Gas Flow Controller MY GAS 2

Operating Instructions

Version 3.0 (03.08)

KLS martin GROUP

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1 Important Startup Notes

1.1 General Information

We thank you for having decided to buy a KLS Martin product. This product carries the CE-mark, which means that it satisfies the essential requirements laid down in the EC Directive concerning medical devices.

We are the manufacturer of this product:

Gebrüder Martin GmbH & Co. KG
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Phone: +49 74 61 706-0 • Fax: +49 74 61 706-193
E-Mail: info@klsmartin.com • Web site: www.klsmartin.com

1.2 Warranty

Gebrüder Martin's Standard Terms and Conditions shall apply (as revised and updated from time to time). Accessories are consumables and, as such, excluded from the warranty.

Within the warranty period, we will fix free of charge – either through our Technical Service or directly at the factory – any defects caused by a manufacturing defect or the use of defective materials. However, such measure shall not extend the warranty given for this unit.

Important Note

The unit may only be repaired by us or a person or firm expressly authorized by us to carry out such work.

If the repair is performed by a person or firm authorized by us, the repairer is required to issue to the operator of the unit a certificate with details about the nature and scope of the repair work done. This certificate must be dated and signed and include the firm's details. In addition, repaired devices or components must be clearly marked with the service technician's ID label in all cases where a party other than the manufacturer of the product performed the work.

1.3 Hotline

Should you have any technical questions, please contact our hotline:
Gebrüder Martin Hotline

Technical Questions
Phone: +49 74 61 706-343
Fax: +49 74 61 706-190

E-Mail: msc@klsmartin.com

Our service representatives are available Monday through Friday from 8 a.m. to 5 p.m.

In case you have any questions concerning maintenance contracts or training courses, please contact our Technical Service manager under +49 74 61 706-332, or send an e-mail to: msc@klsmartin.com

1.4 Purpose and Scope of these Operating Instructions

This manual provides an extensive description of how to put the unit into service and use it as intended. Please read this information prior to using the unit in the operating room, making sure that you have familiarized yourself fully with its working and operating principles!

As the manufacturer, we guarantee that the unit left our factory after careful testing. Besides, we assume responsibility for its continued safety, reliability and performance. However, this presupposes that only qualified persons specially authorized by us will perform any checks and repairs and that the unit will be subsequently used as intended. We will accept no responsibility for damage caused by improper handling or use!

Note that these Operating Instructions do not provide a detailed description of the surgical technique involved, nor are they suitable for familiarizing a beginner with this type of surgical technique. Therefore, the unit is intended for use only by physicians and medical assistants who have the necessary qualifications.

The safe and long-term use of the unit requires the exclusive use of genuine KLS Martin spare parts!

Keep this manual readily at hand next to the unit!

1.5 Warnings

ATTENTION! The unit is not explosion-proof.
Never operate it in the presence of flammable gases!

Never open the housing! The unit incorporates components that can only be serviced or repaired by trained technicians.
Only non-combustible, non-flammable irrigation gas is permitted for use!

ATTENTION! Never use the MY GAS 2 gas flow controller as an infusion pump or insufflator!

ATTENTION! Never use the MY GAS 2 gas flow controller as an irrigation-suction pump!

2 Description of the Unit

The gas flow controller is intended for connection to the KLS Martin laser units MY30/MY60, MY40e and MY40.

With these Nd:YAG lasers, either an irrigated optical fiber or a focusing handpiece with irrigated supply fiber can be used for laser energy transmission.
The laser light can be applied directly via the irrigated fiber or by using the focusing handpiece. Alternatively, it is also possible to use a bare fiber in conjunction with a flexible fiber irrigation tube.
In all of these cases, the MY GAS 2 gas flow controller is used for gas supply to the laser application site, where the gas is needed for irrigation purposes.

The continuous gas flow is mainly used for clearing the operating site by removing the plume generated during application of the laser light. In some applications, the gas flow is used for tissue dilatation.

When using a footswitch with two switching points, it is possible to set the following operating states for the MY GAS 2 gas flow controller:

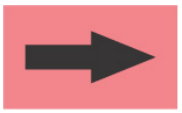
Footswitch Position	**Gas Flow**	**Comment**	**Laser**	
Mains OFF, unit OFF				
any	No gas flow	No control signal	Depending on footswitch position	
Mains ON, unit ON				
 Footswitch not operated	BASE FLOW	Adjustable from 0 l/min to 15 l/min	Laser not activated	
 Footswitch set to position 1	WORK FLOW	Adjustable from base flow to 15 l/min	Laser not activated	
 Footswitch pressed down completely, position 2	WORK FLOW	Adjustable from base flow to 15 l/min	LASER activated	

Table: MY GAS 2 operating states

2.1 Intended Use

The MY GAS 2 gas flow controller is intended for controlling the irrigation gas flow for focusing handpieces and irrigated laser fibers during laser-surgical applications in conjunction with KLS Martin Nd:YAG lasers.

The MY GAS 2 unit can be connected to an irrigation gas supply with a maximum gas pressure of 5 bar. Medical air or medical nitrogen can be used as an irrigation gas.

3 Startup

3.1 User's Inspection

Please check the unit and its accessories for completeness and potential shipping damage immediately upon receipt.

Compensation claims will only be accepted if the seller or carrier is notified immediately of any damage or loss. In such a case, a certificate of damage / loss must be established at once and be submitted either to the nearest Gebrüder Martin representative or to Gebrüder Martin directly so that the compensation claims involved can be duly filed with the insurer.

When returning the unit to Gebrüder Martin or a Gebrüder Martin service shop, always use the original shipping carton and include the following information:

Name and address of owner, type and serial numbers, description of the defect.

3.2 Installing the Unit

The unit is placed on the laser head of the laser unit in such a way that all controls can be operated from the front.

Be sure that the surface on which you place the unit is free from any hardware or small parts. The bottom surface of the unit has a magnetic foil that ensures its firm (non-skid) placement on smooth metal surfaces.

Alternatively, it is possible to use the magnetic underside of the MY GAS 2 to attach it laterally (in vertical position) to the metal housing of the laser unit.

3.3 Connecting the Unit to the Power Supply

The unit may be connected only to a duly installed grounding outlet (i.e. featuring a PE terminal).

Prior to inserting the power plug, please verify that the voltage indicated on the unit's voltage selector complies with your mains voltage.

Note! It is not permitted to connect the unit to the power supply system in hazardous areas (or potentially explosive atmospheres)!

WARNING! The units are factory-preset to 230 volts. If your mains voltage differs, you must adjust the unit to the voltage of your supply system.

3.4 Changing the Mains Voltage Range

If a mains voltage other than 220–240 V is used, the unit must be set to 110–127 V.
To do this, disconnect the mains cable from the power supply socket (1, Fig. 1).
Use a screwdriver to press the clip of the line fuse switch upwards, then remove the drawer containing the line fuses.
Replace the 100-mA slow-blow fuse with a 200-mA slow-blow fuse as required for 110–127 V operation.
Remove the white voltage selector from the power supply connector assembly, then reinsert it so that the voltage range "110–127 V" is visible from the rear of the unit.
Reinsert the drawer with the line fuses into the power supply connector assembly, making sure that the clip of the line fuse switch locks in place correctly. The correct voltage range must now be visible in the narrow display window.
Reinsert the power supply cable to reestablish the connection between the mains socket-outlet and the unit's power supply socket. Push the plug into the socket as far as it will go.

Conversion from 110–127 V to 220–240 V is performed analogously.

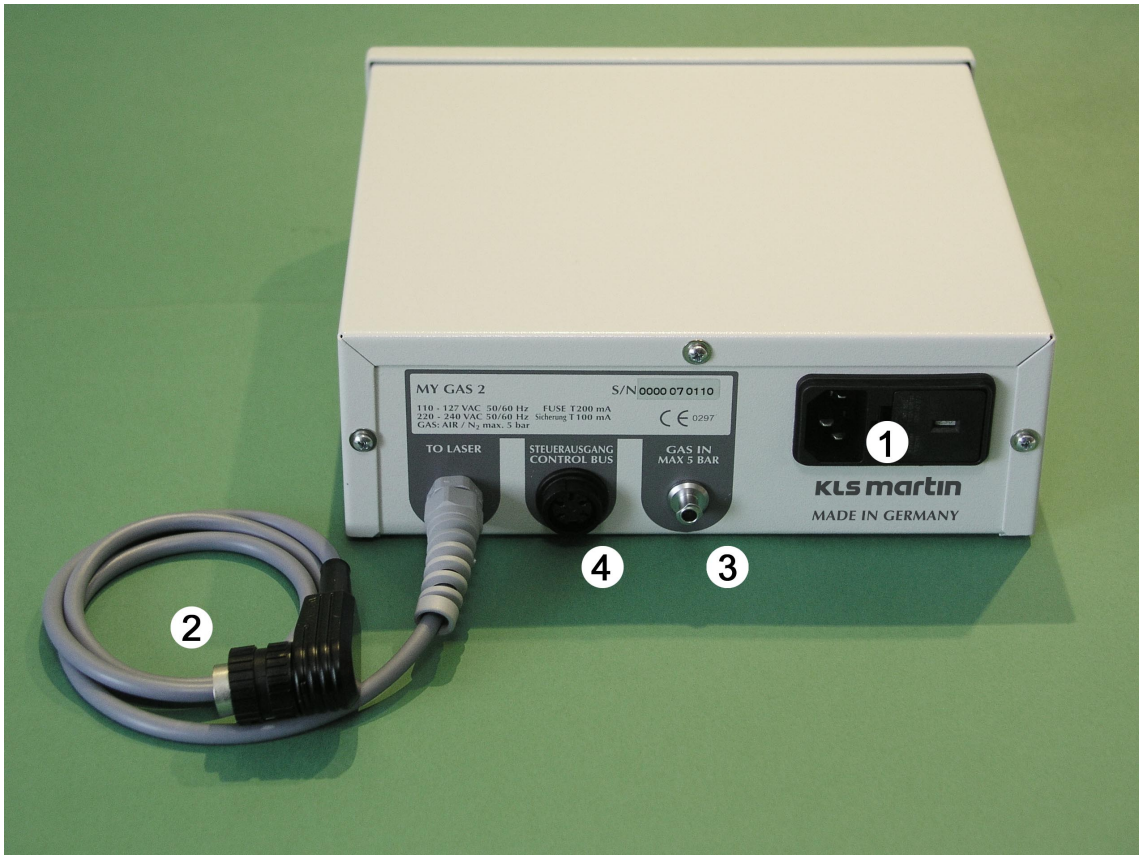


Fig. 1: Connectors on the rear panel of the unit

1 Power supply socket for power supply cable, plus voltage selector with fuse drawer

2 Connecting cable for connection to laser

3 Female Luer-lock connector (GAS IN)

4 Output socket for device control

3.5 Connecting the Unit to the Gas Supply

The rear-side (female) Luer-lock connector "GAS IN" (3, Fig. 1) is used to connect the MY GAS 2 to the gas supply.
The unit can be optionally connected to the central gas supply system of the operating room. In this case, the pressure hose 78-215-01 must be used. However, this requires a maximum input pressure no higher than 5 bar. If the supply gas pressure exceeds 5 bar, it is mandatory to use the pressure hose with pressure regulator 78-215-02. Suitable gases are medical air or medical nitrogen.

Using a gas cylinder for gas supply is possible as well. In this case, the flexible pressure tube with pressure reducer as contained in the set 79-060-91 must be used.

3.6 Connecting the Gas Flow Controller

1) Connect the unit to the mains by inserting the power supply cable into the unit's power supply socket (1, Fig.1).

2) Connect the footswitch to the footswitch socket of the laser unit.

3) Connect the TO LASER output cable (2, Fig. 1) to the "STEUERAUSGANG" (control bus) socket of the laser unit, then lock the plug in place by rotating it clockwise.

4) Connect the Luer-lock connector of the gas supply line (see "Accessories") to the GAS IN connector (3, Fig. 1) located on the MY GAS 2's rear panel.

5) The "STEUERAUSGANG" (CONTROL BUS) socket can be used for connecting other laser-controlled units (4, Fig. 1).

ATTENTION! The "CONTROL BUS" output will only be active after the MY GAS 2 has been turned on!

The gas flow control output is located on the front panel. Connect the Luer-lock connector (2, Fig. 2) with your laser applicator or your laser focusing handpiece. Should you require a female Luer-lock connector, just use the Luer adapter attached to the chain (Fig. 3).

4 Controls & Operation of the Unit

4.1 Controls

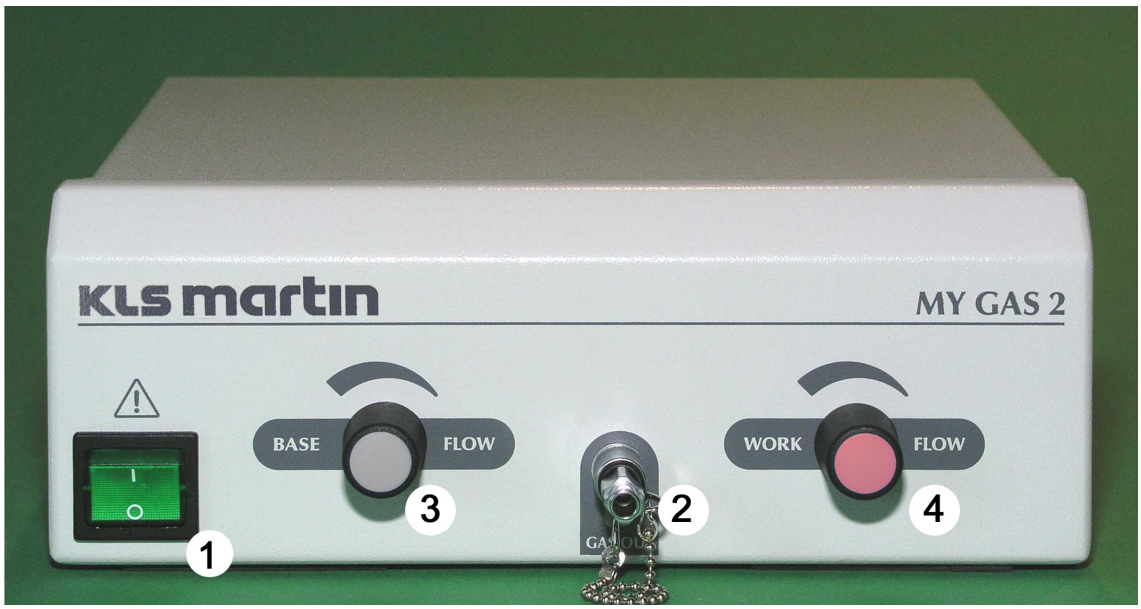


Fig. 2: MY GAS 2 controls

1 Power switch
2 Male Luer-lock connector (GAS OUT)
3 BASE FLOW rotary switch (gray)
4 WORK FLOW rotary switch (red)

Fig. 3 Luer adapter for connecting a male Luer connector to socket 2, Fig. 2

4.2 Operating the Unit

1) The supply gas pressure must not exceed 5 bar. Turn on gas supply.
2) Turn on the power switch. This switches on the BASE FLOW.
3) Adjust the BASE FLOW with the rotary switch 3 (marked gray), Fig. 2.
4) Operate the footswitch until the first pressure point is reached. This activates the working gas flow (WORK FLOW).
5) Adjust the WORK FLOW with the rotary switch 4 (marked red), Fig. 2.
6) Press down the footswitch as far as it will go. This activates the laser in addition to the working gas flow (WORK FLOW).

4.3 Working in a Sterile Environment

To connect the gas flow controller to a sterile handpiece or a sterile, irrigated fiber, the output 2 (Fig. 4) must be fitted with a sterile disposable filter (item no. 80-181-90).
Either the sterilizable flexible connecting tube (item no. 83-100-30) or a sterile Heidelberg extension tube must then be used for connecting the output side of the sterile filter to the supply tubing of the laser focusing handpiece. If irrigated fibers are used, the fiber's gas connection tubing can be directly connected to the sterile filter.

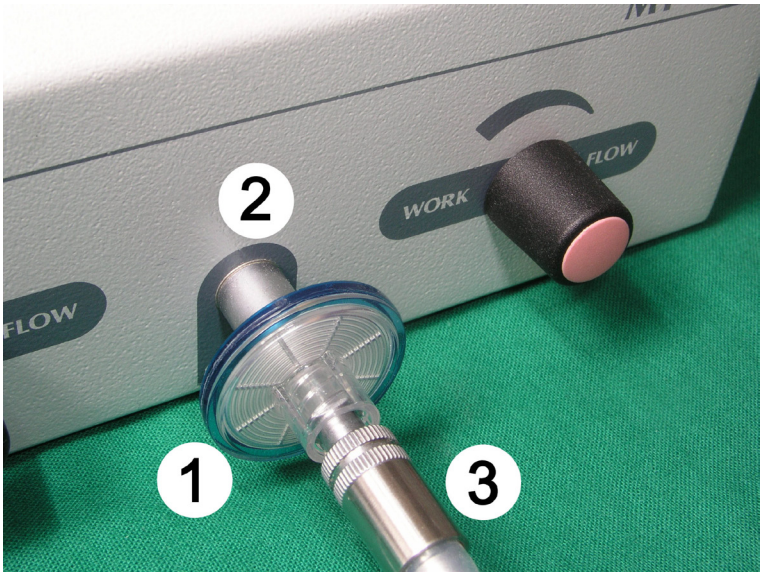


Fig. 4 Sterile filter (1) on gas outlet (2) with connected connection tubing (3)

5 Care and Maintenance of the Unit

5.1 Cleaning

Cleaning and surface disinfection must be carried out in accordance with the hospital's in-house regulations. As regards the concentration of the disinfectant used, please observe the product manufacturer's instructions.

The following agents / substances are not permitted because they would attack and destroy the base material of the magnet:

nitric/azotic acid, benzine (petroleum ether), acetone, 90% alcohol, benzol (benzene), chlorinated solvents.

5.2 Annual Inspection by Technical Service

The unit should be checked once a year by an authorized service technician. Otherwise, the manufacturer will assume no responsibility or liability for the operational safety of the unit. Any service work – such as modifications, repairs, calibrations, etc. – may be performed only by the manufacturer itself or by qualified service technicians specially authorized by the manufacturer.

Any such checks or repairs must be documented by the service technician, who is required to issue to the operator of the unit a certificate with details on the type and scope of the work performed and the company carrying it out. The certificate must be dated and signed.

Any unauthorized opening of the unit, as well as repairs and / or modifications performed by third parties, shall release us from any responsibility for the operational safety of the unit.

6 Accessories

Description	**Item number**
Pressure hose for central gas supply	78-215-01
Pressure hose for central gas supply, with pressure regulator	78-215-02
Flexible connecting tube for gas cylinder, with pressure reducer, set	79-060-91
Silicone tubing with Luer-lock connector, f/m, 1 m, sterilizable	83-100-30
Sterile filter, disposable product	80-181-90

7 Technical Data

Designation	Gas flow controller
Type	MY GAS 2
Item no.	78-231-00
Power requirements	110–240 V
	50–60 Hz
Power input	10 VA
Line fuses	100 mA, slow-blow, for a mains voltage of 220–240 V
	200 mA, slow-blow, for a mains voltage of 110–127 V
Design	in accordance with DIN IEC 601
Protection class	I
Type	BF
Class of equipment (MDD)	IIa
Temperature range	+10°C to +40°C (50°F to 104°F)
Air humidity	30–70%
Degree of protection	IPX1 (drip-proof)
Gas inlet connector	Luer-lock, female
Medical gases permitted for use	Air, N_2 (nitrogen)
Gas pressure	max. 5 bar
Gas output connector	Luer-lock, male
Dimensions	200 x 70 x 190 mm (W x H x D)
Weight	1.6 kg
Safety check	annually

CE 0297 Conforms to 93/42/EEC

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