FlowStar Touch Digital

Mixer Flowmeter 50 %, 70 % with Bag Tee

Instructions for Use

MADE IN GERMANY

Prologue

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 Touch Digital Mixer Flowmeter 50 %, 70% with Bag Tee, immediately contact Air Techniques, Inc or your 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:

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

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

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1. General information

1.1. Warnings and Cautions

Table 1: Warnings and Cautions

WARNING	1. 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. 2. The patient should be continuously monitored during the use of nitrous oxide. 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 for emergency help if a quick response cannot be obtained. 3. Not suitable for use with Oxygen 93. 4. The FlowStar Touch Digital Mixer Flowmeter must not be combined with anesthetic devices or used as an anesthetic device. 5. After sedation and before discharging, the patient must be given pure oxygen for approx. 5 minutes. 6. Before initial use please check that the gas cylinders are correctly connected. To do this, open the N_2O cylinder valve. Set the concentration to 0 % and increase the flow. If the cylinder is correctly enclosed, there should be no flow. 7. If connecting to a facility provided piped gas system, assure it is compliant with the requirements of NFPA-99, Health Care Facilities. 8. 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 Touch Digital Mixer Flowmeter may not be used for any other purpose. 9. Please comply with the recommended ambient air contamination limit of your country (USA: The recommended exposure limit is 25 ppm averaged over a 10-hour work shift). 10. It may be difficult to read the display in bright environments, e.g. if a lamp or the sun is shining directly on it. Ensure that the percentages are set correctly, as incorrect settings may leas to oversedation, for example. 11. Dirt can penetrate into the housing (e.g. when installing into a dental cabinet with the risk of an electric shock or unit damage/destruction).
	Special Electromagnetic Warning: Avoid use near MRI, Diathermy, and other strong electromagnetic signal sources. This device is not MRI safe.
	Avoid using a 5G cellular phone in close proximity to the Mixer

CAUTION	1. Federal law restricts this device to sale by or on the order of a physician. 2. Smoking is strictly prohibited when using the device or changing the gas cylinders. Also, open flames must not be used in the vicinity. 3. Changes to the settings or the system are strictly prohibited, as patients could be endangered. This will void any warranty. 4. This medical device should not be used in combination with X-ray devices that are shielded, protected, and grounded housing, nor with X-ray tubes and other high-voltage components that contain shielded high-voltage cables.

CAUTION	5. The use of accessories, transformers and cables, which are not specified, or provided by the manufacturer of these devices may result in increased electromagnetic emissions or decreased electromagnetic interference immunity of the device and cause incorrect operation. 6. The performance of the medical system can be lost or impaired due to electrical magnetic interference. 7. Portable and mobile RF communications equipment (including peripheral devices such as antenna cables and external antennas) should not be used any closer than the distances specified in Paragraph 1.6, Warning of Minimum Separation from RF Communications Equipment. Otherwise, the performance of this device may deteriorate. 8. The cable lengths and extensions have an impact on the electromagnetic compatibility. 9. If an error code appears, shut down the unit immediately! If you are not able to shut down anymore, please unplug. You may only sedate again once the error has been rectified. 10. After treatment, all components must be cleaned according to the instructions for use. 11. Ensure that oxygen and nitrous oxide are not mixed up. 100 % nitrous oxide will harm your patient. 12. To protect patients and staff, regular checks and maintenance must be performed. 13. If the pressure reducers indicate less than 50 bar oxygen or 30 bar nitrous oxide, the gas cylinder should be changed before the next sedation. Pressure gauges should also be monitored during treatment. 14. Always use clean and dry medical gases. Moisture and contaminants in the system must be avoided. 15. Oxygen and nitrous oxide cylinders must be kept free of oil and grease. 16. The company Baldus Sedation GmbH & Co. KG. is not liable for a possible loss of data. Regular exporting of data to a USB stick and storage on a secure data storage system is expressly recommended. 17. Connect only to Bag Tee Adapter. 18. Please do not change the O_2 and N_2O connections.

Pictograms and technical data

Table 2: Overview pictograms and their meaning

Pictograms	Meaning
	Manufacturer country and date
	Manufacturer
	Distributor
R_X only	Federal law restricts this device to sale by or on the order of a physician
	Not MRI safe. Do not use near an MRI System.
	Avoid close proximity to a 5G cellphone.

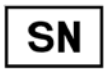
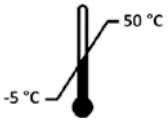
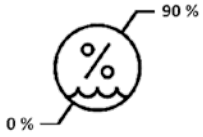
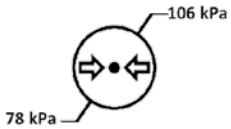
Pictograms	Meaning
	Reference number
	Serial number
	Unique Device Identification
	Dangerous voltage
	Temperature limits
	Humidity limits
	Observe Instructions for Use
	Air pressure limits
	Fragile, handle with care
	Store dry

Table 3: Overview technical data

Technical data	
Storage temperature	-5 – 50 °C (23 – 122°F)
Operating temperature	15 – 35 °C (59 – 95°F)
Humidity	0 – 75 %
Air pressure	78 – 106 kPa
Maximum working height above sea level	2000 m
Service life	10 years*
Disposal	Observe the usual disposal methods
Dimensions Mixer (H x W x D)	300.00 x 135.00 x120.00 mm
Weight Mixer	2.50 kg
Dimensions Bag Tee (H x W x D)	38.00 x 65.00 x 125.00 mm
Dimensions Tube Nozzle Bag Tee (W x H)	40.00 x 8.00 mm
Weight Bag Tee	0.45 kg
Fresh Gas Outlet Size	ID 15.00 mm x AD 22.00 mm
Nitrous oxide (N_2O) inlet	DISS-Connection
Oxygen (O_2) inlet	DISS-Connection

Technical data	
FlowStar Touch Digital Mixer Flowmeter 70 % with Bag Tee	O_2- concentration: 30 – 100 % N_2O- concentration: 0 – 70 %
FlowStar Touch Digital Mixer Flowmeter 50 % with Bag Tee	O_2- concentration: 50 – 100 % N_2O-concentration: 0 – 50 %
Emergency Oxygen Connection	100.00 – 250.00 l/min, Male DISS Oxygen, Oxygen Gas Specific Connection
Maximum O_2-Flush	>30.00 l/min
Total Flow range	3.00-18.00 l/min
Minimum flow (70 % N_2O)	3.40 l/min
Inlet pressure	50 – 72.5 psi (3.50 – 5.00 bar)
Outlet pressure	> 4.4 psi (0.30 bar)
Input voltage	105.00-125.00/ 225.00 – 240.00 V AC
Input frequency	50.00 – 60.00 Hz
Securing	2 x T 1 A H, 250.00 V
Electrical protection class	I
Amps	1.00 – 0.55 A
Non-continuous operation	10.00 h ON, then 1.50 h OFF
USB file format	FAT32 (sizes up to 64 GB)
Duration of O_2-gas shortage information signal	Until the gas cylinder is empty, the pressure is > 3.00 bar or the mixer is switched off
Volume of O_2-gas shortage information signal	51.00 – 62.00 dB
Ambient Air Valve opening negative pressure	0.94 – 0.22 mbar
Maximum differential pressure	21,76 psi (1.50 bar)
Maximum pressure	Depending on the set flow; information signal if pressure is too high
Color oxygen	Green
Color nitrous oxide	Blue

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

1.2. Indications for Use

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

1.3. Description of application

With the aid of the mixer, a percentage of medical nitrous oxide is added to the medical oxygen. The gas mixture is applied to a patient through a Double Hood. He remains conscious but becomes more relaxed and experiences a reduction of anxiety for treatment. According to various books and studies, nitrous oxide sedation up to a maximum of 70 % nitrous oxide is a minimal sedation with the aim of anxiolysis (anxiety relief) in the patient. It is not anesthesia, the patient is awake, breathing independently and is able to respond to external stimuli. For some patients, the sedative effect at 50 % nitrous oxide is not sufficient. For this reason, in addition to the FlowStar Touch Digital Mixer Flowmeter 50, which can administer a maximum of 50 % nitrous oxide, there is also the FlowStar Touch Digital Mixer Flowmeter 70, which is limited to a maximum of 70 % nitrous oxide. This allows the trained user to decide for himself the maximum nitrous oxide dose with which he wishes to work. The nitrous oxide concentration is individually adjusted to the patient response.

1.4. Indications, contraindications and side effects

Table 4: Indications and contraindications

Indications and contraindications	
Indications	• Anxious or difficult patients • Intellectual or physical disabilities • Patients with a strong gag/ swallowing reflex • Stress prevention in case of mild cardiological problems and asthma • Patients to whom anesthesia is contraindicated • Longer or complex surgical treatment
Contraindications	• 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 o Neither female employees in the dental practice nor patients in their first or second trimester o 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 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 >30l/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.
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 after stopping the nitrous oxide delivery
Psychiatric side effects	• Euphoria, dreams and fantasies are described
General	There are no data to support or suggest a teratogenix, mutangenic, carcinogenix, or reproductive-modifying 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.

1.5. ESSENTIAL PERFORMANCE

This device is designed to deliver a specified mixture of Oxygen and Nitrous Oxide gasses in an environment of a dental or other medical office for the purpose of sedation.

EMC-COMPLIANCE CRITERIA DUE TO THE ESSENTIAL PERFORMANCE

No loss of Oxygen or Nitrous Oxide gas flow.
No significant change in the desired concentration of Oxygen or Nitrous Oxide gas.

1.6. Warning of Minimum Separation from RF Communications Equipment.

This equipment passes radiated emissions requirements for CISPR 11 Class B devices and EM field immunity requirements of IEC61000-4-2, -3, -4, -5, -6, -8, and -11. Operating radio frequency devices in the vicinity of this equipment should be evaluated accordingly. The minimum distance between this equipment and other RF devices is given by the formula below and the table. The minimum distance is determined by the power of the RF device operating in the vicinity of the digital flow meter.

Minimum distance: d = $\sqrt{Power} \div 0.388$ meters

Power	**Distance (meters)**	**Distance (feet or inches)**
0.01 Watts	0.258	10 inches
0.1 Watts	0.816	2 feet and 8 inches
1 Watts	2.58	8 feet and 6 inches
10 Watts	8.16	26 feet and 9 inches
over 10 Watts	Operating the digital flow meter within close proximity of such a transmitter is not recommended.	

2. Description of the software and handling

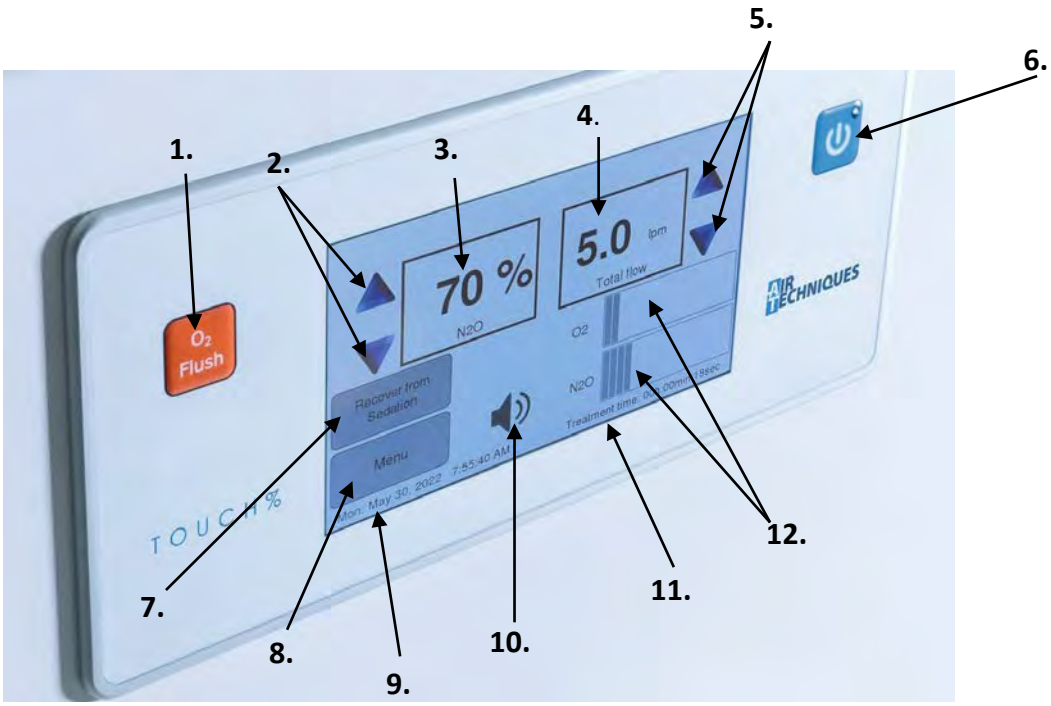


Figure 1: Overview of the FlowStar Touch Digital Mixer Flowmeter

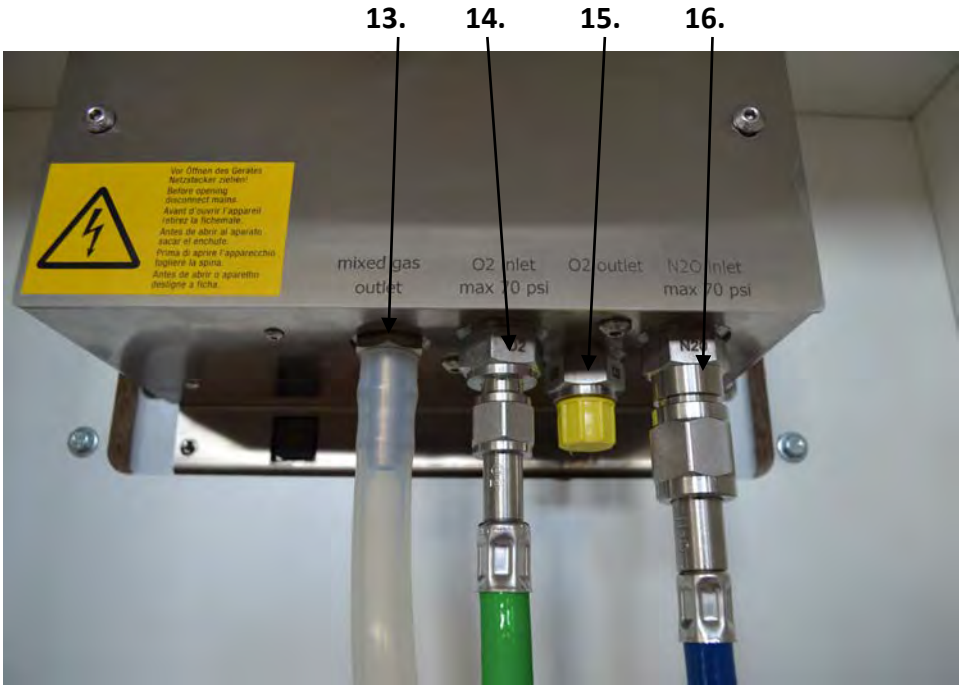


Figure 2: FlowStar Touch Digital Mixer Flowmeter - back

Table 6: Description of the surface of the FlowStar Touch Digital Mixer Flowmeter during sedation

Components	Descriptions
1. O_2-Flush	When the O_2-Flush Button is pressed, a flow of >30l/min with 100 % pure oxygen flows immediately.
2. Concentration regulator	The concentration can be incremented via the upper arrow and decremented via the lower arrow.
3. Concentration display	The percentage and the type of gas is displayed. The settings can be used to specify whether O_2 or N_2O is displayed.
4. Total flow display	The total flow in liters per minute is displayed.
5. Total flow regulator	The flow can be incremented via the upper arrow and decremented via the lower arrow.
6. On/Off/Standby-Knob	The device can be turned on via the button. Standby is switched on by pressing it once in the activated state. The device can be switched off via this button.
7. Recover from Sedation	After sedation and before discharging, clicking on this button will start the flow of 100 % oxygen for a time of 5 – 8 minutes, which can be defined in the settings.
8. Menu	Clicking on the „menu" button opens a window: "Would you like to return to Main menu?" Click on "yes" to return to the main menu (see Figure 4). If you click "no" you will remain in the sedation menu.
9. Display date/time	Display of the current date and time.
10. Mute button	If you click on the loudspeaker, you can switch off the sound. The information signal regarding the lack of O_2 cannot be turned off, but the repetitions become less.
11. Treatment time	A time indicating how long the sedation has been running.
12. Display gas composition	A graphical display of how much N_2O und O_2 is being applied each time. One bar represents approx. 1 l/min. The values are rounded, as only full bars can be displayed.
13. Mixed gas outlet	At this port the mixer delivers mixed gas (N_2O and O_2) and is connected to the Tube nozzle of the Bag Tees (Figure 3)
14. O_2 Inlet	The green pressure hose is attached to this port and supplies medical oxygen to the mixer. The other end of the pressure hose is connected to the gas supply.
15. O_2 Outlet	A separate oxygen demand valve can be connected to this port for oxygen supply. 100 – 250 l/min with 100 % O_2 are applied. If no device is connected to this connection, no gas escapes.
16. N_2O Inlet	The blue pressure hose is attached to this port and supplies medical nitrous oxide to the mixer. The other end of the pressure hose is connected to the central gas supply.

Bag Tee	 *Figure 3: Bag Tee* 1. Inlet Hose nozzle 2. Ambient Air Valve 3. Connection of the Breathing Bag 4. Connection of the Fresh Gas Spiral Tube with integrated one-way valve which prevents the patient from breathing back into the Breathing Bag.

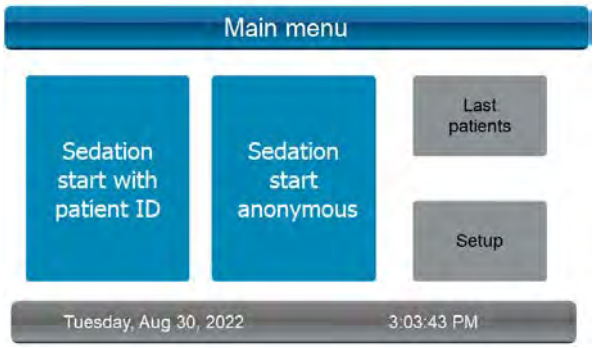


Figure 4: Main menu

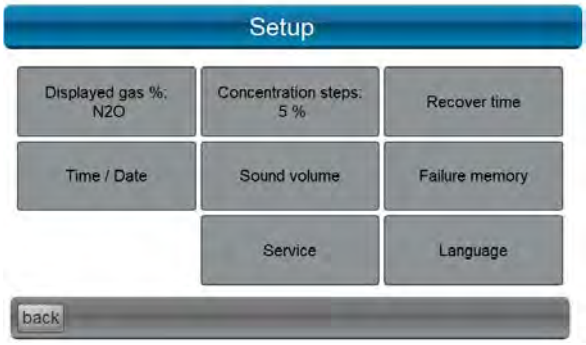
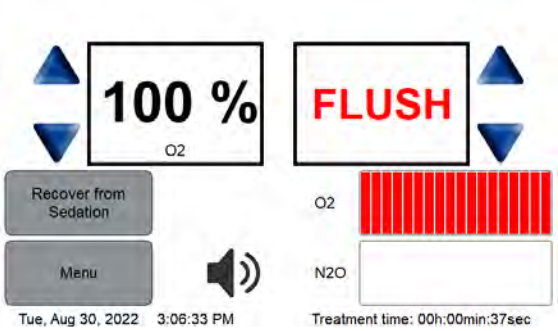
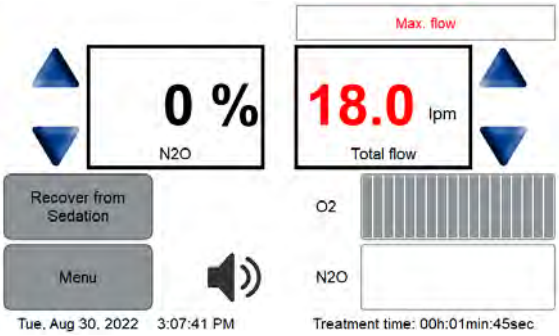
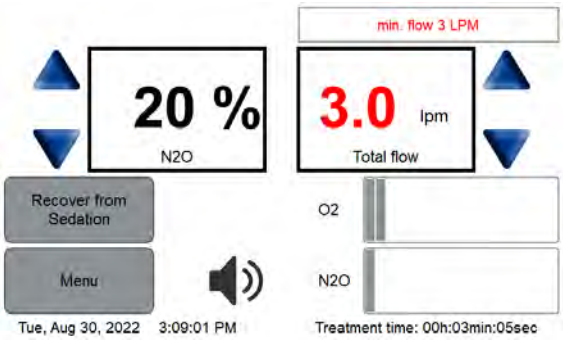
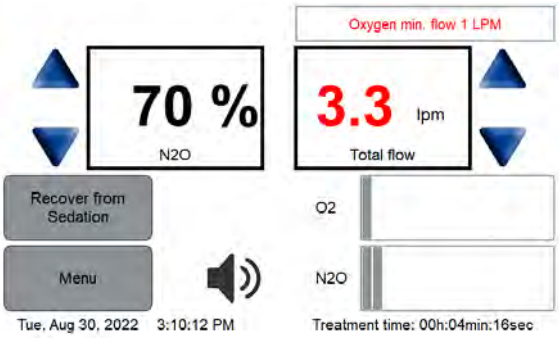


Figure 5: Setup

Table 7: Description of the main menu and setup

Button	Description
Sedation start with patient ID	A menu opens in which a patient can be created with a name or patient ID. If you click on Enter, sedation starts with 5 l/min and 100 % O_2.
Sedation start anonymous	Sedation starts immediately with 5 l/min and 100 % O_2 without saving patient data.
Last patients	Displays the last 50 patients (anonymous or with patient name/ID). Treatment time, start of sedation, date, average total flow, average delivery of N_2O an the maximum N_2O concentration are displayed as an overview. The entries can be deleted from the memory. Via “export data” all patient data can be saved as a .txt. file on a USB stick. The port is located on the right side of the FlowStar Touch Digital Mixer Flowmeters.
Setup	The settings take you to the menu in Figure 5.
Displayed gas %	You can set whether N_2O or O_2 is displayed during sedation.
Concentration steps	It can be set whether the concentration can be changed in 1 % or 5 % steps.
Recovery time	Setting of the recovery time from 5 - 8 minutes.
Time/ Date	Setting of the date and time.
Sound Volume	Setting the volume and key tones.
Failure- memory	All errors that occur are documented with date, time and description. The error memory can be cleared.
Service	The last and next service date, the hardware and software status, the max. N_2O delivery and the serial number of the device are displayed. The number of the service hotline is also displayed.
Language	You can choose between the languages German, English, Spanish and French,

Table 8: Software display

Event	Software display
O_2-Flush	 *Figure 6: O_2 Flush*
Maximum Flow	 *Figure 7: Maximum Flow*
Minimum Flow	 *Figure 8: Minimum Flow*
Minimum Flow at 70 % N_2O	 *Figure 9: Minimum Flow at 70 % N_2O*

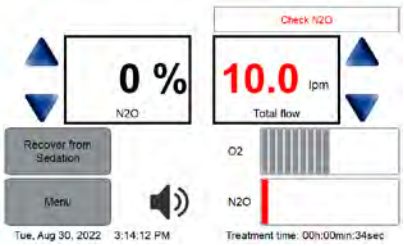
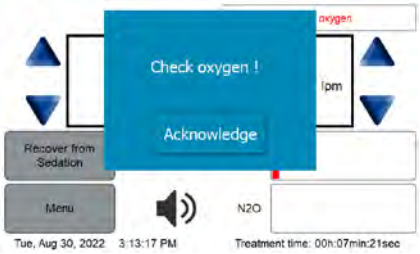
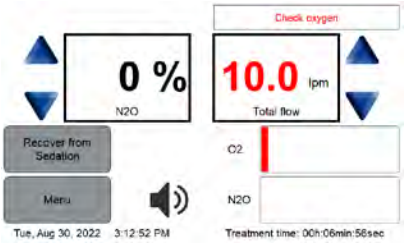
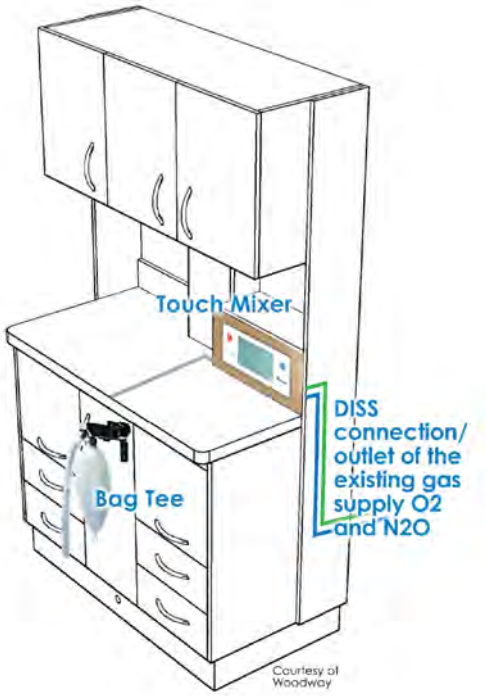
Event	Software display
Lack of N_2O	 *Figure 10: N_2O-lack information*  *Figure 11: N_2O check* If there is not enough N_2O available, a window “Check N2O!” opens; if you press “Acknowledge”, the user sees the display from Figure 11.
Lack of O_2	 *Figure 12: O_2-lack information*  *Figure 13: O_2 check* If there is not enough O_2 available, a window “Check O2!” opens; if you press “Acknowledge”, the user sees the display from Figure 13.

Table 9: 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 green pressure hose must be connected to the two O_2 connections. The blue pressure hose must be connected to the two N_2O connections. Inlet pressure hoses shall comply with ISO 5359;
Handling	Sedation is always started with at least 5 l/min and 100 % oxygen. The level of the flow should be adjusted using the Breathing Bag. If the patient’s breathing movement can be easily seen on the Breathing Bag, the flow has been set correctly. The nitrous oxide concentration must be slowly increased until the patient is individually sedated. The Breathing Bag is the monitor for sedation monitoring.
Service life	We assume an expected service life of 10 years for the FlowStar Touch Digital 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 Touch Digital 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.

Instructions and Information	
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 us for disposal or observe the usual disposal methods.
General information	The FlowStar Touch Digital Mixer Flowmeter is always supplied with Bag Tee. This does not need to be ordered separately. The Scavenging Circuit is connected to the Bag Tee. For more information, see the Instructions for Use “Double Hood Scavenging Circuit”.
Installation of the FlowStar Touch Digital Mixer Flowmeter	 *Figure 14: Dental cabinet with FlowStar Touch Digital Mixer Flowmeter*

3. Scope of delivery

3.1. Product variants

Table 10: Overview of the product variants

Product variant	Ref-number	Description
1	NFT60005	**FlowStar Touch Digital Mixer Flowmeter 50% with Bag Tee**
2	NFT6000	**FlowStar Touch Digital Mixer Flowmeter 70% with Bag Tee**

3.2. Accessories

In addition to the FlowStar Touch Digital Mixer Flowmeter 50%, 70% with Bag Tee, further accessories are required for dental sedation:

Table 11: Overview of necessary accessories. NOTE: The Compressed Gas Association (CGA) developed the Diameter-Index Safety System (DISS)

Art.-No.	Product
Necessary:	
NSC-001	AirTechniques Double Hood Scavenging Circuit, inlet diameter 0.87in
NSP0020	AirTechniques Vacuum Control Block Kit, suction control 45lpm
I	Oxygen pressure hose, green, DISS/DISS (Regarding CGA C-9) in different lengths
	Nitrous oxide pressure hose, blue, DISS/DISS (Regarding CGA C-9) in different lengths
	Breathing Bag Adult 3 l, inlet diameter 0.87in
	Breathing Bag Pediatric 2.3 l, inlet diameter 0.87in
	Central gas supply (NFPA99) or local gas tanks with pressure regulators.

4. Safety and regular checks

Table 12: Safety mechanism of the FlowStar Touch Digital Mixer Flowmeter

Safety mechanism	Description
O_2-gas shortage information signal	If there is no longer sufficient oxygen available, an acoustic signal sounds and "Check O2!" appears on the display to alert the user. As soon as sufficient oxygen is available, no signal sounds. The signal only sounds when the device is switched on.
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-gas shortage	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 50 – 70 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 demand valve can be connected to the O_2-outlet connection. In this case, a flow of approx. 200 – 250 l/min flows.
High pressure signal	If the pressure of a gas is too high, an information signal sounds, and a display appears indicating which gas to check.

Table 13: Check to be carried out regularly

Before treatment:	
Testing of the N_2O lock	1. The mixer should be connected to the central gas supply 2. 50 % N_2O is to be set 3. The flow should be set to any value 4. The oxygen gas supply should be disconnected 5. Both gases shall drop to 0 l/min, an information signal shall sound and "Check O2!" appears on the display 6. If this is not the case, sedation must not be performed

Daily:	
Testing of the mixing ratio	1. Set 0 % N_2O and a flow of 6 l/min 2. N_2O should be 0 l/min and O_2 6 l/min 3. Set the concentration to 30 % N_2O 4. N_2O should be approx. 1,8 l/min (= 2 bars) and O_2 approx. 4,2 l/min (=4 bars) 5. Increase the concentration to 50 % N_2O 6. Both gas displays should show 3 bars

Daily:	
	7. Set the concentration to 70 % N_2O (If the FlowStar Touch Digital Mixer Flowmeter 70 with Bag Tee is used) 8. N_2O should be approx. 4,2 l/min (=4 bars) and O_2 approx. 1,8 l/min (=2 bars)

Weekly:	
Checking for leaks of the Scavenging Circuit	See Instructions for Use „Double Hood Scavenging Circuit“ chapter 4.
Testing 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 one-way valve, breathe into the Fresh Gas Spiral Tube. The Breathing Bag must not fill with air

Monthly	
Testing oxygen	1. Set the concentration to 0 % N_2O 2. Increase the flow 3. The O_2-Display should behave according to the set flow 4. The N_2O-Display must be permanently at 0 l/min
Testing 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 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 central gas supply completely. The pressure must not drop noticeable for more than one hour.
Testing 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 14: Hygiene measures

Hygiene measures:	
FlowStar Touch Digital Mixer Flowmeter	Before first use and between uses, wipe the front of the FlowStar Touch Digital Mixer Flowmeter 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 (anodized aluminium: AA6082, AA5754; stainless steel: 303; hardcoated polyester film). 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.
Double Hood Scavenging Circuit	See Instructions for Use „Double Hood Scavenging Circuit“ chapter 5.

6. Troubleshooting

Table 15: Troubleshooting

Problem	Possible cause	Solution
O_2 does not flow with set flow	1. The unit is not connected to the central gas supply 2. Problems with the central gas supply	1. Connection with wall connection 2. Contact the service partner of the central gas supply
O_2 flows, but no N_2O	1. N_2O supply is not available	1. Check the central gas supply
N_2O flows, but no O_2	1. Serious device error	2. No sedation may be performed, the device must be sent in
Patient does not feel the sedation	1. The Hood is not positioned correctly on the patient' face 2. The mixed gas is not ideally matched to the patient's requirements 3. Inner Hood exhalation membranes are defective/missing 4. The Inner Hood is missing/not fitting right	1. Select another Hood size or press the Hood softly to the face 2. Increase the nitrous oxide concentration 3. Replace membrane 4. Insert the Inner Hood correctly
The Breathing Bag becomes slack during treatment	1. The gas flow is not ideally matched to the patient's needs 2. The Breathing Bag has a leak	1. The total flow must be increased 2. Contact your service partner and order a new bag

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