

Whitepaper FDM

**ENVIRONMENTAL TESTING FOR MEDICAL DEVICES: PRECISION IN
TEMPERATURE AND HUMIDITY CONTROL**

Introduction

Medical devices must operate safely and reliably under a wide range of environmental conditions. Regulatory bodies like the FDA and the European MDR require thorough validation of device performance through controlled temperature and humidity testing. This whitepaper explains how environmental simulation helps ensure compliance, functionality, and product longevity.

Understanding Temperature and Humidity Testing

Environmental testing subjects medical devices to controlled climate conditions that simulate real-world scenarios—such as transport, storage, and operational use. Temperature and humidity are critical because they can influence material properties, sensor accuracy, battery life, and packaging integrity.

Typical test conditions include:

- **Temperature range:** -20°C to +70°C
- **Humidity range:** 10% to 95% RH
- **Stability:** $\pm 0.3^{\circ}\text{C}$ and $\pm 3\%$ RH
- **Cycle speed:** up to $3^{\circ}\text{C}/\text{min}$
- **Combined stress profiles** for accelerated aging and durability

FDM chambers ensure uniformity and repeatability, crucial for regulatory validation.

Standards and Compliance Requirements

Medical device environmental tests follow international standards such as:

- **ISO 11607-1** – Packaging for terminally sterilized devices
 - **IEC 60601-1** – Safety and essential performance of medical electrical equipment
 - **ASTM D4332** – Conditioning for testing
 - **FDA 21 CFR Part 820** – Quality System Regulation
- These standards define the methodology, documentation, and performance thresholds required to demonstrate product safety and reliability under environmental stress.
-

Case Study: Packaging Validation for a Diagnostic Device

A manufacturer needed to validate packaging for a Class II diagnostic device exposed to high humidity during transit. Using FDM's climate chambers, they simulated 72 hours at 70°C and 90% RH. The test revealed minor sealing failures, leading to material improvements. A retest passed ISO 11607 criteria, allowing for regulatory approval and faster market entry.

Conclusion

Accurate temperature and humidity testing is not just a regulatory hurdle—it's a foundation for safe and reliable medical technology. With FDM's customizable climate chambers and expert support, manufacturers gain a trusted partner in compliance, innovation, and performance assurance.

CONTACT US FOR EXPERT CONSULTATION

SEND EMAIL