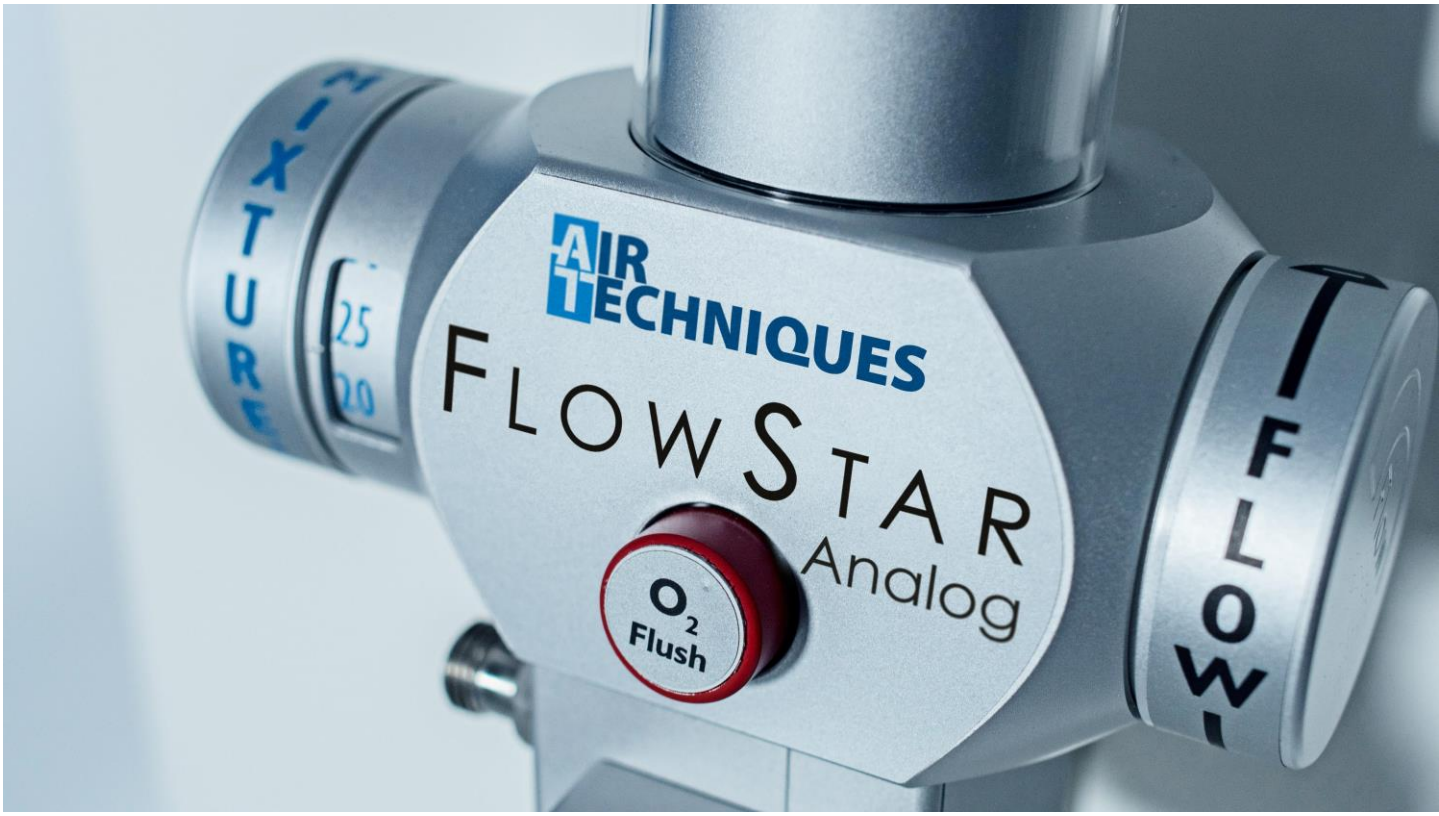
FlowStar Analog

Mixer Flowmeter 50 %, 70 %

Instructions for Use



MADE IN GERMANY

Notice

Please read the Instructions for Use carefully and completely before initial use to protect yourself and your patients from operating errors! This manual also contains instructions and control checks that must be performed regularly by the user. Keep this manual for future reference. The company Baldus Sedation GmbH & Co. KG does not guarantee that the information is up-to-date, correct and complete. We reserve the right to make changes.
If any problems or leaks occur with the FlowStar Analog Mixer Flowmeter 50 %, 70%, immediately contact Air Techniques, Inc or your dental dealer. Do not carry out any repair attempts on your own. Disregard will result in loss of warranty.

R_x Only: Federal law restricts this device to sale by or on the order of a physician.

Environment for Use: Medical and Dental Offices.

Applicable Standards:

The medical device complies with applicable portions of currently recognized versions of:

CGA V-5:2008 (Reaffirmed 2013) Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)

ISO 11195:2018 Gas mixers for medical use – Stand-alone gas mixers

Contact with the manufacturer:

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1. General information

1.1. Warnings and Cautions

Table 1: Warnings and Cautions

WARNING	1. **WARNING! RISK OF FIRE**: An oxygen enriched environment can accelerate the spread of ignited materials. Therefore, when the mixer is used in conjunction with energy producing devices (such as lasers, RF sources, or other heat sources) the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials. 2. In order to prevent the creation of an oxygen rich environment and risk of fire, regularly check for gas leakage and use in a sufficiently ventilated ambient only. For use by trained personnel only. See SAFETY AND REGULAR CHECKS, below. 3. Switch on the suction before sedation and control and adjust it via vacuum control block. The suction capacity must be at least 45 l/min (See Instructions For Use for the Double Hood Scavenging Circuit). 4. Please do not use the device without a proper license for the administration of nitrous oxide/ oxygen. Follow the instructions given to you during the licensing course and the instructions of your service partner. 5. The patient should be continuously monitored during the use of nitrous oxide and the weaning-off phase. As soon as the patient experiences adverse reactions, reduce or stop the flow of nitrous oxide as needed. To supply the patient with O_2 more quickly, a high flow with 100 % O_2 can be applied via the O_2 Flush Button (red). If the patient shows no improvement, treat the patient with pure oxygen using the O_2-outlet with a separate Hood. Call an emergency help if a quick response cannot be obtained. 6. The FlowStar Analog Mixer Flowmeter may not be combined with anesthetic devices or used as an anesthetic device. 7. After sedation, the patient must be given pure oxygen for approx. 5 minutes (weaning-off phase). 8. Before initial use please check that the gas cylinders are correctly connected. To do this, open only the Nitrous Oxide cylinder valve. Set the MIXTURE % knob to 0 and increase the FLOW knob (+) all the way open. If the cylinders are correctly connected, there should not be any gas flow indicated on the Oxygen or Nitrous Oxide flow tubes. 9. The device is only intended to be used in the field of medicine and may only be used by a doctor or dentist to sedate patients with nitrous oxide and oxygen as necessary. The FlowStar Analog Mixer Flowmeter may not be used for any other purpose. 10. Please comply with the recommended ambient air contamination limit of your country (USA: The recommended exposure limit is 25 ppm TWA (time weighted average) over an 8 hour day.). Ventilate the treatment room regularly. 11. Not suitable for use with Oxygen 93. 12. Inlet pressure hoses shall comply with ISO 5359. 13. Patients may become nauseous when the Nitrous Oxide % is increased too rapidly. 14. Only the accessories listed in this Instructions For Use may be used. 15. The pressure reducers O2 and N2O may only have a maximum pressure difference between the output pressures of 0.5 bar.

	MR Unsafe. Do not use near or in conjunction with an MRI System.

CAUTION	1. Smoking is strictly prohibited when using the device or changing the gas cylinders. Also, open flames must not be used in the vicinity. 2. If the mixer is not connected to the central gas supply, a spare cylinder of each gas should always be kept in stock. The nitrous oxide cylinder should always be stored upright. 3. The cylinder valves should always be opened slowly. 4. The gas cylinders should always be closed after use. 5. Changes to the settings or the system are strictly prohibited, as patients could be endangered. This will void any warranty. 6. After treatment, all components must be reprocessed as described in the instructions for use. 7. After each treatment, the filling level of the gas cylinders should be checked. If the gas is no longer sufficient for sedation, the cylinder must be replaced. Always have spare gas cylinders in stock! 8. In order to protect both patients and staff you have to carry out regular checks and maintenance and safety checks carried out by Air Techniques or an authorized service partner every two years. 9. If the pressure reducers indicate less than 725 psi (50 bar) oxygen or 435 psi (30 bar) nitrous oxide, the gas cylinder should be changed before the next sedation. Pressure gauges should also be monitored during treatment. 10. Always use clean and dry medical gases. Moisture and contaminants in the system must be avoided. 11. Oxygen and nitrous oxide cylinders must be kept free of oil and grease. 12. The system should be vented at the end of the treatment day. 13. Please do not change the O2 and N2O connections. 14. Although nitrous oxide reduces pain, a local anesthetic should still be administered. 15. All sedation have to be monitored with a pulse oximeter with individually adjustable alarm limits. 16. Federal law restricts this device to sale by or on the order of a physician.

1.2. Symbols and technical data

Table 2: Overview symbols and their meaning

Symbols	Meaning
	Manufacturer country and date
	Manufacturer

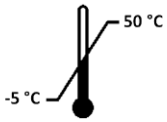
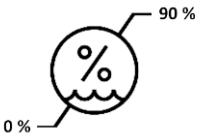
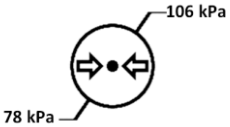
	Distributor
Rx only	Federal law restricts this device to sale by or on the order of a physician
	Reference number
	Serial number
	Unique Device Identification
	Temperature limits
	Humidity limits
	Observe Instructions for Use
	Air pressure limits
	Fragile, handle with care
	Store dry

Table 3: Overview technical data

Technical data	
Storage temperature	-5 – 50 °C (23 – 122°F)
Operating temperature	15 – 38 °C (59 – 100°F)
Humidity	0 – 90 %
Air pressure	78 – 106 kPa
Maximum working height above sea level	2000 m
Service life	10 years*
Disposal	Observe the usual disposal methods
Dimensions (H x W x D)	296.00 x 159.00 x199.00 mm
Weight	3.30 kg
Fresh Gas Outlet Size	ID 15.00 mm x AD 22.00 mm
Nitrous oxide (N_2O) inlet	DISS-connector
Oxygen (O_2) inlet	DISS-connector
FlowStar Analog Mixer Flowmeter 70 %	O_2-Concentration: 30 – 100 % N_2O-Concentration: 0 – 70 %
FlowStar Analog Mixer Flowmeter 50 %	O_2-Concentration: 50 – 100 % N_2O-Concentration: 0 – 50 %
Emergency Hood Connection	100.00 – 250.00 l/min
Maximum O_2-Flush	> 30 l/min
Total Flow range	1.00-15.00 l/min
Internal operating pressure	45.51 psi (3.00 bar)
Initial pressure	50.76 – 72.52 psi (3.50 – 5.00 bar)
O_2-gas shortage information signal	< 45.51 psi (3.00 bar)
Duration of O_2-gas shortage information signal	Until the gas cylinder is empty, the pressure is > 45.51 psi (3.00 bar) or the flow is set to 0 l/min
Volume of O_2-gas shortage information signal	70.00 – 96.00 dB
Ambient Air Valve opening negative pressure	> -0.94 – 0.22 mbar
Maximum differential pressure	21,76 psi (1.50 bar)
Maximum pressure	145.04 psi (10.00 bar)
Color oxygen	Green
Color nitrous oxide	Blue
Bottom Mount	1/2 - 20 Thread (The mixer must be fixed in place, e.g. on a telescopic arm)

* The service life is extended by another 10 years after the major maintenance has been performed on the device

1.3. Indications for Use

Indicated for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen in a conscious spontaneously breathing patient. Rx Only.

1.4. Description of application

The environment is a medical facility or dentist office. The mixer is used to mix medical nitrous oxide into the medical oxygen in an adjustable percentage. The mixture is administered to patients by means of a Double Nasal Hood; the patient remains conscious but becomes more relaxed and loses any fear they have of the treatment. According to various books and studies, up to a maximum of 70 % nitrous oxide, sedation in this manner is minimal with the aim of anxiolysis (removal of anxiety) in the patient. It is not an anesthetic, the patient is conscious, breathing independently and able to react to external stimuli. In some patients, the sedative effect at

50 % nitrous oxide is not sufficient, so in addition to the FlowStar Analog Mixer Flowmeter 50 % device, which can administer 50 % nitrous oxide, we also have the FlowStar Analog Mixer Flowmeter 70 % devices, which are limited to a maximum of 70 % nitrous oxide.

1.5. Indications, patient population, contraindications and side effects

Table 4: Indications and contraindications

Indications and contraindications	
Indications, patient population	• Anxious or difficult patients • Intellectual or physical disabilities • Patients with a string gag/ swallowing reflex • Stress prevention in case of mild cardiological problems and asthma • Patients to whom anaesthesia is contraindicated • Longer or complex surgical treatment • Patient population: Do not perform nitrous oxide sedation on babies and children up to 2 years of age

Contraindications	• Patients in bleomycin chemotherapy
	• Patients with bone marrow suppression (e.g. due to methotrexate or fluorouracil)
	• Chronic obstructive pulmonary disease (COPD)
	• SARS-CoV-2 infection or COVID-19 disease
	• Severe traumatic brain injury
	• Hindered or restricted nasal breathing (rhinitis, sinusitis)
	• Impaired ability to communicate
	• Severe psychological or behavioral and personality disorders
	• Ventilation disorder of the middle ear
	• Severe general diseases (MS, ileus)
	• Status post eye operation with an intraocular gas bubble
	• ASA ≥ 3
	• Vitamin B12 and folic acid deficiency or disorder
	• First and second trimester of pregnancy
	  ○ Neither female employees in the dental practice nor patients in their first or second trimester
	  ○ Third trimester of pregnancy may be exposed to nitrous oxide
	• Nitrous oxide diffuses into hollow spaces. Accordingly, it should not be inhaled following a middle ear infection, an intestinal obstruction, an eye operation with intraocular gas bubble, etc. In the last instance, for example, this could lead to loss of sight or, at least, an unpleasant feeling of pressure. Always take a medical history and observe the content conveyed in the mandatory licensing course.

Table 5: Side effects and complications

Side effects and complications	
Cardiovascular adverse reactions	• No relevant side effects following isolated use • Slight decrease in heart rate • Slight decrease in stroke volume
Respiratory adverse reactions	• Minimal or no respiratory depression • If there is an insufficient effect, consider other forms of anaesthesia
No impact on	• Liver function • Renal function • Intestinal function • Almost no metabolisation

	• Almost entirely excreted via the lungs • Less than 0.04 % of the gas is actually metabolized in the body
Oversedation	Precisely because of the risk of oversedation (e.g. dizziness, increase in pulse, malaise), the user must be trained precisely how to titrate the nitrous oxide individually. In the event of oversedation, either the nitrous oxide can be reduced or the O_2-flush button can be pressed, allowing more than 30 l/min of oxygen to flow into the Breathing Bag. Nitrous oxide is easily controllable and floods off quickly, meaning that the oversedation is over quickly.
Nausea and vomiting	• Mechanism of origin unclear, usually in combination with other anesthetics/analgesics • Increases at concentrations > 50 % nitrous oxide, therefore only apply nitrous oxide above 50 % in exceptional cases. On average, patients are already optimally sedated at approx. 30 – 40 % N_2O. • If the patient unexpectedly has to vomit, it is important to turn the head to the side so that the risk of aspiration can excluded. • Gradually add nitrous oxide by using the concentration knob until desired reaction is achieved. Allow time between each N2O increase for patient to adjust since rapid increasing of N2O % can cause nausea.
Psychosomatic side effects	• Concentration of approx. 20 % nitrous oxide already cause a change in psychomotor activity, such as tingling in the legs or fingers • This is reversible after approx. 15 min
Psychiatric side effects	• Euphoria, dreams and fantasies are described
General	There are no data to support or suggest a teratogenix, mutangenic, carcinogenix, or reproductive-modifiying effect of nitrous oxide. Of course, it is still recommended that all measures be taken to minimize workplace concentrations of nitrous oxide. Nitrous oxide sedation has been used millions of times and in countries such as England, USA, Switzerland, Scandinavia etc. it is part of everyday dental treatment. 89 % of American pediatric dentists sedate with nitrous oxide. In Sweden, for example, 90 % of mothers deliver their babies under nitrous oxide, but for this purpose an oxygen-nitrous oxide mixer with demand valve is used. The company Baldus Sedation GmbH & Co. KG does not guarantee that the information is up-to-date, correct and complete. To prepare your medical history sheet, please use the contents learned during the training as a guide.

2. Description of the components and handling

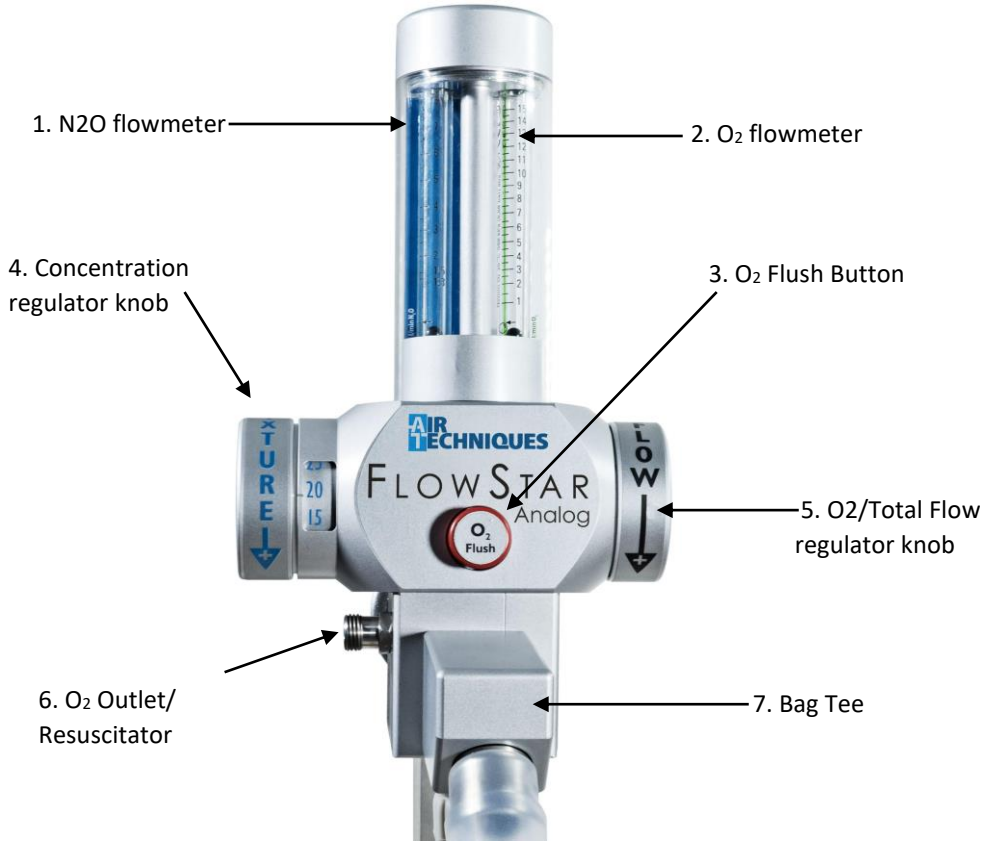


Figure 1: Components of the FlowStar Analog Mixer Flowmeter - Front

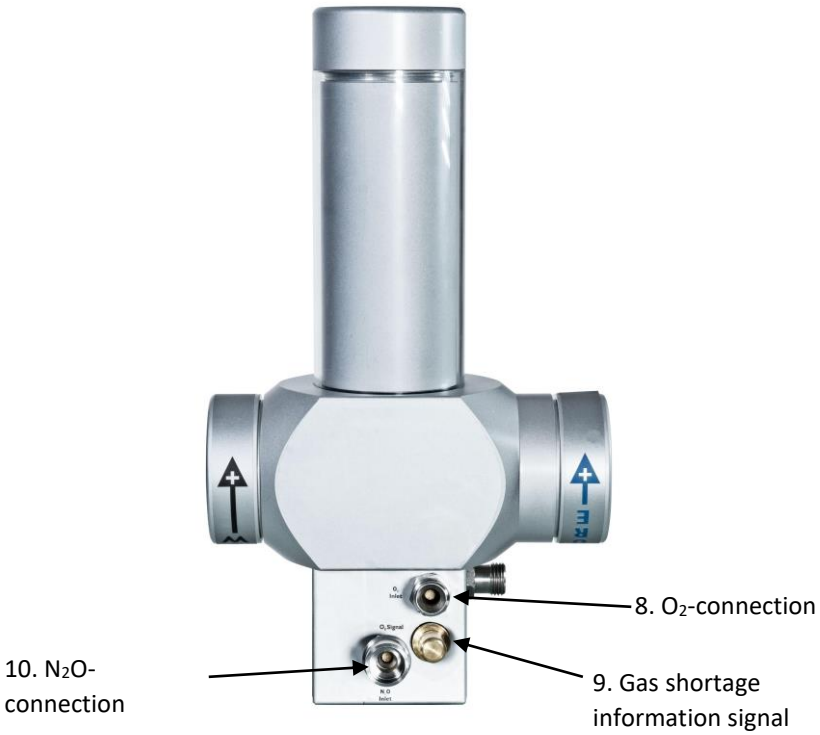


Figure 2: Components of the FlowStar Analog Mixer Flowmeter- Back

Table 6: Description of the components of the Mixer Flowmeter from Figure 1 and Figure 2

Components	Description
1. N_2O flowmeter	Indicates how many liters of nitrous oxide flow per minute
2. O_2 flowmeter	Indicates how many liters of oxygen flow per minute
3. O_2 Flush Button	When the flush button is pressed, a flow of more than 30 l/min with 100 % pure oxygen flows immediately.
4. Concentration regulator	The „MIXTURE"- knob on the left side of the mixer can be used to precisely set the mixing ratio. The number next to it indicates in % how much nitrous oxide is administered.
5. Flow regulator	The regulator on the right side is used to set the total flow in l/min. Close it after each sedation but don't turn it too tight and don't use tools, just hand-tight.
6.O_2 Outlet	There is an additional oxygen connection on the left side. For emergencies, an on demand Hood can be connected there to administer 100 – 250 l/min of pure oxygen. The connection is designed so that oxygen only escapes as soon as a Hood is connected. Do not connect the O2 gas supply pressure hose to the O2 Outlet.
7. Bag Tee	The Bag Tee has two 22 mm connections and an ambient air valve. The Fresh Gas Spiral Tube (see Figure 3, left) is connected to the front connection. The front connection has an integrated Non-Return Valve which prevents the patient from breathing back into the Breathing Bag. The Breathing Bag is connected to the rear connection, which points vertically to the floor. The ambient air valve (see Figure 3, right) opens if the mixer does not apply sufficient flow and supplies the patient with room air. *Figure 3: Bag Tee with two 22 mm connections. Left as connection for the Fresh Gas Spiral Tube. On the right as connection for the Breathing Bag. On the right: Ambient Air Valve*
8. O_2-Connection	The green O_2 pressure hose is connected to this port.
9. Gas shortage information signal	If there is no longer sufficient oxygen available, a signal sounds to inform the user. Low oxygen pressure will activate the oxygen safety system, causing a loud whistling sound. To resolve this, please ensure that there is sufficient oxygen pressure at all times.
10. N_2O-connection	The blue N_2O pressure hose is connected to this port.

Table 7: Instructions and information

Instructions and Information	
Connection of the pressure hoses	The pressure hoses serve as a connection between the gas supply and the mixer. The hose utilize DISS connection to prevent cross-connection within the system.
Handling	Turn on gas cylinders before sedation. Sedation is always started with at least 5 l/min and 100 % oxygen. The centre of the ball in the flow tube serves as the reading point. Subsequently, the nitrous oxide concentration must be slowly increased (10% at a time) until the patient is individually sedated. The Breathing Bag is the monitor for sedation monitoring. The overall flow must be made

	dependent on filling and emptying of the breathing bag. The breathing bag should not be bulging, you should still be able to see the folds and the patient's breathing. Warning- Patients may become nauseous when the Nitrous Oxide % is increased too rapidly.
Venting the system	At the end of a treatment day, the system must be vented. For this purpose, a flow as high as desired is set. The higher the flow, the faster the venting process takes place. First, the maximum nitrous oxide concentration should be set and the N_2O gas cylinder closed. If the N_2O ball drops to 0 l/min and the O_2 flow increases to the total flow, the oxygen cylinder must be closed. After a short time, an information signal sounds, if this stops again, the venting was successful.
Service life	We assume an expected service life of 10 years for the FlowStar Analog Mixer Flowmeter. This is assuming that the maintenance and regular user checks have been properly performed and that the product is used solely for its intended purpose. After 10 years, a major service must be performed to replace all O-rings, sintered metal filters and membranes within the FlowStar Analog Mixer Flowmeter. For the major maintenance, the device must be sent in. For transport it is absolutely necessary to position the yellow caps on the openings of the mixer. The major maintenance extends the service life by another 10 years. The service life is fundamentally dependent on the number of sedations performed. In addition, the environment of use and maintenance of the device have an influence. The specified service life does not represent an additional guarantee.
Storage and disposal	The mixer must be stored in a splash-proof location. If moisture or other contaminants get into this device, it may malfunction. The storage temperature must be between -5°C and 50°C (23 – 122°F; allow to stabilize to room temperature before sedation). Return the device to AirTechniques Inc. for disposal or observe the usual disposal methods.

3. Scope of delivery

3.1. Product variants

Table 8: Overview of the product variants

Product variant	Ref-number	Description
1	NFA40005	**FlowStar Analog Mixer Flowmeter 50 %**
2	NFA4000	**FlowStar Analog Mixer Flowmeter 70 %**

3.2. Accessories

In addition to the FlowStar Analog Mixer Flowmeter 50%, 70%, further accessories are required for dental sedation:

Table 9: Overview of necessary accessories

Art.-No.	Product
Necessary	
NSC-VCB	Double Hood Scavenging Circuit with Vacuum Control Block
	Oxygen pressure hose, green (Regarding CGA C-9)
	Nitrous oxide pressure hose, blue (Regarding CGA C-9)
	Breathing Bag Adult 3 l or Breathing Bag Pediatric 2,3 l
	Mobile E-Stand with Yoke Block
	Or wall mount with telescopic arm

4. Safety and regular checks

Table 10: Safety mechanism of the FlowStar Analog Mixer Flowmeter

Safety mechanism	Description
O_2-gas shortage information signal	If there is no longer sufficient oxygen available, an acoustic signal sounds to alert the user. If the flow is set to 0 l/min or the oxygen cylinder is completely empty, no signal sounds anymore.
N_2O-lock	When there is no longer enough oxygen available, the supply of nitrous oxide is stopped. This prevents a patient from receiving more than 70 % nitrous oxide.
N_2O-lack	If no more nitrous oxide is available, the oxygen flow is raised to the total flow. This ensures that the patient always receives sufficient flow.
O_2- Flush	The patient can be supplied with more than 30 l/min of pure oxygen via the red O_2 flush button.
O_2- Emergency supply	If the patient requires a very high flow of pure oxygen in an emergency, a separate device can be connected to the O2 - outlet connection for emergency use.

Table 11: Check to be carried out regularly

Before treatment:	
Check of the N_2O lock	1. Both gas cylinders must be opened 2. 50 % N_2O is to be set with the concentration regulator knob 3. The flow should be set to any value 4. The oxygen cylinder must be closed 5. Both balls shall drop to 0 l/min and an information signal shall sound 6. If this is not the case, sedation must not be performed

Daily:	
Check of the mixing ratio	1. Set 0 % N_2O and a flow of 6 l/min 2. Set the N_2O ball at 0 l/min and the O_2 ball at 6 l/min 3. Set the concentration to 30 % N_2O 4. The N_2O ball must be approx. 1.8 l/min and the O_2 ball at approx. 4.2 l/min 5. Increase the concentration to 50 % N_2O 6. Both balls must be at 3 l/min 7. Increase the concentration to 70 % N_2O (if the FlowStar Analog Mixer Flowmeter 70 % is used) 8. The N_2O ball must be at approx. 4.2 l/min and the O_2 ball at approx. 1.8 l/min 9. A tolerance of 0.5 l/min is OK. If the deviations are outside the tolerance, the device must be sent in for inspection.

Weekly:	
Checking for leaks of the Scavenging Circuit	See Instructions for Use „Double Hood Scavenging Circuit“ chapter 4.
Check of the ambient air valve	1. Set the flow to 0 l/min, the Breathing Bag should be empty at this point 2. Inhale through the Fresh Gas Spiral Tube 3. The Ambient Air Valve should open, and the ambient air is drawn in through the Fresh Gas Spiral Tube 4. To check the Non-Return Valve, breathe into the Fresh Gas Spiral Tube. The Breathing Bag must not fill with air

Monthly:	
Check of oxygen	1. Set the concentration to 0 % N_2O 2. Increase the flow 3. The O_2 ball should behave according to the set flow rate 4. The N_2O ball must be permanently at 0 l/min
Check of leakages	A special leak detection spray can be used to easily determine whether leaks are present. For this purpose, all screw fittings and connections on the mixer and pressure reducer are sprayed. The leak detection spray consists of soap and water. If there are leaks, bubbles quickly form around the leak. This test is performed every time the cylinder is changed, or monthly at the latest (including after it is sent in for inspection and before it is put into service). All leaks must be repaired immediately. In addition, you should turn off the gas cylinders completely. The pressure must not drop noticeable for more than one hour.
Check of the Concentration regulator	1. Set the concentration to 50 % N_2O with any flow 2. Both balls of the flowmeters must be at the same height 3. The nitrous oxide concentration should now be set to 0 %. 4. The N_2O ball should drop to 0 l/min
Check of the O_2-Flush	The O_2 flush must be held down and the Breathing Bag should fill within five seconds.

Every two years	
Maintenance	For more detailed information, please contact your dealer who performs the maintenance on your device. Please note that the Scavenging Circuit must be autoclaved after maintenance.

5. Hygiene

Table 12: Hygiene measures

Hygiene measures:	
FlowStar Analog Mixer Flowmeter	We recommend: **Before first use**, wipe the entire mixer Analog using a cleaning/disinfectant wipe (i.e., CaviWipes™). Using a new wipe thoroughly wipe the same area and allow the disinfectant to remain in contact with the surfaces for 3 minutes. Additional wipes can be used to achieve the desired contact time. Use clean gloves during the disinfection process and ensure the environment is clean and as free from dust as possible. Ensure that the cleaning/disinfectant wipes used for processing are compatible with (Plexiglas, anodized aluminum, brass, stainless steel, pvc foil). Allow the mixer to air dry. Inspect the mixing device with the naked eye under normal lightning conditions to determine if all adherent visible soil has been removed from the surface. **Between uses** • Repeat the process described above Or • Use single-use barriers films to cover the regulators knobs and all areas which are touched by the dentist or the dental assistant during the treatment. Replace them from application to application.
Double Hood Scavenging Circuit	See Instructions for Use „Double Hood Scavenging Circuit“ chapter 5.

6. Troubleshooting

Table 13: Troubleshooting

Problem	Possible cause	Solution
O_2 does not flow with set flow	1. O_2 gas cylinder is not open 2. The mixer is not connected to the central gas supply or to the gas cylinders 3. The O_2 gas cylinder is empty	1. Open the O_2 gas cylinder 2. Connect the mixer to the central gas supply or gas cylinders 3. Replace with a full gas cylinder
O_2 flows, but no N_2O	1. N_2O gas cylinder is not open 2. N_2O gas cylinder is empty	1. Open the N_2O gas cylinder 2. Replace with a full N_2O gas cylinder
N_2O flows, but no O_2	Serious device error	No sedation may be performed. Please contact your dealer.
Patient does not feel the sedation	1. The Hood does not fit properly on the patient's face 2. The gas mixture is not ideally aligned with the patient's requirements 3. Exhalation membrane of the Inner Hood is defective or missing 4. The Inner Hood is missing or does not fit properly 5. The differential pressure of the gas cylinders is too high, so that too little nitrous oxide reaches the patient	1. Select the appropriate Hood size or press the Hood gently to the face 2. Increase the nitrous oxide concentration 3. Replace membrane 4. Insert the Inner Hood correctly 5. Replace the empty cylinder with a full one
The Breathing Bag becomes slack during treatment	1. The gas flow is not ideally aligned with patient requirements 2. The Breathing Bag has a leak	1. The total flow must be increased 2. The Breathing Bag must be replaced
The patient has difficulty breathing and sedation does not work	The suction is set too high	The ball of the Vacuum Control Block must be in the marked area

Contact for questions and orders:

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Melville, New York 1147 – 3062
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