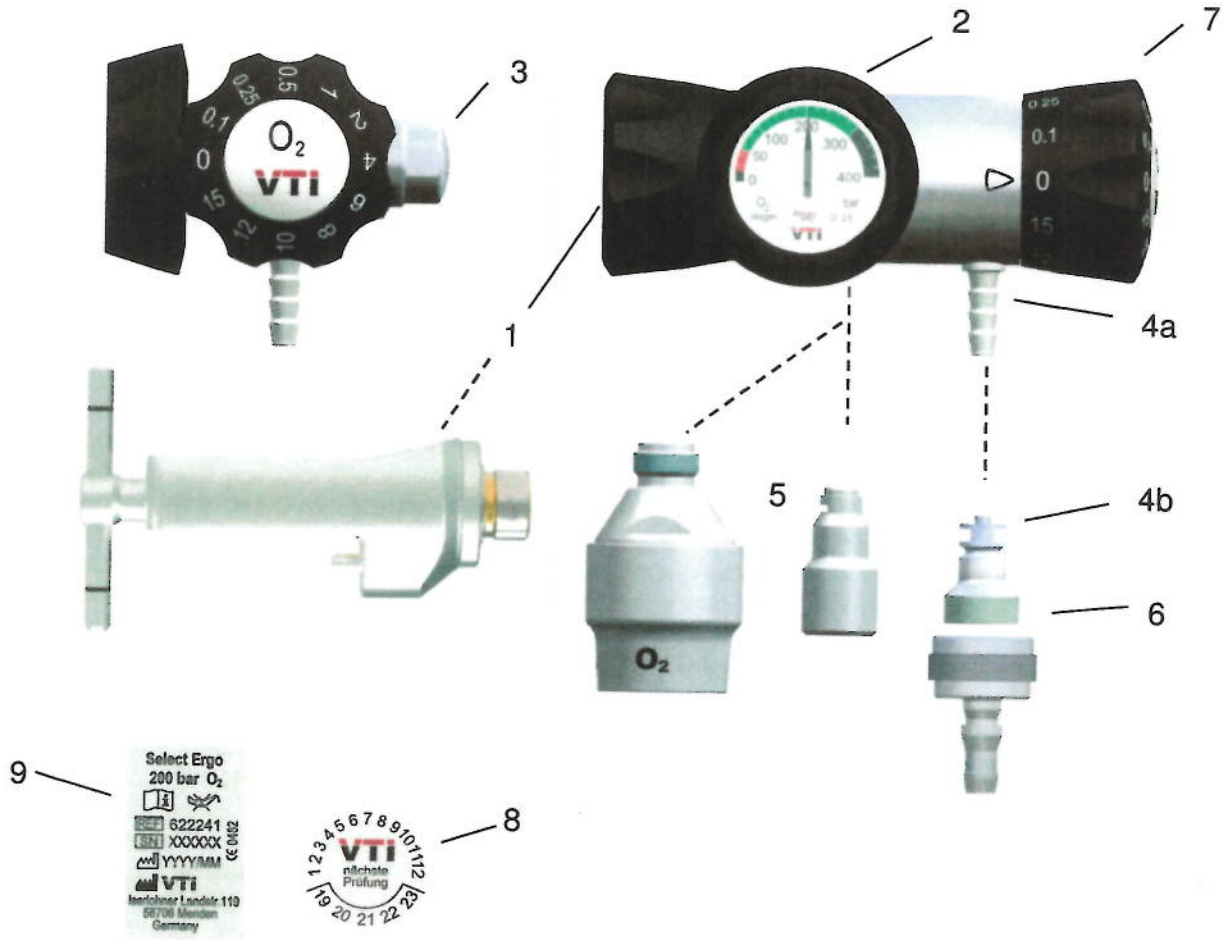
Gebrauchsanleitung für Medizinische Druckregler Select Ergo

Instruction manual for Medical Pressure Regulator Select Ergo



Bitte lesen Sie die Gebrauchsanweisung aufmerksam vor der ersten Benutzung!
Please read the operation instructions carefully before using for the first time!

Beachten Sie unbedingt die Sicherheitshinweise in dieser Gebrauchsanweisung!
Pay particular attention to the safety instructions in these operating instructions!

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Contents

1 General instructions

These operation instructions are valid for the medical pressure regulators of the type "Select Ergo".
Medical pressure regulators are manufactured with great care. Improper handling, e.g. the use of force or dropping the device can lead to malfunctions of the pressure display or at the flow adjustment.
Particular care is required when used in conjunction with oxygen!
For this reason, use of this device requires a thorough understanding of and strict adherence to the operating instructions.
Notify the customer service in the case of malfunction and if you are unable to solve on your own.
(see: "Eliminating possible malfunctions".)

2 Intended use

The pressure regulator is intended to administer medical gases from gas cylinders independently of a fixed gas supply system. It is connected to the output connection of a cylinder valve 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 Pico Ergo pressure regulator is suitable for use by emergency services, in clinics and hospitals as well as in the area of home care - It is **not suitable** for use in aseptic, sterile areas!

3 Product description

This medical pressure regulator is designed for a cylinder pressure of up to 300 bar (see type plate (9)). It is equipped with an inlet connection (1), via which the connection to the cylinder valve is made. The connector is standardized and specific to the type of gas. The current cylinder pressure can be read from the pressure gauge (2) as soon as the valve at the cylinder is opened. The pressure gauge is rotatable and can be adjusted for optimum readability depending on the situation.
The pressure regulator is equipped with a flow outlet whose gas delivery can be adjusted in fixed steps by means of a handwheel (7). The handwheel is scaled in l/min.
The flow outlet is equipped with a hose nipple (4a) or a threaded connection (4b). This outlet is provided for direct patient treatment e.g. via respirator mask or nasal cannula.
The pressure regulator also releases gas even if the handwheel is set between adjacent settings. In this case, the flow is also approximately between 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 equipment, e.g. ventilators or flow meters. For this purpose, the pressure regulator can be fitted with one or two pressure outlets (5). A pressure outlet offers a pressure, which is regulated to 5 bar, and the possibility to withdraw a high flow rate (>120 l/min). The connection is designed as a plug-in coupling or threaded connection (5) that closes automatically when the connected appliance is removed.

The pressure regulator is **not** suitable for use in driving surgical tools!

WARNING: Each pressure regulator is equipped with a pressure relief valve (safety valve) (3). This is pre-adjusted at the factory and must not be altered. Manipulation may override the protective function or lead to the uncontrolled escape of gas.

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!

4 Technical data

Type of gas (depending on version – see type plate)		oxygen 200 bar, oxygen 300 bar, nitrous oxide, medical air, all medical gases and mixtures
Inlet connection in accordance with ISO 5145, ISO 407 or national standards		country- and gas-specific
Inlet pressure (cylinder pressure) P1*		up to 300 bar (gas-specific)
<u>Option pressure outlet</u>	-layout: -outlet pressure: -flow rate:	couplings acc. to DIN, NIST, AGA, AFNOR, BS, etc. fixed setting, nom. 5 bar nom. 120 l/min O2 * – see performance diagram (min. 96 l/min and 3.6 bar at 10 bar cylinder pressure)
<u>Flow outlet</u>	-layout: -flow settings:	Fixed Hose nipple or 9/16" threaded connector + hose nipple adapter 12 steps, 0...max. 25 l/min* (variants on request)
Pressure relief valve	-opening pressure:	approx. 7.5 bar
Temperature range	-operation/storage:	-20 °C ... +60 °C / -20 °C ... +70 °C
Humidity range – operation and storage		10% ... 90% relative atmospheric moisture
Service life		15 years, subject to the recommended inspection and maintenance periods
Inspection / Maintenance		technical inspection after 5 years maintenance after 10 years (see inspection plate)
Checkup		every 6 months
Weight		approx. 620 g (version with 1 flow outlet)
Metallic materials		housing: brass, matt-chromed piston: brass regulating spring: stainless steel No aluminium, no stainless steel in high pressure area.
Plastic parts		polyamide, pressure gauge protection: rubber(SEBS) Contains no halogenated plastics.
O-rings		EPDM, Silicone
Filter		sintered bronze

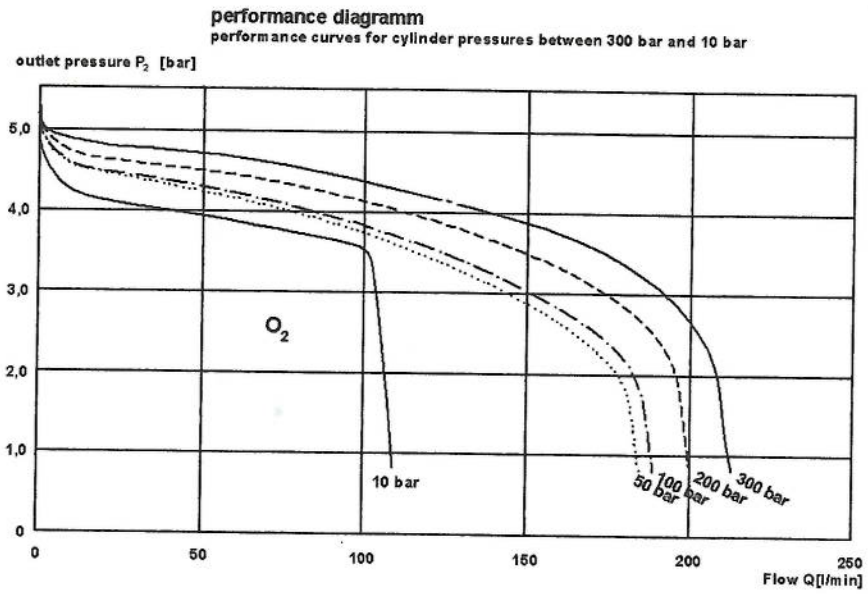
*Standard conditions:
15 °C, 1013 mbar

Complies with
DIN EN ISO 10524-1
and related standards.

Complies with the
requirements of the
Medical Device Directive

CE 0482

Equipment class IIb
93/42/EEC



5 Marking

Every pressure regulator displays a type plate (9) with the following information:

Type designation:	Select Ergo
Service pressure:	e.g. 300 bar
Gas type:	e.g. O2
Item/Type number:	622241
Serial number (6-digit):	XXXXXX
Date of manufacture:	Year\Month
EC conformity mark:	CE 0482
Manufacturer with address:	VTI, Iserlohner Landstr.119, 58706 Menden, Germany

The handwheel is labelled with the flow levels in l/min.
Pressure outlets are marked "5 bar".

6 Operation

Oxygen armatures must be kept free of grease. Wash your hands before you handle the regulator. Do not use hand cream or fatty ointments!

Connecting the pressure regulator to the cylinder valve

Secure the cylinder so that it cannot fall or tip over. In the case of laughing gas or carbon dioxide keep in mind that the cylinder has to stand upright! Unscrew the protective cap on the gas cylinder. Remove the pressure regulator from the packaging. Check first of all:

- Is the seal present on the connector (1) of the pressure regulator?
- Is the connector of the pressure regulator and its counterpart on the cylinder valve free of dirt and contamination?

The connectors at the cylinder valve and at the pressure regulator are standardised and specific to each gas type. As a result, they cannot be confused. Nevertheless, you must check:

- Does the gas cylinder actually contain the correct gas (label/sticker on cylinder shoulder)?
- Is the pressure regulator designed for this gas (see type plate)?

By means of the screw connection (1), screw the pressure regulator by hand clockwise onto the thread of the cylinder valve. Screwing on by hand is sufficient to create a gas-tight connection between the pressure regulator and the cylinder valve.

Do not use any tools!

Pressure gauges (2) must not be used as levers! Never use the pressure gauge to tighten or loosen the pressure regulator from the cylinder!

Commissioning

Make certain that the equipment to be connected is suitable for medical purposes, for use with medical gases and for the pressure range. Make sure that hose fittings and screwed connections are safely fixed and pressure-tight (is the sealing present and intact?).
Thin hose lines may be bent if they are not routed carefully. Make sure that they are lying free and that they cannot be subjected to mechanical stress or crushed!
CAUTION: Every time you open the cylinder valve, check the proper connection between the valve and the regulator first.
Open the cylinder valve **slowly** with at least one turn.
The pressure gauge (2) displays the available pressure in the cylinder in bar.
If the pointer is in the red zone, the supply can only be guaranteed for a limited period. In this case, the cylinder should be replaced as soon as possible.
If the cylinder valve is opened quickly, this can lead to a brief pressure surge which is bled off via the pressure relief valve (3). The noise created as a result does not indicate a fault. The pressure regulator is operating normally.

The uncontrolled discharge of oxygen in closed rooms can lead to a risk of fire! Spontaneous combustion may be caused if high concentrations of gas accumulate in beddings, items of clothing etc!

Make sure that all threaded and hose connections are securely and tightly seated and that respirator masks, nasal cannulas etc. are fitted correctly.
If possible, make patients aware of the potential hazards!

All medical gases – including oxygen – are medicines!
For this reason, medical prescriptions and the instructions of nursing staff and paramedics must be observed!

Turning off the pressure regulator and connecting it to a new gas cylinder

As soon as the pointer on the pressure gauge (2) enters the red zone and continued supply is required, you should prepare to change the cylinder. Always leave some residual pressure in the cylinder. This helps prevent possible contamination of the cylinder.
Close the valve on the gas cylinder by hand. Allow the remaining gas to escape from the pressure regulator via the outlet until the pressure gauge (2) indicates "0". The pressure regulator can now be released from the valve by turning the screw connection (1) anti-clockwise and, if necessary, attached to a new cylinder.
Each time the cylinder is changed, check that the pressure regulator is functioning (read the section "Checkup")!

Do not set up gas cylinders in the immediate vicinity of sources of heat (e.g. heaters, ovens)! Naked flames and smoking are strictly forbidden in the vicinity of valves carrying gas!

Do not use external components, e.g. adhesive plaster, to seal the inlets and outlets!

Always secure cylinders against falling over and uncontrolled movement!

CAUTION: Liquid gas cylinders (e.g. nitrous oxide) must only be used in the upright position!

7 Cleaning

The device must be cleaned regularly.
Cleaning agents must be used in moderation and must **not** enter the inlets or outlets.
Under no circumstances use agents containing oil, grease or wax! Use a clean, dry or damp cloth.

8 Check up

Even devices not in use must be checked at least every six months as follows:

- Are there any signs of external damage?
- Is the O-ring for the inlet connection present and intact?
- Does the pressure gauge display a realistic pressure if the pressure regulator is connected and the cylinder valve open?
- Does gas come out of the flow outlet?

If necessary, inform the customer service of any faults that occur!

9 Maintenance

The pressure regulator must be inspected and maintained at regular intervals by trained personnel. We recommend an inspection every five years and a maintenance 10 years after manufacture – or sooner in case of visible defects.
The interval specified on the inspection plate (7) must also be observed to devices in storage!
Only genuine VTI spare parts and lubricating agents specified by VTI may be used!

10 Storage and transport

The pressure regulator must always be stored in a clean and dry environment!
Take particular care to ensure that the inlet connection is protected against contamination and damage.
Suitable transport protection, e.g. the original packaging, must be used when the devices are transported!

11 Disposal

Metal and plastic parts left over following maintenance and repair work must be properly disposed of. If the pressure regulator is no longer used, it is disassembled by the technical department responsible for carrying out maintenance or by the manufacturer and sent for appropriate disposal.

12 Warranty

For the pressure regulator supplied, we offer a warranty for a period in accordance with our General Conditions of Sale and Delivery, provided that the operating instructions are adhered to and that the device is not subject to improper external interference. The warranty is limited to error-free functionality, impermeability and flawless material. All other claims are excluded, unless otherwise stipulated by mandatory legal provisions.
Also excluded are defects that are not attributable to our product, but to external influences, improper handling or the failure to adhere to our operating instructions.

13 Eliminating possible malfunctions

Fault	Possible cause	Remedy
Pressure gauge (2) does not display a reading	Cylinder valve not opened	Open the valve
	Cylinder is empty	Connect a new cylinder
	Pressure gauge faulty	Inform customer service
Safety valve (3) is activated (allows gas to escape continuously)	Malfunction in regulator system	Inform customer service
Leak at the screw connection between the pressure regulator and valve	Seal missing or damaged	Inform customer service
Screw connection to the cylinder valve cannot be loosened by hand	Residual pressure between valve and pressure regulator	See the section "Turning off the pressure regulator and connecting it to a new gas cylinder"

14 Spare parts

- hose adapter with O-ring (6)
  VTI part no. 62231.14.0-S3
- O-Ring for adapter (6)
  VTI part no. 0171.1.381

O-rings for the cylinder connection

gas	country / standard	VTI part no.
Oxygen 300 bar	ISO-standard	0171.1.535
Oxygen 200 bar	Germany	0171.1.351
	Great Britain, Netherlands	0171.1.381
	Italy, Denmark	0171.1.352
	France, Spain	0171.1.532
Air 200 bar	Germany	0171.1.365
All 200 bar	PIN Index ISO 407	0171.1.372
Nitrous oxide	Germany	0171.1.620
Carbon dioxide	Germany	0171.1.352

15 Manufacturer

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Your specialist retailer/customer service