

Urgent Field Safety Notice



Commercial Name of the Affected Product: NOxBOX_i

(Unique Device Identifier: 05060541640009)

FSN -Identifier: NBL-CAPA-0013

Type of Action: Return of devices to manufacturer

Date: 08 March 2019

Attention: Distributors of the affected devices

Details on affected devices:

The following Serial Numbers have been identified as despatched by NOxBOX Ltd and are impacted by this Field Safety Notice (FSN). NOxBOX Ltd is contacting all affected distributors to notify them of this potential issue and request that the affected units are removed from use and returned to NOxBOX Ltd.

NOxBOX _i SN	Power PCB SN	Device Manufacture date
NI100916	████	07/02/2019
NI100917	████	07/02/2019
NI100918	████	07/02/2019
NI100919	████	07/02/2019
NI100921	████	07/02/2019
NI100922	████	13/02/2019
NI100416 (New board fitted)	████	11/02/2019

Description of the Problem / Reason for the FSCA:

It has been identified that a batch of capacitors used are potentially faulty. These capacitors are used on the Power PCB (Printed Circuit Board). The capacitor may potentially suffer from delamination which may result from an ingress of moisture entering the component during storage or shipping. Then when the component is placed on a PCB circuit and sent through the reflow oven at very high temperatures, the moisture evaporates fracturing/delaminating the component.

All PCBs used within the NOxBOX_i are Automatically Optically inspected, but these fractures may not be seen with the naked eye or the optical equipment. Changes in temperature, humidity and transportation may cause them to fail at any point. If this happened during the use of the device it may cause it to power OFF, causing an immediate cessation of therapy. This is likely to adversely affect the patient, and require immediate intervention.

This issue does not impact any other devices on the market other than those identified as using this batch of capacitors.

As the PCBs cannot be inspected to identify any failure of this nature it is not possible to determine if they are damaged, therefore the devices that have been identified as containing capacitors from the affected batch are to be returned to NOxBOX for PCB rework, where the affected component will be replaced with capacitors from a separate batch.

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NOxBOX[®] Ltd

Action to be taken by the user

The Devices identified in the table above are required to be withdrawn from use immediately and returned to NOxBOX Ltd as soon as possible. Return of the units will be coordinated via our Sales Team and Customer Service Team. Please liaise with your NOxBOX Product Manager (Sales Team) for any assistance.

Distributors must notify any organisation to whom they have supplied an affected unit and inform NOxBOX. They must also follow up with the purchaser to ensure the return of all affected units (if appropriate).

Please respond to this FSN to acknowledge receipt and inform NOxBOX of steps taken under it.

Transmission of this FSN

This notice is to be issued to all affected distributors for the units listed in the table above.

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 (if appropriate).

Please transfer this notice to other organisations on which this action has an impact and, in particular, to any organisation to whom an affected device has been transferred or sold (if appropriate).

This notice will be issued to the manufacturers Notified Body and Competent Authority, and to other Competent Authorities as appropriate.

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

No further advice or information is expected in relation to this FSN.

Contact reference Person

Karen Ring, Quality Manager

NOxBOX Ltd, 1080-1081 Galley Drive, Kent Science Park, Sittingbourne, Kent ME9 8GA, UK

Tel: 01795859430 Email: [REDACTED]

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

Signed: [REDACTED]

Name:	Karen Ring	Position:	Quality Manager	Date:	08 Mar 2019
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4 April 2019

Dear Sir

Re: NOxBOXi Field Safety Notice CAPA-0013

NOxBOX Ltd, has issued the above Field Safety Notice regarding the recall of NOxBOXi medical devices. This FSN is due to a potential fault (fracture) with capacitors fitted on the power printed circuit board. All PCBs used within the NOxBOXi are Automatically Optically Inspected, but these fractures may not be seen with the naked eye or the optical equipment. Changes in temperature, humidity and transportation may cause them to fail at any point. If this happened during the use of the device it may cause it to power OFF, causing an immediate cessation of therapy.

As the PCBs cannot be inspected to identify any failure of this nature it is not possible to determine if they are damaged, therefore the devices that have been identified as containing capacitors from the affected batch are to be returned to NOxBOX for PCB rework, where the affected component will be replaced with capacitors from a separate batch.

The FSN only applies to 7 devices, of these, one unit serial number: NI100919, was shipped to our distributor in Singapore.

Please ensure that the FSN is communicated to the appropriate personnel who need to be aware within your organisation or to any organisation impacted by the FSN. Ensure a copy is circulated to the Chairman Medical Board and relevant Head of Departments.

Yours Faithfully



Karen Ring
Quality Manager
NOxBOX Ltd