

# INCU™ II Skin Temperature Heater Assembly

## *Instructions*

### **Introduction**

The INCU™ II Skin Temperature Heater Assembly (the Product or Accessory) uses a controlled temperature environment to test the skin temperature sensors of incubators or radiant warmers. The Accessory connects to the INCU™ II Incubator Analyzer (the Analyzer). To use the Accessory, see *Skin Temperature Sensor Accuracy*.

### **Intended Use**

The intended use for the Analyzer and skin temperature heater is to test in compliance with standards, perform preventative maintenance, repair verification, and routine verification of baby incubators and radiant warmers. The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on baby incubators and radiant warmers in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology.

This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment. It is intended for over the counter use. Designed around AAMI and IEC standards that specify incubator and radiant warmer sound levels, airflow, and thermal characteristics, the INCU II simultaneously measures airflow, relative humidity, sound, and five independent temperatures. The skin temperature heater measures the temperature of the incubator and radiant warmer skin temperature sensor.

### **Safety**

A **Warning** identifies hazardous conditions and actions that could cause bodily harm or death. A **Caution** identifies conditions and actions that could damage the Product, the equipment under test, or cause permanent loss of data.

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## Warning

To prevent possible electrical shock, fire or personal injury, follow these guidelines:

- Read all safety information before you use the Product.
- Carefully read all instructions.
- Use the Product only as specified, or the protection supplied by the Product can be compromised.
- Do not use the Product around explosive gas, vapor, or in damp or wet environments.
- Do not use the Product if it operates incorrectly.
- Use this Product indoors only.
- Use only the external mains power supply included with the Product.
- Disable the Product if it is damaged.
- Do not use the Product if it is damaged.
- Do not use a two-conductor mains power cord unless you install a protective ground wire to the Product ground terminal before you operate the Product.
- Do not put metal objects into connectors.
- Do not use an extension cord or adapter plug.

Table 1 shows the symbols used on the Product and in this document.

**Table 1. Symbols**

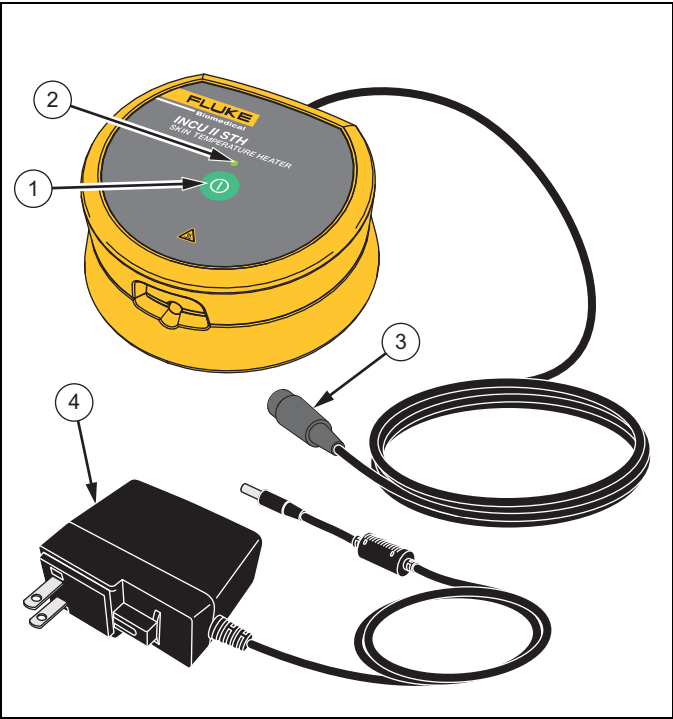
| Symbol  | Description  |
|---|--|
|  | WARNING. RISK OF DANGER.   |
|  | WARNING. HAZARDOUS VOLTAGE. Risk of electric shock.  |
|  | WARNING. HOT SURFACE. Risk of burns.   |
|  | Consult user documentation.  |
|   | Battery polarity   |
|  | This product complies with the WEEE Directive marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Product Category: With reference to the equipment types in the WEEE Directive Annex I, this product is classed as category 9 "Monitoring and Control Instrumentation" product. Do not dispose of this product as unsorted municipal waste. |

## Set Up the Accessory

Table 2 shows the Accessory indicators and connections.

**Important note:** Set the calibration factors before first use.

**Table 2. The Accessory**



|   |                           |
|---|---------------------------|
| ① | Power button              |
| ② | Power indicator           |
| ③ | Connector to the Analyzer |
| ④ | Power cord                |

## Skin Temperature Sensor Accuracy

201.12.1.103 (Baby Incubator)

201.12.1.103 (Transport Incubator)

201.12.1.101 (Radiant Warmer)

Use the Accessory to compare the skin temperature sensor indication to a calibrated temperature sensor.

### Pass Criteria

Skin temperature sensor indication = Analyzer measurement  $\pm 0.3$  °C

### Prepare for the Test

To get accurate results:

- Make sure there is a good contact between the skin sensor and the heater. Use a thermal compound to get the highest accuracy.
- Set the DUT to measure from the skin temperature sensor.
- Put the Accessory on a flat surface next to the Analyzer.
- Put the Accessory in an environment where the temperature is  $<30$  °C. An environment  $\geq 30$  °C can decrease the accuracy of the test due to ambient interference and can decrease predictability of the rise time.

### Procedure

1. Connect the Accessory to the Analyzer.
2. Connect the Accessory to ac power.

#### Note

*Do not push the power button on the Accessory until the Analyzer prompts you to turn on the Accessory.*

3. Attach the skin temperature sensor from the DUT to the heater assembly.
  - a. Open the Accessory and put the skin temperature sensor on the center of the base.
  - b. Close the Accessory.
4. On the Analyzer:
  - a. Select the test environment.
  - b. Select Skin Temperature Sensor Accuracy.
  - c. Push **TEST**.

The Analyzer detects the temperature of the Accessory.

If the temperature is  $<30$  °C the Analyzer prompts you to turn on the Accessory.




If the temperature is  $\geq 30$  °C the Analyzer continues to monitor the temperature. When the temperature is  $<30$  °C the Analyzer prompts you to turn on the Accessory.

- d. On the Accessory, push the power button to turn on the heater.

The Analyzer waits until the temperature is stable and then takes a measurement.

### Note

The test will not start if the temperature is  $\geq 30$  °C.

- On the Analyzer, use  and  to enter the temperature shown on the DUT and then push .

## Maintenance

The Accessory needs little maintenance or special care. Treat the Analyzer as a calibrated measurement instrument. Do not drop or cause other mechanical abuse.

To clean the Accessory, wipe with a damp cloth.

## Specifications

### Temperature

|   |   |
|---|---|
| Operating .....                         | 10 °C to 30 °C                                      |
| Accuracy .....                          | $\pm 0.05$ °C                                       |
| Display Resolution .....                | 0.01 °C   |
| Storage.....                            | -20 °C to 60 °C (-4 °F to 140 °F)                   |
| Humidity .....                          | 10 % to 90 % non-condensing                         |
| Altitude .....                          | 2000 m  |
| Ingress Protection Rating .....         | IP-20   |
| Weight .....                            | 0.2 kg (0.5 lb)                                     |
| Size .....                              | 75 mm x 70 cm x 38 cm (2.9 in x<br>2.7 in x 1.5 in) |
| Power Adapter – Universal voltage ..... | Input: 100 V to 240 V with adapters<br>50/60 Hz.    |
| Output .....                            | 15 V dc, 1.3 A max                                  |

### Safety

|                   |  |
|-------------------|--|
| IEC 61010-1 ..... | Overvoltage Category none,<br>Pollution Degree 2 |
|-------------------|--|

### Electromagnetic Compatibility (EMC)

IEC 61326-1: Basic

Emissions Classification..... IEC CISPR11: Group 1, Class A.

*Group 1 have intentionally generated and/or use conductively coupled radio-frequency energy which is necessary for the internal functioning of the equipment itself.*

*Class A equipment is suitable for use in nondomestic locations and/or directly connected to a low voltage power supply network.*

USA (FCC)..... Intentional Radiators

*This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.(15.19)*

## Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase. During the warranty period, we will repair or at our option replace, at no charge, a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty covers the original purchaser only and is not transferable. The warranty does not apply if the product has been damaged by accident or misuse or has been serviced or modified by anyone other than an authorized Fluke Biomedical service facility. NO OTHER WARRANTIES, SUCH AS FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSED OR IMPLIED. FLUKE SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA, ARISING FROM ANY CAUSE OR THEORY.

This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. Recalibration of instruments is not covered under the warranty

This warranty gives you specific legal rights and you may also have other rights that vary in different jurisdictions. Since some jurisdictions do not allow the exclusion or limitation of an implied warranty or of incidental or consequential damages, this limitation of liability may not apply to you. If any provision of this warranty is held invalid or unenforceable by a court or other decision-maker of competent jurisdiction, such holding will not affect the validity or enforceability of any other provision.

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Cleveland Calibration Lab  
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Email:  
[globalcal@flukebiomedical.com](mailto:globalcal@flukebiomedical.com)

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