

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/73

Issued: 19 October 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Nellcor N-595 pulse oximeters N-395, NPB-290 and NPB-295 pulse oximeters (with serial numbers after G01844386).</p>	▶ ①
<p>Problem: The failure rate of the loud speaker component in N-595 and some N-395, NPB-290 and NPB-295 pulse oximeters is higher than expected. This may result in the monitor losing its audio alarm. Neither the visual nor remote alarm functions are affected.</p>	▶ ②
<p>Action by: All nursing and medical personnel using these devices.</p>	▶ ③
<p>Action: Users should be aware of this problem and the appropriate action to take, (See Appendix for manufacturer's letter), to test the alarm system and have the corrective action undertaken if required.</p>	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Detail of manufacturer and NIAIC contact for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Nellcor N-595 pulse oximeters
N-395, NPB-290 and NPB-295 pulse oximeters (with serial numbers greater than G01844386).

2. PROBLEM:

Tyco Healthcare issued a customer letter (see Appendix) in October 2004 to advise users of the appropriate action to take. Effectiveness checks indicate that a number of customers have not yet contacted Tyco Healthcare regarding speaker replacement. This notice is an update to Tyco Healthcare's corrective action. The company will again contact those customers.

3. ACTION BY:

All nursing and medical personnel using these devices.

4. ACTION:

- Users should use the self test alarm system (ensure that the monitor emits an audio tone when it is turned on) as described in the monitor's Operators Manual.
- Users should be aware of this problem and note the advice in the Tyco Healthcare customer letter (see Appendix). Note JCAHO recommendations mentioned in the customer letter are not applicable to the 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
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- All Wards and Departments
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Intensive Care
- Special Care Baby Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Customer Services
Tyco Healthcare
154 Fareham Road
Gosport
Hampshire PO13 0AS

Tel: 01329 224 226

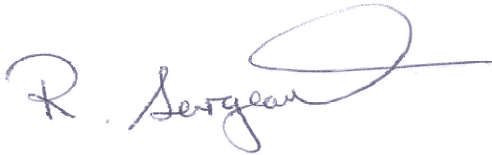
Enquires to NIAIC should quote reference number MDEA(NI)2005/73 and be addressed to:

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:

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)2005/01. 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)2005-73

October 21, 2004

AUDIO ALARM ADVISORY

Dear Valued Nellcor Customer

As part of Nellcor's standard quality activities, our analysis of service data has indicated that the speaker component used in the *Nellcor*[®] N-595 pulse oximeter, and in limited units of the N-395, NPB-290 and NPB-295 pulse oximeters (after serial number G01844386), is experiencing a failure rate which is slightly higher than has been typical with other speakers. In isolated instances when the failure mode is present, the audio alarm of the unit may not sound. The rate of failures is extremely low (less than two tenths of one percent of the installed instrument base have experienced the failure), and neither visual nor remote alarm functions, nor other device features are affected. However, we felt it was important for us to bring this to your attention, because of our shared interest in patient safety, so that we could remind you of various practices you can follow to ensure the appropriate operation of audio alarms and to mitigate the risks of alarm speaker failure.

1. Utilise self-testing alarm system functions: The *Nellcor* N-595, N-395, NPB-290, and NPB-295 all feature a Power-On-Self-Test (POST). This POST test, which is described in our Operator's Manual, forces the monitor to emit an audible tone when powered on. We recommend you confirm that your staff is trained to recognize this tone and to check to determine that it is present when initiating monitoring on patients.

2. Test alarm systems whilst in use: We recommend that your staff routinely check monitor alarms to ensure that they are set appropriately and are functional, at an interval defined by your facility. We concur with JCAHO's recommendation that healthcare organizations should establish routine preventative maintenance programs for all monitoring equipment, and further believe that verification of alarm operation to be an important part of any such program. Many healthcare facilities utilise policies that instruct their staff to check alarms when assuming responsibility for a patient, and you may wish to consider implementing similar practices if not already present. For instructions on how to check alarm volume and other functions, please refer to the enclosed Quick Guides or the monitor's Operator's Manual, or contact Nellcor Technical Services department. Please note that in the next few weeks we will make available an optional adhesive sticker that can be applied to the monitor as a reminder to periodically perform an alarm check. The optional alarm reminder sticker can be obtained at no charge by contacting our Customer Service or Technical Services departments at the number listed below.

3. Utilise pulse tones when monitoring: Nellcor pulse oximeters feature an audio pulse tone when the patient's pulse is detected, and pulse tone volume is set at a level to be audible. The presence of a pulse tone indicates the monitor's audio circuit is functional. Distortions and/or the absence of pulse tones may indicate audio difficulties, and alert users to a potential problem.

4. Consider use of remote alarm annunciation: The *Nellcor* N-595, N-395, NPB-290, and NPB-295 all feature the ability to be connected to nurse call systems for remote annunciation of monitor alarms. Remote annunciation is an important feature for complying with JCAHO's current directive that monitor alarms must be of sufficient magnitude to be heard throughout the care unit. Remote annunciation of alarms also provides greater confidence that an alarm will be heard. In the event of a speaker failure, serial port alarm status messages and/or nurse call functions will continue to be sent, thus alerting staff.

APPENDIX TO MDEA(NI)2005-73

5. **Service resources:** If your facility determines, by any means, that a Nellcor monitor's alarms are not working appropriately, please contact Tyco Healthcare's Technical Services on 01869 328090 and they can provide troubleshooting assistance, and help in the identification of spare parts. We also make our monitor Operators and Service Manuals available 24 hours a day via our website. For a free download from our website, manuals may be accessed at:

http://www.mallinckrodt.com/respiratory/resp/serv_supp/productmanuals.html

If you are unable to access our website, you can contact Tyco Healthcare on 01329 224226

We are committed to continuous quality improvement. We are actively investigating this matter and are working to provide you with a timely solution. If you have questions regarding this matter, please contact your local Tyco Healthcare Sales Representative.

Sincerely,
Terry Wardle
Divisional Marketing Manager, Critical Care
Tyco Healthcare Commercial (UK) Ltd