

Urgent Field Safety Notice

NObreath® V2 Fractional Exhaled Nitric Oxide (FeNO) Device

FSCA-identifier: #443655

Type of Action: Corrective Action Notice

Date: 04/12/19

Attention: NObreath® V2 Distributors

Details on affected devices

Serial Numbers affected: All devices

Description of the Problem

It has come to our attention that the NObreath® V2 batteries are becoming drained outside of the device technical specification. This means that the internal, rechargeable batteries can become fully drained. This can result in the power needed to keep the sensor stable to be lost and result in the readings becoming lower than the technical specification states. This can also result in the power needed to run the internal real time clock to be lost and result in the device losing its date/time settings. If the latter occurs the device will revert to its factory date settings and will prevent the user from performing tests.

Devices affected may present the following symptoms:

1. Lower than expected reading or zero reading
2. Time and date resetting
3. Sensor warning screen shown
4. Maintenance reminder screen shown
5. Battery going flat and then unable to fully recharge within 8 hours

Investigation

It has been discovered that the NObreath screen is out of specification and requires replacement. The screen draws more current than designed; this falsely triggers the device power management circuit protection system cutting power to the internal batteries.

To improve the power management circuit on the NObreath® V2 device, Bedfont have made an improvement to the NObreath® V2 screen, which will reduce the amount of current being drawn from the battery.

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Action to be Taken by User

Bedfont recommends all devices are sent back for the battery/power management upgrade, these devices should be sent back at your earliest convenience.

Any devices presenting these symptoms should be quarantined immediately and returned.

If your device has not presented any of the above symptoms, and until such time your device can be sent back please follow the below instructions to ensure the battery management is kept within the stated technical specification.

1. Keep the NObreath® V2 charged and to not let the device battery become fully drained.
2. If the NObreath® V2 battery becomes fully drained, this may result in the device showing the symptom states listed above.
3. A great way to keep the NObreath® V2 charged when not in use is to use the docking station included.
4. This can be connected via the mains adapter supplied, or plugged into a working USB port, to ensure the NObreath® V2 has charge for when it's needed.
5. Under no circumstances should you remove the NObreath® V2 battery, unless instructed to by a Bedfont representative.
6. Additionally, if the NObreath® V2 is being stored, it must be fully charged every 30 days to ensure the device operates correctly. The NObreath® V2 takes 8 hours to fully charge.
7. The NObreath® V2 should be charged for a minimum of 4 hours before first use.

Please contact Bedfont or your local distributor for a returns number or advice on how to send your device back.

Transmission of this FSN

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference Person

If you are experiencing any of these issues and would like additional information on what to do, please contact your local distributor or Bedfont for advice.

Between the hours of 9:00am – 5:00pm GMT please call Bedfont Scientific and request to speak with the 'NObreath® V2 Upgrade Engineer'

Tel: +44 1622 851 122

Alternatively you can email service@bedfont.com

Closing Paragraph

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency (MHRA)

Signed:

Name: ...

Position: QA & RA Manager

Date: 04/12/19