Operating, cleaning and maintenance instructions

medinBLENDER - Gas mixer for air and oxygen

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Contact and ordering information

Model 1085_15:

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Adam-Geisler-Str. 1
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Sales and customer service:
by authorised partners: www.medingmbh.com

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Information on the validity and retention time of documents

This document is valid until it is changed or revoked by the manufacturer and it must be available until the end of the lifespan of the product.

Classification

II B according to guideline 93/42 EEC

CE 0483

Model 1090:

BioMed Devices Inc.
61 Soundview Road
Guilford, CT 06437
CE 0086

Sales and service:
Medin GmbH und partners

Warranty

With this warranty, the manufacturer guarantees, for a period of 24 months, that this product has no material and processing defects at the time of initial purchase. If the product should have any defects during the period of the warranty (at the time of the initial purchase) based on material or workmanship, the manufacturer or his authorised sales and service partner will repair the product at no charge for labour or material costs under the following conditions, or (at the manufacturer's discretion) will replace the product itself or its defective parts. The manufacturer and his authorised sales and service partner may replace defective products or parts with new or reconditioned products or parts. All replaced products and parts become the property of the manufacturer.
Conditions:

1. Warranty claims can only be made if the model name or the serial number on the product has not been changed, effaced, removed, or made illegible.
2. This warranty does not cover the costs for transporting the product to the manufacturer or its authorised sales and service partner, or any risks associated with the transport.
3. This warranty does not cover:
   - regular maintenance and repair or replacement of parts due to normal wear and tear
   - consumables (components which could be expected to need regular replacement over the course of the life of the product)
   - damage or defects caused by use, operation or handling of the product not in accordance with the intended use specified in the instructions for use
   - damage or changes to the product caused by:
      a) improper use
      b) improper installation
      c) improper cleaning
      d) failure to follow the manufacturer's instructions for use and installation
      e) failure to follow the manufacturer's care and maintenance instructions
      f) connecting or using the product in a manner that is contrary to the applicable technical or safety regulations or to the standards of the country in which the product is used
      g) use of the product in systems or under conditions which are not intended for use with the product
      h) use of the product with accessories, accessory devices and other products which differ in nature, condition or standard from those authorised by the manufacturer
      i) repairs or attempts at repair made by persons not authorised by the manufacturer
      j) adaptations or changes without prior written agreement of the manufacturer
      k) product upgrades beyond the specifications or features described in the instructions for use
      l) modifications to the product to adapt it to national or local technical or safety standards in countries other than those for which the product was specially manufactured
      m) neglect
      n) accidents, fire, liquids, chemicals, other substances, flooding, vibrations, excessive heat, insufficient ventilation, sudden power spikes, overly high or inverse voltage or input voltage, radiation, electrostatic discharges (including lightening strikes, other external forces and impacts).

Warranty Exclusions and Limitations
With the exception of the points mentioned above, the manufacturer does not provide any express, tacit, legal or other guarantees regarding the quality, performance, accuracy, reliability, suitability for a particular purpose or other properties of the product. If this exclusion is not admissible according to applicable law or has only limited admissibility, the manufacturer excludes its guarantees as permitted by applicable law or limits them to the minimum allowed by law. Each guarantee which cannot be fully excluded is limited to the duration of this warranty, if permitted by applicable law.

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Note
Please read these instructions carefully before using the device.
Please keep the original packaging in the event the device needs to be returned.
Please make a note of the serial number on the identification plate on the backside of the gas mixer (1090) for your records. Please be aware that the serial number of the easy medinBLENDER (1085_15) can be found on the bottom, and that the Bubble System does not have any serial number.

Warning:

- Do not use any oil or lubricant on or near the oxygen equipment
- Do not place any containers with liquids on the device
- Oxygen may only be supplied via the connection provided
- The oxygen supply must be monitored
- The settings can be changed without being noticed.

Important note:
Only trained hospital staff are authorised to use the gas mixer on patients.
For hospital use only!

1. Product Description

1.1. Description

The medinBLENDER is an air and oxygen mixer with an integrated flow regulator.
It has an acoustic alarm unit and a safety warning system in the case of low gas pressure.
Normal operating pressure of the mixer is 3.5-6.0 bar (350kPa to 600kPa).
In the case of reduced inlet pressure of one of the gases, the mixer automatically reduces the pressure of the other gas, as long as the difference between the two gases is not more than 100 kPa (1 bar).
In addition, the mixer has a 'bleed flow'. This function ensures that the adjusted concentration is immediately available. The 'bleed flow' is normally 7 l/min.
The flow regulator with a needle valve is available in various designs (adjustable from 0 - 15 l/min).
In case of medinBLENDER 1090 you can find two flowmeters (0 – 15 l/min and 0 – 3,5 l/min). The small flowmeter is combined with a bleed of 3 l/min.

WARNING:

If the difference between the gas pressures of the two gases is more than 1 bar, an internal valve opens in order to compensate for the lower gas supply. This will trigger an acoustic alarm. As of this point in time, the mixer loses its function and the oxygen content of the gas mixture becomes uncontrollable.

Important note:
To ensure a sufficiently high flow of the breathing gas, the mixer must be properly connected to full gas cylinders (O_2 and air) or a central gas supply.

Important note:

- The gas supply must be controlled and monitored.
- When gas bottles are used: set initial pressure regulator to a pressure between 3.5 and 6.0 bar.
- When connected to a central gas supply system, the pressure must be constant and demonstrate fluctuations of max. 1 bar.

1.2. Intended Use

The medin gas blenders enrich breathing gas with oxygen for therapeutic use and measure out the quantity delivered to patients.
They can be used in combination with the nCPAP generator Medijet® or Miniflow®, in combination with an option for being able to measure the CPAP pressure generated and in combination with monitoring of the oxygen concentration in the patient's blood for CPAP therapy of premature and newborn infants.
The medin gas blenders may only be used by trained personnel and are only suitable for use in a hospital setting.

The gas supply must consist of clean, dry, and oil-free medical compressed air and medical oxygen. The supply pressure must be between 3.5 and 6 bar. The pressure difference may not be more than 1 bar. In the case of a higher pressure difference, an acoustic alarm is triggered.

2. Product Specifications

The product specification is based on your specific product.

2.1. Operating Ranges

- 21-100% continuous adjustment of the oxygen concentration - accuracy 3 vol.% of the set value
- Flow rate 0 to 3,5 l/min or 15 l/min – accuracy ±0.5 L/min

2.2. Controls

- Knob to operate mixer (oxygen concentration)
- Knob to operate flow regulator
- Push-rotate for opening and closing the bleed (flowmeter 0 – 3,5 l/min)

2.3. Monitoring

- Oxygen supply pressure
- Air supply pressure

2.4. Alarms

- Alarm in the event of low air supply pressure
- Alarm in the event of low oxygen supply pressure
- Alarm in the event of a difference in pressure between oxygen and air that is greater than 1 bar
- The volume of the alarm is 45dbA - 85dbA, depending on the flow

2.5. Pneumatic Supply

2.5.1. Gas discharge to the patient:

- Possible outlets: tapped connection or M22/F15 connection

2.5.2. Gas supply inlet

- Connection form: DISS or NIST for 1085_15, only NIST for 1090
- Pressure range: 3.5 to 6.0 bar

2.6. Operating Conditions

- Temperature range: Operation and storage 10 - 40°C
- Relative humidity: Operation and storage 0 – 95% non-condensing

2.7. Dimensions and Weight

2.7.1. Model 1090

- Dimensions (W x H x L): 210 x 170 x 120 mm
- Weight: 1900 g

2.7.2. Model 1085_15

- Dimensions (W x H x L): 160 x 175 x 100 mm
- Weight: 800 g

2.7.3. Model 1085_easy (can only be used as a replacement part)

- Dimensions (W x H x L): 70 x 115 x 100 mm
- Weight: 650 g

2.8. Connection Options

- Permitted systems: all types of breathing gas humidifiers (Fisher & Paykel, Wilamed, ResMed, Intersurgical, etc.)
- Systems not permitted: untested systems

2.9. Number List

Description	REF
medinBLENDER	1090
medinEASY BLENDER (without flowmeter - replacement part)	1085_easy
medinBLENDER with 15 L flowmeter	1085_15
Outlet converter (F15 mm, M22) optional	51091
Tapped connector (4-7 mm internal diameter tube)	1244-3DW
Bracket for mounting to a rail (10 x 25 mm) - 1085_15	5005
Bracket for mounting to a rail (10 x 25 mm) - 1090	2013BFEU
Bracket for mounting to a pole – 1090	2013B
dual pole clamp	20CL02
Fastening screw for fastening the bracket to a rail	5007-2
Gas supply tubes	various versions available

Table 1: Order numbers

2.10. Accessories

Description	REF
Medijet® – Active CPAP Generator	1000 (single-use) 1010/ 1020 re-use
Miniflow® – CPAP Generator	4000
Prongs (7 sizes available)	various
Masks (4 sizes available)	various
Patient tube kit (with and without humidifier chamber) – heated, single-use for Medijet®	1207/ 1207MKI
Patient tube kit (with and without humidifier chamber) – heated, single-use for Miniflow® in combination with 2040	206746, 206748
Patient tube kit – re-use	Various
Surge tank	1050
Bubble water column	2040

Table 2: Accessory order numbers

3. Unpacking and Set-Up

3.1. Mounting on a 10 mm x 25 mm rail

Push the bracket for mounting onto the base on the back of the mixer.
Now you can easily attach the medin mixer (any model) to any standard rail (10 mm x 25 mm) using a screw.

3.2. Mounting 1085_15 with Bubble Water Column (2040)

For this system, medin offers a special bracket for two systems to be mounted at the same time (humidifier and Bubble Water Column). This can be attached to a rolling cart using a star-shaped screw knob. For order number, see Table 1: Order numbers.

3.3. Gas Supply Connection

1. Connect the air and oxygen tube to the two inlet connections of the mixer. These are marked on the device and coded as per the connections (DISS or NIST).
2. Connect the other end of the tubes to the gas supply.

3.4. Patient Circuit Connections

Connect the patient to the discharge of the flow regulator. The standard connection is a tapped connector or, in the case of model 1090, a outlet converter.
If necessary, this can also be ordered individually (REF see Table 1: Order numbers).

3.5. Serial Number

The serial number of the device can be found on the backside of the mixer. Make a note of this number in your files and on all documents concerning the mixer.
In the case of a 1085_15 mixer, a part number can be found on the bottom of the mixer.

Warning:

It must be ensured that the alarm opening (on the back of the device) is never closed and that the device is placed such that the alarm opening remains unobstructed!

This is ensured when the original bracket for rail or pole mounting is used.

4. Operation

4.1. Model 1090

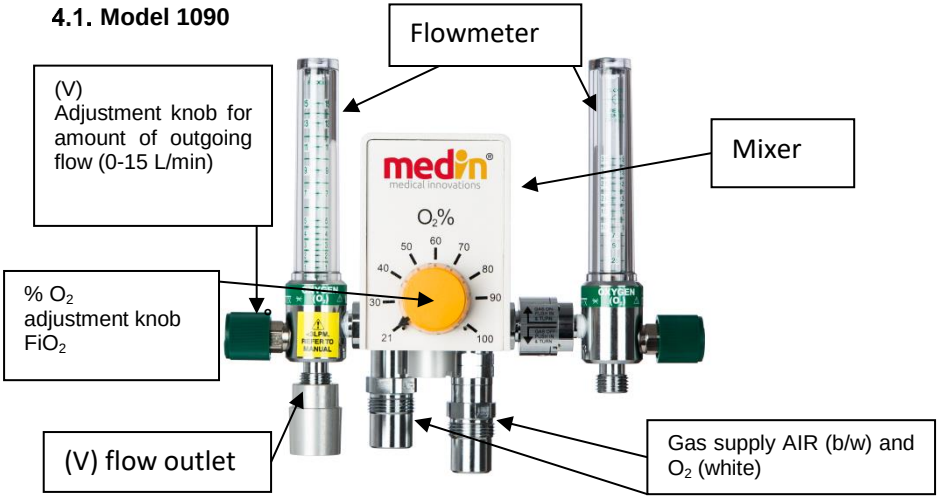

Figure 1: medinBLENDER - components

4.1.1. FiO2 Concentration

Turn the FiO_2 knob of the mixer to the right (increase in FiO_2) or to the left (decrease in FiO_2) in order to adjust the FiO_2 concentration. (Adjustment range: 21 to 100% oxygen).

4.1.2. Flow

The ball in the flowmeter indicates the flow rate. If the control knob of the flowmeter is turned to the right, the flow rate decreases (adjustment range: 0 – 3,5l/min or 0 to 15 l/min). If you are using the small flow meter there is a adjustable (on/off) bleed (by push and rotate).

4.1.3. Important Note

Do not turn the flow rate knob forcefully.

Check the tube connections and the condition of the tubes before each use.

Warning:

The medinBLENDER 1085 may be used for CPAP therapy only in combination with the surge tank (REF 1050) and the Medijet®. Feedback regarding the CPAP pressure generated can only be obtained with this combination.

4.2. Model 1085_15

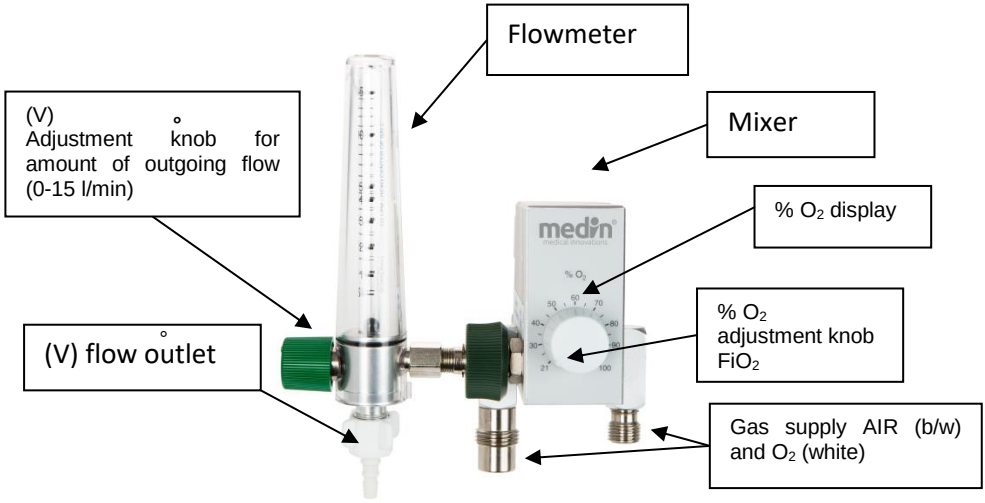

Figure 2: 1085_15 - components

4.2.1. FiO2 Concentration

Turn the FiO_2 knob of the mixer to the right (increase in FiO_2) or to the left (decrease in FiO_2) in order to adjust the FiO_2 concentration. (Adjustment range: 21 to 100% oxygen).

4.2.2. Flow

The ball in the flowmeter indicates the flow rate. If the control knob of the flowmeter is turned to the right, the flow rate decreases (adjustment range: 0 - 15 L/min).

4.2.3. Important Note

Do not turn the flow rate knob forcefully.
Check the tube connections and the condition of the tubes before each use.

Warning:

The medinBLENDER 1085_15 may be used for CPAP therapy only in combination with the surge tank (REF 1050) and the Medijet®. Feedback regarding the CPAP pressure generated can only be obtained with this combination.

If used as a Bubble CPAP System, the Miniflow® is to be used.

4.3. Model 1085_15 in combination with Bubble Water Column (2040)

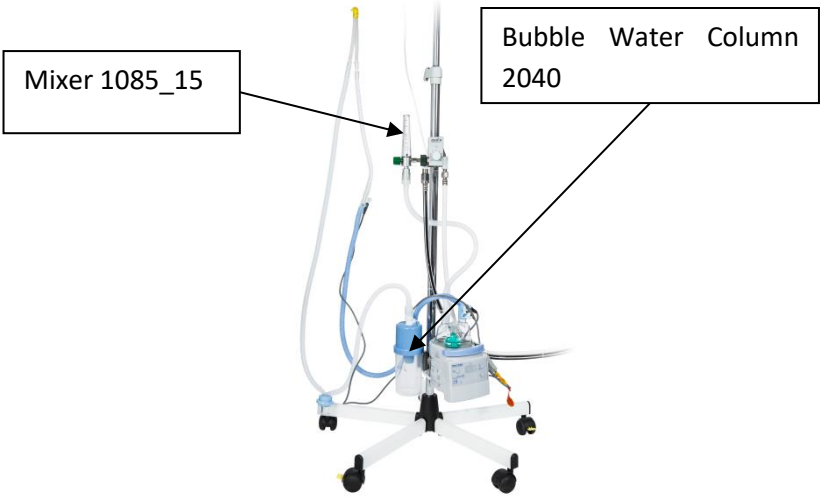

Figure 3: Bubble CPAP System medin

4.3.1. FiO2 Concentration

Turn the FiO_2 knob of the mixer to the right (increase in FiO_2) or to the left (decrease in FiO_2) in order to adjust the FiO_2 concentration. (Adjustment range: 21 to 100% oxygen).

4.3.2. Flow

The ball in the flowmeter indicates the flow rate. If the control knob of the flowmeter is turned to the right, the flow rate decreases (adjustment range: 0 to 15 L/min). A constant flow rate of 7 L/min is recommended. This offers the best mix of effectiveness and low stress for the patient.

4.3.3. CPAP

Adjust the desired CPAP pressure on the head of the Bubble Water Column by turning the white lever. You may vary the pressure between 0.5 mbar and 9 mbar.

4.3.4. Overpressure Valve

Mount the overpressure valve provided (for order number, see Table 1: Order numbers) on the humidifier chamber. The tube to the Miniflow® is connected to the T-piece (which belongs to the overpressure valve). Adjust the overpressure valve by turning to the desired value (recommendation: 15 cm H_2O).

4.3.5. Important Note

Do not turn the flow rate knob forcefully.
Check the tube connections and the condition of the tubes before each use.

Warning:

The system may only be used with an overpressure valve. This is provided in the shipment.

5. Alarm Functions and Displays

5.1. Acoustic alarm in cases of

- Low pressure in the oxygen supply
- Low pressure in the air supply
- Difference in pressure between oxygen and air greater than 1 bar

5.2. If an alarm sounds, check if

- the mixer is correctly connected to oxygen and AIR.
- the oxygen and air pressures are high enough.
- when gas cylinders are used, it should be checked that the cylinders are not empty and that the outlet pressure of both gases is equally high.

5.3. Alarm Specification:

The medinBLENDER alarm is a mechanical alarm. This alarm is triggered when the difference between the two gases is greater than 1 bar or if one of the two supply gases is missing.
In this case, a carriage inside the block is moved so that it guides the path of the gas to the alarm reed. This has a metal gutter through which the gas flow is induced and causes a high-pitched whistle. The sound volume is between 45 dbA and 85 dbA, depending on the setting and gas supply pressure.

6. Explanations

6.1. Explanation of the Symbols

The following symbols are found on the medin mixer or in the accompanying documentation.

Symbol	Source/ Compliance	Meaning	Symbol	Source/ Compliance	Meaning
	EN 980:2008	Manufacturer		MDD Regulation 93/42/EEC	CE mark
	EN 980:2008	Year of manufacture		EN 980:2008	Serial number
	In-house	Maintenance interval sticker		ISO 60601-1	Follow instructions for use
	EN 980:2008	Reference number			

Table 3: Symbols

6.2. List of Abbreviations

CPAP	Continuous positive airway pressure
dbA	Decibel (unit of measurement for sound volume)
DISS	Gas connection designation
FiO_2	Oxygen concentration
L/min	Litres per minute (unit of measurement for flow)
NIST	Gas connection designation

7. Cleaning and Maintenance

7.1. Cleaning

Disinfect the surface of the mixer before using it for the first time, after every use on a patient, and after any maintenance/repair.
A 70% isopropyl alcohol solution can be used.

Warning:

The mixer must never be sterilised or immersed in cleaning fluid.

7.2. Maintenance

Every 12 months:
The manufacturer recommends a complete operational test of the mixer every 12 months in order to check the accuracy of the mixing process. In doing so, the function of the lip valve which prevents reverse gas flow must be checked. For the testing, the gas supply is connected at the outlet and it is checked whether there is any gas leaking at the two bases (actual gas supply connection).
At this point in time the mixer should also be checked corresponding to the requirements of the device passport.
If the mixer demonstrates any damage, repairs are necessary.

Important Instructions:
During the operational test or maintenance procedure, the mixer must not be connected to the patient.
Check the accuracy of the mixing procedure as well as the function of the alarms at least once per year.
Fill out the device passport after each maintenance procedure.
If the device should have any cracks or leaks in the plastic parts, the mixer should not be used any further, since the measurement values could be distorted and inexact.
Contact the manufacturer and/or the sales and service partner responsible for your country.

Every 3 years:
It is additionally recommended that all filters, the lip valves and O-rings that move frequently be replaced every three years. These parts can be ordered as replacement parts under REF 9060.
A full operational test must be performed thereafter corresponding to the requirements of the device passport.

8. Maintenance Record/Device Passport (1090)

Device Passport **medinBLENDER REF 1090**			
Blender SN:		**Gas connection system:**	☐ NIST
Front panel:	☐ medin		
Test equipment:			
Test of oxygen calibration:			
21% ±3%	☐ ok / ☐ nok	40% ±3%	☐ ok / ☐ nok
60% ±3%	☐ ok / ☐ nok	100% ±3%	☐ ok / ☐ nok
Test settings:			
Gas supply 3.5 bar	☐ ok / ☐ nok	Flow 7.0 LPM	☐ ok / ☐ nok
Alarm test:			
Oxygen	Low pressure	FiO_2 = 60%, 7 LPM	☐ ok / ☐ nok
Air	Low pressure	FiO_2 = 60%, 7 LPM	☐ ok / ☐ nok
Flowmeter check:			
Accuracy	2,0/7.0 LPM	Range ± 1 LPM	☐ ok / ☐ nok
Operating range	0 – 3,5/15 LPM	Ball can move up/ down	☐ ok / ☐ nok
Blender Check:			
Knob	No damage	Cap mounted	☐ ok / ☐ nok
Sign:			
Production:			
Date	Signature	Name	
Final check:			
Date	Signature	Name	

9. Maintenance Record/Device Passport (1085_15)

Device Passport **medinEASY BLENDER REF 1085_15**			
Blender SN:		**Gas connection system:** ☐ DISS	☐ NIST
Front panel:	☐ medin		
Test equipment:			
Test of oxygen calibration:			
21% ±3%	☐ ok / ☐ nok	40% ±3%	☐ ok / ☐ nok
100% ±3%	☐ ok / ☐ nok		
Test settings:			
Gas supply 3.5 bar	☐ ok / ☐ nok	Flow 7.0 LPM	☐ ok / ☐ nok
Alarm test:			
Oxygen	Low pressure	FiO_2 = 60%, 7 LPM	☐ ok / ☐ nok
Air	Low pressure	FiO_2 = 60%, 7 LPM	☐ ok / ☐ nok
Flowmeter check:			
Accuracy	7.0 LPM	Range ± 1 LPM	☐ ok / ☐ nok
Operating range	0 – 15. LPM	Ball can move up/ down	☐ ok / ☐ nok
Blender Check:			
Knob	No damage	Cap mounted	☐ ok / ☐ nok
Sign:			
Production:			
Date	Signature	Name	
Final check:			
Date	Signature	Name	

10. History of changes

Revision	Validity date	Changes
Rev01	01.08.2013	- New document
Rev02	11.12.2013	- Update of the device passports - Insertion of a new company label
Rev03	01.06.2014	- new Logo, new Address - name: medinBLENDER
Rev04	14.11.2014	- new product fotos
Rev05	06.04.2016	- formatting - warranty to 24 month
Rev06	18.08.2016	- change from single to dual clampl - Symboles according to EN980:2008
Rev07	07.03.2017	- Chang in device passport REF 1085_15 - correction of REF for mounting 1090

Notes: