Urgent Field Safety Notice

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NOxBOXi Inhaled Nitric Oxide Delivery and Monitoring Device

FSCA-identifier #643755

Type of Action: Advisory Notice

Date: 08/06/2015
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.

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Action to be taken

'Critical Delivery Fault' Alarm

Dismiss 'Critical Delivery Fault' notification by pressing the 'X' on the alarm banner and re-set the delivery dose. If the 'Critical Delivery Fault' occurs again and the device is connected to a high frequency ventilator set to a frequency of 10Hz, adjust the frequency by up to 0.5Hz, based on your clinical judgment. If either action does not resolve the alarm the manual override should be employed, follow instructions set out in the 'NOxBOXi Operating Instructions'.

Bedfont is evaluating a firmware fix whereby the acceptable tolerance is being increased to a more suitable level and also must be breached by 3 consecutive seconds. This means only a true component failure will result in the 'Critical Delivery Fault' alarm being triggered. We will inform you immediately when this validation is complete and ready for release.

Visual LED Alarm Band flashing and device shutting down

If the device powers off unexpectedly the manual override should be employed, follow instructions set out in the 'NOxBOXi Operating Instructions' & replace the device as soon as possible. However, if a replacement device is not available; whilst in manual override mode the device can be switched back on. Select the service engineer icon on the home screen, then enter the code 1977.7 & switch back to the intelligent mode. An appropriate dose can then be set. Please follow the troubleshooting section of the manual if any alarms remain triggered. When in intelligent mode we recommend the device is kept within visual contact.

Bedfont is evaluating a firmware fix whereby the operating system framework anomaly has been eradicated. We will inform you immediately when this validation is complete and ready for release.

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.

LBateman

Louise Bateman
Quality Manager

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