

Technical Description and Manual for medical Valve Integrated Pressure Regulator "MediLight"





Please read the operation instructions carefully before using for the first time!

Pay particular attention to the safety instructions in these operating instructions!

Item No. of this document: 0172.14.241, Index c, 2014-03-19



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Appendix ADuration of gas cylindersAppendix BEU Declaration of conformity



1 Legal information

- VTI Ventil Technik GmbH develops and manufactures high pressure gas cylinder valves for technical, aggressive and medical gases. These valves are developed and produced as standard catalogue products as well as customised OEM products. The information contained in this document is our intellectual property. We reserve all rights regarding this document including all drawing documents and possible copies which are produced by the customer.
- 2. The customer commits himself to precisely comply with the safety information detailed in this manual, to observe all copyrights and other legal reservations and not to modify our documents.
- 3. We reserve the right to modify this manual, delete or complete certain sections. The customer may through this not derive any rights.
- 4. <u>Warranty:</u> For the supplied valve integrated pressure regulators we provide a warranty for a period corresponding to our General Sales and Delivery Conditions provided the information in the manual was complied with and provided there is no evidence of misuse. The warranty is restricted to proper functioning, leak tightness and faultless material. Further claims shall be excluded except legal requirements should demand a different ruling. Exempt from the warranty are deficiencies the cause of which is not due to our products themselves but due to evidence of misuse, improper handling and disregard of information provided in our manuals.

2 General instructions

This manual applies to all valve integrated pressure regulators (in the text below also simply called "pressure regulators") "MediLight".

Improper handling, for example applying force or dropping, can cause a malfunction of the pressure indicator or at the flow adjustment.

Particulary the use of oxygen demands special care!

For this reason handling of this armature requires the precise knowledge and observance of the information provided in this manual. In the case of possibly occurring malfunctions, the after sales service must be informed (see: "Troubleshooting").

3 Intended use

The pressure regulator is intended to administer medical gases from gas cylinders during the treatment and care of patients, independently of a fixed gas supply system. It is mounted directly on the cylinder and reduces the cylinder pressure to a low, constant value. This constant low pressure (backpressure) enables the provision of a defined flow that is largely independent of the cylinder pressure.

The pressure regulator "MediLight" is suitable for use by

- emergency care and rescue services,
- in clinics, hospitals and doctor's practices,
- in home-care as well as in mobile applications.

It is suitable for stationary use, but due to it's low weight especially for mobile applications too.

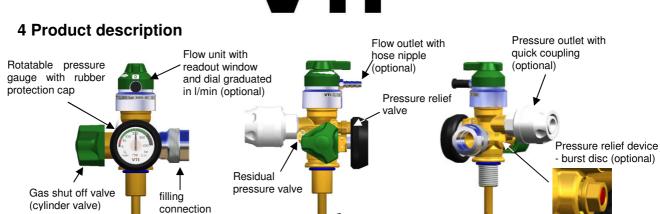
The pressure regulator **is not** suitable for use in aseptic or sterile areas! The pressure regulator **is not** suitable for use in driving surgical tools!



Important note:

All medicinal gases – including oxygen – are to be considered as medication and for this reason prescriptions as well as instructions by nursing staff and rescue staff must be observed !





Pressure gauge - For the purpose of monitoring the pressure within the cylinder, the integrated valve has been equipped with a pressure gauge. Depending on the option model, the pressure gauge features a non-permanent readout, which shows the cylinder pressure after the cylinder valve was opened or a constant pressure readout so that the actual pressure within the cylinder can be read off even if the cylinder valve is in the closed position.

Dust tube

Oxygen, med. Air, and all other gaseous filled gases:

The instrument dial has been arranged so that the pressure ranges are colour-coded:

Green: 50 bar up to nominal service pressure (300 bar or 200 bar)

Red: 50 bar and less

The displayed pressure equals to the charging level of the cylinder.

Liquid gases nitrous oxide and carbon dioxide:

The instrument dial has a "bar"-scaling.

It is <u>not possible</u> to interpret the charging level of the cylinder out of the displayed pressure.

Flow Unit and User Connections - The integrated valves are provided with a pressure outlet and/or a flow outlet. The flow outlet is the outlet at the flow hand wheel where the gas is discharged through a hose nipple. This outlet supplies gas directly to the patient, for instance via a nasal cannula or a breathing mask. The flow outlet also releases gas even if the handwheel is set between adjacent settings. In this case, the litre capacity is also approximately within the range of the two adjacent levels. This function is designed to ensure patient safety. To ensure that the patient receives a precisely defined dose at all times, you must make sure that the handwheel is correctly engaged in the desired setting!

The flow outlet **is not suitable** for operation with downstream medical apparatus nor any flow regulating devices. For this purpose, the pressure regulator can be fitted with an additional pressure outlet where the flow is not regulated.

It is provided with a quick-connect coupling specific to the kind of gas.

Gas- shut-off valve - The shut-off-valve (cylinder valve) directly at the high pressure of the gas cylinder.

Filling Connection - A separate filling connection exclusively serves the purpose of refilling the cylinders by the supplier. The filling connection is located opposite the hand wheel for the cylinder valve. It is provided with a protection cap or a closing nut. Only the filling station is permitted to remove this cap/nut.

Pressure Relief Valve (PRV) - Each pressure regulator has been equipped with a pressure relief valve (safety valve) so as to protect the user connection against overpressures. This pressure relief valve has been adjusted in the factory and must not be readjusted. Any manipulations here may influence the accuracy of the flow or effect an uncontrolled discharge of gas.

Residual Pressure Valve (RPV) - The integrated valves are equipped with a residual pressure function. This permits maintaining a slight overpressure in the gas cylinder when gas is discharged by the user so as to prevent a contamination of the cylinder contents with atmospheric air.

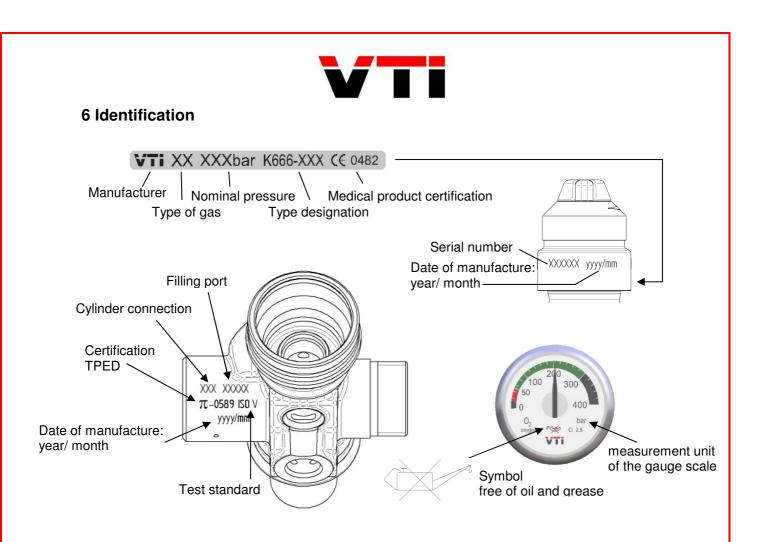
Pressure Relief Device (PRD) – Bursting Device – As an option, the MediLight can be equipped with a bursting device. For example when the cylinder is exposed directly to fire this causes an unallowable high cylinder pressure. A pressure-containing disc bursts and a defined flow off of the gas prohibits the bursting of the cylinder.



5 Technical Data

		Oxygen 200 bar, Oxygen 300 bar, Nitrous oxide,	
Types of Gas (depends on the model – see type plate)		Medical air, all medical gases and gas mixtures	
Cylinder connections		M18x1,5 / 17E / 25E / ¾" – 16 UNF	
Filling ports		gas-specific, acc. to ISO or national standards	
Primary pressure P1 at 1 (service pressure)	5℃	up to 300 bar (dependent on the type of gas)	
Optional pressure outlet		Schrader, AGA, AFNOR, DIN, NIST, DISS	
Nominal outlet pressure at pressure outlet	P2	4,5 bar – 5 bar	
Flow at the pressure outl (oxygen at 15°C / 1013 h		240 l/min at a cylinder pressure of 50 bar 40 l/min at a cylinder pressure of 10 bar	
Flow settings at the flow	outlet	0 – 0.1 25 l/min (depends on the model) in 12 positions	
Pressure Relief Valve	 Opening pressure Relief pressure 	~ 7,5 bar max. 10 bar	
Residual Pressure Valve	- Closing pressure - Opening pressure	~ 5 bar max. 11 bar	
Ambient temperature	- Operation - Storage	-20℃ to +60℃ -40℃ to +70℃	
Ambient humidity		10% to 90% rH	
Service life		10 Years, (15 Years after Maintenance)	
Maintenance		Optional after 10 Years to extend the service life.	
Checking		After each filling, minimum every 6 months. Flow check and Leakage test.	
Weight		~ 600 – 800 g (depends on the model)	
Metallic materials		Valve body: Brass Flow housing: Brass, chrome plated Regulator spring: Stainless steel	
Plastic parts		Polyamide, Pressure gauge protection: Rubber Valve sealing: PEEK	
O-rings		EPDM, silicone	
Filter		Sintered bronce	
Equipment class 93/42/EEC		llb	
Standards met		ISO 10524-3 and standards quoted therein	

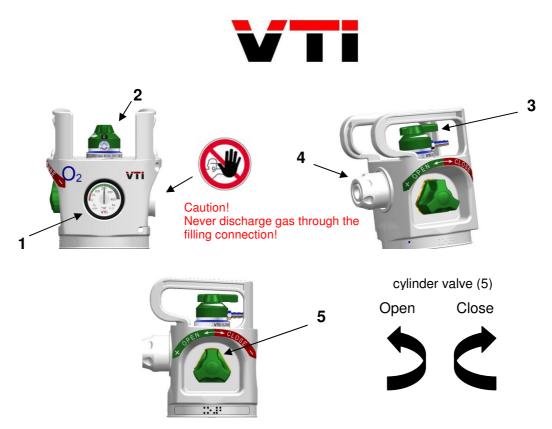




7 Operating and Commissioning of the MediLight

(see illustration on the next page)

- Check the contents of the cylinder by means of the pressure gauge (1).
- Ensure that the cylinder valve (5) is closed and that the flow hand wheel of the flow regulator (2) has engaged at position "0".
- Connection via hose nipple (3): push the hose onto the flow outlet (3) and make sure that the hose is firmly seated.
- Connection via a quick-connect coupling (4): first make sure that the plug of the respirator, for example is compatible. Connect plug and quick-connect coupling (4).
- Open the cylinder valve (5) slowly and completely (approx.1 turn).
- When using the hose nipple (3), select the needed flow with the flow handwheel (2).
- If the cylinder valve is opened quickly, this can lead to a brief pressure surge which is bled off via the pressure relief valve (see Illustration, Chapter 4). The noise created as a result does not indicate a fault. The pressure regulator is operating normally.



After each use:

- Close the cylinder valve (5) by turning the hand wheel in the clockwise direction.
- Allow the remaining gas in the regulator to discharge.
- Turn the flow handwheel to position "0" (6).
- Separate the connections at hose nipple (3) and quick-connect coupling (4).

* Due to the volume of the regulator the flow will not stop immediately after closing the cylinder valve. Wait a few seconds – never use excessive force to turn further a supposed hard-steering handwheel!



The pressure regulator, as well as <u>all equipment coming into contact with the gas</u>, must be kept <u>absolutely free of oil and grease</u>! There is a risk of fire in the case of oxygen, oxygen mixtures and nitrous oxide!



Never place gas cylinders in the vicinity of a heating facility (e.g. radiator, stove)! Open fires and smoking are strictly prohibited!



Oxygen supports fire! An uncontrolled discharge of oxygen in closed rooms may cause fire hazard! Materials which don't burn in normal conditions, may be easily flammable in an oxygen-enriched environment. Pay attention that all hoses, couplings and threaded connections are tightened and breathing masks and nasal cannulas are closely fixed.



Do not use any inappropriate parts like plaster, for example to seal the inlets and outlets!



Make cylinders safe from falling over or rather uncontrolled acceleration!

Attention! Cylinders containing liquid gases (e.g. nitrous oxide) must be used standing vertical!



8 Fitting the Pressure Regulator to the Cylinder



Before mounting observe / inspect:

- The inside of the cylinder has to be absolutely free of oil and grease, free of rust and free of any sort of particles! The cylinder thread also has to be clean and free of burrs!
 Particulary the lower end of the cylinder thread is often afflicted with burr, which can release and fall into the cylinder while mounting the regulator. Such burrs have to be removed and the cylinder has to be cleaned again afterwards!
- Keep the MediLight in the original packaging as long as practicable to prevent possible contamination.
- Always check the cylinder thread (valve stem) and the dust tube of the MediLight for contamination directly prior the assembling to the cylinder.
- If a used regulator is supposed to be mounted again, it has to be maintained and cleaned for oxygen prior to that.

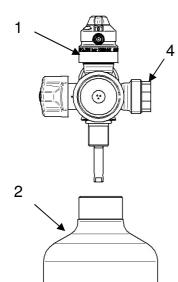
For the sealing of taper threads (17E/25E) exclusively oxygen-approved PTFE tape must be used.

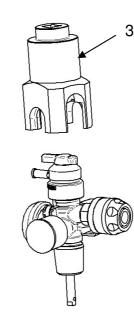
For the sealing of parallel threads (M18x1,5 / ³/₄"-16UNF) exclusively oxygen-suitable o-rings must be used.

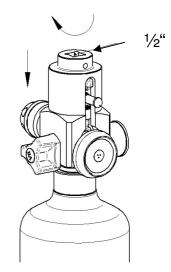
- 1. Screw the pressure regulator with the sealing (1) by hand into the cylinder (2).
- 2. Attach the valving tool (3) over the Medi Light (1) as far as it will go.
- 3. Apply the tightening torque using a torque socket wrench, 1/2", regarding the following torques:

Steel cylinders:				
cylinder thread	M18 x 1,5	¾" – 16 UNF	17 E	25 E
torque	80 – 100 Nm	80 – 100 Nm	120 – 130 Nm	200 – 210 Nm

Aluminium cylinders and composite cylinders with aluminium thread				
cylinder thread	M18 x 1,5	³ ⁄4" – 16 UNF	17 E	25 E
torque	80 – 100 Nm	80 – 100 Nm	75 – 95 Nm	90 – 110 Nm









9 Filling instructions

Notes on how to fill the gas cylinder

- Filling of the gas cylinder must be left to authorised vendors only. •
- Exclusively original VTI filling adaptors must be used.
- Pay attention to a particle-free filling!
- The filling pressure after cooling down may not exceed the nominal cylinder pressure.
- Neither at filling, nor at discharging the allowed operation temperature limits may be exceeded.
- The sealing area of the filling port must not be contamined by liquids or leak-testing-agents, which

1

2

(:•

6

3

5

Yes: Regulator must

be maintained!

- could cause corrosion or reaction with oxygen. Remains of liquid testing-agents
- The cylinder valve always must be opened completely, but not in an abrupt or jerky mode.

Before filling

Check:

- Is the type label (1) damaged?
- Are there any outer damages visible?
- Has the maintenance interval reached (see date)? • Is the fill port free of contaminants?
- Clean the MediLight with a clean and dry piece of cloth.

Fillina

Check:

- Is the filling adaptor clean and undamaged?
- Is the pressure behind the fill port down to the residual pressure level:
 - Close the cylinder valve and discharge the remaining gas in
 - the regulator via an outlet.

➔ Never screw on the filling adaptor if the filling port is pressurised with the cylinder pressure! This will damage the check valve in the filling port!

- Screw on the filling adaptor to the limit stop.
- Open the cylinder valve slowly complete. (Residual gas from the cylinder discharges into the filling line).

Regarding the filling process observe the following time parameters:

- → Filling time for instance for an 1-l-cylinder: min.1minute
- \rightarrow Don't pressurise the regulator with the on-screwed filling adaptor longer than 1 hour!

After the filling process:

- · Close the cylinder valve.
 - Depressurize the filling line as slow as possible.
 - → An abrupt pressure release has to be avoided!
 - · Screw off the filling adaptor.

After the filling

After the disconnection of the filling adaptor a dwell time of 15 minutes should be observed, until the cylinder valve will be opened again!

• Does the pressure gauge (3) indicate a realistic value?

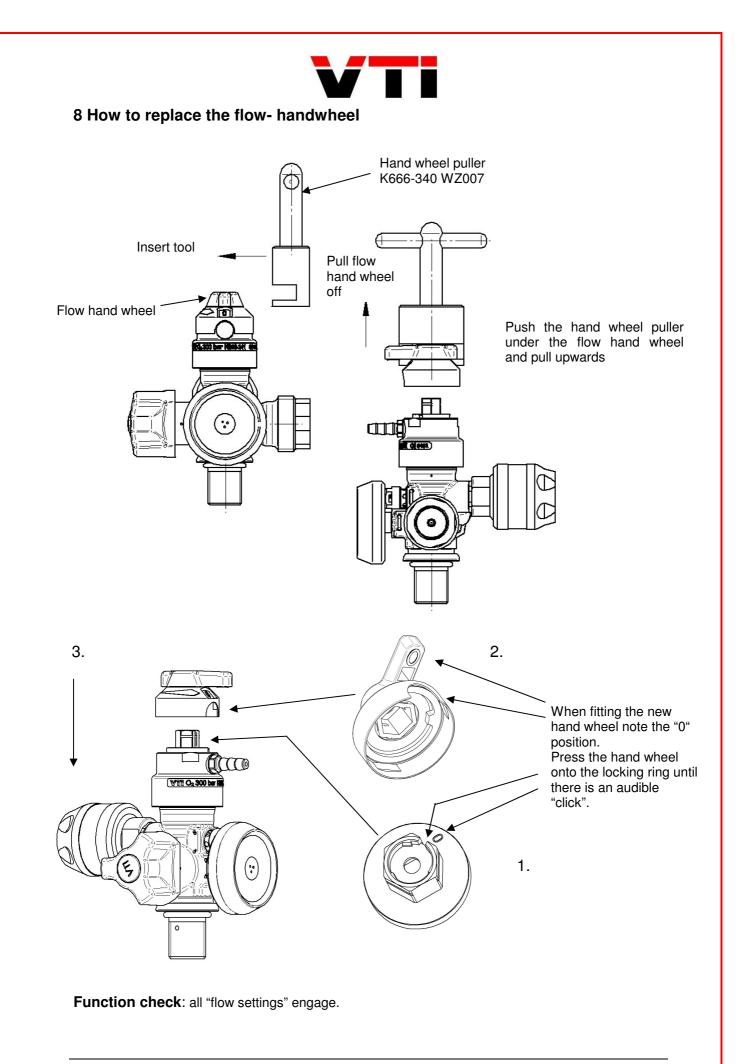
- Function check for the flow settings (4) (if available).
- Function check for the cylinder valve (5).
- 🖉 leak test

Gur

- → The sealing area of the filling port must not be contaminated by liquids or leak-testing-agents, which could cause corrosion or reaction with oxygen. Remains of any sort of liquid agents have
- to be removed after testing. For this purpose use dry and oil-free compressed air or clean cloth
- put on protective caps (optionally:protective screw nut) (6 + 7)



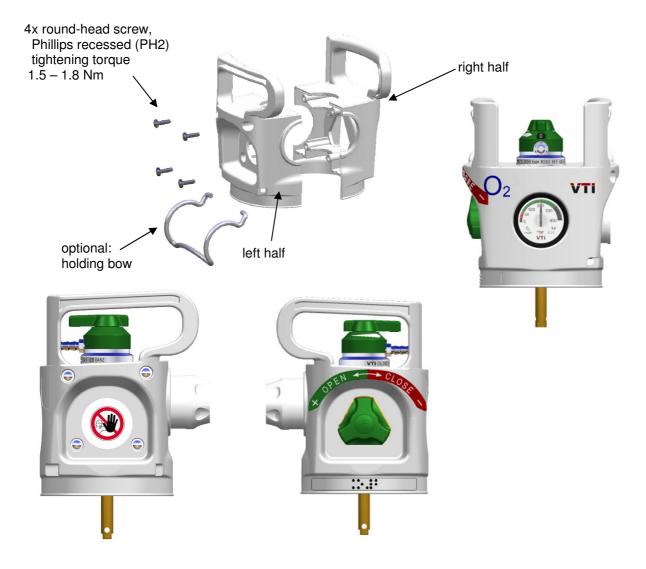
While the filling is in progress, the maximum operating temperature of 65°C as well as the corresponding highest permissible operating pressure (e.g. 360 bar when nominal pressure is 300 bar) must not be exceeded!





11 Protective cage

An additional basket guard is available and should be fitted permanently. This is to avoid damage to the attached parts. The design of the cage allows easy access to all functions of the valve. As a specially useful detail it offers two handles for lifting and short-time carrying, and depending on the specific model, a holding bow for reliable securing to hospital beds (max. 5l-cylinders).



12 Cleaning

Use cleaning agents in moderate quantities and do not allow cleaning agents to penetrate the inlets or outlets. Never use any oil, grease or wax containing agents! Simply use a clean, dry or slightly moistened piece of cloth.

13 Checking

After each filling, at least after 6 months even if the device was not in service it should be checked as follows:

- Is any external damage apparent?
- Is a realistic pressure indicated by the pressure gauge?
- Is the regulator tight, when the cylinder valve is opened and the flow knob is on pos."0"?
- Is the flow at the flow outlet correct?

In the case of malfunctions, immediately inform the after sales service!



14 Maintenance

Each time the cylinder is refilled, the pressure regulator must be checked. Stored devices even must

be checked in intervals of 6 months. The Regulator needs no maintenance, if this checking rules are observed. If required, the service life can be extended to 15 years by a maintenance after 10 years. Maintenance work must be performed by authorised personnel. Only genuine VTI spare parts and lubricating agents specified by VTI may be used! If spare parts are replaced by third-party products, then if there is no proof of the suitability of the product

combinations, there may be restrictions regarding function or biocompatibility. Furthermore claims of warranty would be inapplicable.

15 Transport and storage

Transport and storage on cylinder:

In accordance with ADR a transport protection cap is not required at 25E flange connection thread with a maximum packaging weight of 55 kg or M18x1.5 and 17E with cylinders up to 5 litres. To avoid any damage to the accessory, we recommend the usage of our special developed protective

To avoid any damage to the accessory, we recommend the usage of our special developed cage.

Transport and storage not fixed on a cylinder:

Always store the device in a dry and clean environment! Suitable protection, e.g. the original packaging, must be used. Take particular care to ensure, that the valve stem and the fill port are protected against contamination and damage.

16 Troubleshooting

Malfunction	Likely cause	Remedy
Cylinder pressure indicator (1) does not indicate	Cylinder is empty	Fill cylinder
anything	Mechanical damage	After sales service
Safety valve (3) responds	Malfunctions affecting the regulator	After sales service
(possibly blowing out gas)	Valve was opened suddenly	Close and open slowly
Leak which can be heard and felt	Damage	After sales service
Inadequate flow performance	Valve was not opened properly	Fully open the valve

17 Manufacturer's Information:

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