

# Urgent Field Safety Notice



**NOxBOXi Inhaled Nitric Oxide Delivery and Monitoring Device**

**FSCA-identifier #643755**

**Type of Action: Corrective Action**

**Date: 23/07/2015**

**Attention: NOxBOXi Distributor and or user**

## **Details on affected devices**

All NOxBOXi units.

## **Description of the Problem(s)**

### **'Critical Delivery Fault' Alarm**

The NOxBOXi firmware is designed to be as safety conscious as possible, monitoring a multitude of parameters at any and all times during use. One of these parameters monitors the flow of gas through the device in order to ensure it doses the correct values to the patient. If this flow breaches the acceptable tolerance in the event of a component failure a 'Critical Delivery Fault' alarm will sound and dosing to the patient will cease. This acceptable tolerance is measured in units of voltage (V). It has been identified that the acceptable tolerance in the device's firmware may be too close to the tolerance of the mass flow sensor used to monitor the gas flow. Therefore it is possible that when changing doses in large increments or if the device is connected to a high frequency ventilator set to a frequency of 10Hz and the mass flow sensor is at the upper or lower end of its technical tolerance, the 'Critical Delivery Fault' alarm can be falsely triggered by a momentary spike in voltage. This is a latching alarm and therefore must be resolved manually as described below.

### **Visual LED Alarm Band flashing and device shutting down**

The NOxBOXi is equipped with a high intensity red visual LED band covering the circumference of the device which flashes when a high priority alarm has been triggered, in some cases this is accompanied by an audible alarm. If the device is shut down, the LED alarm band will flash to alert users that it is about to power off and gas delivery will cease but no audible alarm is triggered. There is a small possibility that due to an operating system framework anomaly, the device may shut down during use, the user will be alerted to this fact by the visual LED alarm band flashing.

#### **Bedfont Scientific Ltd**

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## Action to be taken

The new firmware is now available V17.0, which you must install on your device(s) immediately.

There are two options for installing the new firmware:

Option 1: You can send your unit back to Bedfont Head Office for the new firmware upgrade and we will also upgrade your unit with the new water trap (see [Technical Bulletin:TB.101.010](#)) which will all be free of charge.

Option 2: You can download the new firmware from the below link and install this using the firmware checklist (see below link), which once completed must be signed and scanned back to us ([amber@bedfont.com](mailto:amber@bedfont.com)) for confirmation the firmware has installed correctly.

[Firmware Version 0.0.17.0](#)  
[Firmware Checklist](#)

## 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

Between the hours of 9:00am – 5:00pm BST please call Bedfont Scientific Ltd: +44 1622 851 122

## Closing Paragraph

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

