PRODUCT: NOxBOXi Nitric Oxide Delivery System
SUBJECT: NOxBOXi Device Rapid Succession of Conflicting User Inputs (Button Pushes)
UDI-DI: 05060541640009
EU Manufacturer Single Registration Number (SRN): GB-MF-000009734
Reference: NBL-TB-0004-EN
Date: 10 Nov 2025

URGENT FIELD SAFETY NOTICE

NOxBOXi Nitric Oxide Delivery Device (NOXBOX-I, UDI-DI: (01)05060541640009)

RE: NOxBOXi Nitric Oxide Delivery Devices, Rapid Succession of Conflicting User Inputs (Button Pushes)

Attention: NOxBOX's Distributors and their customers

Dear Distributors and Customers,

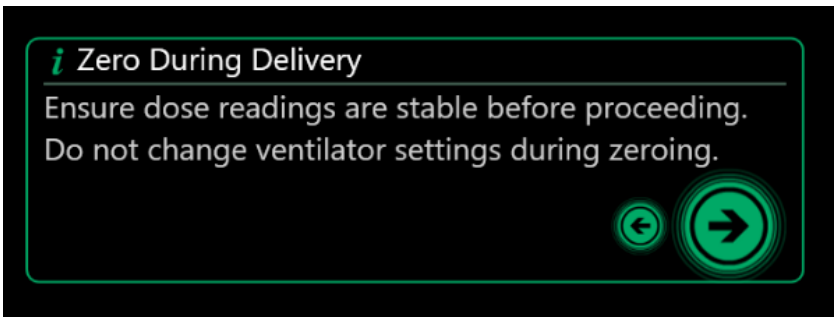
This letter is to inform you of a field safety corrective action involving the NOxBOX Ltd. ("NOxBOX") NOxBOXi® Nitric Oxide Delivery Device. NOxBOX is initiating this voluntary corrective action after becoming aware of potential malfunctions associated with rapid pushing of buttons on all NOxBOXi devices which could occur on all currently released software versions.

NOxBOX has received 13 complaints from customers in the U.S. with two reported adverse events related to the use of the NOxBOXi Nitric Oxide Delivery System due to users performing a rapid succession of conflicting inputs that may cause the device to trigger a system restart. To date, NOxBOX has not received any complaints or reports of adverse events related to this issue outside of the U.S.

In the event this issue occurs and cannot be promptly resolved by troubleshooting or the device is not promptly restarted and a backup device is not available, there is a potential risk of an interruption in therapy, which could cause a drop in blood oxygen levels (desaturation) or increased pressure in the artery that carries oxygen from the heart to the lungs (pulmonary artery) which may pose risks to patients with congenital heart disease. Any further complications will depend upon the nature of the patient's condition.

This issue may occur when two or more on-screen buttons are pressed by the user in a rapid succession (e.g., sensor zero, see Figure 1 below):

Fig. 1



Actions Required by the Distributor

Please complete and return the Distributor Response Form provided as **Attachment A** to NOxBOX.

Pass on this notice to all those who need to be made aware within your organization.

Pass on this notice together with Attachment B to your customers. Please add your contact details in Attachment B before passing on.

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

Please report all device related incidents to the manufacturer, or local representative and to the Competent Authority if appropriate.

Actions Required by End Use Customer

Please complete and return the Customer Response Form provided in **Attachment B** to the distributor.

Pass on this notice to all those who need to be made aware within your organization or to any organization where the potentially affected devices have been transferred or for which this action has an impact (as appropriate). Customers should ensure that all personnel using the device are provided with a copy of the recommendations below and to post this notice near the device.

Please report all device related incidents to the manufacturer, distributor, or local representative and to the local Competent Authority if appropriate.

Recommended Actions for Users

Users should avoid rapidly pressing buttons in quick succession (e.g., go to next screen, accept a value, change a value, backing out, repeating this) as it is necessary to allow an opportunity for the device to respond to user inputs before the next command to avoid a potential software interruption and subsequent restart.

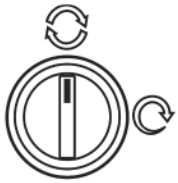
In the event of an unexpected NOxBOXi system restart while interacting with the device on screen prompts, the device will display the 'System Diagnostics' notification (see Figure 2 below). To continue therapy, the user should switch the device to Manual Mode from the Intelligent Mode to deliver Nitric Oxide (NO) via the NOxMIXER™ (manual mode, see Figure 3 below) and select the red on-screen 'restart' button.

NOTE: There are other situations where a 'System Diagnostics' notification might be issued by the device, and the following instructions will not resolve this error message.

Fig. 2

Fig. 3

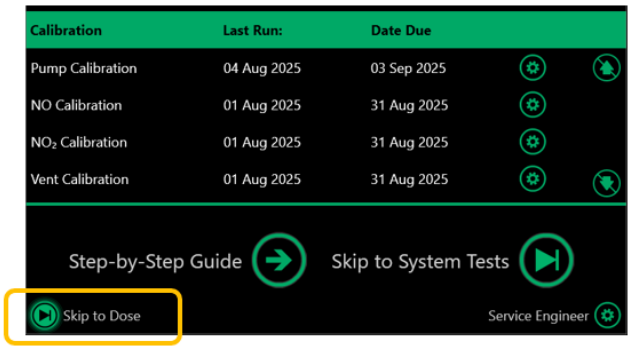
Intelligent Mode



Manual Mode

Once the System restart has completed, Intelligent delivery may be resumed via the 'Skip to Dose' function (see Figure 4 below).

Fig. 4



Further Information

NOxBOX has notified the applicable Regulatory Authority regarding this Field Safety Notice.

NOxBOX is in the process of developing a new software version that will include a modification to the software to resolve this issue, which will be released pending required regulatory review and approval. Once the software version is released, NOxBOX will contact distributors to make arrangements for updating the software in devices. Thus, it is very important to complete and return the Response Forms at Attachment A and B as soon as possible.

We appreciate your assistance in responding to this notification. If you have any questions about this notice or need assistance, please contact a Quality Assurance representative at NOxBOX_qatech@linde.com.

Thank you for your prompt attention to this matter.

Sincerely,

Karen Ring
Quality & Regulatory Manager

TECHNICAL BULLETIN

Bulletin Reference:	NBL-TB-0008
Date:	23 March 2026

NOxBOX
A Linde company

PRODUCT: NOxBOXi

SUBJECT: V18.6 Software Update

Dear Customer,

A new software update for the NOxBOXi Nitric Oxide Delivery Device is now available, release version 18.6.0.14. This software was developed to add new features and address issues previously communicated in via FSN (Technical Bulletin NBL-TB-0004). The software has been fully validated for release to upgrade devices in the field.
This update is recommended to be installed on all NOxBOXi devices at their next scheduled periodic maintenance/service, or sooner should the device become available.

The update introduces the following summarised changes to the user interface and experience:

- Cylinder Low pressure detection improved to avoid false positives for low cylinder alarms.
- Change in priority for the 'Vent Flow Idle' alarm based on risk evaluation and to reduce nuisance alarms during limited use in operating rooms.
- Enhanced background calibration of Vent Flow sensor.
- Changes to NO_2 Calibration process to reduce sensor false failures during servicing.
- Turkish (Türkçe) language selection added.
- Increase in data captured in Log files to better indicate settings when changed by user.
- Software displayed on-screen additionally includes control firmware version to support servicing.

Distributors should contact their NOxBOX representative to coordinate obtaining the software download and appropriate instructions for upgrading the NOxBOXi System.

If you require more information regarding the contents of this Technical Bulletin, please contact a Quality Assurance representative at NOxBOX_qatech@linde.com, alternatively you can raise a support ticket.

Thank you for your continued business.

Yours Faithfully,

Karen Ring
Quality & Regulatory Manager

NOxBOX Ltd
Unit 1, Eurolink Gateway,
Castle Road, Sittingbourne,
Kent, ME10 3AG, England

Phone +44 (0)1795 859430
Email: ask@noxboxltd.com

Registered in England and Wales
Company no. 9563860
VAT 217896861

Registered Office:
Forge, 43 Church Street West,
Woking, Surrey, GU21 6HT, England