IMPORTANT REMINDERS FOR QUALIFIED SERVICE TECHNICIANS

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

Date: October 11, 2024

Objective of the FSCA: Important safety information concerning maintenance 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 be made available to each distributor concerned on request.

Basic UDI-DI	**Description**
Devices registered under Council Directive 93/42/EEC	
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	
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; IN000260; IN000261; IN000262; IN000263; IN000264; IN000265; IN000266; IN000267;	

iNOsystems
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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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Basic UDI-DI	Description
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 qualified technicians who service these products in your distribution area.

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 preventive maintenance of the iNO Delivery and Monitoring system and its backup system.

Furthermore, lessons learned in the field by INOSYSTEMS since August 2022 show that compliance with maintenance procedures for checking the functioning of the backup system (see Section 2) during preventive maintenance by persons qualified by INOSYSTEMS is an effective method of identifying and dealing with malfunctions in the backup system during maintenance, and preventing incidents during clinical use.

2. Preventive action

If you have devices as described in the introduction, we ask you to remind, **within 3 months**, all qualified staff carrying out preventive maintenance on these products, of the preventive maintenance procedures for detecting malfunctions in the backup system, as indicated in the current Maintenance Manual [YL180193 EN/YL180192 FR, version 2 issued in April 2024].

- A leak in the backup system is detected:
    - during the leak test for NO inlets, described in Chapter 5.4.1 Gas administration module.
    - and/or during the leak test on the backup system, described in Chapter 5.4.2 O_2 backup system.
- A blocked backup system, not delivering NO, is detected during the check conducted after calibrating the gas analysis apparatus, described in Chapter 5.3.2 Backup system verification.
    - Checking of the backup delivery system must be carried out with a single cylinder of NO gas connected at a time. The check must be carried out for both NO inlets.

Please note that any non-conformities detected during these maintenance operations must be reported to INOSYSTEMS by lodging a complaint in the complaint management tool provided. If the malfunction is confirmed, the device should be returned to clinical working order by replacing the delivery unit (reference IN000290).

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 persons carrying out preventive maintenance for the SoKINOX, ServiNO and Monnal iNO models of the iNO Delivery and Monitoring systems in my distribution area.
☐	*I have informed the persons identified in this way of the Field Safety Notice.
☐	Neither I nor any of my colleagues/partners are 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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