Investigation into Ceratherm Radiant Warmer Failure

Customer: North Middlesex University Hospital (a/c 00003070)
Instrument p/n: 0310302 – Ceratherm 600-3 wall-mounted radiant warmer
Serial Number: 304-3-0813
Date supplied: 05/09/13

Initial incident reported by Kamal Pacitti, Medical Equipment Management Services / EBME Department, 19/1/15

Reported failure: the head unit of a Ceratherm 600-3 radiant warmer is hanging down at an angle and the plastic casing on the head unit is showing signs of burn marks. The following images were sent to Viamed to illustrate the issue.

Fig. 1

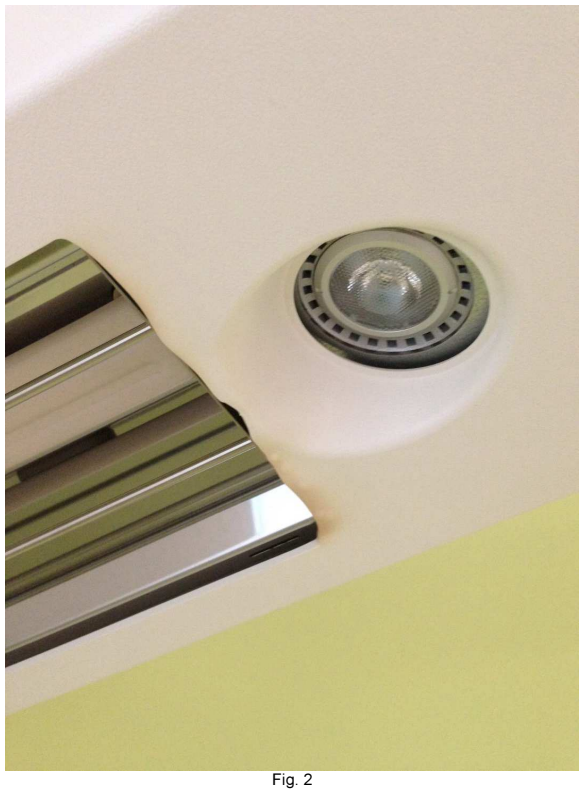
Fig. 2

Immediate Actions

Viamed advised NMUH that the radiant warmer be immediately taken out of service if it has not been already, whilst Viamed investigate in more detail and assess the risk.

Viamed will start an internal technical assessment using an identical device in order to determine the possible modes of failure and to assess potential risk.

Concerning the mechanical failure of the mounting arm

Fig.3 and fig.4 below show the workings of the arm mechanism and can be used to illustrate the failure that has occurred.

Firstly, it is important to note that the radiant warmer was in no immediate danger of falling off the arm: the mechanical failure is attributed to a mechanism designed to lock a rotating hinge into the right-angled position; the strength of that rotating hinge was not compromised.

In fig.1, it can be seen that a plastic hinge cover that is normally flat to the arm has risen in the region of 20-30 degrees. This cover serves a cosmetic function only and is secured in place by a small plastic tab, as can be seen in fig.3 below (the tab is located above the letter C in this image).

Fig. 3

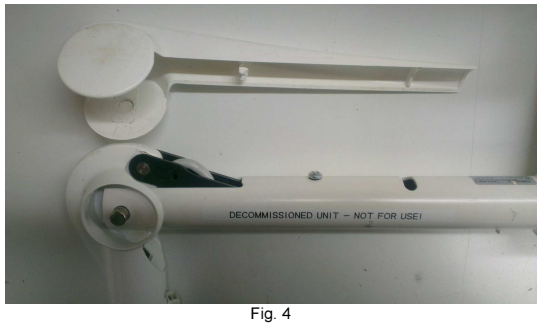

Fig. 4

The hinge cover can be completely removed, as shown in fig.4, by pulling apart the circular sections of the cover. This reveals a sturdy hinge mechanism, which is designed to rotate in other intended applications for this mounting arm, hence there is no risk of the head unit detaching through having rotated to this angle.

Fig.3 and fig.4 also show a Philips-head screw towards the middle of the mounting arm on the top: this screw is designed to lock the final section of the mounting arm into the vertical position at right angles to the horizontal section.

The locking screw passes through a non-threaded hole in the top of the mounting arm and screws into a plastic cylinder (fig.5) via a self-tapping method (fig.6). Removal of this screw allows the plastic cylinder to travel along the inside of the tubular mounting arm, providing some resistance and allowing the hinge to rotate.

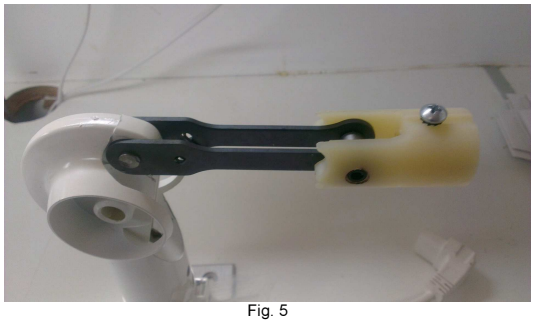
Fig. 5

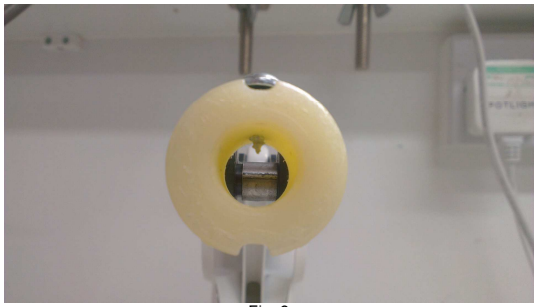
Fig. 6

Further investigation into the customer's device is required, however, it is apparent that the securing mechanism has failed in some way.

Viamed recommends that the arm section be returned to Viamed for a more detailed investigation, although a preliminary examination by on-site engineers may be able to determine the cause of failure and whether it might be possible to re-secure the mechanism without further parts: for example if the screw has simply come loose or has been unscrewed.

If the securing mechanism has suffered a failure involving physical damage to the component parts, for example if the screw head has sheared off or if the plastic cylinder has become damaged or deformed, then Viamed would recommend the return of the mounting arm for repair.

Analysis of the securing mechanism components may provide some indication of the cause of the failure: if the securing screw has been sheared off or pulled out of the plastic cylinder with sufficient force to damage the plastic cylinder, this would indicate that excessive load was applied.

This model of mounting arm was designed and tested to safely support a load of up to 130N at full extension, which equates to a device of up to approximately 13Kg in weight. The radiant warmer head unit weighs less than 5Kg. Under normal operating conditions, and in the absence of misuse or wilful damage, this type of mechanical failure is both completely unexpected and unprecedented.

To qualify the preceding statement: Viamed has supplied over 500 radiant warmers that utilise this mounting arm over a period in excess of 15 years and this is the only reported mechanical failure of this nature.

Based on the known strength and integrity of the mounting arm in question, and pending further evidence, Viamed is initially surmising that the radiant warmer head unit was subject to considerable downward force, which is outside of its intended use.

It would be beneficial if the department in which the device is installed could clarify the circumstances leading up to the failure and whether a Staff member observed the failure occur. If the department has filed an incident report, Viamed would like to request a copy of this, or at least a summary of the pertinent facts, so as to assist in the documenting of the investigation.

Concerning the scorch marks on the radiant warmer casing

The scorch marks and deformation of the head unit's plastic casing is only evident at the end of the casing that was left in a raised position following the mechanical failure.

During normal operation in a horizontal place, the casing will not suffer from heat damage, regardless of the length of time for which the device is operated. Viamed surmises that the action of operating the radiant warmer on an inclined place has created an upward convection of hot air towards the raised end of the warmer, subjecting the casing at that end to excessive heat. This is outside the normal operating parameters of the device.

In line with European regulations governing medical radiant warmers, this radiant warmer has a safety function that causes the device to alarm after 15 minutes in operation, and if the alarm is not silenced manually, to enter into a safety-power mode that reduces the power output to 20% of maximum.

In the worst-case normal operating scenario, the maximum amount of exposure to convected heat would be full power for 15 minutes, followed by 20% power indefinitely, unless a user continued to operate the device following the mechanical failure.

Pending further testing to replicate the angle, Viamed is not yet able to determine whether the damage evident could occur under these conditions or whether the device may have been operated following the mechanical failure of the arm. Testimony from Staff that used this device may help to clarify the conditions under which the scorching occurred.

Recommended actions by NMUH Medical Equipment Management Services

1) Immediate inspection of the arm and securing mechanism to determine whether the mounting arm requires return to Viamed.

Note: the head unit can be removed from the mounting arm prior to removing the arm from the wall following the instructions in the Operator's Manual to disengage the securing mechanism that connects the head unit to the mounting arm. The mounting arm can be removed from the wall bearing by lifting vertically.

2) Function and safety testing of the radiant warmer head unit to ascertain whether the device is operating within specification: if it is not, then it should be returned to Viamed for investigation. If the device is operating within specification, the damaged casing can be repaired in-house using the following replacement part available from Viamed:

P/n 0330001 – Ceratherm 600-3 casing @ £98.00+VAT

3) Obtain further evidence as to the circumstances surrounding the failure, for example, user testimony and an incident report if one has been lodged, and to provide this to Viamed to assist in the investigation.

Inspection of the returned mounting arm

The mounting arm was returned to Viamed for inspection. The following images illustrate that the plastic cylinder inside the securing mechanism has broken into 3 separate pieces (fig.7).

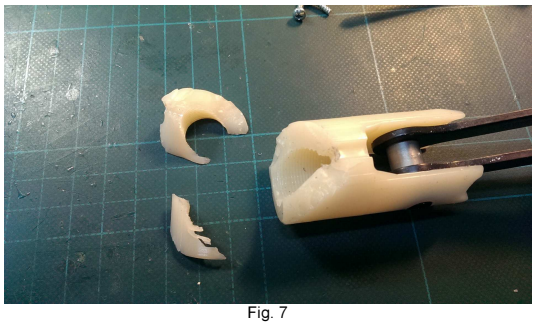

Fig. 7

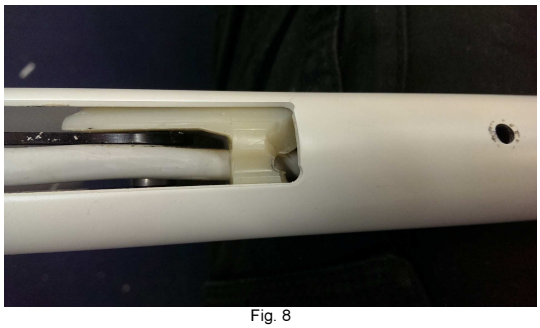

Fig. 8

It is apparent from inspecting the arm that the retaining screw was in place originally, as can be seen from the compression marks around the hole that the screw passes through, which are created by the lock washer (fig.8).

The plastic cylinder has broken away at the point where the screw enters it and appears to have been caused by a lateral force in a direction that is consistent with the effect of pulling the head unit downwards from the front.

Based on the evidence of this inspection, it is Viamed's conclusion that the radiant warmer head unit was subject to considerable downward force, exerting a loading in excess of the design specification, which resulted in mechanical failure.

The radiant warmer has clear warning labels advising that a distance of at least 80cm must be maintained from the surface that the patient is placed on, to the underside of the head unit; the arm is not intended to be height-adjustable.

Viamed concludes that the failure of the mounting arm was caused by either misuse or accidental damage and is not representative of an in-service failure that could affect other systems under normal operating conditions. As such, beyond the repair of the mounting arm and documenting of this incident, no further action is deemed necessary.

A quotation will be provided to North Middlesex University Hospital for the repair of the arm with a request for permission to proceed.