URGENT FIELD SAFETY NOTICE FOR USERS

FSCA reference: ANSM: R2426769/Manufacturer: PDCA-2024-081

Date: October 11, 2024

Objective of the FSCA: Important safety information concerning use of inhaled NO (iNO) Delivery and Monitoring systems

Products concerned: All models of the iNO Delivery and Monitoring System, whether registered under Council Directive 93/42/EEC by Maquet Critical Care between 2014-12 and 2022-07 or registered under Regulation (EU) 2017/745 by INOSYSTEMS from 2022-08: SoKINOX, ServiNO, Monnal iNO.

A detailed list of the serial numbers will made available to each distributor concerned on request.

Devices registered under Council Directive 93/42/EEC	
Basic UDI-DI	**Description**
B-FRMF000011282IN000196CR	SOKINOX iNO Delivery and Monitoring System
Reference: 66 94 550	
B-FRMF000011282IN000279CW	ServiNO iNO Delivery and Monitoring System
Reference: 68 81 700	
Devices registered under Regulation (EU) 2017/745	
Basic UDI-DI	**Description**
376033338INOTHERAPYEF	iNO Delivery and Monitoring System, SoKINOX, Monnal iNO models
References: IN000100; IN000101; IN000103; IN000104; IN000105; IN000106; IN000108; IN000109; IN000111; IN000112; IN000120; IN000121; IN000122; IN000123; IN000254;	

iNOsystems
PARC DE HAUTE TECHNOLOGIE
7 RUE GEORGES BESSE, 92182 ANTONY CEDEX, France
SIMPLIFIED JOINT STOCK COMPANY (SAS) WITH CAPITAL OF €4,000,010
REGISTER OF COMPANIES OF PARIS No. 844 799 239 – COMPANY UNIT REGISTRATION NUMBER (SIRET) 844 799 239 00018 - VAT No. FR 62 844 799 239 - CORE ACTIVITY CODE (APE) 6420Z

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IN000260; IN000261; IN000262; IN000263; IN000264; IN000265; IN000266; IN000267; IN000272

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Dear Customer,

In connection with monitoring feedback from customers, INOSYSTEMS wishes to distribute this Field Safety Notice to all customers who own SoKINOX, ServiNO or Monnal iNO models of the inhaled NO Delivery and Monitoring system.

We ask you to read the information provided in this document and to distribute it to all your users.

The health authorities concerned have been informed of this voluntary safety information.

For further information, do not hesitate to contact your usual representative.

1. Description of the risk

In the course of post-market surveillance, INOSYSTEMS has received several **reports from maintenance workshops** of malfunctions in the backup system of devices for inhaled NO (iNO) delivery and monitoring.

The backup NO treatment system is pneumatic and autonomous. This system is intended for short-term use in the event of:

- Manual ventilation of patients with or without power supply to the device, e.g. transport of patients within the institution,
- Breakdown, or the iNO Delivery and Monitoring system is not operational, until it can be replaced by another iNO Delivery and Monitoring device,
- Breakdown or unavailability of the ventilation system to which the iNO Delivery and Monitoring system is connected, until it can be replaced by another ventilation device.

In all three cases, a fully operational backup system limits the risk of the unexpected rebound of pulmonary arterial hypertension, described as a side effect for patients in the User's Manual if the NO treatment is suddenly interrupted. This rebound effect can cause serious damage to health or the death of patients who are already vulnerable.

Analysis of feedback from the field reveals corrosion in the pneumatic circuit check valves of the backup system as the main cause of malfunctioning of the backup system. For safety reasons, there are two check valves in the pneumatic circuit of the backup system. As long as one of the check valves is operational and supplied, the risk for patients is negligible.

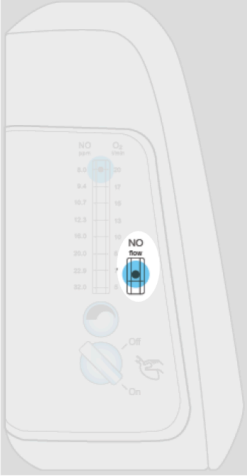
The corrosion is due to the presence of corrosive substances such as nitrogen dioxide (NO_2), resulting from the combination of nitric oxide (NO) with atmospheric humidity. Atmospheric

humidity enters the circuits of the device mainly when connecting/disconnecting NO hoses.

This information was used to update the risk analysis of the backup system; as the level of residual risk has increased, and in spite of **the absence of feedback from users concerning patients during treatment**, INOSYSTEMS considers it necessary to remind users of the good practice for use of the iNO Delivery and Monitoring system and its backup system.

2. Reminder of the User's Manual

If you have devices as described in the introduction, we ask you to remind all potential users in your distribution area, **within three months**, of the good practice for use of these products:



- Carry out a check before use, before connecting the system to a patient [User's Manual Section 4.3].

- Connect the device and open the two cylinders of NO gas, as indicated in the form of warnings or instructions in the User's Manual [Sections 3.1.1, 3.3.1, 4.1, 4.3.2, 9.1.2, 9.1.9].

- Check the delivery of NO via the backup system before and during use by checking the O_2 flow meter and the NO flow indicator at regular intervals [User's Manual Section 4.11.1].

- Have preventive maintenance carried out according to the maintenance policy in force by personnel qualified by INOSYSTEMS [User's Manual Section 6.3].

Reminder: any malfunction in the backup system identified during the check before use or during preventive maintenance must be reported to INOSYSTEMS by lodging a complaint in the complaint management tool provided. If the malfunction is confirmed, contact your maintenance manager in order to replace the delivery unit (reference IN000290) before putting the device back into service.

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Field Safety Notice R2426769 dated 10/14/2024
Please complete and return this form by email to:
materiovigilance@inosystems.fr

☐	*I confirm that I have received, read and understood the Field Safety Notice.
☐	*I have identified the users of SoKINOX, ServiNO and Monnal iNO models of the iNO Delivery and Monitoring systems.
☐	*I have informed the users identified in this way of the Field Safety Notice.
☐	Neither I nor any of my customers have devices concerned by this Field Safety Notice.

Country*	The distributor writes the countries in his/her distribution area here.
Name*	The distributor writes his/her name here.
Position	
Email* and phone number	
Signature*	The distributor signs here.
Date *	The distributor writes the current date here.

Required information is marked with an asterisk (*).

It is important that your organization takes the measures detailed in this Field Safety Notice and confirms receipt of it.

We need your organization's reply as proof, in order to monitor the distribution of this safety information.

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