

Technical Report

Precise pressure measurement in cGMP steam sterilizers. Belimed relies on Baumer.

With its BST and PST sterilizers, Belimed AG has again reinforced its position as a technology leader. These systems feature easy maintenance, durable construction, premium manufacturing quality, high reliability and are energy efficient as well as economical. Hygienic PBMH pressure sensors from Baumer are crucial to the operation of these systems.

For over 40 years, the Swiss Belimed Group has been designing, producing and selling innovative cleaning, disinfecting and sterilization system solutions in the fields of medicine and life sciences. Their autoclaves and systems are used in companies ranging from globally operating pharmaceutical and biotech manufacturers to regionally based hospitals and large medical practices. Belimed has representation in over 80 countries, with 10 locations in Europe, North America and China, including authorized partnerships. Their BST, PST and LST sterilizers are developed and produced at the Sulgen site in Switzerland. They comply with current cGMP, GAMP V and FDA recommendations and directives. Depending on the requirement, single or double door versions are available with different sterilization processes and an effective volume

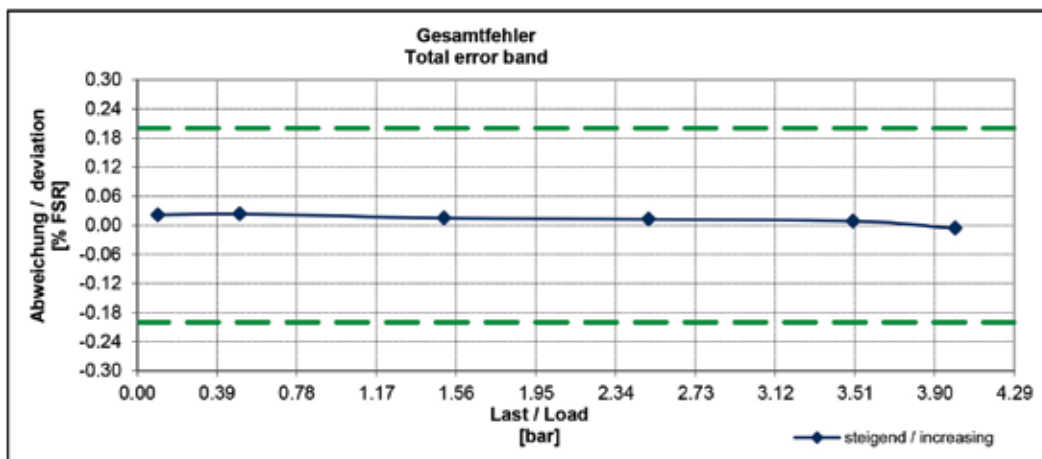
ranging from a few hundred liters up to 60 m³. Currently they are used in several thousand plants of leading pharmaceutical and biotech companies.

High demands from the pharmaceutical and biotech industry

The variety of products requiring sterilization in the pharmaceutical and biotech industry is enormous. They range from fluids in glass bottles, to sprays and vials, surgical instruments and fabrics, and plant components. Hygienic requirements in the industry are extremely high. The quality-compliant sterilization processes are the prerequisite for the required safety levels. Suitable methods must be used in order to validate whether sterilization processes provide the desired effect. Only by precisely matching the sterilization processes to the items



Belimed BST, LST and PST series sterilizers have been manufactured with carefully selected, high quality materials designed and produced to conform to cGMPs, guaranteeing reliable, reproducible processes.



Despite the high pressure and temperature load, the PBMH remains stable in its behavior across the entire pressure range.

to be sterilized is it possible to achieve perfect sterilization results. In addition, economic and ecological concerns also play a major role in these processes.

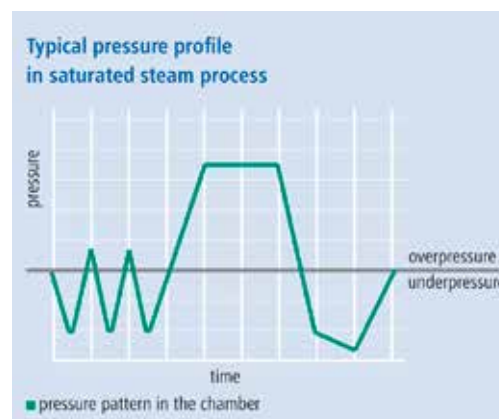
A safe and reliable solution

With BST and PST series steam sterilizers, Belimed helps its life science customers meet high demands and guarantees a smooth qualification and validation process. The autoclaves are particularly designed for the sterilization of vacuum-proof and porous products as well as products from which air cannot be easily removed. In the process, air is removed from the chambers with one or several initial vacuum pulses. Heating and sterilization are performed by saturated steam, and drying is performed using one or several vacuum pulses. The process parameters can be adjusted to the particular requirements. The typical parameters are ≥ 15 minutes at 121 °C and 2 bar.

Measuring pressure in chambers

The sterilization chambers of the new BST and PST series feature three PBMH pressure sensors from Baumer. One sensor is on the steam supply line and two are on the sterilization chamber. The sensor in the steam supply line is used to monitor the steam delivery pressure. This delivery pressure must continuously exceed both an absolute value as well as a relative value compared to the chamber pressure. If the pressure is below these values, an alarm is triggered. The chamber sensors are used for control during the pressure-regulated steam sterilization process. There are two sensors so they can monitor each other while also ensuring that the process is recorded separately from the general process control. These are standard requirements that must be maintained. In ac-

cordance with EN 285:2015 (D), Section 23.3.2.3, Point d, the pressure measuring chains for process control are not permitted to exceed the maximum permissible measurement error of 1 kPa regardless of ambient conditions such as temperature, humidity and pressure.



Typical pressure response in a saturated steam process with extreme pressure differences in the case of vapor fractions in a vacuum during the heat-up phase, with persistent high pressure during sterilization and low pressure during the drying and cooling phases.

Reproducible measuring accuracy

"The challenge for this application is in the ability to reproduce the measuring accuracy", explains Paul Bahr, a development engineer in Process Engineering at Belimed AG. "In a typical pressure response with saturated steam, the sensors used need to overcome extreme pressure fluctuations ranging from 50 mbar to 3100 mbar and abrupt temperature variations from 0 °C to 135 °C. They also have to provide stable, precise measurements without long-term drift", he continues. The PBMH features a high temperature tolerance. With active thermal compensation and high long-term stability, it contributes immensely to ensuring process reliability. The surface roughness of its process connection is $Ra \leq 0.8$ and fulfills the strictest hygienic requirements. Its fully welded, compact design complies with all requirements for a hygienic de-



PBMH pressure sensor in the BST sterilizer system chamber. Cooling fins on the sensor isolate process temperature from the electronics, enabling use in a high temperature environment with no time restrictions.

sign in accordance with EHEDG or ASME BPE.

Teamwork

"With the powerful PBMH pressure sensors from Baumer, we have found the best components for our innovative sterilizers", confirms Paul Bahr. "They are attractive because of their technical superiority while also fitting every aspect of our expectations exactly. Such solutions can only be achieved in close partnerships where our business partner focuses on our specific needs in detail and desires that both parties to continue to advance. Like us, Baumer has expertise, industry knowledge and the power to get things done. Together we want to set the standards and always stay one step ahead."

Further information:

www.baumer.com/pressure; www.belimed.com



AUTHOR

Thomas Schneider
Product Market Manager,
Baumer Electric AG

Baumer
Passion for Sensors

Baumer Group
Phone +41 (0)52 728 1122
sales@baumer.com
www.baumer.com