FLUKE®
Biomedical

INCU™ II

Incubator Analyzer

Getting Started Manual

PN 4715708
October 2015, Rev. 2, 1/16

Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase OR two years if at the end of your first year you send the instrument to a Fluke Biomedical service center for calibration. You will be charged our customary fee for such calibration. 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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Notices

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Copyright Release

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 850-4608 or 1-440-248-9300. In Europe, email techsupport.emea@flukebiomedical.com or call +31-40-2965314.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Returns and Repairs

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double–walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-440-498-2560.

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service or

In the U.S.A and Asia.:
Cleveland Calibration Lab
Tel: 1-800-850-4608 x2564
Email: globalcal@flukebiomedical.com

In Europe, Middle East, and Africa:
Eindhoven Calibration Lab
Tel: +31-40-2675300
Email: ServiceDesk@fluke.com

To ensure the accuracy of the Product is maintained at a high level, Fluke Biomedical recommends the product be calibrated at least once every 12 months. Calibration must be done by qualified personnel. Contact your local Fluke Biomedical representative for calibration.

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the International System of Units (SI) through recognized national measurement institutes, ratiometric techniques, or natural physical constants.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The INCU II is manufactured for Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

Table of Contents

Introduction

The INCU™ II (the Analyzer or the Product) is a portable incubator analyzer that verifies the operation and environment of baby incubators, transport incubators, and radiant warmers. The Analyzer verifies the parameters that are important to the care of infants over time. These parameters include: temperature, airflow, sound, and humidity. The Analyzer has a rechargeable battery and can stay in the incubator chamber up to 24 hours without compromise to the integrity of the environment.

Intended Use

The intended use for the Analyzer 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.

Safety Information

A **Warning** identifies conditions and procedures that are dangerous to the user. A **Caution** identifies conditions and procedures that can cause damage to the Product or the equipment under test.

⚠⚠ Warning

To prevent possible electrical shock, fire, or personal injury:

- **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 touch voltages > 30 V ac rms, 42 V ac peak, or 60 V dc.**
- **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 mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.**
- **Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.**
- **Use only the external mains power supply included with the Product.**
- **Use only current probes, test leads, and adapters supplied with the Product.**
- **Use only products accessories listed as standard or optional in this manual. Use only accessories approved by Fluke Biomedical.**
- **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.**

Symbols

Table 1 is a list of symbols used on the Analyzer and in this manual.

Table 1. Symbols

Symbol	Description	Symbol	Description
	WARNING. RISK OF DANGER.		Consult user documentation.
	WARNING. HAZARDOUS VOLTAGE. Risk of electric shock.		This product contains a Lithium-ion battery.
	Conforms to relevant Australian EMC standards.		Conforms to European Union directives.
	Conforms to relevant South Korean EMC Standards.		Certified by CSA Group to North American safety standards.
	Complies with 47 CFR Part 15 requirements of the U.S. Federal Communications Commission.		
	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.		

Unpack the Analyzer

Carefully unpack all items from the box and check that you have the following items (See Figure 1):

① INCU II

② Air Flow Probe

③ Humidity Probe

④ Sound Probe

⑤ Temperature Probes (5 connector types: red, yellow, white, blue, and green)

⑥ 5 Temperature Pucks (5 connector types: red, yellow, white, blue, and green)

⑦ Placement Pad

⑧ 4 Tripods

⑨ USB Cable (Type A to Micro B)

⑩ K-Type Thermocouple

⑪ Power Adapter

⑫ Carrying Case

Included, but not pictured:

- Getting Started Manual
- Users Manual CD
- Skin Temperature Heater Assembly (optional)
- Carrying Case (pucks)

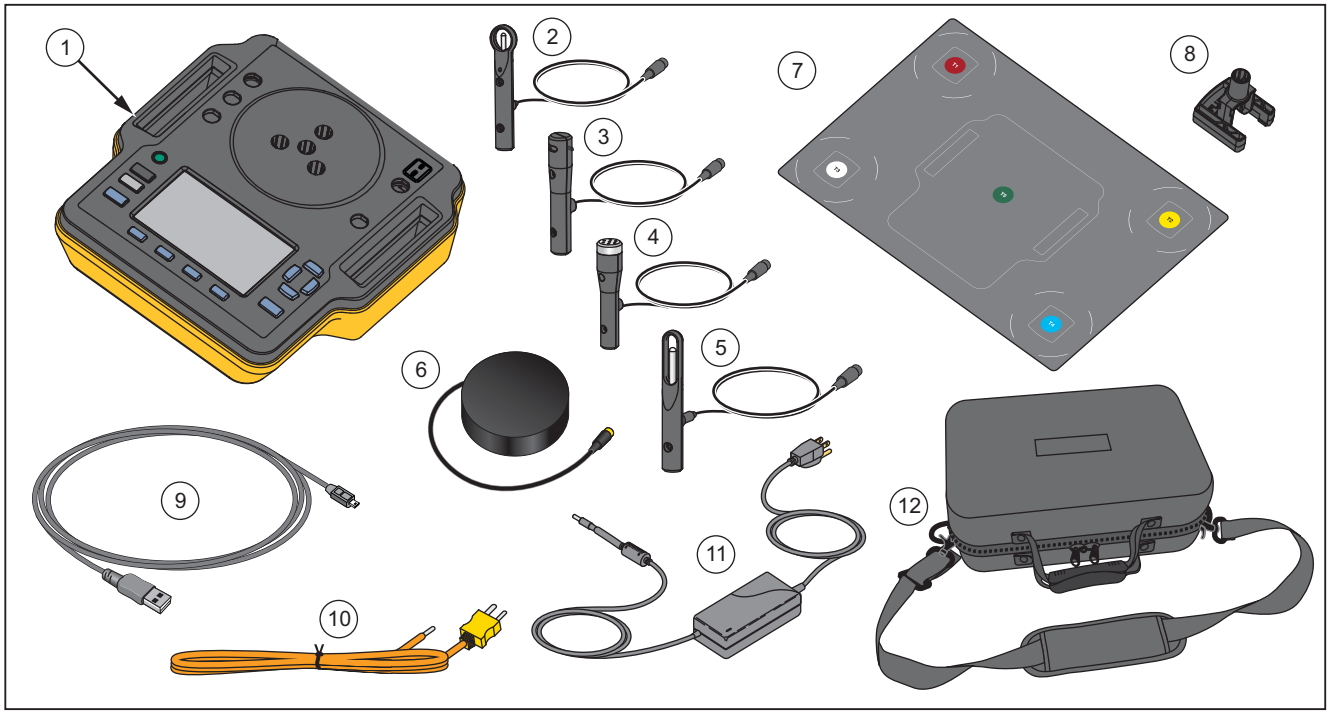

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Figure 1. Items included with the Analyzer

Analyzer Familiarization

Figure 2 shows these connections on the top and back of the Analyzer:

① Temperature sensor connections (T1 through T4)

② Temperature sensor connection (T5)

③ Temperature probe connection for K-Type Thermocouple

④ Power connection

⑤ Sound probe connection

⑥ Humidity probe connection

⑦ Airflow probe connection

⑧ Skin Temperature connection

⑨ USB port

⑩ Tripod spacers

For complete operating instructions, refer to the Users Manual on the accompanying CD. (To download the Users Manual, go to www.flukebiomedical.com.)

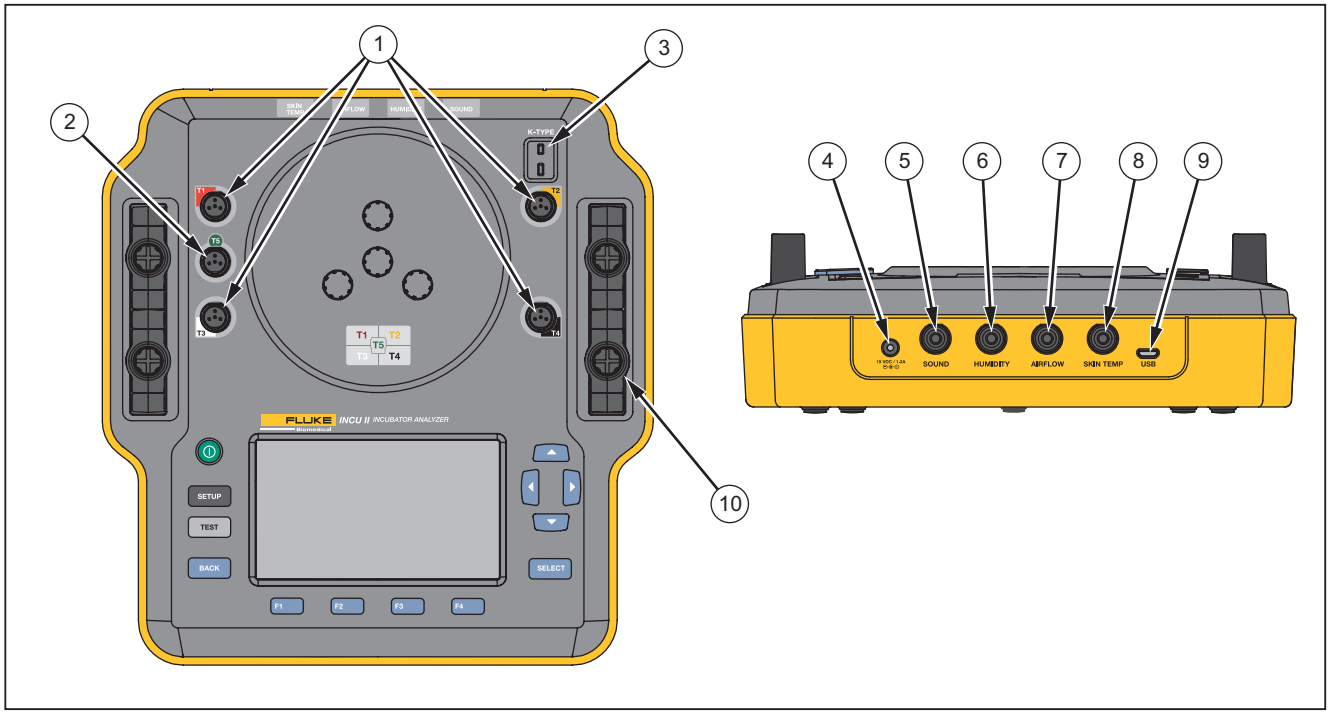

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Figure 2. Connections

Analyzer Controls

Table 2 and Figure 3 identify the controls on the Analyzer.

Table 2. Front-Panel Controls

Item	Description	
①	⏻	On/Off power switch.
②	SETUP	Access the Setup menu.
③	TEST	Start the test.
④	BACK	Go back to the previous screen.
⑤	F1 F2 F3 F4	Softkeys that select the function shown on the screen.
⑥	▲ ◀ ▶ ▼	Directional arrow keys used to position the cursor.
⑦	SELECT	Select the highlighted text.
⑧	--	Display

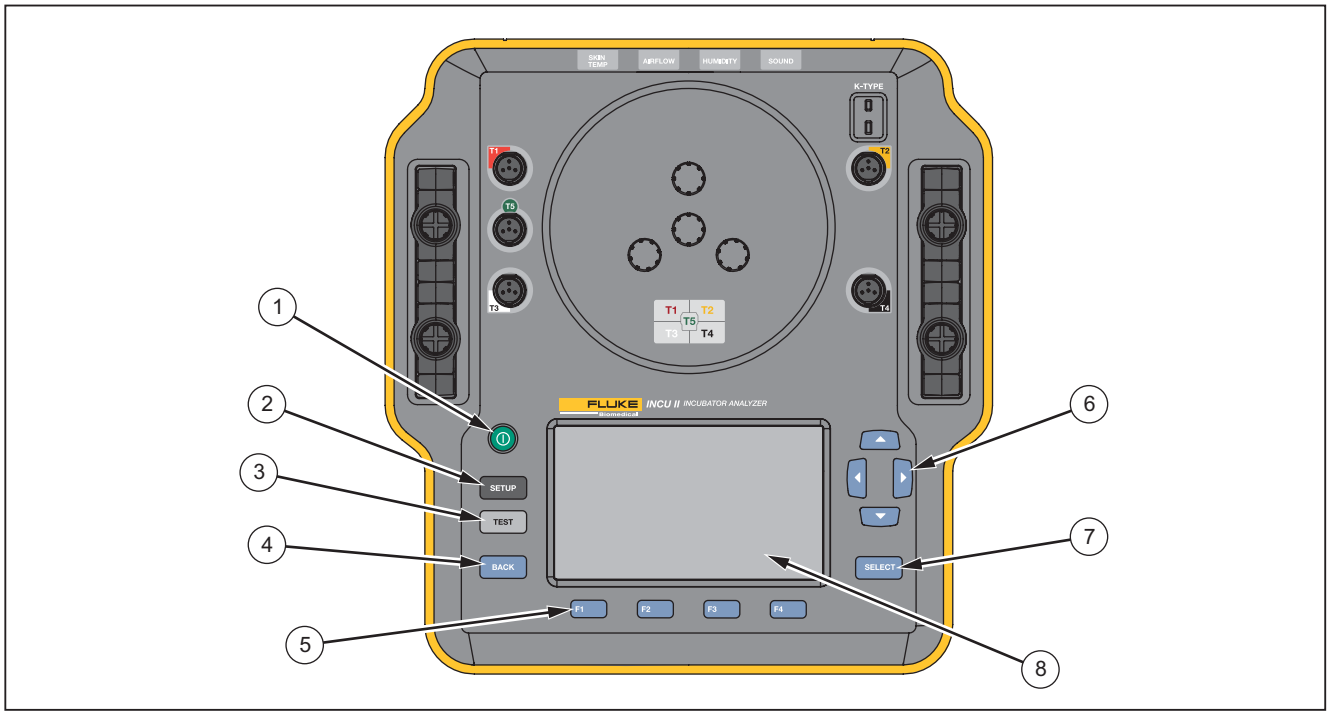

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Figure 3. Front-Panel Controls

Set Up the Analyzer

Turn on the Analyzer

Before you turn on the Analyzer, check all cables and connections for damage or wear. Replace any damaged components before use.

Secondary cells and batteries need to be charged before use. Always use the correct charger and refer to the manufacturer's instructions or equipment manual for proper charging instructions.

To turn on the Analyzer, push ⏻.

The Analyzer does a self-check. When the Analyzer is ready for operation, the Main menu shows on the display.

Select a Menu Item

To make a selection:

1. Use ▲ and ▼ to highlight the menu item.
2. Push SELECT.

Set the Language on the Analyzer

To set the language:

1. Push SETUP.
2. Use ▲ and ▼ to highlight **Language** and then push SELECT.
3. Highlight the language to use and then push SELECT.

Use the Analyzer Keyboard

Some options open a keyboard to enter text or numbers. To use a keyboard on the Analyzer:

1. Use ▲ ▼ ◀ and ▶ to move the highlight.
2. Push SELECT to accept the entry.
3. Use the softkeys to edit the entry.

Clear Memory

When the memory is 80 % full the Analyzer indicates the percentage of memory in use. To clear the memory:

1. Push SETUP.
2. Use ▲ and ▼ to highlight **Instrument Information** and then push SELECT.
3. To clear the memory, push F2 (**Clear Memory**) and then push SELECT.

Analyzer Operation

Placement Pad

Some tests use measurements from the center of each mattress quadrant. Determine the center of each quadrant for accuracy and repeatability. Use the placement pad to make sure the Analyzer and the sensors are in the correct and repeatable positions.

1. Align the placement pad on the center of the mattress. (See Figure 4.)

2. Find the center for each quadrant of the mattress.
3. Put a probe (on a tripod) or puck in the center of each quadrant.

Note

Mattresses can have different dimensions. Put the placement pad in the center of the mattress and measure to find the center of each quadrant. Typically, the center of each mattress quadrant is within the circles on the placement pad. You can make a mark on the placement pad for different mattress dimensions. Use the mark to make sure the sensors are in the same position each time you do the test.

Pretest Check

Before beginning a test, check the battery life and the available memory:

1. Push SETUP.
2. Use ▲ and ▼ to highlight **Instrument Information** and then push SELECT.

   The display shows the percentage of available battery life and the percentage of available memory.

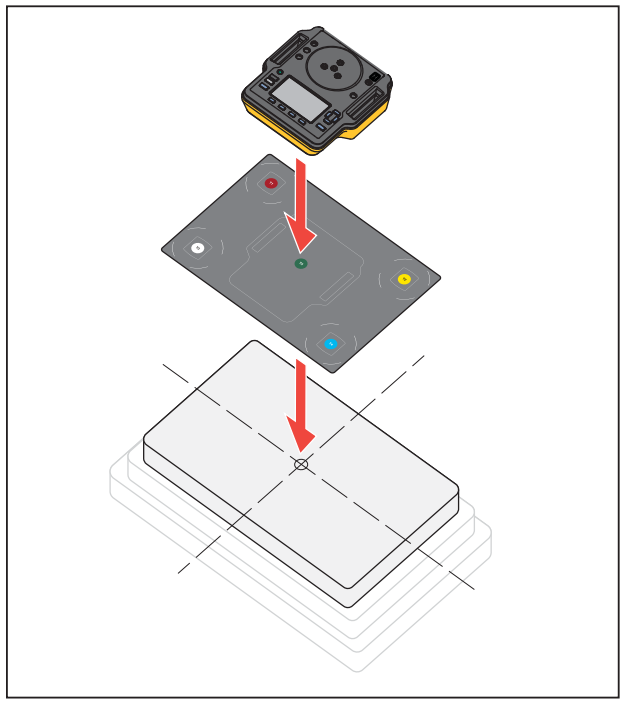

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Figure 4. Analyzer Placement

STC

STC is a steady temperature condition for at least one hour. When the Analyzer calculates that the DUT has reached STC, the Analyzer records the time on the results screen.

Test Preparation

Before you begin any test:

- Make sure you can support the requirements for each test. Some tests require a change in ambient temperatures or a probe in a specific location.
- Make sure there is enough memory to store the complete set of measurements for the test. Higher sampling rates will require more memory.
- Make sure the battery is fully charged before beginning tests that use battery life. See *Pretest Check*. Tests that require additional time after STC or that have a higher sampling rate use more battery. To prevent potential data loss, Fluke Biomedical recommends that you plug the Analyzer into power for longer tests.
- Unless directed, set the DUT for normal operation.
- Connect the probes or pucks before you start the test. The Analyzer shows the results only from the sensors that are connected before the start of the test.
- Make sure that the Analyzer uses the correct calibration factors for temperature tests. Always use probes for an incubator or transport incubator. Always use pucks for a radiant warmer.
- Each sensor has a unique set of calibration factors. If you replace a probe or puck, you must enter the new calibration factors before you use the sensor. The Analyzer requires the correct calibration factors for measurement accuracy.
- To make sure the Analyzer uses the correct calibration factors, always connect the temperature probes or pucks to the correct color-coded jack. See Figure 5.
- For tests that have the Test Time option **Run Continuously (runs until stopped)**, the test must run for the minimum test time to get a valid result.
- Some tests require specific actions after the DUT gets to STC. To make sure the test results are valid for the standard, you must complete all the steps in the procedure within the Test Time.
- To maximize the accuracy of the data, Pass/Fail calculations are based on a sample rate of 1 sample per second. If you change the sample rate, it impacts the exported data. Exported data with the modified sample rate shows the general shape of the data.

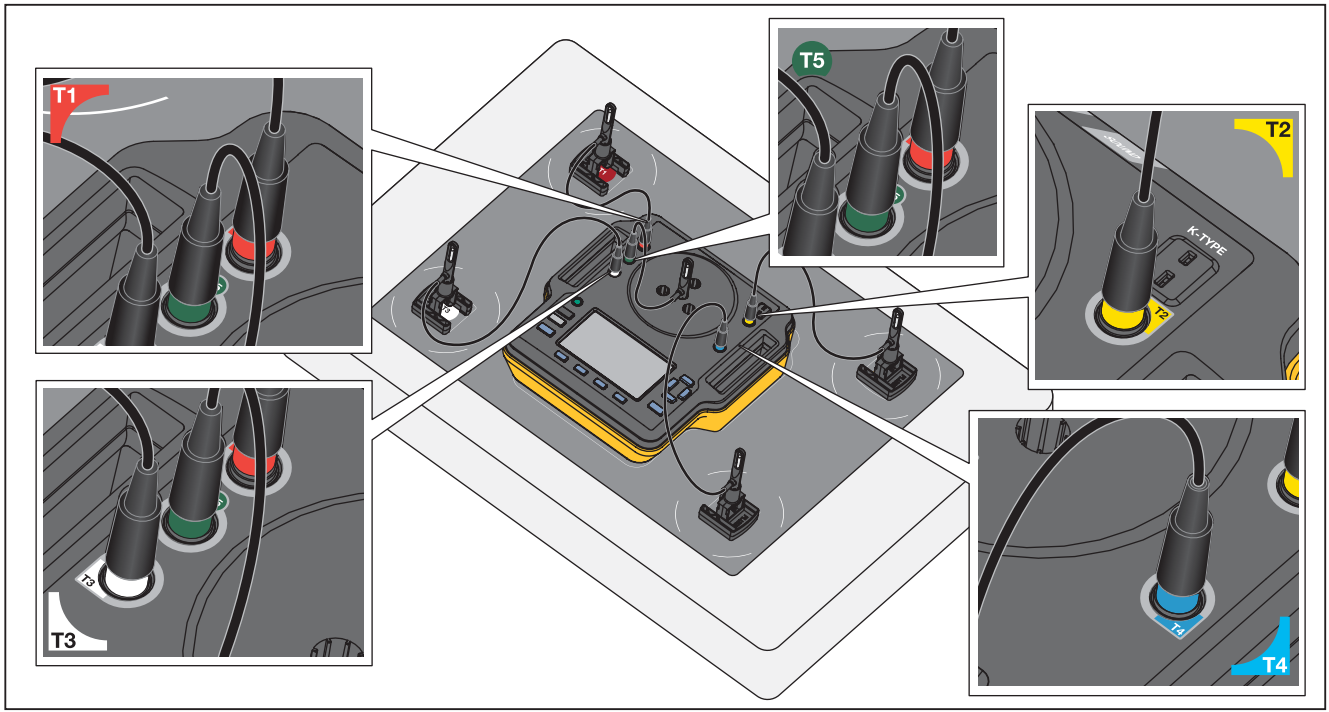

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Figure 5. Temperature Probe connections

Save a Test

You can save the results from an individual test or save all the results for a test group. The Analyzer prompts you for information.

To save an individual or general test, push F3 (**Save**).

To save and exit a test group, wait until the group is complete or push F4 (**Stop**) to stop the test. On the Overview screen, push F3 (**Save**). The Analyzer stops the test group and saves the results.

Delete Tests

You can delete tests from the Main menu. Push F4 (**View Saved Data**). From the Saved Data screen you can:

- Delete all the tests: push F3 (**Delete All**) then highlight **OK** and push SELECT.
- Delete an individual test:
  a. Use ▲ and ▼ to highlight the test or test group.
  b. Push F2 (**Delete**) then highlight **OK** and push SELECT.

Menus

From the Main menu, you can select a test environment, take a general test, or view saved tests.

General Test

Use the General Test to take readings from any sensor that is connected to the Analyzer. To do a General test:

1. Push F1 (**General Test**).
2. Use ▲ and ▼ to highlight the type of temperature sensor you have connected and push SELECT.

   ⚠Caution

   Make sure to select the correct type of sensor. The wrong type of sensor will give inaccurate readings.
3. To select the sampling rate:
   a. Push F3 (**Sample Rate**).
   b. Highlight the sample rate to change and push SELECT.
   c. Highlight the new sample rate and push SELECT.
   d. When you have set the sample rates, push F4 (**Done**).
4. Push TEST.

   The Analyzer takes measurements from each of the attached sensors and shows the results on the display.

Note

Airflow measurements require time for the environment to stabilize. For more accurate air flow measurements, allow readings to stabilize for ten minutes.

Note

To maximize the accuracy of airflow measurements, do not use other probes when you make an airflow measurement. If other probes are attached, position the probes to prevent interference with the airflow path to the airflow probe. Place the airflow probe perpendicular to the direction of airflow inside the incubator.

Individual Test

To take an individual test:

1. Use ▲ and ▼ to highlight the test environment and push SELECT.
2. Highlight the test and push SELECT.

Test Groups

Use the test group feature to create a list of tests that execute in a sequence.

You can schedule a single test to execute multiple times to accommodate different specifications. For example the same test can measure at 32 °C and another instance can measure at 36 °C.

Create Test Groups

To create a test group:

1. Use ▲ and ▼ to highlight the test environment and push SELECT.
2. Push F4 (**Create Test Group**).

   The Analyzer shows the list of available tests. Tests that have sub-modes are indicated with a black arrow when the text is highlighted.
3. Select the test to add the test to the group.

   If a test has different sub-modes, the Analyzer shows a list of the available modes.

   a. Select the combination of modes for this test group.

   b. Highlight **Done** and push SELECT.
4. If you can define the duration of the test, the Select Test Time screen shows. Highlight the duration and push SELECT then highlight **Done** and push SELECT.
5. To remove a test from a group, highlight the test and push SELECT.
6. When you are finished, push F4 (**Done**).
7. Use the keyboard to enter a name for the test group. See *Use the Analyzer Keyboard*.

View and Start a Test Group

To view or start a test group:

1. Select the test environment.
2. Push F3 (**View Test Group**).

   The Analyzer shows the list of test groups.
3. To view the tests in the test group, highlight the test group and push SELECT.
4. To view the test details, select the test. Use F2 (**Sensor Placement**) and F3 (**Test Summary**) for information on how to set up the test.
5. To start the test group sequence, push TEST.

Maintenance and Troubleshooting

⚠⚠ Warning

To prevent possible electrical shock, fire, or personal injury:

- **Repair the Product before use if the battery leaks.**
- **Use only Fluke Biomedical approved power adapters to charge the battery.**
- **Batteries contain hazardous chemicals that can cause burns or explode. If exposure to chemicals occurs, clean with water and get medical aid.**
- **Do not disassemble the battery.**
- **Remove the input signals before you clean the Product.**
- **Use only specified replacement parts.**
- **Have an approved technician repair the Product.**
- **Be sure that the battery polarity is correct to prevent battery leakage.**
- **Disconnect the battery charger and move the Product or battery to a cool, non-flammable location if the rechargeable battery becomes hot (>50 °C) during the charge period.**
- **Replace the rechargeable battery after 5 years of moderate use or 2 years of heavy use. Moderate use is defined as recharged twice a week. Heavy use is defined as discharged to cut off and recharged daily.**
- **Verify the safe state of the equipment after repair.**
- **Recycle spent batteries according to local ordinances.**

⚠Caution

Changes or modifications not expressly approved by Fluke Biomedical could void the user's authority to operate the equipment.

After maintenance, check the Analyzer for safe operation. Check all cables and connections for damage or wear. Replace any damaged components before use.

Clean the Analyzer

The Analyzer needs little maintenance or special care. Treat the Analyzer and probes as calibrated measurement instruments. Avoid dropping or other mechanical abuse.

To clean the Analyzer, wipe with a damp cloth. Do not allow liquid to get into the Analyzer.

Wipe down the probes and cables with the same care.

Radio Frequency Certification

For more information, go to www.flukebiomedical.com and search for Radio Frequency Data for Class A.

Troubleshooting

Table 3 lists common problems and solutions.

Table 3. Troubleshooting

Symptom	Resolution
The Analyzer does not show the Top Menu.	Connect the Analyzer to Power and make sure the battery is charged.
The Analyzer fails during the initial self-test.	Contact Fluke Biomedical Technical Support
The readings are inaccurate.	Make sure the probes are plugged into the correct plug. Make sure the probe calibration factors are correct.

Replaceable Parts and Accessories

Table 4 lists the available accessories for the Analyzer.

Table 4. Accessories

Item	Fluke Biomedical Part Number
Skin Sensor Heater Assembly	4721175

Table 5 lists the replaceable parts for the Analyzer.

Table 5. Replaceable Parts

Item		Fluke Biomedical Part Number
Carrying Case		4715749
Power Adapter – Universal Voltage 100 V to 240 V with adapters		4721194
USB Cable (Type A to Micro-B) 2m		4721166
Placement Pad		4715713
Tripod set of 4		4721109
Radiant Warmer Pucks set of 5	Red	4721111
	Yellow	4721130
	White	4721148
	Blue	4721153
	Green	4721127

Table 5. Replaceable Parts (cont.)

Item			Fluke Biomedical Part Number
Probes	Temperature probes	Red (T1)	4721039
		Yellow (T2)	4721056
		White (T3)	4721063
		Blue (T4)	4721074
		Green (T5)	4721042
	Air Flow probe (1)		4721017
	Sound probe (1)		4721000
	Humidity Probe (1)		4721021
	K-Type Thermocouple		4720996
INCU II Getting Started Manual			4715708
INCU II Users Manual CD			4715690

Specifications

Physical

Size
(LxWxH-without sensors) ... 23 cm x 21 cm x 6 cm (9.0 in x 8.5 in x 2.5 in)
Total Weight ..... 3.9 kg (8.5 lb)
With sensors only ..... 1.4 kg (3 lb)
With Pucks (5) ..... 2.5 kg (5.5 lb)
Carrying case ..... 1.1 kg (2.5 lb)

Power

Power Adapter –
Universal voltage ..... Input: 100 V to 240 V with adapters 50/60 Hz.
Output: 15 V dc, 1.3 A max.

Rechargeable lithium-ion battery, internal ..... 7.4 V, 7800 Ah, 58 Wh powers the unit for 24 hours with sample rate set at 30 seconds

Interface

Push navigation buttons ..... Power On/Off, Test, Select, Back, and arrow keys
User Preferences ..... Adjust backlight, Display brightness, and Set clock
View Verification history
Recall and run templates on tester
Recall past saved and stored tests results
Templates ..... time duration, frequency of data capture and tests.
Select user preferences ..... units of measure, view test results of current and past tests on the Analyzer
View battery life ..... indicator bar shows life remaining

Environmental Specifications

Temperature

Operating temperature ..... 10 °C to 40 °C
Storage temperature ..... -20 °C to 60 °C
Humidity ..... 10 % to 90 % non-condensing
Altitude ..... 2000 m
Ingress Protection Rating ... IP-20

Safety

IEC 61010-1:Overvoltage Category none, 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)

Korea (KCC) .....Class A Equipment (Industrial Broadcasting & Communication Equipment)

Class A: Equipment meets requirements for industrial electromagnetic wave equipment and the seller or user should take notice of it. This equipment is intended for use in business environments and not to be used in homes.

Wireless Module Listing

FCC (United States) compliant (Class A).....FCC ID: X3ZBTMOD3

IC (Industry Canada) compliant .....IC: 8828A-MOD3

CE (European) certified CE0051

802.15.1 qualified .....QD ID: B019224

Wireless Radio

Frequency range.....2412 to 2483 MHz
Output Power.....10 mW

Measurements and Test Specifications

5 Air Convection Temperature for Incubator – Sensors in probes (T1-T5).....0 °C to 50 °C
- Accuracy .....±0.05 °C
- Display Resolution .....0.01 °C

5 Air Convection Temperature for Radiant Warmers – Sensors in pucks (Black discs) .....0 °C to 50 °C
- Accuracy .....±0.2 °C
- Display Resolution .....0.01 °C

Relative Humidity.....0 % to 100 %
- Accuracy .....±3 % RH (0 % to 100 %, non-condensing)
- Display Resolution .....0.1 % RH

Air Flow.....0.2 m/sec to 2.0 m/sec at 35 °C, 50 % RH
- Accuracy .....±0.1 m/sec
- Display Resolution .....0.01 m/sec

Sound Pressure – (Class II) .....30 dB(A) to 100 dB(A)
- Accuracy .....±5 dB(A)
- Display Resolution .....0.1 dB(A)

IEC-61672-1 Class 2 from 31.5 Hz to 8 kHz

Surface temperature.....-5 °C to 60 °C
- Accuracy ..... ±0.5 °C
- Display Resolution .....0.05 °C