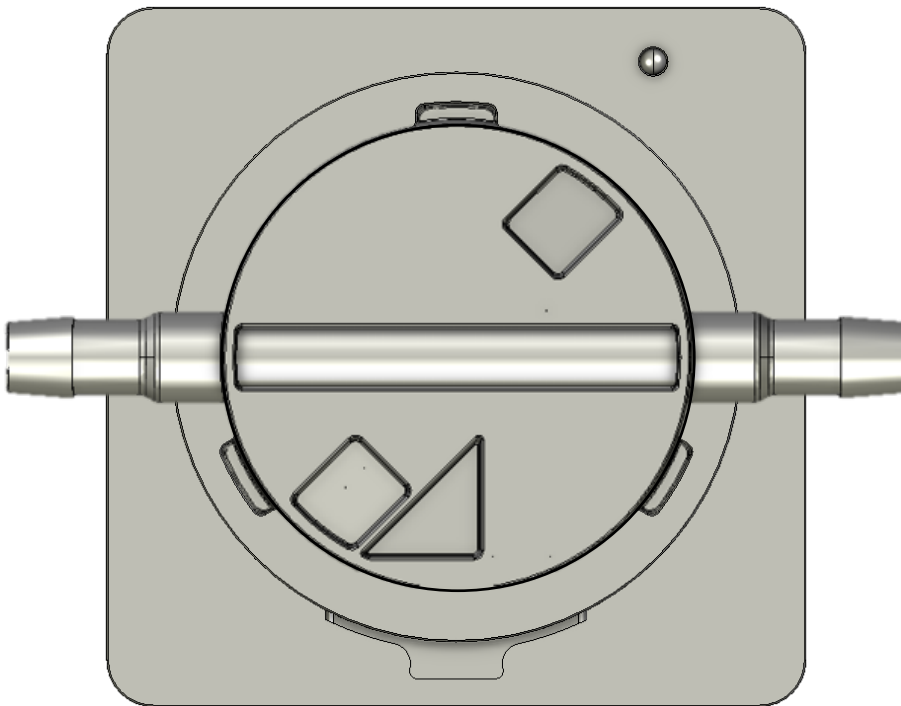


# BioProTT™ FlowSU System On-Site Adjustment Guide



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## Subject to Technical Changes

Owing to our policy of continuous product development, the illustrations and technical data contained in this document may differ slightly from the current version of the device.

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## 1 General Information

### 1.1 General Information



- 
- This document describes the on-site adjustment of the BioProTT™ FlowSU System, not the use as such.
    - For information regarding the integration and use of the BioProTT™ FlowSU System, please read the respective user manual carefully.
    - The user manual is available for download [here](#).
  - em-tec GmbH strongly advises against the use of the flow values provided by the BioProTT™ FlowSU System to serve as the basis to control a closed-loop system.
    - If this is done, the risk must be fully analyzed and additional risk control measures have to be established.
  - It must be ensured that the grounding of the system the BioProTT™ FlowSU System and the BioProTT™ FlowSU Sensor are part of complies with installation standards.
  - Ensure that no particles or water enter the BioProTT™ FlowSU System or the USB port of either device at any time. Only plug in when dry.
  - Prior to each measurement, a zero flow adjustment must be carried out.
  - The BioProTT™ FlowSU System and the BioProTT™ FlowSU Sensor form a sensitive sensor system. Electromagnetic fields or mechanic vibrations can lead to interferences affecting the measurements or the accurate function of the system.
  - The BioProTT™ FlowSU System consists of components sensitive to electrostatic discharge.
- 

Although the BioProTT™ FlowSU System represents a state-of-the-art technology, the user may be put at risk if the device is operated incorrectly. You should therefore read this user manual carefully before use. In addition, inspect your equipment for completeness and damage when unpacking.

## 1.2 General Safety Instructions

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The following safety instructions must be strictly observed and adhered to in order to ensure a safe handling of the BioProTT™ FlowSU System!

- The BioProTT™ FlowSU Sensor fulfills the requirements of USP Class VI standards and is packaged under cleanroom class ISO 7 conditions.
    - To ensure that the single-use sensor continues to fulfill those requirements, it must be opened, installed, and handled under the respective conditions.
  - Ensure that the BioProTT™ FlowSU Sensors are not contaminated in any way!
  - If any part of the system or its accessories (cables, sensor, etc.) is damaged in any way, it must not be used.
  - The BioProTT™ FlowSU System must not be immersed in liquids at any time and the connection ports must be kept dry.
    - To protect the connection port at the front, use the protective cap for when no sensor is connected (part of the scope of supply).
    - In the event of ingress of liquid into the device, immediately disconnect the power and stop using the device.
  - The use of any accessories, cables, and sensors other than the specified ones is not permitted at any time.
  - The BioProTT™ FlowSU System may be influenced by radio frequency (RF) devices. This includes mobile RF communication equipment. The use of a RF device in the vicinity of the BioProTT™ FlowSU System may therefore cause malfunctions of the components which, in turn, could lead to inaccurate or incorrect flow values.
  - The device should not be covered or exposed to direct heat or sun.
  - The device must not be opened. Any repairs must be carried out by em-tec GmbH or authorized service personnel only.
    - Unauthorized opening or repair means the warranty will be void.
  - Neither the BioProTT™ FlowSU System nor the BioProTT™ FlowSU Sensor should come into contact with any chemicals other than those specified in chapter "[Cleaning and Disinfection of the BioProTT™ FlowSU System](#)".
- 



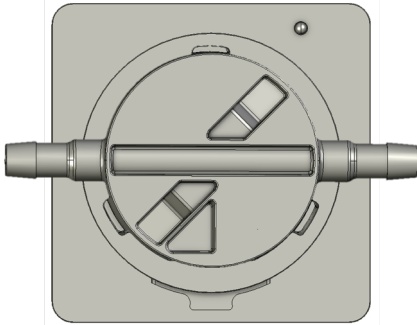
## 1.3 Definitions and Abbreviations

Definitions, Abbreviation	Meaning
BioProTT™ FlowSU System	multi-use flow meter (in combination with a single-use sensor) <b>Please note:</b> As the BioProTT™ FlowSU System can only carry out flow measurements when used in combination with the BioProTT™ FlowSU Sensor, the BioProTT™ FlowSU System refers to the combination of both components unless clearly stated otherwise.
BioProTT™ FlowSU Sensor	single-use sensor
multi-use part	BioProTT™ FlowSU System
sensor	BioProTT™ FlowSU Sensor
single-use part	BioProTT™ FlowSU Sensor
EMC	<b>ElectroMagnetic Compatibility</b>
N/A	<b>Not Applicable</b>
PoE	Power over Ethernet
PLC	<b>Programmable Logic Controller</b>
ID	<b>I</b> nn <b>D</b> iameter or <b>I</b> dentification (i.e. article number)
flow range	range from minimum to maximum flow
Qmin	Minimum flow
Qmax	Maximum flow
calibration	Checking the accuracy of the flow measurement system by comparing its measurement values to those of a device with a known accuracy.
adjustment	The act of modifying the allocation of pico seconds and flow values underlying the measurement system.

Table: Definitions and Abbreviations

## 2 Introduction

### 2.1 BioProTT™ FlowSU System

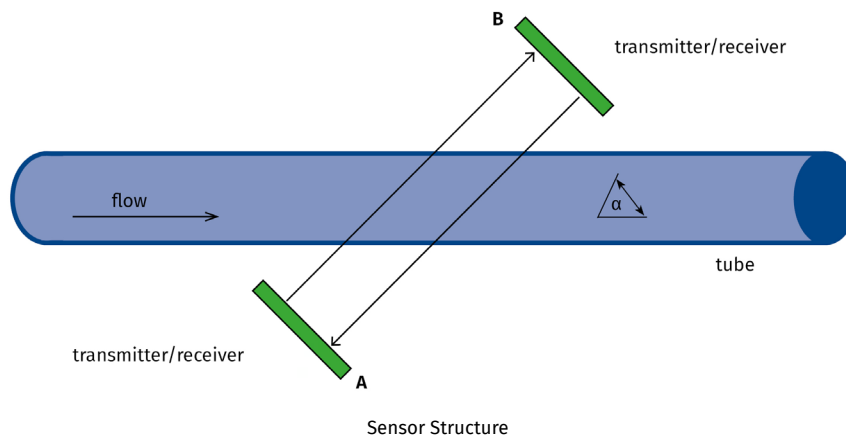


BioProTT™ FlowSU System

- The BioProTT™ FlowSU System consists of
  - the multi-use holder with integrated electronic and namesake of the system, the BioProTT™ FlowSU System, which is mounted to the skid and
  - the single-use BioProTT™ FlowSU Sensor, which is inserted into the BioProTT™ FlowSU System
- The BioProTT™ FlowSU System and the BioProTT™ FlowSU Sensor must only be used in combination with each other.

### 2.2 Operating Principle

The function of the BioProTT™ FlowSU System is based on an acoustic measurement principle and utilizes the transit time method to determine the flow. For this, the system utilizes two ultrasonic piezo ceramics that each function as both transmitter and receiver for the burst of sound energy that is sent between them. For each transmission, the difference in transit time that it takes for the pulse to travel between the ceramics is measured. As the difference in transit time, which is measured in pico seconds, is directly related to the velocity of the liquid, it can be used as the basis to determine the volumetric flow rate.



When sending ultrasonic signals through the measuring section, the transit time difference depends on the flow direction of the medium:

- The ultrasonic sound signals that are sent along the flow direction and volume flow of the medium, i.e. downstream, need less time to travel through the measurement section than
- the ultrasonic sound signals that are sent against the flow direction, i.e. upstream.

The calculation of the flow rate is then carried out inside the BioProTT™ FlowSU System.

## 2.3 Adjustment and Calibration

The BioProTT™ FlowSU System is not individually calibrated but comes with a default calibration that works for and fits the parameters of the majority of biopharma applications. However, to ensure an even higher accuracy, there are the following options for users to apply:

- Determining a calibration factor tailored to your specific application.
  - By using the calibration factor, the measured flow is adjusted linearly (by the set factor, i.e. for a calibration factor of 1.5 and a measured flow of 200 ml/min, the final flow value would be 200 ml/min x 1.5 → 300 ml/min).
  - This can compensate for changes in the temperature and/or viscosity of the medium that is used by adjusting the transit-time and flow rate correlation for the given conditions.

For more information regarding this process, you can access and download the respective TechNote on our [website](#).

- Carrying out an on-site adjustment.
  - During the on-site adjustment, a new regression line is created, meaning that each pico second value is connected to a new, i.e. adjusted, flow value.
  - This regression line replaces the original line that was based on default values only and represents the actual conditions and values of your application.
  - See the following chapter for more information and for instructions on how to carry out the on-site adjustment.

## 3 On-Site Adjustment

### 3.1 On Site Adjustment



**Please note:**

- Once an on-site adjustment is carried out, em-tec can provide no guarantee for the overall accuracy of the flow measurement system.
- The on-site adjustment must be carried out using Mozilla Firefox.
- The file created during the on-site adjustment replaces the parameters that were previously used.

To carry out an on-site adjustment, you will need the following equipment:

- the BioProTT™ FlowSU System (i.e. the multi-use BioProTT™ FlowSU System and a single-use BioProTT™ Flow SU Sensor),
- a pump,
- a reference flow measurement system with an accuracy that is four times higher than the target accuracy,
- and a tubing circuit.

Ideally, the relevant parameters (i.e. distance between BioProTT™ FlowSU System and pumps and/or valves, installation position, etc.) are the same during the on-site adjustment as they are during the application itself. This is due to the fact that the positioning can have an influence on the performance of the system.

Once everything is set up, follow the steps listed below to create a new calibration table, i.e. to carry out an on-site adjustment:

1. Clear the cache of the internet browser, i.e. Mozilla Firefox.
2. Access the web interface of the BioProTT™ Flow SU System.
3. Go to the configuration page.
4. Click onto the "Flow Sensor Adjustment" field.

⇒ Here you will be asked for a user name and password which is available upon request from [em-tec GmbH](http://em-tec.com).

**Please note:**

- Only access this page when a sensor is connected to the BioProTT™ FlowSU System.
- Do not remove the sensor while this page is accessed, i.e. opened.
- Ensure that no other tabs are open in your browser and that no one else tries to access the web interface of the BioProTT™ FlowSU System during the adjustment process.

5. On the BioProTT™ FlowSU Sensor Adjustment page, you have these options:

- select and set a calibration table by selecting the respective number
- re-name the currently selected calibration table
- save table name and temperature

**Please note:**

Only when selecting the 'save' field do any of the changes become active and saved.

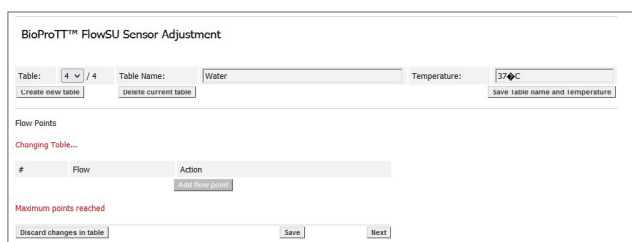
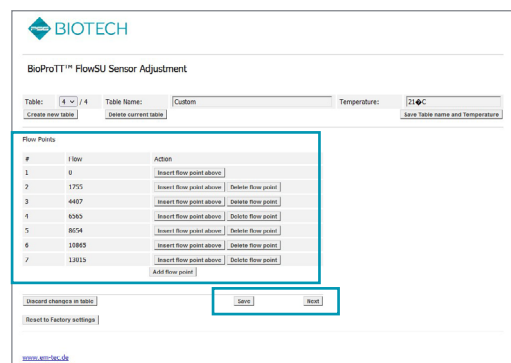
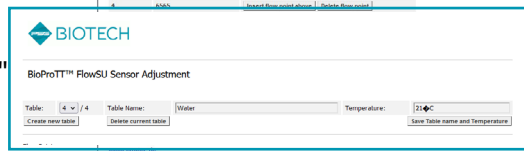
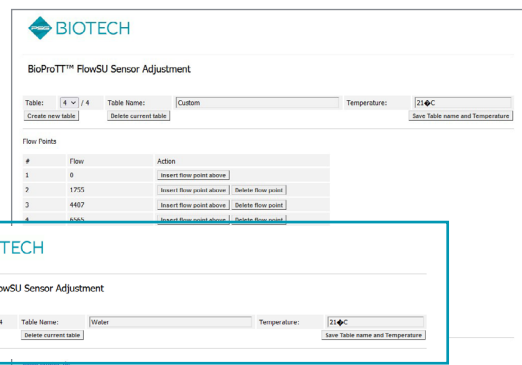
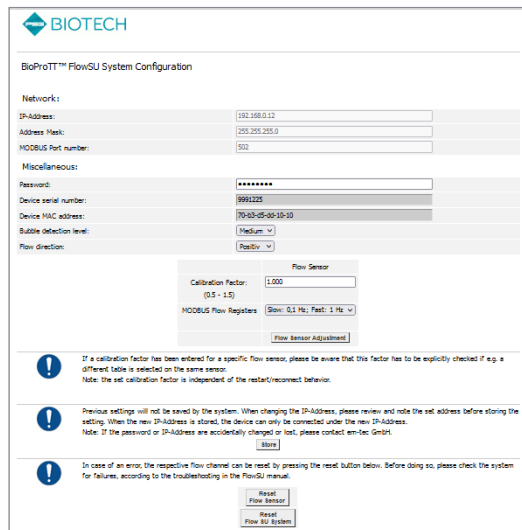
- create new table
- delete current table

6. To create a new table, select the "create new table" field.

7. You can change, add, or delete flow points.

**Please note:**

- The flow points are indicated as ml/min.
- The more flow points you target, the more accurate the adjustment.
  - Within the target flow range, i.e. the flow range the sensor is going to be mainly used in, several flow points should be targeted during the adjustment process.
- It is only possible to set positive flow values during the on-site adjustment.
  - Any negative values must be deleted or changed into positive ones.
- When the red text appears, do not refresh the page or do anything else as this indicates the system is working.

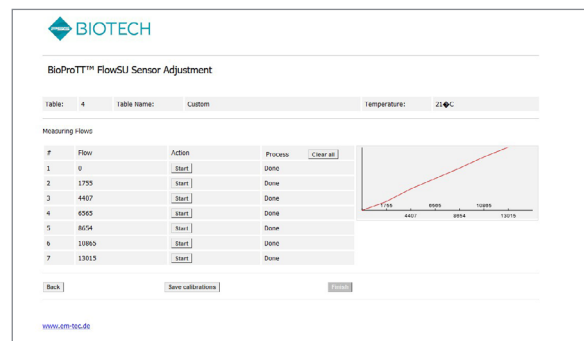
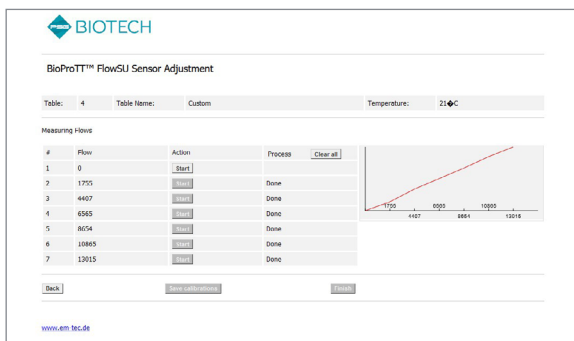


8. Once you've decided on the flow points, select "Save", then "Next".
  - Selecting 'Next' opens a new page.
9. Now target the set flow values by adjusting the pump accordingly.

**Please note:**

- Ideally, a zero flow adjustment is carried out before targeting the flow values.
- Some of the flow points might be labeled as 'done' although no adjustment was performed. In this case, please press 'clear all'.

10. Once you've reached the respective flow value, click 'start'.
  - The on-site adjustment for this particular flow point starts automatically.
  - Once the process is finished, i.e. has reached 100 %, the status changes to "Done".
11. Repeat step 9 and 10 for each of the individual flow points.
12. Once the status for every flow point is displayed as "Done", click the "Save calibrations" fields.
13. To finish, click the now activated "Finish" button.



**Please note:**

Before ensure that the graphs displayed on the right are strictly monotonically increasing.

13. If there are no additional changes you want to implement, you can go back to the main page of the web interface by clicking onto the PSG Biotech logo.



**Please note:**

Before carrying out a flow measurement using the newly created calibration table,

- ensure that the correct table is set.
- make sure to carry out a zero flow adjustment.

## 3.2 Multiplying the Created Calibration Table

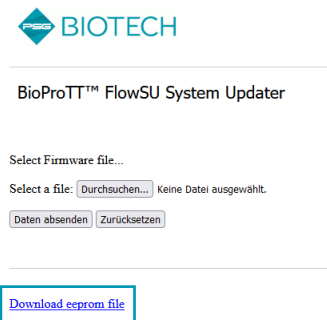
It is possible to multiply the created calibration table, e.g. to use the same table in several skids without having to carry out the on-site adjustment for every individual BioProTT™ FlowSU System.

To do so, follow these steps:

1. Carry out the on-site adjustment as described in the previous chapter.
2. Download the created file from the web interface (see image to the right).
  - For the link to the respective site, see document D143-705 BioProTT™ FlowSU System Firmware Update Guide.
  - The download file is a .bin file.
3. Contact em-tec GmbH using the following e-mail address:

[em-tec-service@psgdover.com](mailto:em-tec-service@psgdover.com)

You will receive further instructions in regard to handling the file transfer.



**Please note:**

Do not include any files in the e-mail to our service department.

4. em-tec will convert the file into an .emt file and send it back to you.
5. Once you've received the file, you can upload it to every BioProTT™ FlowSU System.



**Please note:**

- Make sure to only send one EEPROM file and not several.
- Both the file created during the on-site adjustment as well as the .emt file sent back by em-tec (see step 4) replace the parameters that were previously used, i.e. the EEPROM file.
  - The factory settings are not impacted by that.

## 4 Contact Information for Technical Support

Technical support is provided by:

**em-tec GmbH**  
Am Graben 6-8  
86923 Finning  
Germany

e-mail: [em-tec-info@psgdover.com](mailto:em-tec-info@psgdover.com)

phone: +49 8806 9236 0

fax: +49 8806 9236 50

For returns/RMAs or service support, please contact: [em-tec-service@psgdover.com](mailto:em-tec-service@psgdover.com)

## About em-tec GmbH

em-tec has been a specialist for flow measurement systems in the medical and bioprocessing technology sector for over 30 years. The company's core competence is the non-invasive flow measurement using the ultrasonic transit-time method, that is used for applications in extracorporeal circulation systems of life-sustaining systems as well as in biopharma applications that use flexible tubes. Headquartered in Finning, Germany, em-tec is part of PSG®, a Dover company.

For more information about em-tec, please visit [psgdover.com/em-tec](https://psgdover.com/em-tec).

## About PSG Biotech

PSG® Biotech is dedicated to Caring For Every Drop in the biopharmaceutical industry by providing a comprehensive portfolio of specialty flow-control solutions. With its ground-breaking innovation, PSG Biotech offers pumps, sensors, and flow meters that have been designed to safely transfer and precisely meter the most delicate biologics, medicines and therapeutics, all while increasing yield, throughput and speed to market.

PSG Biotech is a product brand of PSG®, a Dover company, Oakbrook Terrace, IL, USA, which is comprised of several leading pump and flow-measurement brands, including Abaque®, All-Flo™, Almatec®, Blackmer, Ebsray®, em-tec, Griswold®, Hydro™, Malema, Mouvex®, Neptune®, Quantex™, Quattroflow®, RedScrew™ and Wilden®. You can find more information on PSG Biotech at [psgdover.com/biotech](https://psgdover.com/biotech) and on PSG at [psgdover.com](https://psgdover.com).



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