FLUKE®

Biomedical

Neonatal Test Solutions

Neonatal quality assurance solutions from an ISO 13485 medical device company.

First moments

The smallest patients can be at the greatest risk. The external world is very different from the safe haven of a mother's womb. From the moment they enter the world, babies are exposed to a barrage of stimuli from ambient noise and light to temperature variations. Most babies adapt quickly, helped by radiant warmers, phototherapy, and routine monitoring.

Other infants, especially those born prematurely, require immediate medical assistance. If born in a facility without a neonatal intensive care unit (NICU) or incubator, they might be placed in a transport infant incubator, and then moved to a children's hospital or larger medical facility with a NICU.

Once in the NICU, these babies are placed in an infant incubator, which supports their growth with a carefully controlled environment aimed to replicate the womb. Temperature, oxygen, humidity, airflow, and sound are meticulously modulated to create the safest and most effective environment to heal and grow as possible. They might also be hooked up to a ventilator, cardio-respiratory monitor, IV pump, or pulse oximeter.

Because infants can't say whether they're uncomfortable, having difficulty breathing, or experiencing pain, it's important to regularly test and verify the performance and safety of the medical devices used in maternity wards and NICUs—especially because of the high sensitivity and fragility of these small patients.

Fluke Biomedical offers a range of test devices to verify neonatal medical devices are working as expected, and also meet global safety and performance standards to ensure the smallest patients have the best chance for thriving and eventually, going home.

FLUKE®
Biomedical

Ensure the safety of your smallest patients

Nurturing

The transition from the womb to the world can be difficult; incubators and radiant warmers are designed to be nurturing—providing a warm and protective environment. The **INCU II Incubator/Radiant Warmer Analyzer** is an all-in-one device designed to simplify testing and verifying the safety and performance of incubators, transport incubators, and radiant warmers.

Healing

Many newborns are born with high bilirubin levels in their blood, resulting in jaundice—a condition treated by phototherapy. The **Dale 40 Phototherapy Radiometer** reliably and accurately tests the blue part of the spectrum from 400–480 nanometers to help ensure infants are receiving the optimal levels of phototherapy.

Validating

Because an infant cannot tell you what is wrong with their environment, it's important to monitor their vital signs both before and after birth. The **PS320 Fetal Simulator** simplifies testing and verifying the performance of electronic monitors by simulating fetal and maternal ECG and uterine activities.

Measure and confirm the concentration of oxygen in an infant incubator with the **Max O2 PLUS AE Oxygen Analyzer**. This hand-held analyzer can also be used to measure the concentration of oxygen from ventilators or anesthesia systems, or a source of gas such as an oxygen tank.

ProSim 4 Vital Signs Simulator and the **SPOT Light SpO2 Tester** are intuitive-to-use patient monitor test tools to verify neonatal monitors are adjusted to effectively test infant vital signs.

FLUKE®
Biomedical

INCU II Incubator/ Radiant Warmer Analyzer

Functionality you need. Compactness you desire.

The Fluke Biomedical INCU II is an all-in-one incubator and radiant warmer analyzer that simplifies testing, and helps ensure the proper performance and safety of infant incubators, transport incubators, and radiant warmers.

Portable and intuitive to use, the INCU II simultaneously tests temperature, airflow, sound, and humidity. Test results and parameters can be monitored in real-time on a large easy-to-read LCD screen, or be transferred to your computer wirelessly*. A general testing option enables you to complete a quick test in just 15 minutes.

All-in-One

- Simultaneously measures:
  - Temperature (in six different locations)
  - Sound
  - Humidity
  - Airflow
- Can stay in incubator chamber for up to 24 hours using rechargeable battery or 48 hours on ac power, without compromising the integrity of the test environment

Portable and easy-to-use

- Portable and compact design, weighing less than 3 lb (1.4 kg)
- Simplifies test set-up with color-coded temperature probes that match color of input ports
- Large, color LCD screen containing on-screen test direction, real-time data, and results

Test automation and customization

- On-board test automation allows standardized work flow
- Creates personalized test sequences for automatic test completion
- Both standards-based testing templates and general testing options, allowing you to create a protocol specific to your needs and complete a test in just 15 minutes

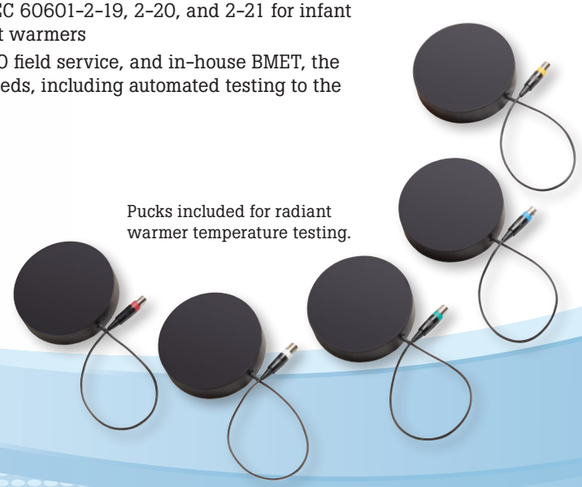
Simplifies test results, analysis, and reporting

Displays real-time test results and pass/fail indicators for fast and easy troubleshooting.

Standards-compliant

- Complies with global standards, including IEC 60601-2-19, 2-20, and 2-21 for infant incubators, transport incubators, and radiant warmers
- From OEM factory floor, OEM field service, ISO field service, and in-house BMET, the INCU II is equipped to satisfy your testing needs, including automated testing to the IEC 60601-2-19, 2-20, and 2-21 standards

*Ask your local distributor about wireless availability in your country.



Pucks included for radiant warmer temperature testing.

Dale 40 Phototherapy Radiometer

Accuracy across blue spectrum

The **Dale 40** is used to measure light radiation in medical devices used to treat hyperbilirubinemia in newborns. It can accurately capture measurement, across the blue color spectrum from 400 to 480 nanometers.

Features:

- Intuitive to use with LCD screen
- Accurate to ± 5 % of full spectral range of 429 to 472 nanometers
- Measurement range of 0 to 1999 µW/cm$_2$ with 1 µW/cm$_2$
- Probe lens matches the cosine receiving function of human skin
- Portable, weighing less than 9 ounces with a 9 V battery
- Verifies output power and provides continuous measurement of irradiation
- Saves costs by eliminating premature replacement of lamps

Max O2 PLUS AE Oxygen Analyzer

Portable, on-the-go testing

The **Max O2 PLUS AE Oxygen Analyzer** measures the oxygen concentration in infant incubators, ventilators, anesthesia systems, or oxygen tanks.

Portable and straightforward to use, it can capture measurements from 0 % to 100 % with ± 3 % accuracy (actual oxygen level overfull operating range).

Features:

- One-touch calibration with reminder
- Long battery life, approximately 5,000 hours
- Impact resistant and drip-proof
- External Max-250E Oxygen Sensor

PS320 Fetal Simulator

Test. Troubleshoot. Train.

At week five, a fetus' heart starts beating, increasing to 155 to 195 beats per minute prior to birth. The strength and number of beats can be measured by a fetal electronic monitor is used to determine whether a fetus is in distress.

The **PS320 Fetal Simulator** mimics fetal and maternal heartbeats (ECG), along with uterine activity during labor to accurately test and troubleshoot fetal electronic monitors.

Features:

- Mechanical heart for ultrasound simulation
- TOCO simulation, external or IUP
- Ultrasound simulation, including twins
- Maternal ECG simulation
- Fetal ECG, tracks ultrasound #1
- Internal (DECG) and external fetal ECG
- Uterine-activity selections
- Fetal beat-to-beat variability
- Periodic and non-periodic fetal ECG changes
- Arrhythmia selections
- Compact, lightweight, pocket-size plastic housing
- Battery operated with status indications
- Special kits available with all required accessories and cables to test fetal monitors for specified manufacturers

SPOT Light Sp0$_2$ Pulse Oximeter Tester

Test in 15 seconds or less

- Lightweight, easy-to-use, with LCD display
- Test any combination of saturation, heart rate, perfusion, transmission, artifact noise, and r-curve
- Rechargeable battery lasts up to 10 hours minimum
- Use with the ProSim 4

ProSim 4 Vital Signs Patient Simulator

Quick checks in 30 seconds

- Tests 12-lead ECG, respiration, IBM, and NIBP
- Provides one-tap testing of most patient monitor checks in one minute or less with onboard pre-sets and auto sequences
- Runs all day on a single battery charge
- Touchscreen technology

FLUKE®
Biomedical

Advantage Training

Learn anytime, from anywhere

Get the most from your investment with self-paced training modules, educational tutorials, and electrical safety testing support materials available on the Fluke Biomedical website.

- Learn more about electrical safety standards and practices
- View comprehensive device/testing tutorials
- Sample PM procedures and checklists

CarePlan Packages

Priority services to keep you up and running

CarePlan packages offer priority bench service, extended warranties, value pricing on services, VIP technical support, expedited return shipping, productivity consultation services, educational training, and more.

- Fastest turnaround and expedited shipping
- Extended warranties and reminder notifications
- Loaners and discounts

Fluke Biomedical.
Trusted for the measurements that matter.

Fluke Biomedical
6045 Cochran Road
Cleveland, OH 44139-3303 U.S.A.

Fluke Biomedical Europe
Science Park Eindhoven 5110
5692EC Son, The Netherlands

For more information, contact us at:

(800) 850-4608 or Fax (440) 349-2307
Email: sales@flukebiomedical.com
Web access: www.flukebiomedical.com