

MDA ref 2000220724.030-9

Ceratherm overhead warmer.

Manufactured by Nufer Switzerland.

This product has a CE mark class IIb

The report is relevant in part to other equipment incorporating this heater module.

The only reports, verbal or written have originated in the UK

Approximately 1000 have been sold over the last two years.

There have been no abnormalities in the manufacture and all the points raised refer to design

The is relevant to a CE-marked device but there have been no incidents leading to death or a deterioration in health. In fact there have been no adverse comments from the clinical environment.

In order to clarify the situation I am dealing with each point raised separately.

1. The heating element

- a. This is a 600watt heating element whose sole purpose is to generate heat to warm the patient.
- b. If a grill was to be placed in front of the element this would rise in temperature and be too near to the operators head. In many cases the operator has to bend over the patient and temporarily is between the element and the heater.
- c. The top surface of the heater container is metal and ventilated. It will become hot.
- d. The Ceratherm 600 unit has been tested to ISO 60601-2-21 by TUV and a copy of the certificate is enclosed
- e. Operator and service manuals both draw attention to the fact that the reflector and grating get hot and there is a danger of fire and burns.

Fig 1 Reference to manuals

- f. Warning stickers are placed on both sides of the heater unit

Fig 2. Photograph of sticker

2. The heater assembly

- a. This is centrally fixed by one large allen screw to enable it to rotate. The top plate is pegged such that it cannot rotate and is isolated from the top surface by a spring washer. The only two physically rotating surfaces are the inside surface arm joint to the pin of the bracket. There is no twisting force being applied to the bolt top or the threads. The threads are long enough (     mm) so that it is very unlikely to shear and impossible to unscrew totally with the operators having adequate advance warning.

Fig 3 Photograph of bolt and ruler

Fig 4. Photograph of assembly dismantled & Fig 5. assembled

- b. There are two extra features that can be added.
  - i. The screw can be loctited in
  - ii. The top surface can be drilled and pinned.
  - iii. This will be offered to all users
- 3. The Heater stand
  - a. The heater can be raised or lowered by 25cms by loosening one large knob.
  - b. At present there is no damping, as we perceive no risk.

fig 6 Highest     &     Fig 7 Lowest with ruler

- c. The knob has to be loosened most of the way without holding the heater for the heater to fall the 25cms.
- d. There are handrails on either side of the heater unit.

Fig 8 Photograph of hand rails

- e. Warning symbols will be placed next to the knob.
  - f. The only risk is to an operator who
    - i. Stands beneath the heater whilst unscrewing it
    - ii. Tries to adjust the height with the heater on or recently switched off.  
This could conceivably cause damage if the operator was not holding the rails and for some reason not being aware of the 25cm limit tried to stop the falling enclosure by using a hand on the element side.
    - iii. These two hazards mentioned in the user instructions or will be added
    - iv. A damping mechanism is available and can be offered although a large number of similar products without damping have been in use in the UK market for over 30 years..
4. Mains Plug.
- a. Due to confusion over hospital protocols for accepting equipment i.e some demand no plug to be fitted whilst others require a moulded plug the manufacturer has no way of knowing in advance what to supply.
  - b. This problem has been addressed in the UK
5. The routing of the mains lead has not been a problem however it is possible that through carelessness it could become trapped. This has now been addressed and p clips will be added to all existing models.

Fig 9 cable route

Fig 10 solution

6. The poor labels have been addressed as the main source of the problem was a batch with poor adhesive properties.
7. One further complaint has been raised concerning the black knob on the arm pivot. Whilst pushing the stand across an uneven car park surface the thread came loose and the knob jumped off. Usually these knobs are fitted so tight that they cannot be removed. However in future the thread will be loctited.

Fig 11 Photograph of black knob

Encl. Ceratherm 600 leaflet  
TUV certificate  
Nufer CE registration