25th May 2001

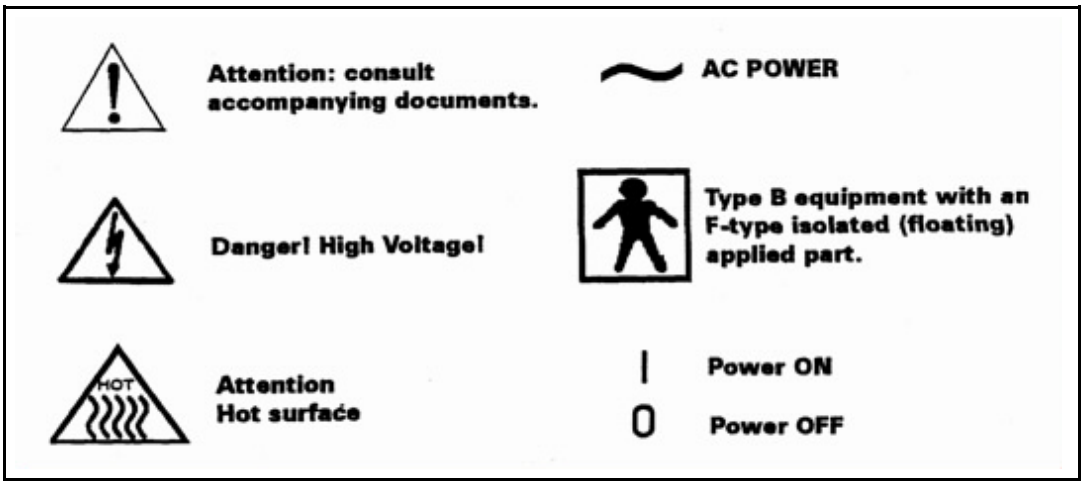
Issues that require attention regarding Nufer Ceratherm Radiant Warmers.

A customer has raised the following concerns regarding the radiant warmers.

Type Marking

i) The manual is misleading: Section 2 "Definitions and Symbols" contains symbols used on the warmer itself.

The type symbol used is that of type BF.



Section 3 "General" contains specifications which appear to describe the type as type B

.

Current requirement	220-240 V AC 50/60 Hz 630W
Protection class	I
Degreee of protection	B IP 20
Test provision	IEC 601-2 TUV / CE
Size	Width 21cm Length 55cm Height 90cm
Weight	4,9kg heat radiator
Trolley	Width 61cm Lenght 82cm Height 10cm
Upright tube	170 / 195 max. Height
Height adjustment	25cm
Swivelarm	45°

Action Required:
Needs a definitive answer as to the correct type. The manual needs to be amended.

ii) There is no type mark label on the warmer itself. Customer insists that it should have some external marking to display the classification type of the warmer.

Action Required:
Need a definitive answer as to whether an external label is required for whichever type of appliance this is determined to be.

If a label is required then Nufer need to be informed so as to ensure the labels are applied before we receive the heaters, it should not be Viamed's responsibility to alter the product if it does not comply to CE regulations.

Internal markings

iii) The customer insists that the warmer contravenes regulations by not having a protective earth symbol at an appropriate point internally.

Action required:
Need to determine whether a protective earth symbol is required, and if so inform Nufer so that the correct symbol can be applied during manufacture.

Risk of explosion

iv) Section 1 "Precautions" states the following:

> The heat radiator must not be used in rooms where there is a risk of explosion, i.e. in the immediate vicinity of anaestheticgases.

However, section 4.4 "setting the heating power" states the following:

> Level 4 is for increased heat requirement in the operating theatre, during anaesthesia or for adults

And section 5.1 "Structure and use" states:

> The mobile radiator is used for warming baby changing tables and resuscitation stations and for additional heat supply in incubators and for adults in the operating theatre and during anaesthesia.

Action required:
Need a definitive answer as to whether the unit is for use in theatres and the manual needs amending to reflect this.

v) If it is decided that the warmer is for use in theatres then the issue of anti-static wheels for the mobile stand needs to be addressed, the manual makes no indication of the wheels complying with the anti-static regulations for theatre devices and they do not appear to be anti-static due to the style of wheel used and the lack of markings on the wheels themselves.

Alarm Condition

vi) Section 4.4 “Setting the heating power” states that when the alarm is not cancelled the power output will drop and “the audible alarm signal stops and the flashing red LED lights continuously”. This is misleading as it does not light continuously, it continues flashing.

> The alarm is cancelled with the red button, causing the red LED to extinguish and the audible signal to stop. The alarm flashing generator is deactivated. If the alarm is not cancelled within 8 seconds, the heating output set is reduced to a preset value (20%) (safety setting). The audible signal stops and the flashing red LED lights continuously.

Action required:
This may be a case of different possible interpretations but it needs clarification and the text rewording.

vii) When in alarm condition the previous power setting light still remains lit, this can lead the user into thinking the warmer is still operating at this power setting rather than have dropped into its safe state of 20% power. The way to determine the true power output of the warmer is by a small flashing LED which shows the duty cycle of the heating element; when on full power it is lit almost constantly with only an intermittent blink, when on the safety setting it is on for only one fifth of the time. No mention is made of the operation of this LED in the manual except for a mention of its existence in section 4.5 “Controllers, displays and connections”.

10	LED heating monitor	Display indicating that heating active

Action required:
It may not be necessary but a reference to this LED showing the actual duty cycle of the element would allow the operator to see that the power is in fact only at 20% rather than at any higher setting whilst in alarm condition and help clarify the issue.

Thread lock

viii) An incident in which the movement of a heater on a mobile stand across a non-smooth surface for some distance caused the shaking loose of the spring loaded retaining pin on the upper horizontal section of the free standing mounting has brought up the issue of whether thread lock would be recommended to secure it.

Action required:
A decision needs to be made on whether thread lock is required or whether it is unnecessary under normal circumstances and this incident was a case of mishandling by the user. Should thread lock be deemed necessary then any relevant documentation needs to be obtained by ourselves to ensure it will not cause any hazard when used with the warmer.

Progress is required on the 8 issues detailed above and a follow up report required to show all points have been dealt with satisfactorily.

Steve Hardaker

6th June 01.

Issues that require attention regarding Nufer Ceratherm Radiant Warmers.

All customer complaints investigated, cross referenced to EN 60601-1 and queries raised with Nufer Medical as detailed below in the content of fax sent today :-

"We have recently supplied a large order of Nufer products to a UK based customer.

During the customers goods-in checks, they have raised a number of issues regarding the Ceratherm 600-2 heat radiator and the mobile stand where they believe the products contravene CE marking legislation and also errors in the operators /servicing manuals.

They have raised a formal complaint against us regarding the issues below :-

1. Equipment type ?

   Within the manual, Section 2 "Definitions & Symbols" shows a Type BF symbol whereas in Section 3 "General" the says the equipment is type B.

   We believe the equipment is type B - can you please confirm ?

2. External type label on the heater case ?

   The heater is not externally marked with it's respective type symbol.

   EN 60601-1 states that "equipment should be externally marked with the respective symbol for type B, BF or CF".

   Could you please comment ?

3. Internal marking of Earth terminations ?

   EN60601-1 para 6.2 (f & g) state that functional and protective earths shall be marked with the prescribed symbols.

   From the mains inlet socket, there are two earth leads terminating at the reflector and chassis.

   Could you please comment as to whether the two terminations are functional earth and the respective lack of markings ?

4. Risk of explosion in presence of anaesthetic gases ?

   Section 1 says "The heat radiator must not be used in rooms where there is a risk of explosion, i.e. in the immediate vicinity of anaesthetic gases".

Section 4.5 says “Level 4 - for increased heat requirement in the operating theatre, during anaesthesia or for adults”.

Section 5.1 says “The mobile radiator is used for warming baby changing tables and resuscitation stations, for additional heat supply in incubators and for adults in operating theatre and during anaesthesia”.

We suspect that since the heater has a detachable mains cord that it will adhere to EN60601-1 para 39.1(c) being not for use in the presence of explosive anaesthetic gases or mixtures.

Could you please clarify and if for use in the presence of explosive anaesthetic gases or mixtures, could you please forward details of testing or justification?

5. Use of the heater in theatre ?

   As above, section 5.1 says for use in operating theatres’.

   Does the mobile stand have anti-static castors fitted as standard ?

   Could you please comment ?

6. Alarm conditions and cancellation ?

   Section 4.4 says that when the alarm condition is not cancelled, that the “audible signal stops and the flashing LED lights continuously”.

   In testing we have found that after a non cancelled alarm condition, the flashing red alarm indicator continues to flash, i.e. there is no change.

   Could you please comment ?

7. Further clarification of the LED heating monitor ?

   As I understand, the LED heating monitor is lit when the element is being heated and not lit when the element is not being heated.

   No mention is made of the operation of this indicator in the manuals except for a mention of its existence in Section 4.5 “Controllers, displays and connections”.

   Could you please comment as to whether a paragraph could be inserted into both manuals to expand on the purpose of the LED heating monitor and the direct link between the heater output and it’s behaviour ?

In reading the manuals through thoroughly, I have found several ambiguous statements with unclear meaning. I have taken the liberty of rewriting the manuals in such a way that I personally feel is clear and would be difficult to misinterpret. I have provided copies of these documents by e-mail today (6-6-01).

Also, I am unclear myself on the purpose of "programming the alarm activation". What is the purpose of this function - in changing it's value and retesting the heater I have been unable to find a change in the operation of the heater or it's behaviour in alarm condition?

Our customer is very unhappy with the above points to the extent that he is insistent that Viamed log his complaint, follow up all the issues raised and provide a written report of findings and rectification action carried out. If this is not completed within a reasonable time scale, the entire order will be rejected.

Speaking on behalf of Viamed, we would very much appreciate a speedy response to the points raised above so we may issue a statement to our customer."

7th June 01.

Telephone call from Nufer Medical stating that they will be looking into the points raised, however they require some time to liase with their manufacturer and to formulate a response.

14th June 01. Repeat fax sent for response.

20th June 01.

Telephone call from Nufer medical, verbally confirming the following :-

1. Equipment type ?

   Agreed that the equipment is Class 1, Type B.

2. External type label on the heater case ?

   The heater should be externally marked with it's classification type - this is to be done at manufacture.

3. Internal marking of Earth terminations ?

   The heater should be internally marked with stickers for functional earth- this is to be done at manufacture.

4. Risk of explosion ?

   Not for use in the presence of explosive anaesthetic gases or mixtures.

5. Use of the heater in theatre ?

   The heater has standard castors fitted unless specified in the order. These have grey coloured tyres. Anti-static wheels can be supplied when specified in the order. Anti-static castors have black tyres.

6. Alarm conditions and cancellation ? *

   Was not aware that the functioning of the alarm cancellation had been changed - will look into this.

7. Further clarification of the LED heating monitor ? *

   Appreciated that the manual may require further clarification and suggested that a new paragraph be added.

* Agreed to send new copies of Operators / Servicing manuals including amendments for (6) & (7). Sent today.

21st June 01.

Emailed Nufer attaching copies of Ceratherm 600-2 operators & servicing manuals for proof reading.

22nd June 01.

Received faxes from Nufer Medical as attached.

Further action req'd :