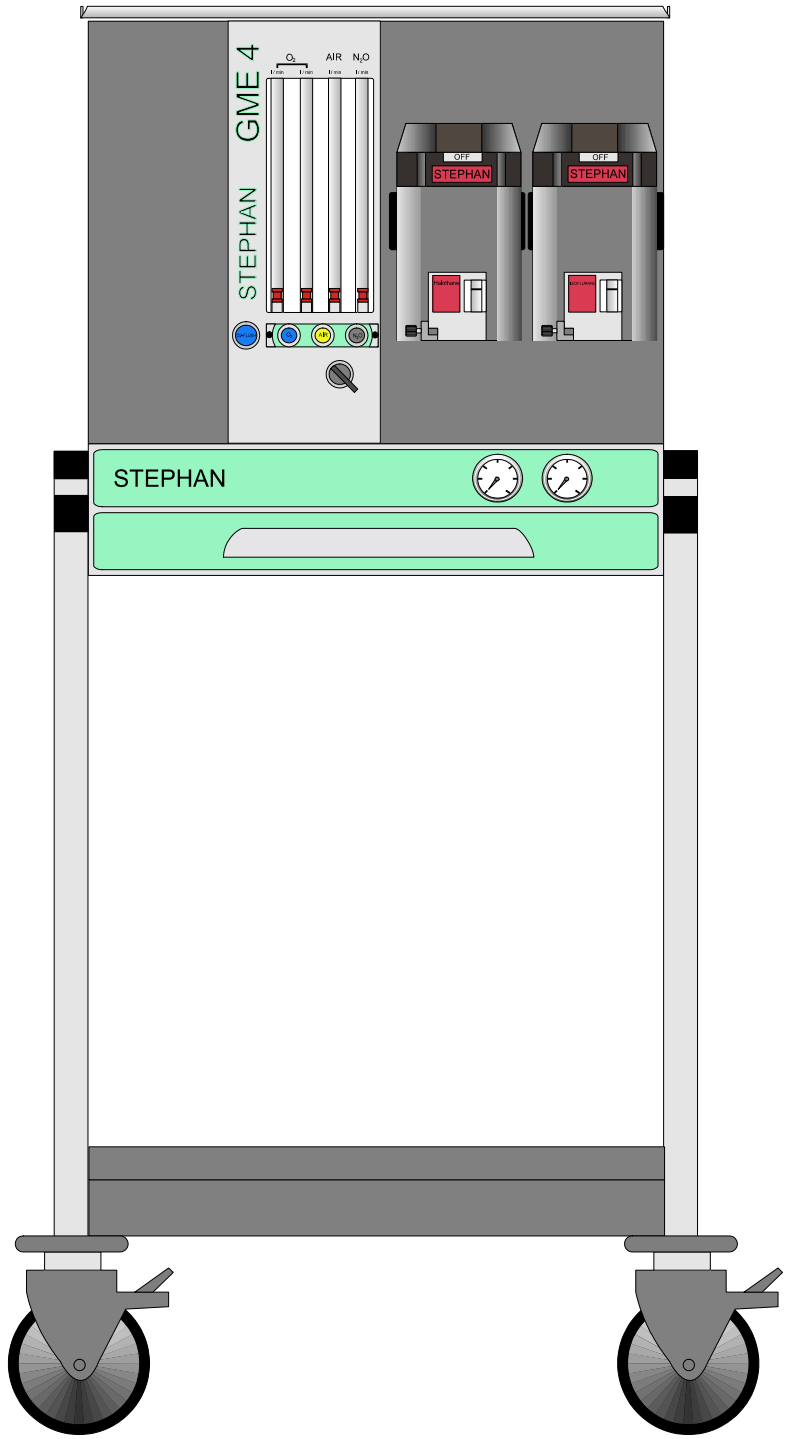


# ARTEC

Anaesthesia Machine



## Operating Instructions

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# 1 General Information

The „ARTEC inhalation anesthesia unit is in compliance with all current directives and regulations.

During the design and development of the unit, the following regulations and standards have been taken into consideration.

DIN 13 152	Inhalation Anesthesia Units
IEC 601/VDE/0750	Electrical Safety of Medical Products
VBG 62/04.69	Oxygen
VBG62/03.70	Operating Instructions for UVV Oxygen

The Medical Equipment Regulations (MedGV), and the law on technical medical working materials (MPBetreibV) stipulate that the attention of the operator must be drawn to the following:

The operation of the Unit must be carried out only by qualified personnel. Exact knowledge and understanding of the Operating Instructions is a pre-conditioned for operation.

Use of the equipment is solely for that as stipulated in the Operating Instructions. Inspections and servicing must be duly entered in the Logbook of the Unit. The Equipment must be inspected at regular intervals by qualified personnel only.

F.Stephan GmbH stipulates a half-yearly inspection and maintenance by one of its authorized Service Technicians.

Before each use of the unit, a complete function test of the unit must be carried out.

In the case on medico.technical devices with electrical connection, the standards of particular VDE 0751 and IEC 601 must be closely complied with. According to these standards, such devices may only be set up and put into operation by the manufacturer or his expressly authorized technician or dealership.

Unit equipped with a pressure reducer should undergo a basic overhaul at least every 5 years for reasons of safety.

An emergency ventilation system (e.g. Ambu-Bag) must always be in close proximity of the unit.

F. Stephan shall assume no responsibility or liability for any damage or defects arising from non-observance of the above-mentioned information.

## 2 Technical Description

Driven by customer requests and requirements, the ARTEC model series had been designed and developed as a compact universal version. At the same time high quality-standards and maximum economy has been achieved.

The elementary structure ensures a good overview and quick allocation and adjustment of parameters for the respective unit components. The ARTEC anesthesia unit is an inhalation anesthesia unit that is equipped with a anesthesia agent specific vaporizer for use in a semi-closed system

The unit consists of a basic housing of stainless steel in which a drawer is provided. Located above that is the gas-mix unit (GME, with which the available medical gases O<sub>2</sub>, N<sub>2</sub>O and (optional) compressed air can be dosaged.

The GME consists of an integrated pneumatic unit with relevant safety valves providing for N<sub>2</sub>O block and O<sub>2</sub> deficiency signal (in compliance with DIN 13252 and the dosage unit for the above-mentioned medical gases.

On the right-hand side, an anesthesia agent specific vaporizer can be mounted on special mounting racks ( one or two-fold).

Located on the basic unit and depending on model, there is provided a stainless steel shelf for additional monitoring or a ventilation module with integrated monitoring (according to DIN 13252).

On the reverse side of the unit there are standard connections for gas supply linea and depending on model, holding racks for reserve bottles with integrated high-pressure reducers.

The unit is also equipped with four plug sockets for electrical power supply for additional monitors. These sockets are constantly supplied with current regardless of the Ventilators ON/OFF power supply status.

### 2.1 Possible Expansion and Upgrading of the Unit

#### Basic Model

The ARTEC basic model is suitable for wall mounting. For such mounting, the mounting rails of the basic unit are attached to the V<sub>2</sub>A rails.

For wall mounting, exact vertical mounting of the unit must be strictly observed, otherwise inexact mounting could lead to false measuring results of gas flows. An adjustable distancer device provides a precise alignment of the unit.

#### Unit Model with Mobile Stand

The unit can be mounted on a mobile stand that enables and ensures variable site operation.

The basic unit can be mounted on the mobile stand profile (80x30) by tightening the four mounting bolts. The mobile stand can be equipped with a stand-alone oxygen, compressed air and vacuum generator module „STAXEL“

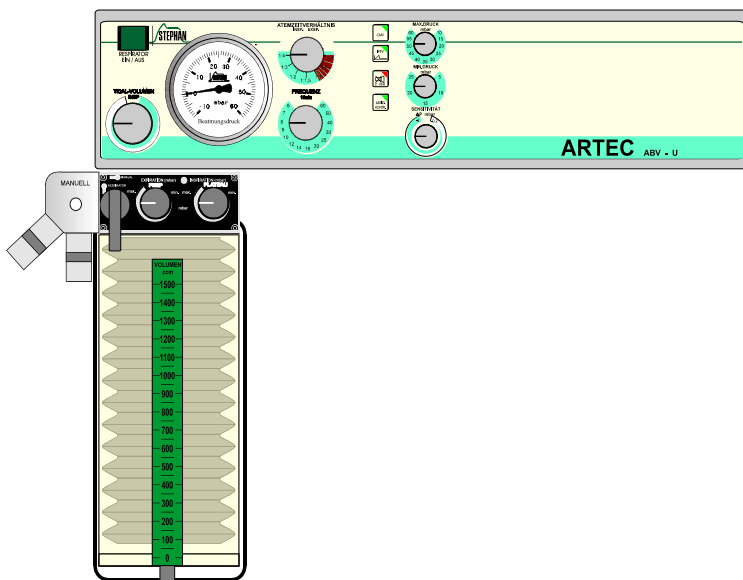
## Gas Supply:

The unit is designed with a central gas supply coupling connection in compliance with DIN 13253. A set of hoses is supplied with the unit for the three types of gases O<sub>2</sub>, N<sub>2</sub>O and compressed air ( if air is provided).

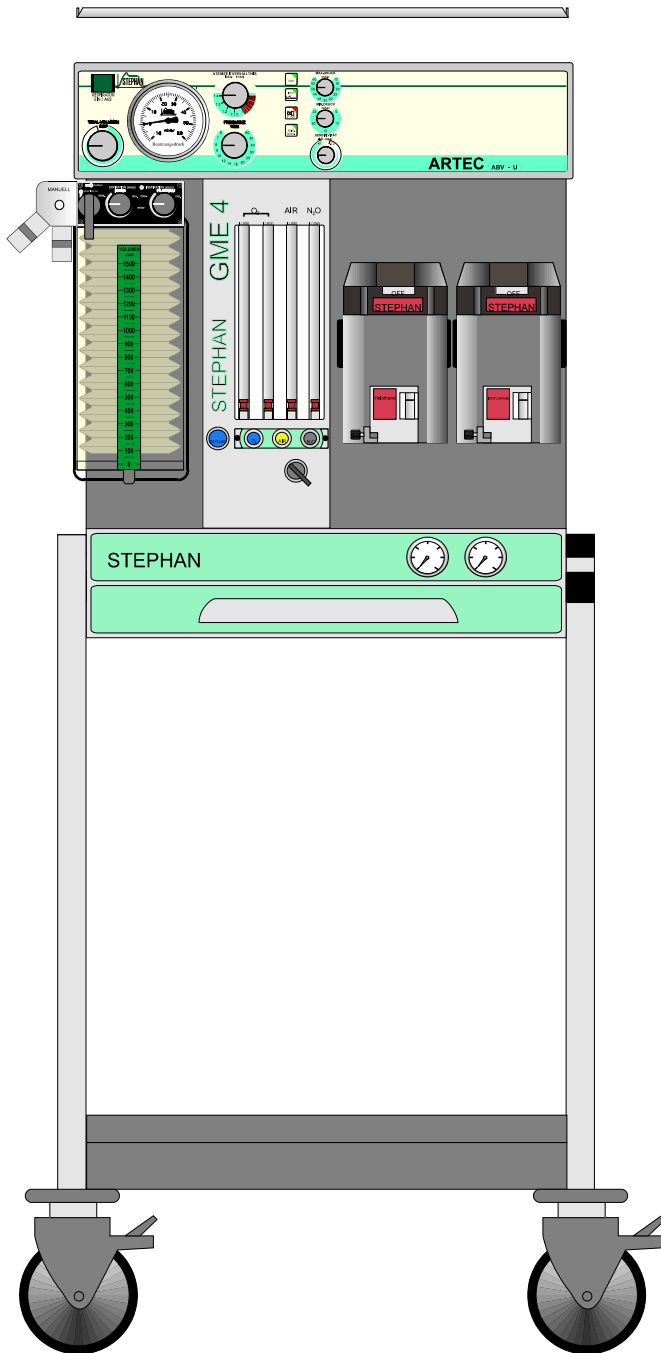
Gas supply can either be via a central gas supply network, or via bottle supply with 10 litre bottles O<sub>2</sub> and N<sub>2</sub>O. To ensure uninterrupted gas supply, in the event of breakdown of the central gas supply, 2 litre reserve bottles can be connected.

An alternative to bottled gas supply, the ARTEC anesthesia unit offers the possibility of a decentralized oxygen supply via the supply „outlet“. This is the „STAXEL“ that has been especially developed as an oxygen / compressed air and vacuum generator.

## Ventilation Module:



The ventilation module ABVA is easy to use and can eventually be mounted to the basic unit later on. For this the V<sub>2</sub>A shelf is removed from the basic unit. After that the ventilation module can be mounted to the basic unit via two mounting bolts. The compressed air supply of the ventilator is created via a connection line to the basic unit.



After attaching the V<sub>2</sub>A shelf, you now have a respiratory-controlled anesthesia ventilation system with the current necessary state-of-the-art monitoring system.

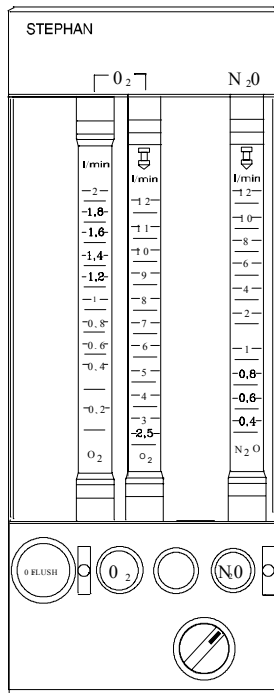
It is strongly advised to have the installation carried out by our specially trained Stephan Service Team.

## 2.2 Scope of Use and Application

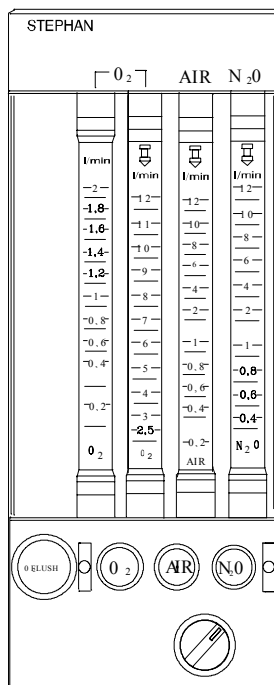
The ARTEC is an inhalation anesthesia unit for the manual anesthesia of infants, children and adults.

It can be used in conjunction with a ISO circuit system, but can also be operated with open ventilation systems. The scope of applications of the ARTEC anesthesia unit ranges from use in the practitioner's surgery to hospital operation theatres.

### 3 Description



Gasmischeinheit GME 3  
Art.Nr. 150 61 070



Gasmischeinheit GME 4  
Art.Nr. 150 61 071

#### 3.1 Gasmixingunit 3 and 4

The gasmixingunit serves as a dosage unit for medical gases (e.g. O<sub>2</sub>, N<sub>2</sub>O, Air). The chosen gases can be mixed in an arbitrary relation, but the ratio-system guarantees an O<sub>2</sub>-concentration higher than 21 % (see below). The different gases are clearly displayed with rotary buttons.

To avoid mistakes, the O<sub>2</sub>-rotary button discerns from the others.

An unintentional move is prevented by a protection.

The dosing device makes a continuous flow enable, when opening the valves by rotation against clockwise.

The O<sub>2</sub>-measuring range contains two measuring devices. This makes a fine dosage possible.

The left measuring tube has a range from 0 to 2 l/min O<sub>2</sub>, the right tube has a range from 2 to 15 l/min O<sub>2</sub>. As a point of observation serves the upper surface of the floating body.

#### 3.2 O<sub>2</sub> – Ratiosystem

The Gasmixingunits GME 3 and GME 4 can be equipped optionally with a pneumatical system to assure at every flowrange of N<sub>2</sub>O a minimum concentration of oxygen of 25 % O<sub>2</sub> (+/- 5%).

The so-called O<sub>2</sub> - Ratiosystem avoids the delivery of pure N<sub>2</sub>O to the breathing system.

##### Mode of operation

The O<sub>2</sub> – Ratiosystem examines the O<sub>2</sub> – Flowrate. If there is no O<sub>2</sub> – Flow the N<sub>2</sub>O – Line is blocked. Thus it is impossible to apply pure N<sub>2</sub>O to the breathing system without opening the O<sub>2</sub> – Valve at the GME.

Only when the O<sub>2</sub> – Valve is opened counterclockwise, a N<sub>2</sub>O – flow according to the flowrate of O<sub>2</sub> can be adjusted. The minimal achievable oxygen concentration is 25 % +/- 5%.

##### Control of function

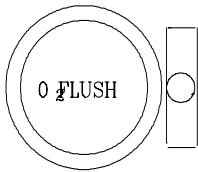
1. Close O<sub>2</sub> – and N<sub>2</sub>O – Valve at the GME.
2. Open N<sub>2</sub>O – Valve to maximum ⇒ There should be no N<sub>2</sub>O – Flow
3. Open O<sub>2</sub> – Valve counterclockwise ⇒ N<sub>2</sub>O – Flow is increasing
4. Adjust 1 l/min O<sub>2</sub> ⇒ N<sub>2</sub>O – Flow should be 3 l/min +/- 0,2 l/min
5. Adjust 3 l/min O<sub>2</sub> ⇒ N<sub>2</sub>O – Flow should be 9 l/min +/- 0,6 l/min

Caution

The O<sub>2</sub> – Ratiosystem controls the O<sub>2</sub> – concentration in the freshgas. It does not prevent in any case a hypoxic gasmixture in the circsystem.

**Please do control the inspiratory O<sub>2</sub> – concentration by using an oxygenmonitor.**

3.3 O<sub>2</sub>-Flush

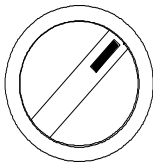


By pressing the O<sub>2</sub> Flush push-button, a fast oxygen supply (approx. 50 litres per minute) is activated directly to the fresh-air outlet (not via the anesthesia vaporizer). After releasing the O<sub>2</sub> Flush push button it must return to its original position.



3.4 AIR/N<sub>2</sub>O Mode Switch

The Air / N<sub>2</sub>O Mode Switch is located below the rotary knobs for (AIR /N<sub>2</sub>O). This offers a pre-selection of the gases AIR or N<sub>2</sub>O. The respective dosage of the gases is effected via the regulation valve.



3.5 O<sub>2</sub>- supply deficiency signal

In the event of a pressure drop in the supply system (oxygen below 2.0 to 1.5 bar) an acoustic warning alarm is activated for a duration of at least 7 seconds. An interruption is not possible).

3.6 Nitrous Oxide Block

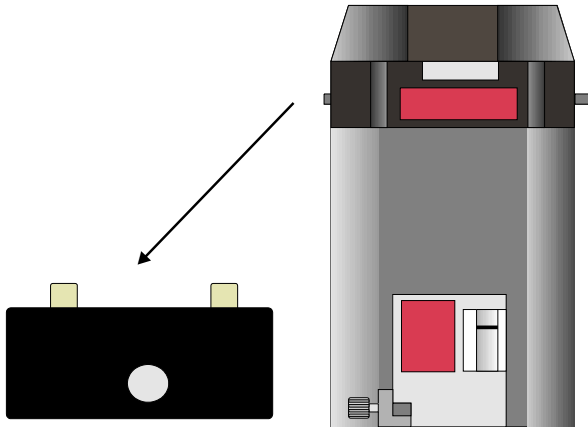
In the event of a further fall in pressure of oxygen to about 1 bar, the ratio of N<sub>2</sub>O is reduced proportionately to the oxygen supply. Should there be a total fallout of oxygen, the N<sub>2</sub>O flow is set to zero. Release of N<sub>2</sub>O is then closed.

The unit stand-by mode can be resumed only by setting the stipulated oxygen pressure of at least 2 bar at the network inlet.



### 3.7 Vaporizer

On request, the ARTEC inhalation anesthesia unit can be equipped with various vaporizer-systems. In the standard model, the vaporizers come in use which are equipped with an „Interlock“ locking system to enable alternating operation of two vaporizers.



The anesthetic agent is mounted to the selected vaporizer rack by means of a click-in mechanism. The locking lever secures the vaporizer on the holding rack.

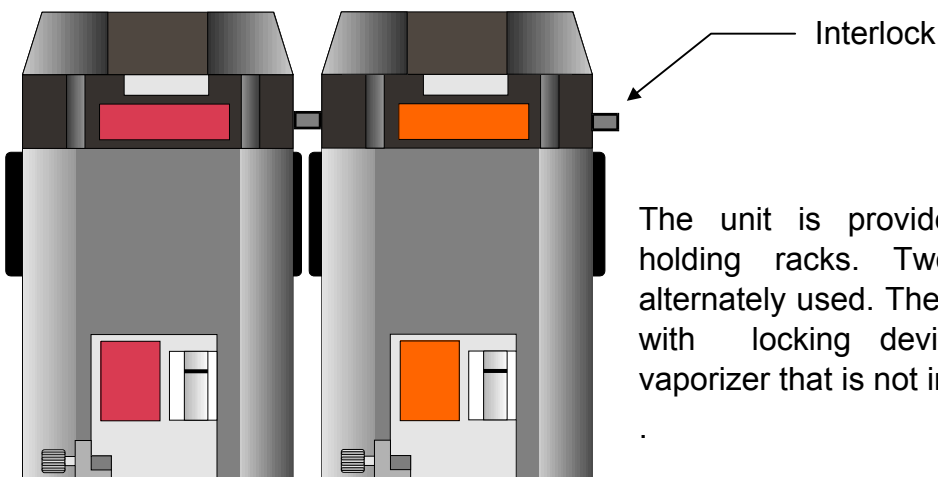
Please read the operating instructions of the respective model of vaporizer with which the ARTEC anesthesia unit is equipped.

#### Vaporizer holding-rack „single“

The unit is equipped with one vaporizer rack holder. Only one vaporizer can be put into operation.

The vaporizer holding rack is provided with automatic closing valves. The seal between the vaporizer and the holding rack takes on the function of a gasket ring placed on the valve. Optionally, a side-rail possibility for a second vaporizer can be provided besides the active vaporizer holding rack.

#### Vaporizer holding rack „two-fold“ Interlock locking system:



The unit is provided with two vaporizer holding racks. Two vaporizers can be alternately used. The vaporizers are provided with locking devices that disables the vaporizer that is not in operation.

### 3.8 Gas-cylinder Supply Component

When in the gas-cylinder operation mode, the gas is reduced from 200 or 50 bar to a working pressure of 5 bar.

The cylinder pressure can be read on the pressure gauge and indicates the status of level fill of the gas bottles.

The feed of the gases to the actual unit is effected via the quick-fit couplings or the DIN threaded couplings which are unmistakably coded according to type of gas being used.

**IMPORTANT:**

**When transporting, it is absolutely necessary to close the cylinder-valves.**

## 4 Testing Unit Functions

### 4.1 Dosage valves of the Gas Mix Unit

When closing the dosage valves make sure that the respective floating marker of the respective measuring tubes are re-set to zero. Otherwise, a leakage of the respective spindle will result that must be remedied by a service technician.

### 4.2 O<sub>2</sub>-Flush

Before each operation of the ventilation unit check to see whether the O<sub>2</sub> bypass valve immediately and automatically closes after releasing the push-button.

Basic Setting:

Dosage valve (1) on measuring tube section is closed.

Conducting Test:

Briefly press the bypass button. On release of the push-button it immediately return to its initial position.

### 4.3 AIR / N<sub>2</sub>O Mode Switch

Basic Setting:

- O<sub>2</sub> dosage valve closed
- N<sub>2</sub>O dosage valve set to 3 litres per minute
- AIR dosage valve set to 3 litres per minute
- Mode Switch in „N<sub>2</sub>O“ position
- Anesthesia aspiration unit connected
- O<sub>2</sub> monitor calibrated and in operating mode

Conducting Test:

The measuring tubes for N<sub>2</sub>O must show 3 litres per minute flow, while the compressed measuring tube must indicate no flow. The O<sub>2</sub> monitor shows approx. 0% O<sub>2</sub> (after a brief waiting time).

When switching from N<sub>2</sub>O to AIR – without changing dosage valve status – indication of floating marker of the N<sub>2</sub>O measuring tube must return to zero, while, at the same time the display of the compressed-air measuring tube must indicate 3 litres per minute. The O<sub>2</sub> monitor shows 21% O<sub>2</sub> as confirmation.

## 5 Gas Type Test and Testing Safety Devices

### 5.1 Testing Gas Type:

Check for proper connection of the anesthesia unit to the central gas supply system before operation of the unit.

Basic Setting:

Unit in operation mode

Anesthesia gas aspiration unit connected

O<sub>2</sub> monitor in standby mode and calibrated. Measuring at fresh gas outlet.

Conducting the test:

#### **Oxygen ( O<sub>2</sub>):**

Open the O<sub>2</sub> dosage spindle to approx. 1.5 to 2.0 litres per minute.

The O<sub>2</sub> monitor must display approx. 98 to 99 O<sub>2</sub>.

#### **Nitrous Oxide (N<sub>2</sub>O):**

Open the N<sub>2</sub>O dosage spindle to approx. 1.5 to 2.0 litres per minute.

The O<sub>2</sub> monitor must display 0 % O<sub>2</sub>.

#### **Compressed air (AIR)**

Open the AIR dosage spindle to approx. 1.5 to 2.0 litres per minute

The O<sub>2</sub> monitor must display approx. 21% O<sub>2</sub>

**In the event of any deviance, the unit must undergo a service inspection!**

## 5.2 Testing the O<sub>2</sub> deficiency signal / nitrous oxide block:

### Basic Setting:

Unit in operation mode  
Anesthesia aspirator device connected  
All dosage valve spindles opened to 3 litres per minute  
AIR / N<sub>2</sub>O Mode Switch in N<sub>2</sub>O position

### Conducting test:

remove angle plug for O<sub>2</sub> from circuit  
the oxygen flow must continuously decrease  
at approx. 2.0 to 1.5 bar circuit pressure the **O<sub>2</sub> deficiency signal** is activated

When pressure further decreases to approx. 1 bar, the nitrous oxide block is activated and the N<sub>2</sub>O flow sinks parallel to the oxygen flow, until for a fully empty system both volumens flows fall to zero.

By re-connecting the O<sub>2</sub> angle plug, the oxygen supply is re-established.

Interruption of the N<sub>2</sub>O feed line. The N<sub>2</sub>O flow sinks to zero.

**In the event of deviations of the description above, please inform customer service.**

## 5.2 Testing the Vaporizer / Vaporizer holding rack

The anesthesia agent vaporizer is to be check for its proper function before using the unit.

### Basic Setting:

Unit set in operation mode  
Anesthesia agent vaporizer filled and ready for operation

### Conducting the test:

#### **Vaporizer:**

Check adjusting and locking device for proper functioning  
Check level status display for damage  
Check adapter for safety support for damage  
Check vaporizer locking lever

#### **Condition of Vaporizer:**

Check sealing valve for leakage  
Inspect sealing gasket for exterior damage

## **6 Cleaning and Care of Anesthesia Unit**

The anesthesia unit is to undergo a thorough cleaning at appropriate intervals; whereby servicing measures must also be conducted that will prolong the service life of the machine.

After removing the vaporizer, the unit can be wiped clean using a common detergent agent. It is highly recommended to follow this up by using a dry cloth to remove any moisture and thus limiting any danger of corrosion.

Special attention should be given to the O-rings located at the vaporizer holding rack. These are to be carefully removed, cleaned and replaced in a dry condition. Should these rings show damage of any type, they are to be replaced by new O-rings.

## 7 Notes on Potential Malfunctions

<b>Error</b>	<b>Possible Cause(s)</b>	<b>Remedy</b>
Floating marker of the measuring tubes do not return to zero	Measuring tube is dirty Dosage valve leakage	Clean measuring tube Loosen rotary knob and re-set (Service)
When using Mode Switch AIR/N <sub>2</sub> O switch, the selected gas is not activated (indicated via O <sub>2</sub> monitor)	Mode switch valve is not properly sealed.	Replace mode switch valve (customer service)
Oxygen concentration too high	Leakage in oxygen dosage valve Flush Valve does not close properly	Loosen rotary knob and re-set (customer service) Replacement of Flush Valve by customer service
O <sub>2</sub> deficiency signal is constantly activated	Supply pressure too low Valve is defect	Set pressure reducer of the bottle supply higher Have customer serve replace valve

## 8 Technical Data

Inhalation Anesthesia Unit MPG-Class 2b, Model Registration Number: 11 / M-01491

Typ: B Protection Class: 1

U: 230 V AC

P: 80 VA (with ventilator)

### Dimensions (with Ventilator ABVA)

Width: 500 mm

Height: 1350 mm

Depth: 630 mm

### Dimensions (without Ventilator ABVA)

Width: 500 mm

Height: 1240 mm

Depth: 630 mm

### Connections (threaded) for Gas Types:

O<sub>2</sub>: M 12 x 1

AIR: M 20 x 1.5

N<sub>2</sub>O: M 14 x 1

Fresh Gas: M 16 x 1.5

Circuit pressure 5 bar +/- 0.5 bar

### Measuring range for measuring hoses:

O<sub>2</sub> (fine) : 0 to 2 litres per minute  
 (roughly) : 2 to 15 litres per minute

AIR : 0 to 15 litres per minute

N<sub>2</sub>O : 0 to 15 litres per minute

### Precision of Measuring tubes:

+/- 10% of the respective end scale value. For integrated micro measuring range +/- 10% of the measuring endscale value (under standard conditions 20°C and 1.013 bar)

### O<sub>2</sub> deficiency signal:

Trigger pressure: 2.8 bar

Duration of acoustic warning signal 7 seconds

### N<sub>2</sub>O Block:

Trigger pressure: 2.0 bar



## 9 Maintenance and Servicing

Medico-technical products are required to undergo at regular intervals inspection and servicing in compliance with MedGV (Medical Equipment Regulations).

Such inspections and servicing are to be carried out by authorized personnel only (Service Staff) of the Supplier.

Periodic Maintenance is generally semi-yearly.

Safety Technical Inspections

Recommended Scope:

1. Visual check of necessary identification markings and Exterior detected damage
2. Check for completeness of Unit
3. Check proper functioning and alarm functioning
4. Measure earthing resistance, replacement unit ground contact and the insulation resistance in compliance with VDE 0751 Part 1/12.84

The Maintenance Agreement ensures the best guarantee, and provides semi-annual inspections with automatic replacement of parts subject to wear.

Should maintenance and servicing of the unit be carried out by unqualified and unauthorized persons, the Manufacturer cannot be held liable for the safe and proper functioning of the unit.