

# BIOBOX

## Solution for 37°C Medical Device Testing

Within the medical device industry, regulatory agencies often test internally-based devices and implants in a physiological state. The Instron® BioBox meets the growing trend of testing actual medical devices and biomaterials at body temperature (37 °C). For large or long devices, testing in a liquid may not be practical. As an alternative, testing inside a controlled air environment at body temperature provides a powerful solution.

The BioBox can be incorporated as a standard item on a new single column frame or in selected models already in operation. This box permits full system travel for testing of sutures, catheter tubings, latex gloves, and a wide variety of other devices and biomaterials at physiologically relevant temperatures.

#### PRINCIPI F OF OPERATION

The BioBox consists of four polycarbonate side-walls with an internal heating tube that provides the appropriate levels of heat and airflow to perform mechanical tests at 37 °C. The centrally located, high-level air ducts provide consistent air flow for uniform temperature distribution during testing. Although the frame is situated inside the box, the operational panel and emergency stop button are relocated outside the box. Access to the test space is ergonomically designed with a unique dual door panel arrangement.



### **FEATURES**

- Allows full travel of the test instrument at body temperature (37°C)
- Allows for testing on Instron 68SC, 34SC, and 5940 systems
- Temperature range from ambient to 40 °C
- Temperature control accuracy of ± 2 °C
- · Accommodates most standard test grips, fixtures, and platens
- Spacious door allows for quick access to the test space
- Compatible with Bluehill Universal, including Traceability Module to meet 21 CFR Part 11 compliance
- Temperature data may be collected using Bluehill software\*

<sup>\*</sup>Requires spare sensor conditioner card

The BioBox is equipped with a temperature controller, which provides fast ramp to temperature, as well as accurate temperature control. Almost all Instron® grips, fixtures, and platens can be operated within the temperature ranges of the box. The modular design allows for an easy installation of the BioBox. Access ports on the side of the BioBox provide excellent electrical cord management.

Instron Professional Services can provide temperature verification services to conform to internal validation processes often required by regulatory agencies.

#### **SPECIFICATIONS**

		CP128993	CP128994
Compatible System	-	68SC & 34SC	68SC & 34SC
Temperature Range	°C °F	Ambient to 40 Ambient to 104	
Temperature Control Accuracy	°C °F	± 2 ± 3.6	
Time to Temperature	mins	5+ load cell compensation time (15)	
$\textbf{Dimensions}~(W\times D\times H)$	in mm	30.9 × 30.9 × 69.9 784 × 784 × 1775	
Weight	lbs kg	80 36	
Electrical Power	V	120	240
Power Requirement	Watts	800	

BioBox is not compatible with the following fixtures: AVE/SVE, 90° and Variable Angle Peel Fixtures, COF Fixture, Extra Long XL Extensometer







Dual doors allow for flexible access and reduced heat loss

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