

Technical data

Classification	Unit class to EU guideline 93/42 annex IX, class IIb
Relevant norm	EN ISO 10524-1
UMDNS-Code	13-323 (Universal Medical Device Nomenclature System)
Type of construction	Single stage piston pressure regulator
Inlet pressure	200 / 300 bar (1 bar = 1 kPa×100)
Outlet pressure SWISS optio basic	2 or 4.5 bar (1 bar = 1 kPa×100), pre-set
Outlet pressure SWISS optio varius/regflow Gases	4.5 bar (1bar = 1 kPa×100), pre-set
Flow ranges flow selector	Medical gases and their mixtures various flow ranges available
Measuring accuracy	Flow selector: ±30% at Q ≤ 1.5 l/min ±20% at Q > 1.5 l/min Flowmeter: version 3, 16, 32 l/min ±10% or ±0.5 l/min (higher value applicable) with residual pressure in cylinder P1 = 10 bar 100 l/min (AIR) with residual pressure in cylinder P1 = 20 bar 150 l/min (AIR) with residual pressure in cylinder P1 = 30 bar
Maximum flowrate	Country- and gas specific screwed gas cylinder connections various hose connector or threaded connection
Inlet connection	Temperature -20 up to +60°C (for operation and storage)
Outlet connection	Humidity 10-100% relative humidity (for operation and storage)
Surrounding conditions	Ambient pressure 600 – 1200 hPa (for operation and storage)

Disinfection / Cleaning

⚠ Attention – the user has to care for adequate hygiene of the device. Clean the product regularly after every use. When cleaning / disinfecting, it is mandatory to follow hygiene rules. There is a risk of infection.

For disinfection, use substances from the range of surface disinfecting agents. For material compatibility reasons, substances based on the following active agents are suitable

- Aldehydes
- Alcohols
- Quaternary ammonium compounds

The product must only be cleaned with wiping disinfection. The device is not suitable for autoclaving. We recommend the consultation of national admission offices for the choice of a suitable substance. The active ingredient basis of each disinfection agent is described in the lists of the respective admitted disinfection agents.

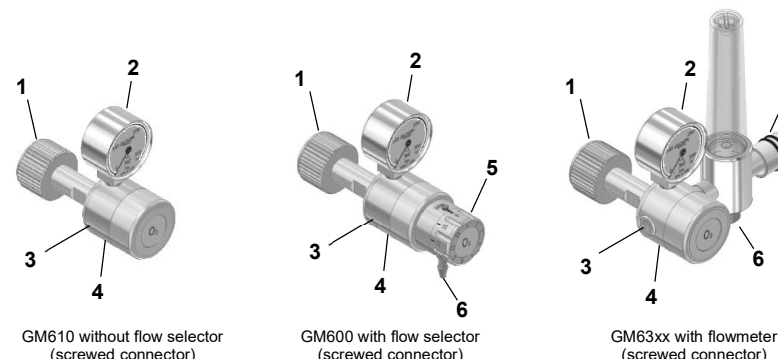
⚠ Note – the product must not be immersed in liquids!



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Instructions for use BM0100E
Order No.: 66854-E
11th edition (09/2020)

Instructions for use
SWISS optio basic / varius / basic regflow 200/300 bar



- 1 Cylinder connection
- 2 High pressure gauge with indication of cylinder pressure
- 3 Outlet 4.5 bar (if available)
- 4 Relief valve bores (two pieces on bottom side)
- 5 Flow selector for the adjustment of the flow
- 6 Outlet connector of the selected flow rate

Symbols used on labels and in instructions for use

- | | | |
|---------------------|-------------------------------|--------------------------|
| Attention | Manufacturer | Date of manufacture |
| Storage temperature | Relative humidity for storage | Keep oil and grease free |
| Use by date | Follow instructions for use | |

User

The user of this product is the medical staff. They must have specialist knowledge in medical fields as well as in the use of the present product.

⚠ Note – technical staff is in charge of the maintenance of the product, must be authorised by Gloor Bros Ltd. and must be familiar with the special features of medical devices.

Follow the instructions for use

⚠ Prior to the use of the product, do read the complete instruction for use. Follow these instructions at all times to ensure the safe use of the product for its designated purpose. Keep the instruction for use close to the product, allowing its consultation at any time.

Handling gases, especially oxygen O₂ and nitrous oxide N₂O (laughing gas)

The product is designed to be used with a gas cylinder appropriate for the gas type. In this respect, the cylinder connection is pressure-, gas- and country specific. The product is marked with the allowed gas for which it can be used.

Warning – Gases in the gas cylinder are under high pressure and appropriate precautions should be taken when handling the cylinder. Gas cylinders must not be left free standing and must be fixated by suitable means.

Warning – wrong type of gas or wrong working pressure result in health impairments. The product must only be used with the gas type mentioned on the product label. Use the correct gas type for its medical purpose. Prior to every use, make sure the working pressure to the consumer does meet the requirements of the treatment.

⚠ Warning – uncontrolled gas flow results in health impairments or danger of suffocation. Never allow the gas to be released freely. Check product for leakage, close valves. The place of use must be well-ventilated to avoid excessive saturation of the ambient air with the gas.

Warning – Oxygen O₂ and nitrous oxide N₂O promote combustion. Do not use gases near open flames or hot objects and do not smoke.

Warning – Oxygen O₂ in combination with oil, grease or combustible fluids promotes combustion. Keep product always clean, oil and grease free.

Note – skin care products may contain substances that promote fire hazard.

Handling the pressure regulator

Warning – the pressure regulator with its gas cylinder connection must always be connected gas-tight to the gas cylinder. Please follow the instructions regarding bringing into service.

Warning – no modifications should be made to the pressure regulator. These can be hazardous and jeopardize your safety or that of the patient!



Warning – the pressure regulator is equipped with a relief valve that releases over-pressure that may be caused by an internal leakage. Its sole function is the protection of the pressure regulator and must not be modified. Once activated, the pressure regulator must be removed from service immediately and repaired by the manufacturer or an authorised service partner.

Caution – only if the pressure regulator is equipped with yellow symbol stating "MR", it can be used in magnetic resonance (MR) environment up to the Tesla-value stated on the label.

Warning – special note for use by emergency services

If the pressure regulator is pressureless connected to the gas cylinder, models that are tightened by hand can loosen slightly during transport as a result of the jolting movements and vibrations.



Prior to every use and before opening the valve of the gas cylinder, the user must always secure that the cylinder connection is still tightly fastened to the gas cylinder valve. If necessary it must be tightened again prior to opening the gas cylinder valve.

Otherwise the gas can leak and, with the supply of oxygen, the gasket of the cylinder connection may ignite. This may also result in burns to the individuals involved.

Purpose

The pressure regulators SWISS optio basic / varius / basic regflow 200/300 bar are designed to reduce the pressure of medical gas cylinders to the requested working pressure. Depending on the version, they are equipped with a flow control to limit or adjust the gas flow.

Functional description

Pressure regulators reduce the pressure of medical gas cylinders to the requested working pressure. They are connected to the gas cylinder with the inlet connection. The gas cylinder pressure can be read on the high pressure gauge. The function principle of the single stage piston pressure regulator assures a constant working pressure. The SWISS optio basic exclusively performs a pressure reduction. The SWISS optio varius and SWISS optio basic regflow can additionally adjust the flow rate by means of adjusting the flow selector. For SWISS optio varius, the selected value can be read on the flow selector. For SWISS optio basic regflow, the selected value can be read on the flowmeter. Via outlet connector, the reduced pressure will be supplied to the connected equipment. Typical applications are therapeutic use, acute medicine, especially emergency services or other medical applications.

Start-up procedure

1. Remove all protective caps from the connections. Keep the protective caps for eventual transport or storage.
2. Check that all fittings are clean, oil and grease free. Pay attention that hands are also clean, oil and grease free.
3. Carefully check the pressure regulator for damage (connector seals, outlet connector, pressure indication, flowmeter). If damage is evident, the pressure regulator must not be used. It must then be repaired by technical personnel within the framework of his/her competence, or sent to the manufacturer or an authorised service partner for repair.
4. Check that the two bores of the relief valve (at the bottom side of the main body) are not blocked or covered. If one or both bores are blocked or covered, they must be decongested or uncovered prior to the start up.
5. Check that the flow selector (if available) can be adjusted freely without using large strain and turn it to close position afterwards.



Warning – if the flow selector can only be adjusted by using large strain, the pressure regulator must not be used. It must then be repaired by technical personnel within the framework of his / her competence, or sent to the manufacturer or an authorised service partner for repair.

6. Connect the pressure regulator with the screw connection (hand or tool fastening) to the gas cylinder and ensure that it is gas-tight.



Note - Do not use a tool for a hand fastening screwed connector.

Caution – for versions with lateral flowmeters, to ensure correct adjustment and readability of the flow, the measuring tube must be in vertical position pointing north.

7. Connect the consumer/s.
The pressure regulator is pre-set. If the pressure regulator is equipped with additional pressure outlets of 2 bar or 4.5 bar, on which no consumers are connected, make sure that they are correctly closed with locking screws. If the regulator is connected to the gas cylinder and the cylinder is opened before the gas-consuming equipment is connected, gas can be freely released!

8. Open the cylinder valve with the hand wheel or spanner (PIN-Index) slowly and steady and check on pressure gauge that the medical gas cylinder still disposes sufficient pressure. Change the cylinder accordingly when residual pressure drops below 10 bar (1 bar = 1 kPa×100).



Warning – after each interruption of service and prior to every opening of the gas cylinder valve, check if the gas cylinder connection is still tightly fastened to the gas cylinder valve.

Caution – prior to start-up, make sure the correct and required equipment for the treatment is available and correctly connected.

9. Check the pressure regulator for leakage on the cylinder and outlet connection, on the relief valve and all further connections. Should the product show leakage, it must be taken out of service immediately and must then be repaired by technical personnel within the framework of his / her competence, or sent to the manufacturer or an authorised service partner for repair.

10. Adjust the desired flow rate on the flow selector. Always ensure that the flow selector is locked into position. For versions equipped with flowmeter, the flow rate can be continuously adjusted and be read on the marking of the measuring tube.

Warning – incorrect flow rate settings can endanger the patients' health and damage connected devices. Assure the correct flow rate setting for the treatment to be performed.

Warning – if the flow selector is set in position between two flow rates, no flow is available. Always ensure that the flow selector is set to a locked-in position.



Warning – if multiple outlets are used at the same time, please be aware that the total flow capacity is distributed to the number of outlet connections in use.

Warning – in case of interruption of the gas consumption, the pressure within the connection tube to the pressure regulator increases up to the set working pressure P2 of the pressure regulator.

End of operation / Change of cylinder

1. Close cylinder valve by using the hand wheel or spanner (PIN Index).
2. Keep the flow selector or consumer open until the pointer on pressure gauge is at "0" and no more gas emerges from the outlet or consumer. Afterwards turn the flow selector again to zero position.
3. Disconnect the consumer of gas (if necessary) from the outlet connection.
4. If required (change of cylinder, permanent shutdown) the pressure regulator can now be removed from the medical gas cylinder.



Note: For pressure regulators with manual tightening connection the tightening nut can only be released when pressure has been completely released from the entire fitting. Do not use a tool for this purpose.

5. After cylinder change, follow the instructions in the start-up procedure.
During non-use, keep the pressure regulator in a safe place, protected from the access of unauthorized person, risk of damages and environmental influences.



Warning – lack of care and hygiene can affect the functionality of the device and therefore endanger the health of patients.

Maintenance (overhaul and repair)

The regulator is designed for a service life of 18 years from the date "YYYY/MM" indicated on the type identification plate. It must be given a complete overhaul after 9 years and has to be disposed at the end of its service life. The regulator is either tagged with a maintenance sticker with the date for the next general overhaul or with a sticker indicating the end of service life. If returned to the manufacturer, the product will be properly recycled.

If the regulator is stored for more than 9 years, it must be given a general overhaul before putting into service.

Function and safety are only guaranteed, if maintenance of the product is documented and performed by the manufacturer or through the manufacturer authorized companies and by using original GLOOR spare parts.

If the delays for the overhaul are exceeded, the liability of Gloor Bros Ltd expires.

Warning – damages, deferred overhaul or modification on the product may lead to health impairments of user and patient. To maintain and service products, authorisation from Gloor Bros Ltd. is mandatory. Use only original GLOOR spare parts.



Note: product must be disinfected before sending for repair

Note: disinfect product after repair / overhaul

Status and function check

According to the start-up procedure, a check of the device must be performed prior to every start up. In case the device is not regularly taken out of service, the check must be performed when changing the cylinder or latest every six months.

This includes the following points:

- Is the device damage free, clean and grease free?
- Are all labels and displays still perfectly readable?
- Are the bores of the relief valve free of blockage?
- Can the flow selector be adjusted without using excessive force?
- Can the pressure regulator be properly attached to the gas cylinder and is the connection gas-tight?
- Do all connected parts fit the pressure regulator?
- Is the pressure indicated on the gauge readable?
- Does the relief valve stay tight?
- Is the pressure regulator gas-tight at all potential leak points?
- Has the overhaul interval been complied with?
- Has the service life not been exceeded?