Mallinckrodt™ Pharmaceuticals

INOblender®

Operation and Maintenance Manual

(English)

Part No. 20732 Rev-02
2014-02

User Responsibility

This Product will perform in conformity with the description contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked prior to use following the Pre-Use Checkout procedure described in section 3. A defective Product should not be used. Parts that are broken, missing, visibly worn, distorted or contaminated should be replaced immediately.

Should such repair or replacement become necessary, the manufacturer recommends that a telephone request for service advice be made to the local distributor. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by the manufacturer or local distributor. The Product must not be altered. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Mallinckrodt Representatives.

Outside the U.S.A. and Canada, check local laws for any restrictions that may apply. Caution: U.S. Federal and Canadian law restrict this device to sale by or on the order of a licensed medical practitioner.

Inhaled Nitric Oxide mixtures must be handled and stored in compliance with federal, state and local regulations.

These products have unit serial numbers with coded logic which indicate the year of manufacture and a sequential unit number for identification.

BL 20051234	The first two digits indicate the product, the next four numeric digits indicate the year of manufacture, and the next four digits are the sequential unit number produced that year.
10026	INOblender (DISS, 800 ppm, English)
10004	INOblender (DISS, 800 ppm, English)
10021	INOblender (NIST, 400 ppm, English)
10070	INOblender (NIST, 800 ppm, English)

Contents

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1/ General Information

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Cautions and Warnings

WARNING:

Warnings tell you about dangerous conditions that can cause injury to the operator or the patient if you do not obey all of the instructions in this manual.

Caution:

Cautions tell you about how to properly use the equipment and conditions that could cause damage to the equipment.

Read and obey all warnings and cautions.

Note:

Notes provide clarification or supplemental information.

Blue arrow denotes required user action.

Cautions:

- Outside the U.S. and Canada, check local laws for any restrictions that may apply. U.S. federal law and Canadian law restrict this device to sale by or on the order of a licensed medical practitioner.
- Proper use of this product depends on careful reading and understanding of labeling and instructions.
- To help ensure proper operation of this product, complete the pre-use checkout prior to each use.
- When not in use, the O_2 flow meter and the INOMAX cylinder valve should be turned off.
- When cleaning, do not submerge in liquid.
- Do not autoclave.
- Refer to the manufacturer's procedures for using the resuscitation bag.

WARNINGS:

- **The purge procedure must be followed to help ensure NO_2 is purged from the pressure regulator, INOblender and hoses before the manual resuscitator bag or nasal cannula is connected to the patient. The manual bag should be squeezed repeatedly during use to avoid NO_2 building up in the bag. If the bag is not squeezed repeatedly while delivering INOMAX the bag should be removed from the patient and the purge procedure performed before continuing.**
- **The INOblender should only be used in accordance with the indications, usage, contraindications, warnings and precautions described in the INOMAX drug package insert and labeling. Refer to this material prior to use.**
- **Persons using this device should be trained on and experienced in the use of this device to assure effective administration of INOMAX and to avoid injury to the patient or others resulting from inhalation of excess INOMAX, nitrogen dioxide or other reaction products.**
- **The National Institute for Occupational Safety and Health (NIOSH) in the U.S. has a recommended time-weighted (8 hours) average concentration of 25 ppm for NO and a limit of 1 ppm for NO_2. Persons using the INOblender who may be particularly sensitive to NO or NO_2, or who may be exposed to these agents for prolonged periods as a result of the use of this device, should be aware that the INOblender does not scavenge the exhaust drug, and that this is vented at the resuscitator bag. Ambient concentrations of NO or NO_2 are expected to be less than 0.2 ppm when using the INOblender, see Section 1 Environmental Effects.**

Introduction

The INOblender allows users to select a concentration of INOMAX, (nitric oxide in a balance of nitrogen), to be mixed into a user set flow of oxygen which is delivered to a patient. The intended use for the INOblender is as a back up to a primary INOMAX delivery system; or for short term attended use when a primary delivery device cannot practicably be used. This intended use includes applications within a medical facility and transport outside of a medical facility. The INOblender is not intended for use as a primary INOMAX delivery system for long term use.

Definitions and abbreviations

N_2	Nitrogen
NO	INOMAX (nitric oxide) for inhalation
NO_2	Nitrogen dioxide
NO/N_2	Nitric oxide (NO) and nitrogen (N_2) gas mixture
O_2	Oxygen
ppm	Parts Per Million
Set NO	The dose of INOMAX set by the user
v/v	Volume to volume

Note: This manual shows the Set NO displays associated with the 0-80 ppm range.

Symbols used in this manual or on the system

Symbols replace words on the equipment and/or in this manual. These symbols include:

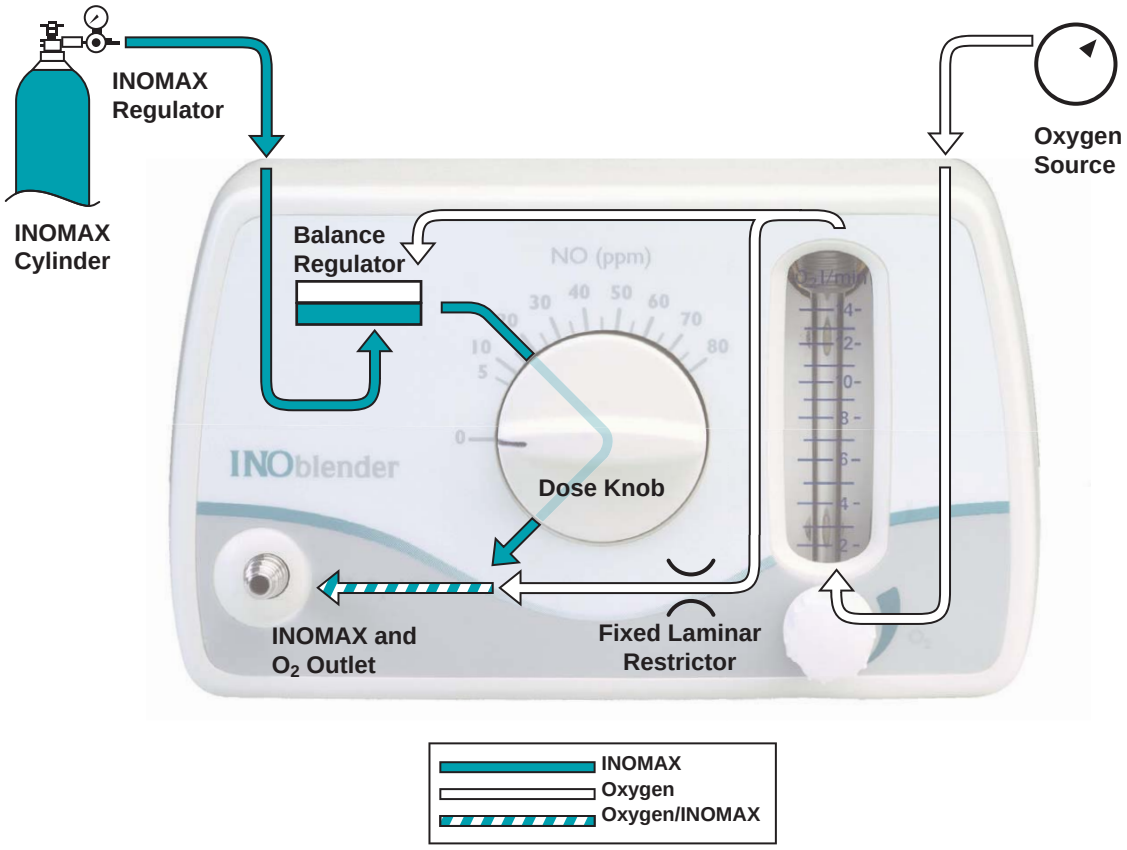
	Attention, consult accompanying documents!
	Authorized Representative in the European Community
	Catalog Number
	Date of Manufacture
	Fragile, handle with care
	Keep Dry
	Manufacturer
	NO or O_2 Gas Inlet
	NO Gas Outlet
	Pneumatic Inlet

	Pneumatic Outlet
Rx ONLY	Prescription use only
	Pressure
	Product packaging is able to be recycled
	Protect from heat and radioactive sources
SN	Serial Number
	Storage Temperature Limitation
	Storage Humidity Limitation
CE	This product is in compliance with the European Council Directive 93/42/EEC and its amendments concerning medical devices

Theory of Operation

1. The INOblender connects to a 3-5 bar (45-75 psig) oxygen supply. The oxygen flow is then controlled by an integrated oxygen flow meter (2-14 lpm). There is a fixed restrictor in the oxygen flow path which creates a pressure proportional to the oxygen flow rate.
2. The INOblender is also connected to a 2 bar (30 psig) INOMAX (800 ppm or 400 ppm) supply.
   - The INOMAX flow is controlled by a balance regulator in proportion to the oxygen pressure caused by the fixed restrictor and the INOblender setting.
   - The balance regulator maintains a constant INOMAX dose for varying oxygen flow rates.
3. The flows of O_2 and INOMAX are mixed prior to exiting the INOblender outlet.

INOblender Schematic Diagram



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Environmental Effects

The National Institute for Occupational Safety and Health (NIOSH) has recommended exposure limits as follows (ref 1).

NO	time-weighted (8 hours) average concentration limit of 25 ppm
NO_2	ceiling limit of 1 ppm.

The environmental build up of nitric oxide in a well ventilated ICU room can be evaluated using the following calculation:

Room size	10 ft square (approx. 3 meters)
Room volume of air	27,000 L
Room ventilation at 6 room changes / hr	2,700 L/min
NO flow into room	14 L/min at 80 ppm
Average room concentration of NO	80 x 14 / 2,700 = 0.4 ppm of NO

This theoretic calculation can be supplemented by measurements as performed by Hess et al. The NO and NO_2 concentrations were measured using a chemiluminescence analyzer when 100 ppm of NO at 8 L/min was delivered into a room with no scavenging being used. The maximum NO and NO_2 concentrations measured over a one-hour period were 0.12 ppm of NO and 0.03 ppm of NO_2.

Both methods show that the exposure levels are significantly less than the levels recommended by NIOSH.

If the location for using NO has uncertain ventilation, then the location should be evaluated for NO and NO_2 build up prior to use.

Ref. 1 Centers for Disease Control, Atlanta, GA 30333 USA. NIOSH Recommendations for Occupational Safety and Health Standards 1988. August 26, 1988 / vol. 37 /No. 9.

Ref. 2 Hess et al, Use of Inhaled Nitric Oxide in patients with Acute Respiratory Distress Syndrome, Respiratory Care, 1996, vol. 41, No 5, pg. 424-446.

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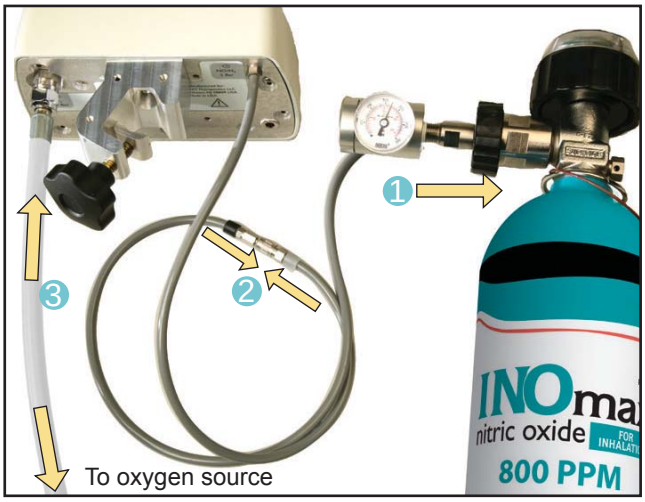
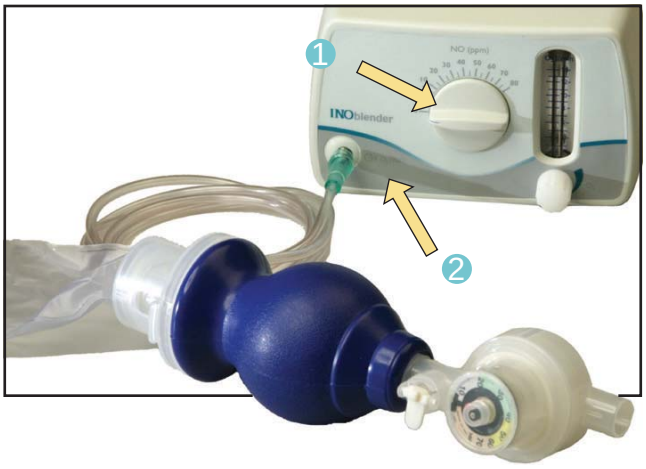
Setup

Check the INOMAX gas cylinder for the correct product identity labels, cylinder concentration (800 or 400 ppm) and expiration date. Ensure the INOMAX gas cylinder has > 14 bar (200 psig).

Note:	• For the CGA-type INOMAX regulator connector, ensure the white plastic tip is not chipped or cracked. Remove and replace as necessary. (see Replacing the tip on the INOMAX regulator, Page 16). • For the ISO-type regulator connector, check that the O-ring is present and is not damaged (see Replacing the tip on the INOMAX regulator, Page 17).



1. Connect a high-pressure regulator to an INOMAX cylinder and hand tighten the fitting to the INOMAX cylinder.
2. Connect the INOMAX regulator hose to the INOblender inlet hose using the quick connect fittings.
3. Connect the oxygen supply to the O_2 inlet fitting. (see part list for correct oxygen hose) Note: 3.5 bar (50 psig) nominal



1. Make sure the NO dose setting dial is turned to zero.
2. Attach a manual resuscitation bag to the INOblender outlet fitting.

The INOblender is now set up. Proceed to Section 3/Pre-use Checkout.

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3/ Pre-Use Checkout

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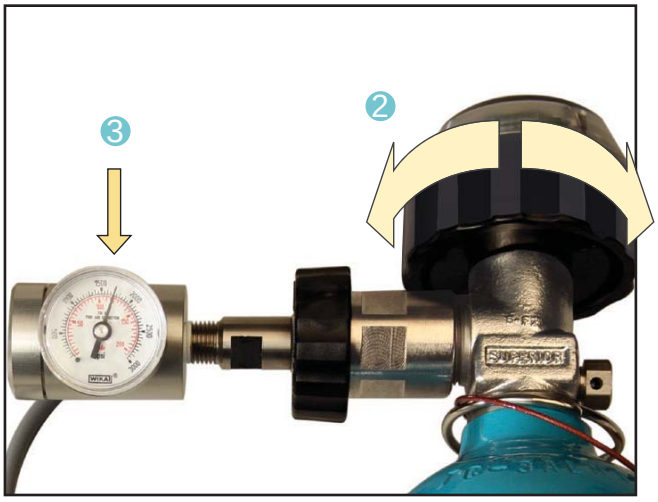
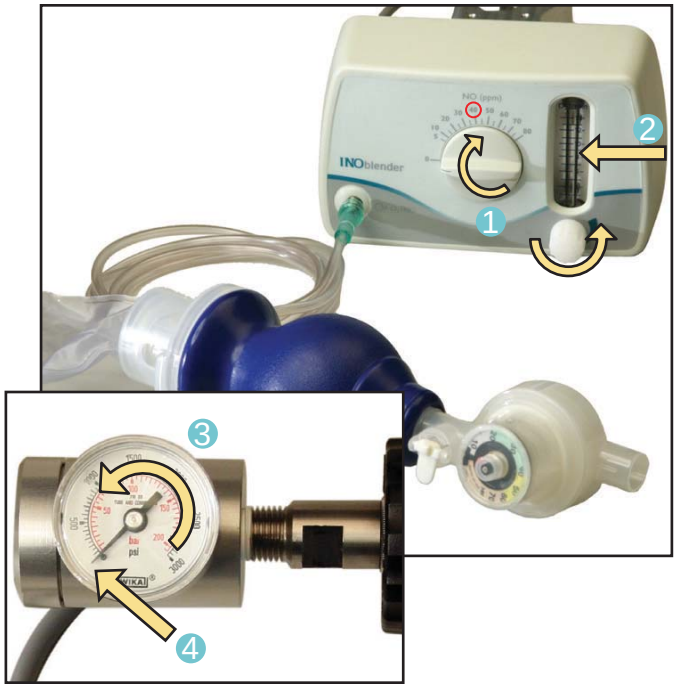
Pre-use Checkout

Caution:	To help ensure proper operation, complete the pre-use checkout prior to each use.

Set-up the INOblender as described in Section 2/Setup





High-Pressure Leak Test

1. Make sure NO dose setting dial is turned to zero and flow meter is OFF.
2. Open and then close the cylinder valve.
3. Pressure gauge should indicate > 14 bar (200 psig).
4. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no pressure decrease is observed, high-pressure leak test successful, proceed to Delivery Confirmation and Purge.
5. If observed pressure decrease continues, see Section 5/ Maintenance; Cylinder Leak Check.
6. If leak cannot be traced, replace the INOblender.

Delivery Confirmation and Purge

1. Set the INOblender to 40 ppm when using an 800 ppm cylinder (20 ppm when using a 400 ppm cylinder).
2. Set the oxygen flow on the INOblender flow meter to 10 L/min to begin purge.
3. Ensure the pressure gauge decreases approximately 14 bar (200 psig) in 10 seconds (± 2 sec.).
4. Continue purging until pressure gauge reads zero.

Note:	If the pressure does not decrease, then the INOblender is not delivering NO and the INOblender should be replaced.

The INOblender is now ready for use. Proceed to Section 4/Operation.

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Operation

WARNINGS:

- **The purge procedure must be followed to help ensure NO_2 is purged from the system before the manual resuscitator bag is connected to the patient.**
- **The manual bag should be squeezed repeatedly during use to avoid NO_2 from building up in the bag.**
- **If the bag is not squeezed repeatedly while delivering INOMAX, the bag should be removed from the patient and the bag purge procedure performed before continuing.**
- **The INOblender should be upright when setting the oxygen flowrate for accurate setting.**
- **Do not use pneumatically powered nebulizers with the INOblender. This will result in significant over delivery of INOMAX (nitric oxide) for inhalation in excess of 80 ppm (40 ppm with a 400 ppm cylinder).**
  - **The INOblender outlet pressure has been validated for use up to 400 millibar (5.8 psig) pressure. The amount of back-pressure generated by pneumatic nebulizers is significantly greater [1.4 - 2.0 bar (20-30 psig)] and will result in over delivery of INOMAX in excess of 80 ppm with an 800 ppm cylinder (40 ppm with a 400 ppm cylinder). The user adjusted dose setting on the INOblender will not correlate with, or have an effect on, the actual delivered dose.**
  - **In addition, the INOblender flowmeter is not back-pressure compensated and will display a lower than actual flow rate when pressure is applied to the outlet.**

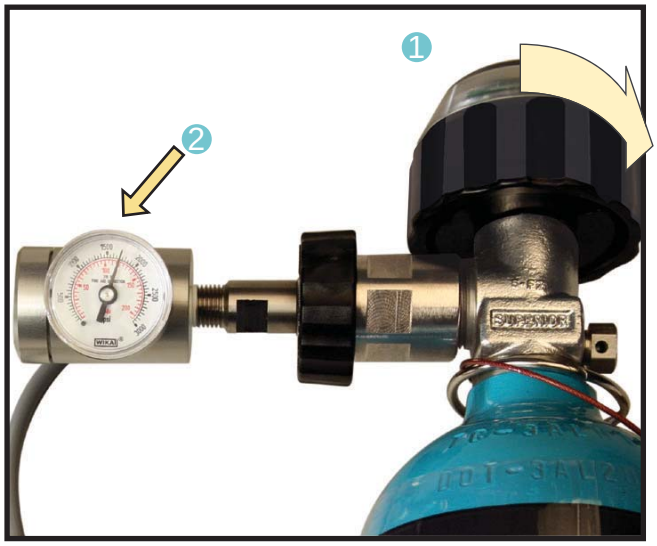
Cautions:

- When not in use, the oxygen flowmeter and the INOMAX cylinder valve should be turned off.
- When the INOblender is used with an oxygen/air blender:
  - The specification for INOMAX delivery when using the INOblender with 100% oxygen is +/- 20% of setting or 2 ppm (whichever is greater). The use of 100% oxygen at 3.4 bar (50 psig) is the labeled specification for the INOblender.
  - A user may determine that some clinical conditions may necessitate the use of an oxygen/air blender with the INOblender to achieve FiO_2 levels less than 100%.
  - Using oxygen/air mixtures (21% to 95% v/v) will reduce the delivered NO concentration by up to 10% of setting or 1 ppm (whichever is greater) compared to using 100% oxygen alone, resulting in a cumulative error up to +/- 30% of setting or 3 ppm (which ever is greater).
- Refer to the manufacturer's procedures when using the manual resuscitator bag.
- When finished, turn the NO cylinder valve OFF and allow the oxygen to flow until the NO pressure gauge reads zero, then turn the oxygen flow OFF.

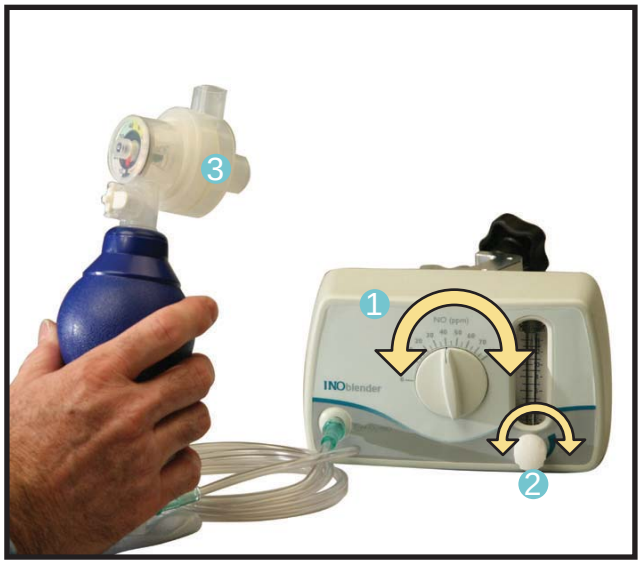
Prior to operation, complete the Pre-Use Checkout in Section 3.

The purge procedure contained in the Pre-use Checkout helps ensure any NO_2 is purged from the pressure regulator, INOblender and hoses before the manual resuscitator bag is connected to the patient.

Note:	Depressurize the INOMAX regulator by using the purge port on the back of the INOmax DS_{IR} prior to removing from the cylinder valve.



1. Open the INOMAX cylinder valve.
2. Check for supply pressure of > 14 bar (200 psig).



Adjust Settings

1. Turn the INOblender setting dial to the desired concentration (5 to 80 ppm for an 800 ppm cylinder and 2.5 to 40 ppm for a 400 ppm cylinder).
2. Turn the O_2 flowmeter to the desired flow rate (5 to 14 L/min).
3. Squeeze the manual resuscitator 3-4 times to purge the NO_2 from the system.

The INOblender is now ready for patient use.

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Maintenance

Cautions:

- When cleaning, do not submerge in liquid.
- Do not autoclave.

Note:	The INOblender does not contain any user repairable parts.

Cleaning Procedure

Caution:

- Apply cleaning agent to a cloth before application; do not spray cleaning agent directly on the device. It is important to prevent pooling and direct contact with open connections which can cause damage over time.
  - Clean the outer surface of the INOblender with a soft cloth dampened in a mild soap and water solution (Example: Palmolive Ultra antibacterial, 4 drops per 50 mL of warm water), isopropyl alcohol (70%), or with one of the following cleaning agents while following the manufacturer's recommendations.

Cleaning Agent	Active Ingredients
Precise Hospital Foam Cleaner Disinfectant by Caltech Industries	o-Phenylphenol < 0.37% Other ingredients 99.63%
Pure Green 24 by Pure Green, LLC	SDC – silver ions 0.003% Citric acid 4.84% Other ingredients 95.157%
PDI Super Sani Cloth by PDI	n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.25% n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.25% Isopropyl alcohol 55% Inert ingredients 44.50%
Sani Cloth HB by PDI	n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.07% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.07% Inert ingredients 99.86%
Asepti-HB by Ecolab Inc.	n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.07% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.07% Inert ingredients 99.86%
Cavicide and CaviWipes by Metrex	Diisobutylphenooxyethoxyethyl dimethyl benzyl ammonium chloride 0.28% Isopropyl alcohol 17.2% Inert ingredients 82.52%

Bioquell Hydrogen Peroxide Sterilant

Bioquell Hydrogen Peroxide Sterilant and hydrogen peroxide vapor generators are regulated by the US Environmental Protection Agency (EPA) as pesticide chemicals in accordance with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Use of these products in cleaning/disinfection processes have not been validated with the INOblender. Do not use these products to decontaminate the INOblender or any ancillary products used with the INOblender.

Yearly Calibration

The INOblender calibration should be checked every 12 months using the NO monitor of the primary NO delivery system. The test points should include all the control settings at oxygen gas flows of 5 and 14 L/min. If the INOblender is outside of the accuracy specification, it should not be used.

Contact Customer Support at the number on the back cover of this manual for repair.

Replacing the CGA 626 tip on the INOMAX regulator

Note:	• Depressurize the INOMAX regulator by using the purge port on the back of the INOmax DS_{IR} prior to removing from the cylinder valve. • Check the INOblender and connection hoses for signs of wear and damage. • For the CGA-type regulator connector, ensure the white plastic tip is not chipped or cracked. Remove and replace as necessary. (see Figure 5-1).

Figure 5-1

1. Disconnect the regulator from the INOMAX gas cylinder.
2. Remove the old CGA 626 tip (for ISO see Figure 5-2) by pulling on the tip (a) and turning it counterclockwise (b) (see Figure 5-1).
3. Ensure the threads are clean on the regulator tip (if required, use a lint free cloth).
4. Install the new tip:

   Flex the four prongs by squeezing two prongs at a time using only your fingers. This will help start the new tip into the threads. Turn the tip clockwise when threading the tip. When the tip is fully inserted, it should turn freely.

Replacing the O-ring on the ISO 5145 INOMAX regulator fitting

Note:	• Depressurize the INOMAX regulator by using the purge port on the back of the INOmax DS_{IR} prior to removing from the cylinder valve. • Check the INOblender and connection hoses for signs of wear and damage. • For the ISO-type regulator connector, check that the O-ring is present and is not damaged (see Figure 5-2).

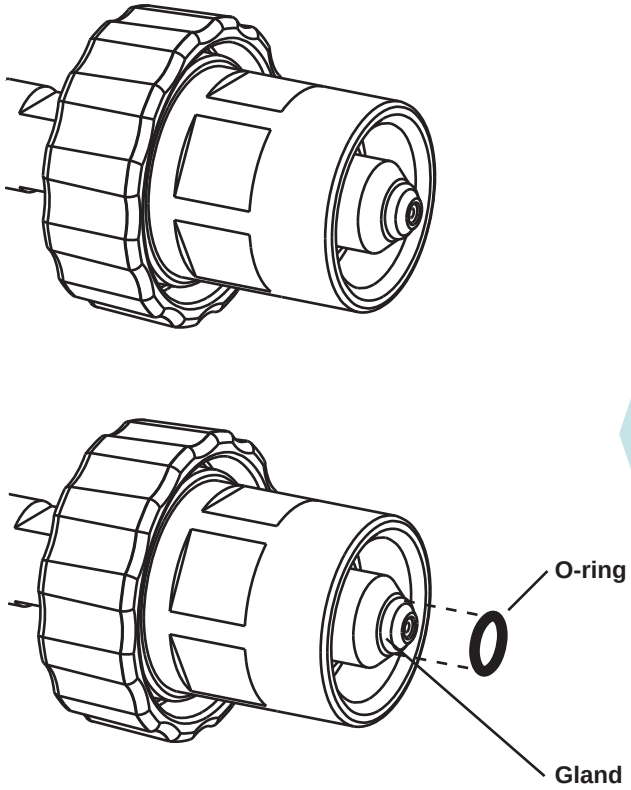


Figure 5-2

Note:	Depressurize the INOMAX regulator by using the purge port on the back of the INOmax DS_{IR} prior to removing from the cylinder valve.

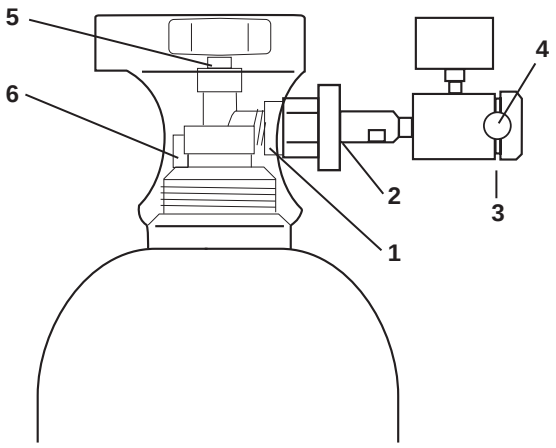
1. Disconnect the regulator from the INOMAX therapy gas cylinder.
2. Remove the old ISO O-ring by rolling it off its groove (see Figure 5-2).
3. Clean the connector tip (if required, use a lint free cloth).
4. Roll the new O-ring into its groove. When correctly installed, it should not be removable by turning it.

Caution:	Do not use hard objects to remove the O-ring as they may damage the metal gland and cause a leak.

Cylinder Leak Check

If a leak is suspected during the high-pressure leak test (see Section 3/Pre-Use Checkout; High Pressure Leak Test), the following steps can be taken to check for leaks (see Figure 5-3 for possible cylinder gas leak locations) in the INOMAX regulator or INOMAX cylinder.

Note:	Refer to hospital policies and procedures for dealing with leaking gas cylinders. Additional information regarding environmental effects can be found in the section 1/General Information.



1. Cylinder Valve Regulator Connection
2. INOMAX Regulator Hand Wheel Connection
3. Regulator End Cap Connection
4. Tamper Evident Tape
5. Valve Nut
6. Safety Pressure Release Device

Figure 5-3

1. Ensure that INOMAX regulator is connected to cylinder valve outlet (hand-tighten only), that the cylinder valve is open, and that the cylinder has more than 14 bar (200 psig).
2. Apply soapy water to points 1, 2, 3, 5 and 6 (see Figure 5-3); if bubbles form, there is a leak.
3. If there are no bubbles, leak may be inside INOblender or INOmax DS_{IR} and cannot be repaired. Replace INOblender or INOmax DS_{IR} and contact Customer Support.

Recommended actions should a leak be detected:

1. A leak detected at points 1 and 2 (see Figure 5-3) may be corrected by tightening the INOMAX regulator hand wheel.
   a. If cylinder valve is open, close cylinder valve and tighten INOMAX regulator hand wheel.
   b. Open cylinder valve and reapply soapy water to points 1 and 2.
   c. If bubbles form, there is a leak.
   d. Remove INOMAX regulator and check white plastic tip on INOMAX regulator for chips or cracks. Replace if necessary (see replacing the tip on the INOMAX regulator, page 16). For the ISO type regulator connector, check that the O-ring is present and is not damaged. Replace if necessary (see replacing the O-ring on the INOMAX regulator, page 17). Repeat step b (note: If leak remains, replace INOMAX regulator).
2. If a leak is detected between the regulator body and regulator end cap (see point 3), replace INOMAX regulator and contact Customer Support.
3. A leak detected at cylinder valve nut connection (see point 5) may not be repaired. Replace INOMAX cylinder and contact Customer Support.
4. A leak detected at safety pressure release device (see point 6) may not be repaired. Replace INOMAX cylinder and contact Customer Support.

Parts and Accessories

WARNING: **Use only parts/accessories designated for use with this system.**

Parts/Accessories	Part Number
Clamp Assembly	10008
Hose Assembly, Oxygen Green, DISS to DISS, 15 Feet	80344
Hose Assembly, Oxygen White, DISS to DISS, 15 Feet	80345
Hose Assembly, Oxygen White, DISS to SIS, 15 Feet	80353
Hose Assembly, Oxygen White, NIST to NIST, 15 Feet	80481
INOMAX Regulator, CGA 626	10006
INOMAX Regulator, ISO 5145	10020
INOMAX Regulator Extension Hose	10014
Operation and Maintenance Manual	20732
O-ring, ISO 5145 INOMAX Regulator	80470
Tip, CGA 626 INOMAX Regulator	1605-3149-000
Transport Mounting Bracket Assembly/Spacer	50041

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Czech	20795
Danish	20809
Dutch	20823
Finnish	20837
French-EU	20851
French-Canadian	20873
German	20892
Hungarian	20906
Italian	20920
Japanese	20935
Korean	20956
Norwegian	20961
Polish	20975
Portuguese	20989
Spanish-EU	21024
Spanish-LATAM	21022
Swedish	21039

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INOblender

Product Specifications

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Product Specifications

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Specifications

INOblender

NO Set Range	5 to 80 ppm (800 ppm cylinder) 2.5 to 40 ppm (400 ppm cylinder)
Setting accuracy	+/- 20 % indicated or 2 ppm, whichever is greater
Gas flow range	5 to 14 L/min of O_2
O_2 inlet connection	DISS (male), 3.4 bar (50 psig, nominal)
NO/N_2 inlet pressure	1.7 to 2.4 bar (25 to 35 psig)
NO inlet	Quick disconnect with shut-off (Female)
NO/O_2 outlet	Barb fitting for oxygen supply tubing
Max. Dimensions	200 mm (W) X 120 mm (H) X 110 mm (D) DISS (clamp included) 200 mm (W) X 120 mm (H) X 131 mm (D) NIST (clamp included)
Max. weight	1.7 kg (clamp included)

Operating and Storage Conditions

Operating Temperature	10 to 40°C
Operating Humidity	15% to 95% non-condensing
Operating Barometric Pressure	57 to 110 kPa
Storage Temperature	-40 to + 70°C
Storage Humidity	15% to 98% non condensing
Storage Barometric Pressure	57 to 110 kPa

INOMAX Pressure Regulator

Cylinder Valve Connector	CGA 626 or ISO 5145 valve
Inlet Pressure	14 to 155 bar (200 to 2,248 psig)
NO Outlet Pressure	1.7 to 2.4 bar (25 to 35 psig)

Manual Resuscitators

*The INOblender is compatible with most types of manual resuscitation bags when used within the specifications of this device. The INOblender has been validated against the following manual resuscitation bags.**

* Airlife Adult Manual Resuscitator with reservoir tubing
* Allegiance ½ L Pediatric Manual Resuscitator with reservoir tubing

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Manufacturer
North America
Mallinckrodt Manufacturing LLC
6603 Femrite Drive,
Madison, WI 53718-6801 USA
877-566-9466
www.mallinckrodt.com

EC REP

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European Authorized Representative
MDSS GmbH
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30175 Hannover, Germany

Europe

CE
0086

Australia
Australia Representative
Ikaria Australia Pty Ltd.
1300-198-565

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