

29th February 2016

IMPORTANT FIELD SAFETY NOTICE

(Ref: RMA 7912 FSCA)

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

**Devices: NIPPY 3+, NIPPY JUNIOR+, NIPPY ST+, and NIPPY S + ventilators.
All ventilators manufactured since 2007 and fitted with an internal battery**

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

Description of the problem: Patients have come to use their ventilator on internal battery when mains electricity has not been available and the battery has been unable to power the ventilator due to the battery's poor state of health.

Potential hazard: If users have not checked their battery run times or had their battery replaced every 2 years there is the potential risk of the device not operating on battery power when they need to rely on it when no mains electricity is available.

Action required: This Field Safety Notice has been issued to remind users/carers of correct battery care procedures.

The ventilator instructions for use do include detailed information on battery care and all users, carers, clinical staff and technicians should be made aware of these instructions and ensure the instructions are followed.

We have updated these instructions to ensure the guidance is as clear and detailed as possible for all users including more details on how to identify a failed battery if battery run times have not been checked regularly.

In addition to assist our users and the technical & clinical staff supporting them we have produced a short information sheet on battery usage and maintenance –copy attached, which gives guidance on how to check the health of your battery and when it should be replaced.

Copies of all documents may be downloaded from our website
www.nippyventilator.com/downloads

Distribution of this FSN: Please forward 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 and implementing the action required by this notice.

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

For more information or assistance please contact:

Mrs Alison Speechly
Quality & Compliance Manager
B&D Electromedical Limited

A handwritten signature in black ink, appearing to be 'Alison Speechly', with a long horizontal line extending to the right.

e-mail: alison@nippyventilator.com
phone: 01789 293460



B & D Electromedical Ltd
Unit A2 The Bridge Business Centre
Timothy's Bridge Road
Stratford-upon-Avon
Warwickshire CV37 9HW
Tel: (01789) 293460
Fax: (01789) 262470
VAT Reg No: 551 3055 73
www.nippyventilator.com

Confirmation of receipt of Field Safety Notice (ref. RMA 7912 FSCA)

Please complete the section below and return it to B&D Electromedical by 29th April 2016

Date

Name

Position.....

Department

Hospital / Organisation:

Address.....

I confirm that I have read this field safety notice and transmitted the information to all persons concerned.

Signed.....

Email to: quality@nippyventilator.com

Or

Fax to: 01789 262470

Or post to:

**B&D Electromedical Ltd
Unit A2 The Bridge business Centre
Timothy's Bridge Road
Stratford upon Avon
CV37 9HW**

B & D Electromedical Ltd
Registered in England and Wales: Reg No 07190611
Registered Office: Barclays Bank Chambers, Bridge Street,
Stratford-upon-Avon CV37 6AH



MD558596

This Information Sheet To Be Handed to the Carer/User

Running the Nippy+ on Internal Battery Power

IMPORTANT BATTERY CARE RULES

1. Regularly check battery run times for your device including all accessories (humidifier, circuit etc.) at your prescription settings and record the information.
2. If you have more than one ventilator, check this one too.
3. Never check the on-screen run time estimate when running on mains power.
4. Failure to perform regular battery performance checks could result in failure during loss of mains power. Check monthly.
5. Know the difference between battery run time and battery state of health. The run time is the running time expected from a healthy battery. The state of health is the condition of the battery in terms of its total service life.

Battery Run Times

Run times will gradually reduce as the battery ages regardless of how much use the battery has had.

To Check Estimated Run Time

1. Run ventilator on internal battery for approx. 5 minutes.
2. Double press the SET button to display a bar graph of estimated run time.
3. This is an indication of the battery state of charge not its health.

When checking expected battery run time the ventilator must NOT be connected to the mains.

The results shown assume that the connected battery is in good serviceable condition.

Battery Run Time Test (Health test)

1. Ensure the battery is fully charged.
2. Run the ventilator from the battery until the low battery alarm operates and record the running time. Look up the run time in the table (in User manual). If the battery is not achieving minimum run time make arrangements to have it replaced.
3. Always fully recharge the battery immediately after testing.

Battery Health Quick Test

If it is not practical to check battery run times, a crude quick test may be performed to identify a battery that is at the end of its life and has not been noticed by the user or for a quick check on a battery that has not been used regularly. This test is not an indication that the battery is in good health, but is a useful way of identifying a failed battery.

This test is not intended to replace regular run time testing used to determine battery state of health.

Quick Test Procedure

1. Remove the external battery from the Aux Power socket if being used.
2. Connect Nippy+ to mains power supply and fully charge the internal battery overnight.
3. Turn the Nippy+ on with the patient circuit fitted to the outlet.
4. Remove the patient circuit from the outlet and allow the Nippy+ to 'free flow'. This will create maximum flow and load on the battery.
5. If the battery symbol turns red or the Nippy+ shuts down within 2 minutes the battery MUST be replaced immediately.

Battery Life

All batteries will deteriorate due to age and usage.

- An internal battery that is not used will age prematurely.
- An internal battery that is heavily used will age gradually and lose its capacity after around 200 full discharge cycles (run until low battery alarm)
- An internal battery that is moderately used will last longest.
- When a battery is towards the end of its life, the run times will be much shorter. Check regularly.
- Service life is 2 years. Replace the battery when running times drop below those indicated or after 2 years.

If the battery icon remains RED after several hours charging there may be a fault with the battery of the ventilator.