

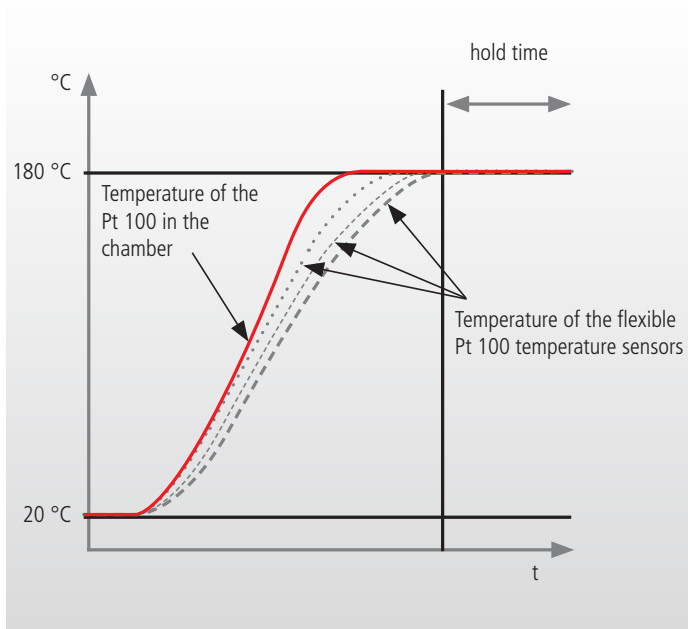
Information on Validation of Hot Air Sterilisers

Process validation for Memmert hot-air sterilisers is no problem at all. As an example, the Schwabach manufacturer of temperature control appliances commissioned the independent and accredited test laboratory biomedis to validate two appliances. The test setup was based on the international standard ISO 20857 for the validation of sterilisation processes by means of hot air, published in August 2010

In order to protect patients, the requirements made on the quality of medical products are extremely strict, and quite rightly so. For this reason, it was important for Memmert to have the absolute reliability of its hot-air sterilisers verified by an independent organisation. The test setup was based on the guidelines of the DGKH (German Association for Hospital Hygiene) and on the specifications of the standard ISO 20857 for the sterilisation of medical products.

The test was performed once without load, once with mixed load and twice at full load, with some metallic instruments partially wrapped in plastic or aluminium foil as well as glass containers. In the SNE 200 steriliser (with a chamber volume of 32 litres), a total of 16 measurement sensors monitored the constant temperature.

Due to the larger volume of 108 litres in the SFP 500 steriliser, 27 sensors were distributed in the chamber and attached directly on the chamber load. The results were identical for both appliances. During each measurement, the minimum temperature of 180 °C was reached and maintained for at least 30 minutes at each measuring point.



Setpoint-dependent sterilisation time

Apart from optimum temperature distribution and temperature stability in the working chamber, a third, crucial requirement is made of hot-air sterilisers: Sterilisation time only starts after setpoint temperature has been reached. The SPWT setpoint wait function of the Memmert hot-air steriliser, the continuation of the programme depending on the setpoint being reached, guarantees that this requirement is fulfilled. In addition to the standard Pt100 temperature sensor, up to three flexible temperature sensors placeable in the load, can be integrated in the Memmert hot-air steriliser programme sequence. This ensures that the sterilisation time does not start before the set temperature has been reached at all the measurement points.

The setpoint wait function ensures that the sterilisation time is exactly maintained in the Memmert hot-air steriliser