

Accompanying Letter

The purpose of this letter is to be an addendum to the medin-NC3 IFU for software version V1.30 with regards to IFU version REV07.

The sections that are revised with the new software and hardware are listed below.

Cover page

New Software version:

CPU V1.30 – Pneumatics A.14.00 – Display V120 – ATtiny V3.00 – Bootloader V2.00 – Touchboard V00.92.01

Chapter 2.2.1 – Functional principles

Update of 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 two hours without mains power thanks to its rechargeable battery.

Chapter 2.2.2 – Technical data

The following aspects have been updated:

Power supply	1x battery, 14.4 VDC, battery run time approx. 2 hours, rechargeable External power supply 100 to 240 V AC / 50 to 60 Hz
Data	Patient pressure (diagram and measurement) Trend (up to 28 days): - CPAP mode: CPAP/FiO2 - Apnea CPAP mode: CPAP/FiO2, RR/Push frequency - NIPPV mode: CPAP/FiO2, Rate/I:E - SNIPPV mode: CPAP/FiO2, Synch rate/Push frequency - High Flow mode: Flow/FiO2
External data	- USB/RS232 port, export of live and trend data - RS232 block protocol

Chapter 2.5 – Warnings and notes

The following warnings and notes have been added:

Warning: While the device is in operation on the patient, the medin-NC3 must not be subjected to any maintenance or repairs.
Warning: The use of a breathing system filter at the patient outlet of the device is mandatory. Either the medin-approved filter (Article U50) must be used, or an equivalent breathing system filter that is CE-marked (or otherwise approved according to applicable local medical device regulations) for use in respiratory circuits and has a proven filtration efficiency of $\geq 99.96\%$ for particles in the 0.1–0.3 μm range (tested according to ISO 23328-1 or an equivalent method).

Chapter 3 – Installation of the medin-NC3 – Conditions

The following subsections have been updated:

When first starting the medin-NC3 after transport or storage, please start the device with mains power connected. This will wake the battery up out of transport mode.

Chapter 3.2.2 – Battery operation

The medin-NC3 contains an internal battery. It can work on a fully charged battery for up to 2 hours.

Chapter 3.5 – HAMILTON Block protocol

The medin-NC3 can send data (mode settings, measured parameters and alarms) to external devices via the HAMILTON Block protocol and RS232. For more information, please read the service manual.

Chapter 4.1 – CPAP system components

The following additional CPAP system components is required:

- Breathing system filter at the patient outlet of the device

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

The following texts have been updated:

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. The internal 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 2 hours.

Connecting the patient tube circuit set:

A particle filter must be placed between the device and the circuit to prevent bi-directional contamination of the gas path.

Connecting the patient tube circuit set – High Flow:

A particle filter must be placed between the device and the circuit to prevent bi-directional contamination of the gas path.

Chapter 5 – Operation

The following parts of the below mentioned subsections have been updated:

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 four CPAP modes and one High Flow mode:

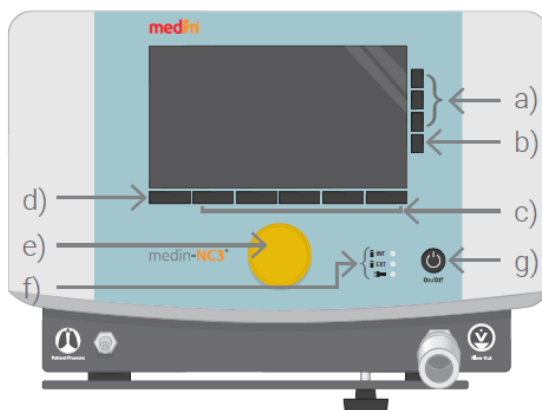
- SNIPPV: ventilation is provided here on two different flow and pressure levels synchronized with the patient's inhalation. The intensity of the second level as well as the changeover frequency and the time spent at the higher level can be adjusted by the user.

In addition, the Leak-Assist can additionally be switched on (see chapter 5.6).

The sixth 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.

Chapter 5.1 – Operator console

Figure 5-1



g) ON/OFF & Standby

- ON/OFF: (Figure 5-1–g) to switch the medin-NC3 on and off or to activate Standby

Chapter – 5.2 Display Screen

Figure 5-2



a) Flow & Leak Assist

Chapter 5.6 CPAP Mode

The setting, action and information options are:

- Flow (chapter 5.3) & Leak Assist (chapter 5.7)

Chapter 5.7 Leak-Assist

The leak assist can be started centrally using the Flow & Leak Assist Button (figure 5-2a). When started, the current CPAP average value is taken from the measurement line and set as the target pressure. Leak assist can also be stopped again using the Flow & Leak Assist Button (figure 5-2a).

The function ends either by direct switching off or changing into Standby. When changing modes, the leak assist and the fixed target pressure remain unchanged.

Chapter 5.8 – Apnea CPAP mode

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

- Flow (chapter 5.3) & Leak-Assist (chapter 5.7)

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 the 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

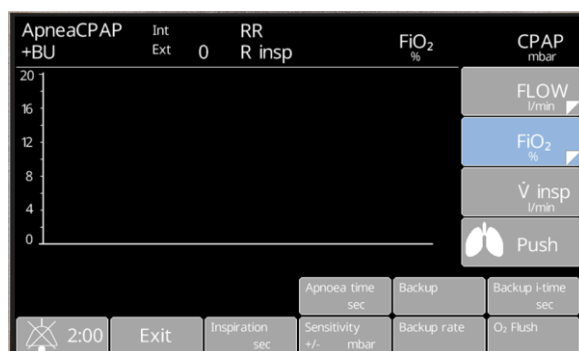


Figure 5-3: Sub-menu Apnea settings to change

- Inspiration time
- Apnea time
- Sensitivity
- Backup on/off
- Backup rate
- Level of the O₂ flush
- Backup i-time

Inspiration: Figure 5-3

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

Backup i-time: Figure 5-3

The setting in this field determines the duration of pushes automatically triggered in the event of an activated backup. It can be set to a time between 200 milliseconds and 3 seconds.

Chapter – 5.9 Backup function

The Backup function can be activated in the Apnea CPAP and the SNIPPV 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 Backup i-time. The greater the Backup i-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 when Leak Assist is OFF. If Leak Assist is activated the backup needs to be deactivated manually.

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.

Chapter 5.10 – NIPPV mode

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

- Flow (chapter 5.3) & Leak-Assist (chapter 5.7)

Figure 5-4



Figure 5-4: Submenu NIPPV settings to change the

- Inspiration time
- NIPPV rate
- Level of the O2 flush

Chapter 5.11 – SNIPPV mode

The difference between the SNIPPV mode and the NIPPV mode is that in this case, an automatic push is triggered synchronously with inspiration.

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

- Flow (chapter 5.3) & Leak-Assist (chapter 5.7)
- FiO₂ oxygen concentration (chapter 5.3) and start and discontinuation of the O₂ flush (chapter 5.4)
- Finsp additional flow to reach the upper flow level and manual PUSH (chapter 5.5)
- Alarm settings (chapter 5.14)
- Trend graphs (chapter 5.15)

There are special settings for the SNIPPV mode. These SNIPPV settings can be opened by pressing the p button in Figure 5-2, which offers the possibility of changing the 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 5-5

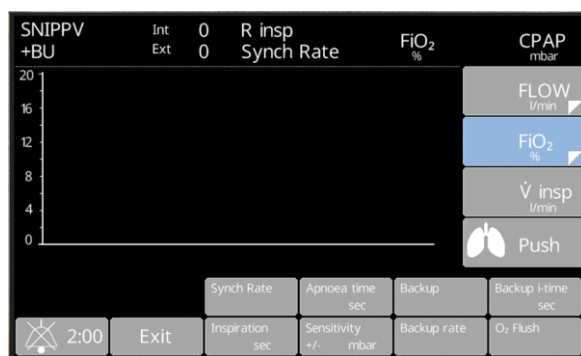


Figure 5-3: Sub-menu SNIPPV settings to change

- Synch Rate
- Inspiration time
- Apnea time
- Sensitivity
- Backup on/off
- Backup rate
- Level of the O₂ flush
- Backup i-time

Synch Rate: Figure 5-5

Maximum number of synchronized pushes during patient's inspiration. It depends on the set inspiration time.

Inspiration: Figure 5-5

The setting in this field determines both the duration of pushes automatically triggered in the event of apnea and the duration of pushes triggered manually. It can be set to a time between 200 milliseconds and 3 seconds. In addition, this setting also determines the duration of synchronized pushes.

Apnea time: Figure 5-5

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

Sensitivity in the SNIPPV mode determines the threshold pressure fluctuations in the CPAP signal at which the medin-NC3 should respond. The lower threshold of this sensitivity is used as a trigger for a push synchronized with respiration. If the CPAP pressure reading is below this threshold, the medin-NC3 triggers a push. The sensitivity setting is also used to identify apnea.

Consequently, it is important to select a value that is greater than the pressure fluctuations (e.g. due to condensate in the tube system) caused by the CPAP system and smaller than the pressure changes caused by respiration.

When selecting sensitivity, it is important to bear in mind that there may be a delay of up to 0.1 seconds between the time at which the pressure falls below the trigger threshold and the time when CPAP pressure is increased.

Backup on/off:

See figure 5-5 and see chapter 5.9.

Backup rate:

See figure 5-5 and see chapter 5.9.

Backup i-time:

See figure 5-5 and chapter 5.9.

Level of the O2 flush:

See figure 5-5 and see chapter 5.4

Display:

In SNIPPV mode, the operator sees the current push frequency (Rinsp - pushes per minute) in the bar at the top of the screen in addition to the information referred to in chapter 5.2. Additionally, the setting of the Synch Rate is displayed.

If the backup function is additionally activated, this is likewise displayed in the top left-hand area.

Chapter 5.12 – High Flow mode

New chapter number

Chapter 5.13 – Mode change

New chapter number

Chapter 5.14 – Alarm settings

New chapter number

Chapter 5.15 – Trend

New chapter number

Rinsp / Synch rate: In SNIPPV mode, the push frequency (number of pushes per minute) and the synch rate can also be shown. If backup is actively running, the line of the push frequency is shown in blue.

Chapter 5.16 – Standby

New chapter number

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 by pressing the ON/OFF button and confirming standby, 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.

Chapter 6.1 – Software switch-off

Update of chapter 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 “Exit” button and confirming this selection by pressing the dial.

By pressing the “Standby” button and confirming this selection by pressing the dial the Standby mode is activated, see chapter 5 – Standby.

Pressing the “Shutdown” 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 10 seconds, and the display returns to active operating mode.

Chapter 6.2 – Hardware switch-off

Update of chapter hardware switch-off:

There is no hardware switch-off available from software version:

CPU V1.30 – Pneumatics A.14.00 – Display V120 – ATtiny V3.00 – Bootloader V2.00 – Touchboard V00.92.01

Chapter 7.1 – Accessories

Additional accessory for Table 1:

Name	REF	Description
Pall Ultipor®50	U50	Proven efficiency of $\geq 99.96\%$ for particles in the 0.1–0.3 μm range (tested according to ISO 23328-1)

Chapter 8.1 – Error messages during system startup

The following error messages have been updated:

Table 3

Error message text	Possible cause	Correction
Battery needs replacing – device function in battery mode cannot be guaranteed. Device must be connected to mains for use!	The internal 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.

Chapter 8.2 – Error messages during operation

The following error messages have been updated:

Table 6

No external battery will be available for the medin-NC3. The alarms will therefore no longer be available.

Error message text	Priority	$\Delta t(1)$	Cause and device response	Correction
Remote communication timeout	Medium	2 sec OR 1 min	Alarm is triggered if confirmed delivery is active AND - no ACK is received for more than 2 seconds OR - 5 ACKs with the wrong block number are received	Check connection to RS232 OR restart with confirmed delivery

Chapter 8.4 – Indicator lights

No external battery will be available for the medin-NC3. The LEDs for battery status for the external battery will therefore no longer be available.

Chapter 9.3 – Preventive maintenance

No external battery will be available for the medin-NC3. No more preventive maintenance necessary. Additionally, the following component must be considered during preventive maintenance:

Action	Spare part number	Frequency of action
Replacement of the blower	30-202	After 20000 operating hours (dynamic monitoring of blower required)

Chapter 12 – Abbreviations

New abbreviations:

Abbreviations	Meaning
SNIPPV	Synchronized Non-Invasive Positive Pressure Ventilation