

COUGH ASSISTORS, VENTILATORS & BREATHING SYSTEMS

B & D Electromedical LLP

Unit A2 The Bridge Business Centre Timothy's Bridge Road Stratford-upon-Avon Warwickshire CV37 9HW Tel: (01789) 293460

Tec Support: (01789) 721577

16th January 2013

IMPORTANT FIELD SAFETY NOTICE

B&D Electromedical is voluntarily advising its customers of important safety information regarding the following products.

Devices: NIPPY 3 ventilator, NIPPY JUNIOR ventilator, NIPPY ST ventilator, NIPPY S ventilator. All devices manufactured between 2003 (first production) – 2007 (last production) This FSN does not apply to our current range of ventilators, Nippy 3+, Nippy Junior +, ST+ and S+.

Attention: All clinical staff, managers and users of the above devices.

Description of the problem: Our post market surveillance procedures have identified a potential safety risk if oxygen is entrained when using the **Nippy 3, Nippy Junior, Nippy ST or Nippy S.** The use of oxygen with these devices is not recommended as they were not designed for such use.

Potential hazard: If used with oxygen, under certain circumstances, there is a potential for a build-up of oxygen inside the machine. As oxygen supports combustion, there is a risk of fire.

Type of action: B&D Electromedical has updated the instructions for use to include a statement warning that these devices are not suitable for use with entrained oxygen. Copies may be downloaded from our website www.nippyventilator.com/downloads

Distribution of this FSN: Please transmit this notice to all those who need to be aware within your organisation or any other organisation where these devices may have been transferred. **Please return the acknowledgment form after reading this notice.**

Please be aware B&D Electromedical have notified the MHRA of this action.

For more information or assistance please contact:

Mr Noel Davis - Director B&D Electromedical LLP

e-mail at: support@nippyventilator

phone: 01789 293460



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Confirmation of receipt of field safety notice

Please complete the section below and return it to B&D Electromedical

Date
Name
Position
Department
Hospital / Organisation:
Address
I confirm that I have read this field safety notice and transmitted it to all persons concerned.
Signed