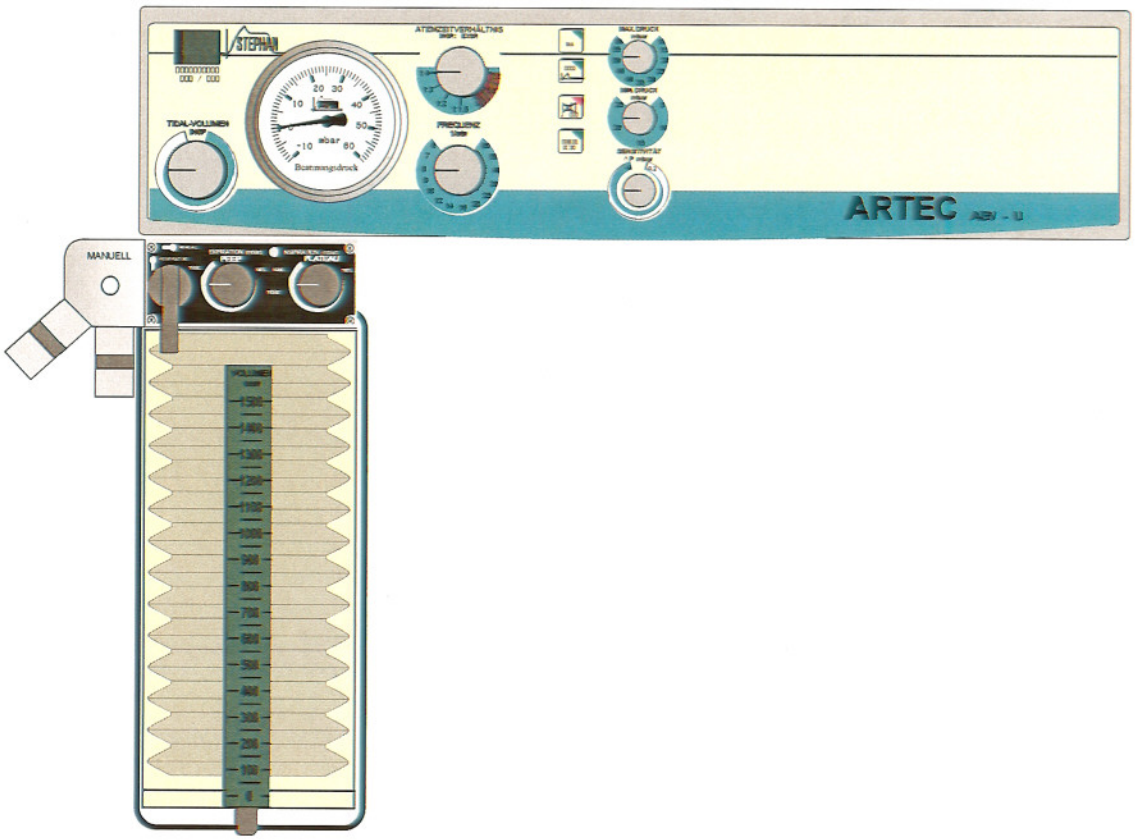
OPERATING INSTRUCTIONS

RESPIRATOR A B V - A/ - U



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1. Attention

This product is in compliance with all current directives and statutory regulations
The design and construction of this device comply with the following regulations and norms:

DIN EN 60601-1 (and following)	Medical electrical equipment
DIN 13 252	Inhalation Anaesthesia Devices
DIN VDE 0750-211	Medical electrical equipment, partial Requirements for safety of anaesthesia machines
VBG 62/04.69	Oxygen
VBG 62/03.70	Implementing Ordinance for UW Oxygen

In compliance with the law governing technical operational devices (Instrument Safety Act) of June 24 1968 (German Civil Code Gazette/BGBI, page 717) in the wording of Amending Act of August 13 1979 (BGBI, page 1432) in the law governing Safety of Medical Devices (MedGV) of January 14 1985 (BGBI 2. page 93) we point out that:

1. The operation of this device is to be carried out by duly trained personnel only. Exact knowledge and understanding of the operating instructions are necessary.
2. The device may only be used for the purposes indicated in the operating instructions.
3. The device must be serviced at regular intervals by trained personnel. Such servicing must be recorded in the device logbook provided.
4. The manufacturer stipulates servicing and maintenance every six months by an authorised service technician. For this reason, a maintenance agreement must be concluded.
5. Devices equipped with pressure relief systems should, for safety reasons, undergo a general reconditioning at least every five years.
6. For medico-technical devices with electrical connections, strict compliance with VDE directives and IEC 601 (VDE 0751) is necessary. Accordingly, these devices may only be serviced by the manufacturer or his expressed authorised representative.
7. An emergency respirator (e.g., ambu bag) must be kept near the device.
8. Operating conditions:
   Power supply: 230 V mains voltage
   Room temperature: between 10°C and 40°C
   relative humidity 90%

Do not place any large heat source around or on the device. Make sure there is sufficient space around the device for ample heat dissipation.

9. Check all functions carefully to see that they are working properly according to the checklist and operating instructions.
10. Under the above conditions the device can be used in „continuous operation" mode.
11. Functioning of this device can be negatively influenced by other devices being used in close proximity: such as short-wave surgery and diathermy devices, defibrillators, radiothermy, etc.

The manufacturer is not liable for any damage to the machine caused by improperly operating the machine or non-compliance with the instructions mentioned above.

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2. Design and description of functions

2.1 Overview

The respirator module consists of a pneumatic and an electronic control component (respirator ABV-A / U and patient component), as well as an electronic pressure monitor and, as an option, monitors for oxygen concentration, anaesthetic gases and ventilation parameters.

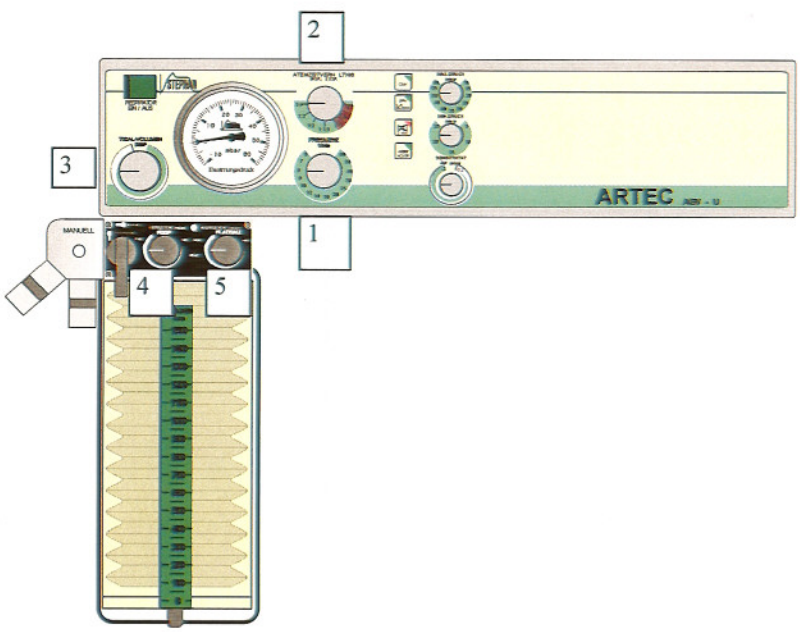
The electronics of the respirator module are supplied with mains power (230 V / 50 Hz), while the pneumatic requires propellant in the form of compressed air (3 - 5 bar)

The respirator is suitable for controlled anaesthesia in a semiclosed system for children and adults.

The patient component can easily be disconnected and replaced by means of snap couplings for purposes of hygiene (partly autoclaveable up to 134°C).

General Description

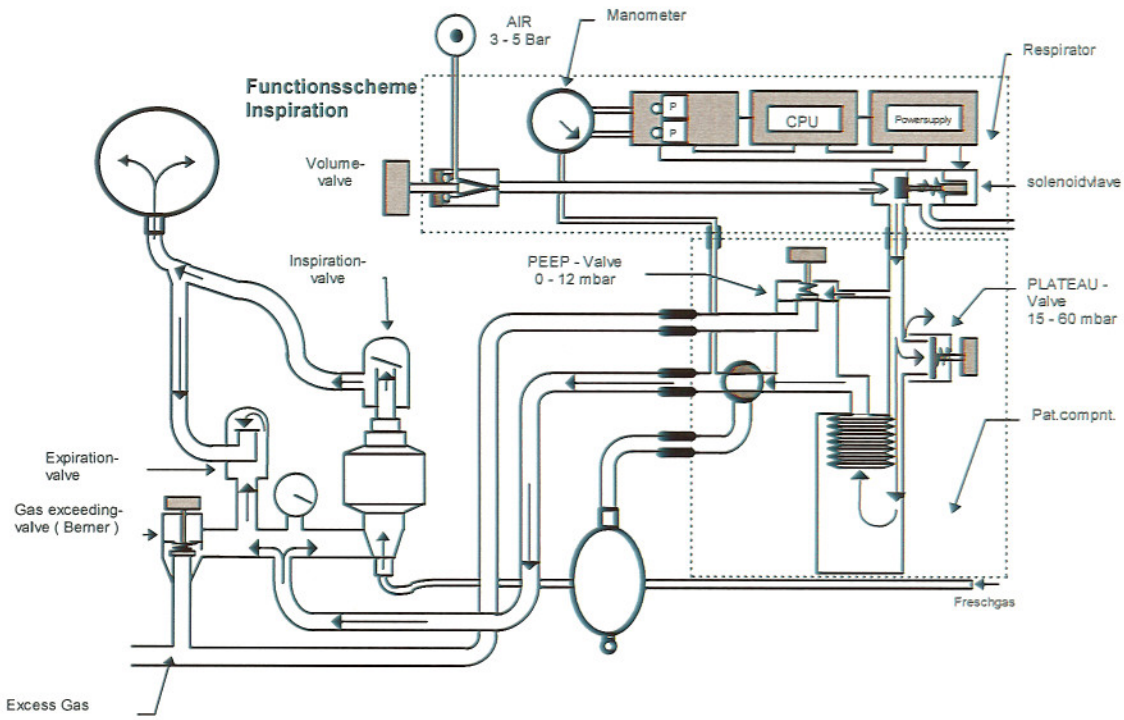
Compressed air with a line pressure of 3-5 bar must be used to supply the respirator ABV-A with a propellant. The various respiration parameters can then be set on the respirator.



1) Frequency
2) Respiratory time quotient
3) Volume
4) PEEP
5) Plateau

A sufficient flow of fresh gas must be ensured. Observation of the respiration schemes of the anaesthetic device „ARTEC“ is analysed in two parts.

2.2 Technical function during the „inspiratory phase".

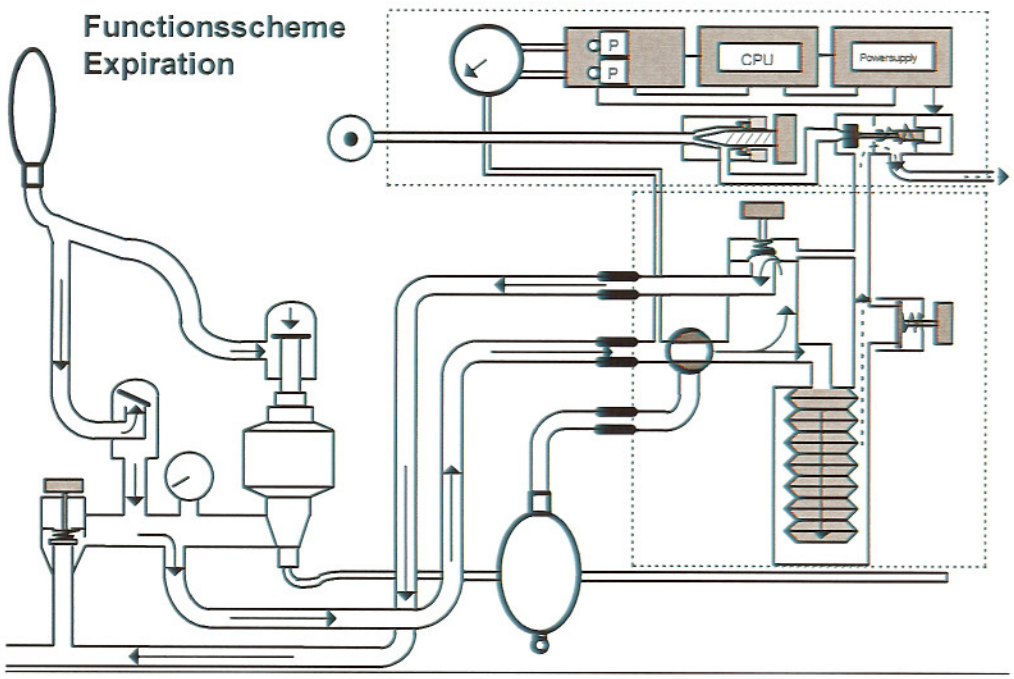


To begin inspiration, the solenoid valve of the respirator opens. Via the ZGA connection, compressed air (so-called „propellant") flows into the patient component. The amount of inflowing gas is adjusted at the volume valve. Opening time of the solenoid valve is regulated by respiratory frequency and time quotient.

The build-up of pressure in the Plexiglas cylinder (bottle) compresses the bellows bag. The gaseous mixture consisting of fresh gas and returned patient gas present in the bellows bag closes the expiration valve and is led to the CO_2 absorber. The gas opens the inspiration valve and flows to the patient. Respiration pressure can be read both on the pressure gauge of the respirator and on the circuit system. When the respiration pressure reaches the pre-set plateau pressure limit before the end of the inspiration time, the PLATEAU valve opens, releasing propulsion gas into the open. The integrated pressure monitor allows continuous monitoring of pressures during the inspiration phase. A visual and acoustic signal warns when the pre-set upper pressure limit has been exceeded.

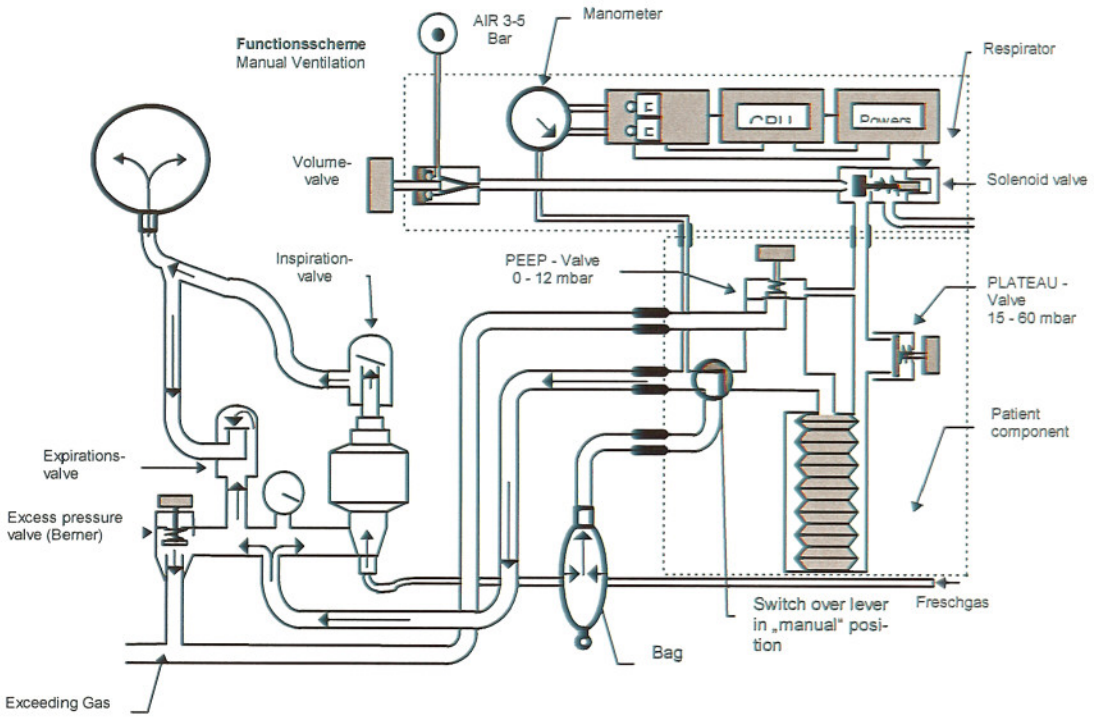
2.3 Technical function during the „expiratory phase“

Functional scheme expiration



Following the inspiratory phase, the solenoid valve shuts off the flow of propulsion gas. Pressure in the lungs of the patient closes the inspiration valve and opens the expiration valve. The patient exhales into the respiration bellows which is then pressed down. At the same time, fresh gas flows into the bellows. The propellant gas being pressed out of the glas cylinder is released into the open via the solenoid valve. The excessive exhaled air is fed via the PEEP valve diaphragm. The PEEP diaphragm retains as much pressure in the system as had been pre-set on the patient component adjustable PEEP value.
The reduction in respiratory pressure and the remaining positive end expiratory pressure (PEEP) are displayed on the pressure gauges of the circuit system and the respirator.

2.4 Technical function during „manual respiration“



By means of the switch over lever „Manual / Respirator“ on the patient component, the manual respiration bag is connected directly to the circuit system. Pressure build-up now develops directly via the manual respiration bag.

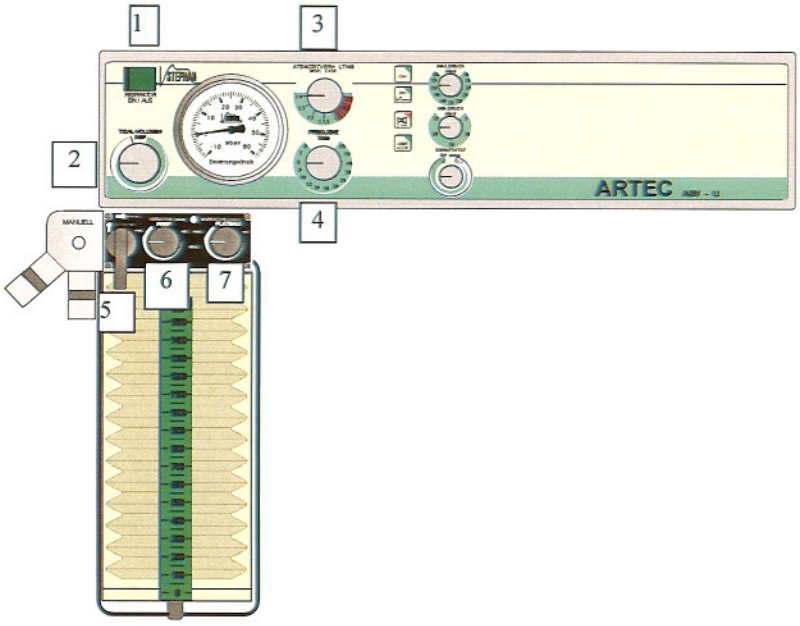
CAUTION !

Pressure limitation is effected only via the excess valve (Berner valve) of the circuit system !
The PLATEAU valve of the patient component is disabled.
Make sure the Berner valve is open after switching over to „Manual“.

The PEEP and PLATEAU functions of the patient component are disabled. The residual pressure remaining in the circuit system can be pre-set in a range of 0 - 50 mbar via the Berner valve.
Make sure that an additional connection of the scavenging system (NGA) is made to the Berner valve.

2.5 Respirator with patient component

The ABV-A / U respirator has been designed for controlled anaesthesia respiration in compliance with state-of-the-art technology.
Operation of the respirator is driven by compressed air, timed and volume constant; the maximum inspiration pressure can be pre-set at the patient component
The patient component is based on the „bag-in-bottle principle" with which a separation of respiratory gas from control gas is achieved. In addition, the patient component serves as a reservoir.

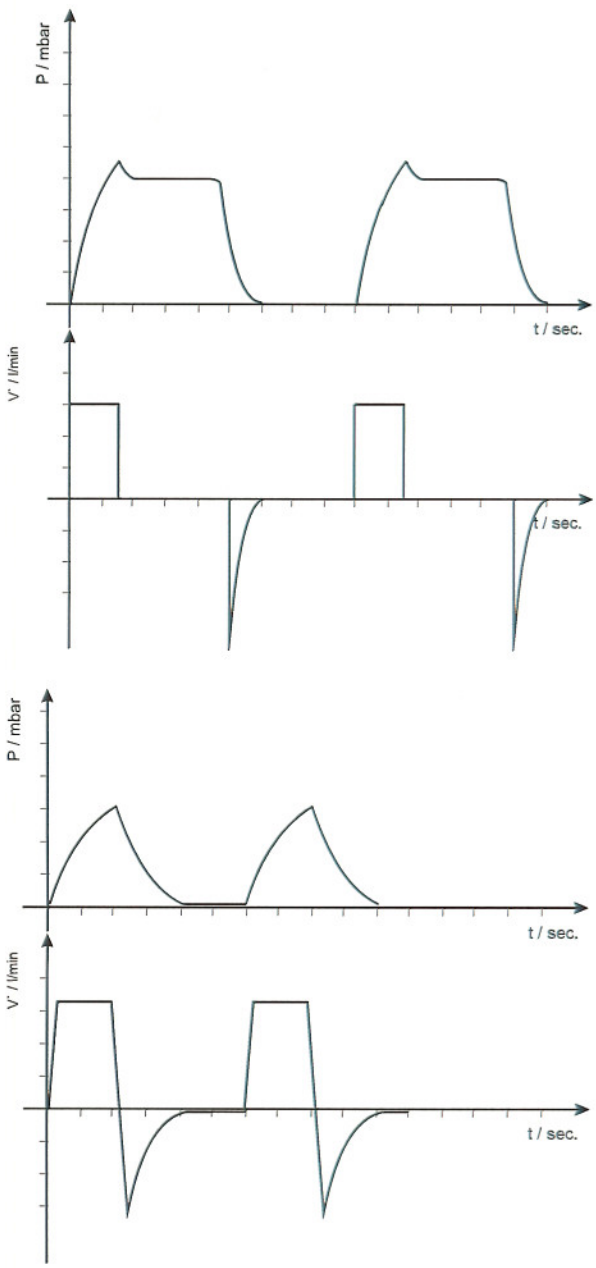


The ON/OFF switch (1) is situated at the upper left of the front control panel. Immediately below is the volume regulation valve (2) with which the volume flow to the patient's lungs during the inspiratory phase can be regulated. The frequency of the respiratory cycle can be varied between 6 and 60 inspirations per minute by means of the potentiometer „Frequency" (3). The ratio between inspiratory phases and expiratory phases of 1:4 to 2:1 can be pre-set using the range switch „Respiratory time quotient" (4).
A pressure-proof respiratory pressure gauge shows the circuit system pressure in the range of -10 to 60 mbar.
In the event of power failure, an acoustic signal is activated for at least 60 seconds. By using the switch-over lever (5) found on the patient component, either the respirator or manual respiration can be activated.
The PEEP valve (6) regulates the end expiratory pressure up to a maximum of 12 mbar. The PLATEAU valve (7) achieves a constant upper limit respiratory pressure of maximum 60 mbar.

2.6 Adjusting respirator parameters

Inspiration flow changes on volume regulating valve

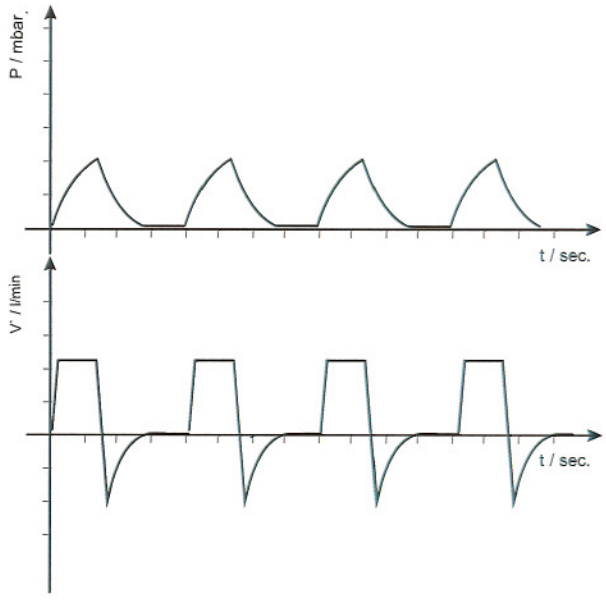
Principally, it is possible to vary the inspiration flow, using the volume regulating valve, to achieve a tidal volume of 0-1500 ml. Together, however, with the PLATEAU pressure distinct respiratory curves can be generated.



For greater inspiratory flow, the maximum pressure, here limited by the PLATEAU valve, is quickly reached. Thereafter, the pressure does not change until at the end of the inspiratory phase. This PLATEAU serves to improve the alveolar exchange of gas. Volume flow to the patient falls, after initially reaching the PLATEAU pressure, back to „0“until it slips to negative values through the introduction of expiration. Because as much gas must flow back from the patient in the expiratory phase as had been led to him in the inspiratory phase, the unit area of the inspiratory flow curve must be equal to that of the expiratory flow curve.

The inspiration flow can be reduced so far that the PLATEAU pressure is reached exactly at the end of the inspiratory phase. In the case of renewed reduction in inspiratory flow, a respiratory curve can be realised, in which the maximum pressure reached lies below that of the PLATEAU pressure.

Frequency adjustment

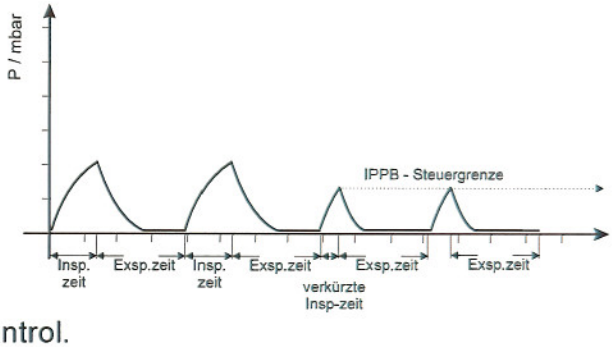


The frequency, i.e., the number of inspirations per minute can be infinitely adjusted from 6 to 60 per minute. It must be remembered, however, that in the case of increased frequency the respiratory minute volume does in fact remain constant, but the tidal volume sinks. Very high frequencies can result in the maximum pressure desired not being reached and this, in turn, leads to respiration that is too flat. To prevent this occurrence, increase the inflow volume at the volume control stem.

Respiratory time quotient (insp:exp)

The respiratory time quotient, i.e., the ratio of inspiration time to expiration time, can be randomly varied from 1:4 to 2:1, whereby the respiratory frequency is not influenced.

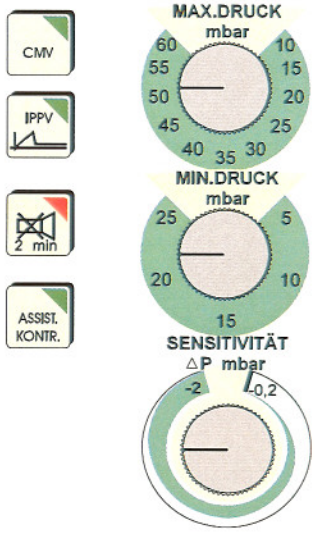
Control limit IPPB



This respirator model allows you to carry out pressure-controlled respiration (IPPB), where the expiratory phase is introduced upon reaching the pre-set maximum pressure. The pressure limit alarm of the integrated pressure monitor is used as a pressure control.

The new inspiratory phase is then triggered by the pre-adjusted frequency time.

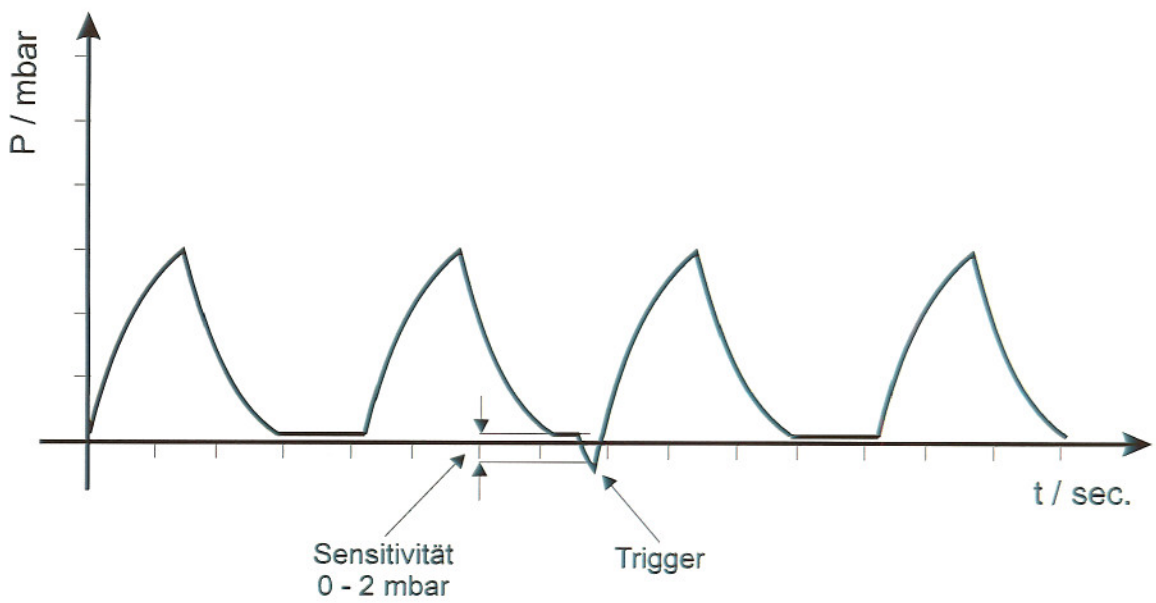
Sensitivity adjustment (optional, only for ABV-U respirators)



In order to work more effectively in the case of not completely disabled breathing or reoccurring spontaneous breathing of the patient, we provide a respirator module „ABV-U" with an additional function for assisted-controlled respiration.

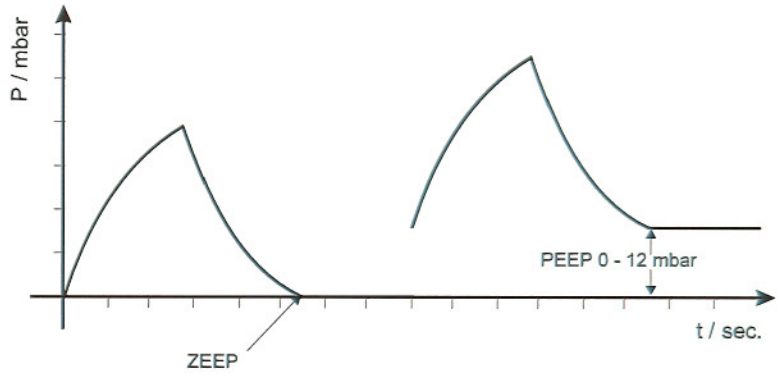
Through the inhalation efforts of the patient, a vacuum develops in the system which induces the respirator to carry out an additional completely controlled tidal volume according to the pre-set respiration parameters. If the patient's spontaneous breathing comes to a complete standstill, respiratory frequency is reduced to the pre-set values and controlled respiration continues automatically.

The suction produced by the patient that is necessary to trigger this function can be set at a sensitivity of 0.2 to 2 mbar pressure difference using the sensitivity adjustment knob. Should possible end expiratory pressure be used, the trigger threshold automatically uses this value.



PEEP adjustment

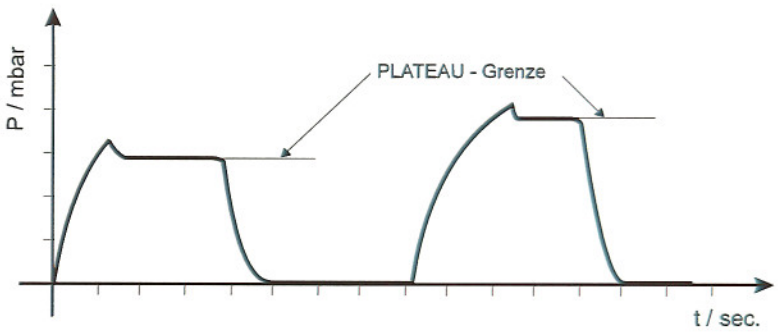
The so-called „positive end expiratory pressure" is adjusted with the left control knob of the patient component. The purpose of increasing the pressure curve in the expiratory phase is to deny the alveoli the possibility of collapsing or even to re-expand already collapsed alveoli so that they can participate in exchange of gas once again. This PEEP can be infinitely adjusted from 0 to 12 mbar; however, a certain dependence on flow of fresh gas exist which must be considered when adjusting.



The first curve runs with the PEEP value zero or called ZEEP (zero end expiratory pressure), whereas the second curve depicts true PEEP.

PLATEAU adjustment

The maximum inspiratory pressure is set using the right control knob at the patient component. The purpose of the so-called PLATEAU is to retain the inhaled gas at a constant pressure in the lungs for a short time, in order to improve the alveolar exchange of gas. In addition, the PLATEAU can be used as an upper pressure limit or security against excessive build-up of pressure. The PLATEAU value can be varied from 10 to 60 mbar.

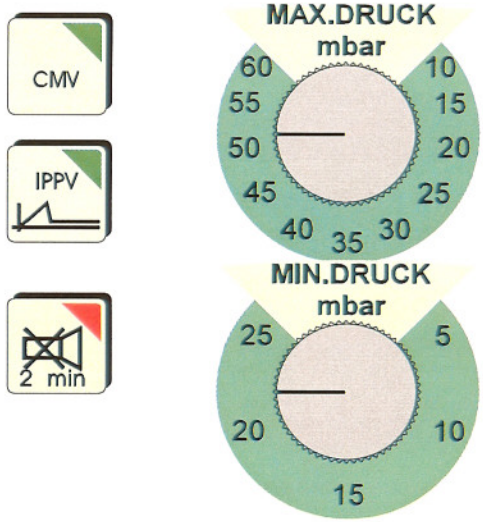


The first curve shows a low PLATEAU value, at which a considerable piece of the respiratory pressure curve is cut off.

The second curve requires higher pre-set value of the PLATEAU, but it is visible that pressure limit has no influence on the duration of inspiration.This PLATEAU is, however, to be seen only as pressure limitation, and is in no way to function as a pressure- controlled respirator.

Pressure monitor

The pressure monitor is an electronic module, divided into two pressure measuring ranges for continuous monitoring of patient pressure.



1. Max. pressure

The max. pressure monitor is equipped with a potentiometer, with which the maximum respiratory pressure can be infinitely adjusted from 6 to 60 mbar.

Should the patient pressure exceed the pre-set max. pressure, the pressure monitor sets off an optic and acoustic warning for the duration the limit is exceeded.

2. Minimum pressure or disconnection component

The minimum pressure range can be infinitely adjusted from 5 to 25 mbar using the potentiometer. During the respiratory phase, the minimum pressure must exceed and fall below this pre-set limit, otherwise an optic and acoustic alarm is triggered.

> blinking red: constant exceeding of the minimum limit (PEEP too high) or constantly falling below the minimum limit value. (disconnection).

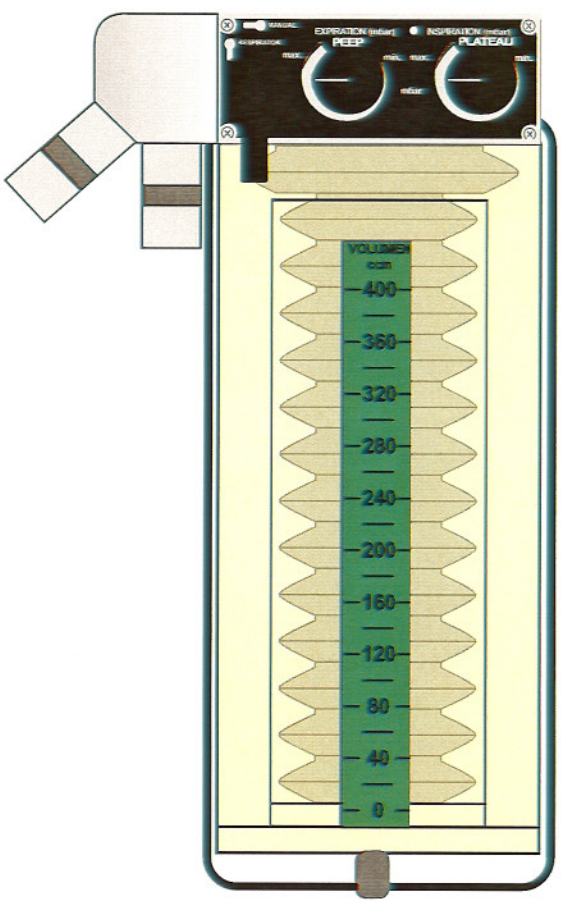
Should a disconnection exist in the respiration system that leads to a steep drop in pressure, a disconnection alarm is triggered with a 15 second delay.
By pressing the membrane key „Stand-by“ of the pressure monitor, the acoustic alarm can be suppressed for the duration of 2 minutes.
The pressure monitor is activated via the ON switch of the respirator.
It is only in operation while the respirator is switched on.

3. MODIFICATIONS AND OPTIONS

Patient component for paediatric respiration

To enable the user to easily and quickly use the respirator for paediatric purposes without the need of tedious refitting, a special plexi-bottle with inner chamber has been designed. A rubber bellows designed for paediatric respiration is inserted in the inner chamber. The plexi-bottle can be fitted in place in no time. The volume of the paediatric system is variable from 0 to 400 ml.

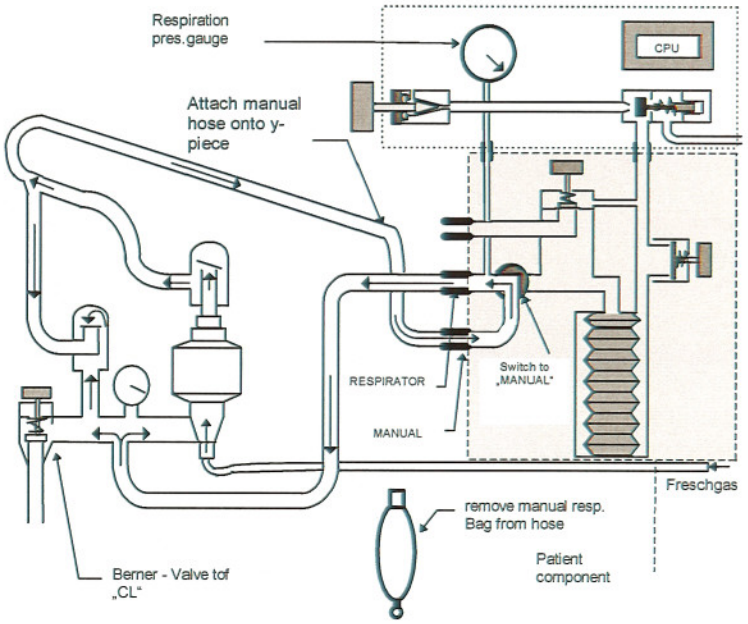
Furthermore, it is recommended to adjust the circuit system of the respirator to the special conditions of paediatric anaesthetisation through the use of a volume reducing children's hose system (Ulmer set) and removing one CO_2 absorber.



4. OPERATION CHECK

4.1 Leakage test of complete system

The leakage test of the respirator is carried out in conjunction with that of the circuit system. In this way leakage is checked for the entire system.



Leakage test of entire system:

Basic setup:

- close flow regulator valve on gas mixing unit
- adjust pressure regulator valve to CL
- remove mask from Y-piece

(1)

- separate manual respiration bag from corrugated hose
- attach corrugated hose (3) to Y-piece to form closed system between circuit system and respirator
- adjust switch lever on the patient component from „respirator" to „manual"

Test procedures:

- After having checked that the respiratory pressure gauge is set at zero (2) carefully open the oxygen flow regulator valve until the pressure gauge remains constant at 60 mbar.
- The amount of gas leagkage can be read on the respective measuring tube
- Should leakage be below 250 ml/min, the circuit system is sufficiently sealed for operation.
- Should leakage exceed 250 ml/min, the following points are to be checked:

⇒ tightness of connection union

⇒ tightness of threaded couplings

⇒ gaskets and o-rings

⇒ damage to corrugated hose

⇒ damage to o-rings of the patient component connection (firmly mounted under the repirator)

Should unacceptable leakage still exist after a second test, notify technical support.

4.2 PEEP (postive end expiratory pressure)

Basic setup:

- circuit system in operation mode
- on circuit system switch excess valve to CL (closed) position
- remove mask from Y-piece
- calibrate respiratory pressure gauge on respirator
- connect Y-piece to test lunge
- switch lever on patient component to respirator

Test Procedure:

- adjustment of oxygen or compressed air flow of 5 l/min
- adjust PEEP valve to „max.". PEEP value at respiratory pressure gauge must rise to 12 +/- 2 mbar within a few seconds.
- adjust PEEP valve to „min.". PEEP value at respiratory pressure gauge must fall again to 0 mbar
- tolerance +/-1 mbar
- notify technical support if deviations from these values are observed.

4.3 PLATEAU (upper pressure limit)

Basic setup:

- circuit system in operation mode
- on circuit system switch excess valve to CL (closed) position
- remove mask from Y-piece
- connect Y-piece to test lunge
- switch lever on patient component to respirator
- calibrate respiratory pressure gauge on respirator
- adjust PEEP valve to „min"
- adjust PLATEAU valve to „max" and switch respirator on
- open volume valve completely
- adjust respiratory frequency to 10/min
- set respiratory ratio to 2:1
- adjust on gas mixing unit dosage of fresh gas to 5 l/min.

Test Procedure

- In the inspiration phase the respiratory pressure must register 60 mbar at the respiratory pressure gauge
- Tolerance: +5 mb mbar
- When adjusting down the PLATEAU during the inspiration phase, the pressure is to continuously drop to approx. 10 mbar (tolerance: +5 mbar)

4.4 Respirator function

- Turn on mains power switch on the respirator module
- Switch on respirator's operating switch
- The key of the operating switch must illuminate green showing readiness for operation
- If key is not lit green, disconnect the power plug and check fuses, and if necessary replace.

Power failure alarm of the respirator

- Turn on operating switch of the respirator
- After one minute switch off the power switch of the respirator module
- An audio warning signal will sound at the same time

4.5 Pressure monitor

Basic setup:

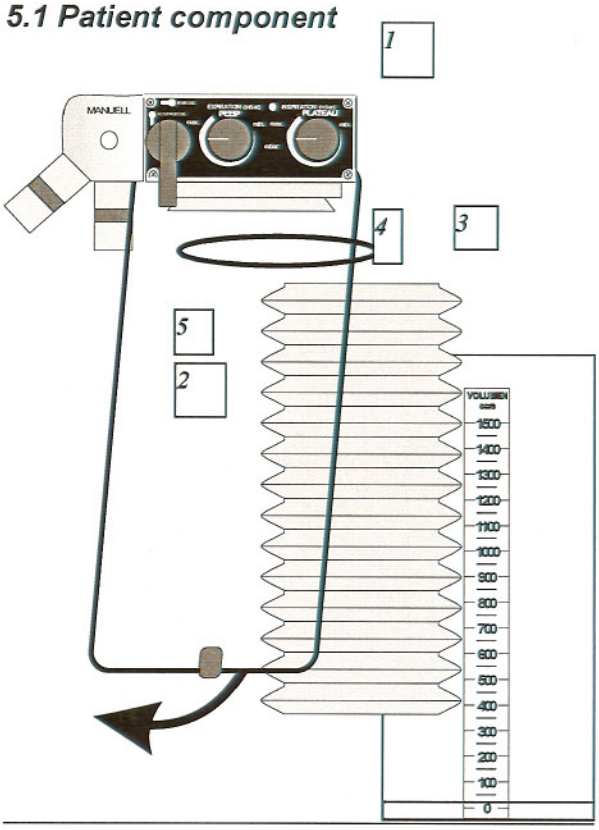
- Circuit system in operation mode
- connect Y-piece to test lunge
- switch lever on patient component to „respirator"
- turn excess valve to „CL"
- adjust fresh gas to approx. 3 - 5 l/min.
- switch on respirator

Test Procedure

- adjust potentiometer to 30 mbar for „max. pressure limit alarm"
- adjust potentiometer to 10 mbar for „min. pressure limit alarm"
- set „PLATEAU" pressure at approx „40 mbar"
- an optic and acoustic warning signal must result for the duration of exceeding the „upper limit pressure alarm
- set „upper limit pressure alarm" at „60 mbar"
- disconnect corrugated hose from circuit system
- after 15 seconds, at the latest, the pushbutton will blink red and an acoustic signal is activated
- activate „stand-by" pushbutton — alarm must be suppressed for 2 minutes

5. Cleaning the respirator

5.1 Patient component



5.1.1 Disassembly

- Loosen knurled thumb screw (1)
- Pull out patient component
- According to sketch pull off clamps (2) forwards and laterally unhook
- Remove plexiglass cylinder (3)
- Remove bellows (4) and o-ring (5)

5.1.2 Cleaning

Apart from the patient component's basic unit, all components are to undergo a preliminary cleaning or preliminary disinfection according to the following procedure.
The components (rubber parts as well) are put in a disinfectant.
After elapse of the recommended time (manufacturer's recommended time) for effective disinfection, the parts are to be thoroughly rinsed with clear water.
It is recommeded to thoroughly dry the components to prevent corrosion and the growth of bacteria.
Rubber parts are not to be cleaned with hard objects.

5.1.3 Sterilisation

The bellows (4) and the o-ring (5) are to undergo superheated steam sterilisation at 121°C (glove programme).

The patient component's basic unit is to be autoclave sterilised at 134°C. A compressed-air blow gun may not be used for final drying of the basic unit.

5.1.4 Re-assembly

After all parts have been throughly and hygienically cleaned and dried, they can be re-assembled in reverse order of their disassembly.
Apply a small amount of lubricant to the threads of the knurled thumb screw (1) before re-attaching the patient component.

5.1.5 Front panel and housing of the respirator

At appropriate intervals the front panel and the housing of the respirator module are to be cleaned with common cleaning liquid (non-aggressive agent). Liquid may not enter the housing of the respirator.

6. Calibration

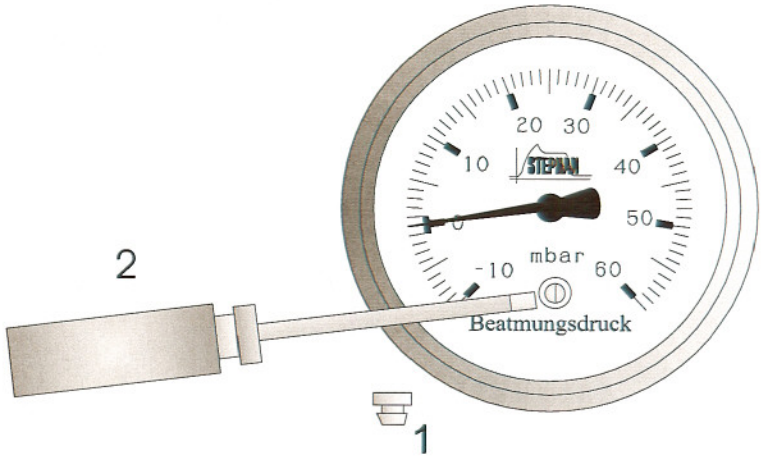
Respiratory pressure gauge of the respirator

Basic adjustment:

- Close the flow regulator valve at the measuring pipe block.
- Set excessive pressure valve to SP so that the circuit system is pressureless. (or take the corrugated hose from „RESPIRATOR“)

Procedure for calibration

Remove plastic plug (1) from the calibrating opening in the manometer glass.
With a screw driver turn the calibrating screw until the needle rests at zero. Turning the screw in the left direction induces the needle to wander to the right.
The respiratory pressure gauge must be replaced should calibration not be possible due to constant use and wear.



7. Troubleshooting Guide

Problem	Possible cause	Correction
Unit's power switch is not lit green after activation	– Cable not connected to mains supply – One of primary fuses is defect (2 x 0,1 AT)	– Plug cable into mains supply – Check fuses
Insufficient respiration pressure	– PLATEAU valve open – Excessive pressure valve not in „CL" postition – Leakage in circuit system or patient component – Switch lever on patient component in „manual" position – Pressure supply not connected (propellant)	– Close PLATEAU valve – Set excessive pressure valve to „CL" position – Check for leakage – Set lever to „Respirator" position – Connect pressure supply
Rrespiration pressure display greatly deviates from alarm limits on the pressure monitor	– respiration pressure gauge not adjusted	– Adjust to zero
No respiration pressure	– Volume valve closed	– Open volume valve
„PEEP" too high	– PEEP diaphragm sticks (eg, improper sterilisation method)	– Have PEEP diaphragm cleaned by technical service
Difference in tidal volume is > 300 ml	– Leakage in circuit system – Excessive pressure valve not in „CL" position	– Check for leakage – Set excessive pressure valve to „CL" position

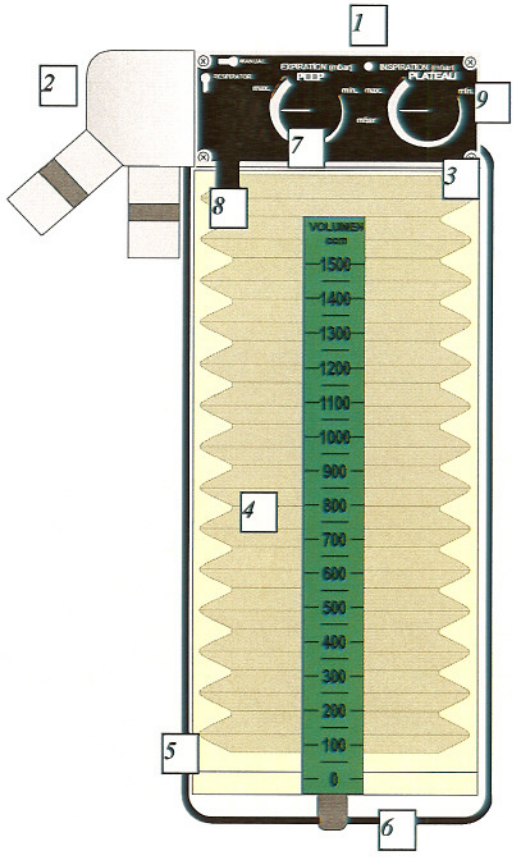
Problem	Possible cause	Correction
Pressure Monitor Minimum pressure alarm is triggered	– Minimum pressure limit is pre-set too low – PEEP is over the minimum pressure limit – Disconnection on anesthesia unit (circuit system) – Changes in patient (compliance, resistance, tubus)	– Set minimum pressure limit to over 10 mbar – Lower PEEP or increase minimum pressure limit – Find disconnection and re-connect
Excessive pressure alarm is triggered	Pressure limit set below PLATEAU pressure Pressure limit set below respiration peak pressure Change in tubus Change in Patient (stenosis)	Reduce PLATEAU pressure or increase pressure limit Reduce respiration pressure or increase pressure limit

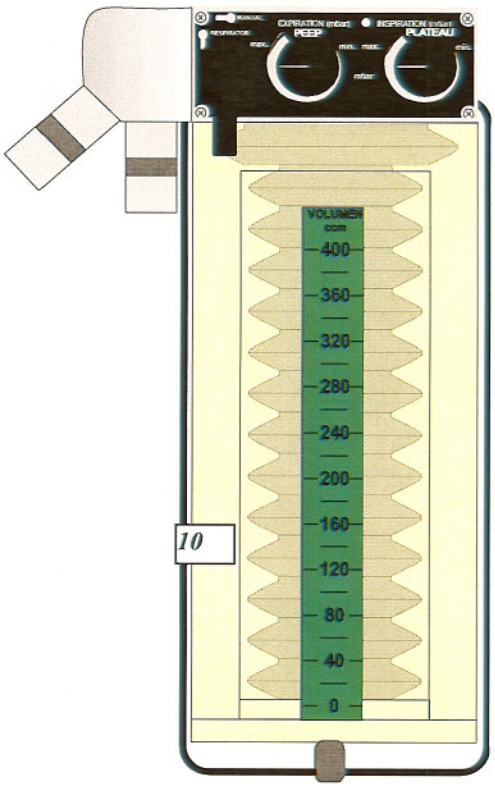
8. SPECIFICATIONS

8.1 Respirator module

Dimensions:	Width:	530 mm
	Height:	120 mm
	Depth:	280 mm
Weight:		12 kg
Fuses:		2 x 0.1 A slow-blow. micro fuse 3 x 20 mm
Power requirements:		220 V / 50 Hz
Power consumption:		18 VA 220 V / 50 Hz
Fuses:		1.25 A slow-blow micro fuse 5 x 20 mm
Respiration frequency:		infinitely variable from 6 to 60 per minute
Respiratory time quotient:		variable in stages, Insp:Exp 1:4 - 2:1
Respiration pressure gauge:		-10 to 60 mbar excessive pressure-proof up to 600 mbar
Power failure alarm:		acoustic, for at least 40 seconds

DATA SHEET





8.2 Patient component

Tidal volume: 0-1500 ml

Adult patient component

Tidal volume: 0-400 ml

paediatric patient component

PEEP valve: 0- 10 mbar

PLATEAU valve: 10-60 mbar

(upper pressure limit)

<u>Spare Parts List:</u>

1. 153 61 016 knurled thumb screw
2. 153 40 024 basic unit
3. 950 60 020 o-ring
4. 153 61 009 bellows
5. 153 40 014 plexi-bottle
6. 153 40 023 stirrup clamp
7. 926 60 007 adjustment knob
8. 153 42 022 switch lever
9. 153 62 018 front panel
10. 153 61 017 paediatric bottle with bellows

DATA SHEET

8.3 Pressure monitor

Measurement range:	0 - 60 mbar
Measurement accuracy:	+/- 2%
Measurement principle:	piezoresistive pressure absorption gauge
Excess-pressure alarm range:	5 - 60 mbar
Minimum-pressure alarm range:	5 - 25 mbar
Visual alarm excess pressure	LED, red
minimum pressure	LED, blinking red
acoustic alarm:	electronic signal generator 2 minutes suppressable

9. Maintenance and Servicing

Medico-technical devices are to undergo, in compliance with MedGV, inspection at regular intervals.
Such inspections are to be carried out only by authorised personnel (service staff) of the supplier.

Periodic servicing, semi-annually

The servicing agreement provides the best guarantee which schedules semi-annual inspections with automatic replacement of components subject to wear.

Servicing carried out by non-technical and unauthorised persons, automatically results in forfeit of manufacturer's liability for the safe operation of the device.