

1. DEVICE/EQUIPMENT:

Inditherm OTM1, OTM2, GTM1, RB1 & OTB1 operating theatre blankets and mattresses, used for maintaining patients' body temperature.

2. PROBLEM:

Repeated folding of these devices can cause internal damage to the heating element.

This can result in patient burns caused by localised hot-spots.

The manufacturer is carrying out a modification which will detect this type of failure. This requires alteration of both the mattress and the control unit.

3. ACTION BY:

All those involved in the purchase, use or maintenance of these devices

4. ACTION:

- Identify all of the above devices and contact Inditherm (tel: 01709 761000) to arrange for an upgrade.
- Inspect the devices and if there are signs of folding, or if you are in any doubt, remove from use and seek advice from Inditherm.
- Ensure that these devices are stored flat or loosely rolled, but not folded.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E departments
- All wards
- EBME departments
- Equipment stores
- Estates departments
- Independent Health and Social Care Providers
– Private Clinics, Residential and Nursing
Homes through RQIA
- Intensive care units
- Nursing and medical directors
- Theatre managers

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Andy Curtis
Inditherm plc
Houndhill Park
Bolton Road
Wath Upon Dearne
Rotherham
S63 7LG
Tel: 01709 761 000
Fax: 01709 761 066

E-mail: sales@indithermplc.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/ 05 and be addressed to:

Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

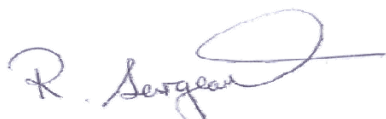
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 19 January 2007
Deadline (action underway)	: 25 January 2007
Deadline (action complete)	: 08 February 2007



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX to MDEA(NI)2007/05

Houndhill Park
Bolton Road
Wath Upon Dearne
Rotherham
S63 7LG

Tel. +44 (0) 1709 761000
Fax. +44 (0) 1709 761066
e-mail: sales@indithermplc.com

Date: 01/12/06

ADVISORY NOTICE SAFETY INSTRUCTIONS

Customer Name:
Address:
For the attention of:
Subject: Care and Handling of Operating Theatre Products
Product Description: Operating Theatre Blankets and Mattresses
Product Code: OTM1, OTM2, GTM1, RB1, OTB1
Product Serial Number:

Manufacturer's Comments – The purpose of this notice is to advise you that following receipt of information about the above product(s), we recommend that you respond or otherwise act in accordance to the instruction marked below.	
Nature of the problem: Please ensure that the mattress or blanket is not folded. Repeated folding of the product can damage the internal components, which could result in malfunction.	
	Isolate the product(s) as soon as possible and await further advice or information from us. Label the product(s) so that is not accidentally used.
	Destroy the product(s) described in this notice. A replacement will be delivered to you.
	Remove the product from your stock and await collection by ourselves A replacement will be delivered to you.
✓	We recommend you treat the product as follows: Inspect all products for any sign of folding, and if found or if in any doubt, contact Inditherm for advice. Ensure that the products are kept flat or loosely rolled when moved or stored. PLEASE DO NOT FOLD. Please contact Inditherm at above address to arrange a free upgrade to latest specification, which will ensure any malfunction is automatically detected.
We are sorry for any inconvenience that may be caused to you by this request. Your prompt reaction to our advice will help us improve our products and service to you.	

Additional Comments: Inditherm would be happy to visit and advise if you are in any doubt.		
Signed:	Date: 01/12/06	Position: QA Representative