
NITROSCAV™

Nitrous/Oxygen
Scavenger Pump

USER MANUAL

Model: HDA-1



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1. INDICATIONS FOR USE/ DEVICE DESCRIPTION

The NITROSCAV™ scavenger pump is intended to remove patients exhaled waste gases during procedures where analgesia is administered to a patient via inspiration of mixtures of nitrous oxide and oxygen from a nitrous oxide/oxygen delivery device such as a flowmeter, or breathing circuit, for example. Not intended for use with flammable anesthetic gases.

Briefly described, the subject device is a small, portable, vacuum pump that generates a constant vacuum that can be connected via standard flexible suction tubing to the nitrous oxide/oxygen delivery equipment.

This device is intended for professional use only in healthcare facilities, clinics, and physician and dentist offices. Federal law restricts this device to sale by or on the order of a physician or a dentist.

Figure 1 – NITROSCAV™ Scavenger Pump and Accessories



2. INSTRUCTIONS FOR USE

- Upon receipt of the NITROSCAV™ scavenger pump, unbox the unit and check the contents shown in Figure 1. Note: It is advisable to retain the original packaging for future service requirements.
- Install a rigid pipe venting assembly in an outside wall (Option 1) as schematically shown in Figure 2, or a Vent Connector to a proximal sink drain (Option 2) as shown in Figure 3.
- Connect a suitable length of suction tubing between a nitrous/oxygen delivery device (e.g., flowmeter) and the barbed inlet nozzle on the front panel of the NITROSCAV™ scavenger pump.
- Connect the “female” end of the transfer hose to the “male” inlet connector on the rear or back panel of the NITROSCAV™ scavenger pump and connect the opposite end of the transfer hose to the rigid pipe wall vent assembly, or to the sink drain Vent Connector, as the case may be, as shown in

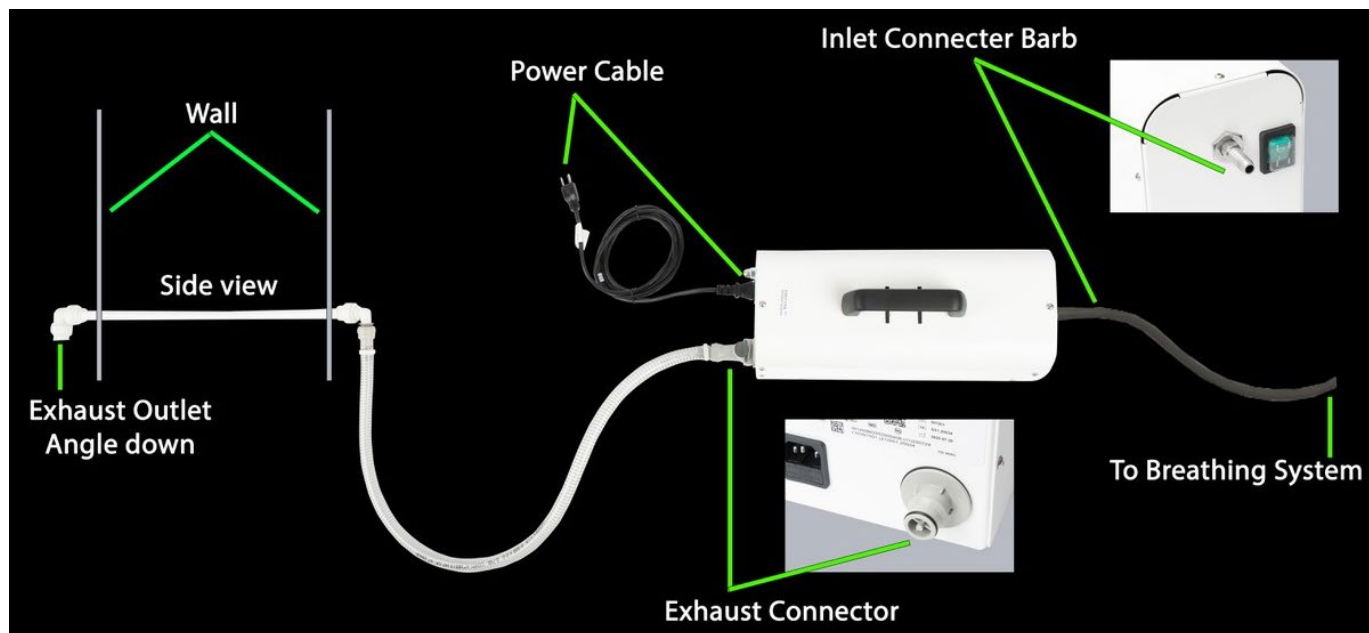
Figures 2 and 3, respectively.

- Install the electrical power cord between the electrical (AC) receptacle on the rear panel of the NITROSCAV™ scavenger pump and a proximally located wall receptacle.
- Depress the switch on the front panel to the “on” position to turn the NITROSCAV™ scavenger pump on.
- Depress the switch again on the front panel to turn the NITROSCAV™ scavenger pump off.

3. CAUTIONS

- The NITROSCAV™ scavenger pump is intended for connection to the vacuum outlet of a nitrous oxide/ oxygen delivery device, such as a flowmeter, and to direct the waste gases to the outside via the transfer hose.
- Do not place the NITROSCAV™ scavenger pump close to the patient; typical distance is not closer than 1.5 meters. Ensure sufficient space around the NITROSCAV™ scavenger pump to ensure adequate cooling of the device. Do not cover the NITROSCAV™ scavenger pump with anything.
- Make sure that all connections are secure and that all tubing is in good shape, not kinked or twisted. If you suspect any tubing is compromised, replace it immediately.
- Remember to check before each use for correct installation.
- Only connect the NITROSCAV™ scavenger pump to the “VAC” outlet nozzle of the flowmeter.
- Connect the NITROSCAV™ scavenger pump to a properly grounded electrical outlet that meets the power requirements as listed in the specifications section of this Manual.
- Always turn the NITROSCAV™ scavenger pump “off” after each use, or the end of a procedure.

Figure 2 – Simulated Installation and Venting to an Outside Wall (Option 1)



- The exhaust conduit from the outlet of the NITROSCAV™ scavenger pump to the wall outlet should not be more than 15 meters (50 feet) in length.

4. VENTING OPTIONS

- The preferred option (Option 1) for venting the exhaust from the NITROSCAV™ scavenger pump to the outside of the building is to install an external wall vent assembly (e.g. a straight industrial ½ Inch

ID pipe) in an outside wall as shown in Figure 2. A suitable straight pipe wall vent assembly may be obtained by order from Sedation Systems LLC.

- Alternatively, the internal transfer hose assembly can be connected by a Vent Connector to the drainpipe of a sink (Option 2) as shown below in Figure 3.

Figure 3 – Vent Connector Connection (Option 2)

The vent connector is an accessory available by order from Sedation Systems LLC.



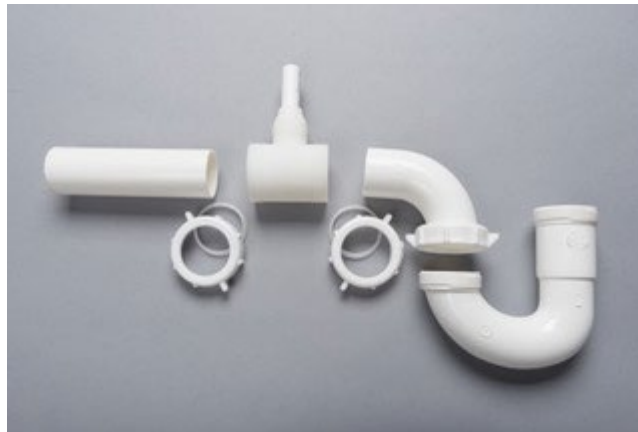
- To install the vent connector, follow the step-by-step instructions illustrated below. This is a simple procedure requiring only the skill of a handyman and can be performed in less than about 20 minutes.

Figure 4 – Preparing the Drainpipe



- Cut out a 1 3/4" section of pipe between the sink P-trap and the adjacent wall (Figure 4).

Figure 5 – Placing the Vent Connector



- Place the vent connector in the gap (Figure 5) and insert the sections of pipe before and past the gap into the vent connector until they stop. Make sure to install the slip-joint nuts first, then the plastic washers before inserting the vent connector.

Figure 6 – Completing the Vent Connector



- Next, securely tighten the nuts to ensure a watertight seal (Figure 6).

Figure 7 – Attaching the Transfer Hose



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- Finally, attach the transfer hose to the vent connector (Figure 7).
 - The NITROSCAV™ scavenger pump exhaust will pass through the vent connector and be exhausted through the building riser in the wall, then out through the roof-top vent which is always present in every building.

5. SYMBOLS

- “O” and “1” on the front panel green power switch mean “Off” and “On” respectively.

6. CLEANING

- Disconnect the power cord from the NITROSCAV™ scavenger pump.
- Clean the outer surface of the NITROSCAV™ scavenger pump with a soft cloth moistened with mild soap and water.
- Do not allow moisture to enter the unit.
- It is not necessary to clean the accessory hoses as they are downstream of the patient.

7. MAINTENANCE AND SERVICE

- Replace the 19 mm transfer hose if there are any suspicions of wear, holes or tears.
- Return the NITROSCAV™ scavenger pump to vendor when service is required.
- To disconnect the unit, the front panel power switch should be turned off and the electric power plug can be removed from its receptacle.
- There are no user serviceable parts. If service is needed contact your dealer.
- The NITROSCAV™ scavenger pump incorporates a thermal cutoff safety mechanism that turns off the motor if it gets too hot (lack of air flow, shut in a box etc.). If the front panel-light is on, but the pump is not operating, the thermal cutout may have been activated. To reset the thermal cutout, unplug the device for 30 minutes and try again. If the device still does not function, it will need to be returned for service.

8. PRE-USE CHECK

- Check that all connections are intact and secure. Also, ensure that all tubing is not kinked prior to use.
- After turning on the NITROSCAV™ scavenger pump check to see that there is a positive vacuum flow at the barbed inlet nozzle by placing your finger over the inlet and feeling the suction.
- Ensure that there is no kinking in the tubing or hoses.
- Check that all connectors and connections are fully secure and intact to ensure that there is no gas leakage into the room.

9. HOW TO CHECK NORMAL OPERATION

- When running the NITROSCAV™ scavenger pump on/off green switch will be illuminated.
- One should hear a low humming sound which is the vacuum motor running and be able to feel suction by placing a finger over the inlet nozzle on the front panel.
- If one does not feel any suction, check the NITROSCAV™ scavenger pump and ensure that it is running and that the tubing or hoses are not obstructed or kinked.

10. COMPATIBILITY

A. Equipment

- The NITROSCAV™ scavenger pump is intended for use with standard N2O/O2 flowmeter delivery systems and has been tested with Porter, Pronox, Accutron, and Nitronox equipment, specifically: Porter C3000 MXR, Digital MDM, Analogue MDM, Nitronox and Nitronox+, Accutron Ultra and Digital Ultra.
- The NITROSCAV™ scavenger pump provides a Flow Rate of 42 Lpm +/- 5 Lpm at a fixed or constant vacuum of <= 90 mmHg, which the ADA has determined to be appropriate for the scavenging of nitrous oxide with these types of delivery systems.

B. Patient Circuits

- The nitrous/oxygen delivery equipment can be used with standard patient breathing circuits. A particularly compatible patient breathing circuit is the Nitrouseal® circuit exclusively sold by Sedation Systems LLC (SKUs CA0120MX-Small Adult, CA0130MX-Ped, CA0140MX-YOUTH Medium, and CA0150MPX-Mouthpiece).

11. WARNINGS

- MR unsafe – do not place NITROSCAV™ scavenger pump in an MRI environment.
- To avoid the risk of electric shock, the NITROSCAV™ scavenger pump must only be connected to a grounded electrical supply circuit.
- The NITROSCAV™ scavenger pump should be placed outside the reach of patients, generally considered more than 1.5 meters.
- Ensure sufficient space around the NITROSCAV™ scavenger pump to ensure adequate cooling of the device.
- Do not cover the NITROSCAV™ scavenger pump with anything.
- Make sure all connecting tubing or hoses are secure and not kinked or obstructed.
- The NITROSCAV™ scavenger pump is not user serviceable. Return the NITROSCAV™ scavenger pump to the vendor if service is required.
- Do not use the NITROSCAV™ scavenger pump in the presence of flammable anesthetics.
- Make sure the device is used in consideration of the electromagnetic compatibility environment described below.
- Only use the device in environmental descriptions as set forth below
- This device and accessories should only be cleaned, disinfected with mild surface disinfectant products.
- Do not attempt to modify or alter the NITROSCAV™ scavenger pump.
- Ensure that the exhaust hose is firmly connected. A louder noise will be heard if it becomes disconnected.

12. ENVIRONMENTAL CONDITIONS

A. Operating Conditions

Operating temperature	5 to 40°C (41 to 104°F)
Relative humidity	5 to 95% (non-condensing)
Altitude	-382 to 3011 m (-1253 to 9878 ft)

B. Transport and Storage Conditions

Temperature	-40 to 70°C (-40 to 158°F)
Storage life	10 years
Relative humidity	5 to 95% (non-condensing)
Altitude	-382 to 5,572m (-1253 to 18280 ft)
Fuse ratings	5x20mm, 250V, 2A, T

13. ELECTROMAGNETIC COMPATIBILITY

The information contained in this section (such as separation distances) is in general specifically written regarding the NITROSCAV™ scavenger pump. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes:

- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TROSCAV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).
- Care should be taken if the equipment is used adjacent to or stacked with other equipment. If adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

Electromagnetic Emissions

This NITROSCAV™ scavenger pump is intended for use in the electromagnetic environment specified below.
The user of this equipment should assure that is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
RF emissions (CISPR 11)	Group 1	The NITROSCAV™ scavenger pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. *
CISPR Emissions Classification	Class B	The NITROSCAV™ scavenger pump is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	

Electromagnetic Immunity

This NITROSCAV™ scavenger pump is intended for use in the electromagnetic environment specified below.
The user of this equipment should assure that is used in such an environment.

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
Electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: 6 kV air discharge: 8 kV	6 kV 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.
Electrical fast transients / bursts (IEC 61000-4-4)	power supply lines: 2 kV longer input / output lines: 1 kV	2 kV 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges on AC mains lines (IEC 61000-4-5)	common mode: 2 kV differential mode: 1 kV	2 kV 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	Equipment which emits high levels of power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference.

Electromagnetic Immunity			
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95%, 0.5 periods dip 60%, 5 periods dip 30%, 25 periods dip >95%, 5 seconds	>95%, 0.5 per. 60%, 5 per. 30%, 25 per. >95%, 5 sec.	Main power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions, ensure that batteries are installed and charged. Insure that battery life exceeds longest anticipated power outages or provide an additional uninterruptible power source.
IEC 61000-4-39 Immunity to proximity magnetic fields	30 kHz 8 A/m 134.2 kHz 65 A/m 13,56 MHz	30 kHz 8 A/m 134.2 kHz 65 A/m 13,56 MHz	Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.

This NITROSCAV™ scavenger pump is intended for use in the electromagnetic environment specified below. The customer or the user of should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 6 V rms in ISM radio bands	3 Vrms 6 V rms in ISM radio bands	The NITROSCAV™ is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80MHz-2.7 GHz	3 V/m 80MHz-2.7 GHz	

14. SPECIFICATIONS

Vacuum Pump:	Diaphragm type, fixed flow rate and fixed vacuum
Flow rate:	>37 Lpm
Vacuum:	Fixed – maximum 90 mmHg +/- 10 mmHg
Power Requirements:	115 VAC +/-10% 60 Hz 2.0 A
Protection Class:	Class 1 (Protectively Earthed)
Size:	Width 160mm, Length 370mm, Height 260mm
Maximum length:	15 meters (50 ft.) in length outlet tubing
Ingress Protection:	The device is not protected against ingress of water or particulate matter
Weight:	9.25 kg
Mode of Operation:	Continuous

Recommended separation distances between portable and mobile RF communications equipment and the NITROSCAV™ scavenger pump

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitters in meters		
	150 kHz – 80 MHz $d=1.2/\sqrt{1}P$	80 MHz to 800MHz $d=1.2/\sqrt{1}P$	800 MHz to 2.5 GHz $d=2.3P$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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