

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/59

Issued: 4 October 2006



HEALTH ESTATES

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For:

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

	Section
<b>Medical Device/Equipment:</b> <b>PHYSIOTHERAPY ULTRASOUND MACHINES: CALIBRATION OF ACOUSTIC POWER / INTENSITY</b>	▶ ①
<b>Problem:</b> A number of concerns have been reported following independent testing of physiotherapy ultrasound machines during commissioning or after being serviced by manufacturers or suppliers. In many cases, the acoustic powers and intensities were found to be substantially different from those expected. This relates directly to the efficacy and safety of patient treatment.	▶ ②
<b>Action by:</b> This Notice should be brought to the attention of all appropriate managers, staff and users.	▶ ③
<b>Action:</b> Users and medical physics / clinical engineering staff should be aware of the problems described in this notice and the recommendations contained in the publication <i>Guidelines for the Testing and Calibration of Physiotherapy Ultrasound Machines</i> <sup>(3)</sup> published by the Institute of Physics and Engineering in Medicine as IPEM Report 84.	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
<b>Contacts</b> NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None required.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Physiotherapy ultrasound machines: calibration of acoustic power / intensity

## 2. PROBLEM:

A number of concerns have been reported following independent testing of physiotherapy ultrasound machines during commissioning or after being serviced by manufacturers or suppliers. In many cases, the acoustic powers and intensities were found to be substantially different from those expected. This relates directly to the efficacy and safety of patient treatment.

Concerns have been expressed involving the following problems on various models / manufacturers of Physiotherapy ultrasound equipment:

- a) Acoustic powers outside +/-20% tolerance, due to poor calibration at manufacture. Deviations have been measured as much as -90% to +100% compared to that indicated;
- b) Treatment heads with effective radiating areas (ERA) outside +/-20% tolerance (e.g. 3.0 cm<sup>2</sup> rather than 5.0 cm<sup>2</sup>) due to poor characterisation by the manufacturer or test-house. This has led to machines delivering effective intensities considerably greater than the radiation safety limit of 3 W/cm<sup>2</sup>;
- c) Manufacturers and suppliers using old testing equipment, which use old standards that have been withdrawn or revised (e.g. IEC 150; IEC 60601-2-5, 1984);
- d) Incorrectly calibration of acoustic power from divergent beams. Calibration using reflecting rather than absorbing target radiation force balances. This will provide incorrect calibration unless divergent beams are taken into account when calibrating the power, leading to higher output than expected (e.g. 2W delivered at a 1W setting).

Eighteen of out 30 (60%) of newly purchased machines tested by a medical physics department between 2002 and 2006 were found to be outside the performance limits for power and/or intensity laid down by current standards (1,2).

Faulty physiotherapy ultrasound machines often appear to function normally while in use, even when they have gross calibration errors. As neither the therapist nor the patient can usually see or feel any immediate effect of the ultrasound therapy, there is no immediate feedback on the performance of the device.

**Note:** *The above figures and testing were carried out on behalf of Incident Reporting & Investigation Centre, Scottish Healthcare Supplies and this Alert has been drawn up from their material. Although no incidents of this nature have been reported to NIAIC or the MHRA this does not mean that a similar problem does not exist across the rest of the United Kingdom.*

### REFERENCES

- (1) BS EN 60601-2-5 (2001) Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of ultrasonic physiotherapy equipment.
- (2) BS EN 61689 (1997) Ultrasonic's. Physiotherapy systems. Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz.

## 3. ACTION BY:

This Notice should be brought to the attention of all appropriate managers, staff and users.

## 4. ACTION:

A review should be undertaken of maintenance and calibration procedures for existing physiotherapy ultrasound machines to ensure that any gross calibration errors are eliminated and that the devices can be used with confidence in their accuracy.

Before procuring new devices, manufacturers and suppliers should be required to provide evidence that their

products are built and tested to relevant standards. In addition, independent testing should be considered. Such testing should be designed to detect treatment heads with diverging beams and measure the output.

Users should ensure that all devices are enrolled in a calibration programme, including a weekly quantitative test to ensure that the devices are operating within parameters specified at the time of calibration. This may be by means of a simple calorimeter or a water balance test.

Users and medical physics / clinical engineering staff should be aware of the problems described in this notice and the recommendations contained in the publication Guidelines for the Testing and Calibration of Physiotherapy Ultrasound Machines <sup>(3)</sup> published by the Institute of Physics and Engineering in Medicine as IPEM Report 84.

## REFERENCES

(3) *Guidelines for the Testing and Calibration of Physiotherapy Ultrasound Machines*, Stephen Pye and Bajram Zeqiri, Report 84, Institute of Physics and Engineering in Medicine, 2001, ISBN 0 904181 98 7. The publication can be ordered from the IPEM website <http://www.ipem.ac.uk/>.

## 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:

- Liaison Officers
- Device Managers
- Estates Managers
- Medical Physics
- Physiotherapists
- Podiatry
- Rehabilitation
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Clinical Directors (for information)
- Nurse Directors (for information)

## 6. CONTACTS:

Users may wish to direct enquiries regarding the testing and calibration of ultrasound machines to their local medical physics department, who may in turn contact the authors of IPEM Report 84 (see report for contact details). Enquiries on specific equipment should be directed to the manufacturer, distributor or agent.

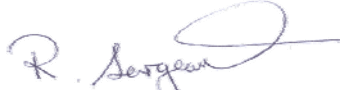
Enquires to NIAIC should quote reference number MDEA(NI)2006/59 and be addressed to:

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

## 7. FEEDBACK:

None required

  
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](http://www.dhsspsni.gov.uk/niaic)

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