus eliminating the time that is otherwise needed to discuss calibration parameters.





For an easy integration, the flow measurement system is powered over Ethernet and uses a standard Modbus TCP interface. For the safe connection of the tube to either side of the sensor, the sensor features standard hose barb connections for a simple and secure attachment.

2.3 Medium Treatment

Many biopharma applications deal with highly sensitive products and media that flow through the tubing system and that can be negatively impacted by shear forces. Due to this, the design of the BioProTT™ FlowSU Sensors features an integrated, straight flow path which automatically reduces the shear stress on the medium. Another factor that is beneficial for both cell and media

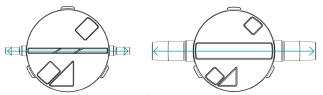


Figure 3: Straight flow path of the BioProII™ FlowSU System

integrity is the fact that the measurement principle the BioProTT™ FlowSU System is based on is non-invasive, using ultrasound signals that do not harm, change, or impact the medium.

2.4 Handling

Complex systems cannot always be easy to handle, but there are things that can make users' lives easier. One of them being the toolless attachment of the single-use sensors to the multi-use station. Using a simple and innovative locking mechanism there are neither force nor tools necessary to secure the sensor in place. To clean the skid or overall system without having to take off the BioProTT™ FlowSU System, there is a cleaning cap available to ensure IP 65 protection-having the sensor attached to the BioProTT™ FlowSU System does the same thing, i.e. ensure the IP 65 protection of the system.

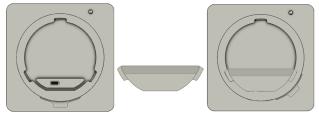


Figure 4: BioProTT™ FlowSU System without (left) and with (right) cleaning cap

2.5 Flexibility and Scalability

With continuous progress and innovation and complex, tep applications, the requirements within the biopharma sector continue to change and adapt as well, leading to a rising demand for flexible systems. Not only are there several installation positions possible for the BioProTT™ FlowSU System depending on the respective skid and process setup, but the multiuse part is also fully compatible with all five available sensor sizes, meaning one flow measurement solution can be used for tube sizes ranging from 1/4" to 1".

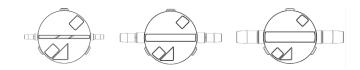


Figure 5: 1/4", 1/2", and 3/4" BioProTT™ FlowSU Sensor

Changing sizes is as easy as exchanging the sensor, meaning the BioProTT™ FlowSU System enables an instant and easy scale-up and -down. The sensor size, once connected, is recognized automatically without any additional action from the user other than the sensor exchange.

2.6 Customer Specific

With the field of biopharma and bioprocessing being a broad and diverse one, there is a wide range of different applications and process setups with individual needs

and requirements.

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order to do justice to that and to enable customerspecific settings, the BioProTT™ FlowSU System incorporates several customizable features. Among them is the passwordprotected interface where both

the flow averaging rate and the bubble sensitivity can be selected. While the flow averaging rate indicates how often the flow value is transmitted to the host system, the bubble-sensitivity decides what size of bubbles should be reported to the host system—depending on how bubble-sensitive the application is.



Knowing just how diverse and complex most biopharma and bioprocessing applications are, the BioProTTTM FlowSU System also offers the option of an on-site adjustment. During this process, a new regression line is created, meaning that each picosecond value is connected to a new, i.e. adjusted, flow value.

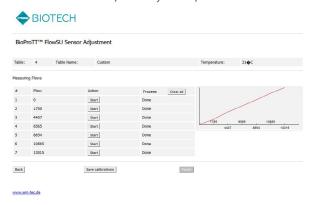


Figure 7: On-Site Adjustment of the BioProTT™ FlowSU System

By doing so, the new regression line replaces the original line that was based on default values only, meaning the newly created line represents the actual conditions and values of your application. As a result, For more information and a detailed description of this process, see document D143-704 BioProTTTM FlowSU System On-Site Adjustment Guide, which is available upon request from em-tec GmbH.

2.7 Purity and Sterilization

To also fit into process and applications setups with strict hygienic requirements, the BioProTT™ FlowSU Sensors are manufactured in an ISO 13485 environment and packaged under ISO 7 clean room conditions. The material is a USB class VI material (polycarbonate) and can be gamma-sterilized once with up to 50 kGy.

3 Applications

As mentioned before, the BioProTT™ FlowSU System is suitable for a wide range of both upstream and downstream applications within the bioprocessing and biopharma field.

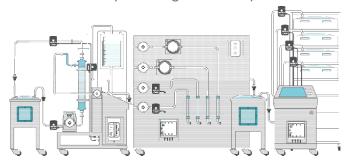


Figure 8: BioProTT™ FlowSU System (highlighted) within a biopharma skid (example)

With its 2-in-1 function it provides both a reliable flow measurement function and an air-in-line detection and can be used within applications with maximal burst pressures of 5.1 bar. Due to the standard tube connections and the in-line design, the BioProTTTM FlowSU System is compatible with all kinds of tubes, providing an additional layer of flexibility. Some of the most common applications where the BioProTTTM FlowSU System is integrated in are described in the following but do in no way cover all possible uses for the system.

3.1 Chromatography



In simple terms, chromatography is a process that separates a mixture into its individual components. This is done through the different distribution of two immiscible phases by sending the mixture through e.g. a column or a capillary tube. Due to the different properties and compositions of the

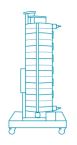
components, they each take a different amount of time to pass through the system and travel at different velocities within the moving fluid.

For chromatography, the flow rate is most commonly measured at the column outlet where it can provide information regarding retention time or volume, making it a key factor when it comes to reproducibility. Furthermore, knowing and monitoring the current flow rates helps detect and thus prevent any anomalies or issues that might occur early and to consequently minimize any process disruptions.





3.2 Filtration



Another common application for the BioProTT™ FlowSU System is filtration. While there are many different types of filtration, such as depth filtration, tangential flow filtration (TFF), or virus filtration, the way they generally function is the same for all of them as they mechanically separate—or filter—

particles, dividing solids from liquids.

With an implemented flow measurement solution, it is not only possible to monitor and control dosing, pump speed, filter loading rates but also to see how much liquid is derived from the filtration process. Based on this information, anomalies such as clogged filters can be detected and prevented early which helps prevent issues that might disrupt the process.

3.3 Buffer Prep



Buffers are a fixed part throughout the entirety of processes and consequently of utmost importance for the process itself and the final product. To prepare a buffer solution means mixing acid with an aqueous solution while ensuring the pH values remains within a certain range—depending on whether

the buffer used is an acidic or basic one.

To ensure and maintain an adequate pH value, the mixing ratio must not change drastically which is why the flow rates of the added liquids are monitored at all times. Consequently, a reliable flow measurement function helps protect the integrity and quality of the final buffer solution.

3.4 Filling



At the end of most processes is the filling process of the (for now) final product. During this step, the product is filled into the corresponding container (e.g. bags, vials, bottles, etc.) in which it will be transported for its next step.

Here, a flow measurement function ensures that the correct amount of produce is filled while a bubble detection feature can help prevent air from entering the final container.

4 Flow

Easy spec-in and order handling, smart and seamless integration paired with a high level of features and a low level of maintenance make the BioProTT™ FlowSU System an innovative and well-rounded flow measurement solution.

To learn more about the system, visit us or watch this video.

5 Contact

If there are any questions concerning the information in this document, please do not hesitate to contact us.

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