Mallinckrodt™ Pharmaceuticals

INFORMATION FOR LIMITED DISTRIBUTION

Technical Bulletin

Ref: **TB-20007-ENG**

Issue date: June 2024

Product: INOmax DS$_{IR}$®, INOmax DS$_{IR}$® Plus, INOmax DSIR Plus MRI, INOflo® DS, Investigational Blinded NO Delivery System, Investigational NO Delivery System for Human Use Only, Investigational NO Delivery System for Animal Use Only.

Priority: Low

Affected parts: Injector Module; Device and component external surfaces.

Classification: INFORMATION FOR LIMITED DISTRIBUTION

Subject: Cleaning, Disinfecting and Sterilizing the Injector Module and System Components.

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1. The purpose of this Technical Bulletin is to instruct the user on updated cleaning, disinfecting and sterilizing procedures.
2. A new disinfecting method for Injector Modules utilizing Sporox II has been approved as per the instructions below.
3. To identify the performance test that should be performed prior to reuse and to detail instructions for disposal of devices that fail.

Cleaning the INOmax DS$_{IR}$ System Components

This section provides procedures for cleaning the following INOmax DS$_{IR}$ components.

- INOmax DS$_{IR}$, INOmax DS$_{IR}$ Plus, DS$_{IR}$ Plus MRI, INOflo DS, Investigational Blinded NO Delivery System, Investigational NO Delivery System for Human Use Only, Investigational NO Delivery System for Animal Use Only (all variants hereafter referred to as “device”)
- INOmax DS$_{IR}$ Cart
- INOmeter
- Water Trap Bottle
- INOregulator

For cleaning instructions for the INOblender, refer to the INOblender Operation and Maintenance Manual.

CAUTIONS

- Do not use Bioquell Hydrogen Peroxide Sterilant to disinfect the device components. This product has not been tested and validated for cleaning/disinfection processes.

- 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)

- Not all specific cleaning/disinfection products mentioned in this Technical Bulletin are available in all regions of the world. Should this be the case in your region, please follow hospital specific infection control procedures with materials that have the same ingredients as those listed in this bulletin.

- Products described in this Technical Bulletin may not have been licensed in accordance with Canadian law. (Canada Specific).

When the device is cleaned:

- Do not autoclave or gas sterilize the device
- Do not clean with the power connected
- Do not spray or saturate the device with excessive cleaning solution. Liquid can flow into the system and damage internal components.
- Do not use the device until it is completely dry

Do not spray alcohol in the Sample Line Inlet on the front of the device. Alcohol vapors cause the device NO2 sensor to read high (as much as 6 ppm) and the device NO sensor to read low (approximately 0.5 to 1 ppm). As the alcohol dries, the monitored values stabilize.

NOTE: Use of unapproved cleaning or disinfecting agents may damage the device.

Table 1-1 Cleaning Agents that can be Used with the Injector Module

Cleaning Agent	Active Ingredients
pH neutral detergent and sterile water solution	Chlorhexidine gluconate (CHG), Chloroxylenol (PCMX), and Triclosan (e.g., Steris Prolystica 2X Concentrate Neutral Cleaner)
Ethyl or isopropyl alcohol (70%)	Alcohol

Table 1-2 Cleaning Agents that can be Used on Components Listed

Cleaning Agent	Active Ingredients
Pure Green 24 by Pure Green, LLC	SDC – silver ions 0.003% Citric acid 4.84%
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%
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%
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%

Table 1-3: High Level Disinfectant agent that can be used with the Injector Module

Caution: Refer to Sporox II instructions for use for a complete set of cautions, warnings and instructions prior to use.

Disinfecting Agent	Active Ingredients
Sporox II by Sultan Healthcare	Hydrogen peroxide (7.5%) Phosphoric acid (0.85%)

To Clean the External Surfaces of the Components, and the device Display:

WARNING: Do not sterilize or disinfect with the power connected.

NOTE: Always follow manufacturer recommendations, particularly for minimum contact time.

1. Disconnect electrical power to the device and turn it OFF prior to cleaning.

Clean

2. Dampen a soft lint-free cloth (or use pre-moistened cloth) with any of the cleaning agents in Table 1-2.
3. Apply the cleaning agent using the moistened cloth in a circular motion to firmly contact all surfaces. Clean the device display first, followed by any remaining surfaces to remove organic or inorganic material.

Rinse

4. Dampen a soft, lint-free cloth in sterile water (or use pre-moistened cloth) and wipe in a circular motion to firmly contact all surfaces.

Dry

5. Allow the device to air dry for at least 30 minutes at room temperature, or until completely dry.
6. Visually inspect to ensure that the surfaces are clean and intact.

Storage

1. Store in a cool and dry area that is cleaned/maintained per health care facility policy.

Transportation

2. When transporting the system be careful to avoid dropping and/or other handling that can cause contamination.

Cleaning, Disinfecting and Sterilizing the Injector Module

WARNINGS

Do not use the Injector Module unless it is cleaned and disinfected properly using Sporox II with a 30-minute soak time before and after each patient use to prevent cross-contamination. If the Injector Module was used in the wet/ humidified part of the breathing circuit, clean and apply Sporox II with an extended 6 hour soak time or sterilize it between uses. The inspiratory side of an anesthesia circuit is considered wet/humidified.

Thoroughly rinse and dry the Injector Module after immersion to prevent patient contact with chemicals.

Automated cleaning, disinfection and drying methods are not validated. The design complexity, physical characteristics of the Injector Module and electronic components including the flow sensor may limit automation.

Store in a cool and dry area that is cleaned/maintained per health care facility policy.

When transporting the injector module be careful to avoid dropping and/or other handling that can cause contamination.

CAUTIONS
Do not insert anything into the Injector Module passage in an effort to remove contamination or to dry (Figure #1). This will result in damage to the hot wire sensor.

The pre-use procedure is required to confirm the Injector Module is functioning properly and within specification before starting therapy on a patient.

Complete a visual inspection of the Injector Module prior to cleaning to determine potential damage, which would result in end of life for the Injector Module (e.g., unacceptable deterioration such as cracked NO inlet, damaged Injector Module housing, damaged electrical connection).

If an Injector Module does not pass a pre-use procedure, contact Customer Care or country manager for assistance. Do not attempt to reuse an Injector Module after it has demonstrated a failure.

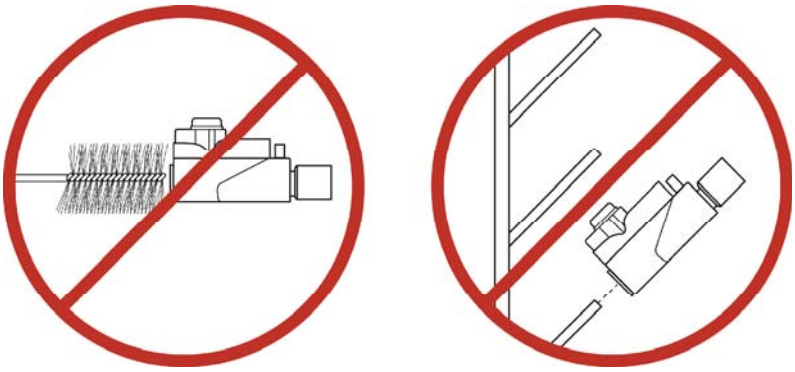

Figure #1 Do not insert anything in the Injector Module passage

To Clean the Injector Module with 70% Ethyl Alcohol or 70% Isopropyl Alcohol:

NOTE: Always follow manufacturer recommendations, particularly for minimum contact time.

1. Disconnect the electrical cable and the injector tube from the Injector Module before cleaning.

Clean:
2. Dampen a soft lint-free cloth (or use pre-moistened cloth) with sterile water and pH neutral detergent (e.g., Steris Prolystica 2X Concentrate Neutral Cleaner).
3. Apply the cleaning agent using the moistened cloth in a circular motion to firmly contact all surfaces of the Injector Module.
4. Clean all external surfaces of the Injector Module to remove organic or inorganic material.
5. Fill a container with 70% alcohol (sufficient volume to completely submerge the Injector Module).
6. Totally submerge the Injector Module in the alcohol for at least 30 minutes.
   NOTE: If lint or fibers are attached to the internal flow grid, gently agitate the module to move the alcohol through the module openings (see Figure #2).

Rinse: Not Required

Dry:

7. Remove the Injector Module from the container and drain the excess alcohol from the module's electrical connector, injector port and internal passage (see *Figure #3*).
8. Allow the Injector Module to air dry for at least 30 minutes at room temperature, or until completely dry.
9. Visually inspect to ensure that the surfaces are clean and intact.
10. Ensure proper function prior to patient use by completing the Pre-Use Checkout.

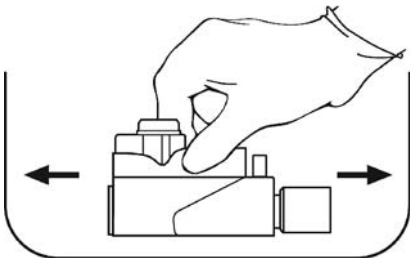

Figure #2 Agitating/rinsing the submerged Injector Module

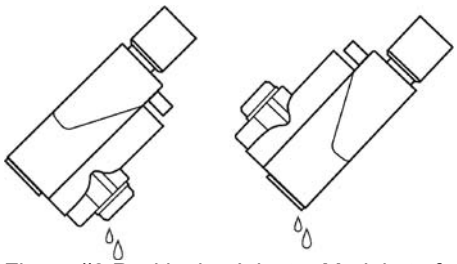

Figure #3 Positioning Injector Module to facilitate air-drying

To Disinfect the Injector Module with Sporox II:

Refer to Sporox II instructions for use for a complete set of cautions, warnings and instructions prior to use.

NOTE: Always follow manufacturer recommendations, particularly for minimum contact time.

1. Disconnect the electrical cable and the injector tube from the Injector Module before cleaning.

Clean

2. Dampen a soft lint-free cloth (or use pre-moistened cloth) with sterile water and pH neutral detergent (e.g., Steris Prolystica 2X Concentrate Neutral Cleaner).
3. Apply the cleaning agent using the moistened cloth in a circular motion to firmly contact all surfaces of the Injector Module.
4. Clean all external surfaces to remove organic or inorganic material.
5. Fill a container with fresh, sterile water (sufficient volume to completely submerge the Injector Module).
6. Rinse off the cleaning agent by totally submerging the Injector Module in the sterile water and gently agitating the Module to move the water through the openings (see *Figure #2*).
7. Allow the Injector Module to air dry for at least 30 minutes at room temperature, or until completely dry.

Disinfect

8. Fill a second container with Sporox II. Do not dilute the solution with water.
9. Affix a label to the Sporox II container. Write on the label the date the solution will expire (21 days after filling the container).
10. Totally submerge the Injector Module in the Sporox II for at least 30 minutes at 20 °C to disinfect (see Figure #4). If the Injector Module was used in the wet/humidified part of the breathing circuit, apply an extended 6 hours soak time at 20 °C or sterilize by autoclaving as per instructions below. The inspiratory side of an anesthesia circuit is considered wet/humidified.

NOTE: If lint or fibers are attached to the internal flow grid, gently agitate the module to move the Sporox II solution through the module openings (see Figure #2).

Rinse

11. Fill a container with fresh sterile water.
12. Gently agitate the module to move the sterile water through the module openings. A 70% isopropyl alcohol rinse may follow a water rinse to facilitate the drying process.

Dry

13. Remove the Injector Module from the water or alcohol container and drain the excess fluid from the module's electrical connector, injector port and internal passage (see Figure #3).
14. Allow to air dry for at least 30 minutes at room temperature, or until completely dry.
15. Ensure proper function prior to patient use by completing a Pre-Use Checkout.

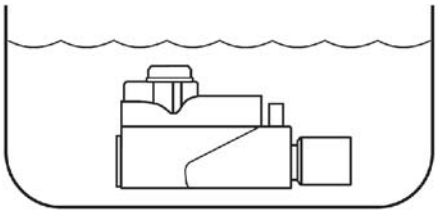

Figure #4 Soaking the Injector Module in Sporox II

Packaging

16. Immediately package the injector module in a clean, dry plastic bag.

To Sterilize the Injector Module by Steam Autoclave with Dynamic Air Removal Cycle:

1. Disconnect the electrical cable and the injector tube from the Injector Module before cleaning.

Clean:

2. Dampen a soft lint-free cloth (or use pre-moistened cloth) with sterile water and pH neutral detergent (e.g., Steris Prolystica 2X Concentrate Neutral Cleaner).
3. Apply the cleaning agent using the moistened cloth in a circular motion to firmly contact all surfaces of the Injector Module.
4. Clean all external surfaces to remove organic or inorganic material.
5. Fill a container with fresh, sterile water.
6. Rinse off the cleaning agent by totally submerging the Injector Module in the sterile water and gently agitating the module to move the water through the openings (see Figure #2).
7. Allow the Injector Module to air dry for at least 30 minutes at room temperature, or until completely dry.

Sterilize:

8. Autoclave the Injector Module at 134 degrees C for three minutes, or at 132 degrees C for four minutes.
9. Visually inspect to ensure that the surfaces are clean and intact.
10. Ensure proper function prior to patient use by completing the Performance Test.

Packaging

11. Make sure that the injector module is not moist before packaging.
12. The packaging must conform to ISO 11607-1 and be suitable for vapor sterilization and be sufficiently permeable to vapor.
13. Only use packaging suitable for sterilization.

Cleaning the Water Trap Bottle

WARNING
Dispose of the Water Trap Bottle contents in accordance with universal precautions for contamination.

CAUTION
If alcohol is used to clean the Water Trap Bottle, ensure the alcohol completely evaporates before the Water Trap Bottle is put back in place. Alcohol vapors cause the device NO2 sensor to read high (as much as 6 ppm) and the NO sensor to read low (approximately 0.5 to 1 ppm). As the alcohol dries, the monitored values stabilize.

1. Remove the Water Trap Bottle from the device by pulling it straight down (see Figure #5).
2. Discard the contents (see Warning above).

Clean:

3. Dampen a soft lint-free cloth (or use pre-moistened cloth) with any of the cleaning agents in Table 1-2.
4. Apply the cleaning agent using the moistened cloth in a circular motion to firmly contact all surfaces of the Water Trap Bottle.
5. Clean all internal and external surfaces to remove organic or inorganic material.
6. Fill a container with fresh, sterile water.
7. Rinse off the cleaning agent by totally submerging the Water Trap Bottle in the sterile water and gently agitating the Water Trap Bottle to move the water over the surfaces.
8. Allow the Water Trap Bottle to air dry for at least 30 minutes at room temperature, or until completely dry.
9. Visually inspect to ensure that the surfaces are clean and intact.

Figure #5 Removing Water Trap Bottle to clean Bottle and Optical Sensor

To Clean the Optical Sensor

CAUTION
If alcohol is used to clean the Optical Sensor, ensure the alcohol completely evaporates before the Water Trap Bottle is put back in place. Alcohol vapors cause the device NO2 sensor to read high (as much as 6 ppm) and the NO sensor to read low (approximately 0.5 to 1 ppm). As the alcohol dries, the monitored values stabilize.

1. Remove the Water Trap Bottle from the device by pulling it straight down (see Figure #5).
2. Discard the contents (see Warning above under *Cleaning the Water Trap Bottle*).

Clean:

3. Dampen a Q-tip with sterile water and pH neutral detergent (e.g., Steris Prolystica 2X Concentrate Neutral Cleaner).
4. Apply ethyl or isopropyl alcohol using the Q-tip in a circular motion to firmly contact all surfaces of the Optical Sensor.
5. Clean all external surfaces to remove organic or inorganic material.
6. Allow the Optical Sensor to air dry for at least 30 minutes at room temperature, or until completely dry.
7. Visually inspect to ensure that the surface is clean and intact.
8. Re-install the clean water trap bottle.

For technical assistance regarding any of the above devices, please contact Product Support at 1-877-566-9466 (North America) or your specific country manager.

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TB-20007 - ENG Cleaning and Diss Injector Module_CAN_AUZ Specific

DCC Review

Name/Signature	Title	Date	Meaning/Reason
David Jameson (DAVID.JAMESON)	Director Of Quality	14 Jun 2024, 01:54:34 PM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Erica Mullaney (ERICA.MULLANEY)	Director Regulatory Affairs	18 Jun 2024, 10:09:58 AM	Complete & Quit
Christopher Rath (CHRIS.RATH)	Sr. Manager, Product Support	18 Jun 2024, 03:54:13 PM	Complete & Quit
Rafael Taylor (RAFAEL.TAYLOR)	Quality	20 Jun 2024, 11:12:20 AM	Complete

Doc Control Review

Name/Signature	Title	Date	Meaning/Reason
Mary Lanney (MARY.LANNEY)	Quality Systems Specialist	20 Jun 2024, 01:28:03 PM	Complete

Approvals

Name/Signature	Title	Date	Meaning/Reason
David Jameson (DAVID.JAMESON)	Director Of Quality	20 Jun 2024, 01:38:29 PM	Approved
Jay Fisher (JAY.FISHER)	Sustaining Engineer - Usa	20 Jun 2024, 02:05:36 PM	Approved
Abofu Alemka (ABOFU.ALEMKA)	Manager, Design Quality	20 Jun 2024, 02:20:04 PM	Approved
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Martina Moyne (MARTINA.MOYNE)	Design Verification Manager	20 Jun 2024, 02:44:09 PM	Approved
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Rafael Taylor (RAFAEL.TAYLOR)	Quality	20 Jun 2024, 08:13:51 PM	Approved

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Name/Signature	Title	Date	Meaning/Reason
Jennifer Xiong (JENNIFER.XIONG)	Quality Assurance Analyst	21 Jun 2024, 12:48:03 PM	Approved

Development Set Dates

Name/Signature	Title	Date	Meaning/Reason
Mary Lanney (MARY.LANNEY)	Quality Systems Specialist	21 Jun 2024, 01:16:13 PM	Approved

Notification

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Lee Morehart (LEE.MOREHART)	Senior Operations Manager	21 Jun 2024, 01:16:14 PM	Email Sent
Rafael Taylor (RAFAEL.TAYLOR)	Quality	21 Jun 2024, 01:16:14 PM	Email Sent

TB-20007 - ENG Cleaning and Diss Injector Module_CAN_AUZ Specific

DCC Review

Name/Signature	Title	Date	Meaning/Reason
Abofu Alemka (ABOFU.ALEMKA)	Manager, Design Quality	17 Jul 2024, 10:23:35 AM	Approved
Emily Weber (EMILY.WEBER)	Senior Quality Analyst	17 Jul 2024, 01:47:05 PM	Approved

Doc Control Review

Name/Signature	Title	Date	Meaning/Reason
Varun Prabhakar (VARUN.PRABHAKAR)	Quality	17 Jul 2024, 03:18:51 PM	Complete

Change Control Approval

Name/Signature	Title	Date	Meaning/Reason
Emily Weber (EMILY.WEBER)	Senior Quality Analyst	17 Jul 2024, 03:33:40 PM	Approved

Release for Production

Name/Signature	Title	Date	Meaning/Reason
Elizabeth Bunting (ELIZABETH.BUNTING)	Sr Technical Specialist, EQMS	17 Jul 2024, 03:54:00 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
T.J. Bartzen (T.J.BARTZEN)	Materials Manager	17 Jul 2024, 03:54:00 PM	Email Sent
Lee Morehart (LEE.MOREHART)	Senior Operations Manager	17 Jul 2024, 03:54:00 PM	Email Sent
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