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Temperature testing of Ceratherm 600-2 radiant warmer within an enclosed space

Objective

To determine the level of risk posed should a Ceratherm 600-2 radiant warmer (comprises part of a Viamed resuscitation cabinet system, p/n 0310002) be left switched on and delivering heat when sealed into an enclosed space.

Background

The Newcastle upon Tyne Hospitals NHS Foundation Trust is considering installing Viamed wall-mounted infant resuscitation cabinet systems into bespoke cupboard furniture at a midwifery development at the Royal Victoria Infirmary.

Concerns have been raised as to the temperatures that may be achieved should the cupboard be closed whilst the radiant warmer is operational and delivering heat.

The Ceratherm 600-2 radiant warmer has a maximum power output at the ceramic heating element of 600 W, heat output is adjusted using 4 user-selectable heat output settings. In normal use, setting 3 (75% of maximum) or setting 4 (99% of maximum) is used, so for testing purposes full power should be used.

As per European regulations, the radiant warmer is designed to reduce the power output to a nominal safety-power setting of 20% of the maximum power output if an alarm is not silenced within 8 seconds of the onset of the alarm. The following is a comprehensive description of the safety power function taken from the Operator's Manual:

> **Alarm and Safety-Power Function**
> The radiant warmer incorporates a safety feature, which reduces the output power if the device is left unattended. An audible and visual alarm is triggered a period of 15 minutes after the last key-press; this is to inform the operator that the device is still active.
>
> The safety alarm activates an audible alarm signal, which consists of a series of beeps over a 5 second period, and the red Alarm Indicator on the front panel begins to flash.
> The alarm is cancelled by pressing the flashing Alarm Indicator, if this is done during the first 8 seconds after the onset of the alarm condition, the radiant warmer will continue to function at the current power setting, the Alarm Indicator stops flashing and the 15-minute timer begins again.
>
> If, after 8 seconds from the onset of the alarm condition the alarm has not been cancelled, the heat output of the radiant warmer reduces to a pre-set value, which is 20% of the maximum power output of the device.
>
> **Note**: when the radiant warmer enters the reduced safety-power setting, the yellow power level indicator remains illuminated at the previous power level; this is to inform the user of the power level that the device will return to when the alarm is cancelled.
>
> When the alarm is cancelled, the radiant warmer reverts back to the previous power level, the Alarm Indicator stops flashing and the 15-minute timer begins again.

To clarify how the heat output is regulated: the element operates on a 1 second duty-cycle. On the maximum power setting, power is delivered to the element for 99% of the time (990 ms) and is switched off for 1% (10 ms). When the unit enters safety-power mode, the output is reduced to 20%, which is achieved using a duty-cycle of 200 ms on to 800 ms off.

As the unit starts a 15-minute countdown from the last user intervention, the worst case scenario is that the warmer could be closed into the cupboard on full power and could operate at that level for 15 minutes, before powering down to 20% power, at which level it could run indefinitely. For the purpose of evaluating the 'worst-case' scenario, the test should be performed by allowing the radiant warmer to achieve full temperature and starting the test from a full 15-minute countdown cycle.

Method

The radiant warmer was mounted into a mock-up cupboard offering the same internal dimensions as the proposed finished cupboard.

The radiant warmer was installed at the appropriate height relative to the cupboard to achieve the upper clearance that will be achieved in the actual installation (minimum of 50 cm from the upper grille of the radiant warmer head unit to the ceiling of the enclosure).

A front panel representing the proposed cupboard door was sized to fit the mock-up and a hole was drilled through this panel to allow for a temperature probe to be inserted into the space above the radiant warmer to monitor the internal temperature towards the top of the cupboard.

The ambient temperature was raised to 27% to represent realistic environmental temperatures within an operational maternity unit.

The radiant warmer was activated and operated at full power for a few minutes to achieve the working temperature, then the setting was reduced to level 3 and immediately back to level 4 to reset the 15-minute countdown timer.

The front panel 'door' was screwed into place and the temperature probe connected to a calibrated Digitron 2046T was inserted. (fig.1)

[fig.1]

Results

For the worst-case scenario of a completely sealed cupboard with no ventilation, the following temperatures were recorded.

Measured Parameter	Temp
Temp ambient	27℃
T0	27℃
T5	42.7℃
T10	50℃
T15	53.4℃
Tmax (@ 18 mins)	57℃

It was recognized that the above test would determine the maximum possible achievable temperature, the results were obtained by creating a scenario that could not be achieved in a physical installation as all possible means of ventilation were removed.

To facilitate a test that gives a true representation of the conditions that the radiant warmer will operate under, the following modifications were made to the cupboard to allow non-mechanical ventilation as would be found in the final installation:

- A Viamed resuscitation cabinet was installed in the cupboard below the radiant warmer as would be present in the final installation.
- A 7mm gap was allowed below the cupboard door.
- A 2mm gap was allowed at the centre of the door to recreate a central hinge.
- 65mm diameter holes were drilled each side of the cupboard, top and bottom.

Under these conditions, the following temperatures were observed:

Measured Parameter	Temp
Temp ambient (start)	21℃
Temp ambient (finish)	27℃
T0	22℃
T5	32.5℃
T10	41.5℃
T15	45.4℃
Tmax (@ 18 mins)	48℃

It was observed that the top surface of the cabinet, upon removal of the doors following completion of the test, was still hot to the touch; the sides, front and handles were all cool.

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Conclusions

In the absence of specific building regulations specifying maximum allowable temperatures within enclosed spaces of this nature, Viamed would recommend following the guidelines that refer to the safety requirements of radiant warmers with regards to patient safety.

With reference to the ***British Standard document EN 60601-2-21:1994 Medical Electrical Equipment Part 2. Particular requirements for safety – Specification for infant radiant warmers***

section 42.3

The temperature of surfaces accessible to an infant PATIENT on the mattress shall not exceed 40 °C for metal surfaces and 42 °C for other materials when the EQUIPMENT is operating under a STEADY TEMPERATURE CONDITION at its maximum CONTROL TEMPERATURE.

Under conditions of warm-up to STEADY TEMPERATURE CONDITION or that of a SINGLE FAULT CONDITION these surfaces shall not exceed 42 °C for metal or 45 °C for other materials.

The term SINGLE FAULT CONDITION is defined as:

aa) failure of a SKIN TEMPERATURE SENSOR;
bb) disconnection of the SKIN TEMPERATURE SENSOR from the EQUIPMENT;
cc) failure of the heater control circuit.

None of the above conditions apply directly to the scenario of enclosing an active radiant warmer into the cupboard, but should that scenario occur and a patient is subsequently introduced to the equipment, the patient may be exposed to the same hazards posed by the listed fault conditions.

As such, Viamed suggest that the temperature of any part of the metal cabinet accessible to the patient should not be allowed to exceed 42 °C. These parts would include the side restraint bars on the door and the parts of the cabinet to the sides that may be within reach, but not necessarily the outer top panel.

Recommendations for further action

Viamed would recommend that a surface temperature test be performed to determine the temperature of surfaces accessible to a neonatal patient.

A final caveat: Viamed have analysed the results from the position of adherence to European guidelines with regards to patient safety. Viamed are not versed in construction techniques, building regulations or the hazards posed by the exposure of construction materials to various temperatures; should doubts remain as to the safety of the proposed installation, further advice should be sought from an appropriately qualified source.