Operating, cleaning and maintenance instructions

medinSINDI® Universal Gas Supply Unit with Pressure Monitor

Contact and ordering information
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D-82140 Olching

Sales and customer service:
by authorised partners
a detailed list can be found on the website
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 kept until the end of the lifespan of the product.

Disposal

Separate collection of electrical and electronic devices according to guideline 2002/96/EEC: The product may not be disposed of together with household waste. It must be collected separately from household waste and disposed of in an environmentally safe manner in accordance with local regulations.

Classification
II B according to guideline 93/42 EEC

CE 0483

Warranty

With this warranty, the manufacturer guarantees, for a period of 12 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 partners 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 and the safety seal must not be removed or damaged.

2. This warranty does not cover the costs for transporting the product to the manufacturer or its authorised sales and service partners, 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 lightning 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.

The service life of the device is defined as 8 years.

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Note - Instructions for Use and Serial Number

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 back of the device for your records.

Warning - Handling

- Do not operate the device in the vicinity of highly flammable gases
- 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
- This equipment may be changed without prior notice
- The medinSINDI® may not come into contact with flammable anaesthesia gases or other flammable materials while in use.

Electromagnetic Compatibility

It is confirmed that the device meets the EMC guidelines 89/336/EEC, 93/68/EEC and 93/42/EEC.

Intended Use

Therapeutic use for enriching the breathing gas mixture with oxygen for premature and newborn infants as well as in connection with the nCPAP generator Medijet® to support respiration with continuous positive airway pressure with monitoring and alarm parameters.

FOR HOSPITAL USE ONLY

Important Note - Haemodynamic Monitoring

The device may only be used with simultaneous haemodynamic monitoring of the patient.

Only trained hospital staff are authorised to use the device on patients.

1. Product Description

medinSINDI® universal gas supply unit with pressure monitor is an electronic unit with microprocessor-controlled monitoring and is used to display the set parameters. The unit is battery-operated and is charged by an external power supply plug. The screen is backlit. The operating time without mains power is approximately 5 hours. The oxygen concentration is determined in the gas flow delivered. The O_2 cell is delivered ready to use by a known manufacturer. This cell generates an analogous DC voltage proportional to the oxygen concentration. The cell itself does not need any supply voltage. It should be treated like a battery. The cell is a consumable and must be calibrated in the device from time to time and replaced every 12 months. The calibration is performed using internal software as a two-point calibration (21% and 100% O_2).
The CPAP generated is determined by an electronic pressure transducer. This has a supply voltage of 9 V. The CPAP pressure value to be recorded is between 0 and 20 cmH_2O. The clinically relevant value is 5 - 8 cmH_2O.
The design of the displays ensures easy operation by the user. All necessary calibration steps run automatically and are accessed via a service menu. This is provided with a security code.
The system consists of two main components:

1.1. Pneumatic Blender

The pneumatic blender is an air and oxygen mixer with an integrated flowmeter. It has an acoustic alarm unit and a safety warning system in the event of low gas pressure. Normal operating pressure of the mixer is 350 kPa (3.5 - 6.0 bar). In the event 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 greater than 100 kPa (1 bar). The flowmeter with a needle valve can be adjusted from 0 to 16 L per minute.

1.2. Electronic Monitoring Unit

The oxygen content is read into a memory by pressing the "Confirm FiO_2 Alarm“ button and it is compared with deviations of ± 10% from the current concentration and monitored. If the FiO_2 is changed on the device, this must be confirmed by once again pressing the "Confirm FiO_2" button, otherwise the device alarm will sound.
The oxygen concentration is shown in digital and analogue form on the display. In the event of an alarm, the display blinks and an acoustic alarm is triggered. The alarm can be silenced for 2 minutes by pressing the "Reset" button. The visual alarm remains active until any problems are corrected.
The channel for the CPAP (continuous positive airway pressure) is fully independent from the FiO_2. It is likewise displayed in analogue and digital form. The analogue value is shown in coordinate axes whose size is shown by the abscissa (perpendicular plane). The low scan speed for the ordinate was deliberately selected.

Warning – Gas Supply Pressure

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 – Supply Gas

- To ensure high respiratory flows, the mixer must be properly connected to full gas cylinders (O2 and air) or a central gas supply.
- 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: use pressure reducers at the gas supply tubes to compensate for pressure differences (see list of accessories on page 29)

2. Product Specifications

2.1. Modes

- Automatic shutoff of the pressure monitor if no CPAP use is taking place
- 21–100% continuous adjustment of the oxygen concentration
- Reset for alarms – 2-minute alarm silencing (make silent or end):

Warning – Alarm Silencing

Silencing the alarm requires additional monitoring of vital signs!

- Confirmation of the nCPAP alarm setting for automatic monitoring
- Confirmation of the FiO_2 concentration setting for automatic monitoring (± 10% of the O_2)
- Disconnection or leakage alarm (if the patient pressure falls below 1.5 cm H_2O) - Alarm after 3 seconds
- Battery monitoring with charge status display and alarm
- Overpressure alarm in 3 seconds (if the patient pressure exceeds 10 cm H_2O)
- Microprocessor-controlled input of programmes on FLASH (= technical upgrade)

2.2. Controls and Displays

- Flow adjustment control knob
- FiO_2 adjustment control knob
- Soft-touch membrane keypad
- Monitor with integrated 96 x 61 mm LCD display and illumination resolution 240 x 128 dots b/w

2.3. Monitoring

- Oxygen supply pressure, air supply pressure
- Spontaneous respiratory rate
- Alarm functions:
    - CPAP
    - FiO_2
    - Battery charge indicator
    - Mute setting
    - Automatic alarm system for loss of oxygen or air pressure:
    - acoustic and pneumatic

2.4. Pneumatic Properties

- Patient gas outlet: Connection with 22 M and 15 F converter
- Patient flow: 0 – 16 L/min, working area 4-10 l/min
- Gas supply: Oxygen and air
- Range: 3.5 – 6.0 bar
- Adjustment range: 21% to 100% oxygen (tolerance ±3%)
- Gas connections: for DISS supply (alternative to NIST)
- Oxygen sensor for FiO_2 measurement - sensor type MLF16 (unleaded)
- Overpressure valve 80 mbar

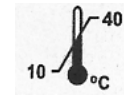
2.5. Power Supply

The electronic system is fully battery-operated and can be recharged with an external power supply plug. Uninterruptible operation for an intensive care unit, with an external power supply plug (automatic 100 to 230 V AC)

- Input voltage, external power supply plug, mains adapter: 100 - 230 V AC
- Input frequency mains adapter 50 – 60 Hz
- Power input: 400 mA
- Output voltage 24 V DC/625 mA
- Internal battery: rechargeable– NiMh 9.6 volts/1100 mA
- Internal battery life: approx. 5 hours (when fully charged)
- Battery charging time – max. 5 hours

2.6. Atmosphere and Environment

- **Temperature Range**
  Operation: 10 – 40° C
  Storage: 10 – 40° C
- **Relative humidity**
  Operation: 0 – 95% non-condensing
  Storage: 0 – 95% non-condensing



Environmental conditions for the medinSINDI® **during operation:**

Ambient pressure: 700hPa to 1100hPa
Altitude: ≤ 2000m above sea level

Environmental conditions of the power supply unit during operation:

Temperature:

- between 0°C and 40°C
- do not use power supply unit in locations exposed to significant temperature fluctuations.

Moisture:

- use only in dry locations
- do not use in locations exposed to significant amounts of moisture or condensate
- do not use in locations exposed to significant environmental stress
- do not use outdoors

Vibrations:

- do not use in locations exposed to constant vibration

Environmental conditions of the power supply unit during transport and storage:

Temperature:

- not in locations exposed to significant temperature fluctuations.

Moisture:

- only in dry locations
- not in locations exposed to significant amounts of moisture or condensate
- not in locations exposed to significant environmental stress
- not outdoors

Vibrations:

- not in locations exposed to constant vibration

2.7. Dimensions and Weight

- Dimensions (height x width x depth):
  180 x 240 x 145 mm (without connections and holder)
- Weight: 2.6 kg (without holder)

2.8. Overview of the General Technical Description

- Information on these points can be found in the chapters indicated:
- Conditions for use, transport and storage: see chapter 3.7
- Characteristics and accuracies of the device: see chapter 2
- Information on the installation of the device: see chapter 3
- Description of the supply gases required: see chapter 3.3
- Description of the power supply: see chapter 3.4
- The device is disconnected from the mains by pulling the power supply unit cable of the medinSINDI® out of the electrical outlet. Thus when installing the medinSINDI®, it should be ensured that this plug is always freely accessible and can be disconnected from the mains without difficulty. The medinSINDI® does not contain any switch which disconnects it from the mains.
- Changes and modifications to the medinSINDI® are not permitted without the permission of the manufacturer: see chapter 6.4
- Repairs and an exchange of parts may only be made by trained, professional service personnel and only in accordance with the instructions in the Maintenance Manual, observing warnings in the manual and in these instructions for use: see chapter 6.3
- The medinSINDI® and its power supply unit are not suitable for use in the direct vicinity of the patient. Only the patient tubes, the Medijet® and the masks and prongs used are used in the direct vicinity of the patient.

2.9. Accessories for medin medinSINDI® REF 1080

REF	**Description**
Optional	NIST connection
2020/2030	Air and oxygen supply tubes DISS
2020/2030_NIST (alternative to DISS)	Connection gas supply air and oxygen NIST
2120/2130	Connection gas supply air and oxygen, DIN DISS
2120/2130_NIST (alternative to DISS)	Connection gas supply air and oxygen, DIN NIST
2220/2230	Connection gas supply air and oxygen AGA DISS
2220/2230_NIST (alternative to DISS)	Connection gas supply air and oxygen AGA NIST
2320/2330	Connection gas supply air and oxygen Parcodex DISS
2320/2330_NIST (alternative to DISS)	Connection gas supply air and oxygen Parcodex NIST
5002	Mounting rail for rolling cart
5001	Rolling cart
MFL16	O_2 cell (unleaded)
FW7555/24	Power supply unit
51091	Flow outlet converter (ID F15mm, OD M22mm)
1244-3DW	Tapered outlet adapter (from 4 to 8 mm tube ID)
11810	Conversion kit for central control/ nurse alarm
SMPV	Push-Bag for manual ventilation

Table 1: Accessories for medinSINDI®

3. Unpacking and Set-Up

3.1. Mounting and Setting Up the Parts

- Remove device and equipment from the packaging

- Attach device to wall/rolling cart rail mounting and secure in place:
- Loosen the knurled head screws of the rail clamps on the back of the device
- Hang device on wall rail or rolling cart rail
- Tighten the knurled head screws.

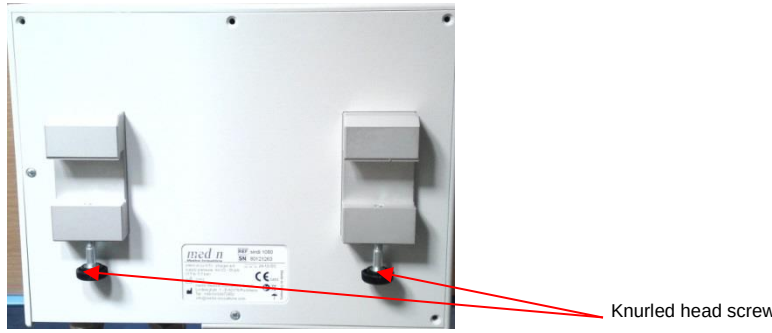


Figure 1: Screws for attachment to the rolling cart rail

The medinSINDI® can be transported when it is not in use; however, when it is in use, it must be securely mounted. However, if the medinSINDI® becomes damaged during this transport or due to rough handling, its function must be checked by a service technician. It is not allowed to be used until then.

3.2. Connection to Gas Supply

medinSINDI® requires clean, oil-free and dry air as well as medical oxygen; both gases need to be at an operating pressure of 3.5 to 6.0 bar respectively.
The central gas supply or gas bottles with a connected pressure-regulating unit can be used as sources of air and oxygen.
Air and oxygen must have the same pressure stage (maximum difference ± 1 bar). medinSINDI® monitors the pressure of both gases to ensure this correct gas mixture.
medinSINDI® requires both gases simultaneously for the connection, otherwise an acoustic alarm will immediately sound. (Loss of gas)

Important Note – Gas Supply

- The oxygen content of the gas mixture can no longer be controlled if the difference in the supply gas pressures is greater than 1 bar. In this case, an internal valve opens and connects the air and oxygen supply channels to compensate for the lower gas supply. As of this point, the mixer loses its function and an acoustic-pneumatic alarm is triggered.
- Connect medinSINDI® properly to the central gas supply or full gas bottles (oxygen and air). This will ensure high gas flows.
- When using gas bottles, set the initial pressure regulator to a pressure between 3.5 and 5.0 bar and check the alarm function.
- Ensure that the pressure reducers of the gas supply tubes – if available (see list of accessories, page 29) – are set to 3.5 bar.
- Supply gases only via the connections provided.

3.3. Gas Supply Connection (see Figure 3)

- Screw air gas supply tube (b/w) onto medinSINDI®
- Screw oxygen gas supply tube (white) onto medinSINDI®
- Attach air gas supply tube (b/w) to central gas supply or full gas cylinder (3.5 – 6 bar)
- Attach oxygen gas supply tube (white) to central gas supply or full gas cylinder (3.5 – 6 bar)

- Disconnect the power supply unit from the mains during thunderstorms or if the device is not used for a longer period of time.

3.4. Power Supply Connection

medinSINDI® is immediately ready for use if the battery is charged. If the battery is depleted, the power supply unit must be connected.

3.4.1. Initial start-up and long-term storage:

For the initial start-up and after a longer period of storage, the external power adapter provided must be connected in order to charge the battery. The charging time is approx. 5 hours. An oxygen and pressure calibration must be performed before the initial start-up (see 4.4.3. Service Menu Page 19).

3.4.2. Connection

Plug external power adapter into the connector provided (see Figure 3)

3.4.3. Operating and Idle Times

- Without external power supply:
  Operation for 5 hours is possible with a fully charged battery for brief operating or transport times.
- With external power supply: Continuous operation possible (ICU)

Important Note – Battery

When the battery is nearly depleted, an alarm sounds once per minute for 1 second.

The charging process is shown on the medinSINDI® monitor when the device is switched off.

Figure 2: Symbol to indicate the charging process

3.4.4. Interruption of the External Power Supply

The power supply can be disconnected or connected during operation without any effect on functionality or loss of data.

3.4.5. Background Illumination Display

- brightly lit when external power supply is used
- dimmed when internal battery is used (energy-saving mode)
- off when battery is nearly depleted

3.4.6. Power supply connection:

To disconnect the medinSINDI® from the mains, the plug of the power supply unit of the medinSINDI® must be pulled out of the electrical outlet. Otherwise the medinSINDI® is still connected to the mains, even when it is turned off.
Therefore, when setting up the medinSINDI®, it should be ensured that the plug of the power supply unit is still accessible even when set up and the medinSINDI® can thus be easily disconnected from the mains.
Disconnect the power supply unit from the mains during thunderstorms or if the device is not used for a longer period of time.

Warning:

The plug of the power supply unit of the medinSINDI® must also always be freely accessible even when set up, in order to allow the medinSINDI® to be quickly disconnected from the mains in the event of a hazardous situation.

Do not insert the power supply plug of the medinSINDI® into ceiling outlets since, due to its weight, it can be pulled out of the outlet in this case.

3.5. Connection to Medijet®

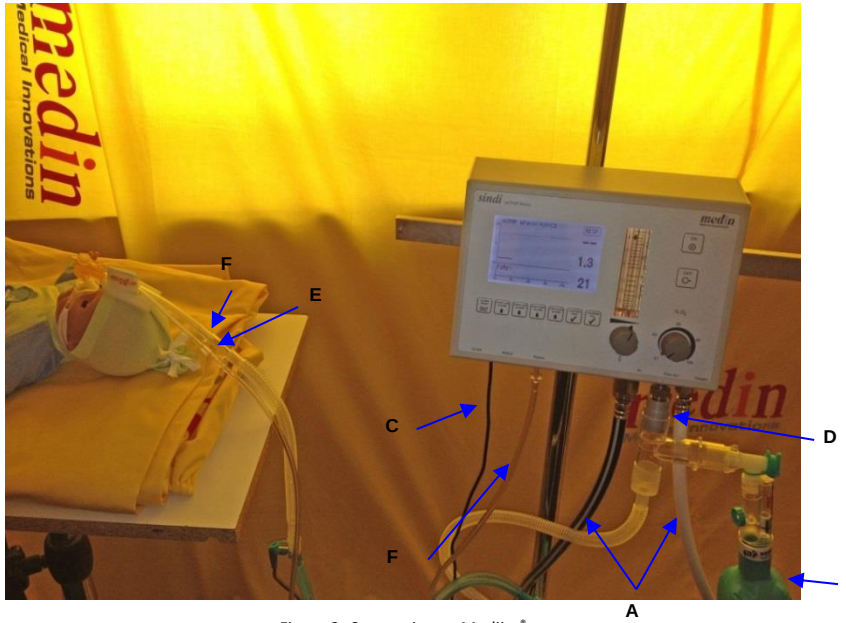


Figure 3: Connection to Medijet®

A. Screw air gas supply tube (b/w) and oxygen gas supply tube (white) onto medinSINDI®.
B. Connect air gas supply tube (b/w) and oxygen gas supply tube (white) to the central gas supply or a full gas cylinder.
C. Insert external power adapter plug into connector provided and screw in place.
D. Connect short tube from the patient tube set on the outlet converter (REF 51091) and connect to humidifier chamber - any type of humidifier chamber is suitable.
E. Using the long tube from the patient tube set, connect the humidifier outlet to the inlet of the Medijet® nCPAP generator. Connect temperature probe and power cable.
F. Connect the nCPAP pressure line on the Medijet® and guide back to the medinSINDI®. It will be connected there at the "PATIENT" connection in order to measure nasal pressure and display on the screen. The nCPAP connection to medinSINDI® is a female Luer-type. The pressure line can be found in each patient tube set.
G. Optimal manual push ventilation (SMPV)

3.6. Connection to nasal cannula

The system is set up as described in chapter 3.5, A to D. The difference is in step E: the nasal cannulas are connected instead of the Medijet®. Steps F and G are omitted.

Important note when using nasal cannula

- During device start-up, nothing should be connected to the medinSINDI®® and also no flow should be emitted.
- After the device start, activate "alarm silent". Then "CPAP alarm off" appears in the upper right-hand part of the display.
- Now the therapy can be started and the flow as well as the concentration can be adjusted accordingly.

Warning

The nasal cannulas to be used may not exceed a stagnation pressure of 80 mbar during use!

4. Operation

The device should not be connected to a patient during set-up and system start. In addition, during set-up, system start and operation, the user should not simultaneously touch the patient and the device. This applies above all to the power supply, the alarm or RS232 Interface and the accessible metal parts of the pneumatic unit (gas connections).
The adapter should not be used if it has visible damage to the housing or cord.

4.1. Operating Controls

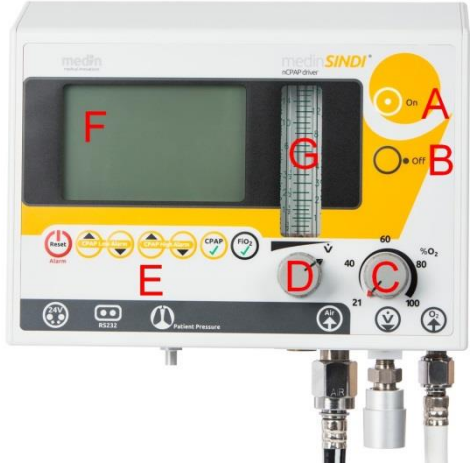


Figure 4: medinSINDI® front

Operating Controls

A. "ON" soft-press button
B. "OFF" soft-press button
C. Adjustment knob for FiO_2
D. Adjustment knob for amount of outgoing flow
E. Soft-press buttons for alarm adjustment (see chapter 4.3.4 and chapter 5)
F. Monitor with integrated 96 x 61 mm LCD display, resolution 240 x 128 dots b/w, including illumination
G. Display for amount of driving flow

4.2. Display Elements

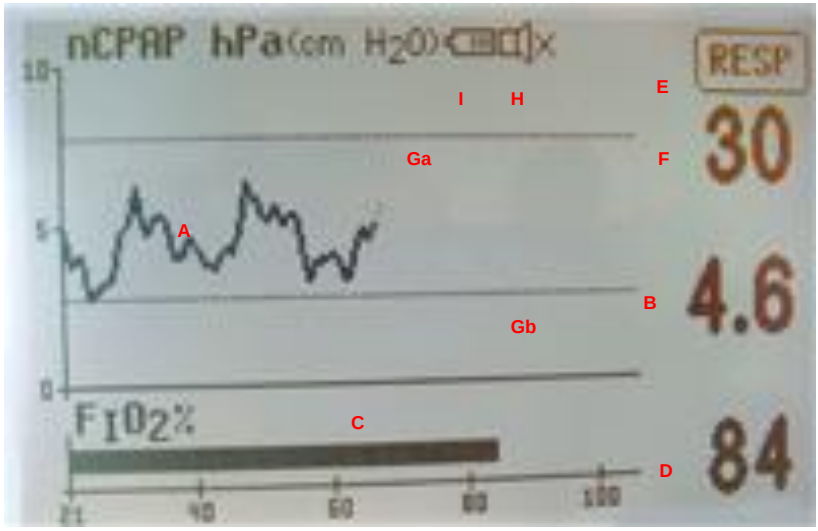


Figure 5: medinSINDI® Monitor

Features of the display:

A. nCPAP pressure display: analogous graph in cmH_2O
B. nCPAP pressure display in cmH_2O (Fair value)
C. Oxygen concentration display: as bar chart
D. Oxygen concentration display in %
E. Triggering of spontaneous respiration: blinking
F. Spontaneous respiratory rate display: Breaths per minute
G. Upper (a) and lower (b) pressure alarm limits
H. Loudspeaker symbol: to indicate alarm mute setting
I. Battery charge monitoring display

Up to software version 1.016 only a pressure of a maximum of 10 cmH_2O can be measured and displayed in pressure curve (A) and at pressure value (B).
Starting with software version 1.017 values up to 10 cmH_2O are displayed in pressure curve (A) and a pressure up to 35 cmH_2O is displayed at pressure value (B).
Starting with software version 1.021 the mute setting must be activated
Starting with software version 1.022 current CPAP low and CPAP high values change in conjunction
Starting with software version 1.023 larger visual alarm displays, automatic trending stop in the event of an alarm
Starting with software version 1.024 Update via RS232 Interface

4.3. Starting Up and Adjusting Settings

Important Note – Start-Up

Training after installation by authorized sales and service partners!

For use by trained professionals only!

After long idle times, oxygen calibration must be performed - see service menu oxygen calibration (page 20).

4.3.1. Starting Up

Turn medinSINDI® on using the "ON" button on the front panel of the device. medinSINDI® starts a SYSTEM CHECK which takes approximately 15 seconds. A bar on the monitor shows the test time.
Starting with software version 1.017 the installed software version is shown in the lower part of the display during the start.
After this procedure is completed, medinSINDI® is ready for use.

4.3.2. Adjusting the Oxygen Concentration

Turn the FiO_2 knob of the mixer to the right or left to adjust the FiO_2 concentration. Adjustment range from 21 to 100% oxygen.
If the control knob of the mixer is turned to the right, the FiO_2 increases.

4.3.3. Adjusting the Driving 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. The value is read at the lower end of the ball.

Important Note – Flow Adjustment

Do not turn the adjustment knob for the amount of outgoing flow forcefully (the needle valve may otherwise become damaged).

4.3.4. Alarms

Important Note – Medijet Connection

If Medijet® is not connected and if no propellant is flowing, the medinSINDI® monitor displays "LOW CPAP" and an acoustic alarm signal is triggered. Press the "RESET" button to turn the alarm off. "CPAP ALARM OFF" is displayed in the upper right-hand part of the monitor.

If no nCPAP pressure is registered in the next 30 seconds, medinSINDI® automatically turns off the blinking alarm symbol "LOW CPAP" in the middle of the monitor.

If medinSINDI® measures an nCPAP pressure greater than 1.5 cmH2O after the pressure line has been attached, medinSINDI® automatically turns on the measurement function of the nCPAP and displays it. The text "CPAP ALARM OFF" is once again dimmed and all alarm systems are active.

medinSINDI® contains an overpressure alarm with fixed settings which is activated in the case of pressures of 10 cmH_2O or higher, and a disconnection alarm in the case of a CPAP pressure of less than 1.5 cmH_2O. Both of these alarms have fixed settings and cannot be changed.
In addition, there is an over- and underpressure alarm which can be adjusted by the user. There is also a built-in mechanical overpressure valve which opens at 80 mbar or higher. These alarm limits (CPAP-LOW ALARM and CPAP-HIGH ALARM) are automatically set after the first time the device is turned on. For this purpose, medinSINDI® measures the nCPAP level and calculates a margin of ± 3 cmH_2O for the alarm limits.

By using the respective arrow buttons (CPAP-LOW/-HIGH ALARM ⬆ and ⬇), the alarms can be manually adjusted to the desired values.

Important Note – CPAP Alarms

Up to software version 1.014 each change in the alarm limits or the nCPAP pressure level must be confirmed by pressing the "CONFIRM CPAP" button. If the change is not confirmed, no acoustic and visual alarm will be triggered.

Starting with software version 1.015 the CPAP alarm limits are automatically activated. The change can be confirmed using the "CONFIRM CPAP" button but this is no longer necessary.

Starting with software version 1.022 the current CPAP low and CPAP high values change in conjunction.

Starting with software version 1.0124 Alarms are prioritized with melody

After setting the desired oxygen concentration with the control knob on the mixer, the alarm can be activated to monitor the concentration by pressing the "CONFIRM FiO_2" button. The alarm sounds in the case of deviations of ± 10%.

Important Note – O2 Alarm

Any change in the alarm limits of the oxygen concentration must be made by pressing the “CONFIRM FiO2" button, otherwise an alarm will be triggered. (± 10% of the concentration)

4.3.5. Spontaneous Respiratory Rate

A sensitive nCPAP pressure measurement is necessary to determine the respiratory rate. The pressure difference must be approx. ± 1 cmH_2O during inhalation and exhalation.
The rate is determined, calculated and displayed in each case for 30-second intervals.
If no spontaneous respiration is detected, 2 lines are seen instead of the spontaneous respiratory rate display.

4.3.6. Oxygen Concentration Adjustment Trend

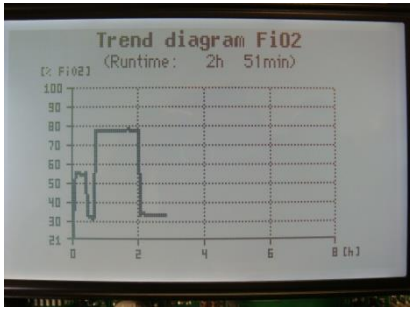


Figure 6: Oxygen concentration trend

Starting with ***software version 1.019***, the adjusted oxygen concentration of the past 8 hours can be displayed. To do this, hold down the "CONFIRM FiO_2" button for 5 seconds. After 20 seconds, medinSINDI® automatically switches back to the regular CPAP monitor. If medinSINDI® is switched off, the saved FiO_2 values are deleted.
Starting with ***software version 1.023,*** trending is automatically discontinued in the event of an alarm.

4.4. Special Functions

Figure 7: Special function buttons

4.4.1. Software Failure

In the event of a software failure, a “soft reset” function is available. Simultaneously press “CONFIRM CPAP” and “CONFIRM FiO2 and the CPU will be reactivated. (Case 1 in Figure 7)

4.4.2. Acoustic Alarm Off

Starting with software version 1.021e, the "Acoustic alarm off" function is deactivated when the medinSINDI® is delivered. If necessary, it can be activated for individual devices in the service menu. (See individual chapter) The function is then operated as described below.
To turn off the "ACOUSTIC ALARM", press “ALARM RESET” (Figure 7 -3) for 5 seconds until you hear three brief beeps. A loudspeaker with a line running through it will then appear on the display.
The acoustic signal is now turned off in the event of an alarm. In the event of an alarm, only a visual signal appears on the monitor and incorrect data are indicated by blinking.
To reactivate the acoustic alarm, the "ALARM RESET" button must be pressed for 5 seconds until a beep can be heard.

Warning – Alarm Silencing

Alarm silencing should not be activated without additional monitoring of vital signs and only by qualified staff!

4.4.3. Service Menu

To open the service menu, medinSINDI® must be switched off.
Up to software version 1.018, the 24V cable must not be connected to medinSINDI®, however it must already be in the electrical outlet. Press the “CPAP-HIGH-ALARM ⬆ ” and “CPAP-HIGH-ALARM ⬇ ” buttons (Figure 7 -2) simultaneously, hold down the buttons and connect the 24V cable to medinSINDI®.
Starting with software version 1.019 the cable can remain on the device. It is sufficient to hold down the “CPAP-HIGH-ALARM ⬆ ” and “CPAP-HIGH-ALARM ⬇ ” (Figure 7 -2) buttons and press the ON button. Both CPAP buttons must be held down for another 3 seconds.

The CPU will then start the “SYSTEM TEST” and open the service menu after this test. The display then appears.

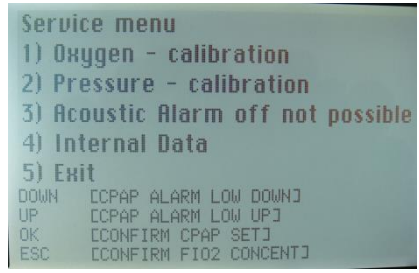


Figure 8: Service Menu

The desired procedure can be set by using the function keys on the keypad. Follow the directions on the display. The display is controlled by the CPU programme.
To exit the service menu, select "Exit" and confirm with the "Confirm CPAP" button

Warning – Service Menu

The service menu may only be opened by technically trained staff who have the necessary knowledge and equipment. If calibrations are performed improperly, medinSINDI® will no longer work correctly and the patient will be at risk.

4.4.3.1. Oxygen Calibration

Connect a calibrated oxygen measuring device to the patient gas outlet.
Open the flow of the medinSINDI® and adjust the FiO_2 knob to 21%. Then check whether the external oxygen measuring device shows 21% ± 3 vol%. If this is not the case, technical services must be called.
Open the flow of the medinSINDI® and adjust the FiO_2 knob to 100%. Then check whether the external oxygen measuring device shows 100% ± 3 vol%. If this is not the case, technical services must be called.
Select the Oxygen – Calibration item and follow the instructions of the CPU.

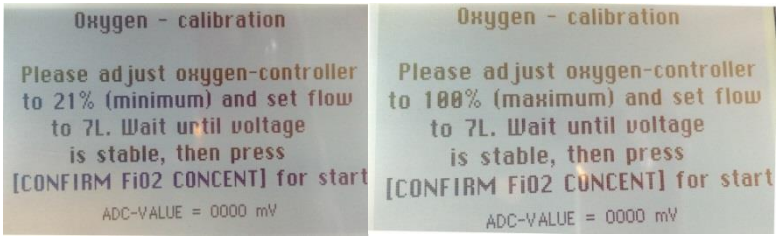


Figure 9: Oxygen calibration

Important Note – Oxygen Calibration

Wait until the ADC VALUE is STABLE! Then confirm.

After the calibration is completed, the service menu reappears.

4.4.3.2. Pressure Calibration

Select the Pressure – calibration item and follow the instructions of the CPU

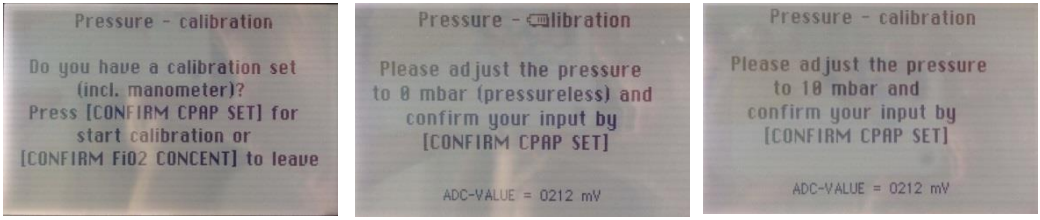


Figure 10: Pressure calibration

In the first calibration step (pressureless), the CPAP pressure connection must remain open.
In the second calibration step, there must be a stable pressure of 10 cmH_2O at the CPAP pressure connection.
This can be achieved using a syringe and must be checked using a manometer connected via a T-piece.

Figure 11: Manometer for pressure calibration

After the calibration is completed, the service menu reappears

Important Note – Pressure Calibration

Use an external precision manometer and connect it in parallel to the medinSINDI® patient pressure connection and generate the 10 cmH2O with an injection syringe.

4.4.3.3. (De-)activation of "Acoustic alarm off" Function

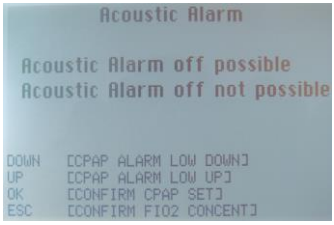


Figure 12: Acoustic Alarm

Starting with software version 1.021e, the "Acoustic alarm off" function is deactivated when the medinSINDI® is delivered. To be able to use it, it must be activated in the particular device.
In order to do this, the service menu must be opened and then the item "Acoustic Alarm off (not) possible" must be selected.

In the next step, the desired setting is selected using the two CPAP low-alarm buttons and confirmed using the Confirm CPAP button.
Meaning of the Setting:
Acoustic Alarm off possible: In this setting, the acoustic alarm can be switched off during normal operation. If the Alarm Reset button is only briefly pressed during normal operation, the acoustic alarm is silenced for 120 seconds and then automatically becomes active again. However, if the Alarm Reset button is held down for 5 seconds, a brief tone is heard and from this point, all alarms are only indicated visually and no longer acoustically. This setting does NOT automatically reset itself; instead it must be reactivated by holding down the Alarm Reset button for 5 seconds.
Acoustic Alarm off not possible: In this setting, the option of deactivating the acoustic alarm for a longer period of time is not available. In normal operation, there is only the option here of silencing acoustic alarms for 120 seconds by holding down the Alarm Reset button. Then the alarms are automatically acoustically reactivated. Holding down the Alarm Reset button for 5 seconds does not have any effect on the device.

4.4.3.4. Internal Data

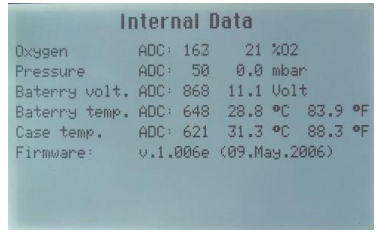


Figure 13: Internal Data

The current software version can be found in this file. This is used to identify the CPU system and the special functions for the measuring transducer and the O_2 cell. The CPU works with "Flash Memory". At the customer's request, medin can update the programme with the most recent software version at any time in the Puchheim plant.
To close this menu, hold down the “Confirm FiO_2” button for more than 2 seconds.

4.4.3.5. Restarting after Calibration

The service menu can be left by selecting the "Exit" item. All calibration data are stored in the internal memory. medinSINDI® now starts automatically or can be started using the "ON" button, at which time the system check is performed.

4.4.4. External Alarm

Starting with software version 1.016 it is possible to combine medinSINDI® with an external alarm feature. For this purpose, the conversion kit for medinSINDI® central control/ nurse alarm (accessory REF 11810) must either be retrofitted or medinSINDI® must be ordered with this modification already included. This external alarm feature allows alarms from medinSINDI® to be indicated via a central ward alarm.

The cable supplied by medin must be used to connect the medinSINDI® to an external alarm system in order to achieve EMC according to DIN EN 60601-1-2:2007 (REF 11810) and the connection must be set up initially by an appropriately trained technician.

Attention

The medinSINDI® may only be connected to an external alarm system using the connection cable provided by the manufacturer (REF 11810), otherwise the functionality and EMC of the device cannot be guaranteed.

Attention

The medinSINDI® data interface must be connected using the cable specified above and a computer system that meets the medically relevant requirements in terms of electrical safety and EMC, otherwise the functionality and EMC of the medinSINDI® cannot be guaranteed.

4.4.5. Illumination of the Flowmeter

For medinSINDI® units built in 2009 or later, the flowmeter display is illuminated, allowing the amount of flow set to also be read in darkened rooms.
For older medinSINDI®s, this illumination can be retrofitted if needed.

5. Alarm

medinSINDI® differentiates between two different alarm centres: the gas mixer and the CPU monitor.

5.1. Gas Mixer

Pneumatic-acoustic alarm: is triggered independently of the electronics if one of the two supply gases is missing (air/O2) or the pressure difference between air and O_2 is greater than 1 bar.

5.2. Monitoring Alarms in the medinSINDI® CPU Monitor:

Fix Levels

- Low CPAP Alarm (CPAP ≤ 1.5 cm/H_2O): Disconnection alarm – check all tube connections.
- High CPAP Alarm (CPAP ≥ 10 cm/H_2O): Overpressure alarm – check flow settings and tubes

Setting Levels

- Low CPAP: Monitoring of the limit values set (up to software version 1.015, activation necessary "CONFIRM CPAP")
- High CPAP: Monitoring of the limit values set (up to software version 1.015, activation necessary "CONFIRM CPAP")

Low or High Oxygen Concentration

Monitoring of the oxygen concentration set. Activation with "CONFIRM FiO2" necessary

Battery
In the event of a shortfall of the minimum charge, there will be a 1-second beep each minute

5.3. Error messages during operation

Alarm Text	Δt	Meaning and reaction of medinSINDI®
CPAP Low	3 sec	Disconnection of pressure line / Flow
	20 sec	leackage at prong / mask / circuit turn up flow
CPAP High	60 msec	flow to high Alarms incorrectly set Patient exhaling heavily against the CPAP pressure
	5 sec	flow to high Alarms incorrectly set Patient exhaling heavily against the CPAP pressure
FiO_2 Low	5 sec	check gas supply Correctly adjust oxygen concentration and confirm with "Confirm FiO_2"!
FiO_2 High	5 sec	check gas supply Correctly adjust oxygen concentration and confirm with "Confirm FiO_2"!
Gas supply Alarm	30 sec Loud acoustic alarm	mechanical, one gas is missing Check gas supply: - Air connected? - Oxygen connected? - Difference between oxygen/air > 1 bar? - Difference between oxygen/air 3.5 – 6 bar? - Pressure setting of pressure reducer (if available) set to 3.5 bar?
"Battery low"		Connect power supply unit to charge battery

Table 2: Errors and causes

Alarm condition:	Measured sound pressure level (dB)	A-weighted background level (dB)
High priority (tall/ flashing)	69	53
Medium priority (small/ flashing)	67	52
Low priority (Tone)	67	52

If the medinSINDI® is restarted, the alarms are reset to these levels. This cannot be changed by the user.

Warning

When setting the alarm thresholds for CPAP pressure high, CPAP pressure low and oxygen concentration, it must be ensured that the alarm thresholds are set so as to be as limited as necessary for the individual patient, since otherwise these alarms are unusable.

5.4. Signals

Font + Tone	Meaning
Tall + high frequency	An alarm with high priority is active – immediate action by the user is necessary.
Small + mean frequency	An alarm with medium or low priority is active – prompt reaction by the user is needed.
only Tone	Flashing battery symbol with continuous tone and one gas is missing

6. Cleaning and Maintenance

6.1. Cleaning

The surface of the device should be disinfected prior to the initial use as well as after each use on a patient. For this purpose, a 70% isopropyl alcohol solution can be used.

Warning – Cleaning

- The device should never be sterilized or immersed in liquid solutions.
- No abrasive materials should be used on the surface.
- Liquids should not get inside the device.

6.2. Exchange of the Internal Batteries

- The internal rechargeable battery must be replaced as required or every three years at the latest. The replacement battery must be a rechargeable battery of the same type (can be ordered from medin, REF 51095).

Warning

The internal battery may only be replaced by the battery types listed above and only by trained, professional service personnel and in accordance with the instructions in the service manual.

After each maintenance or repair of the medinSINDI®, a complete function test must be performed and passed before this medinSINDI® can be used on a patient once again.

6.3. Repairs

Warning

Repairs may only be made to the medinSINDI® by specially trained, professional service personnel in accordance with the instructions and warnings in the service manual. After each maintenance or repair of the medinSINDI®, a complete function test must be performed and passed before this medinSINDI® can be used on a patient once again.

6.4. Device Modifications

Warning

The medinSINDI® may not be modified without permission from the manufacturer and subsequent appropriate examinations and testing to ensure continued safe use.

6.5. Power Supply Unit (Cleaning, Maintenance, Repairs and Modifications)

Cleaning:

Prior to cleaning, the power supply unit of the medinSINDI® must be disconnected from the mains.

Do not clean with chemical cleaning agents.

Maintenance/Repairs/Modifications:

The power supply unit FW7555M/24 of the medinSINDI® is maintenance-free. It should not be opened.

The power supply unit may only be repaired by authorized specialists.

Warning

To avoid an electrical shock, the housing of the power supply unit of the medinSINDI® should not be opened.
Modification of the power supply unit is not permitted. (Termination of the warranty)

6.6. Maintenance

6.6.1. Every 2 months - oxygen calibration:

Before the initial start-up and at least every 2 months, an oxygen calibration must be performed.
In the event of frequent or longer-term operation of medinSINDI®, oxygen calibration must be performed if these criteria are met:
Up to software version 1.019 – if the control knob for setting the oxygen concentration is turned completely to the left (21%) and an oxygen concentration of ≤ 19% is shown on the display.
Starting with software version 1.020 – if the control knob for setting the oxygen concentration is turned completely to the right (100%) and an oxygen concentration of ≤ 98% is shown on the display.

Important Note – Test for Oxygen Calibration

Before each use of medinSINDI® on a new patient, it is recommended that a test be conducted to determine if oxygen calibration must be performed.

Important Note – Test for Oxygen Calibration

Never test while medinSINDI® is connected to a patient, since the oxygen concentration is changed in the driving flow during this time.

6.6.2. Maintenance intervals:

The manufacturer recommends preventive maintenance every 12 months (see maintenance interval sticker on the right-hand side of the device housing). The oxygen cell (REF OOM102) is to be replaced and the electronics are to be calibrated. In the case of the oxygen cell (REF MLF16) is a replacement needed every 3 years. The internal rechargeable battery is to be replaced every 3 years. In case of doubt, please contact the manufacturer or the sales and service partner authorised for your country.

Important Note – Maintenance

- The maintenance of the device may only be performed by trained personnel authorised to perform such maintenance!
- The device must be disconnected from the patient
- Check the mixing accuracy and the overall function of the device
- Check the tube connections and the gas connector prior to each use

Note – Device Passport

For maintenance and after each opening, the device passport must be filled out and a new safety seal must be affixed. (see appendix)

6.7. medinSINDI® - Basic Construction of the Monitor and the Mixer

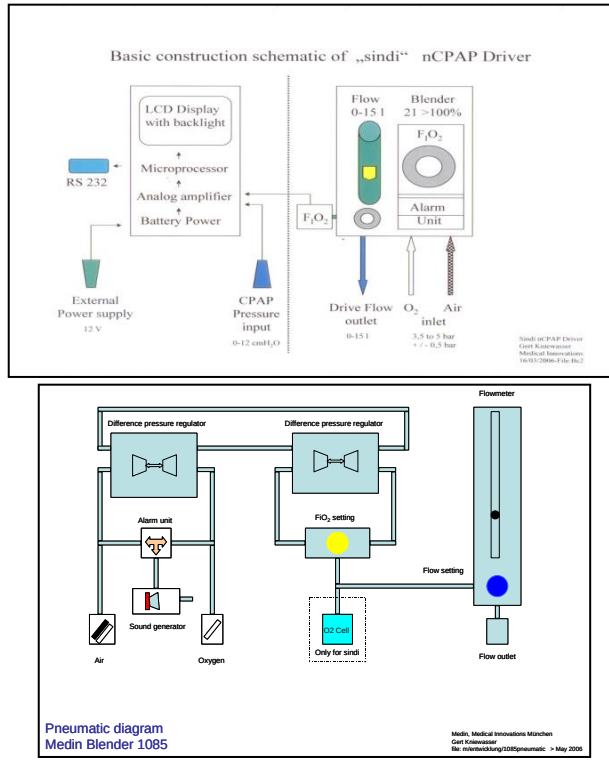


Figure 14: Construction of the monitor and mixer and pneumatic diagram of the mixer

Figure 15: medinSINDI® CPU and open housing with mixer and CPU

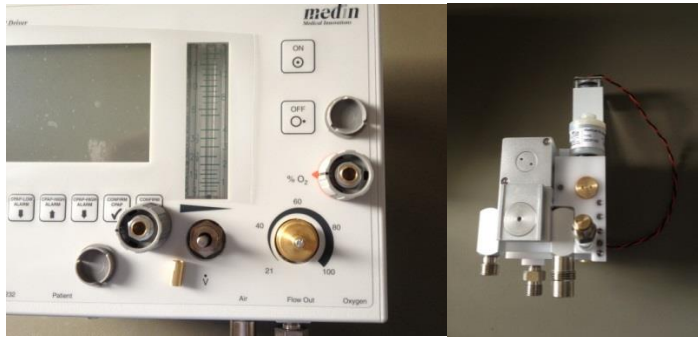


Figure 16: Disassembly of the knobs on the front panel and mixer with oxygen cell

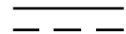
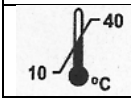
Important Note – Flowmeter

If the flowmeter should have fissures or cracks in the display block, the device should no longer be used, since accurate data cannot be guaranteed. Please contact the manufacturer and/or the sales and service partner authorised for your country

7. Explanation of the Symbols

7.1. Device Symbols

The following symbols are used on medinSINDI® or in the accompanying documentation.

Symbol	Source/ Compliance	Meaning	Symbol	Source/ Compliance	Meaning
	60601-1 ISO 7010-M002	Follow instructions for use		EN 980:2008	Store protected from sunlight
	EN 980:2008	Manufacturer		EN 980:2008 ISO 7000-0626	Store in a dry place
	EN 980:2008	Year of manufacture		EN 60601-1 IEC 60417-5031	Direct current
	Symbol #5032 IEC 60417 Symbol #01-14 IEC 65878	Device is suitable for alternating current.		ISO 7000-2606 EN980:2008	Do not use if packaging is damaged
	MDD Regulation 93/42/EEC	CE Mark		EN 980:2008	Serial number of the device for clear identification
	ISO 15223:2000 (3,11)EN 980_2003 (5.7.3)	Operating temperature range of the device		EN 980:2008	Order number for labelling the product identification

	**2002/96/EG**	**Separate collection of electric and electronic devices**		**Dreko Co.**	**Maintenance interval sticker (testing seal)**
Made in Germany	**upon customer request**	**made in Germany**			

Table 3: Device Symbols

7.2. Symbols Used on Buttons

The following symbols are used to label user input fields within the graphic display:

Symbol	Meaning	Symbol	Meaning
	**Means ON (current supply)**		**Means OFF (current supply)**
	**Reset acoustic alarm**		**Lower CPAP alarm level for minimum CPAP "downwards"**
	**Upper CPAP alarm level for maximum CPAP "upwards"**		**Upper CPAP alarm level for maximum CPAP "downwards"**
	**Lower CPAP alarm level for minimum CPAP "upwards"**		**Confirm nCPAP setting**
	**Confirm FiO_2 settings**		**"Flow"**
			**Inspiratory oxygen concentration**

Table **4**: medinSINDI® Display Symbols

Remaining components of the CPAP system

The medinSINDI® must be used in combination with the CPAP generator Medijet® and the associated accessories of hats, masks, prongs and tubing sets.

Detailed information can be found in the homepage www.medingmbh.com.

8. Glossary

Term	Meaning
Apnoea	Transient inability to breathe (respiratory arrest)
LBR	Low breathing rate
CPAP	Ventilation with continuous positive airway pressure
Generator	Patient connection for supplying CPAP, used with a prong or a mask (active generator Medijet®)
NCPAP	Nasal CPAP
R_{SP}	Spontaneous respiratory rate of the patient (per minute)
S/sec	seconds
PEEP	Positive End-Expiratory Pressure
PIP	Peak Inspiratory Pressure

Table 5: Glossary

9. Electromagnetic compatibility

The information in this section is provided in order to enable the operator of the medinSINDI® to decide whether the medinSINDI® is suitable for its electromagnetic environment.

Attention:

- The medinSINDI® is a medical electrical device. Consequently, in order to guarantee the function of the medinSINDI® precautions with regard to electromagnetic compatibility must be taken and the medinSINDI® must be set up and used in accordance with the conditions set out below.
- Portable or mobile RF communications equipment (e.g. mobile phones) can affect the medinSINDI® and must therefore not be used near the medinSINDI®. The minimum separation distance required must be calculated in accordance with chapter 0 on the basis of the transmission frequency.

9.1 Electromagnetic transmission

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The medinSINDI® is intended for use in the electromagnetic environment specified below. The customer or user of the medinSINDI®, or the organisation responsible, should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions, CISPR11</td><td>Group 1</td><td rowspan="2">The medinSINDI® uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions, CISPR11</td><td>Class B</td><td rowspan="3">The medinSINDI® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions, IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions, IEC 61000-3-3</td><td>Complies</td></tr>
</table>

9.2 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The medinSINDI® is intended for use in the electromagnetic environment specified below. The customer or user of the medinSINDI®, or the organisation responsible, should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV electrostatic discharge ± 8 kV air discharge	± 6 kV electrostatic discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T for 1/2 cycle (> 95% dip) 40% U_T for 5 cycles (60% dip) 70% U_T for 25 cycles (30% dip) < 5% U_T for 5 s (> 95% dip)	< 5% U_T for 1/2 cycle (> 95% dip) 40% U_T for 5 cycles (60% dip) 70% U_T for 25 cycles (30% dip) < 5% U_T for 5 s (> 95% dip)	Mains power quality should be that of a typical commercial or hospital environment. Thanks to its built-in battery, the medinSINDI® continues to operate during power mains interruptions. It therefore does not need to be powered from an uninterruptible power supply or external battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The strength of power-frequency magnetic fields should correspond to that of a typical commercial or hospital environment.
Note:	U_T is the a.c. supply voltage prior to application of the test level		

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the medinSINDI®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is to be recommended. If the measured field strength in the location in which the medinSINDI® is used exceeds the applicable RF compliance level above, the medinSINDI® must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the medinSINDI®.		
b	Over the frequency range 150 kHz - 80 MHz field strengths should be less than 3 V/m.		

Recommended separation distances between portable and mobile communications equipment and the medinSINDI®			
The medinSINDI® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the medinSINDI®, or the organisation responsible, can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the medinSINDI®, as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance acc. to transmission frequency m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at an output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the relevant column, where *P* is the rated maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

10. Appendix – Device Passport

Gerätepass/Device Passport medinSINDI® REF 1080			
SN:			
CPU-Monitor SN:		**Akku-SN:**	
Software Version:		**Oxygen cell SN:**	
Blender SN:		**Gas connection system:**	☐ DISS ☐ NIST
Front panel:	☐ sindi	☐	
Test equipment:	☐ Oxygen measurement (IF) ☐ Oxi Quant MC (Envitec)	☐ Flow analyser PF-302 LOW (IMT) ☐ Flow analyser PF-300 (IMT)	☐ Mass flowmeter Model 4143 (TSI) ☐ Manometer 0-25 cm WS (Suchy)
Test of oxygen calibration:			
21% ±3%	☐ ok / ☐ nok	40% ±3%	☐ ok / ☐ nok
60% ± 3%	☐ ok / ☐ nok	100% ±3%	☐ ok / ☐ nok
Test of pressure calibration:			
0 cmH2O ± 0,5	☐ ok / ☐ nok	10cm H2O ± 0,5	☐ ok / ☐ nok
Overpressure valve:	☐ ok / ☐ nok		
Alarm test:			
Dissconnection alarm (P<1,5cmH20 ~ 5sec)	☐ ok / ☐ nok	High pressure alarm P> 10cmH2O ~5sec	☐ ok / ☐ nok
nCPAP low alarm (P< CPAP low alarm ~ 20sec)	☐ ok / ☐ nok	nCPAP high alarm (P>CPAP high alarm ~5sec)	☐ ok / ☐ nok
Audio alarm (dis)able	☐ ok / ☐ nok	Audio alarm off / on	☐ ok / ☐ nok
Oxygen high low / alarm	☐ ok / ☐ nok		
Gas supply pressure Air/O_2	☐ ok / ☐ nok		

Electric check:

Battery check	☐ ok / ☐ nok	Charge	☐ ok / ☐ nok
Device check without power supply	☐ ok / ☐ nok		
Power supply	☐ ok / ☐ nok / ☐ at customer	LOT No:	SN:

Accessories:

☐ Central alarm ☐ Flowmeter light

☐ Outlet converter 51091 ☐ Power supply holder

Production:

Date	Signature	Name

Final check:

Date	Signature	Name

11. Revision history

- 2005	Initial stages of development for Medijet® driver
- 2005	Development of the compact gas mixer
- 2006	Development of the computer-aided data monitor
- 2006	Integration of the mixer with the CPU
- 2006	First medin medinSINDI® models for testing
- 2006	Laboratory measurements and EMC laboratory testing
- 2007	Start of production
- 2007	Upgrading of the software for better patient monitoring
- 2007	Safeguarding of the outgoing flow in the mixer via the overpressure valve
- 2007	Enhancement of CPAP application by means of manual support SMPV (Synchronized Manual Pressure Ventilation)
- 2008	SW 1.017 + 1.018 + 1.019 + 1.020
- 2009	Ferrite core
- 2010	SW 1.021 + new drill hole POM, a graduated flowmeter
- 2011	SW 1.022 (additional languages: DE, ES, FR)
- 2012	SW 1.023 (larger Alarms)
- 2013	SW 1.024 (Alarm sounds, mean CPAP, Update via RS232 Interface)
- 2013	Update of the device passport and insertion of a new logo
- 2014	new address, new pictures
- 2014	usage of nasal cannula
- 2015	electromagnetic compatibility
- 2016	formatting
2017	new layout, update pneumatic properties