Application note

Testing radiant warmers: What you should know and best practices

FLUKE® Biomedical

Each year about 130 million babies are born worldwide, according to the World Health Organization. Birth is an awe-inspiring event, and most babies are born healthy and without complications. These babies are usually placed under a radiant warmer to help them establish thermo-regulation. The baby is normally dried, evaluated and wrapped, then placed in the mother's arms or in a bassinet. However, sometimes things don't go as planned.

At least 1 in 9 babies are born premature, and many more are born with illnesses or are injured due to complications during birth. These premature babies, or those requiring resuscitation, frequent medical intervention or surgical procedures will be placed under a radiant warmer before being placed in an incubator. For these fragile patients, their first several days, or even months, of life are especially critical.

It is easy to see that radiant warmers play a vital role in the initial minutes or even days of a baby's life. They are relatively high-risk devices and must be operated according to protocols and tested regularly to ensure that they are operating properly. This application note provides information on best practices in preventive maintenance of radiance warmers.

How radiant warmers work

Radiant warmers provide a warm environment while allowing medical staff to directly observe and access the infant. They provide thermal support for newborns in the delivery suite or for critically ill infants who require consistent nursing intervention, as well as for infants undergoing treatment in a cool environment.

The devices are open to the air and have overhead electrical heating elements that emit infrared rays toward the patient. They typically also have one or two skin-temperature sensors, a servo-control unit and alarms. The mattress often doubles as a weigh scale and there are short walls to prevent the patient from falling off the mattress.

When the infant is placed in the radiant warmer, the infrared rays heat the infant's skin and transfers heat through blood convection and tissue conduction to the rest of the body. However, it provides unequal distribution of heat, and measurements of skin temperatures may not reflect core body temperatures.

The FDA classifies radiant warmers as Class II medical devices, meaning that they are higher risk devices than Class I and require greater regulatory controls to ensure safety and effectiveness. Without proper monitoring and testing, there is a risk of burns, hyperthermia and even death.

When using a radiant warmer, staff should monitor the infant closely. They should not rely on the device's alarm system to alert them to abnormal temperatures. Steps to be followed include:

- Obey hospital procedures and the manufacturer's service manual.
- Verify skin temperatures monitored by the device by conducting auxiliary temperature checks frequently.
- If the warmer is in manual mode, monitor it constantly and adjust as needed.
- Use the servo mode unless the manual mode is specifically prescribed. This reduces, but does not eliminate, the risk of hyperthermia and burns.

The importance of testing

Radiant warmers are powerful devices and can cause serious harm to a patient. Testing radiant warmers to ensure they are functioning properly can reduce patient risk, and help shorten the time that patients must spend in the hospital due to faulty device performance.

Testing is designed to meet the regulations set out by the FDA and Ministries of Health. The International Electrotechnical Commission (IEC) sets standards which are critical in helping assess the safety of each medical device and ensuring patient safety.

The manufacturer uses the IEC standards to specify testing procedures in the Manufacturer's Service Manual. Though the performance testing of radiant warmers is generally the same, the service manual will provide model-specific directions on testing the radiant warmer, such as the need to ensure warning lights turn on when they should.

Radiant warmer testing best practices

It is essential to adopt a consistent frequency for testing. The manufacturer's manual and the FDA will often give a recommendation for testing frequency. Most radiant warmers have a minimum testing frequency of once per year, but some models (especially older ones) recommend performance testing every six months.

A tool that can help you determine the frequency of testing for your facility is the risk assessment survey. The risk assessment survey is used by the University of Vermont Biomedical Department detailed in the Medical Device Quality Assurance book by Tobey Clark, and shown in Figure 1b.

In addition to determining the frequency of testing, it is imperative the testing procedure used within your facility is standardized. Repeatable procedures in which as many variables are controlled at once is ideal to obtain accurate test information. The manufacturer's service manual will often outline these procedures, but if the manufacturer's procedure and specs are not known, the IEC 60601-2-21 standards will serve as a more than suitable replacement. The following steps will guide you through the testing procedure.

Criteria - choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	4
Device is used for life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure models are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventative maintenance	4	
Specific regulatory or manufacturers' requirements dictate preventative maintenance or testing	5	5
Incident history		
No significant history	1	
A significant history of incidents exist	2	2
Manufacturers'/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total score:		**16**
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		**2**

Figure 1b. Sample Risk Assessment (Fluke Biomedical)—Infant Incubator.

The risk assessment from Fluke Biomedical differs slightly from the University of Vermont in two categories: Problem avoidance probability and Incident History. Problem avoidance probability was rated a 5 as opposed to 2 because both regulatory and manufacturer guidelines recommend weekly, quarterly, and yearly preventative maintenance schedules. Incident history was rated a 2 instead of 1, as incubator incidences would result in patient harm (if incidences would not result in patient harm, the score would be 1). The total score is 16 (instead of UV's score of 12), indicating semi-annual (twice per year) testing for infant incubators.

1. Test setup

One of the important parts of radiant warmer testing is ensuring the type of equipment and sensors we are using to make our measurements, and the placement of our sensors and tester.

According to the IEC 60601-2-21 standard for Infant Radiant Warmers, 5 "pucks" should be used to test radiant heat, one in the center of the mattress, and one in the center of each quadrant of the mattress.

The pucks are aluminum bodies coated with a black matte paint, with a temperature sensor built inside. The idea of this is to mimic the skin of the newborn, and absorb the heat from the radiant warmer as the infant would.

A simple K-type thermocouple or open-air sensor should not be used to assess the output of radiant warmers; remember, these devices are open to the air, and air currents (from movement in the room or vents) can drastically affect our measurement and give us false information.

2. Skin sensor accuracy

Radiant warmers are often set to adjust their heat output according to the reading from the skin temperature sensor(s) on the baby. The sensor attached to the baby's skin must be accurate to allow the radiant warmer to provide the appropriate level of heat. The test of the Skin Temperature Sensor requires the use of a separate temperature-controlled "oven" module. The "oven" is set to a temperature between 28 °C and 40 °C. The Skin Temperature Sensor is plugged into the temperature control module and the temperature sensing element is placed in the "oven". The difference in temperature between the "oven" and the sensor should not exceed 0.3 °C.

3. Temperature

According to the IEC 60601-2-1-21, there are two tests that can be carried out to effectively measure temperature—one for each general mode of operation: (1) skin temperature control, (2) manual temperature control. When testing for temperature, it is important to keep in mind that radiant warmers are capable of very potent heat output, which to a small infant could be incredibly detrimental, and cause burns or even death.

Skin temperature control

It's important that the radiant warmer be able to accurately monitor the baby's temperature and adjust the output of its radiant heat accordingly. This can be tested by selection of Baby Temperature Control test at 36 °C in Servo Control Mode. The pre-tested Skin Temperature Sensor is attached to the black metal "puck" at the center of the mattress. The radiant warmer is allowed to reach the Skin Temperature Control level. Once this level has been reached, the difference between the Skin Temperature Sensor and the Control Temperature must not exceed 0.5 °C.

Manual temperature control test

A radiant warmer must be able to provide a consistent energy output to maintain the infant's body temperature. It is recommended to conduct the test at 36 °C.

Baby temperature control

The Skin Temperature Sensor is attached to the Test Device at the middle point of the mattress. The Manual Temperature Control test is performed along with a check to make sure the temperature measured by the Skin Temperature Sensor does not differ from the Control Temperature by more than 0.5 °C.

4. Sound and alarms

Audible alarm sound level

Newborns' ears are very fragile. Alarms should be tested to ensure they draw the attention of the staff but should not be so high that it risks damaging the baby's hearing. It should be between 50 and 65 dBA at a distance of 3 meters from the front of the radiant warmer. Compliance can be checked with the microphone of a sound level meter placed 1.5 meters above the floor and 3 meters in front of the radiant warmer.

Routine checks

The nurses and clinical staff should usually do checks after each patient. They should clean the radiant warmer and replace any single-use components.

The performance inspection should include checking:

- The battery is working. The battery should be replaced every 24 to 36 months
- The fan is operating properly
- The probe is providing accurate temperatures
- The high-temperature alarms are working
- Model-specific performance tests are being conducted
- The skin temperature probe and servo control are functioning

Test automation and archiving test data

Automating testing can reduce test time and increase efficiency. Using a device such as the Fluke Biomedical INCU II incubator and radiant warmer analyzer, your test time can be substantially reduced. Technicians simply need to set up the device and start testing. An automated device can track data, simplify data extraction for reporting and reduce human error.

Test results should always be archived. Long-term trending of information provides the basis for predictive maintenance. This can save money and increase the amount of time the medical device is available for use.

The test results should be stored in a database or Computer Maintenance Management System (CMMS). In contrast, archiving results in filing cabinets rarely results in anyone looking at the long-term implications of failures. For legal reasons, it is important to have a record to show that medical devices and test instruments used to evaluate them are accurate and traceable.

Contact us for more information

This paper provides a summary for maintaining and testing radiant warmers. For additional information, watch the webinar **(www.flukebiomedical.com/radiantwarmer)** or refer to the manufacturer's service manual. Our team members are available to answer any questions.

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