April 1990

NHS PROCUREMENT DIRECTORATE

evaluation

NUMBER 8

INFANT RADIANT WARMER

Viamed Thermacot TC400 Mk1

BRIEF DESCRIPTION

The Viamed Thermacot TC400 Mk1 non-servo controlled infant radiant warmer comprises: a mobile base frame which supports a tiltable gantry, into which a clear plastic bassinette is mounted; and an overhead infrared radiant heater, complete with controls. Below the cot a perspex shelf is mounted on the vertical columns of the H shaped base frame. The unit is mounted on castors, the front two of which are fitted with foot operated brakes.

MAIN FEATURES

power supply
240 V 50 Hz

heater control
0% to 100% power, continuously variable

bassinet tilting mechanism
Yes, 0° to 15°

SUMMARY

Advantages: easy to use, clean and service.

Disadvantages: heater module, close to head height, did not fully comply with BS 5724: Part 1. (See Manufacturer's Comments.)

Overall: an easy to use, basic unit which was given a good performance rating.

Price
£850

Weight
25 kg

Size H x W x D
1700 x 470 x 990 mm

Made in
U.K.

Product certificated? No

DH Registered Manufacturer? No

Note: Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register of manufacturers to check current status

Manufacturer
Viamed Ltd
Cross Hills, Keighley
Yorkshire, BD20 7DT

Free to the NHS £5

Viamed Thermacot TC400 Mk 1

DESCRIPTION

The Viamed Thermacot TC400 is a non-servo-controlled infant radiant warmer which incorporates a cot with an overhead infra-red radiant heater and control unit.

The heater assembly and perspex cot are fixed in relation to each other and are mounted on a light-weight stand. The stand has four castors, two of which have foot actuated brakes.

User facilities

Access: the mattress rests in the open cot. The cot and heater assembly can be set foot down, to a maximum angle of 15° using a continuously variable tilt mechanism.

Storage and shelving: a large perspex shelf is mounted below the cot.

Heating control

All controls and indicators are positioned on the front of the heater module. The warmer can only be operated in the manual mode. The heater output power is set by a continuously variable rotary control to between 0% and 100% of the maximum heater output power.

Auxiliary power supply

A shuttered IEC 3 A/240 V socket is provided on the rear of the heater assembly. (See Manufacturer's Comment 1.)

USER EVALUATION

The Thermacot TC400 was used for seven months in a post-natal ward. The equipment was used to nurse infants immediately after birth or after surgery within the first 24 hours of life, and their weights ranged from 2 to 3 kg, after which the users were asked to score the facilities and attributes of the warmer on a five point scale. These were aggregated and are depicted in Fig 1, on page 5, as a bar chart. All the staff found the unit easy to use and the controls were accessible and clear. The heating control range was good, allowing both the rapid warming of cold infants and the maintenance of stable temperatures for all infants nursed.

The cot was a good size and the tilt mechanism was effective. Access to the baby was satisfactory, but the proximity of the heater sometimes made it uncomfortable to attend to the infant. (See Manufacturer's Comment 2.) The heater enclosure was at head height and care had to be taken to avoid it, especially when the cot was tilted, as the front of the enclosure projected some three inches over the end of the cot. (See Manufacturer's Comment 3.)

The perspex shelf was useful but staff felt that it would be improved with a lip around the edge to prevent items falling off. (See Manufacturer's Comment 4.)

PRODUCT SUPPORT

supplier	Viamed Ltd 15 Station Road Cross Hills Keighly West Yorkshire BD20 7DT Tel: 0535 34542
guarantee	1 year
maintenance provisions	
service contract	Yes
will service engineer call?	Yes
maximum response time quoted	24 hrs
temporary equipment replacement?	Yes
spare parts	
spares availability	7 years

Viamed Thermacot TC400 Mk 1

RESULTS TABLE

electrical safety	
earth leakage current	PASS
patient leakage current (PASS <1000 µA)	PASS
heater output	
maximum power density	522 Wm^{-2}
temperature control[1,2]	Satisfactory
temperature uniformity[1,2]	Satisfactory
construction	
stability	PASS
mobility[2]	Good
mechanical construction[2]	Satisfactory
serviceability[2]	Good
reliability	
faults on delivery	None
breakdowns in service	None
manuals	
user instructions[2]	Good
servicing information[2]	Good
clinical[2,3]	
controls	Good
temperature control	Good
patient area	Good
medical procedures	Satisfactory
nursing procedures	Satisfactory
overall	Good

Notes
1 Measurec using test device as per BS 5724: Section 2.25
2 Scale used excellent/good/satisfactory/poor/unacceptable
3 Assessments by our users

The cot was very mobile and easy to move around.

Nursing staff found that the warmer was very easy to clean.

TECHNICAL EVALUATION

The results of the technical evaluation of the Thermacot TC400 are given below and are summarized in the Results Table. A full list of deviations is given below under 'Compliance with Standards'.

Safety and performance

The Thermacot TC400 met most of the safety and performance requirements and there were no major safety shortcomings. Detailed test findings are as follows.

Stability: the warmer was mobile and stable in normal use. The wheel locking mechanisms were effective. The original friction locks for the cot tilt mechanism were not effective and allowed the cot to swing down if leant on. The manufacturer improved the mechanism and this was found to be satisfactory. The cot was well supported.

Heating performance: When operated at the maximum heater output control setting, the warmer maintained a stable mid point average temperature. The maximum temperature differential between the central test disc and external discs was 1.9°C.

Reliability: There were no faults on delivery and no breakdowns in use. The unit was reasonably well constructed and operated in a simple fashion, suggesting satisfactory reliability. (See Manufacturer's Comment 5.)

Serviceability and manuals: the manufacturer's handbook was a combined instruction and service manual and was very good. There were clear operating and cleaning instructions. The service section of the manual gave a technical description and a circuit diagram and associated description. Also included was a constructional diagram and a full parts list, together with maintenance instructions. Access to the unit was easy and the components were well laid out so servicing should be easy.

COMPLIANCE WITH STANDARDS

BS 5724: Part 1 is the current British Standard for the safety of medical electrical equipment. The UK Health Deparments recommend that purchasers specify compliance with Part 1.

The manufacturer's handbook stated that the Thermacot TC400 Mk1 was designed to comply with BS 5724: Part 1 but, on the warmer examined at BSI, the following points of non-compliance were found against BS 5724: Part 1. (See Manufacturer's Comments.)

6.1 External symbols missing

6.3 Mains switch and heater control not identified with their function

7.1 Power consumption of unit exceeded rated value when auxillary mains socket in use

42.5 Radiant heater guard exceeded 85°C under normal conditions

57.1 Mains isolating switch did not isolate appliance outlet

57.4 Replacement of the mains cable required a crimping tool

58.1 Special preparation of mains cable required for correct connection

57.6 The appliance outlet was not fused

59 The mains appliance outlet and energy regulator terminal block failed the ball pressure test

Viamed Thermacot TC400 Mk 1

MANUFACTURER'S COMMENTS

The findings of the report were sent to the manufacturer who responded as follows:

"1. The auxiliary power output facility has been removed.

2. The function of the unit is to provide heat to keep the infant warm, therefore, whilst attending to the infant, the nurse will also feel the heat generated by the unit especially if the heater output is set at maximum.

3. The length of the frame has been increased so now there is less chance of the heater enclosure coming into contact with the staff when tilting the cot.

4. In line with the reports recommendation the perspex shelf will be improved to include a lip around the edge to prevent items falling off.

5. The construction of the unit has since been improved.

Clause 6.1 All required external symbols are now present and have been checked by BSI.

Clause 6.3 The mains switch and heater controls are now identified with their function and have been checked by BSI.

Clauses 7.1, 57.1, & 57.6 The auxiliary mains outlet socket has been removed so these points are not now relevant.

Clauses 57.4 & 58.1 Replacement of the mains cable does not now require a crimping tool or any special preparation.

Clause 7.1 The auxiliary mains outlet socket has been removed and the energy regulator now has flying leads as opposed to a terminal block.

Clause 42.5 With reference to BS 5724: Part 1: (1979) clause 42.1 and 42.5, the radiant heater guard did exceed the maximum permitted temperature of 85°C at an ambient temperature of 40°C. The purpose of the Thermacot, however, is to provide radiant heat and this is not correctly taken into account with the present standards. It is assumed that when the BS 5724: Part 2: protocol for non-servo controlled infant radiant warmers is published, that the function of the unit will be taken into account and the appropriate standards will supercede BS 5724: Part 1: (1979) clauses 42.1 and 42.5. The design of the heater enclosure has also beenmodified and it is hoped that with the improved ventilation and heat conduction away from the element guard that the temperature of the element guard will be reduced.

MANUFACTURER'S INFORMATION

Manufacturer/supplier	Viamed
DH manufacturer registration[1]	No
Certificated product	No
country of origin	UK
cost[2]	£850
physical dimensions	
overall size (h x w x d[3])	1700 x 470 x 990 mm
baby cot (d x w)	659 x 340 mm
weight	25 kg
power supply	240 V 50 Hz
bassinet tilting mechanism	Yes, 0° to 15°
temperature control	
maximum heater power	400 W
manual control	Continuously variable, 0% to 100% power

Notes

1 Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register of Manufacturers to check current status.

2 Prices do not include P&P or VAT.

3 Was 890 mm.

PRODUCT SUPPORT: Spare Parts.

With the availability of spare parts and taking into account the simplicity of the unit and the ease of fitting spare parts it should not be necessary to provide temporary replacement equipment. However, to cover all eventualities temporaryequipment replacement if necessary.

SUMMARY: Disadvantages.

The heater module needs to be about head height. If the module was lower it would be more difficult to attend to the infant and if it was higher more heat would have to be generated, so making it more uncomfortable for the nurse to attend to the infant. The heater control is also on the heater module as it needs to be at a height where it can easily and safely adjusted by the majority of nursing staff.

As previously mentioned it is now more difficult for the nursing staff to accidentally come into contact with the front of the heater enclosure when tilting the unit.

Besides correcting problems highlighted in the report we have generally improved the construction of the Theracot TC 400 Mk1 and improved the design so that it is easier to use and transport."

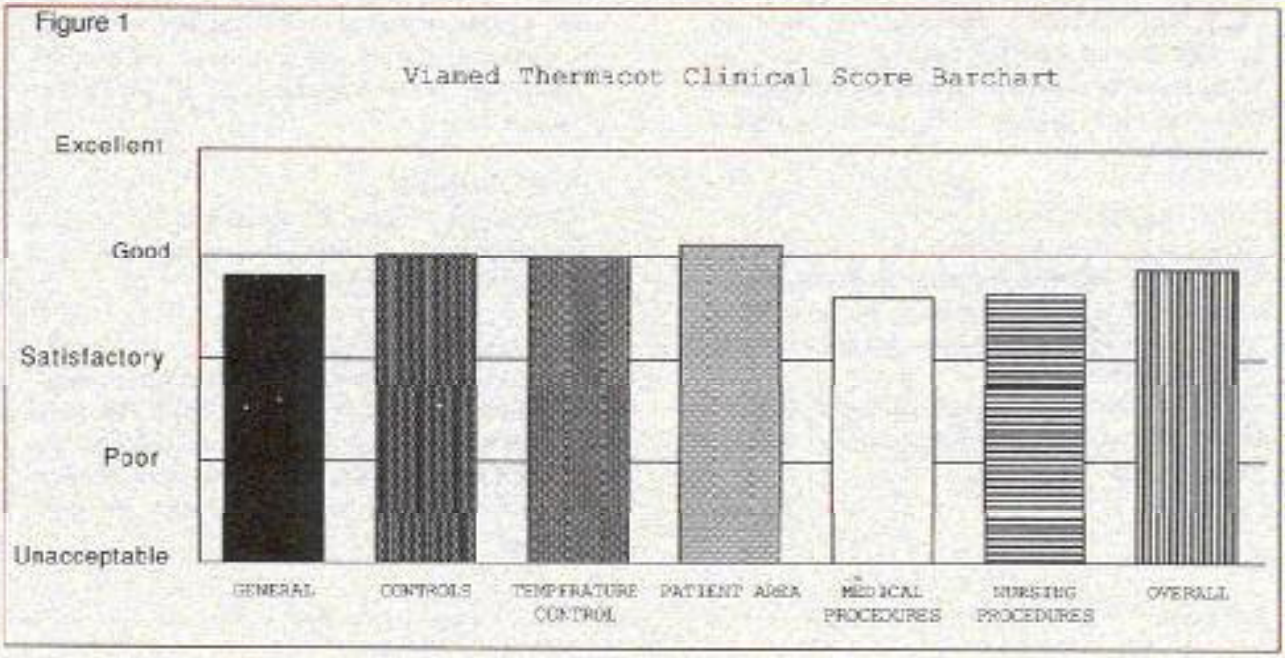
ACKNOWLEDGEMENTS

The DH thanks the following staff from the Bioengineering Unit at Cardiff Royal Infirmary, South Glamorgan Health Authority, who were responsible for the evaluation and preparation of the text.

Dr D G Spendley
Mr R Vine
Mr J McCarthy

We also thank the following Sister for her co-operation in the hospital trials:
Sister J Thomas, East Glamorgan Hospital,
and all the nursing and medical staff of the Post-natal ward who helped in the evaluation.

Figure 1



APPENDIX 1: HOW TO BUY WITH CONFIDENCE

Compliance with standards

BS 5724: Part 1 is officially recognised by the Department of Health[1] (DH): when purchasing equipment preference should be given to products which comply with this standard. (For this product, see the Technical Evaluation and Manufacturer's Comments on pages 4 to 6.)

Manufacturer's Quality Control

The summary table on page 1 shows whether the manufacturer has registered, or applied for registration under the DH Registration Scheme for Manufacturers of this category of medical electrical equipment. The Scheme has been in operation since April 1985. A manufacturer seeking registration for a specific category of medical equipment is required to declare that the quality system used to control the manufacture of that category is in compliance with the requirements of the DH Guide to Good Manufacturing Practice for Medical Equipment (the "Green Guide").

The quality system subsequently becomes subject to inspection by the Supplies Technology Division of the Department's, NHS Procurement Directorate, in order to assess its compliance. [In general, Registration does not imply that all products offered by the manufacturer are from registered manufacturing sources: you should ask the supplier whether the particular product you want is manufactured under the DH Registration Scheme.]

NOTE
1. See HEI 145 Item 18/85.

APPENDIX 2: STANDARDS USED FOR TESTING

TECHNICAL STANDARDS

The technical performance and safety assessment in this issue were carried out at BSI Testing Services at Hemel Hempstead, and by the Bioengineering Unit at Cardiff Royal Infirmary, South Glamorgan Health Authority.

For this evaluation, two samples were assessed: one at BSI, the other at Cardiff. The conclusions are therefore based on the assumption that the samples were typical of normal production.

SAFETY

The Electro-medical Laboratory of BSI Testing Services at Hemel Hempstead tested a unit for compliance with the following current British Standard to assess the technical safety aspects of the equipment:

BS 5724 Part1: 1979 Medical electrical equipment: specification for general safety requirements.

BS 5724 Part 1 is the UK equivalent of the international standard IEC 601-1. A revised edition of IEC 601-1 has been published; a similarly revised BS 5724: Part 1 was published during October 1989.

There is presently no Particular standard for non-servo-controlled infant radiant warmers. However, at Cardiff, we assessed the product against the relevant parts of BS 5724: Part 2: Section 2.25.

PERFORMANCE

Similarly, at Cardiff, we assessed the product against an unpublished protocol based on BS 5724: Part 2: Section 2.24.

THE USER EVALUATIONS

User assessments were carried out in a Hospital within the Ogwr Health Authority (see Acknowledgements). The protocol used for the user trials was devised in co-operation between the evaluators, the nurses involved in the user trials and DH.

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COMING NEXT

Other infant radiant warmers now being evaluated:
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ENQUIRIES

For information on the evaluation of Infant Radiant Warmers, please contact Peter Oddy, Department of Health, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 01 636 6811 ext 3023).

'Evaluation' series editor is Charles Herrington, Department of Health, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 01 636 6811 ext 3053).

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Viamed Thermacot TC400 Mk 1

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DIRECTORATE

14 Russell Square, London, WC1B 5EP
Telex 883669 DHSSHQ G
Fax 01-637 8990
Telephone 01-636 6811 Ext.
3023

Mr S Nixon
Viamed Ltd
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT

COPY

Your reference:

Our reference:

30 April 1990

Dear Mr Nixon,

"EVALUATION NO 8" REPORT

Please find enclosed three copies of our latest single model Evaluation publication, featuring your infant radiant warmer, with our compliments.

Thank you for your co-operation and comments during the period of the evaluation programme.

Yours sincerely,

P A Oddy.

Peter Oddy
Supplies Technology Division