



VIAMED

15, STATION ROAD, CROSS HILLS,
KEIGHLEY, WEST YORKSHIRE,
BD20 7DT

Telephone Cross Hills (0535) 34542
Telex 557061 (Linkup G)

Your ref: SEV/00/05/05/
Our ref: TCOT/2409

8th February '88

Dear Mr Judge.

Please find enclosed the MLQ2 form as requested by G.Arnold.

Yours sincerely

Stephen Nixon.

With Compliments

Please return this form when completed to:

Gordon Judge
Room 616
DHSS Supplies Technology Division
14 Russell Square
LONDON WC1B 5EP

PRODUCT: VIAMED THERMACOT TC400 Mk1

I have arranged for a sample of the above equipment to be supplied by us to the Electromedical Laboratory, BSI Test House, Hemel Hempstead, for assessment of its compliance with BS 5724 Part 1.

The date arranged is

15th March '88

I understand that the work will be charged to DHSS Scientific & Technical Branch and that we shall receive a copy of the BSI Report in due course.

Signed.....

Date.....

7th March '88

Standard Questionnaire for the supply of Electrically Operated Medical Equipment and Hospital or Dental or Ophthalmic Laboratory Equipment.

Product Information: MLQ2

For Health Authority use.

Please refer to guidance notes MLQ3 before completing this form.

Please enter YES, NO or N/A (Not Applicable) in each box except where otherwise indicated.

| | |
|-------------------|-----------------------|
| Supplier | VIAHED |
| Product type | INFANT RADIANT WARMER |
| Model No. | THERMACOT TC 400 MKI |
| Manufacturer | APPLEYARD AND SONS |
| Country of Origin | BRITAIN |

Indicate whether the equipment is medical, dental, ophthalmic, hospital laboratory, dental laboratory or ophthalmic laboratory equipment.

MEDICAL

QUALITY ASSURANCE (Medical, dental & dental laboratory equipment only).

- 1 Is the manufacturer of this product registered with the DHSS as complying with the Guide to Good Manufacturing Practice for Medical Equipment?

NO

If yes, give the registration number

N/A.

EQUIPMENT STANDARDS

Medical and Dental Equipment

- 2

(a) Does the equipment comply with BS 5724 Part 1?

YES
- (b) If the answer to 2(a) is 'NO' indicate in the box that a list of points of variance is attached.

N/A
- (c) Has the relevant section of BS 5724 Part 2 been published? If so put the Part 2 number in the box.

NO
- (d) Does the equipment comply with the Part 2 specified in 2(c)?

N/A
- (e) If the answer to 2(d) is 'NO' indicate in the box that a list of points of variance is attached.

N/A

Hospital and Dental Laboratory Equipment

- 3

(a) Does the equipment comply with the Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE)?

N/A
- (b) If the answer to 3(a) is 'NO' indicate in the box that a list of points of variance is attached.

N/A

All Equipment

- 4

(a) List below any British or International Standards (other than those referred to in 2 and 3) applying particularly to this equipment and indicate in the boxes whether or not the equipment complies.
- (i).....

N/A
- (ii).....

N/A
- (b) List below the Standards indicated by the Health Authority in MLQ1, if different from those listed in 4(a), and indicate in the boxes whether or not the equipment complies.
- (i).....

N/A
- (ii).....

N/A
- (c) If any answer in 4(a) or 4(b) is 'NO' indicate in the box that a list of points of variance is attached.

N/A
- 5

Please provide information on equipment type-testing carried out for any Standards referred to in 2(a), 2(c), 3(a), 4(a) or 4(b).

| Tested by | Standard | Passed Yes/No | Date |
|-----------|----------|------------------|------|
| | | | |
| | | | |
| | | | |

RATINGS, MARKINGS AND DOCUMENTATION

- 6

(a) Is the equipment correctly rated for connection to the UK supply mains?

YES
- (b) Are all written equipment markings, labels and documentation in English?

YES

RADIO FREQUENCY INTERFERENCE

- 7

Does the equipment comply with the requirements of the relevant Standards detailed in the Guidance Notes? If not please give details on a separate sheet..

YES

CLEANING, DISINFECTION AND STERILIZATION

- 8 (a) Are there parts of the equipment which by their nature and function must be cleaned and disinfected or sterilized before use? No
- (b) If the answer to 8(a) is 'YES' please specify the methods of cleaning and sterilization. See Guidance Notes.

Attach a separate sheet if more room is needed

MAINTENANCE

- 9 (a) Is a clear and legible maintenance manual available (including, for example, circuit diagrams and descriptions, component lists, and fault finding procedures)? Yes
- (b) If 'YES' state the cost, if any, of
- (i) the first copy £ FOC
- (ii) additional copies £ FOC
- 10 (a) Indicate in the box that a list of the recommended preventive maintenance tasks, if any, and intervals is attached. Yes
- (b) Are you able to provide on a contractual basis:
- (i) the preventive maintenance specified at (a)? Yes
- (ii) repair? Yes
- (c) Indicate in the box that details (including contract conditions) and current annual cost of such a contract are attached. Yes
- (d) Indicate in the box that details of non-contract maintenance and repair services are attached. Yes
- 11 Are you able to offer a course of maintenance instruction, if appropriate, on the equipment to enable local Health Authority maintenance staff to:
- (i) provide "first-line" maintenance? Yes
- (ii) provide a complete maintenance service? Yes
- 12 (a) Are qualified staff normally available by phone to deal with problems which occur? Yes
- (b) If 'YES', give the appropriate telephone number. 0535-34542

ACCESSORIES, SPARES, REPLACEMENT PARTS AND CONSUMABLES

13 (a) Are there accessories or consumables supplied as sterile for single use?

NO

(b) Is the manufacturer of these products registered with the DHSS as complying with the Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products, 1981?

N/A

If 'YES', give the registration number.

N/A.

14 (a) Is a list of accessories, recommended spares, replacement parts and consumables available, with prices?

YES

TO FOLLOW

(b) Are there lists of recommended spare parts in the maintenance manual?

YES

TO FOLLOW

15 For what period after delivery of the equipment do you undertake to maintain a supply of specialised spare parts?

7 years

16 Will all spares and replacement parts, together with the requisite information, be made readily available for use and fitting by the purchaser

YES

WARRANTY

17 Please attach copies of the warranty for the equipment, showing all relevant terms and conditions.

DECLARATION

Before signing, see Important Notes in the Guidance Notes: Form MLQ3.

I am authorised to sign this declaration. I have made all reasonable enquiries and to the best of my knowledge and belief the information given herein is correct.

Signature

J. S. Lamb

(Not a photo-copy)

Name (please print)

J. S. LAMB

Position in Company

MANAGING DIRECTOR

Date

7th FEBRUARY '88



14 Russell Square, London, WC1B 5EP
Telex 883669 DHSSHQ G
Fax 01-637 8990
Telephone 01-636 6811 Ext. 3040

Mr A Butvenick
Electromedical Laboratory
BSI Test House
Maylands Avenue
HEMEL HEMPSTEAD
HP2 4SQ

Your reference:

Our reference:

TIP/25/0406

Date:

29/2/88

Dear Mr Butvenick

I have arranged for the following supplier to contact you to arrange submission of equipment to your Laboratory for assessment of its compliance with the indicated Parts of BS 5724, as part of the DHSS programme of comparative evaluation of medical equipment:

| | | | |
|----------------|--|-----------------------|--------------|
| BATCH NO: C 11 | EQUIPMENT CATEGORY: INFANT RADIANT WARMERS | | |
| SUPPLIER | CONTACT | EQUIPMENT | BS5724 PARTS |
| VIA MED | Mr John Lamb | THERMACOT TC400 Mk II | Part 1 only |

Would you please make the necessary arrangements with the supplier to place his equipment as early as possible, and in due course let me have monthly reports of progress, especially noting any hold-ups. It would help if you could advise the supplier when he first contacts you of any extra parts you may need, as far as this is possible. I have advised him that you will inform him should equipment breakdown prevent your tests from being completed, and that only repairs (not modifications) will be permitted, and that you may impose a deadline for their completion.

On completion of your work on this model, would you please send me three copies of your Report and return the equipment direct to the supplier. I shall then send him one copy of your Report.

I have agreed that this work may be charged to the Department's account.

Yours sincerely,

Gordon Judge.

Gordon Judge
SUPPLIES TECHNOLOGY DIVISION

copy to Evaluation Centre
copy to Supplier

PD LAEI



RECEIVED
- 1 MAR 1988
TELEPHONE UNIT

14 Russell Square, London, WC1B 5EP
Telex 883669 DHSSHQ G
Fax 01-637 8990
Telephone 01-636 6811 Ext.3040

Mr J. S. Lamb,
Viamed
15 Station Road
Cross Hills
KEIGHLEY
W. Yorks. BD20 7DT

Your reference:

Our reference:

TIP/25/02/06

Date:
29/2/88

Dear Mr. Lamb,

PRODUCT: VIAMED THERMACOT TC400 Mk1

I am writing to record the arrangements agreed during your talk on the phone last week, with Simon Bishop.

You will be arranging with BSI Test House (Mr Alan Butvenick, telephone Hemel Hempstead [0442] 230442) for them to assess the above equipment for compliance with BS 5724 Part 1. (BSI will require certain additional data and samples: these are detailed on the attached sheet).

I enclose a copy of my letter to BSI authorising the work to be charged to DHSS, and indicating that a copy of their eventual Report will be sent to you. BSI will inform you should equipment breakdown prevent their tests from being completed, but please note that only repairs (not modifications) will then be permitted, and that in order to keep to our schedule a deadline for their completion may be imposed.

I would be grateful if you would complete and return the enclosed reply slip, so that I shall know when the work is due to be done.

Thanking you for your co-operation.

Yours sincerely,

Gordon Judge.

Gordon Judge
SUPPLIES TECHNOLOGY DIVISION

- # enc: 1 - reply slip ✓
- 2 - BSI info ✓
- 3 - copy of BSI letter ✓
- # copy to evaluation centre

PS: An order, for a TC400 for our evaluation centre at Cardiff, will follow shortly.

G.J.

PDLAAM

**ASSESSMENT OF COMPLIANCE WITH BS 5724: ADDITIONAL DATA AND
SAMPLES REQUIRED BY BSI**

1. Please note that BSI ask for the following data and samples to be supplied at the same time as the equipment is submitted (these will not be returned):

- # Operator Manual
- # Service Manual
- # Circuit Diagram(s)
- # Components List
- # Mains Transformer - one sample*
- # Mains Switch - one sample*
- # Non-approved Thermostats*

[* with engineering drawings of these components, if available]

2. BSI also offer the following general notes:

Submissions to BS 5724

1. The Operator Manual is treated as part of the equipment unless otherwise directed.
2. All components operating at mains potential, as defined by Clause 56.1, must comply with the relevant IEC or British Standard. Evidence of compliance must be supplied at the time of submission, or alternatively components may be separately submitted for approval to the Head of the Electrical Section of the Test House. Mains transformers are excluded from this requirement. However, one sample must be supplied for test together with the equipment.

LETACL
PDLAAT



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

Mr J Lamb
Vianied Ltd
15 Station Road
Cross Hills
Kithley
West Yorkshire
BD 20 7DT

Your reference:

Our reference: *Rm 422*

Date: *12 Feb 90*

Dear Mr Lamb,

PRODUCT: *Vianied Thermacot TC 400 Mk I Infant Radiant Warmer*

You have already received the technical findings from our evaluation of the above equipment, which was done in collaboration with BSI Test House.

I now enclose a draft copy of the full evaluation report, which includes comments from users, and invite your written comments for publication with the report in the next special Comparative Evaluation issue of 'Health Equipment Information' (HEI) covering this type of equipment.

Around 5000 copies are distributed, mainly within the NHS, and publication is planned for

In addition to your comments on the report, would you please complete the enclosed Form A, so that we may correctly describe the equipment, its price, and the guarantee and servicing arrangements.

We are trying to monitor the timing of HEI publication in relation to the market life of the products on which it reports. In this respect it would be most helpful if you would also complete as much as you feel able of Form B: this information, unlike that on Form A, will be treated in strict commercial confidence.

In order to keep to the publication schedules, I must ask that your written comments on the report reach me no later than *16 Mar 90*. However, if you would like to discuss the report in detail before finalising your response, would you please contact me, preferably within the next week, to arrange a convenient date?

Yours sincerely,

P. D. Oddy

SUPPLIES TECHNOLOGY DIVISION

PDLABK

enc: Report /Form A/ Form B



14 Russell Square, London, WC1B 5EP
Telex 883669 DHSSHQ G
Fax 01-637 8990
Telephone 01-636 6811 Ext. **3069**

Mr John Lamb,
Viamed,
15 Station Road,
Cross Hills,
Keighley
W. Yorkshire

Your reference:

Our reference:

Date:

27/9/88

Dear **Mr Lamb,**

PRODUCT: **INFANT RADIANT WARMER- Thermo cot TC400 Mk1.**

I enclose a copy of the BSI Report on the above equipment, which you kindly agreed to lend to BSI for the purpose of assessing its compliance with BS 5724. (BSI will be arranging with your company the equipment's return, if they have not already done so).

As you can see there are a number of points where the equipment did not comply with BS 5724. These should be declared on all MLQ forms until these points have been corrected in production.

As you know, the Report will form part of our evaluation of this model. The full evaluation report, including comments from hospital trials, will ultimately be published in the form of a comparative evaluation with other models in a special issue of 'Health Equipment Information'. Around 5000 copies of these Evaluation Issues are distributed, primarily within the NHS: they are also reviewed by a number of journals.

I am sending you the BSI Report now, in case there are any implications for production or field service changes. I shall send you later a copy of the draft full evaluation report, suggesting that we then meet to discuss it and inviting your written comments for publication.

In the meantime, if you have any queries about the enclosed BSI Report, I would suggest that you contact the BSI Test House direct in the first instance.

Yours sincerely,

Nigel Jennings
N. JENNINGS

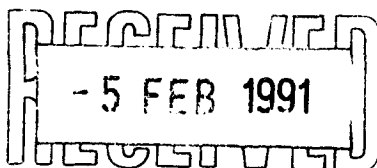
SUPPLIES TECHNOLOGY DIVISION

PDLAAX

Your ref:

Our ref: T/D/65

Date: 1 February 1991



Maylands Avenue
Hemel Hempstead
Herts HP2 4SQ
Telephone: 0442-230442
Telex: 82424 BSIHHC G
Fax Gr 2/3: 0442-231442

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

Dear Mr Nixon

**THERMACOT TC400 MK1 INFANT RADIANT WARMER
RE-SUBMISSION OF BSI JOB NO.138544**

With regard to the above equipment, we should like to make the following estimate to test for compliance with BS 5724: Part 1 1979 (IEC601-1:1977) including the production of two copies of the report, and subject to the requirements being met, two copies of the test certificate.

Cost: £1550 + VAT

Duration: 6 - 8 weeks

Earliest start date: One week from receipt of equipment and pre-payment

This estimate excludes all packaging and transport costs to or from the BSI Laboratories and any such charges will be invoiced as appropriate.

This estimate is valid for a period of thirty days from the above date. Beyond this time a price increase may apply.

Since this will be the first submission we have received from your company, we require the above amount to be paid before work can commence.

Should you wish us to proceed with this test work, please complete the attached 'Application for Test' form, and return to us together with an order number. In the event that the cost seems likely to exceed the estimate by more than 10%, then we will notify you immediately and will require your agreement before finalising.

Alan Attryde
Managing Director

Dr Ivan Dunstan
Director General

Mr Nixon

1 February 1991

If further information and components are required, we will inform you of our additional requirements once an initial inspection of the equipment has been completed.

Thank you for your enquiry, and please do not hesitate to contact us should you have any further queries.

Yours sincerely

P. R. Shiels

P.R. SHIELS
Electromedical Section

PS/CL

Enc. Application for Test Form
Test Leaflet 1

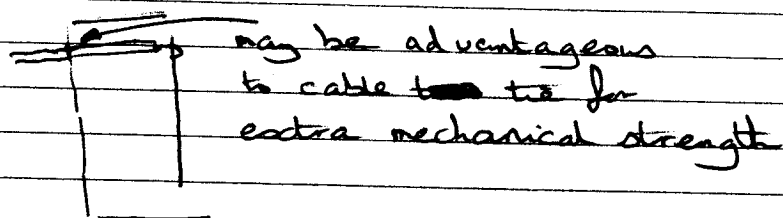
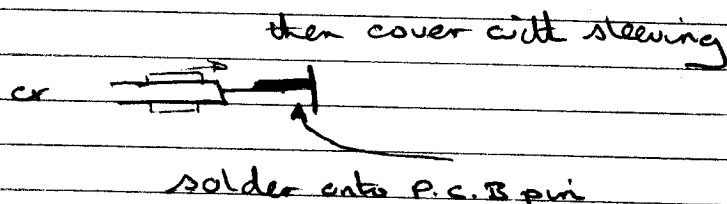
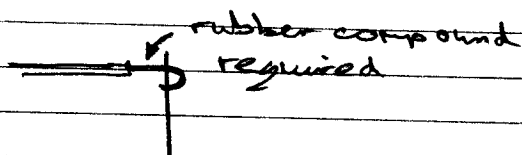
10/1/89

Telephone conversation with Mr P. Shields (B.S.)
regarding thermacot

with reference to my letter terminal blocks 1 and
2 panned, number 3 panned

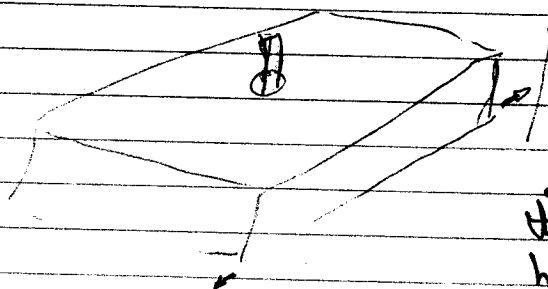
I suggest as use #1. L.N. (⊕) Labeling should
be either on the body of the block, ~~or~~ or on the
casing. Labeling should not be on the block cover

Regulator.



Large 100uf cap too close to top cover therefore
requires insulating strip on top cover.

Creepage of L and N connections on P.C.B too close
to casing sides therefore insulation required on sides
of casing.



if creepage from open ends
of regulator are less than 4mm
then insulation is required of
head casing.

I asked if we could use earth terminal 143-552 from Farnells. Mr. P. Shields said we could as long as we label it. \downarrow equipotential.

The only outstanding problem is the guard Mr. P. Shields said that we should be able to get around it by extending the guard by say 2".

- 1) I suggest that this may be a more physical hazard
- 2) Other cots must have a similar problem except those without a fixed height
- 3) Is he measuring the guard or radiant temp.

He said he will discuss the guard problem with his colleagues and get back to me ASAP

A TC 600MK II can be sent for testing at any time.

UAL

10/1/89.

I talked to Mr J.C. Leather. He is prepared for UAL to modify the ZVS ER 4016 T for just a small additional cost. He will send a sample when he receives my modified unit

unmodified

| | | |
|------|------------------|---------------------|
| 1off | 20.35 + p+p 3.50 | 23.85 + VAT = 27.43 |
| 10 | 18.68 | |
| 50 | 16.05 | |
| 100 | 13.70 | |