



Wanted: Climatic test chamber for extreme conditions

Climate testing of medical products before they are approved has long been a given. The renowned ikfe GmbH (Institute for clinical research and development in Mainz) turned to the specialist laboratory supplier Novodirekt with very extraordinary requirements for a new climate chamber.

The **climate chamber** had to be able to cover as wide a range of temperature-humidity-combinations as possible, reaching from tropical to arctic climate. In addition, the operating personnel were to be enabled to operate the **medical devices** inside the chamber from the outside without having to open the door. A development project was started. Dr. med. Petra B. Musholt, laboratory director at the institute, calls it a "perfect cooperation" between **ikfe**, Novodirekt and the **Memmert** customisation department.

Compressed air drying unit lowers relative humidity.



Climatic test chamber CTC

One viewing window and two entry ports were installed in the door of a Memmert **climatic test chamber** CTC. The design drawings were sent to the laboratory beforehand and the position of the ducts in the door was adjusted to the requirements of its future users. Prior to certain tests, **ikfe** can now equip the **climate chamber** with gloves and can operate the **medical devices** on the inside while the temperature/humidity conditions are constant. In order to reach chamber-dependent, physical limits, such as an interior temperature of +12 °C and a relative humidity of less than 25 % and in order to restore them as quickly as possible after opening the door, the Memmert customisation department integrated one additional adjustable compressed air drying unit.

Testing equipment for in vitro diagnostics

Ikfe tests in particular **in vitro diagnostics** such as glucometers or insulin pumps in the customised **Memmert climatic test chamber** CTC in accordance with the applicable ISO standards. Before it is approved and launched on the market, each new in vitro diagnostic undergoes a long process of function and security testing as well as diagnostic testing, the so-called performance evaluation, carried out by independent institutions. This is legally stipulated, in particular for in vitro diagnostics such as glucometer, which is used for therapeutic decisions when treating a patient.

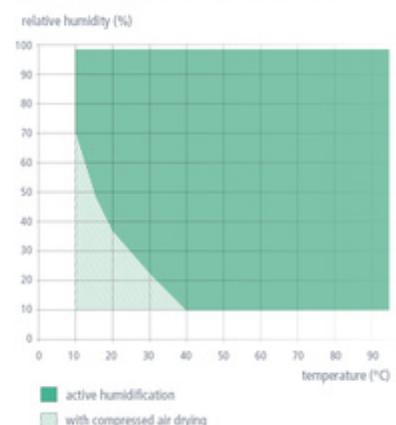
The constant temperature/humidity parameters are different for each study. The testing time varies between 30 minutes and one hour. Of course, responsibility and reproducibility of the testing conditions are vital for the validity of the studies. Therefore, the **climate chamber** is validated prior to each new testing round. In order not to exceed the maximum deviation in the inside of the chamber required by the ISO standards (usually ± 2 °C and ± 5 % rh) under any circumstances, **ikfe** performs tests with the help of chamber-independent additional sensors on the working surface of the chamber. Since the testing parameters are

Incubating caries bacteria in the cooled incubator

At required temperatures of +37 °C for incubation and similarly high room temperatures, most incubators come up short. The cooled incubator IPS cools without compressor in a reliable and energy-saving way.

[more information](#)

Temperature/humidity working range



Extended temperature/humidity working range in the climatic test chamber CTC due to integrated compressed air drying unit

also documented through the interior sensors of the **climate chamber**, the laboratory can confirm the excellent compliance of the two parallel running protocols.

Atmosafe wants to thank **ikfe GmbH** and Dr. med. Petra B. Musholt in particular for her assistance in writing this article. Given the everyday amount of work in a research laboratory, this kind of assistance does not go without saying.

An overview of the main topics

- Approval of medical products, medical devices
- Clinical research
- Climate chamber, Climatic test chamber
- ikfe, institute for clinical research and development
- Compressed air drying unit
- Tropical climate, arctic climate

Laboratory equipment for incubation

[Incubator I](#)

[Cooled incubator ICP](#)

[Peltier-cooled incubator IPP](#)

[CO2 incubator INCOmed](#)

[Cooled storage incubator IPS](#)

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