
VIAMED Customer Complaints - VIAMED Customer Complaints

CCN149 Ceratherm 600-3 Serial No. 516-3-0514

Issue ID #92677

Date Created 11/Apr/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Notes:

Added by Steve Nixon sent to Derek Lamb

Nufer emailed the following to us:

Hello Steve,

I hope you are all right?

Please see below a customer complaint for you. I suggest that you take contact with this customer shortly!

We need the defective unit back for investigation. I will organize an exchange unit for you (FOC, Incoterms Ex Works), which should be sent next week (because of Easter), if this is ok for you?

Please give me a short feedback.

Kindest regards

Jonas Boss

Leiter Technik & Logistik
Beratung und Verkauf Fluke Biomedical Schweiz

Head of Technical Division & Logistics
Consulting and Sales Fluke Biomedical Switzerland

Nufer Medical AG
Morgenstrasse 148
CH-3018 Bern

Phone +41 (0)31 958 66 66

Fax +41 (0)31 951 46 73

j.boss@nufer-medical.ch

www.nufer-medical.ch

Betreff: Fault with Ceratherm 600-3 radiant heater

Anrede: Herr

Name: Paul Kemp

E-Mailadresse: paul.kemp@nnuh.nhs.uk

Organisation: Norfolk and Norwich University Trust Hospital

Funktion: Hospital NHS

Strasse: Colney Lane Norwich

Postleitzahl: NR4 7UY

Ort: Norwich Norfolk

Telefon: (44) 01603 286555

Nachricht:

dear sir,

we have a ceratherm 600-3 (Serial No. 516-3-0514) where the heater connector mounted on the pcb has failed and burnt both the connector and pcb. I would not have expected this to happen on a three year old device. Is this a known fault? would you be prepared to send me a new board FOC?

Paul Kemp
Clinical Engineering Dept.

12 Apr 2017 Derek Lamb

Subject Changed From Ceratherm 600-3 Serial No. 516-3-0514
Subject Changed To CCN149 Ceratherm 600-3 Serial No. 516-3-0514

12 Apr 2017 Derek Lamb
Barcode :762777
Stock Reference :0310304
Description: Radiant Warmer - Free Standing
Serialnumber: 516-3-0514
Barcode: 76277
Sold Invoice : IN133075
Invoice Date: 19 June 2014

Date Received Viamed17/06/14
Purchase Order: POR09703

12 Apr 2017 Derek Lamb
Opened Paper Customer Complaints file

13 Apr 2017 Steve Nixon
Upon initial review from images supplied and the product design, there doesn't appear to be any direct patient risk.

- 1) The warmers are supplementary, so if they fail they are not critical for life support. Infants that require life support would be in NICU.
- 2) The warmers are isolated from the patient and the design and warnings ensure that there is clearance from patients and surfaces. If there is a reoccurrence, the likelihood is that staff will smell burning and/or the unit will stop functioning.

13 Apr 2017 Steve Nixon
Should the problem be due to a design issue, the likelihood is that just the Ceratherm 600-3 models are affected. We have a long history of the Ceratherm 600-2 and to date have not had this kind of problem.

First of all, ourselves and Nufer need to inspect and review the units. If the fault is due to design, then corrective action can be taken and we can quickly identify and advise customers of a course of action.

The warmers have been sold as part of resuscitation cabinet systems and as standalone units. The range of individual parts numbers are:

0310300, 0310301, 0310302, 0310303, 0310304, 0310305

13 Apr 2017 Steve Nixon
Should the problem be due to a design issue, the likelihood is that just the Ceratherm 600-3 models are affected. We have a long history of the Ceratherm 600-2 and to date have not had this kind of problem.

First of all, ourselves and Nufer need to inspect and review the units. If the fault is due to design, then corrective action can be taken and we can quickly identify and advise customers of a course of action.

The warmers have been sold as part of resuscitation cabinet systems and as standalone units. The range of individual parts numbers are:

0310300, 0310301, 0310302, 0310303, 0310304, 0310305

20 Apr 2017 Steve Nixon
email sent to Nufer 13th April

Hi Jonas

Regarding the reported problem with the Ceratherm 600-3, as you are probably aware the customer has another unit with the same problem.

May I ask you, is this the first occasion that you have been made aware of such a problem, or have you had the same problem from other customers?

If you are already aware of the problem and assuming it is a design issue, are you working on a solution?

--
Steve

Steve Nixon
Director - Viamed Ltd.

20 Apr 2017 Steve Nixon
email received from Nufer 15th April

Dear Steve

We had the same problem with a device in the Netherlands. But we could not clear the cause exactly. The terminals are designed for a current of 10A (2.5 times safety).

However, we chose another brand as a preventive measure. All devices from the production of the last 2 years have been equipped with the new product.

But more than 1500 units are equipped with the first brand and have been in use without any problem for several years.

Important: There is no risk at all to the patient or the user! If the heating fails, a technical alarm is issued.

Kind regards

Daniel Urfer

Managing Director

20 Apr 2017 Steve Nixon
email sent to Nufer

Hi Daniel

Sorry to trouble you again, but can you please let me know the serial number and date of when you started to use the revised component. This way we can monitor units in the field and carry out service inspections.

Can we assume that all Ceratherm 600-3 units prior to this had the version that may be problematic?

Regards

Steve

20 Apr 2017 Steve Nixon
It looks like two Ceratherm units have been returned to us from the customer. We don't appear to have received any replacement units yet from Nufer.

21 Apr 2017 Steve Nixon
email from Nufer

Dear Steve

There was unfortunately a mistake in my mail. The new terminal has been installed for 1 year (not 2). Before that, we never had any feedback about defective terminals.

All Ceratherm 600-3 until serial number 1085 3 0516 are equipped with the first terminal brand. From serial number

1086 3 0516 the new version was installed.

I hope this information will help you.

Kind regards

Daniel Urfer

21 Apr 2017 Steve Nixon

Not sure how Daniel has determined over 1500 units have the affected part.

Can you pull out the serial number bar code movement history for units:

Up to and including S/N 1085 3 0516

From S/N 1086 3 0516 (fitted with improved part)

Looks like the change over was May 2016

02 May 2017 Steve Nixon

email to Nufer 25th April:

Hi Daniel

Just a quick update for you. We are in receipt of the two reported faulty units from the hospital and have sent them back to you for assessment

We have also received the two replacement units from Nufer, thank you. Are these permanent replacements in exchange for the hospital's units or are they temporary loan units?

Also, is it possible to have a data sheet for the original connector block and also for the replacement one? I just want to be prepared in case we get any enquiries from the MHRA, it is better to be prepared in advance. If the original part was over rated then it should not have failed, do you have any comments from the manufacturer of the part?

Regards

Steve

02 May 2017 Steve Nixon

email from Nufer 1st May

Dear Steve

Please find the data sheets for both version of the heating element connecting terminal.

The heating element has an electrical power of 600W (max. current less than 3A).

Concerning the replaced units:

These are permanent replacements in exchange for the hospital's units.

I hope to help you with this information.

Kind regards

Daniel

02 May 2017 Steve Nixon

See attached datasheets for the previous and current PCB terminal.

01 Aug 2017 Steve Hardaker

In addition - a second customer, Furness General Hospital has reported that they have a unit where the connector to the element has blown. This makes 3 so far in the UK.

The engineer was testing it and says the device was fine on power levels 1-3 but blew as soon as he turned in to 4, this looks like a connector malfunction under the higher current draw.

Serial Number 69-3-0612, sold 29/6/12, IN121972, a/c 2471, Furness General.
