

Quality testing made quick and easy: Reducing five years to just one



Aesculap products touch a part of almost every person's life at some point. A subsidiary of the medical technology and pharmaceutical manufacturer B. Braun Melsungen AG, the company's business activities focus on abdominal surgery, cardiothoracic surgery, interventional vascular diagnostics and therapy, neurosurgery, orthopedic joint replacement and regenerative therapies, spinal surgery, and sterile goods management.

It has belonged to the family-operated B. Braun group since 1976.

The advancements in medical science that Aesculap is able to achieve mean that it is constantly developing new products, which its experts then subject to exhaustive rounds of quality and durability testing. To assist in this process, the company relies on its regional partner BINDER – located just 500 meters away. As a manufacturer of simulation chambers, BINDER has kitted out Aesculap's laboratory facilities with several units so far.

Aesculap's research and development activities use nine different BINDER constant climate chambers, currently serving as storage locations for numerous packages with trocars – which are endoscopic instrument ports used for accessing the abdominal region in minimally invasive surgical procedures.



> Trocars and their packaging ready to go into a constant climate chamber for testing.

Remit

- Temperature range up to 70°C
- Humidity range up to 80% RH
- Precise temperatures during continuous operation
- Must be possible to read out measured values for documentation

BINDER solutions

- Temperature range: 0°C to +70°C
- Humidity range: 10% RH to 80% RH
- APT.line™ preheating chamber technology
- Humidity regulation with capacitive humidity sensor and steam humidification
- Intuitive touchscreen controller with time-segment and real-time programming
- Internal data logger, measured values can be read out in open format via USB
- Unit self-test for comprehensive status analysis
- Tightly sealed inner door made of tempered safety glass
- Special TIMELESS coating to prevent glass corrosion

The packages will be left inside for a little over a year before the experts take them out and inspect them for changes, a process that simulates five years of use in real time. The KMF 720 constant climate chamber, one of the items of equipment in use, achieves this by simply maintaining a constant interior environment with a temperature of 45°C and 35% relative humidity over 398 days.



› The color of the instruments has to remain unchanged. Bernd Blender takes a look during the test process.

Bernd Blender, head of testing in the R&D laboratory, explains that the packages should then emerge in an undamaged state. “The trocars shouldn’t experience discoloration during the test phase, and the packages’ mechanical stability and sterile barrier should remain intact,” he says, adding: “This is what we’re currently testing in our BINDER chambers, which we’ve found to be highly reliable and durable. Our test laboratory also deals with several other products, however. In the accelerated aging processes we conduct, we ensure compliance with the ASTM 1980-2016 standard and the ICH guideline Q1A_R2 in particular.”

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Bernd Blender, Aesculap AG

Blender uses a KBF 240 constant climate chamber for label testing, which involves an aging test that simulates ten years within just 456 days in an environment with a temperature of 55°C and 60% relative humidity.

Once the test is complete, the labels should ideally emerge from the chamber with the same standards of legibility, color, and adhesion as they had when they went in. Blender expects the BINDER chamber to deliver this and, although he is still awaiting the final results, feels confident based on what he has already seen from the company: “BINDER provides excellent service and advice. We recently had an issue with one of our PCs and BINDER was able to help us retrieve the data it had recorded from the previous two months.”

Advantages of constant climate chambers from the KBF series

- Temperature range: 0°C to 70°C
- Humidity range: 10% RH to 80% RH
- APT.line™ preheating chamber technology
- Humidity regulation with capacitive humidity sensor and steam humidification
- Intuitive touchscreen controller with time-segment and real-time programming
- Internal data logger, measured values can be read out in open format via USB



› KBF 240 model

Further models are available here › go2binder.com/en-constant-climate-chambers

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