

# Advisory Field Notice



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## **NObreath® Fractional Exhaled Nitric Oxide (FENO) Device**

**FSCA-identifier #751766**

### **Type of Action: Final Corrective Action**

Date: 06/12/16

Attention: NObreath® Distributor

### **Details on affected devices**

Serial numbers **NBR023443 – NBR023894**

### **Description of the Problem**

A problem has been observed by some customers whereby the NObreath® screen can freeze during use, this also resets the devices' internal clock. **Please note:** The functionality or safety of the NObreath® is unchanged and it will accurately measure FENO levels on the patients' breath.

You can identify if this has happened to your device in a few ways:

- Switching the device off and back on, during the start-up the date will show as 01-01-01.
- Switching the device off and back on, once the device has settled the calibration icon will be shown. You can bypass this and continue to use the device by selecting the red X.
- With the device switched on go to the settings, select the calendar icon and observe the date, if it is set to 01-01-01 the fault has occurred.

### **Investigation**

It has been concluded that the cause of this problem is due to a manufacturing process, whereby one of the components can be formed incorrectly prior to installation which can damage the component and cause it to work intermittently.

### **Action to be taken**

If you observe this problem with a NObreath® device or you have devices in stock Bedfont will replace the potentially affected component free of charge by sending your unit back to Bedfont, please contact Bedfont for a returns number.

### **Transmission of this FSN**

This notice needs to be passed on to 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.

**Bedfont Scientific Ltd**  
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Registered in: England and Wales. Registered No: 1289798

breath analysis is the new blood test

## Contact reference

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

Tel: +44 1622 851 122

Alternatively you can email [ask@bedfont.com](mailto:ask@bedfont.com)



## Closing Paragraph

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

Signed:



Louise Bateman  
Quality Assurance & Regulatory Affairs  
Manager