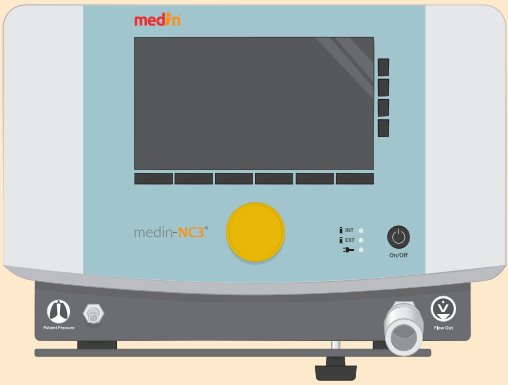

medin-NC3

SW-Version: V1.20/A.14.00/V111

Instructions for use

medin®
A Hamilton Medical Brand

The medin-NC3 contains batteries and electrical components. Consequently it cannot be disposed of in domestic waste but must be collected separately and recycled in accordance with local regulations. (WEEE directive 2012/19/EU)

The user is obligated to report all serious incidents which occur in connection with the product to the manufacturer as well as the competent authority of the member state/country in which the user is located. Serious incidents are defined as malfunctions, breakdowns or changes in the characteristics or the performance or inadequacies in the labeling or instructions for use of a medical device which directly or indirectly lead to, could have led to or could lead to the death or a serious worsening in the state of health of a patient, user, or another person.

CE 0483

CE mark according to the current conformity assessment procedure and declaration of conformity (see website).
Classification (MDR (EU) 2017/745 Annex VIII): IIb

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Made in Germany

IFU_medin-NC3_REV07_EN

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Table of contents

1. Introduction

1.1 About these instructions for use

These instructions for use contain information about starting up, using and maintaining the medin-NC3. They also contain safety information, describe the device's functions and give an overview of the ancillary equipment needed.

Users must be very familiar with the information and warnings given in these instructions for use in order to operate the medin-NC3 safely. Nonetheless, they are no substitute for training.

Keep these instructions for use close to the medin-NC3 and easily accessible.
The current instructions for use are also always available in the download area of our homepage at www.medin-medical.com.

Please contact the dealer or the manufacturer directly if you have any questions or comments about these instructions for use.

1.2 General liability terms

The general terms of trade of medin Medical Innovations GmbH (hereinafter referred to as medin) are binding.

medin accepts no responsibility or liability for the safe use of the medin-NC3 if the device is serviced or repaired by individuals who have not received appropriate specialist training or if an operation that does not comply with correct use is performed. medin also accepts no responsibility or liability for the safe use of the medin-NC3 if the function tests and maintenance that are specified are not carried out. The user is responsible for respecting maintenance and function test intervals. The service life of the device is defined as 8 years.

medin accepts no liability for damage caused by failure to comply with these instructions.

2. Description of the device and conditions for use

2.1 Intended use

The medin-NC3 is used for non-invasive respiratory support and oxygen therapy of newborn infants. The medin-NC3 is used under the supervision of competent personnel trained for this purpose in a clinical environment while monitoring the patient's oxygen saturation.

Indications: Neonatal respiratory insufficiency.

Contraindications: Non-invasive respiratory support is contraindicated if certain clinical situations, anatomic malformations or the degrees of severity of a disease necessitate intubation and mechanical ventilation or make non-invasive treatment impossible.

Benefits: The medin-NC3 improves or maintains the gas exchange in the lungs of the patients.

Intended patient/target group: Neonatal patients.

Intended user: medin-NC3 is intended to be use by trained health care professionals under the direct supervision of a licensed physician.

Intended environment: In a clinical environment while monitoring the patient's oxygen saturation.

2.2 Technical description of function

2.2.1 Functional principles

The medin-NC3 is a CPAP driver that can be used in combination with the Medijet nCPAP generator to administer CPAP therapy. The role of the medin-NC3 in this CPAP system is to provide the necessary, possibly oxygen-enriched flow volume of the gas, which is fed to the nCPAP generator Medijet via the tubes connected to the patient and is converted into CPAP pressure within the generator. In addition, there is the option to connect Nuflow nasal cannulas and perform High Flow therapy.

An internal electronic blender combines the oxygen coming from an external source and ambient air provided by an integrated blower and administers the total volume so that the flow volume of the gas reaching the patient is enriched with oxygen as necessary to any oxygen level between 21% and 100%.

The flow volume of the gas mix can be set by the operator within a range of 0 L/min to 17.5 L/min depending on the mode selected. Depending on the mode selected, the medin-NC3 provides a constant flow volume of the gas which creates a constant CPAP pressure in the CPAP generator Medijet or evaluates the CPAP pressure signal measured in the Medijet in order to react to the patient's respiration. In the event of apnea, the medin-NC3 triggers a higher flow pulse which triggers a pressure impulse in the CPAP generator Medijet with increased CPAP pressure. In High Flow mode, the medin-NC3 provides a constant flow up to a maximum of 8 L/min (following confirmation from the user up to a maximum of 12 L/min).

The monitor which is part of the medin-NC3 displays the parameters selected by the user, the sensors' readings, the length of time that CPAP pressure has been applied by Medijet in the form of a graph, and any alarms. The medin-NC3 can operate for up to four hours without mains power thanks to its rechargeable batteries.

2.2.2 Technical data

Basis of measurement: DIN 1343 at 0°C, 1013.25 mbar and 0% air humidity (0/1013)

Dimensions (L x W x H)	34x25x25cm
Weight	6.25kg
Gas feed system	Computer-controlled electronic gas mixer with integrated oxygen sensor and integrated blower; flow-controlled Basic flow setting range: 0L/min to 15 L/min Basic flow + push: max. 17.5 L/min Accuracy: ± 1 L/min (2 to 10 L/min) ± 2 L/min (10 to 17.5 L/min)
Gas feed	Air: Ambient air, internal blower Oxygen: 300 to 700 kPa (= 3.0 to 7.0 bar)
Gas connection	Connector standard: DISS or NIST (as preferred)
Patient flow outlet	Dimensions M22 (OD) or F15 (ID)
CPAP pressure meter connection	Luer-type – 4.3 mm ID
Power supply	1x internal battery, 1x external battery (optional), 14.4 V DC, run time approx. 2 hours per battery, rechargeable External power supply 100 to 240 V AC / 50 to 60 Hz
Display	7.0“ – color, 800 x 480 pixel
Data	Patient pressure (diagram and measurement) Trend: CPAP, FiO , RR, push frequency, flow, rate, I:E (up to 28 days)
CPAP	Measurement range 0 to 20 mbar (in 0.1 mbar increments) Verification: Redundant measurement by two sensors Accuracy: ± 1.3 mbar

Push (inspiration support)	Setting range Additional flow during the inspiration push with up to 70% of the basic flow: Min: 0 L/min Max: 17.5 L/min (basic flow + push flow) Duration 200 ms to 3 seconds Manual and automatic triggering of pushes Accuracy: Analogous to the accuracy of the basic flow, after the adjustment time has expired
Leak-Assist	Leakage compensation (± 5 L/min to maintain the target pressure) in all CPAP modes (not in High Flow mode)
RR (respiration rate)	Optional display of the measured respiratory rate, no display up to 120 breaths per minute, in CPAP and Apnea CPAP mode
Apnea time	2 to 30 s (in 1 s increments)
$T_{insp.}$	0.2 to 3.0 s (in 0.1 s increments)
Triggering	Pressure trigger, based on the CPAP pressure sensitivity, ±0.2 to ±1.0 mbar (in 0.1 mbar increments)
FiO_2	Oxygen concentration Setting range: 21 to 100% (in 1% increments) Measurement range: 21 to 100% Alarm settings: ± 2-5% difference O_2 flush (level: +5, +10, +15% (vol.) above set target oxygen concentration) for 60 s Accuracy delivered gas mixture: ± 5% (2 to 4 L/min), ± 2% (from 4 L/min) Accuracy measurement: ± 3 % (Vol.) Total system response time < 17s to 90 % of final value

Alarms	Visual (LED & display) and acoustic (adjustable push alarm settings) Alarm countdown
Safety	Mechanical overpressure valve (opening pressure 6 kPa (= 60 mbar))
External data	USB/RS232 port, export of live and trend data
Operating time	The medin-NC3 can be used for continuous, long-term operation up to 4 weeks without a restart in the interim.

2.2.3 Software settings

Languages	EN, DE, FR, IT, NL, ES, EL, CS, PL, NO, DA, SV, RU, LT, ZH, TR, JA, RO, FI
Pressure units	mbar or cmH_2O
Pressure scale	Three settings: 0 to 10, 0 to 15 and 0 to 20 mbar
Respiration rate	Optionally shown on display

2.2.4 Standards and approvals

Meaning	The medin-NC3 is manufactured in accordance with a certified quality assurance system pursuant to EN ISO 13485, EN ISO 9001, Regulation (EU) 2017/745. medin-NC3 meets the general safety and performance requirements of regulation (EU) 2017/745, Annex I.
Classification according to Regulation (EU) 2017/745	Class IIb
IEC certification	60601-1, 60601-1-2, 60601-1-6, 60601-1-8, 62366-1, 62304
Protection class	Class II device
IP protection class	IP20

2.3 Environmental conditions (operation / transport / storage)

The medin-NC3 must not be used in rooms at risk of explosion, near to flammable substances or close to locations exposed to splash water.

Environmental conditions for the medin-NC3 during operation:

Temperature:	15°C to 35°C
Relative air humidity:	Air humidity 5% to 95% (not condensing)
Moisture:	The device is to be kept dry during operation
Ambient pressure:	700 hPa to 1100 hPa
Oxygen environment:	O_2 content < 25%
Altitude:	≤ 3000m above sea level
Cleanliness:	The hygiene regulations valid for the hospital are to be observed. In addition, the medin-NC3 is to be operated under standard hospital ambient conditions

The medin-NC3 has no included barometric pressure compensation. There is no quantitative effect on the gas reading.

Environmental conditions for the power supply unit during operation:

Temperature:

- Between 0°C to 60°C
- Do not use power supply unit in locations exposed to significant temperature fluctuations

Moisture:

- Use only in dry rooms
- Relative air humidity ≤ 90%, not condensing
- Do not use in locations exposed to significant amounts of moisture or condensate formation
- Do not use in locations exposed to significant environmental burdens
- Do not use outdoors

Vibrations:

- Do not use in locations exposed to constant vibration

Environmental conditions for the medin-NC3 during transport/short-term storage:

Temperature:	-20°C to 50°C (longer-term storage only at room temperature)
Relative air humidity:	5% to 95% (not condensing)
Moisture:	During transport and storage, the medin-NC3 must be protected from wet conditions
Cleanliness:	The medin-NC3 must be protected from contamination during transport and storage

Long-term storage of the medin-NC3:

Temperature:	Room temperature (approximately 20°C)
Relative air humidity:	20% to 80% (not condensing)
Moisture:	During storage, the medin-NC3 must be protected from wet conditions
Cleanliness:	The medin-NC3 must be protected from contamination during storage

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

Temperature:

- Do not use in locations exposed to significant temperature fluctuations

Moisture:

- Use only in dry rooms
- Do not use in locations exposed to significant amounts of moisture or condensate formation
- Do not use in locations exposed to significant environmental burdens
- Do not use outdoors

Vibrations:

- Do not use in locations exposed to constant vibration

2.4 Disposal

The medin-NC3 contains batteries and electrical components. Consequently it cannot be disposed of in domestic waste but must be collected separately and recycled in

accordance with local regulations. (WEEE directive 2012/19/EU)

According to directive 2012/19/EU (WEEE – Waste of Electrical and Electronic Equipment) Appendix III, the device falls in category 5 (Small Devices) and accordingly, based on its type, it is not a household appliance.

The main components of the device consist of or contain the following materials, among others:

Component	Materials
Metal tub	Aluminium
Plastic cover	ABS
Plastic assembly parts	PC/ABS
Pneumatic unit	Aluminum body & various assemblies
Blower	Various
Circuit boards	Various
Display	Various
Power supply unit	Various
Touch panel	Glass
Pneumatic lines	Silicone & PA
Batteries	Lithium batteries

For the packaging of the device follow all local, state, and federal regulations with respect to waste management and environmental protection.

2.5 Warnings and notes

The instructions and warnings are categorized as follows:

Warning: Warnings must be followed in order to prevent possible serious consequences for the patient or the operator.

Attention: This indicates hazards that could damage the device or impair its functionality.

Please note: This indicates how the medin-NC3 can be used more efficiently.

The following table provides an overview about warnings and notes that have to be considered:

Warning: An alternative CPAP system or respiration system (e.g. bag valve unit) must always be available while the medin-NC3 is in use.
Warning: The medin-NC3 may not be modified without permission from the manufacturer and subsequent appropriate examinations and testing to ensure continued safe use.
Warning: The device may only be used in a securely mounted, upright position.
Warning: The medin-NC3 may only be used with the accessories specified in chapter 7.1 – Accessories.
Warning: The medin-NC3 may only be used in combination with the products tested for combinability specified in chapter 7.2 – Combinable products.
Warning: The medin-NC3 may not come in contact with flammable anesthesia gases or other flammable materials while in use.
Warning: The medin-NC3 may not be operated in an oxygen-enriched environment
Warning: The medin-NC3 must not be covered while in use, and none of the openings or ventilation slits may be blocked.
Warning: The overpressure valve must be kept clear whenever the device is in use, and it must always hang free in the air.

Warning:
A damaged medin-NC3 may not be used.

Warning:
The medin-NC3 may only be run on the local mains grid using the power supply unit provided by the manufacturer and suitable power lines, otherwise the function and EMC of the device cannot be guaranteed.

Attention:
When the medin-NC3 is running on battery power, an alarm is sounded when the internal battery is low. It must then be immediately connected to an external power source, as otherwise the medin-NC3 will stop working.

Note:
Since the battery of the medin-NC3 also discharges while switched off, it is recommended that the device is charged during longer periods of storage. Otherwise the battery becomes deeply discharged.

Attention:
The medicinal oxygen supplied to the medin-NC3 must meet the quality requirements laid down in chapter 3.3 – Gas feed, as otherwise the device could be damaged.

Attention:
In order to avoid fires, oxygen must not come into contact with oil or grease. It is therefore essential to ensure that all parts of the device and the CPAP system which come into contact with oxygen remain free from oil and grease.

Warning:
During transport, storage and operation, the environmental conditions specified in chapter 2.3 – Environmental conditions (operation /transport /storage) must be observed.

Attention:
If the medin-NC3 is exposed to temperatures of ≤15°C during transport, it must be acclimatized at room temperature for at least 24 hours at the location where it is to be used before being switched on and used for the first time. If this is not done, the condensate which has formed could damage the device.

Warning:
If errors are detected on the medin-NC3 before first use on a patient, or the device is found to be damaged or does not behave as expected, it must not be connected to a patient under any circumstances.

Warning:
Patients may only be connected to the device after the system start-up test has been successfully completed.

Warning:
The power supply unit should not be used if it has visible damage to the housing or cord.

Warning:
To avoid an electrical shock, the housing of the power supply unit of the medin-NC3 should not be opened. Modification of the power supply unit is not permitted.

Warning:
The power supply unit should not be used in the direct vicinity of the patient since there may be temperatures of >71°C.

Warning:
When starting in High Flow and switching to CPAP therapy, please restart the device to ensure the Medijet functions properly.

Warning:
If the Leak-Assist function is activated in CPAP mode, it is automatically deactivated by adjusting the flow. If it is once again desired, it has to be restarted manually.

Warning:
Use of the Leak-Assist does not replace regular monitoring of the patient interface.

Note:
It should be noted that any change becomes immediately active for the next push, even without pressing the dial. The setting F_{max} may only be changed in small increments.

Warning:
Significant amounts of condensate formation in the tube system must be avoided since, as a result, the respiratory signal in the CPAP pressure curve will be covered up, detection of apnea phases can be prevented, and the triggering of pushes can be influenced.

Warning:
The deivce alarms may only be switched off while the patient is under the clinical supervision of the user.

Warning:
If the user alters the brightness or sound settings, he/she must take account of the specific surroundings and may only change the settings to such an extent that the screen content remains visible and the alarm sounds can still be heard.

Warning:
Standby mode may only be used when no patient is connected to the medin-NC3.

Note:
When the device is connected to a humidifier during standby, please consider that the humidifier will continue to operate. This may lead to excessive heating of the gas flow, and when subsquently switching the device back on, to „hot-shots“ which may cause patient harm. Therefore, please switch off the humidifier during longer periods of standby mode to prevent „hot-shots“.

Attention:
Please select alarm thresholds that are appropriate for the patient.

Warning:
While the device is in operation on the patient, the medin-NC3 must not be subjected to any cleaning, maintenance or repairs.

Warning:
The medin-NC3 may only be cleaned according to the procedure specified by the manufacturer and the cleaning agents that are defined in chapter 9.2 - cleaning.

Warning:
The batteries may only be replaced by the battery types listed in chapter 9.3 – Preventive maintenance and only by trained, professional service personnel and in accordance with the instructions in the service manual.

Warning:
Repairs may only be made to the medin-NC3 by specially trained, professional service personnel in accordance with the instructions and warnings in the service manual. After each maintenance or repair of the medin-NC3, a complete function test must be performed and passed before the device can be used on a patient once again.

Note:
For the maintenance activities described in chapter 9.3 – Preventive maintenance, only the spare parts specified by the manufacturer may be used.

Attention:
The medin-NC3 is a medical electrical device. In order to guarantee the functionality of the medin-NC3 the conditions regarding electromagnetic transmission and electromagnetic immunity must be taken into account when operating the device in an electromagnetic environment.

Warning:
The medin-NC3 is not suitable for use near magnetic resonance imaging equipment (MR-unsafe) or electrosurgical equipment.

Warning:
The product may be disposed of in accordance with the manufacturer’s instructions, see chapter 2.4 - Disposal.

Warning:
The maintenance and service intervals for the specified components listed in chapter 9.3 must be observed.

Warning:
The device must be operated in combination with a respiratory gas humidifier.

Attention:
The respiratory air humidifier should be placed lower than the patient and lower than the medin-NC3.

Attention:
The external battery may not be replaced during operation of the medin-NC3.

Attention:
Only devices and systems which are approved for medical use and which meet the relevant electrical safety and EMC standards may be connected to the medin-NC3 data interfaces. Integration into such systems can lead to risks for patients, operators or third parties which were not previously known. The person in charge of the integration must determine, analyze, evaluate and manage these risks.

Changes to the system can lead to new risks. Such changes include, for example:

- Changes to the configuration
- Connection of additional elements
- Removal of elements
- Update of connected devices
- Upgrade of connected devices

Attention:
The data interfaces of the medin-NC3 may be used only with the cables specified in chapter 3.4.3 – cable. The connected computer system must meet the medically relevant requirements with regard to electrical safety and EMC, otherwise the functionality and EMC of the medin-NC3 cannot be guaranteed.

Note:
When reading the trend data, there may be time delays upon receipt at the computer or data system. For this reason, when reading the data, wait until the last line (***;2016-0407;14:22:51;medin-nc3 1004;record complete;) has been issued. Only then has the trend data been received in full.

Warning:
Do not load the trolley with more than the permissible weight. The maximum permissible weight (safe working load) is 40 kg (88 lb).

Attention:
Lock the wheel brakes of the trolley before you begin the installation.

Attention:
Release the brakes before you move the trolley in order to avoid tipping.

Attention:
Do not lean against the trolley.

Attention:
Ensure that all accessories are correctly assembled on the trolley.

Attention:
The trolley may tip if the floor has an incline of more than 5°.

Warning:
The device must not be operated with an oxygen concentrator.

Warning:
Reuse of single-use accessories (see chapter 7.1) may lead to hazardous situations, e.g. contamination, leakage. The instructions for use of these products must also be considered.

Warning:
Preventive maintenance must be carried out according to the requirements in chapter 9.3.

3. Installation of the medin-NC3 – Conditions

Before putting the medin-NC3 into service, the following must be considered:

3.1 Assembly

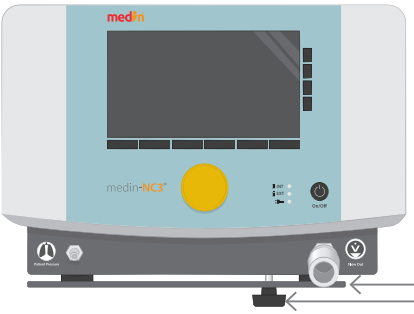


Figure 3-1

a) Trolley plate
b) Knurled screw

The medin-NC3 must always be securely assembled before the device is started up. To do this, it is placed on the baseplate of the trolley such that the feet lie in the intended grooves and then it is fixed in place manually using the knurled screw (Figure 3-1– b).

The medin-NC3 can now be transported on this trolley provided that the oxygen supply is also attached to the trolley. However, if the medin-NC3 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 Power supply

3.2.1 Mains operation

The power supply unit (REF 30-113) of the medin-NC3 may only be connected to a power supply with the following properties:

- Voltage: 100 – 240 V~ (alternating current)
- Frequency: 50 – 60 Hz
- Strength of current: at least 1.1 A

The power supply unit of the medin-NC3 has a C7 appliance inlet for connection to the mains grid. The power line between the power supply unit of the medin-NC3 and the mains grid must therefore meet the following conditions:

- Power supply side: plug appropriate for the country
- Device side: C8 plug in accordance with EN 60320
- Minimum rated voltage: the minimum rated voltage of the power line must be at least as high as the voltage of the local mains supply (recommended: 240 V)
- Minimum rated current: 1.1 A
- Maximum length 2 meters (in order to achieve EMC in accordance with DIN EN 60601-1-2)

Spare power lines with EU plugs can be ordered under REF 39-115 (supplied as standard as part of the power supply unit). Alternative power lines for other countries are available under these numbers:

- with UK plug REF 39-116
- with plug for USA/Japan REF 39-117
- with Australian plug REF 39-118
- with Chinese plug REF 39-127

3.2.2 Battery operation

The medin-NC3 contains an internal as well as an external battery and can work on a fully charged battery for up to four hours.

Figure 3-2:
Battery charge status display

The charge status of the internal and external battery is displayed in the top left-hand area of the medin-NC3 screen (Figure 3-2).

A full battery is shown with a symbol with five bars. As soon as only two bars remain, the battery symbol is shown in red and the medin-NC3 should be connected to the mains soon. As soon as there is only one bar left, the battery alarm is triggered.

3.2.3 Power supply unit

The power supply unit of the medin-NC3 may only be used according to its imprinted input and output power.

Input power: 100 to 240 V AC / 50 to 60 Hz / 1.5 A
Output power: 24 V DC / 3.75 A (SELV - Safety Extra Low Voltage), limited power source Disconnect the power supply unit from the mains during thunderstorms.

3.3 Gas feed

In order to operate the medin-NC3, it must be supplied with oxygen from an external source that meets the following conditions:

Medicinal oxygen

- 300 to 700 kPa (=3.0 to 7.0 bar)
- Oxygen content: ≥ 99.5%
- H_2O ≤ 67 ppm (V/V) (free from condensate)

Ambient air:

- Provided by an integrated blower

Gas feed connections:
The medin-NC3 can be fitted as standard with NIST or DISS gas feed connections as the customer prefers. The tube kits to connect the device to the external gas source must also meet the selected standard.

3.4 External data interfaces

The medin-NC3 can be connected to a system for archiving and processing patient data.

3.4.1 RS232 data interface

The RS232 data interface of the medin-NC3 can be used to retrieve internal device data. In addition, there is the option to prompt an export of the trend data in the trend by pressing the corresponding buttons. The interface delivers live data during normal operation or trend data during export which must be received and saved by a computer or data management system. Serial data with the following settings are issued:

- Data type: serial
- Baud rate: 115200
- Data bits: 8
- Parity: none
- Stop bits: 1
- Handshaking: none

To connect the medin-NC3 to a system for archiving and processing patient data, a crossover RS232 cable („null modem cable“) can be used (see Figure 3-3: RS232 and USB cable with ferrite). Nonetheless, the function of the medin-NC3 must be observed to avoid disruptions by the entire system with regard to electromagnetic influences.

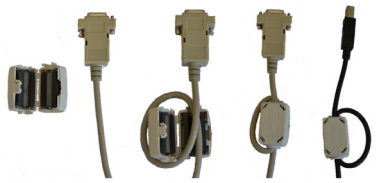
The protocol specification for integration into a system for archiving and processing patient data can be found in section 3.4.4.

3.4.2 USB interface

The USB interface is purely a service interface, for example, to install software updates. Its cover should be opened only by trained personnel.

3.4.3 Cable

The cables to be used (RS232 / USB) must contain a ferrite (REF 39-125; Würth Elektronik – type: 742-711 32, gray or black) with a double wound cable in accordance with Figure 3-3.



a) b) c) d)

Figure 3-3: RS232 and USB cable with ferrite
a) RS232 cable without ferrite
b) RS232 cable with a ferrite that is still open whereby the cable must be carried through the core twice, that is, wrap the ferrite core once.
c) RS232 cable with ferrite
d) USB cable with ferrite (the cable must also be carried through the ferrite core twice as in the case of RS232 cable)

3.4.4 Output data (live and trend data)

- Live data

The live data of the medin-NC3 contain the patient pressure, the set flow, the measured oxygen concentration, information whether a push is currently being emitted, all alarms, the set additional push flow and the current mode. In addition, date, time, device name and software version are regularly indicated. The live data are automatically and constantly indicated in normal operation. However, they are not saved in the medin-NC3. If the live data are of interest, they must be recorded and saved by a computer or data system, otherwise the data will be lost. The exact structure of the live data is described below:

Every 10 min., a line with these data is indicated

- ***;
- Date;

- Time;
- Device name (can be set in the service menu);
- VXXXX (CPU software version)

In the interim, the following data are provided every 0.1 second (separated by ";") via the USB interface:

- The currently measured CPAP pressure (in CPAP and Apnea CPAP mode) in XX.X mbar
- Set target flow in XX.X L/min for the basic CPAP level; in the case of additional activation of the Leak-Assist, the target flow + correction flow is emitted.
- Measured oxygen concentration FiO_2 XXX%;
- Current push activity X: 2 = Backup actively running (independent of whether there is currently a push or not), 1 = push active (without backup), 0 = no push active;

- High-priority alarms (active alarms are indicated by a bit set at the corresponding site). The sum of all active alarms XXXX is given:
  - 0x0001: Disconnection
  - 0x0002: CPAP pressure high (fixed)
  - 0x0004: Feed pressure high
  - 0x0008: Gas feed oxygen
  - 0x0010: Gas feed air
  - 0x0020: Device error – patient pressure measurement
  - 0x0040: Flow stopped, reactivation via alarm reset
  - 0x0100: Device error – restart necessary

- Medium-priority alarms XXXX:
  - 0x0001: Battery almost empty – Connect power supply unit
  - 0x0002: CPAP pressure high (adjustable)
  - 0x0004: CPAP pressure low (adjustable)
  - 0x0008: Oxygen concentration high
  - 0x0010: Oxygen concentration low
  - 0x0020: Internal temperature too high

- Low-priority alarms XXXX:
  - 0x0001: Fan blocked
  - 0x0004: Leak-Assist
  - 0x0008: Power supply unit disconnected
  - 0x0010: External battery low
  - 0x0020: External battery temperature

- Additional flow set during the push XX.X L/min
  - Mode X:
  - C = CPAP
  - A = Apnea CPAP
  - N = NIPPV
  - H = High Flow

Example of live data:

;2016-04-04;14:09:11;medin-nc3 1004;V1.00;
07.0;08.7;021;0;0000;0000;0000;03.8;C
07.9;08.7;021;0;0000;0000;0000;03.8;C
07.9;08.7;021;0;0000;0000;0000;03.8;C
07.7;08.7;021;0;0000;0000;0000;03.8;C
07.5;08.7;021;0;0000;0000;0000;03.8;C
06.7;08.7;021;0;0000;0000;0000;03.8;C

- Trend data

The trend data are divided into two parts: The first part contains logfiles of saved alarms and device starts. This recording contains the data of the last device uses and will continue to be saved even if the medin-NC3 is switched off. The second part of the trend data is deleted each time the medin-NC3 is switched off. It saves the data since the last device start, however for a maximum of 28 days. It contains the CPAP pressure, the set flow, the measured oxygen concentration, the set additional push flow, the mode, respiratory rate, information whether the backup was active, the push rate R_{insp}, the minimum and maximum possible push rate, the maximum pressure during the pushes, the set inspiration time and the set apnea time.

The structure of the trend data is shown below as an example:

###;2016-04-07;14:20:14;medin-nC3 1004;V1.00;alarm record;### start;2015-04-04;10:59; alarm;04;11:07;0000;0008;0000;for 14:48 alarm;04;1:50 PM;0000;0004;0000;for 12:30 AM
alarm;04;2:14 PM;0002;0002;0000;for 12:36 AM
###;2016-04-07;14:20:15;medin-nc3 1004;V1.00;trend record;###
CPAP; flow;FiO2;Finsp;Mode; RR;BU;Rinsp;Pinsp;Tinsp;Tapn; 05.6; 07.0; 021; 00.0; C;018; ; ; ; ; ;

05.6; 07.0; 021; 00.0; C;018; ; ; ; ; ;
05.5; 07.0; 024; 01.0; A;024; -; 000; ; 0.3;10.0;
05.9; 07.5; 024; 01.0; A;018; -; 000; ; 0.3;10.0;
02.5; 06.0; 026; 02.5; N; ; ; ; ; ; ;
04.1; 06.0; 036; 03.7; N; ; ; ; ; ; ;
***;2016-04-07;14:20:51;medin-cnt1004;record complete;###

Start of alarm recording:

- ###;
- Date: YYYY-MM-DD; (current date, set in the service menu)
- Time: HH:MM:SS; (current time, set in the service menu; switching to local time or daylight savings time (summer time) must be performed manually)
- Device name: medin-NC3 ZZZZ (can be set in the service menu)
- SW version: VXXXX (installed main software version)
- Alarm record; ###

Start and alarm recording:

- For each device start, date and time are saved as such:
  start; YYYY-MM-DD;HH:MM;
- For each new alarm, day, time, all active alarms of high, medium and low priority and the duration (min:sec) of the alarms are saved:
  alarm; DD; HH:MM;HHHH;MMMM;LLLL;for MM:SS

The alarm coding takes place analogously to the coding in the live data (for detailed information, see chapter 3.4.4.1). The date is only shown as a day. The month can be determined using the last prior start entry. The alarm duration is indicated in minutes and seconds from the start of the alarm until its end.

Recording the set and measured values:

The trend data contain all values saved in the trend and additional values since the last time the device was switched on. Every 20 seconds, a line is saved. If a value is not available in the current mode, it is replaced with blank spaces.

The structure is as follows:

- Average value of the CPAP pressure in XX.X mbar

- Set flow in XX.X L/min + if applicable, correction flow with activated Leak-Assist
- Measured FiO_2 in XXX%
- Additional set push flow in XX.X L/min
- Current mode: C = CPAP, A = Apnea CPAP, N = NIPPV, H = High Flow, - = Standby
- Measured respiration rate in XXX / min
- Status of backup (B = actively running; -= currently not actively running or generally off)
- Push frequency R_{insp} in XXX / min
- Maximum CPAP value during the push in XX.X mbar
- Set push length T_{insp} in X.X sec
- Set apnea time in XX.X sec

When reading the trend data, there may be time delays upon receipt at the computer or data system. For this reason, when reading the data, wait until the last line (***;2016-0407;14:22:51;medin-nc3 1004;record complete;) has been issued. Only then has the trend data been received in full.

4. First Use

The CPAP system must be established and the device checked before starting any CPAP therapy using the medin-NC3. This check starts automatically whenever the device is started up.

The device should not be connected to a patient during set-up and system start. Moreover, 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 RS232 or USB interface and the accessible metal parts of the pneumatic unit (gas connections, overpressure valve and mounting screws).

4.1 CPAP system components

A CPAP system based on a medin-NC3 comprises the following components:

- CPAP driver: the medin-NC3
- Medijet nCPAP generator together with a suitable prong or mask
- An active respiratory gas humidifier to humidify the respiratory gas
- A patient tube circuit set that fits the patient gas outlet, CPAP pressure meter inlet of the medin- NC3, the Medijet and the respiratory gas humidifier selected
- A bonnet of the correct size
- A system for monitoring the patient's oxygen saturation and checking the efficacy of CPAP therapy (this is an essential condition for the use of the medin-NC3)

4.2 Connecting the medin-NC3 and setting up the CPAP system

Connecting the supply gas:

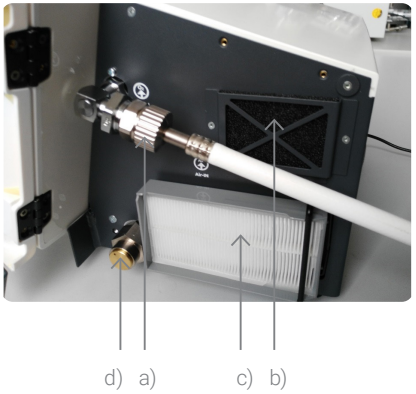


Figure 4-1: Connections of the medin-NC3:
a) Gas supply oxygen
b) Fan intake
c) Air inlet filter
d) Overpressure valve

Before switching on the medin-NC3, its oxygen inlet "O_2-In" (see Figure 4-1 a)) must be connected to an external oxygen supply using a gas supply tube. The oxygen must comply with the quality requirements described in chapter 3.3.

Power supply connection:

The power connection of the medin-NC3 "Power" (Figure 4-2-c) must be connected to the mains by means of the power supply unit for the device. Users are recommended to keep the medin-NC3 connected to the mains at all times while it is in use. The internal and external rechargeable battery in the medin-NC3 allows the device to keep working in the event of a brief interruption in mains power supply. The medin-NC3 can run on a fully loaded battery for up to approximately four hours.

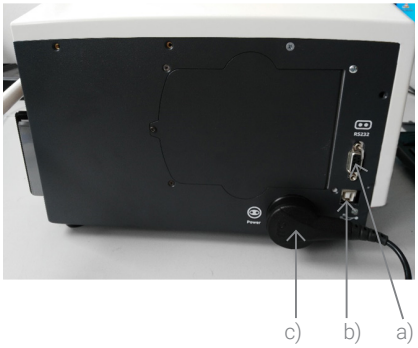


Figure 4-2: Rear connections:
a) RS232 interface
b) USB interface
c) Power supply (power supply unit)

The charge status of the batteries is displayed on the upper left of the screen of the medin-NC3 as well as on LEDs on the front.

Figure 4-3: Battery charge status displayed in the top left-hand area of the screen

To disconnect the medin-NC3 from the mains, the plug of the power supply unit of the medin-NC3 must be pulled out of the electrical outlet. Otherwise the medin-NC3 is still connected to the mains, even when it is turned off.

Consequently, when setting up the medin-NC3, it should be ensured that the plug of the power supply unit is still accessible even when set up and the medin-NC3 can therefore be easily disconnected from the mains.

Disconnect the power supply unit from the mains during thunderstorms.

Connecting the patient tube circuit set:

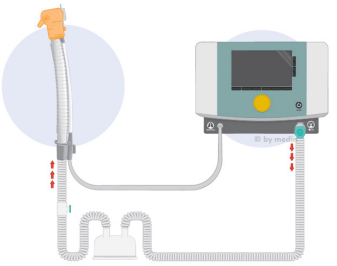


Figure 4-4: Structure of a CPAP system based on the medin-NC3

The patient tube circuit set is used to connect the patient to the medin-NC3. This involves inserting the humidifier chamber into the respiratory gas humidifier and then connecting it to the "Flow out" (Figure 4-4-right) patient gas outlet via the shorter tube. The longer tube connects the humidifier chamber to the Medijet. The humidifier temperature probes and heating cable adapters must be inserted into this tube if required. The thin pressure meter tube connects the pressure meter connection of the Medijet to the CPAP pressure meter inlet “Patient Pressure“ (Figure 4-4-left) of the medin-NC3.

Connecting the patient tube circuit set – High Flow:

When High Flow mode is used, a suitable Nuflow nasal cannula must be connected instead of a Medijet, following mode selection. The system set-up is shown in Figure 4-5.

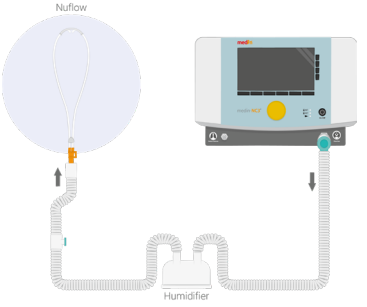


Figure 4-5: Set-up of a medin-NC3 system with Nuflow nasal cannula

4.3 Starting up the system

The medin-NC3 is started and its system test is automatically triggered by pressing the "On/Off" button (Figure 5-1 – g). This test examines the functions of the medin-NC3, checks the oxygen calibration and determines the properties of the tube system to which it is connected.

Make sure that no patient is connected to the medin-NC3 throughout the entire duration of the system test, and press "Ok" to confirm this.

If an error is detected during the system test, this is indicated by an error message. See chapter 8.1 for the meaning of the individual error messages.

The function of the mechanical overpressure valve must also be checked during the system test. This is done by briefly blocking the patient gas outlet (Figure 4-4-right) and observing whether the overpressure valve (see Figure 4-1 d)) opens and closes during this time.

In order to determine the characteristic course of the flow CPAP pressure of the patient tube system used and to check the CPAP pressure sensors, the entire tube system and the Medijet must now be connected to the medin-NC3 and the Medijet prong adapter must be closed. Once this has been done, the process of measuring the tube system can be started by pressing the "OK" button.

If oxygen calibration is necessary, this is carried out automatically.

If the system test is completed without errors, the medin-NC3 starts up in CPAP mode and can be used on the patient.

5. Operation

The medin-NC3 can be used to administer pure CPAP therapy, push-supported CPAP therapy or High Flow therapy. All versions are based on pure CPAP therapy and the pushes are added if required. For this purpose, the medin-NC3 offers three CPAP modes and one High Flow mode:

- CPAP: Pure CPAP mode in which a constant CPAP pressure in the Medijet is generated by a constant flow. This mode operates without automatic pushes. However, operators can trigger manual pushes if necessary.
  In addition, the Leak-Assist can additionally be switched on (see chapter 5.6).
- Apnea CPAP: In this mode, the basic CPAP mode described under CPAP is combined with apnea monitoring. The medin-NC3 assesses the CPAP pressure signal and recognizes from this information whether or not respiratory activity is taking place. If no respiratory activity can be detected for a length of time that can be set, the medin-NC3 automatically triggers a push to stimulate the patient. In addition, the backup function can be used (see chapter 5.9) and the Leak-Assist can be switched on for this purpose (see chapter 5.6).
- NIPPV: In contrast to CPAP mode, ventilation is provided here on two different flow and pressure levels. The intensity of the second level as well as the changeover frequency and the time spent at the higher level can be adjusted by the user.
  In addition, the Leak-Assist can additionally be switched on (see chapter 5.6).
- High Flow (nHFT / HHHFNC): The High Flow mode offers a constant flow up to a maximum of 12 L/min. High Flow mode, the user can only set a flow up to a maximum of 8 L/min, for safety reasons. If he/she wishes to utilize the entire range up to 12 L/min, this must be done deliberately by selecting the flow button, pressing it once again and holding it down and thus setting the flow greater than 8 L/min.

The fifth mode, Standby, can be used for the time between preparation of the medin-NC3 and its actual use as well as for pauses in the CPAP therapy for a patient.

Some operating steps and settings are common to all medin-NC3 modes and are transferred when switching from one mode to another, but some settings are specific to particular modes.

5.1 Operator console

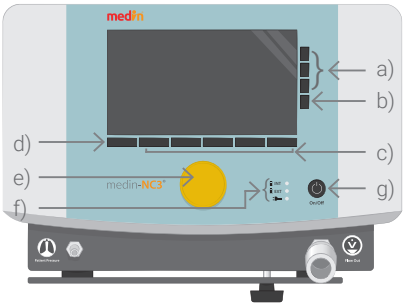


Figure 5-1: Operating unit of the medin-NC3:
a) Buttons for setting the basic CPAP parameters
b) Trigger button for manual pushes
c) Buttons for mode-specific and other settings
d) Alarm button
e) Dial to change and confirm settings
f) Battery and power supply unit LEDs
g) ON/OFF

The medin-NC3 is operated by means of several buttons and a dial. The usual procedure is to press a button to select the parameter indicated next to that button on the display, then use the dial to select the required value. This is confirmed by pressing the dial.

The various buttons are divided into several groups:

- **Basic CPAP settings:** (Figure 5-1–a) to select and adjust the two basic CPAP parameters of oxygen concentration (FiO_2 and Flow). In addition, to set the additional flow for pushes (F_{insp}) and to trigger an O_2 flush.
- **Push button (PUSH):** (Figure 5-1–b) to trigger a push manually and immediately
- **Other settings:** (Figure 5-1–c) to select and alter mode-specific and other settings
- **Alarm:** (Figure 5-1–d) to confirm alarms and control alarm statuses. Pressing this button results in an active alarm being transferred to "Confirmed" status; the associated alarm sound is muted for 120 seconds and then reactivated. By pressing the button again, the alarm sound can be switched to become audible again before the 120 seconds are up. However, if a new alarm becomes active during the mute period, this will also be emitted acoustically. In addition, the status Audio paused can be ended using this button. A countdown shows the user how much time remains in the Confirmed and Audio paused statuses.
- **ON/OFF:** (Figure 5-1–g) to switch the medin-NC3 on and off

In addition to the buttons, the operating unit has a dial for variable setting of the values (Figure 5-1–e), as well as
LED displays for fast information about the battery and charge statuses (Figure 5-1–f).

5.2 Display screen

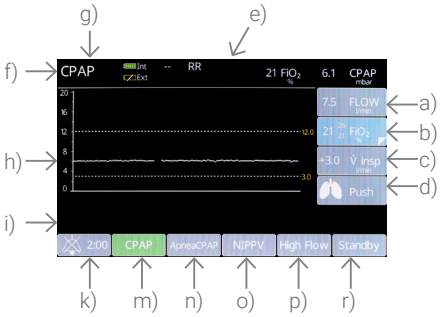


Figure 5-2: medin-NC3 display screen and button assignment
a) Flow; b) FiO_2 or start and end of the O_2 flush; c) Additional push flow; d) Button for triggering manual push; e) Readings; f) Mode; g) Status displays; h) Pressure course graph; i) Alarm messages; k) Alarm reset button; m) to r) Buttons for other settings

The medin-NC3 display screen shows the values set, the readings, status messages and the names of the buttons surrounding the screen:

- **Mode:** Displays the selected mode – Position f in Figure 5-2
- **Basic CPAP settings:** The set target values for flow, FiO_2 and the selected additional push flow are shown on the right in the display – Figure 5-2 Position a (flow), b (FiO_2) and c (additional push flow F_{insp}). Instead of the set target value for FiO_2, the setting of the O_2 flush and its start button are displayed after pressing the b button twice.
- **Manual push:** The trigger button for manual pushes is at position d in Figure 5-2.
- **Readings:** The values measured by the medin-NC3 for the average CPAP pressure (CPAP) and the measured oxygen concentration (FiO_2). In addition, mode-dependent readings such as the respiratory (RR) or push frequencies (R_{insp} – corresponds to the number of inspiration pushes per minute automatically emitted by the medin-NC3) are indicated above in the colored header of the medin-NC3 (Figure 5-2 position e).
- **Status displays:** At position g in Figure 5-2 the medin-NC3 provides information on the battery charge status.
- **Pressure course curve:** The CPAP pressure measured over time is shown as a graph in position h in Figure 5-2. In addition, the maximum measured pressure for each push is marked numerically. The representation of the pressure course can be helpful in selecting CPAP parameter settings.
  The pressure curve can be indicated on a scale of 0-10, 0-15 or 0-20 mbar/cm H_2O.
- **Active alarms:** Information about active alarms is g iven in position i in Figure 5-2.
  If several alarms are active at the same time, they are displayed in alternation. See chapter 8 for a detailed description of alarms and tips on how to avoid them occurring.
- **Alarm button:** Field j in Figure 5-2 and its button are always used to acknowledge alarms. The remaining time of the mute status of the alarms is also displayed in this field.

- **Button assignment:** The fields m to r in Figure 5-2 have changing functions. The current meaning of each button is shown in the display over it. In some menus, two different parameters are assigned to a single button in fields m to r. In this case, the operator can press the relevant button several times to switch between the parameters.

5.3 Basic CPAP settings

The CPAP therapy generated in the Medijet is largely determined by two factors: the flow volume (Flow) emitted by the CPAP driver and the oxygen concentration (FiO_2) contained in this. These two fundamental factors are set in the same way in all modes and are transferred when the operator switches from one mode to another.

Flow:

Press button a as shown in Figure 5-2 to change the flow value that has been selected. This action activates the flow setting (a green background appears). The target value can then be changed by turning the dial. As this also immediately changes the flow volume produced by the medin-NC3, the operator can see the effect of this change on the CPAP pressure produced as shown in graph h in Figure 5-2. The operator can terminate activation, and thereby the ability to change the flow value, by pressing the dial. If the dial is not pressed to conclude the flow change, the medin-NC3 still accepts the flow volume change.

If the flow value is altered in situations when no patient is connected to the Medijet, the Medijet prong adapter must be closed by the operator during this process (e.g. by holding it shut). This simulates the CPAP pressure which is produced. If a patient is connected to the Medijet during flow adjustment, the prong or mask must be checked for leaks before any adjustment to the flow is made as the presence of leaks could affect the CPAP pressure which is produced.

The medin-NC3 automatically produces a flow of 7 L/min on start-up. The user must adjust this flow while keeping the Medijet prong adapter closed until the flow produces the desired CPAP pressure.

Since the set basic flow (Flow) and additionally the set push flow (F_{insp}) are emitted during a push, an increase in the basic flow also increases the CPAP pressure during a push. Therefore the setting for F_{insp} must always be monitored when the Flow setting is changed. (Adjustment according to chapter 5.5)

The mask or prong should always be checked for leaks before adjusting the flow that has been selected, as the presence of leaks affects the CPAP pressure which is produced.

Oxygen concentration FiO_2:

Alter the oxygen concentration by using button b in Figure 5-2 to highlight the current oxygen concentration and then turning the dial to select the desired value. Press the dial to confirm the new value. This completes the process of adjusting the oxygen concentration. It is only now that the medin-NC3 alters the oxygen concentration in the patient flow. If the oxygen concentration adjustment is not confirmed by pressing the dial, the medin-NC3 continues to blend the oxygen concentration that was set before the target value was adjusted.

Depending on the FiO_2 alarm preset in the service menu, the change in the oxygen concentration affects the limits of the oxygen alarm:

- FiO_2 alarm automatic: At the same time as the change in the oxygen concentration, the limits for the oxygen alarm are also adapted to the new oxygen concentration.

- FiO_2 alarm manual: The change in the target oxygen concentration does not affect the limits of the oxygen alarm. After changing the oxygen concentration, these limits have the same values as before the change. They can only be adjusted manually to the new oxygen values. For this purpose, the user must open the Alarm settings menu and manually update the alarm thresholds (see chapter 5.13).

The oxygen concentration in the patient flow does not change until the new oxygen concentration has been confirmed. Only then can the effect of the changed oxygen concentration on the patient be observed.

As long as an O_2 flush is active, the target oxygen concentration FiO_2 cannot be changed. Only after a manual premature end or after an automatic end of the O_2 flush can the FiO_2 setting be changed once again (see chapter 5.4).

5.4 O_2 flush

The O_2 flush offers the possibility of increasing the oxygen concentration emitted for one minute. Then the set target oxygen concentration is automatically emitted once again.

Setting the level:

The automatic duration of the O_2 flush is 1 min. However, it can be discontinued early by pressing the button. The level of the O_2 flush can be changed by the user in the respective Settings mode. This can be opened by pressing the p button in Figure 5-2. Here the setting of the level of the O_2 flush can now be activated by pressing the r button in Figure 5-2. The following are available for selection: +5, +10 and +15, and this can be selected by turning the dial. A final pressing of the dial confirms the new setting which takes effect as of the next newly started O_2 flush. O_2 flushes already in progress will continue to be performed with the old setting. The selected level of the O_2 flush determines the emitted oxygen concentration during an O_2 flush: Thus, for example, during an O_2 flush, an oxygen concentration should be emitted which is 5, 10 or 15 vol. % greater than the set target value of the oxygen concentration (affects setting +5, +10, +15). Given a target oxygen concentration of 25% and an O_2 flush with the setting +10, an oxygen content of 35% would be emitted during the O_2 flush. However, a maximum of 100% oxygen can be emitted.

Start of an O_2 flush:

The start button for an O_2 flush is located behind the FiO_2 button and can be selected by pressing this button twice (button b in Figure 5-2). If the start button has a green background, pressing the dial can start the O_2 flush. Now the medin-NC3 automatically emits an increased oxygen concentration for one minute.

Discontinuation of an O_2 flush:

As long as an O_2 flush is active, the O_2 flush discontinuation button can be found at position b in Figure 5-2 instead of the FiO_2 setting button. If this is selected by pressing button b in Figure 5-2 and then confirmed by pressing the dial, the O_2 flush is immediately discontinued. If, on the other hand, the O_2 flush is not discontinued early by the user, it ends automatically after one minute and the button FiO_2 target value is displayed once again.

As long as an O_2 flush is active, the target oxygen concentration FiO_2 cannot be changed. Only after a manual premature end or after an automatic end of the O_2 flush can the FiO_2 setting be changed once again.

5.5 Push (not in High Flow mode)

In addition to the basic CPAP mode, the medin-NC3 can increase the CPAP pressure if necessary for a short time. These periods are called "pushes" and can be used to stimulate the patient. A push is determined by the additional flow used for it and its duration.

Additional flow during a push - F_{insp}:

In field c in Figure 5-2, set an additional flow (F_{insp}) by pressing the button to activate the setting and turning the dial to select a value which immediately becomes active for the next push and then pressing the dial to confirm. If the dial is not pushed, the change is made nonetheless. During a push, the medin-NC3 emits, as a flow, the sum of the set basic flow (Flow) in Figure 5-2 field a and the additional push flows (F_{insp}).

As an additional push flow F_{insp} a value between 0 L/min (that is, essentially no push is triggered) and a maximum value dependent on the basic flow set can be set. The maximum value is 17.5 L/min minus the set basic flow Flow.

The setting F_{insp} may only be changed in small increments. The effect of each increment (= CPAP pressure that develops during a push) must be monitored by triggering a manual push or by waiting for an automatic push. It should be noted that any change becomes immediately active for the next push, even without pressing the dial.

The CPAP pressure that develops during a push depends on the leakage of the CPAP system (particularly the leakage from prongs or the mask). An increase in the push flow by +1 L/min can cause an increase of up to 3.5 mbar in the CPAP pressure.

Since leakage from the mask and prongs causes a decrease in the pressure during a push, this leakage must be checked before increasing the push flow. An increase in the push flow is not a substitute for leak-proof positioning of the mask or prong!

During a push, the set basic flow (Flow) and additionally the set push flow (F_{insp}) are emitted such that an increase in the basic flow also causes an increase in the CPAP pressure during a push.
When setting the additional flow during a push, the following must be ensured:

- The alarm CPAP pressure high briefly stops the flow to the patient and sounds an alarm starting at a CPAP pressure of 18 mbar; that is, if the push is set such that its pressure is very high, a slight change in the leakage or the expiration against push by the patient will cause the medin-NC3 to briefly stop the flow and trigger an alarm. To prevent this, the push flow must be reduced.

- If a very high overall flow is set in the event of a push, high static pressure may develop in the tube system. If this exceeds 60 mbar, the Feed pressure high alarm is triggered and the flow emission to the patient is stopped. In this case, the push flow set must be reduced and the leakage at the patient reduced. Depending on the duration of the high supply pressure, the medin-NC3 automatically restarts the flow after a short time or not until after confirmation from the user (if Press alarm reset to restart flow is displayed).

- During a push, if a flow is set that is so high that it triggers the Feed pressure high alarm and simultaneously a CPAP pressure high alarm, it is possible that the text Press alarm reset to restart flow may also be displayed. In this case, the medin-NC3 stops the flow until the user restarts it by pressing the Alarm Reset button.

In order to be able to use the manual push function at all times, the level of the additional push flow (F_{insp}) should be set in advance (e.g. at the start of the CPAP therapy) and adjusted as needed in the event of flow changes.

Factors that can exert an influence on the adjusting CPAP pressure during a push:

- Patient's respiration: In a similar way to the pressure fluctuations that are caused by the patient's breathing during CPAP therapy and are displayed on the CPAP pressure curve along with other parameters, the patient's respiratory activity has an influence on the actual level of push which is achieved.

- Tube system volume and push level: The volume of air in the tube system must be compressed before the increased flow triggered by the medin-NC3 causes the CPAP pressure in the Medijet to rise. If large tube systems are used, or if the difference between the basic flow and the total flow during the push is considerable, it will take some time to reach the desired CPAP pressure. If the duration of the push is shorter than this time lag, it will not be possible to achieve the desired push pressure.
- Changes to the CPAP system and changes in leakage conditions: Since the user determines the necessary amount of additional flow during a push (F_{insp}), taking into account any leakage situation present at this point in time, the level of the push

changes when the leakage changes. If the pressure values during a push are too low, check for leaks and resolve them. Decreases in the leakage, changes to the Medijet and tube system or temperature effects may result in increased pressure values during a push.

- The ratio of inspiration time and push flow has an influence on the push pressure which can actually be achieved. In the case of larger push flows and short inspiration times, it is possible that, due to the sluggishness of the blower, the inspiration time ends before the full push flow was reached and transported through the tube system to the patient.

Triggering a manual push:

A push can be triggered manually in all CPAP modes of the medin-NC3. This is done by pressing button d in Figure 5-2. The medin-NC3 responds to this by immediately triggering a push. The duration of the triggered push corresponds to the set duration of the inspiration. If the button is held down, no additional push is triggered after the first one has been completed. Another push can only be triggered by releasing the push button and pressing it again. The precondition for triggering a manual push is that a push flow (F_{insp}) >0 L/min was set.

5.6 CPAP mode

CPAP mode provides a pure basic CPAP therapy. In this mode the medin-NC3 produces a constant flow all the time which is converted into a constant CPAP pressure in the Medijet.

The setting, action and information options are:

- Flow (chapter 5.3)
- FiO_2 oxygen concentration (chapter 5.3) and start and discontinuation of the O_2 flush (chapter 5.4)
- F_{insp} additional push flow and manual PUSH (chapter 5.5)
- Alarm settings (chapter 5.13)
- Trend graphs (chapter 5.14)

Inspiration: Figure 5-3 a
The setting in this field determines the duration of the manually triggered push. It can be set to a time between 200 milliseconds and 3 seconds.

5.7 Leak-Assist

This compensates for the difference between the desired target average pressure and average pressure measured at the patient. The compensation flow is limited to ± 5 L/min. In addition, the total flow is limited to a maximum of 15 L/min and a minimum of 4 L/min. In addition, an alarm (Leak-Assist (yellow)) is triggered if the target pressure is not reached after 30 s with maximum compensation flow.

If there is a higher-priority alarm (red), this function is discontinued. If the alarm ends, the Leak-Assist then starts automatically.

The function is ended either by direct switching off or changing into standby status or another mode. In addition, the CPAP settings contain the setting option for the level of the O_2 flush (see chapter 5.4).

The patient's respiration causes the CPAP pressure produced in the Medijet to change, and brief fluctuations in the CPAP pressure course occur. These are visible on the CPAP graph.

The use of the Leak-Assist cannot be started if the measured average value is below 2 mbar. In apnea CPAP mode, the use of the Leak-Assist is paused, while the backup is actively running and automatically restarts once the respiratory activity can be detected. After the emergency program, the Leak-Assist is suppressed for 10 seconds.

5.8 Apnea CPAP mode

In apnea CPAP, the basic CPAP of the CPAP mode is complemented by apnea monitoring. The apnea monitoring system assesses fluctuations in the CPAP pressure course which are caused by the patient's respiration and responds to phases in which the patient does not breathe by automatically triggered pushes.

In addition to the setting, action and information options which are present in CPAP mode, such as:

- Flow (chapter 5.3)
- FiO_2 oxygen concentration (chapter 5.3) and start and discontinuation of the O_2 flush (chapter 5.4)
- F_{insp} additional push flow and manual PUSH (chapter 5.5)
- Alarm settings (chapter 5.13)
- Trend graphs (chapter 5.14)

There are special settings for the apnea mode. These apnea settings can be opened by pressing the p button in Figure 5-2, which offers the possibility of changing six parameters. To change a parameter, press the corresponding button to select it, turn the dial to the desired setting, and press the dial to confirm your selection.

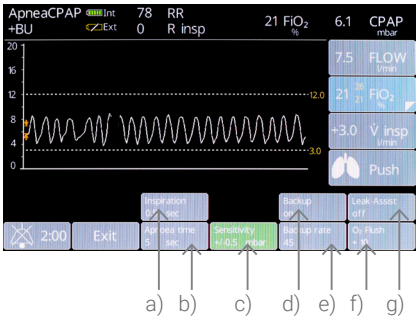


Figure 5-3: Sub-menu Apnea settings to change
a) Inspiration time
b) Apnea time
c) Sensitivity
d) Backup on/off
e) Backup rate
f) Level of the O_2 flush,
g) Leak-Assist. The orange lines are used only to clarify the significance of the sensitivity set as a limit between breathing and apnea and are not displayed by the medin- NC3. Instead, the sensitivity is displayed on the left-hand edge of the CPAP curve as a pair of arrows (orange).

Inspiration: Figure 5-3 a
The setting in this field determines both the duration of pushes automatically triggered in the event of apnea, the backup pushes, and the duration of pushes triggered manually. It can be set to a time between 200 milliseconds and 3 seconds.

Apnea time: Figure 5-3 b
The apnea time determines how long the medin-NC3 waits until an automatic push is triggered, if no respiratory activity can be detected in the CPAP pressure course. If no respiratory activity can be detected even after a push, either the backup pushes are started or the device waits for the length of time set as apnea time before the next push is triggered, depending on the backup setting. The length of time that can be set as the apnea time is any time between 2 seconds and 30 seconds.

The medin-NC3 has an internal block preventing another apnea push being triggered immediately after a push for twice the length of time set as inspiration time. This means that for a selected inspiration time of two seconds, the medin-NC3 does not emit any apnea push for four seconds after the push, even if an apnea time of less than four seconds is set.
Pushes based on the backup rate and manual pushes are not affected by this.

Sensitivity: Figure 5-3 c
The sensitivity setting determines the pressure fluctuations in the CPAP signal at which respiration is detected. For clarification, the sensitivity is shown as a pair of orange arrows on the left-hand side of the CPAP pressure curve around the current CPAP average value. When setting the sensitivity, the value selected here must be lower than the pressure fluctuation caused by the patient's normal respiration. However, the value must also be greater than the pressure fluctuations caused by the CPAP system. For the pressure signal shown in Figure 5-3 (without respiration on the left, with respiration on the right), the sensitivity shown in orange would be correct as it is lower than the pressure fluctuations caused by respiration and greater than the noise of the pressure signal without respiration. The purpose of this setting is to allow the medin-NC3 to deal with periods in which the CPAP pressure signal remains within the limits as apnea and with situations in which these limits are exceeded as respiratory activity.

The sensitivity must be set to less than the patient's respiration and greater than the pressure fluctuations caused by other sources (e.g. condensate in the flow tube).

When selecting the push flow and sensitivity, it is important to ensure that the pressure during the push will become greater than the upper threshold of the sensitivity selected. Otherwise the apnea phase will not be interrupted by the push.

Backup on/off: Figure 5-3 d and backup rate Figure 5-3 e – see chapter 5.9

Level of the O_2 flush: Figure 5-3 f – see chapter 5.4

Leak-Assist: Figure 5-3 g see chapter 5.6 (in the CPAP mode)

Display: When operating in apnea CPAP mode, the current respiration rate (RR - breaths >1 mbar per minute) and number of pushes automatically generated by the medin-NC3 per minute (R_{insp}) are shown in the orange bar on the top of the screen in addition to the information referred to in chapter 5.2.

If the backup function is activated, this is likewise displayed.

5.9 Backup function

The Backup function can only be activated in the Apnea CPAP mode. In the Settings mode, it can be switched on or off and the desired backup rate can be set.

Setting the backup rate is possible in intervals of 5 between 5/min and 120/min. The rate setting depends on the inspiration time. The greater the inspiration time, the smaller the maximum backup rate.

The type of display of the push alarm can be selected from the following setting options: visual, acoustic, visual & acoustic, and text only.

If the backup function is activated, the backup pushes with the set backup rate will be issued in the event of apnea after the apnea time has passed and support or stimulate the patient. If patient respiration is detected, the backup will automatically end.

In addition, the button Push becomes the End backup button. This can be used if the medin-NC3 does not independently detect respiration and the backup function therefore does not automatically end. Then the backup can be manually discontinued by the user with this button.

In the trend, backup pushes administered are indicated with a blue line.

5.10 NIPPV mode

In the NIPPV (Non-Invasive Positive Pressure Ventilation) mode, ventilation is supported on two different pressure levels. The user adjusts the intensity of both levels via the flow and additional flow (F_{insp}) as well as the rate and time spent at the upper pressure level.

In addition to the setting, action and information options which are present in CPAP mode, such as:

- Flow (chapter 5.3)
- FiO_2 oxygen concentration (chapter 5.3) and start and discontinuation of the O_2 flush (chapter 5.4)
- F_{insp} additional flow to reach the upper flow level and manual PUSH (chapter 5.5)
- Alarm settings (chapter 5.13)
- Trend graphs (chapter 5.14)

There are special settings for the NIPPV mode. These NIPPV settings can be opened by pressing the p button in Figure 5-2, which offers the possibility of changing three parameters. To change a parameter, press the corresponding button to select it, turn the dial to the desired setting, and press the dial to confirm your selection.

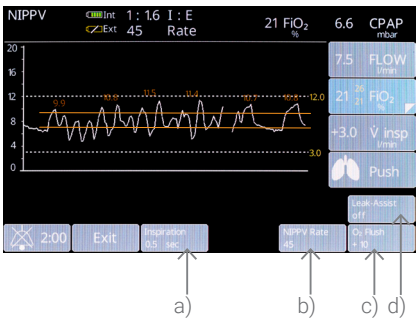


Figure 5-4: Submenu NIPPV settings to change the
a) Inspiration time
b) NIPPV rate
c) Level of the O_2 flush
d) Leak-Assist.
The only purpose of the orange lines is to clarify the approximate situation of both pressure levels. They are not displayed by the medin-NC3.

Inspiration: Figure 5-4 a

The setting in this field determines both the time spent at the upper pressure level and also the duration of pushes triggered manually. It can be set to a time between 200 milliseconds and 3 seconds.

NIPPV rate: Figure 5-4 b – Similar to chapter 5.9 Backup function. The set rate at which a switch is made between the upper and lower flow level and pressure level.

Level of the O_2 flush: Figure 5-4 c – see chapter 5.4

Leak-Assist: Figure 5-4 d – see chapter 5.6 (in CPAP mode)

5.11 High Flow mode

High Flow mode (also known as HHHFNC = Heated Humidified High Flow Nasal Cannula, or nHFT = nasal High Flow Therapy) differs from the CPAP modes in that in this case, no Medijet but rather a suitable Nuflow cannula is used and the flow is limited to a maximum of 12 L/min.

Here, in addition to the general settings and displays, such as:

- Flow (chapter 5.3)
- FiO_2 oxygen concentration (chapter 5.3) and start and discontinuation of the O_2 flush (chapter 5.4)
- Alarm settings (chapter 5.13)
- Trend graphs (chapter 5.14)

Only one special setting exists for this mode. Its overview opens by pressing button p in Figure 5-2. It can be changed by selecting, setting the desired value using the dial and pressing the dial to confirm.

Level of the O_2 flush similar to Figure 5-3 f – see chapter 5.4

Displays: In High Flow mode, information on the pressure is displayed to the operator on the top of the screen only if pressure alarms are activated. In addition, there is no graph of the pressure course, instead only the visualization of a Nuflow nasal cannula.

5.12 Mode change

Mode selection can be opened by pressing the m button in Figure 5-2. In this case the available modes are shown at the bottom of the screen. The user can now select the desired mode by pressing the corresponding button. The selected mode now appears on a green background. The mode selected must then be confirmed by pressing the dial. Only then does the medin-NC3 switch to this mode.

The user can check whether mode switch has taken place correctly by checking the mode display in the top left- hand area of the screen after making the switch.

When switching between two modes, the medin-NC3 transfers all the settings that are available in both modes.

If a highest-priority alarm (e.g. high pressure or lack of gas) and the safety mode triggered as a result are active, the mode may not be changed. The mode can only be changed once again after the error has been corrected. A mode change during the safety mode is only possible if the safety mode was activated by the Disconnection alarm.

5.13 Alarm settings

The alarm sub-menu is available in each medin-NC3 mode. This can be opened by pressing the n button in Figure 5-2.

The points described below can be changed after opening this sub-menu. If two functions are allocated to a button, the operator can press the relevant button repeatedly to switch between the two functions. Individual values are changed by selecting the corresponding parameter (visible thanks to its green background), then using the dial to change the value and finally confirming the new value by pressing the dial.

CPAP high: This corresponds to the freely selectable upper CPAP pressure alarm. If this value is exceeded by the CPAP average value for a certain amount of time, the CPAP pressure high alarm is triggered after a delay (see chapter 8.2).

CPAP low: This alarm monitors the lower threshold of the CPAP pressure. If this value is undershot by the CPAP average value for a certain amount of time, the CPAP pressure low alarm is triggered after a delay (see chapter 8.2).

Because of the scale, it is possible that the CPAP high and CPAP low alarm thresholds (generally shown as dashed lines) are not visible on the display (e.g. if the scale is set from 0 to 10 and the value for CPAP high is 13). In this case, the value of the limit is visible as a number to the upper right next to the graph.

FiO_2: The FiO_2 setting determines the alarm interval of the oxygen alarm. The limits of this alarm depend on the target oxygen concentration and are displayed next to the target oxygen levels. If this value (see chapter 8.2) is exceeded/undershot, an alarm will be triggered after a delay. There are two different setting options for this alarm which must be preset in the service menu by a service technician.

- **Automatic FiO_2 alarm:** Here the FiO_2 limit values are automatically adapted to the new target value for any change in the target oxygen concentration.
- **Manual FiO_2 alarm:** In this case, if there are changes to the target oxygen concentration, the FiO_2 alarm threshold values are not changed. This adaptation can only be performed manually by the user by opening the Alarm setting menu, selecting the button FiO_2 alarm refresh and confirming this by pressing the dial. If adapting the alarm thresholds is not possible because they already refer to the currently set oxygen concentration, the button Refresh FiO_2 alarm is dimmed and instead, the button to change the alarm interval will be visible.

Push alarm: The push alarm setting can be used to determine how the medin-NC3 informs the user in the event of an automatically triggered push. The following settings are available: Information through an acoustic and visual signal, information only through a visual signal, information only through an acoustic signal or information only through text on the display. Manual pushes are always displayed as text in the display, independent of this setting.

Audio alarm pause: Using the Audio Alarm Pause function, the Audio paused status can be started in which the acoustic alarm signaling is muted for 5 minutes. After 5 minutes, the muting ends automatically. The muting can also be reactivated before the 5 minutes have passed using the Audio Alarm Pause function. Alternatively, this can also be performed by pressing the e button (Figure 5-1).

Brightness: The brightness setting changes the brightness of the backlighting of the display.

Scale: Using this setting, the scale of the pressure graphs can be changed. The scales 0-10 mbar/cm H_2O, 0-15 mbar/ cm H_2O or 0-20 mbar/cm H_2O are available.

The value for the CPAP pressure high alarm (red) is 18 mbar. Even if the scale up to 20 mbar is used, the value is still 18 mbar.

5.14 Trend

The trend display shows the course taken by the values set for each mode. Eight hours are shown per page. Overall the values since the last device start, however a maximum of values from the past 28 days, can be displayed by pressing the arrow buttons. If, at the time indicated, the medin-NC3 was in a mode in which the value shown is not available, this time period will be shown as empty in the trend. All trend values, except for the alarms, are deleted when the device is switched off.

CPAP / FiO_2: trend: Both of these trend courses are available in the CPAP modes. They show the course of the oxygen concentration set and the average CPAP pressure.

RR / R_{insp}: In Apnea CPAP mode, the course of the respiration rate (breaths > 1 mbar per minute) and push frequency (number of pushes per minute) can also be shown. If backup is actively running, the line is shown in blue.

Rate / I:E: The course of the NIPPV rate as well as the I:E ratio (inspiration: expiration) can additionally be shown in NIPPV mode.

Flow / FiO_2 trend: Both of these trend courses are available in High Flow mode. They show the course of the oxygen concentration set and the flow.

USB export: The USB export of the trends contains the readings and settings and additionally a logfile of the alarms described in chapter 3.4.4.

5.15 Standby

The standby mode can be used if the medin-NC3 is not being used to treat an acute case but should be kept ready for use. If the device is switched from one of the other modes to this mode, the medin-NC3 stores all the settings that have been selected, stops producing a flow and deactivates the alarms. Pressing the End button takes the device out of standby mode and causes the medin-NC3 to revert to the previous mode.

If the medin-NC3 is switched during CPAP mode with activated Leak-Assist into standby mode, the Leak-Assist needs to be manually restarted after ending the standby.

Ending the standby and reactivating normal operation of the medin-NC3 lasts approximately ten seconds.

6. Switching Off

There are two ways of switching off the medin-NC3.

6.1 Software switch-off

The shutdown menu is opened by pressing the ON/OFF button for at least three seconds. The shutdown menu can be exited by pressing the m button from Fig. 5-2 and confirming this selection by pressing the dial. Pressing the r button and confirming this selection by pressing the dial switches off the medin-NC3. The medin-NC3 stops supplying air and oxygen and switches off the electronic components. If the medin-NC3 is connected to the power supply, the internal battery will be charged, as needed. However, this is not shown on the display. If no action takes place in the shutdown menu, the shutdown process is automatically discontinued after 5 seconds and the display returns to active operating mode.

6.2 Hardware switch-off

Holding button m in Figure 5-2 down while at the same time pressing the ON/OFF button for four seconds immediately switches off the medin-NC3 and the device stops supplying gas. If the combination of buttons is not held down long enough, the medin-NC3 switches off and the gas feed is interrupted, but an alarm sound lasting for two minutes is additionally triggered.

To suppress this two-minute alarm sound early, the medin-NC3 must be started until the step: Attention: Do not connect a patient during system start-up and then the ON/OFF button must be briefly held down once again.

6.3 Disconnection

Once the medin-NC3 has been switched off it can be unhooked from the air and oxygen supply and its power supply unit can be disconnected. The patient tube circuit sets must be removed and disposed of, and the surface of the medin-NC3 cleaned as described in chapter 9.1. Disconnect the power supply unit from the mains during thunderstorms. Do not pull on the cable to disconnect the power supply unit from the mains.

7. Accessories and combinable products

7.1 Accessories

The medin-NC3 may only be combined with the accessories listed in the following table:

Table 1: Accessories

Description	REF	Comments
20x Medijet	1000	nCPAP-Generator, System incl. Medifoam
10x Medifoam	1030	Fixation pillow for Medijet
10x Bonnet (xx-small) 10x Bonnet (x-small) 10x Bonnet (small) 10x Bonnet (medium) 10x Bonnet (large) 10x Bonnet (x-large) 10x Bonnet (xx-large) 10x Bonnet (xxx-large)	1213-10 1214-10 1215-10 1216-10 1217-10 1218-10 1219-10 1220-10	light green white yellow red light blue orange light green white
10x Mask (x-small) 10x Mask (small) 10x Mask (medium) 10x Mask (large) 10x Mask (large +) 5x Mask (x-large)	1200-08 1200-04 1200-05 1200-06 1200-09 1200-07	

10x Prong (x-small) 10x Prong (small) 10x Prong (medium) 10x Prong (large) 10x Prong (x-large) 10x Prong (medium wide) 10x Prong (large wide)	1200-01 1200-21 1200-02 1200-22 1200-03 1200-32 1200-33	
10x Nuflow nasal cannula (small) 10x Nuflow nasal cannula (medium) 10x Nuflow nasal cannula (large) 10x Nuflow nasal cannula (x-large)	1320 1330 1340 1350	
Nuflow starter set s/m	1393	
Nuflow starter set l/xl	1394	
10x nCPAP circuit set (single-limb)	1207	Without humidifier chamber
10x nCPAP circuit set (single-limb)	1207MKI	With humidifier chamber
medin-NC3 trolley	5008	
Basket for medin-NC3 trolley	5020	
Bottle holder bracket for medin-NC3 trolley	5021	
Bottle holder for medin-NC3	5022	

7.2 Combinable products

The medin-NC3 may only be combined with the products tested for combinability listed in the following table:

Table 2: Combinable products

Description	REF
Fisher&Paykel MR850 humidifier	MR850ARU
Fisher&Paykel MR810 humidifier	MR810ARU

8. Alarms and Error Messages

8.1 Error messages during system startup

Tabelle 3: Error messages at system start

Error message text	Possible cause	Correction
Connect power supply unit – battery low	The internal battery is almost discharged.	Please connect the power supply unit to the mains.
Fan blocked	The fan is blocked or defective.	Check whether the ventilation slits are clear or contact a service technician.
Gas feed pressure low, check O_2	The oxygen feed pressure is too low (< 3 bar).	Please check oxygen supply (tube connected?). (1)
Gas feed pressure high, check O_2	The oxygen feed pressure is too high (> 7 bar).	Please check oxygen feed. (1)
Check gas feed air	The blower reported an error.	Clean blower filter or contact a service technician.
Oxygen calibration failed, check O_2	The oxygen calibration could not be performed correctly. The medin-NC3 cannot be operated without oxygen.	Please check whether the oxygen cell is working properly and whether the medin-NC3 is correctly connected to the oxygen feed.
Device error – device shutdown necessary	There is a defect in the device's pneumatic system, at the overpressure valve or rechargeable battery. The medin-NC3 can no longer be used and must be switched off.	Check overpressure valve (blocked?) or contact a service technician.
Error during tube test – restart	An error occurred during the tube test (e.g. leakage).	Check impermeability and repeat the tube test.

Error message text	Possible cause	Correction
Device error – patient pressure. Device must be replaced	The patient pressure sensor is causing an error. The device cannot be used and must be replaced	Please contact a service technician.
3V battery empty – battery has to be replaced	The internal 3V battery is empty and must be replaced.	Please contact a service technician.
Battery needs replacing – device function in battery mode cannot be guaranteed. Device must be connected to mains for use!	The internal/external rechargeable battery is too old or was used too frequently and must be replaced.	Do not use the medin-NC3 on rechargeable battery power and contact a service technician.
Maintenance necessary! Next maintenance necessary: YY.MM.DD	The last maintenance of the medin-NC3 took place at least 11 months ago and must be repeated no later than the date indicated.	Please contact a service technician.
Blower filter blocked	The blower filter of the device is clogged and must be cleaned or replaced.	Please clean blower filter

(1) If this error should occur more frequently despite correctly connected tubes, please contact the person within your organization who is responsible for the central gas supply.

8.2 Error messages during operation

Tabelle 4: High priority alarms

Error message text	Priority	Δt[1]	Cause and device response	Correction
Disconnection (CPAP, Apnea CPAP, NIPPV mode)	High	<6 s[2]	The CPAP pressure is < 2.0 mbar for > 5 seconds – the flow tube or pressure meter tube are no longer connected to the medin-NC3. This alarm starts the emergency program.	Please reconnect the corresponding tube.
CPAP pressure high	High	< 1 s	CPAP pressure > 20 mbar – The medin-NC3 briefly interrupts the flow. This alarm starts the emergency program.	If necessary, reduce flow and check leakage.
Feed pressure high	High	< 1 s	Feed pressure > 60 mbar, the flow supply tube is blocked or is generating resistance that is too high. Please check. – The medin-NC3 briefly interrupts the flow. This alarm starts the emergency program.	Please check patient tube for blockage.
Device error – patient pressure. Device must be replaced!	High	< 1 s	The patient pressure sensor is causing an error. The two CPAP sensors are measuring a difference of > 2 mbar for 500 milliseconds. The device can no longer be used and must be replaced. This alarm starts the emergency program.	Please contact a service technician.

Device error – device shutdown necessary	High	< 1 s	A serious error occurred within the medin-NC3. The medin-NC3 can no longer be used and must be replaced. This alarm starts the emergency program.	Please contact a service technician.
Check gas feed pressure O_2	High	3 s	The O_2 feed pressure is too low (< 2.8 bar) or too high (> 7.0 bar) – the medin-NC3 is only providing pure air. This alarm starts the emergency program.	Please check O_2 feed. (Tube connected?) (3)
Check gas feed pressure air	High	3 s	The blower is reporting an error – the medin-NC3 is emitting pure oxygen. This alarm starts the emergency program.	Please check air supply (blower filter blocked?).
Battery level critical	High	5 s	The voltage of the internal battery is below 12.5 V. The device will switch off in 60 s	Connect power supply unit immediately

1. Delay Δt: This corresponds to the maximum time which passes from the time the alarm condition occurs until the alarm is triggered.

2. After start-up, the Disconnection alarm is suppressed for the first 5 minutes of operation. However, the alarm is activated no later than after 5 minutes or if a CPAP pressure > 1 mbar for at least 30 sec has already been measured. After a CPAP pressure high or Feed pressure high alarm, the Disconnection alarm is suppressed for 3 seconds.

3. If this error should occur more frequently despite correctly connected tubes, please contact the person within your organization who is responsible for the central gas supply.

Tabelle 5: Medium priority alarms

Error message text	Priority	Δt[1]	Cause and device response	Correction
CPAP pressure high	Medium	< 24 s[2]	The CPAP average pressure was continuously higher for > 1 second than the set upper CPAP pressure alarm threshold. - In a normal case, the average value interprets the CPAP readings from the past five seconds which delays the start of the alarm up to < 8 seconds. - If the backup is activated, there may be a maximum delay of 85 seconds until the average value has been fully updated, which can result in a total alarm delay of < 87 seconds. In this case, the medin-NC3 continues to work normally.	Check patient interface and adjust flow or alarm thresholds, if necessary.
CPAP pressure low	Medium	< 38 s(2)(3)	For 15 seconds, the CPAP average pressure was constantly lower than the set lower CPAP pressure alarm threshold. - In a normal case, the average value interprets the CPAP readings from the past five seconds which delays the start of the alarm up to < 22 seconds. - If the backup is activated, there may be a maximum delay of 85 seconds until the average value has been fully updated, which can result in a total alarm delay of < 101 seconds. In this case, the medin-NC3 continues to work normally.	Check patient interface and adjust flow or alarm thresholds, if necessary.
Oxygen concentration high	Medium	100 s	The oxygen concentration measured is higher than the alarm threshold set for ~1.5 min - the medin-NC3 continues to operate normally.	If necessary, adjust O_2 concentration or alarm thresholds.

Oxygen concentration low	Medium	100 s	The oxygen concentration measured is lower than the alarm threshold set for ~1.5 min - the medin-NC3 continues to operate normally.	If necessary, adjust O_2 concentration or alarm thresholds.
Temperature	Medium	90 s	The temperature in the medin-NC3 is too high.	Check the environmental conditions and contact a service technician.
Connect power supply unit – battery low	Medium	6 s	The internal battery is almost discharged.	Please connect the power supply unit.
P_{peak} high	Medium	< 1 s	The pressure during a push is greater than 18 mbar. The medin-NC3 interrupts the active push.	Please check push flow settings and decrease, if necessary.

1. Delay Δt: This corresponds to the maximum time which passes from the time the alarm condition occurs until the alarm is triggered.

2. After start-up, the Disconnection alarm is suppressed for the first 5 minutes of operation. However, the alarm is activated no later than after 5 minutes or if a CPAP pressure > 1 mbar for at least 30 sec has already been measured.

3. Maximum time delay, including maximum required time to completely recalculate the average value.

Tabelle 6: Low priority alarms

Error message text	Priority	Δt[1]	Cause and device response	Correction
Leak-Assist	Low	< 36 s	The average CPAP is different from the target CPAP for > 30 seconds and the Leak-Assist flow of ± 5 L/min is not sufficient for compensation. In this case, the medin-NC3 continues to work normally.	Check patient interface and if necessary, correct larger leaks.
Fan blocked	Low	15 s	The fan is blocked or defective.	Please contact a service technician.
Power supply disconnected	Low	1 s	The power supply unit is removed during ongoing operation. A 5-second message is displayed.	Plug power supply unit back in.
External battery low	Low	6 s	The external battery is almost discharged.	Replace ext. battery or plug in power supply unit.
External battery temperature	Low	90 s	The temperature of the external battery is too high.	Plug the power supply unit in and remove the ext. battery.

1. Delay Δt: This corresponds to the maximum time which passes from the time the alarm condition occurs until the alarm is triggered.

Tabelle 7: Other alarms and messages

Error message text	Priority	Δt[1]	Cause and device response	Correction
Pure alarm sound, medin-NC3 switched off	-	< 1 s	This alarm is triggered if the medin-NC3 power supply fails completely, for example because the power supply unit was not connected to the mains although the battery was discharged. The medin-NC3 was switched off.	Plug in the power supply unit and restart the device or contact a service technician.
Press alarm reset to restart flow	-	-	No alarm – informational message only: Triggered by a prolonged high feed pressure (e.g. if a flow tube is blocked), by several high CPAP pressures successively or by a combination of high feed pressures and high CPAP pressures, the flow supply is interrupted for the time being and is only reactivated after the Alarm Reset button is pressed. Reactivation of the flow takes approximately 10 seconds starting from this moment.	Please check patient tube for blockage.
Push activated	Info	-	Not actually an alarm, just notification that a push was triggered. The user can decide whether to receive this information visually or acoustically.	-

Apnea – push activated	info	-	Not actually an alarm, just a notification that a push was triggered due to apnea. The user can decide whether to receive this information visually or acoustically.	-
Backup push	info	-	Not actually an alarm, just a notification that a backup push was triggered due to apnea. Users can decide whether or not to receive this information aurally. However, this information is always indicated visually.	-

1. Delay Δt: This corresponds to the maximum time which passes from the time the alarm condition occurs until the alarm is triggered.

The alarm volume is:

Type of alarm	Volume in (dB)	In the case of A-weighted background noise volume (dB)
High priority (red)	66 ± 3	53 ± 2
Medium priority (blinking yellow)	66 ± 3	53 ± 2
Low priority (steady yellow)	66 ± 3	53 ± 2
Information signal (push)	66 ± 3	53 ± 2

The functionality of the alarm signal generator is checked at each system start-up. The user must confirm that the alarm sound can be heard.

Alterable alarms:

The user can set the CPAP pressure low, CPAP pressure high (yellow) alarms and the permitted deviation interval for the Oxygen concentration high / low alarms. This can be done using the setting in the Alarm Settings menu (see chapter 5.13). After the numerical

values are adjusted, the modified settings become active and are saved when this change is confirmed by pressing the dial. No other alarms can be modified.

Alarm presettings at device start-up:

Upon start-up, the CPAP pressure high (yellow) alarm is set to 12 mbar and the CPAP pressure low alarm is set to 3 mbar. The alarm interval for monitoring the oxygen levels set is always set to ± 5% at start-up.

If the medin-NC3 is restarted, the alarms are reset to these levels. This cannot be changed by the user.

The alarms CPAP pressure low (yellow) and CPAP pressure high (yellow) analyze whether the average value of the CPAP readings is outside of the alarm thresholds (can be set under Alarm Settings – see chapter 5.13). Thus the alarm CPAP pressure high is triggered if the CPAP average value was above the alarm threshold for more than one second. The alarm CPAP pressure low is triggered if the CPAP average value was below the alarm threshold for more than 15 seconds.

Since the CPAP pressure low and CPAP pressure high alarms refer to the average CPAP pressure, the start and end of the alarm is thus further delayed (see table at the start of the chapter). This likewise causes the CPAP pressure low alarm to not be reset until the CPAP average value is again above the alarm threshold and not directly after adjusting the alarm threshold or correcting the problem.

Verifying oxygen concentration high/low alarm

The alterable alarm can be verified by using the manual FiO_2 alarm and adjusting the target value without changing the permitted deviation interval manually.
The alarm Oxygen concentration high/low is triggered when the measured oxygen concentration is outside of the set
limits. These thresholds are always automatically set in the FiO_2 alarm thresholds mode by the medin-NC3 at the level of the set interval (can be set under alarm settings; see chapter 5.13) around the target oxygen concentration.
In FiO_2alarm thresholds manual mode, they are set via manual updating at the level of the set intervals around the oxygen target value active at this time. The thresholds that are active due to the current setting are displayed in the target oxygen concentration field as superscript and subscript numerals. Thus, for example, at a set target oxygen concentration of 30% and an alarm interval setting of ± 3%, the oxygen concentration low

alarm is triggered if the measured oxygen concentration is less than 27%, and the oxygen concentration high alarm is triggered if the measured oxygen concentration is greater than 33%.

When setting the alarm thresholds for CPAP pressure high (yellow), 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 patient.

If a very high flow is used due to significant leakage or if a very small prong is used, the Disconnection and CPAP pressure low alarms can be negatively affected by the pressure that develops in the generator as a result. In these cases, the threshold of the CPAP pressure low alarm must be set accordingly.

When using pushes which generate a CPAP pressure of 18 mbar or more and which are supplied by means of high push flows or a long patient tube containing a constriction, the Feed pressure high and CPAP pressure high (red) alarms may be generated during pushes. This combination generally also activates the text message Press alarm reset to restart flow, whereby the medin-NC3 stops the flow emission until the Alarm Reset button is pushed. After pressing the button, the reactivation of the flow takes approximately 10 seconds. To avoid this, the push flow must be decreased and constrictions in the tube system must be eliminated.

Alarm resetting:

Alarms are automatically canceled when the alarm condition is no longer present. However, the text message continues to be displayed for approx. one minute and is then deleted.

8.3 Emergency program

If high-priority alarms occur during operation of the medin-NC3 due to errors or supply breakdowns, the medin-NC3 tries to maintain operation as long as possible. In doing so, the normal function of the medin-NC3 is limited as follows:

- Instead of Leak-Assist or pushes, the medin-NC3 limits its operation to a normal basic CPAP; that is, the medin-NC3 does not emit any more manual pushes, apnea pushes and backup pushes. The Leak-Assist function also pauses.

- The mode change of the medin-NC3 is limited: The mode can be changed only if the emergency program has been triggered due to a Disconnection alarm. Otherwise the error must be corrected prior to changing the mode.

- The flow emitted by the medin-NC3 is limited to a maximum of 8 L/min. If a flow of ≤8 L/min was set previously, this setting will be maintained. Otherwise, only a flow of 8 L/min will be emitted instead of the flow set. After the emergency program, the set flow will again be automatically emitted in CPAP and Apnea CPAP mode.

- If the emergency program is triggered by a CPAP pressure high or Feed pressure high alarm, the medin- NC3 stops its flow. If the triggering high pressure decreases immediately (< 200 msec), the medin- NC3 restarts its flow after approximately 4 seconds. If it takes longer than this amount of time for the pressure to decrease, the medin-NC3 restarts its flow gradually, whereby it takes approximately 10 seconds for the medin-NC3 to once again emit its set flow. If the alarm was triggered by a blocked flow supply tube or a combination of several alarms of the CPAP pressure high or feed pressure high type, the flow is stopped for the time being and in addition to the Feed pressure high/CPAP pressure high alarm, a text message appears, informing the user that the flow will be restarted by pressing the Alarm Reset button.

- If the emergency program is caused by the breakdown of one of the supply gases, the medin-NC3 continues its basic CPAP operation with the remaining gas so that an oxygen concentration of 21% or 100% develops.

- If there is a serious error in the device, the flow is deactivated and the device must be restarted.

8.4 Indicator lights

The medin-NC3 contains LEDs with the following meanings:

Alarm LED:

Color	Meaning
Red	A highest priority alarm is present – immediate action by the operator is required.
Yellow	A medium or low priority alarm is present – prompt action is required by the operator.
White	Information signal: two short blinks indicate that a push was triggered. This signal can be deactivated in many situations by the operator (see chapter 5.13) as needed.

LED in the dial:

This white LED is activated if the operator can change or confirm settings by turning or pressing the dial. If this LED is deactivated, the dial does not have any function at the present moment.

LEDs for battery statuses:

These LEDs show the current charge status of the batteries as well as whether they are presently charged or depleted.

LED	Color(s)	Meaning
INT	Blue	Charge status is high enough to ensure operation.
	Yellow	Charge status has decreased such that the alarm "Connect power supply unit – Battery low" was triggered.
EXT	Blue	Charge status is high enough to ensure operation.
	Yellow	Charge status has decreased such that the alarm "External battery low" was triggered.
Charge	White	Blinking information signal indicates that the battery(-ies) is/are presently being charged. Continuously lit information signal indicates that the power supply unit is connected.

9. Cleaning and Maintenance

9.1 Warranty and extensions

Information on warranty can be found on our homepage www.medin-medical.com under the general terms and conditions.

In addition, medin offers two different warranty extensions:

- 3 years (REF 30-912) from the date of production
- 5 years (REF 30-913) from the date of production

These warranty expansions only relate to components with defects caused by production, wear parts, as well as software problems.
In addition, the customer must demonstrate that all required maintenance was performed.

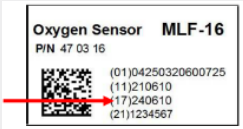
9.2 Cleaning

The surface of the medin-NC3 should be disinfected before first use. The medin-NC3 can be disinfected by using a slightly damp cloth in combination with a 70% isopropyl alcohol solution.
In this context slightly damp has the following meaning:
Take a wet cloth and wring it out. Then wrap a dry cloth over the wet cloth and wring out these two cloths together again.

9.3 Preventive maintenance

The medin-NC3 must undergo maintenance and a device check in accordance with the manufacturer's instructions in the service manual every 12 months. This must be carried out by trained specialists using appropriate measuring and testing equipment.

The following actions must be performed during this maintenance:

Action	Spare part number	Frequency of action
Replacement and cleaning of the prefilter	39-317	Replacement after one year at the latest. Regular inspection and cleaning necessary (every 2 months by tapping or knocking, dry condition)
Replacement and cleaning of the blower filter	30-203	Replacement after one year at the latest. Regular inspection and cleaning necessary (every 2 months by tapping or knocking, dry condition)
Test of the device function and sensor calibration (device test)	Not applicable	Every year and after each replacement
Replacement of the oxygen cell	MLF16	Every three years or if it has a remaining shelf life of less than one year (dynamic monitoring necessary)
	The expiration date can be found on the labeling of the oxygen cell beside the barcode (17): (YYMMDD) 	
Replacement of the 3V battery	39-102	At least every three years or as required
Replacement of the internal rechargeable battery	39-101	At least every three years or a as required
Replacement of the external rechargeable battery	30-150	At least every three years or a as required
Replacement of the blower holder foam	30-139	At least every three years or a as required
Internal tubing: blue tube, connection of the high-pressure oxygen inlet with gas mixing unit	30-206	The internal tubes must be replaced as required or every 3 years at the latest

Internal tubing: transparent tube, connection of gas mixing unit with outlet block	30-207	The internal tubes must be replaced as required or every 3 years at the latest
Internal tubing: blue blower coupling, connection of blower with gas mixing unit	30-204	The internal tubes must be replaced as required or every 3 years at the latest
Replacement of the pneumatic unit	30-200	After 7000 operating hours (dynamic monitoring of necessary)

If an error is detected during this function test and maintenance, the device must not be used or connected to a patient under any circumstances.

9.4 Power supply unit (cleaning, maintenance, repairs and modifications)

Cleaning:

Prior to cleaning, the power supply unit of the medin-NC3 must be disconnected from the mains. Do not clean with chemical cleaning agents.

Maintenance/repairs/modifications:

The power supply unit FSP090-RACM1 of the medin-NC3 is maintenance-free. It should not be opened. The power supply unit may only be repaired by authorized specialists.

10. Electromagnetic compatibility

The information in this section is provided in order to enable the operator of the medin-NC3 to decide whether the medin-NC3 is suitable for its electromagnetic environment.

The characteristics of the medin-NC3 determined by transmissions permit it to be used in industrial settings and hospitals (CISPR 11, class A). When used in a residential setting (for which class B is usually necessary, according to CISPR 11), this device may not offer appropriate protection from radiocommunication services. If necessary, the user must take corrective measures such as moving or reorienting the device.

Portable or mobile RF communications equipment (e.g. mobile phones) should not be used less than 30 cm near medin parts and cables associated with the medin-NC3. Failure to observe these instructions can lead to a reduction in the performance of the device.

Electromagnetic interference may affect the device and this can be manifested through alarms (for a detailed description, see chapter 8) or limitations in normal function of the medin-NC3 (see chapter 8.3).

10.1 Electromagnetic transmission

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The medin-NC3 is intended for use in the electromagnetic environment specified below. The customer or user of the medin-NC3, or the organization 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
according to CISPR11</td><td>Group 1</td><td>The medin-NC3 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
according to CISPR11</td><td>Class A</td><td rowspan="3">The medin-NC3 is intended for use in professional healthcare institutions (CISPR11, group 1, class A).</td></tr>
<tr><td>Harmonic emissions
according to IEC
61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
according to IEC
61000-3-3</td><td>Complies</td></tr>
</table>

10.2 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The medin-NC3 is intended for use in the electromagnetic environment specified below. The customer or user of the medin-NC3 or the organization responsible should assure that it is used in such an environment.			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	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 transients/bursts according to IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines 100 kHz repetition frequency	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations in supply voltage according to IEC 61000-4-11	0% UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	0% UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	Mains power quality should be that of a typical commercial or hospital environment. Thanks to its built-in battery, the medin-NC3 continues to operate during power mains interruptions. The medin-NC3 therefore does not need to be powered from an uninterruptible power supply or external battery.
	0% UT; 1 cycle and 70% UT, 25/30 cycles single-phase: at 0 degrees	0% UT; 1 cycle and 70% UT, 25/30 cycles single-phase: at 0 degrees	
Voltage interruptions according to IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	30 A/m	30 A/m	The strength of power-frequency magnetic fields should correspond to that of a typical commercial or hospital environment.
Note: UT is the a.c. supply voltage prior to application of the test level			

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF disturbances according to IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands a between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands a between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the medin-NC3, including cables, than the recommended separation distance of 30 cm.
Radiated RF according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the medin-NC3, including cables, than the recommended separation distance of 30 cm.
The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.			

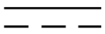
Determination of test values for electromagnetic immunity of casings against high-frequency, wireless communication equipment						
Test frequency MHz	Frequency band MHz	Radio-communication service	Modulation	Maxi-mum power W	Dis-tance m	Immunity test level V/m
385	380 to 390	TETRA 400	Puls-modulation 18 Hz	1,8	0,3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 k Hz Hub 1 kHz sine	2	0,3	28
710	704 to 787	LTE band 13, 17	Puls-modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Puls-modulation 18 Hz	2	0,3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Puls-modulation 217 Hz	2	0,3	28
1845						
1970						

2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Puls-modulation 217 Hz	2	0,3	28
5240	5100 to 5800	WLAN 802.11 a/n	Puls-modulation 217 Hz	0,2	0,3	9
5500						
5785						

11. Symbols

The symbols shown below are used as labels on the medin-NC3 or in these instructions for use:

Tabelle 9: Symbols

Symbol	Meaning	Symbol	Meaning
	CE mark		Manufacturer
	Medical device		Separate collection; Disposal in a municipal collection center
	Follow instructions for use		The instructions for use must be followed
	Article number		Protect from sunlight
	Indicates devices that contain RF transmitters or deliberately emit electromagnetic RF energy		Keep dry
	Serial number		Date of manufacture
	Temperature limit		Air humidity limit
	Air pressure limit		Direct current

	Alternating current		Use before
	Maintenance interval sticker (testing seal)		Approval mark from UL – valid in the USA and Canada
	Class II device		Attention – Follow instructions
	Recycling		Do not use if packaging is damaged
	Material identification – aluminum		Material identification – plastic, other

Other symbols:

Tabelle 10: Other symbols

Symbol	Meaning	Symbol	Meaning
	Acoustic signal paused for the time indicated. Alarm LED and alarm text continue to be displayed.		Acoustic signal paused for the time indicated. Alarm LED and alarm text continue to be displayed.
	Alarm confirmed for the time indicated. Alarm LED and alarm text continue to be displayed.		Settings
	Manual push trigger		Electrical connection to connect the medin-NC3 power supply unit
	Charge status of the rechargeable batteries		Power supply unit connected
	No external battery connected		Information signal for charge status
	Information signal for status of the internal battery		Information signal for status of the external battery
	Patient connection pressure meter line		Patient flow outlet
	Air gas inlet		Oxygen gas inlet

	USB interface		RS232 interface
	On/Off		Pull here
	Release the brakes before you move the trolley in order to avoid tipping.		Do not lean against the trolley.
	The trolley may tip if the floor has an incline of more than 5°.		Do not load the trolley with more than the permissible weight. The maximum permissible weight (safe working load) is 40 kg (88 lb).

12. Abbreviations

Tabelle 11: Abbreviations

Abbreviation	Meaning
% (Vol)	(Volume)percent
(m)bar	(Milli-)bar
(m)s	(Milli-)seconds
(n)CPAP	(nasal) continuous positive airway pressure
°C	Degrees Celsius
AC	Alternating current
BU	Backup
CPU	Central Processing Unit
DC	Direct current
DIN EN	German Institute for Standardization / European standard
DISS	Diameter Index Safety System
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
F_{insp}	Push flow
FiO_2	Oxygen concentration / inspiratory oxygen fraction
HHHFNC	Heated Humidified HighFlow Nasal Cannula

Hz	Hertz
ID	Inner diameter
IEC	International Electrotechnical Commission
kPa	Kilopascal
l/min	Liter per minute
MR	Magnetic resonance
NHFT	Nasal High Flow Therapy
NIPPV	Non-Invasive Positive Pressure Ventilation
NIST	Not Interchangeable Screw Thread
OD	Outer diameter
RF	Radio frequency, Hochfrequenz
R_{insp}	Push frequency (of number of pushes per minute emitted by the medin-NC3)
RR	Respiratory rate
TTN	Transient Tachypnea of the Newborn
USB	Universal serial bus
WEEE	Waste of Electrical and Electronic Equipment

More information: www.medin-medical.com

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