



B & D Electromedical Ltd
Unit A2 The Bridge Business Centre
Timothy's Bridge Road
Stratford-upon-Avon
Warwickshire CV37 9HW
Tel: (01789) 293460
VAT Reg No: 551 3055 73
www.nippyventilator.com

(ref. CA 026/17 FSCA)

Thursday, 11th May 2017

IMPORTANT FIELD SAFETY NOTICE

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

- NIPPY 3+, NIPPY Junior+, NIPPY ST+ and NIPPY S+ ventilators shipped between March 2016 and July 2016 and in the serial number range 2016-25579 and 2016-26728.
- 10,000-hour service kits for the 3+ range of NIPPY ventilators shipped between March 2016 and June 2016.
- Repairs/services undertaken at B & D Electromedical between March and June 2016 where we have replaced the blower assembly.

Attention

Users, Technical and Clinical Staff.

Description of the Problem

From our post market analysis of devices being returned for repair, we have identified a potential problem with the blower assembly used in a small batch of the NIPPY+ ventilators. There is a risk that if the device is subject to impact, the impeller inside the blower assembly may seize and stop the blower from rotating.

Potential Hazard

Failure of the impeller inside the blower assembly may cause the blower to stop rotating and therefore the NIPPY will cease to provide ventilatory support. If the ventilator does stop the device will alarm.

Action Required

- If you have a 10,000-hour service kit containing an affected blower, B & D Electromedical will supply a new blower for exchange.
- Affected NIPPY devices will soon be due for their annual service, we advise that during the annual service the blower is changed. Either return the NIPPY to B & D Electromedical for its annual service or alternatively B & D Electromedical will supply a new blower for exchange, if you are technically trained and carrying out service procedures yourself.

- Repairs/services that are affected should be returned to B&D Electromedical for a new blower to be fitted.

Distribution of this FSN

Please forward this notice to all those who need to be aware of this information within your organisation or any other organisation where the affected devices may have been transferred.

We will be contacting all customers affected by this FSN directly and will ensure we have a suitable plan to replace the affected blowers that meets our individual customer's requirements and expectations, but if you have any concerns, please do not hesitate to contact us.

Confirmation

Please sign and return the acknowledgment form after reading and forwarding this notice to the appropriate people.

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

For more information or assistance, please contact your sales executive or our head office on 01789 293460.

Yours faithfully,



Mrs Alison Speechly

Quality & Compliance Manager
B&D Electromedical Limited
E-mail: alison@nippyventilator.com
Telephone: 01789 293460



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Acknowledgement Form

Subject: Field Safety Corrective Action 3+ Range Blowers

Product: 3+ blowers fitted in 3+ series of ventilators

Date: 10th May 2017

We confirm that we have read and understood the information provided in the Field Safety Notice regarding the 3+ ventilator blowers.

We will implement the actions required and will inform all those who need to be aware within our organisation or to any organisation or person, including e.g. customers, hospitals, homecare providers, patients and / or caregivers, where the potentially affected devices have been transferred.

Reply record completed by:

Organisation:

Name:

Job Title:

Telephone number:

Signature:

Date:

Please scan and return this signed form to B&D Electromedical at quality@nippyventilator.com.
 Alternatively, you can post it to the address above.





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Confirmation of Blower Exchange

As the Field Safety Corrective Action is completed on each device/blower assembly, we require a confirmation to be completed for each blower assembly to ensure we have details of all the blower serial numbers that have been replaced.

Please use this form to complete the blower details and then return the form to B&D Electromedical by e-mail to: quality@nippyventilator.com or post to the address above.

| | Device & Serial No. (if applicable) | Removed Blower serial number | New Blower Serial Number |
|----|--|------------------------------|--------------------------|
| 1 | | 2290204 | 2290204 |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| 7 | | | |
| 8 | | | |
| 9 | | | |
| 10 | | | |

Organisation:

Person responsible for "blower exchange":

Date:

Please note that with regards to entering blower serial numbers, we just need the following details shown in red:

22902041601493346015

The digits 1601 indicate year and week of production, the last three digits are the unique code for the blower.

