

# Medical Device/Equipment ALERT



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**For:**

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION REQUEST	

	Section								
<b>Medical Device/Equipment:</b> Infra-red Ear Thermometer - Home Use	▶ ①								
<b>Problem:</b> Infra-red ear thermometers may give low temperature readings when not correctly placed in the ear canal. This may give false re-assurance and delay medical treatment.	▶ ②								
<b>Action by:</b> Clinical staff advising patients where temperature monitoring in the home is required, including Paediatricians, Oncologists, Paediatric and Oncology Nurses, General Medical Practitioners, Practice Nurses, District Nurses, Health Visitors and Community Pharmacists.	▶ ③								
<b>Action:</b> Patients should be advised to: <ul style="list-style-type: none"> <li>• Use thermometers in accordance with the manufacturers' instructions to avoid incorrect readings;</li> <li>• Take care in placing ear thermometer probes so that they detect heat radiated from the eardrum;</li> <li>• Seek medical attention if they have health concerns, irrespective of the thermometer reading.</li> </ul> The attached Important Advice leaflet (see Annex) may be copied and handed to patients required to monitor their own or their child's temperature.	▶ ④								
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <b>For onward distribution see Section 5</b>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
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<b>Contacts</b> Details NIAIC contacts contacts for technical aspects.	▶ ⑥								
<b>Feedback Requirements to NIAIC</b> None Required	▶ ⑦								

## **1. DEVICE/EQUIPMENT:**

Infra-red Ear Thermometer - Home Use. These devices are now being used as a replacement for the mercury-in-glass thermometer.

## **2. PROBLEM:**

NIAIC has been informed that the Medicines and Healthcare products Regulatory Agency (MHRA - formed on 1 April 2003 by the merger of the Medicines Controls Agency and the Medical Devices Agency) is aware of concerns relating to the performance of some infra-red ear thermometers.

A number of reports have been received concerning temperature monitoring of children in the home who subsequently required urgent hospital attention. Four reports involved children undergoing chemotherapy for leukaemia or drug treatment for a rare blood disorder. Two reports involved children with a virus who suffered a febrile convulsion. In these cases the temperature reading appeared to be normal and falsely re-assured the parents. On admission to hospital temperature readings were found to be between 1°C and 3°C higher than those recorded on the home use thermometer.

An investigation revealed that three thermometers returned for testing met the manufacturer's specification, while another two under-read by 0.5°C due to a dirty lens.

A report was also received from a GP practice where staff found infra-red ear thermometers were recording low patient temperatures of 35°C.

The conclusion from all of these cases was that the user should ensure the lens is kept clean and the probe is correctly placed in the ear canal to detect radiated heat from the eardrum.

Infra-red ear thermometers are designed to detect heat radiated from the eardrum (tympanic membrane), but also respond to heat from the ear canal. The ear canal may be 2°C lower than the eardrum and therefore incorrect placing can give falsely low temperature readings. The heat energy received by the thermometer probe depends on the anatomy of the ear, the design of the thermometer probe and where the probe is placed. The thermometer calculates the patient's temperature from the infra-red energy received. Some models apply an offset to the ear measurement to indicate the temperature at a different site on the body, e.g. oral.

Correct measurement technique is very important to ensure reliable temperature readings. With some patients a gentle but firm pull on the ear may be required to straighten the ear canal. Alternatively, the tragus may be gently retracted. The probe should be placed gently in the ear canal ensuring a snug fit and aimed at the eardrum.

## **3. ACTION BY:**

As outlined on page 1

## **4. ACTION:**

As outlined on page 1

## **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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Directors of oncology
- Directors of Paediatrics
- Paediatricians
- Paediatric Oncologists
- Practice Nurses
- Health Visitors
- District Nurses
- Directors of Public Health
- Consultants in Community Disease Control
- Immunisation co-ordinators
- Community Care Staff
- Independent Health and Social Care Providers

**Issued: 16 April 2003**

**Ref. MDEA(NI)2003/03**

- Paediatric Nurses
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Accident & Emergency Departments

including Residential, Nursing Homes, and  
Private Clinics

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/03 and be addressed to:  
Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

Marked for the attention of Mr Brian Godfrey

Tel: 028 9052 3704

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Brian Godfrey  
NIAIC Manager

### HOW TO REPORT ADVERSE INCIDENTS

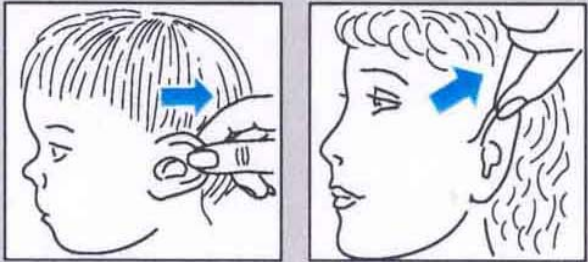
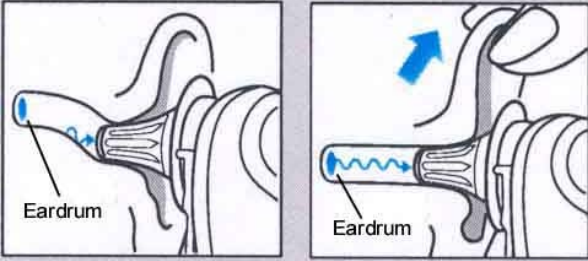
Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2003/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact 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](http://www.dhsspsni.gov.uk/niaic)

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

## Infra-red Ear Thermometers – Important Advice

Infra-red ear thermometers may give low readings when not correctly placed in the ear. These thermometers are designed to detect heat from the eardrum, but also respond to heat from the ear canal. The ear canal may be 2°C lower than the eardrum and can give falsely low temperature readings.

### Seven Steps For Accurate Temperature Measurement

1. Carefully read the manufacturer's user instructions and familiarise yourself with how the thermometer works.
2. Ensure the thermometer probe tip is clean, undamaged and a new hygienic probe cover is fitted if required (note: some models are not designed for use with probe covers).
3. Switch on the thermometer and observe the self-test, check that all segments of the display activate.
4. A gentle but firm pull on the ear is usually required to straighten the ear canal to give a clear view of the eardrum. For adults and children over one year, pull the ear up and back. For children under one year, pull the ear straight back.
5. Place the probe gently into the ear canal ensuring a snug fit. In small children cover the ear opening with the tip of the probe. Always use the same ear when comparing measurements.

False low reading / Correct reading
6. Press the start button. Some models may 'beep' when the temperature has been recorded. Check details for your particular model.
7. When using the thermometer for the first time, or when an accurate reading is essential, take three measurements and note the highest value.

**Do not rely on temperature measurements alone.  
If you have health concerns, seek medical advice.**

For further information see NIAIC website <http://www.dhsspsni.gov.uk/niaic>