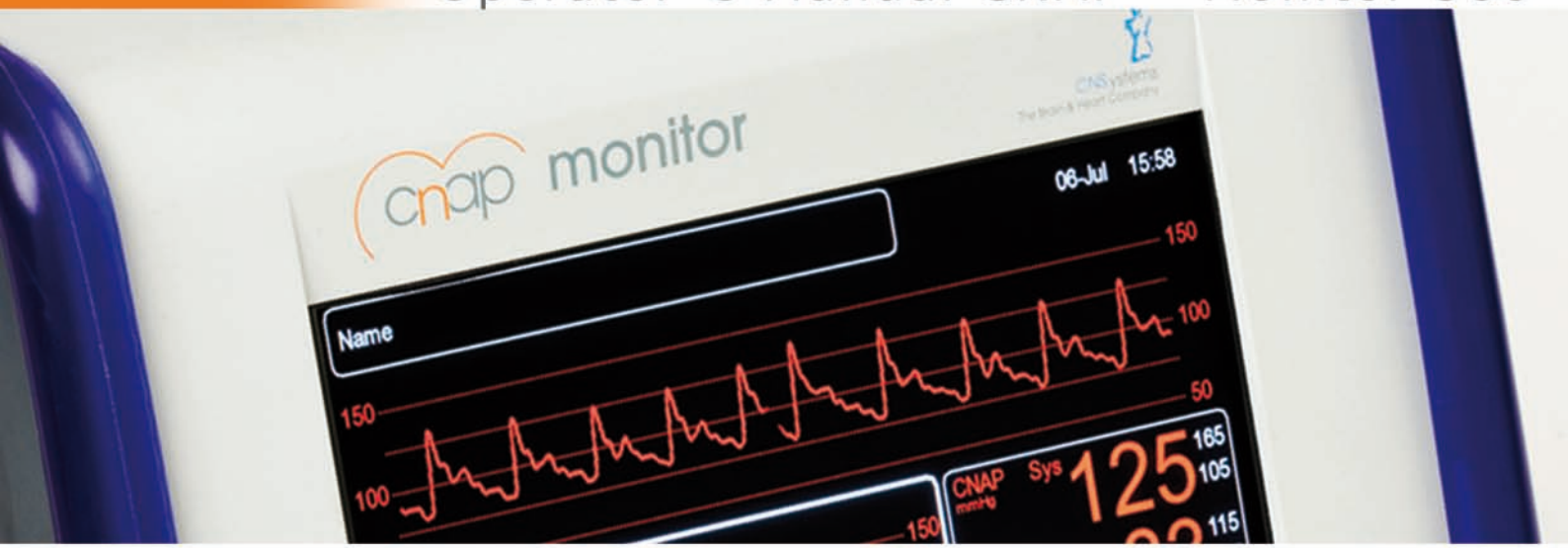
CNSystems
The Brain & Heart Company

Operator´s Manual CNAP™ Monitor 500



cnap
Heartware by CNSystems

The CNAP™ Monitor 500 meets the requirements of CE-mark

CE 0408

according to the European standard for medical devices 93/42/EWG

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1 About this manual

1.1 STOP, CAUTION, NOTES

In this manual the icons "STOP", "CAUTION", and "NOTE" are used to indicate matters of particular interest to keep in mind when operating the CNAP™ Monitor 500 or dealing with subjects.

STOP

The icon STOP indicates important security-relevant information:

STOP:
- Control the correct positioning of the CNAP™ double finger cuff. Make sure that the cuff is not positioned on the finger joints.

CAUTION

The icon CAUTION indicates important information referring to the correct utilization of the CNAP™ Monitor 500:

CAUTION:
- The life time cycle of a CNAP™ double finger cuff is 6 months if in constant use on subjects, or 12 months at the most.

NOTE

The icon NOTE indicates helpful information referring to the utilization of the CNAP™ Monitor 500 and its components:

NOTE:
- Use the graphics on the CNAP™ cuff controller to determine the correct finger cuff size (3 sizes).
- If the size of a subject's finger is between two finger cuff sizes, use the larger CNAP™ finger cuff for the measurement.

1.2 Cross references

Cross references refer to chapters where the operator can find additional information about specific topics. A cross reference includes the number and title of the chapter referred to (e.g. see chapter 2 – General information).

1.3 Settings

Settings available for menu entries are listed as minimum (increment) maximum:

Menu item	Description	Settings
Brightness	Regulates the brightness of the TFT-display	**20(20)100%, Auto**

2 General Information

2.1 Warnings

- For USA: Federal law restricts this device to sale by or on the order of a physician (or proper licensed practitioner).
- The CNAP™ Monitor 500 is not designed for intracardial use.
- Do not connect the device's pneumatic connectors to an intravascular system!
- Do not use the oscillometric cuff on subjects with vascular prostheses!
- Keep the CNAP™ Monitor 500 out of reach of children!
- The CNAP™ Monitor 500 is not fit for operation in potentially explosive surroundings, as may arise from usage or storage of flammable anaesthetics, skin detergents or skin disinfectants. Also, do not use the CNAP™ Monitor 500 in possibly combustible atmosphere (i.e., if the ambient air contains more than 25 % of oxygen or nitrous oxide gas).
- The operator has to prevent prolonged impairment of the subject's blood circulation during the measuring process by inspecting the concerned limbs regularly. This is particularly important in the case of continuous blood pressure measurement. During normal use, the pressure in the finger cuff will be the same as in the artery and therefore greater than normal venous pressure. As a result, depending on variables like skin temperature, thickness, subject age, perfusion or presenting state, venous congestion of the finger distal to the cuff may be observed which will quickly subside with the discontinuation of monitoring. Check the monitoring area frequently and discontinue the continuous blood pressure measurement immediately in case of any signs of total arterial compression or if the subject reports severe pain or discomfort.
- Do not use the compressed air supply valves with any devices of a third party manufacturer.
- Each device is designed for the concurrent measurement of only one subject/test subject at a time. Never measure two or more subjects at the same time applying only one device!
- Please pay attention to the precautions regarding electromagnetic compatibility (see chapter 14.3).
- In perioperative settings the CNAP™ Monitor 500 is not to be used without additional ECG monitoring.

2.2 Precautions

2.2.1 General precautions

- The CNAP™ Monitor 500 is a device of protection class II. The input ports of type BF are protected from defibrillation.
- According to the regulations of IEC 601-2-30/EN 60601-2-30, non-invasive blood pressure measurement is fit for use during electrosurgical surgery as well as during discharge of a cardiac defibrillator.
- The CNAP™ Monitor 500 meets the requirements of EN 60601-1-1 and can be used next to subjects without restrictions.
- While using the CNAP™ Monitor 500, avoid compressing the air hoses or reducing their diameter in any way (e.g. by bending the cables) as this could impair the quality of the measuring signals.
- No liquid must ingress the CNAP™ Monitor 500. In case this should happen, the instrument must not be started up again until after inspection by a qualified technician.
- Any chemicals needed for the use and maintenance of the device are only to be prepared and stored in correspondingly designated containers in order to prevent confusions entailing possible serious consequences.
- Medical devices like the CNAP™ Monitor 500 are to be operated only by accordingly trained persons who can guarantee proper handling of the device on the basis of their special training or their skills and practical experience.
- The operator has to be familiar with the operation of the CNAP™ Monitor 500. Before each measurement process, the operator is to check and control the due condition, operational reliability and functional safety of the device.

- Before connecting any cables to a subject, all connecting cables need to be visually inspected for signs of damage. Any faulty parts (e.g. cables or plugs) are to be replaced immediately. Only original CNSystems Medizintechnik AG accessories and replacement parts are to be used.
- Please pay close attention to the proper storage of the device: Do not bend the cables excessively or coil them up too tightly, as this might result in damaging cables and hoses. Any damaged cables or hoses are to be replaced immediately.
- Take care to ensure regular and sufficient air circulation around the device. Also take into consideration the necessary environmental conditions specified in this manual (see Appendix C – Technical specifications).
- A thorough examination of the device for its operational reliability is due on a regular basis (app. once every month).
- This manual is an integral part of the CNAP™ Monitor 500. By adhering to its safety measures and recommendations, the operator ensures the correct use and operation of the device as well as the operators' and the subjects' safety. Notes and precautions of particular importance are highlighted by the following symbols:  ,  ,  (see chapter 1.1).
- In order to ensure the device's faultless functioning, accuracy of measurement and immunity of interference as well as the subjects' safety, use only original CNSystems accessories and replacement parts. CNSystems will not warrant for faultless functioning and operation if third party manufacturer replacement parts and accessories are used.
- CNSystems Medizintechnik AG is not liable for any warranty claim for possible damages if parts of third party manufacturers are used.
- CNSystems warrants for faultless functioning, reliability and safety of this device on the condition that the procedures of installation, extensions and enhancements, new settings, alterations, maintenance and repair are exclusively carried out by CNSystems or an authorized company. In addition, the appliance and operation of the CNAP™ Monitor 500 must be in accordance with the instructions in this operator's manual.
- All copyrights concerning the devices, procedures, electronic circuits, software programmes and labels mentioned in this manual are reserved to CNSystems Medizintechnik AG.
- Never touch the AUX, ethernet and USB interface together with the subject.
- All devices that get connected to the AUX, ethernet and USB interfaces must meet EN 606950-1 standards.

2.2.2 Blood pressure

CNAP™:

- In rare cases it might happen that the device is unable to detect a continuous blood pressure signal. Usually, the middle and index fingers are best suited for applying the finger cuffs as their phalanges are longest. If it is not possible to obtain a continuous blood pressure signal, it is, in most cases, caused by a vasospasm. Warming the hand, for example in warm water, may solve the problem.
- If no continuous blood pressure waveform is displayed within a few minutes, it is probably due to an insufficient blood flow in the fingers. In this case try using another pair of fingers or the other hand. If this is not successful, please check if the labelling on the CNAP™-double finger cuff (symbol) is on the back of the hand.
- In case of a definite insufficiency of blood flow you have to abandon the continuous blood pressure measurement completely.
- To avoid mechanical damage to the finger cuffs, never start measuring without a finger in the blood pressure cuff. Also, remove all objects (e.g. rings) from the fingers before measuring.

NBP:

- Under the following conditions there might be a decrease in accuracy of the oscillometric blood pressure signal:
  - o weak pulses
  - o irregular pulses
  - o subject movement artifacts
  - o tremor artifacts
  - o respiratory artifacts

2.3 Disposal

Packing material

- The packing material of the CNAP™ Monitor 500 is to be disposed of according to the respective national regulations.

Device and accessories

- Dispose of the CNAP™ Monitor 500 and any accessories at the end of the products' lifecycles in accordance with respective national regulations or send the parts back to CNSystems Medizintechnik AG.

2.4 Declaration of intended use

The NIBP100D (CNAP™ Monitor 500) is intended for the monitoring of noninvasive continuous blood pressure and pulse rate.
The device displays the blood pressure waveform and generates trends, beat-to-beat numerics and alarms for the parameters blood pressure and pulse rate. The NIBP100D (CNAP™ Monitor 500) is to be used for adults and pediatric subjects from the age of 4 year and is to be operated by trained staff.

3 Introduction

3.1 General information

The CNAP™ Monitor 500 is suitable for monitoring in grown-up and pediatric subjects (from the age of 4 years). The CNAP™ Monitor 500 is in principle designed for being operated as a stand-alone device. If required, however, it can be integrated into other subject monitoring systems (BP Wave Out port for CNAP™ blood pressure waveform) and other devices (USB, Ethernet).

3.2 System components

The basic configuration of the monitor consists of the following components:

- CNAP™ monitor
- CNAP™ hardware (CNAP™ double finger cuffs, CNAP™ controller, CNAP™ cable)
- NBP cuff

3.2.1 CNAP™ Monitor 500 - BIOPAC Part Number: NIBP100D

① Carrying handle

② Display

③ Battery LED

④ Click-wheel control

⑤ Power LED

⑥ Control panel

Illustration 1: Front view

① CNAP™ cable port

② BP Wave Out: analog output port

③ NBP cuff connector

Illustration 2: Subject connectors

① Thermal printer

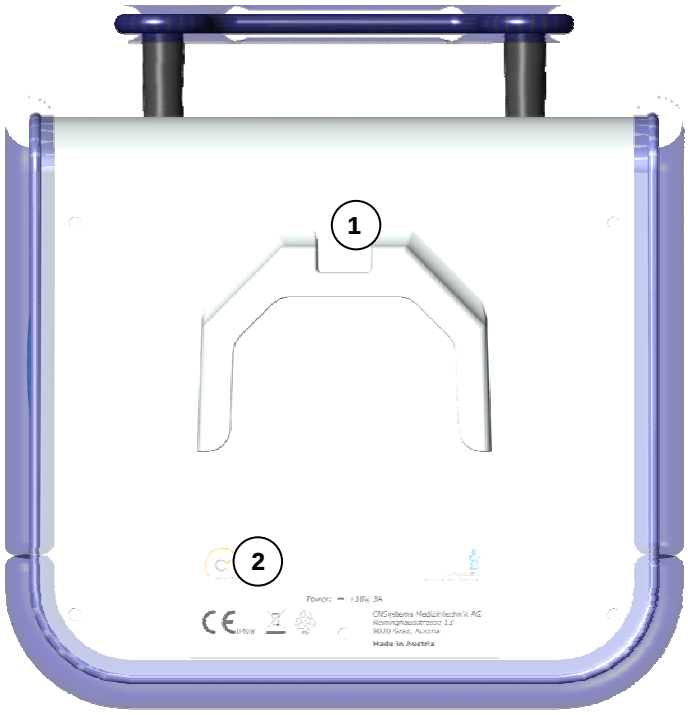
② Mains power port

③ USB connector: software updates

④ Ethernet connector

⑤ AUX: analog output port

Illustration 3: Printer, interface, power supply



① Holding device channel (optional)

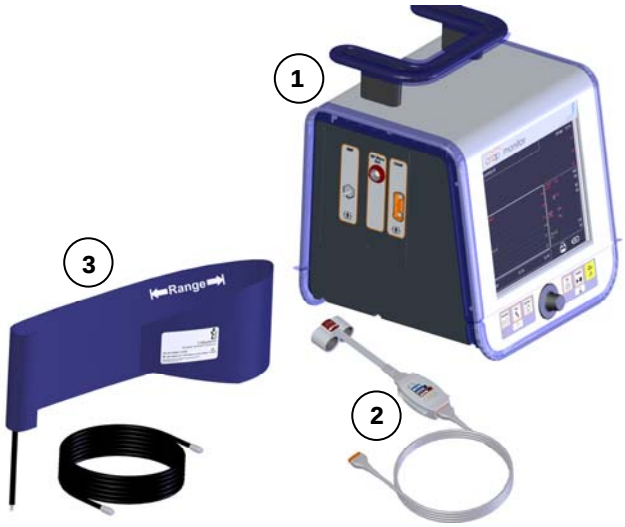
② Type plate

Illustration 4: Back view

CNAP™ Monitor 500 symbols
The following table describes all symbols in use on the CNAP™ Monitor 500 and its components:

No.	Symbol	Description
1		• Power On/Off (monitor on/off)
2		• Setup (monitor-, measurement-, service settings)
3		• Main Screen (return to main screen)
4		• Print
5		• Start/Stop (of a measurement)
6		• Alarm Pause/Off
7		• Input port of type BF is protected from defibrillation pulses
8		• Ethernet connector
9		• USB connector
10	⎓ +18V	• 18 V DC supply required
11	AUX	• Analog output port
12	 2007 01	• Production date
13	CE 0408	• Device meets the European standard for medical devices 93/42/EWG
14		• Recycle damaged sealed lead gel battery
15		• Caution: see accompanying documents
11		• Separate disposal of electric and electronic appliances

3.2.2 CNAP™ hardware



① CNAP™ monitor

② CNAP™ hardware

③ NBP hardware

Illustration 5: CNAP™ Monitor 500

3.2.2.1 CNAP™ double finger cuff

The CNAP™ double finger cuff comes in three sizes, each size being marked by a differently colored hood.

Size	Diameter (mm)	Colour
L	24 - 28	Dark red
M	18 - 24	Dark blue
S	10 - 18	Light blue

Illustration 6: CNAP™ finger cuff

3.2.3 CNAP™ controller

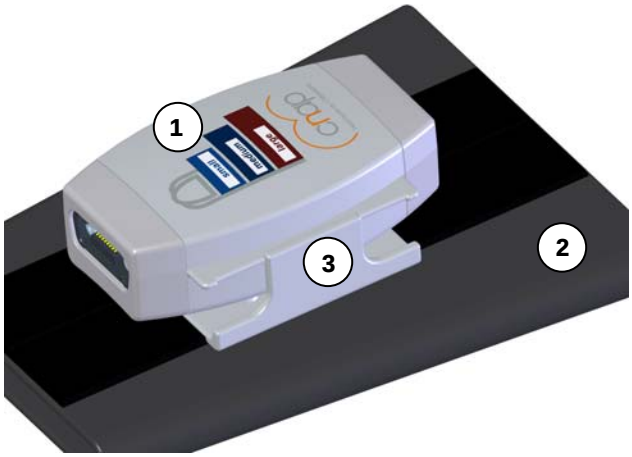


Illustration 7: CNAP™ controller

The CNAP™ controller connects the CNAP™ double finger cuff and the monitor via the CNAP™ cable. The jacks for the CNAP™ double finger cuff and the CNAP™ cable are adequately designed so as to avoid any confusion when putting the cables into the corresponding jacks.

- ① The graphics on the upside of the CNAP™ controller help choosing the right size of CNAP™ double finger cuff.
- ② The CNAP™ controller is fastened to the subject's lower arm by means of the CNAP™ forearm fixing cuff with Velcro fastener.
- ③ The fixture for CNAP™ controller connects the CNAP™ forearm fixing cuff mechanically to the CNAP™ controller.

3.2.3.1 CNAP™ cable

The CNAP™cable connects the monitor and the CNAP™ controller.

Illustration 8: CNAP™ cable

3.2.4 NBP cuff

The NBP cuff is intended for oscillometric blood pressure measurement and is available in four sizes:

Size	Arm circumference (cm)
Child	12 - 19
Small Adult	17 - 25
Adult	23 - 33
Large Adult	31 - 40

Illustration 9: NBP cuff

3.3 Power supply

The CNAP™ Monitor 500 is supplied with power by means of either mains operation via an external power adapter or by an integrated sealed lead gel battery. In case of power supply interruptions or even power outage, the monitor will automatically switch to battery operation.

CAUTION:
- Carefully read and keep in mind the precautions regarding power supply.

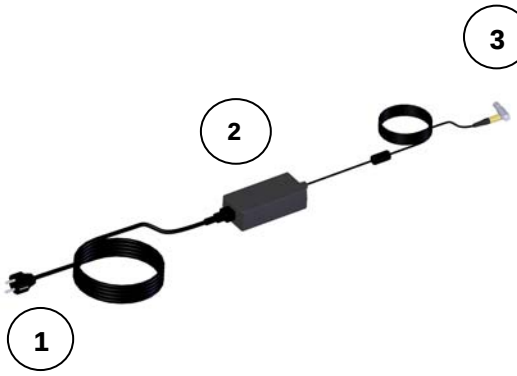
3.3.1 Mains operation

During mains operation the CNAP™ Monitor 500 is connected to a power adapter suited for a supply voltage of 100-240 VAC (± 10%) and a mains frequency of 50/60 Hz (see Appendix C – Technical specifications). When the CNAP™ Monitor 500 is connected to the mains power supply the integrated sealed lead gel battery is recharged as well. There is no time limit on the monitor being on mains operation.

The CNAP™ Monitor 500 can be connected to a supply network system according to CISPR 11.

NOTE:
- The battery recharge symbol  on the battery status of the TFT-display shows when the integrated battery is being recharged.
- The battery status indicates the present battery charge status when the monitor is running on battery (without mains power supply).

CAUTION:
- Do not use any power supply accessories but those intended and authorized by CNSystems Medizintechnik AG for utilization with the monitor!



① Power cord

② Power adapter

③ Cable connecting power adapter and monitor

Illustration 10: Power cord

3.3.2 Battery operation

The integrated sealed lead gel battery enables the CNAP™ Monitor 500 to operate on battery for up to 120 minutes, depending on the CNAP™ calibration intervals, printer use and brightness of display. If the monitor runs on battery, the battery charge status will be indicated on the TFT-display in 25 % steps. The battery charge status is also indicated via the battery LED on the front side of the monitor.

LED colour	Battery charge status
Green	Device runs on battery, battery charge status 100 – 25 %
Orange	Device runs on battery, battery charge status ≤ 25%
Red	Device runs on battery, automatic shut-down within 15 minutes

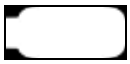
In addition, a low battery charge status (5 minutes of remaining operation time on battery) is indicated by a status report on the TFT-display (alarm window). For security reasons, the measurement is stopped and the monitor shut down automatically. While the CNAP™ Monitor 500 runs on mains power, the integrated sealed lead gel battery is automatically recharged.

STOP:
- Damaged or time-worn batteries might considerably reduce maximal operating time on battery. The accuracy of the device's battery charge status is only guaranteed when using undamaged batteries and under normal operation conditions.

CAUTION:
- High temperature might impair your battery performance. For optimal operability, charge and use the battery at temperatures < 35°C (95°F).
- When disposing of used batteries, adhere to your local waste disposal regulations.
- Do not use any batteries but those authorized by CNSystems. Use of non-authorized batteries might damage the monitor.
- Before turning on the appliance for the first time, be sure to charge the integrated sealed lead-gel battery for 4.5 hours.
- In order to guarantee safe operability of the CNAP™ Monitor 500, the battery has to be replaced after 24 months in the course of maintenance service.

NOTE:
- When switching from mains operation to battery operation, it can take up to a minute until the battery charge status is displayed.
- The thermal printer cannot be operated when the battery charge status is ≤ 25 %.

Battery status

Symbol	Battery charge status	Resulting measure
	• Battery charge status 100%	
	• Battery charge status 75%	
	• Battery charge status 50%	
	• Very low battery charge status (< 25%), battery operation still possible	• Printing deactivated • Current print job cancelled • Switching to mains operation via power adapter recommended • Technical alarm "Battery Low"
	• Battery depleted, operation possible for at least 15 minutes	• Immediately switch to mains operation via power adapter • Current measurement discontinued, monitor switched off automatically
	• Battery depleted, operation possible for 5 minutes at most; monitor is switched off	• Immediately switch to mains operation via power adapter • Technical Alarm „Battery Depleted“ • Current measurement discontinued, monitor switched off automatically
	• Battery malfunction, acoustic technical alarm signal	• Call a service technician
	• Battery is being recharged	

3.4 First steps

3.4.1 Power On / Off

The key **Power On/Off** is located in the left lower corner on the front side of the device.

Illustration 11: Front view

Switching on the monitor

The CNAP™ Monitor 500 is switched on by pressing the key **Power On/Off** located on the front side of the device for two seconds. While the CNAP™ Monitor 500 is booting up, device and software information is displayed on the screen. The green power LED indicates the operation status of the device. The operating system of the monitor initializes and performs a system self-test, then the main screen is displayed. In addition, the monitor also performs an automatic function test of its alarm system during starting-up time (see chapter 6 – Alarm system).

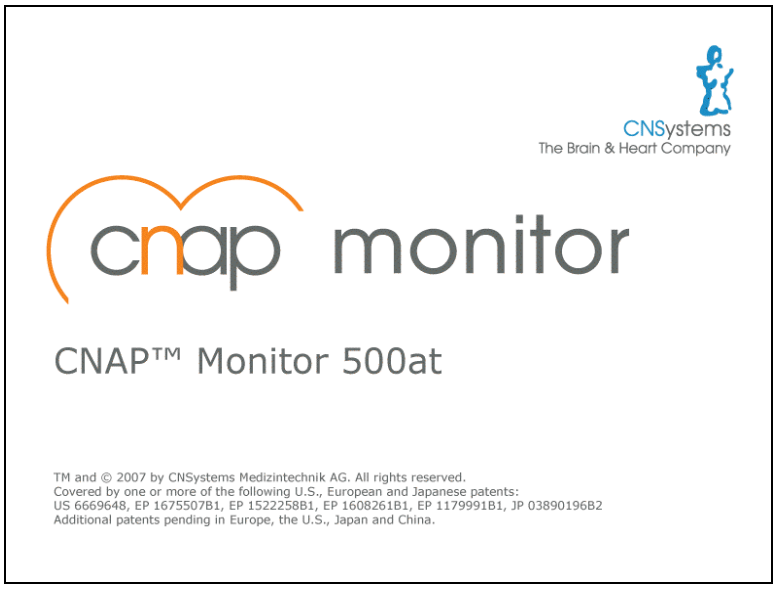


Illustration 12: Splash screen

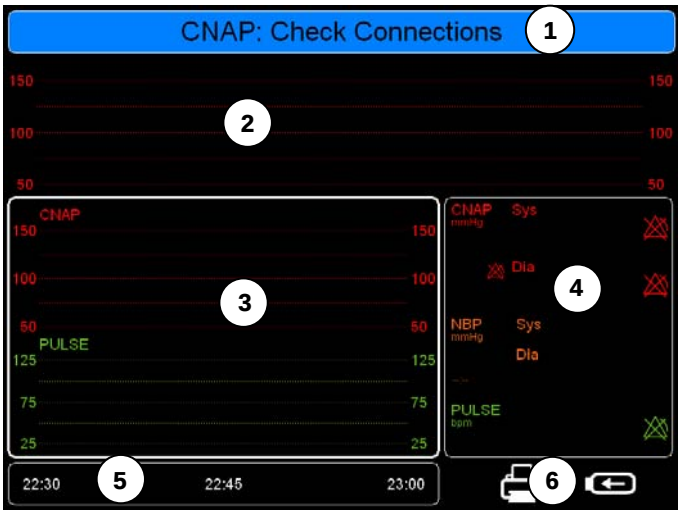
Switching off the monitor
The CNAP™ Monitor 500 is switched off by pressing the key **Power On/Off** for 2 seconds.

CAUTION:
- The key **Power On/Off** does not interrupt the monitor's power supply. In order to interrupt power supply, the operator needs to disconnect the power cord.

3.4.2 Access / return to Main Screen

After having started the monitor, the main screen appears, which displays all measuring parameters and signals and enables to access all menus.

Arrangement of the screen:



① Alarm frame

② CNAP™ signal view

③ Trend frame

④ Parameter frame

⑤ Navigation frame

⑥ Battery charge and printer status

Illustration 13: Main screen

NOTE:
- In order to return to the main screen from any submenu, just press the key **Main Screen** on the front of the monitor.

3.4.3 Fast access keys

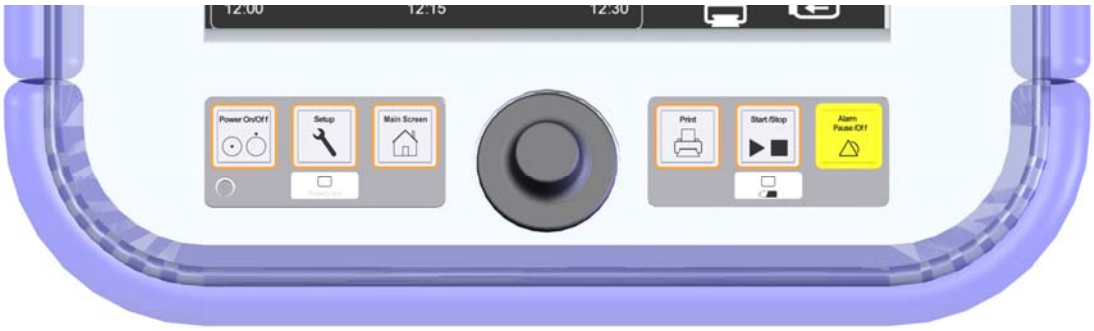


Illustration 14: Fast access keys

Membrane keys on the front side of the CNAP™ Monitor 500 enable fast access to important functions:

	Key	Function
1	**Power On/Off**	Switching on/off the monitor
2	**Setup**	Access to configuration menu
3	**Main Screen**	Return to main screen from any submenu
4	**Print**	Start/stop printing
5	**Start/Stop**	Start/stop measurement
6	**Alarm Pause/Off**	Alarm functions control: Press key Alarm Pause/Off once: set alarm reminder Press key Alarm Pause/Off twice: set alarm pause Press key Alarm Pause/Off three times: re-activate alarm function

CAUTION:

- The key **Start/Stop** controls all CNAP™ measurements. In case of an active NBP measurement, the operator first stops the NBP measurement by pressing the key **Start/Stop** once. Only pressing the key **Start/Stop** for a second time will stop the active CNAP™ measurement.

3.4.4 Menu navigation – click-wheel control

Illustration 15: Click-wheel control

The monitor's click-wheel control enables the operator to navigate through menus and setups and to access certain functions. Wheeling the control enables the operator to navigate through menus, while pressing on the control ("clicking") confirms the menu choice.

Selection and confirmation of functions/menu items:

1. Select the desired function/menu item by wheeling the control (green bar).
2. Pressing the click-wheel control then confirms the selection. Subsequently, either a drop-down list appears or the function is activated automatically (e.g. from o**n** to o**ff**).
3. Wheeling the click-wheel control – drop down menu.

3.4.5 Menu selection

Menus can be accessed to in 2 ways:

- Frequently used functions can be selected by the monitor's fast access keys (see chapter 3.4.3 – Fast access keys).
- Or, menus and their functions can be selected by means of the click-wheel control (see chapter 3.4.4 – Click-wheel control).

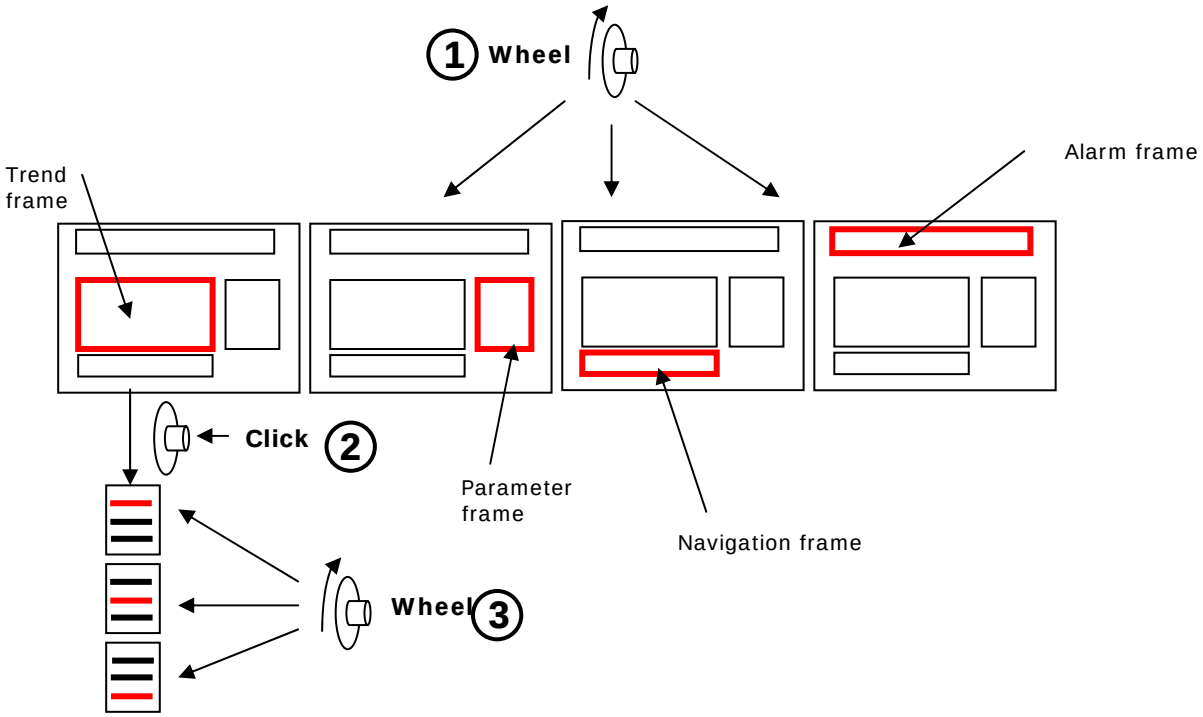


Illustration 16: Menu selection

3.5 Quick setup

Illustration 17: Subject setup

1. Starting up the CNAP™ Monitor 500:
Press **Power On/Off** and confirm the alarm self-test (test alarm signal) by pressing **Alarm Pause/Off**.

2. Subject setup:
   a. Choose the correct CNAP™ double finger cuff size by means of the graphic on the CNAP™ controller. If a subject's finger size is between two cuff sizes, choose the larger cuff.
   b. Assemble the CNAP™hardware by connecting the CNAP™ double finger cuff, the CNAP™ controller, the CNAP™ cable with the CNAP™ Monitor 500. All plugs and connectors are designed so as to making it impossible to switch them accidentally.
   c. Equip the subject with the CNAP™ hardware: The CNAP™ double finger cuff is placed on the proximal joints of the index and middle fingers. Ensure that the cuff cables run along the upper side of the subject's arm.
   d. Fasten the CNAP™ controller to the subject's forearm by means of the fixing cuff (with Velcro fastener) and make sure that the hand with the CNAP™ double finger cuff is placed at heart level (see illustration above).

3. Donning of the NBP cuff:
   a. Make sure that only NBP cuffs authorized by CNSystems are used and that you apply the correct size to the subject (**Child**, **Small Adult**, **Adult**, **Large Adult**).
   b. Place the blood pressure cuff on the subject's upper arm at the heart level. The marker on the NBP cuff should be directly above the brachial artery.
   c. Connect the NBP cuff with the NBP air connector on the left side of the CNAP™ Monitor 500.

4. Subject entry:
   a. Quick (default) entry of adult or pediatric subjects:
   The functions **New Patient: Adult Defaults** or **New Patient: Pediatric Defaults** can be selected in the setup window immediately; the measuring process can start immediately by pressing the Start/Stop key. Detailed subject data input can be performed at a later time.
   b. Use Current Subject Data:
   When selecting the option **Use Current Patient Data** all subject data remains unchanged; the measuring process can start immediately by pressing the Start/Stop key.

Start the CNAP™ measurement by pressing the key **Start/Stop** on the front side of the device.

4 Monitor configuration

4.1 Monitor settings

Menu item	Description	Settings
Brightness	Regulates the brightness of the TFT display	**20(20)100%, Auto**
Language	Language selection	**EN, DE, FR, ES, IT**
Date	Date setting	**yyyy/mm/dd** e.g. 1970/MAR/10
Time	Time setting	**hh:mm:ss**

NOTE:
- Monitor settings are saved automatically. Loss of settings only occurs in case of interruption of power supply (no mains operation, followed by battery depletion).

4.2 Measurement settings

Menu item	Description	Settings
CNAP: Cal Interval	Setting of intervals for automatic change of signal source in the CNAP™ double finger cuff	**5(5)60min**
NBP: Interval	Setting of time interval for automatic NBP measurements	**off, 5(5)30, 45, 60**
Audio Trend	Setting of source and volume of audio-trend	Submenu
Display Options	Setting of trend view: Display and scaling	Submenu
Print Options	Setting of print options: Delay time for snapshot prints, activation of **Print on Alarm** (see chapter 6.3)	Submenu
Parameter Averaging	Averaging of displayed numeric parameters	**off, 5, 10, 15 sec**

NOTE:
- Measurement settings are saved automatically for any current or future measurement.
- Loss of power supply (interruption of mains operation, followed by depletion of battery) entails the loss of measurement settings.

4.3 Service settings

NOTE:
- The service menu is divided into 2 layers which can be accessed by entering a password.
- You find the password for the user menu in the CNAP™ Monitor 500 "Service manual for users".
- You find the password for the service menu in the CNAP™ Monitor 500 "Instructions for service".

NOTE:

In this manual we distinguish between two groups of users: operators and users.
- Operator: a person actually working with this device (doctors, nurses, medical staff, ...)
- User: either the supervisor of the operator or technical employees responsible for general settings (nominated by the owner or chosen according to local regulations).

Menu item	Description	Settings
Restore Factory Settings	Restore factory settings	**yes, no**
Alarm defaults	Enables to adjust alarm limits, reminder, pause and volume for the subject categories (**Adult**, **Pediatric**) within the limits of factory settings. The operator/user can also restore factory settings.	Submenu
Log ...	Lists technical alarms by means of language-independend error codes	Submenu
Function Tests ...	Function tests of the modules IBP analog output, printer and CNAP™ / NBP	Submenu
Advanced ...	Software update	Submenu

4.4 BP Wave Out (subject monitors)

Similar to the BP waveform obtained from an invasive catheter (e.g. radial artery), the CNAP™ registered blood pressure waveform can be interfaced to subject monitors by means of the "BP Wave Out" output port located on the left side of the CNAP™ Monitor 500 (see chapter 3.2.1, illustration 2).

CAUTION:

- In order to connect the CNAP™ Monitor 500 to other subject monitors, the following 2 cables are needed:
  1. CNAP™ transducer cable: interfaces the CNAP™ blood pressure waveform from the CNAP™ Monitor 500 (BP Wave Out connector) - RJ11 6P4C connector is used (e.g. Abbott IBP catheter). The CNAP™ transducer cable is available from CNSystems Medizintechnik AG (refer to chapter 13.4 Connections).
  2. IBP interface cable: connects from the CNAP™ transducer cable to the IBP port of the subject monitor. As there is no cable generally authorized for all brands of subject monitors, we strongly recommend you contact BIOPAC.
     .

Unlike the analog output port (see chapter 4.5), the CNAP™ blood pressure waveform signal via the "BP Wave Out" is standardized. Its sensitivity depends on bridge voltage and amounts to 5 µV/V/mmHg.

If, for example, the supply voltage was 4 V, the sensitivity would be calculated as followed:

5 µV/V/mmHg x 4 V = 20 µV/mmHg.

In order to connect the CNAP™ Monitor 500 to a subject monitor you proceed as follows:

1. Connect the CNAP™ Monitor 500 and your subject monitor using a) the CNAP™ transducer cable and b) the IBP interface cable.

2. Activate “IBP: Zeroing“ from the parameters menu

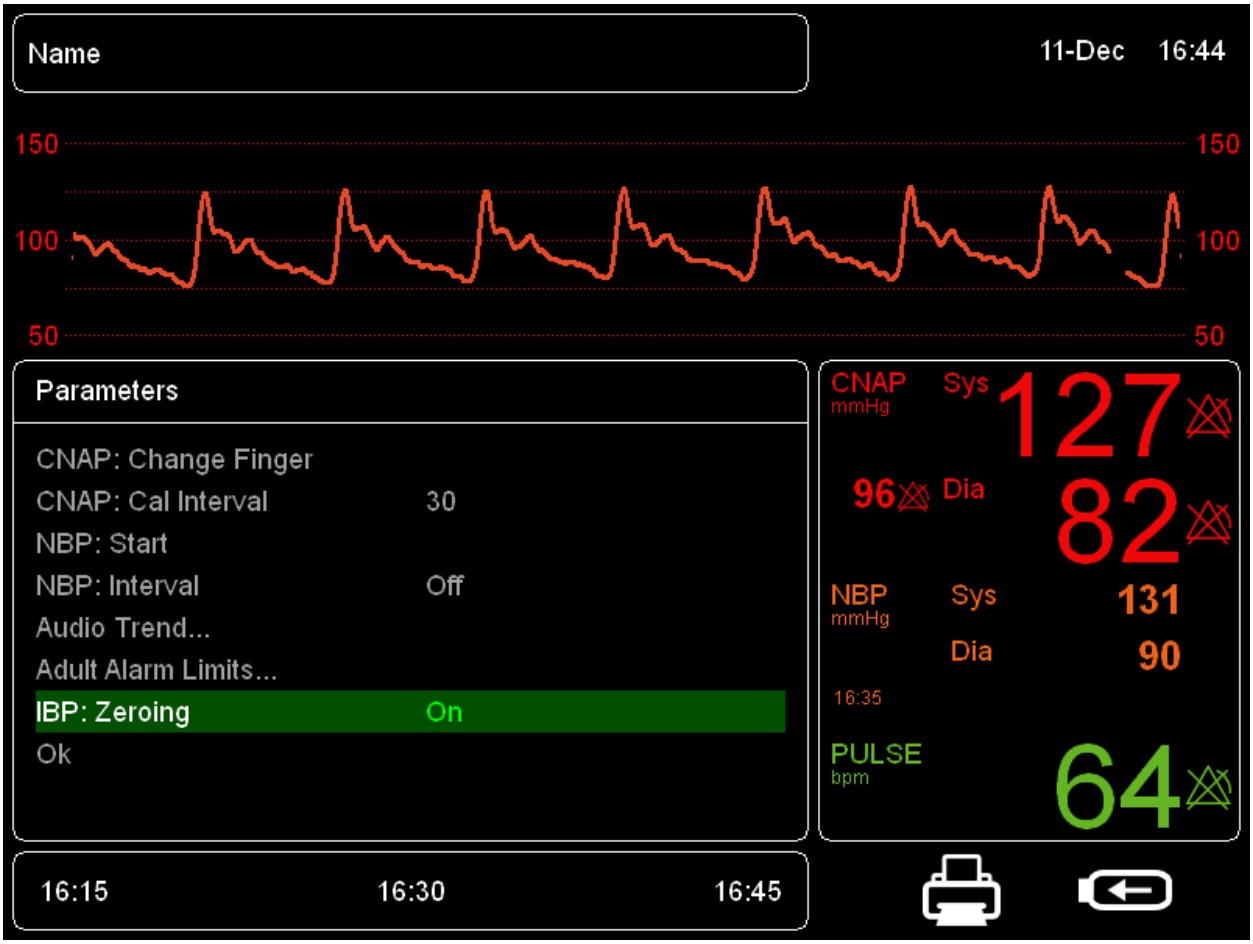


Illustration 18: Parameters menu: IBP: Zeroing

3. Select the pressure sensor on your subject monitor and start the zeroing process. Usually a subject monitor will report successful zeroing (must be within ± 32 mmHg), e.g by signalling "zero completed, offset is xx mmHg".

4. On the CNAP™ Monitor 500 deactivate “IBP: Zeroing“ by returning to "OFF" and return to the main menu. Now the CNAP™ blood pressure waveform will also be displayed on the subject monitor.

NOTE:
- If you don't deactivate "IBP: Zeroing" and leave it on "ON", the pressure signal on the subject monitor will display 0 mmHg.

CAUTION:
In order to ensure full accuracy of the CNAP™ blood pressure waveform and its derived blood pressure values to another subject monitor, do not forget to perform an IBP zeroing when connecting the two devices. In addition, the CNAP™ waveform is to be zeroed according to your institute's regulation (but at least once a day). Plus, IBP zeroing should be performed if there is any doubt as to the accuracy of obtained recordings.

NOTE:
- Blood pressure values obtained by means of CNAP™ and invasively obtained reference values may differ for the following reasons:
    1. Difference in beat detection
    2. Different settings for **Parameter-Averaging** (see chapter 4.2 – measurement settings).

CAUTION:
During the initialization of CNAP™ or when changing the signal source in CNAP™ double finger cuff a calibration waveform (rectangle 50 – 150 mmHg) is displayed on the main screen. The same waveform is transmitted to subject monitors via the "BP Wave Out" port. This may cause misinterpretation of blood pressure, if no blood pressure waveform is displayed on a subject monitor and if numerical values of blood pressure are falsely detected from the rectangle calibration signal. Thus always check the blood pressure waveform on the CNAP™ monitor for the calibration signal when receiving unphysiological readings of blood pressure on an external device (i.e. subject monitor).

4.5 Interfaces (optional)

On the right side of the CNAP™ Monitor 500 the following connectors can be found (see chapter 3.2.1, illustration 2):

4.5.1 AUX (analog output port)

The corrected CNAP™ blood pressure waveform is available from the device's analog output port (AUX).

	Channel 1	Channel 2
Voltage range	+-12 V	+-12 V
Reference	0 / 5 V (0 / 500 mmHg)	-5 / +5 V (0 / 500 mmHg)
Sensitivity	100 mmHg/V	50 mmHg/V
Samling frequency	100 Hz	100 Hz

4.5.2 Ethernet

The CNAP™ Monitor 500 may be connected to a PC via Ethernet standard in future at present the Ethernet port is deactivated.

4.5.3 USB

The USB port is reserved for service functions; e.g. software updates.

5 Management of subject data

Immediately after a subject has been connected to the CNAP™ Monitor 500 and the setup process has been performed correctly (see chapter 3.5 - Quick setup), the subject set-up window is opened automatically. Select the correct subject category and start the measurement process by pressing **Start / Stop**.

NOTE:

- With regard to the safe operation of the CNAP™ Monitor 500 as well as the unambiguous identification and classification of measurements and prints, the input of subject data is a vital prerequisite of essential importance. Entering the respective subject category, for instance, results in the subsequent adjustment of alarm limits as well as of the NBP cuff inflation pressure.

5.1 Input of subject data

Subject data is entered into the subject set-up window appearing on the main screen immediately after subject setup.

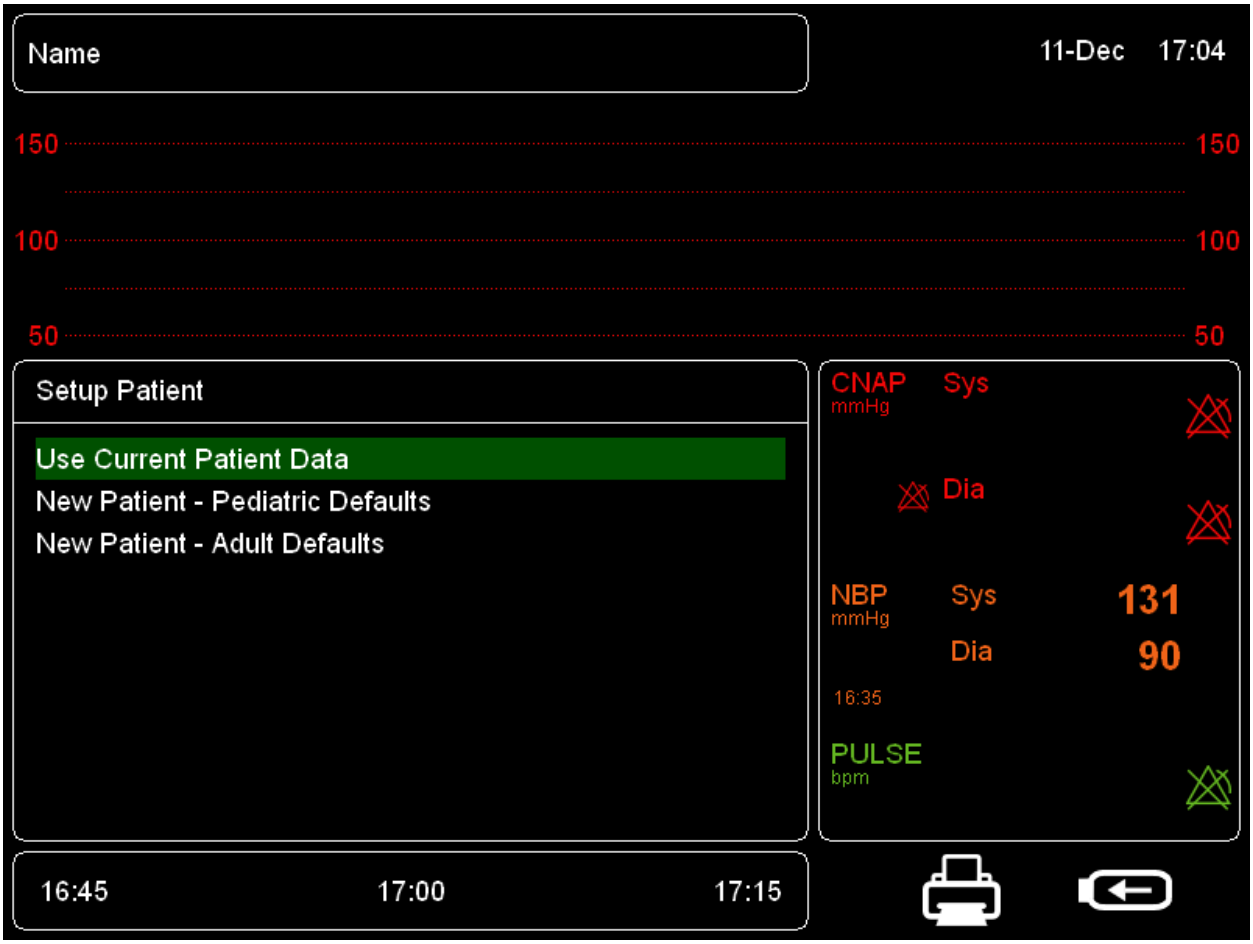


Illustration 19: Subject setup window / subject frame

There are 2 ways of entering subject data before starting a measurement:

a. Quick (default) entry of adult or pediatric subjects:
   The functions **New Patient: Adult Defaults** or **New Patient: Pediatric Defaults** automatically sets the respective subject category; the measuring process can start immediately by pressing the **Start/Stop** key. Detailed subject data input can be performed at a later time via **Alarm frame** and the **Patient menu.**

b. Detailed subject data entry and input:
   By selecting the option **New Patient,** the **Patient menu** (see chapter 5.2 – Editing of subject data) appears immediately.

NOTE:
- Default entry should only be resorted if there is not enough time or not all the necessary information available for a complete subject data input. Lacking subject data must, however, be entered at a later time, or the prints will show no subject data.

5.2 Editing of Subject data

At any given time during a measurement, you can enter subject data by using the click-wheel control to select the **Patient frame** on the main screen and to open the **Patient menu**.

Menu item	Description	Settings
Name	surname and first name (max. 20 characters)	Keyboard
ID#	file number, e.g. 12345678 (max. 15 characters)	Keyboard
Gender	gender	**NA, M, F**
Birth Date	birth date, e.g. 1970-MAR-10	YYYY-MMM-DD
Category	category: ADULT > 14 years PEDIATRIC 4 – 14 years	**Pediatric, Adult**
Discharge	discharge information	**yes, no**
OK		

STOP:
- **Subject category:** Entering the correct subject category is an indispensal prerequisite before starting a measurement process. Be sure to select the correct subject category as this determines the adjustment of alarm limits and the inflation pressure of the NBP cuff.

NOTE:
- During a measurement the **Patient menu** can be selected via **Alarm frame** and the menu item **Patient data**.

5.3 Discharge

Subject data needs to be deleted even when only a default entry has been performed before.

The function **Discharge**

- deletes all information in the **Patient menu**
- deletes all trends of data from the monitor
- deletes all entries of the **Alarm history**

Subject data can be deleted in 2 ways:

a) Patient menu:
Open the **Patient menu** by using the click-wheel contol to select the **Alarm frame** on the main screen. Select **Discharge** and confirm your menu entry in the input window.

b) Setup of a new subject:
Immediately after a new subject has been set up with the CNAP™ double finger cuff the subject set-up window appears on the **Main screen**. Select **New Patient–Pediatric Defaults** or **New Patient–Adult Defaults** and confirm your choice in the input window. This will result in the deletion of any previous data.

NOTE:
- In order to avoid loss of data, all data and entries must be printed before discharging a subject. Deleted data cannot be retrieved.

6 Alarm system

The alarm system of the CNAP™ Monitor 500 distinguishes between two alarm levels: physiological alarms (yellow) and technical malfunction alarms (white).

- MEDIUM PRIORITY: **

Yellow alarms are physiological alarms of medium priority (e.g. exceeding the upper or falling below the lower limit for systolic blood pressure).

- LOW PRIORITY: *

Technical malfunction alarms indicate that the CNAP™ Monitor 500 is unable to take a measurement or to reliably detect possible alarm conditions. Instead of numeric values the parameter frame displays "***", accompanied by an acoustic signal which has to be confirmed by the operator (see chapter 6.3.1 – Acknowledgement of alarms). Depending on the indicated malfunction the operator may have to take a measure (e.g. replace a defective CNAP™ double finger cuff).

NOTE:
- The CNAP™ Monitor 500 has no other than the mentioned 2 alarm levels: physiological alarms (yellow) and technical malfunction alarms (white).

STOP:
If several alarms are activated at the same time
- the alarm signals will be displayed alternately in intervals of 5 seconds in the alarm frame
- physiological alarms and technical malfunction alarms will be displayed one after the other in their order of appearance
- the physiological alarm with the highest priority is accompanied by an acoustic signal
- new alarms and technical malfunction alarms are displayed immediately

6.1 Visual alarm signals

Alarm signals are displayed visually in the **Alarm frame** and the **Parameter frame** directly on the **Main screen**.

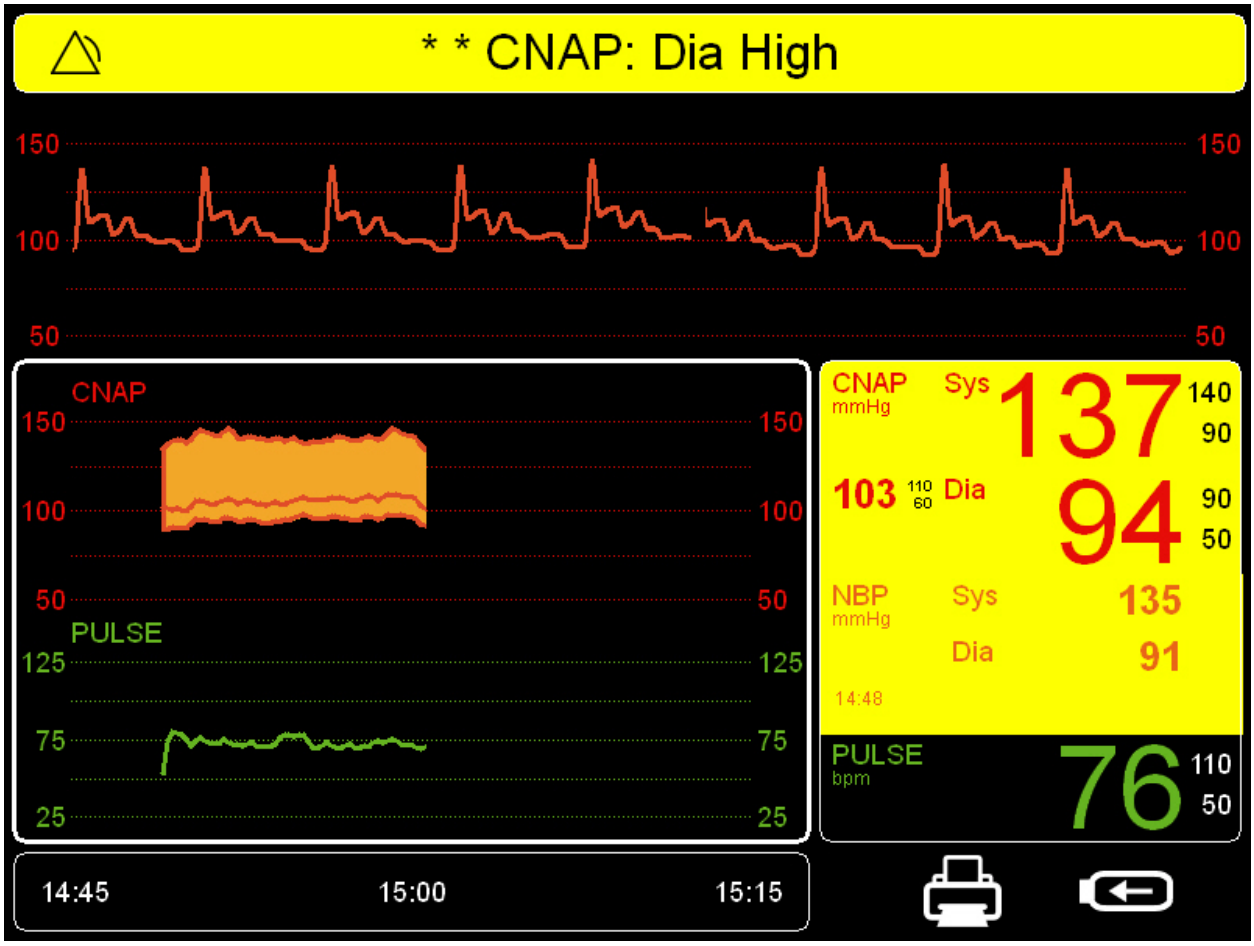


Illustration 20: Visual alarm signals

Alarm frame:

- Background color: YELLOW - Physiological alarms (medium priority)
  WHITE - Technical malfunction alarms (low priority)
  BLUE - Status messages
- Alarm priority: ** - medium priority
  * - low priority
- Alarm system status: - Alarm
  - Alarms Paused
  - Alarms Off
  - Audio Pause
  - Audio Off

- Alarm report: a text with an alarm message describing the cause for the alarm signal appears in the **Alarm frame.**
- Blinking **Alarm frame** for physiological alarms.

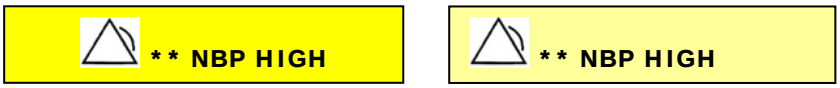


Illustration 21: Alarm frame - alarm conditions

Parameter frame:

- Background color: YELLOW – Physiological alarms (medium priority)
  WHITE - Technical malfunction alarms (low priority)
  BLUE - status messages

- Blinking **Parameter frame**
- Numeric values: unchanged during physiological alarms, blanked during technical malfunction alarms "***"

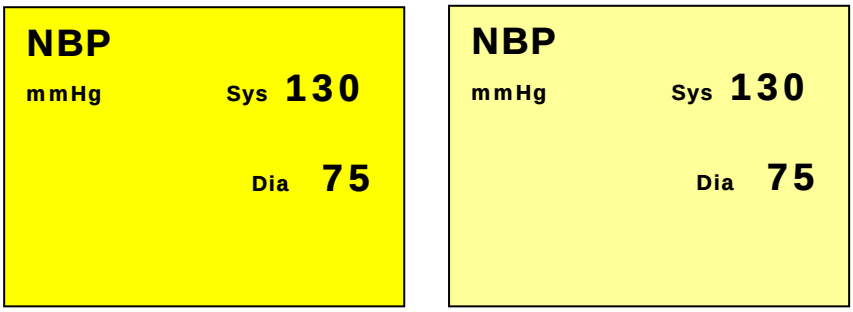


Illustration 22: Parameter frame – alarm conditions

6.2 Acoustic alarm signals

In accordance with the regulations of EN 60601-1-8, the CNAP™ Monitor 500 produces acoustic alarm signals. The differently coded alarm signals are repeated until acknowledged by pressing the key **Alarm Pause /Off.**

NOTE:
Repetition rate for acoustic alarm signals is:
- 5 seconds for physiological alarms
- 18 seconds for technical malfunction alarms.

STOP:
- Do not rely solely on the acoustic alarm signals! Especially if the alarm volume is set low, alarms might be missed which could constitute a possible danger for subjects!

The alarm signal volume is individually adjustable. Factory setting is 80 % of maximum volume and can be adjusted from 20 to 100%. Maximum sound pressure amounts to 93 dB at a distance of 1 meter from the CNAP™ Monitor 500, whereas minimum sound pressure amounts to 60 dB at a distance of 1 meter from the device.

6.3 Alarm system control

6.3.1 Acknowledgement of alarms – ”Audio Off”, ”Audio Pause”

In order to acknowledge all activated alarms (physiological and technical malfunction reports) press **Alarm Pause / Off** once.

Depending on the respective settings of the **Alarm Reminder** feature, the status message ”**Audio Off**“ or “**Audio Pause**“ is displayed.

ALARM REMINDER: If the alarm reminder is activated in the monitor setup, a repeated acoustic signal reminds the operator of alarm conditions that continue to exist after acknowledgement of the alarm signal by the operator. This acoustic reminder may be repeated for a limited or unlimited amount of time.

Menu item	Description	Settings
Alarm Reminder	• Setting of alarm reminder	**off, 1 min, 2 min, 3min**

NOTE:
- During measurements an alarm reminder setting may be entered by using the click-wheel control to open the **Parameter frame** and then to select the menu entry **Alarms Pediatric** or **Adult Alarm Limits**.
- The factory setting of the alarm reminder may be restored by using the click-wheel contro located in the Service Menu.

6.3.2 Pausing /switching off alarms – ”Alarms Paused”, ”Alarms Off”

In order to temporarily deactivate (= pause) physiological alarms, press **Alarm Pause /Off** twice. Temporarily no physiological alarms will be activated, e.g. when a subject is being relocated. Depending on the **Audio Pause** settings either the status “**Alarms Off**“ or “**Alarms Paused**“ is displayed.

“ALARM PAUSE“: Depending on the monitor configuration, the alarms may be paused for a limited or unlimited time. Hence selecting an alarm pause of an unlimited amount of time equals switching off the alarm signal altogether.

Menu item	Description	Settings
Alarm Pause	• Setting of alarm pause	**1 min, 2 min, 3 min, no time out**

NOTE:
- Pausing alarms is only possible if no physiological alarms are activated.
- Technical malfunction alarms or malfunction reports are displayed even when the function "Alarm Pause" has been activated.

NOTE:

- During temporary alarm pauses the remaining pause time is displayed in the **Alarm frame**.
- In case of a temporally unlimited alarm pause the **Alarm frame** displays the message "**Alarm Off**".

6.3.3 Reactivation of paused alarms - "Alarms Off"

In order to reactivate alarms having been paused for an unlimited amount of time, press **Alarm Pause /Off** three times.

6.4 Alarm limits

Alarm limits set the alarm conditions for physiologigal alarm signals.

6.4.1 Display of individual alarm limits

The preset alarm limits (upper, lower) of every measuring parameter are displayed beside the respective measured value in the **Parameter frame** of the main screen. If a parameter's alarm function is deactivated, the symbol for **Alarm off** will appear beside the measured value in the **Parameter frame** (refer to chapter 6.1 – Visual alarm signals).

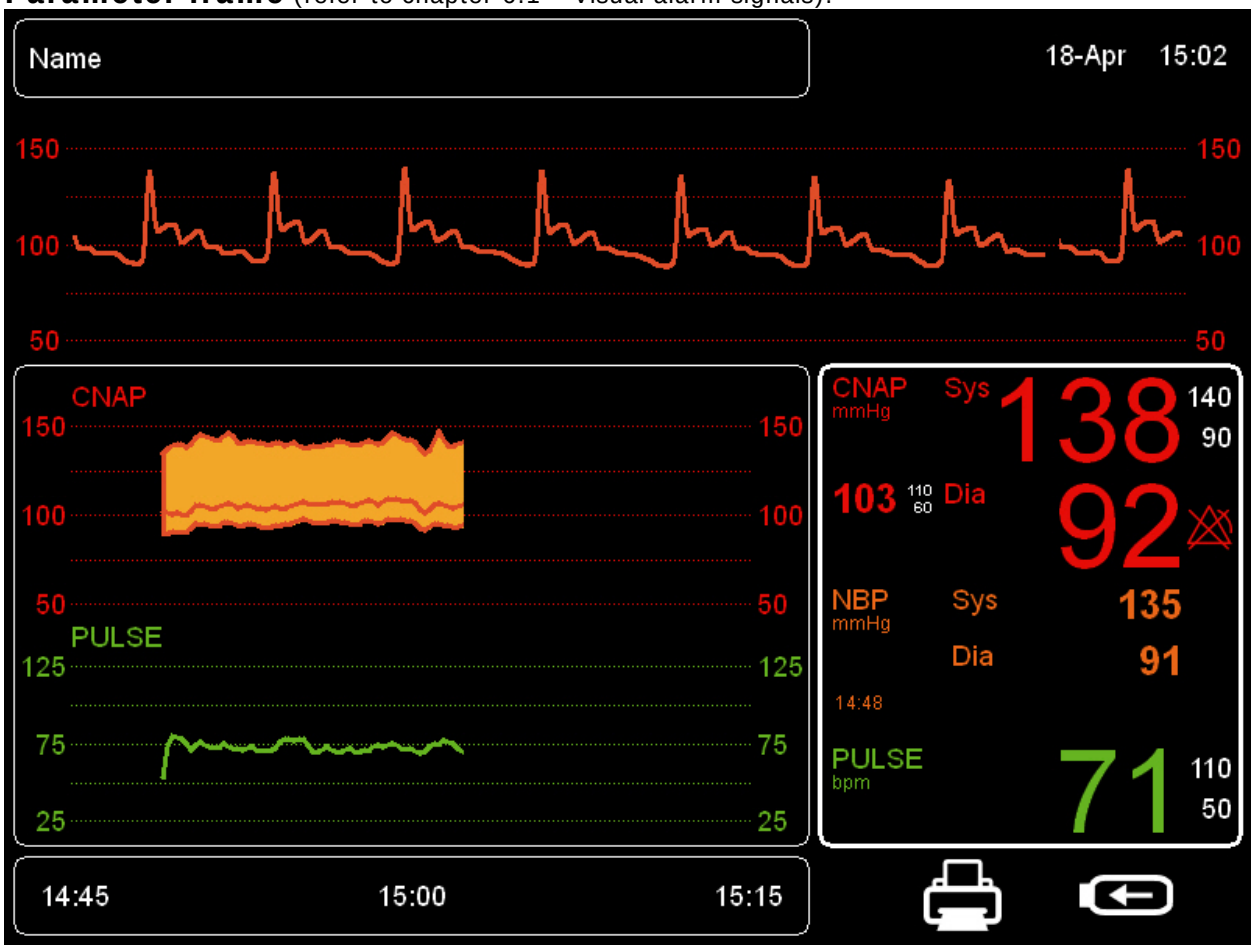


Illustration 23: Parameter frame - alarm limits

In order to view and edit all set alarm limits, use the click-wheel control to select the **Parameter frame** and then to open the **Alarm menu** (see chapter 6.4.2 – Alarm setup).

6.4.2 Alarm setup

The **Alarms Menu** enables the operator to adjust the alarm functions of all parameters.

Menu item	Description	Settings
Auto Limits	Automatic setting of alarm limits for activated alarms	**narrow, wide, Cancel, off**
Sys	Alarm limits for systolic blood pressure	**on, off; lower, upper;**
Mean	Alarm limits for mean blood pressure	**on, off; lower, upper;**
Dia	Alarm limits for diastolic blood pressure	**on, off; lower, upper;**
Pulse	Alarm limits for pulse rate	**on, off; lower, upper;**
Alarm Volume	Volume settings for alarms, (20 – 100 %)	**20(20)100%**
Alarm Reminder	Function to set alarm reminders (see chapter 6.3 – acknowledgement of alarms - "Audio Off, Audio Pause"	**off, 1 min, 2 min, 3min**
Alarm Pause	Pausing of alarms (see chapter 6.3.2 - Pausing /switching off alarms – "Alarms Paused", "Alarms Off")	**1 min, 2 min, 3 min, no timeout**

NOTE:
- The defined safe limits configurated in the factory settings never leave the physiological area.

SYS, MEAN, DIA, PULSE: Setting of alarm function for every single parameter:

- on, off
- Lower: lower limit
- Upper: upper limit
- Current: Display of current numeric value of a given vital parameter.

STOP:
- The CNAP™ Monitor 500 determines the alarm limits on the basis of the entered category. Thus, be sure to enter the correct subject category before starting a measurement.
- The operator can adjust alarm limits within the **Alarm defaults menu**. Alarm limit settings for the subject categories **Adult** and **Pediatric** are to be performed separately. The respective menu is located in a password protected area of the CNAP™ Monitor 500, which can be accessed via the **Service menu**. The necessary password as well as further information about configurating individual user settings or restoring factory settings can be found in the "Service manual for users"of the CNAP™ Monitor 500.

STOP:
- The parallel use of different alarm settings for the same device (or similar instruments) used in different areas (e.g. in the intensive care unit or in cardiac surgery) might constitute a possible danger for subjects.

6.4.3 Auto limits

By means of the function **Auto limits** the operator is able to adjust alarm limits to a specific subject. Therefore it is necessary to wait for the monitor to display physiological signals of a measurement in order to be able to activate **Auto limits**. Later, if subject data is deleted or new subject data is entered, the function **Auto limits** will be deactivated automatically.
Using this function leads to the alarm limits of activated alarms being adjusted to the currently measured vital parameters. The alarm limits will then be set within a predefined safety range based on the measured individual parameters.

- Narrow: currently measured value Sys/Mean/Dia/Pulse ± 20mmHg
- Wide: currently measured value Sys/Mean/Dia/Pulse ± 30mmHg
- Cancel: return to **Alarm limits** menu without changes
- Off: Alarm limits are restored to user settings (**Alarm defaults**).

Alarm limits set by means of **Auto limits** are based on the patient's parameters measured at the time of function activation.

6.4.4 Alarm limits – Factory settings

The CNAP™ Monitor 500 has been preset to the following factory settings and default settings for alarm limits, which apply to both CNAP™ and NBP.

- Alarm limits (ADULT):

	Lower limits			Upper limits		
Parameter	Lower limits	Defaults	Upper limits	Lower limits	Defaults	Upper limits
sBP [mmHg]	40	90	255	45	140	260
mBP [mmHg]	35	60	250	40	110	255
dBP [mmHg]	30	50	245	35	90	250
Pulse [bpm]	30	50	195	35	110	200

- Alarm limits (PEDIATRIC):

	Lower limit			Upper limit		
Parameter	Lower limist	Defaults	Upper limits	Lower limits	Defaults	Upper limits
sBP [mmHg]	40	70	175	45	120	180
mBP [mmHg]	35	50	170	40	90	175
dBP [mmHg]	30	40	165	35	70	170
Pulse [bpm]	30	75	195	35	130	200

NOTE:

- The operator can adjust alarm limits within the **Alarm defaults menu**. Alarm limit settings for the patient categories **Adult** and **Pediatric** are to be performed separately. The respective menu is located in a password protected area of the CNAP™ Monitor 500 which can be accessed via the **Service menu**. The necessary password as well as further information about configurating individual user settings or restoring factory settings can be found in the “Service manual for users“ of the CNAP™ Monitor 500.
- The user can restore all adjusted **Alarm limits** back to factory settings. To do this the user has to select the function **Restore factory settings** which can be accessed via the password-protected **Service menu** (see "Service manual for users").

STOP:

- Setting the **Alarm limits** to extreme and thus unsuitable values results in the alarm system becoming useless and obsolete!

6.5 Alarm history

The **Alarm history** is displayed directly in the main frame and is a list of up to 100 last released alarms and malfunction reports. In order to view the **Alarm history**, use the click-wheel control to first select **Trend frame** and then to open **Alarm history**. Each report of the alarm history includes the following information:

- Date
- Time

Priority: ** (MEDIUM)

- Alarm message

All entries in the **Alarm history** will be deleted either if the CNAP™ Monitor 500 is switched off or if there is a total loss of power supply (e.g. empty battery + no mains power supply).

6.6 Alarm system function tests

When the CNAP™ Monitor 500 is switched on, the alarm system automatically performs a self test in the course of which the operator has to control the functional reliabilty of all acoustic and visual alarm signals.

STOP:
The automatic device self test causes the system to release a technical alarm signal of LOW priority (white alarm), the alarm message reading "**Alarm Self-Test**". Control the functional reliablity of the alarm system during start-up and confirm it by pressing **Alarm Pause/Off**:

- Visual alarm signal:  * Alarm message: **Alarm Self-Test**
- Acoustic alarm signal: LOW PRIORITY.

6.7 Physiological alarms

Alarm message	Priority	Source	Description	Alarm signals
NBP: Sys High NBP: Dia High	Medium**	NBP	Measured NBP pressure value exceeds upper alarm limit. In addition, "Sys", "Dia" indicates which parameter has exceeded the alarm limit.	Blinking NBP values, alarm message and acoustic alarm signal
NBP: Sys Low NBP: Dia Low	Medium**	NBP	Measured NBP pressure value falls below lower alarm limit. In addition, "Sys", "Dia" indicates which parameter has dropped below the alarm limit.	Blinking NBP values, alarm message and acoustic alarm signal
CNAP: Sys High CNAP: Dia High CNAP: Mean High	Medium**	CNAP	Measured CNAP™ pressure value exceeds upper alarm limit. In addition, "Sys", "Mean" "Dia" indicates which parameter has exceeded the alarm limit.	Blinking CNAP™ values, alarm message and acoustic alarm signal
CNAP: Sys Low	Medium**	CNAP	Measured CNAP™ pressure value falls	Blinking CNAP™

Alarm message	Priority	Source	Description	Alarm signals
CNAP: Dia Low CNAP: Mean Low			below lower alarm limit. In addition, "Sys", "Mean" "Dia" indicates which parameter has fallen below the alarm limit.	values, alarm message and acoustic alarm signal
CNAP: Pulse High	Medium**	CNAP	Pulse rate (CNAP™) exceeds upper alarm limit.	Blinking CNAP™ values, alarm message and acoustic alarm signal
CNAP: Pulse Low	Medium**	CNAP	Pulse rate (CNAP™) falls below lower alarm limit.	Blinking CNAP™ values, alarm message and acoustic alarm signal

NOTE:
All technical malfunction alarm messages of the CNAP™ Monitor 500 or its components are found directly in the chapters describing the respective system components.

7 Trends

The CNAP™ Monitor 500 automatically displays the parameters **Sys**, **Mean**, **Dia** and **Pulse** in the **Trend frame** on the **Main screen**. Trends can be displayed as graphical as well as numeric trends. The display of a list of physiological alarms is optional.

NOTE:
- Recorded parameters are saved on a beat-to-beat-basis for a maximum of 24 hours.
- Saved recordings can be displayed in the **Trend frame** at any time (see chapter 7.2.1 – Trend views).

STOP:
- **DISCHARGE**: When a patient is discharged, all recorded data, including the parameters **Sys**, **Mean**, **Dia** and **Pulse** as well as the **Alarm history** are irretrievably deleted.
- **PRINT REPORTS**: The set-up and configuration of the **Trend frame** also determine the selection and the display of the **Print reports (Graphic trend report**, **Numeric trend report** and **Alarm history report)**. Thus, before starting a **Print report**, make sure that the data in the **Trend frame** display is equivalent to the data you wish to include in your **Print report** concerning, for instance, amplitude, time scale and displayed time span (see chapter 8.3).

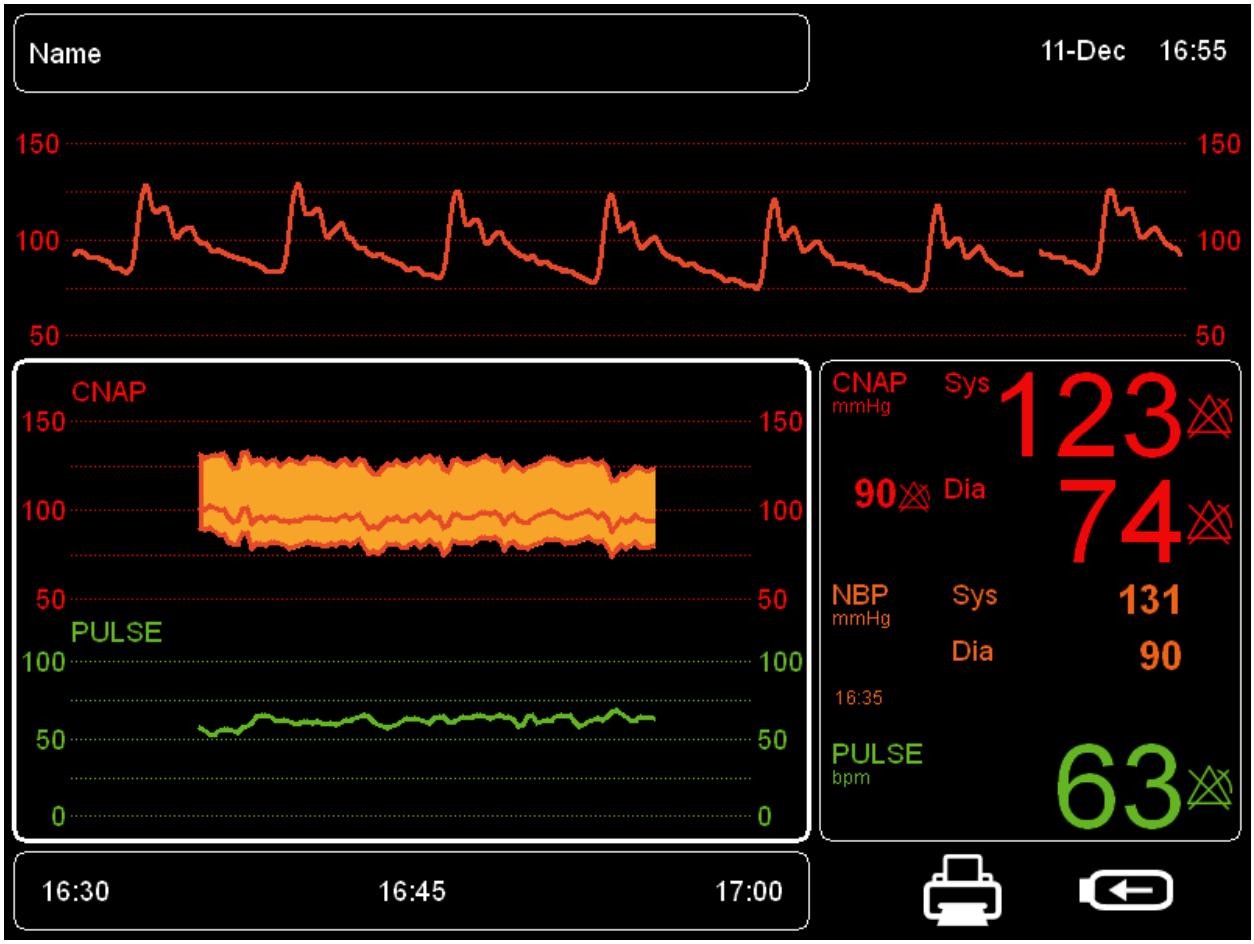


Illustration 24: Trend frame

7.1 Trend – the menu

The menu **Trend**, which can be accessed directly from the Main Screen by means of the click-wheel-control, allows the operator to configure trend views in the **Trend frame**.

Menu item	Description	Settings
Trend Display	Selection of trend view: **Graphic** or **Numeric** display, or **Alarm history**	**graphic, numeric, alarm history**
BP Scale ...	Adjustment of amplitude scales of CNAP™ blood pressure waveform and trend	**BP Mean, BP amplitude**
Pulse Scale ...	Adjustment of amplitude scales of pulse rate trends	**Pulse Mean, Pulse amplitude**
Time Scale	Setting of time scale	Graphic: **30min (default), 1h, 2h, 4h, 8h, 12h, 24h** Numeric: **1 beat, 1min, 5min, 15min, 30min, 1h**

7.2 Setup

7.2.1 Trend views

Recorded data are automatically displayed in the **Trend frame**, including three options:

- **Graphic trend**: graphical trend of measured parameters, displayed on a time axis
- **Numeric trend**: numerical trend of measured parameters; adjustment of time intervals
- **Alarm history**: display of all alarms issued during a measurement

NOTE:

- You can select your trend display option by using the click-wheel control to open the menu **Trend frame** in the main screen, then to select **Trend** and access the menu item **Trend display**.

7.2.2 Graphic trend

The trend view **Graphic trend** allows a graphical view of the following parameters on a time axis:

- CNAP™ blood pressure values: Sys, Dia, Mean
- CNAP™: Pulse

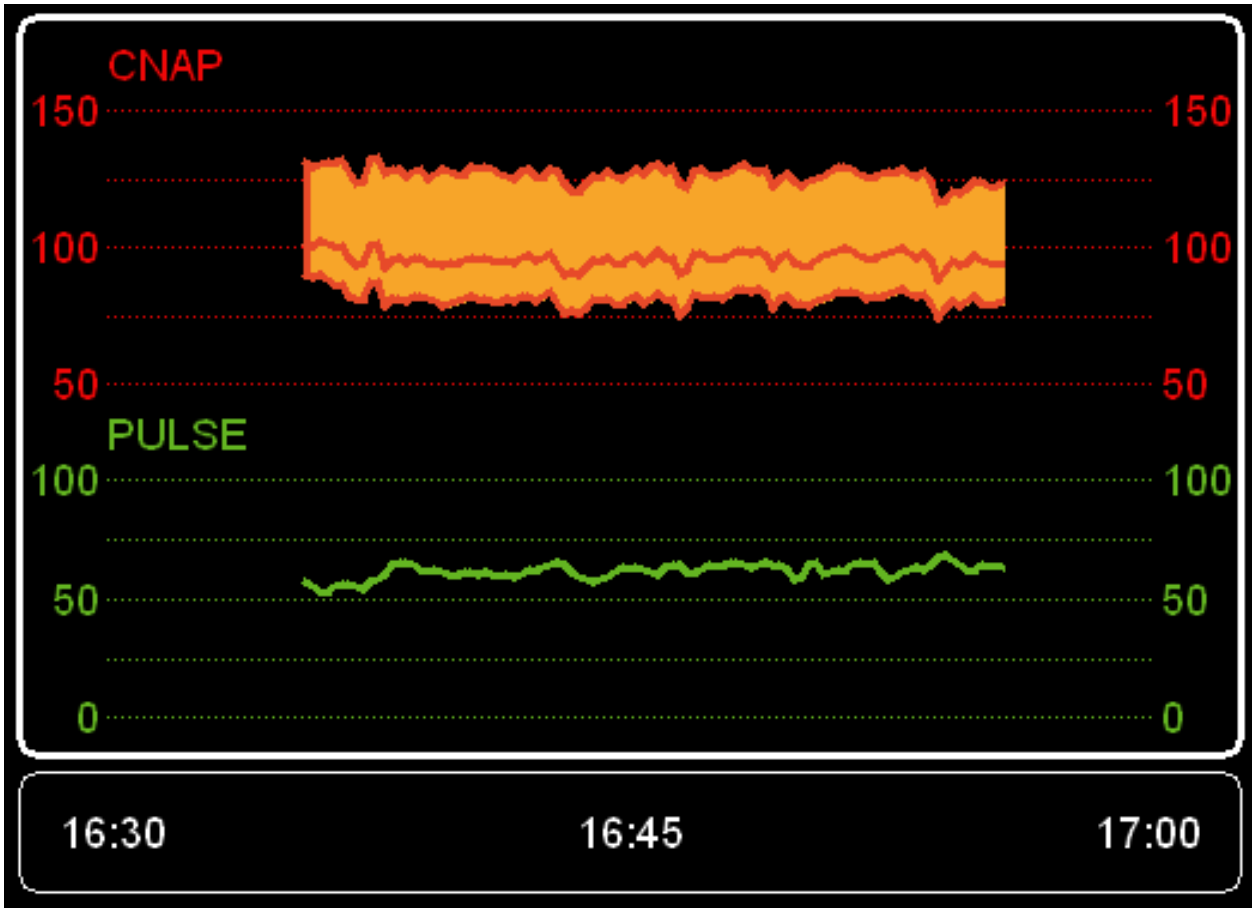


Illustration 25: Graphic trend

NOTE:
- The trend view **Graphic** can be adjusted by changing the following scales: **BP scale**, **Pulse scale** and **Time scale**.
- The displayed data window can be adjusted by means of the click-wheel control in the **Navigation frame** (see chapter 7.2.5 – Scrolling of trend views), which also determines the amount of data to be printed.

BP SCALE:
The scale factor of the CNAP™ blood pressure trend can be configured in the menu entry **BP scale**, which is located in the menu **Trend**. Scales are configured as follows:

Menu item	Description	Settings
BP Scale ...		
BP Mean	Setting of expected mean blood pressure	**20(10)240 mmHg* 50(25)200 mmHg** 100(50)150 mmHg***
BP Amplitude	Setting of expected mean blood pressure amplitude	**40*, 100**, 200*** mmHg**

Example:
Patient's blood pressure: 130/80 (105)

- o BP Mean: 100 mmHg
- o BP Amplitude: 100 mmHg

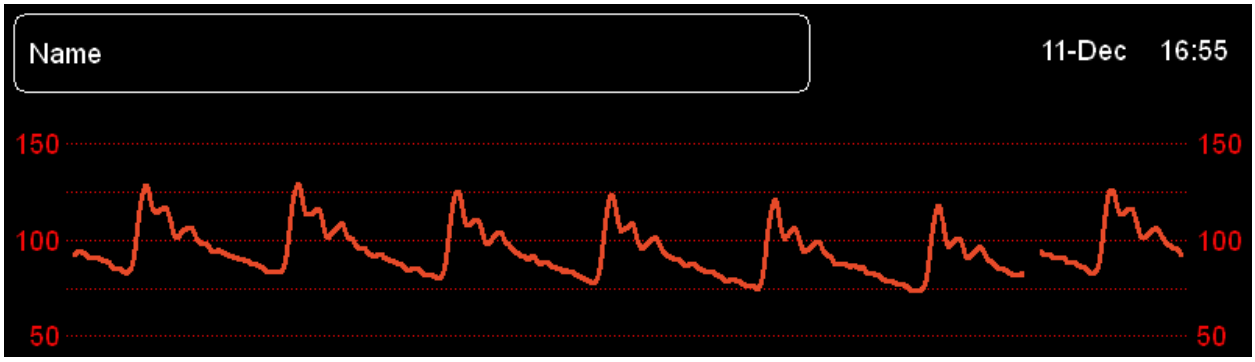


Illustration 26: Example of BP scale

NOTE:
- The scale of CNAP™ blood pressure applies the waveform and trends.

PULSE SCALE:

The scale factor of the CNAP™ pulse rate trend can be configured in the menu entry **Pulse scale**, which is located in the menu **Trend**. Scales are configured as follows:

Menu entry	Description	Settings
Pulse Scale ...		
Pulse Mean	Setting of expected mean pulse rate	**20(10)240 bpm* 50(25)200 bpm** 100(50)150 bpm***
Pulse Amplitude	Setting of expected mean pulse amplitude (max – min)	**40*, 100**, 200*** bpm**

TIME SCALE:

The time scale of blood pressure and pulse rate trends can be set in the menu item **Time scale**, which is located in the menu **Trend**.

Menu entry	Description	Settings
Time Scale	Setting of time scale for **Graphic trend**	**30min (default), 1h, 2h, 4h, 8h, 12h, 24h**

NOTE:

- Time scales of **Graphic trend** always correspond to the entire time slot which is displayed in the **Trend frame**.
- In case of an adjustment of the time scale, the current point of time is displayed on the right end of the **Trend frame**.

STOP:

- Time labels displayed in the **Navigation frame** correspond to the time displayed on the system clock of the CNAP™ Monitor 500. So it is essential to make sure that the monitor's system clock is showing the correct time.

7.2.3 Numeric trends

The trend view **Numeric** allows a numeric view of the following parameters on a time axis:

- CNAP™ blood pressure values: Sys, Dia, Mean
- CNAP™: Pulse

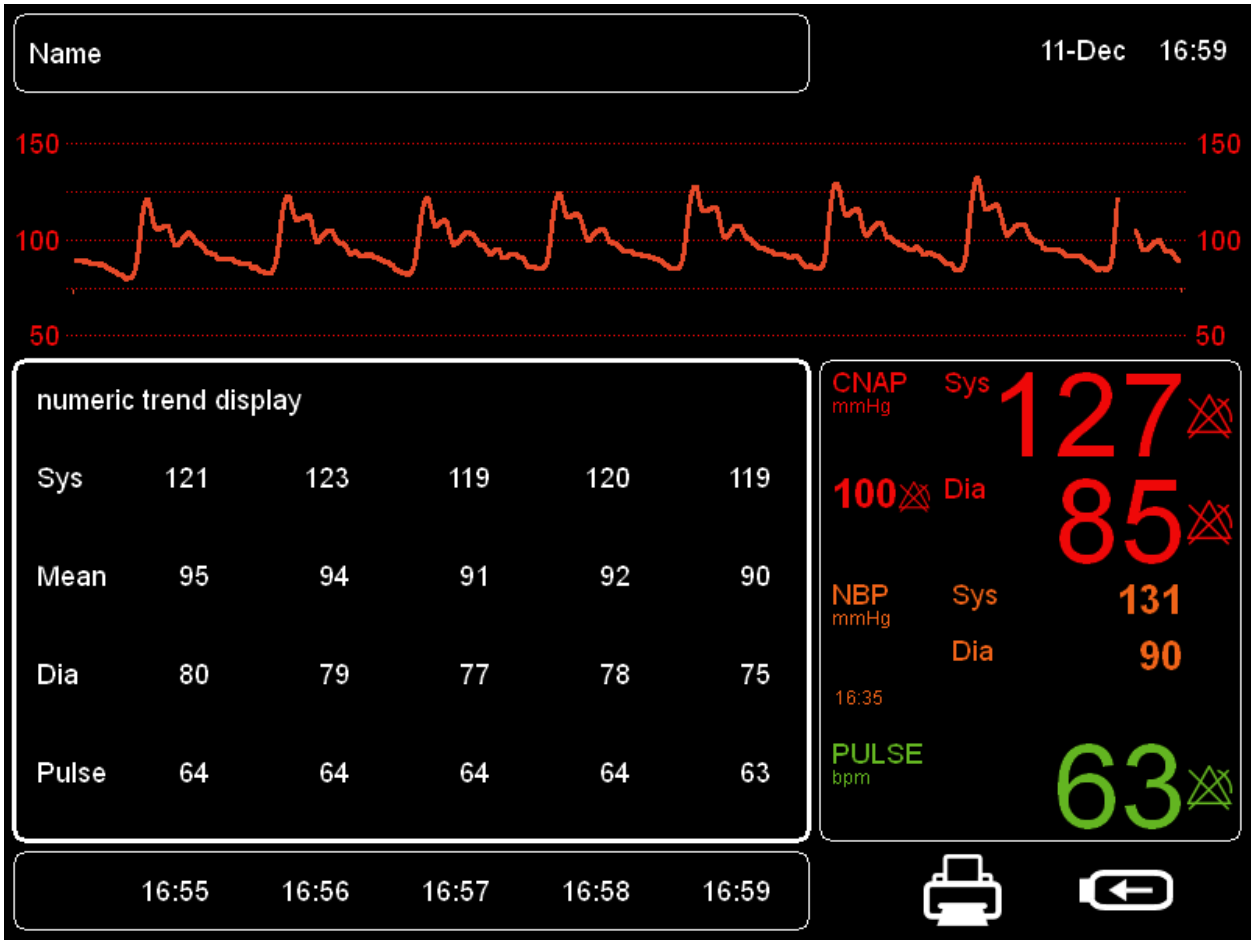


Illustration 27: Numeric trend and Navigation frame

NOTE:

- The trend view **Numeric** can be configured by adjusting **Time scale** from the **Trend menu.**
- The displayed data window can be adjusted by means of the click-wheel control in the **Navigation frame**, which also determines the scope of print reports.

TIME SCALE:
The time scale for the trend views of blood pressure and pulse rate can be set via accessing the menu **Trend** and then selecting **Time scale**.

Menu item	Description	Settings
Time Scale	Setting of time scale for **Numeric trend**	**1beat, 1min, 5min, 15min, 30min, 1h**

NOTE:
- The time scale of the **Numeric trend** corresponds to the time interval between 2 displayed measured values.
- The displayed values are averaged on the basis of the selected time scale (time interval).
- In case of an adjustment of the time scale, the current point of time is displayed in the far right column of the **Trend frame**.

STOP:
- Time labels displayed in the **Navigation frame** correspond to the time displayed on the system clock of the CNAP™ Monitor 500. So it is essential to make sure that the monitor's system clock is showing the correct time.

7.2.4 Alarm history

The **Alarm history** is a list of up to 100 last released alarms and malfunction reports. Each report of the alarm history includes the following information:

- Date
- Time
- Priority
- Alarm message

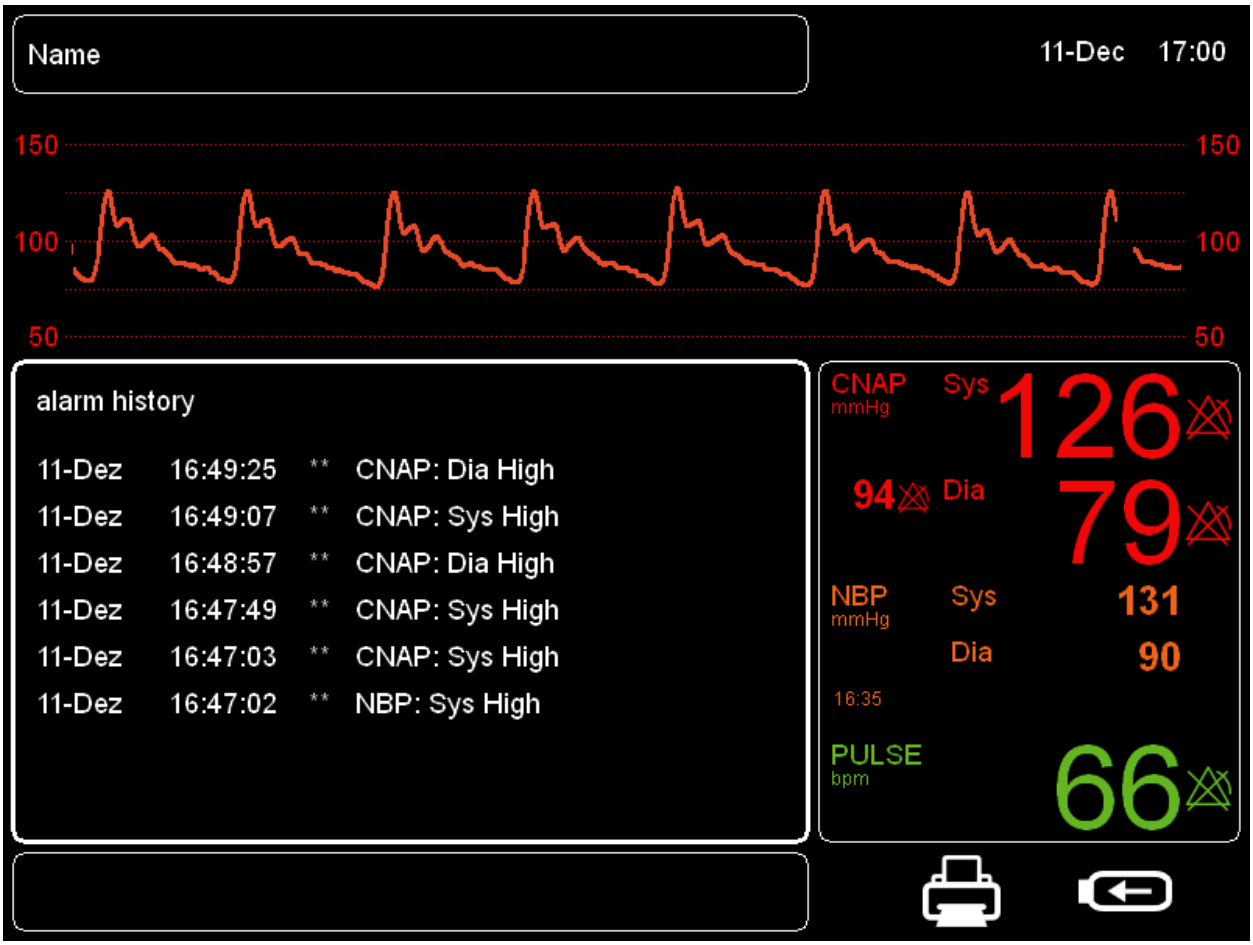


Illustration 28: Alarm history

NOTE:

- The **Alarm history** includes the entire list of the last reported alarms (up to 100 entries). The scroll up and scroll down keys in the Navigation frame can be used to view and complete list of alarms.

STOP: Discharge of a patient

- The deletion of patient data irretrievably deletes all connected recordings, including the parameters **Sys, Mean, Dia** and **Pulse** as well as the **Alarm history** (see chapter 5.3 – Discharge).

7.2.5 Scrolling of trend views

The time slot of the data displayed in the **Trend frame** can be adjusted in the **Navigation frame** by using the click-wheel control:

1) Access the **Navigation frame** using the click-wheel control
2) Select the desired time slot by wheeling the click-wheel control
3) Confirm selection by pressing the click-wheel control

NOTE:

- Scrolling trends by means of the click-wheel control is restricted to the start of a measurement and/or the current time: i.e., the time slot of a trend can neither be scrolled to before the start of a measurement nor to a prospective time.

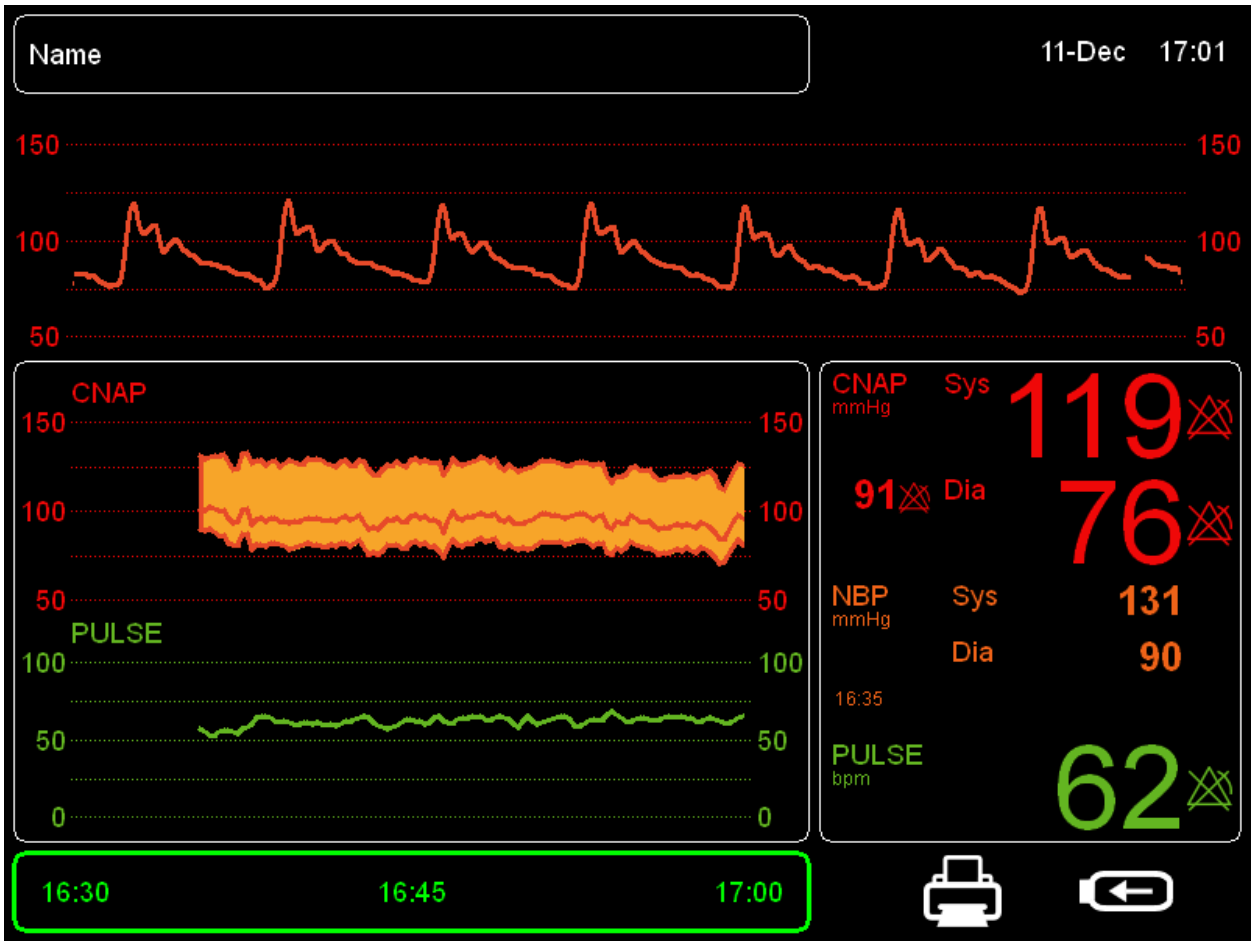


Illustration 29: Navigation frame including time specification

8 Printing

The CNAP™ Monitor 500 is provided with an integrated thermal printer enabling the operator to print a range of predefined **print reports**.

8.1 Launching print reports

The operator can launch **print reports** by means of pressing the key **Print** for variable lengths of time and select **print reports** as follows:

a) Depending on how long the operator presses **Print** he or she can select either **Trend reports** or **Snapshot reports**:
o Press **Print** once: **Snapshot reports** printing is selected.
o Press **Print** for longer than 0.5 seconds: printing of **Trend reports,** which correspond to the data displayed in the **Trend frame**, is selected.

NOTE:
- The duration of **Snapshot reports** is limited to 20 seconds. **Snapshot delay** settings are edited in the menu **Measurement**.

b) The way how recordings are displayed in the **Trend frame** automatically determines the selected **Print report**:
o **Graphic trend** (see chapter 8.3, Illustration 30)
o **Numeric trend** (see chapter 8.3, Illustration 31)
o **Alarm history** (see chapter 8.3, Illustration 32).

NOTE:
- Scaling of trend frame: The time slot displayed in the **Trend frame**, including also the time scale settings, is correspondingly printed.
- If necessary, adjust scales (i.e. BP Scale, Pulse Scale, Time Scale) and the displayed time slot (Navigation Bar).

NOTE:
- Depending on the **Print options**, which can be accessed by means of pressing **Setup** in the **Measurement menu**, the CNAP™ Monitor 500 can automatically launch a **Print on alarm report** if a physiological alarm is issued. In this case printing does not depend on the **Trend frame** data display, i.e. BP scale is fixed to 0-250mmHg.

STOP:
- If the CNAP™ Monitor 500 is on battery operation and battery charge status is ≤25 %, printing will be deactivated. Current print jobs will be cancelled immediately for safety reasons.

8.2 Cancelling print reports

In order to cancel any print jobs, press **Print** once.

8.3 Print reports

The CNAP™ Monitor 500 offers a range of predefined p**rint reports**. All p**rint reports** have the same header containing the following information:

- Print report type
- Name
- Patient ID
- Gender
- Birth date
- Printed (date and time)
- Last NBP (values and time of the last NBP measurement)

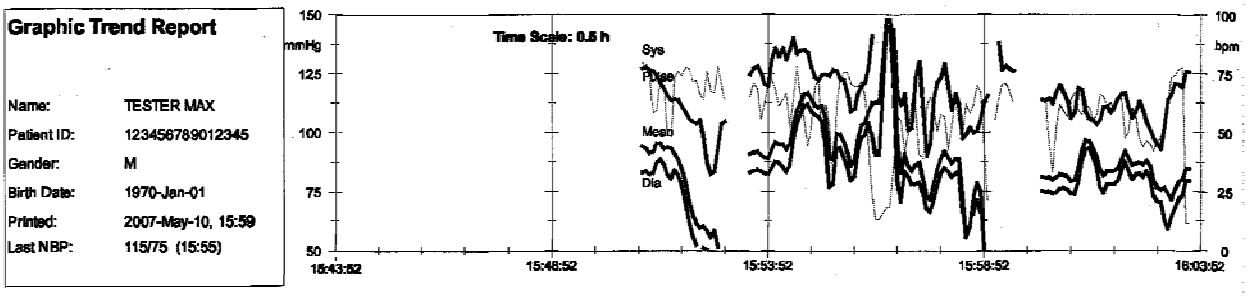


Illustration 30: Graphic trend report

Numeric Trend Report

Name: TESTER MAX
Patient ID: 123456789012345
Gender: M
Birth Date: 1970-Jan-01
Printed: 2007-May-10, 15:50
Last NBP: 125/83 (15:48)

Date	2007-May-10	2007-May-10	2007-May-10	2007-May-10	2007-May-10
Time	15:50:51	15:50:54	15:50:54	15:50:55	15:50:56
Sys	125	125	134	124	126
Mean	79	79	104	103	103
Dia	66	66	97	97	96
Pulse	9	9	27	82	78

Illustration 31: Numeric trend report

Alarm History Report

Name:	Last First
Patient ID:	GE-3441_____
Gender:	F
Birth Date:	2007-May-10
Printed:	2007-May-10, 16:02
Last NBP:	125/85 (16:02)

Alarm history			
2007-May-10	16:02:30	**	Alarm Message 1
2007-May-10	16:02:30	**	Alarm Message 2
2007-May-10	16:02:30	**	Alarm Message 3
2007-May-10	16:02:30	**	Alarm Message 4
2007-May-10	16:02:30	**	Alarm Message 5
2007-May-10	16:02:30	**	Alarm Message 6
2007-May-10	16:02:30	**	Alarm Message 7
2007-May-10	16:02:30	**	Alarm Message 8

Illustration 32: Alarm history report

Snapshot Report

Name:	TESTER MAX
Patient ID:	123456789012345
Gender:	M
Birth Date:	1970-Jan-01
Printed:	2007-May-10, 15:49
Last NBP:	125/83 (15:48)

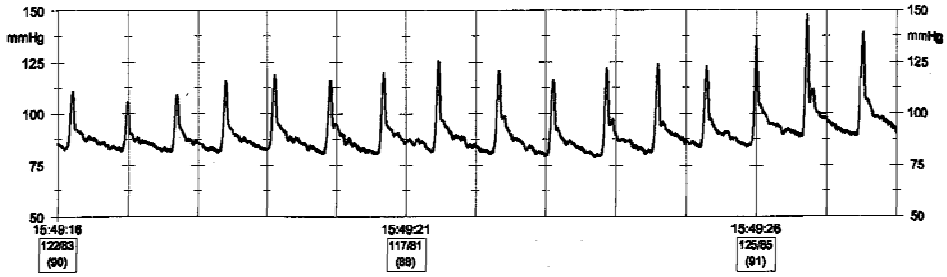


Illustration 33: Snapshot report

8.4 Print options

Menu item	Description	Settings
Snapshot Delay	Setting of delay time of print reports for **Snapshot** and **Print on alarm**	**5sec, 10sec, 15sec**
Print On Alarm	Activation of **Print on alarm** feature	**on, off**

9 CNAP™

9.1 General information

CNAP™ - Continuous Non-Invasive Arterial Blood Pressure – is a non-invasive method for measuring the continuous blood pressure waveform in adult and pediatric patients from the age of 4 years.

A patient's blood pressure waveform is recorded by the CNAP™ Monitor 500 by means of a double finger cuff with an integrated IR light sensor and air chambers in connection with NBP measurement (oscillometric blood pressure measurement). The NBP cuffs can be placed on the patient's upper arm either on the same or on the other arm as the double finger cuff. NBP measurement is essential to ensure absolute accuracy of the recorded blood pressure values.

CAUTION:

- The accuracy of the CNAP™ measurement depends on the accuracy of the accompanying NBP measurement, which is particularly important during calibrations or before interventions.
- Make sure that no movement artifacts occur during measurement, especially during and until 2 min. after measurement initialization.
- Powerful light sources (e.g. cameras with flashlight) may affect the CNAP™ measurement and cause artifacts.

CAUTION:

- Movements of the patient, which result in changes of position of the CNAP™ double finger cuff regarding heartlevel, will have influence on the accuracy of blood pressure readings. To compensate these physical effects (hydrostatic height), recalibrate the CNAP™ measurement by triggering a single NBP measurement manually (see chapter 10.5 - NBP options).

9.2 Safety precautions

CAUTION:

- Do not use CNAP™ and NBP in patients with vascular prostheses!
- CNAP™ is designed for the concurrent measurement of only one patient at a time.
- Be sure to follow local regulations regarding storage of the CNAP™ Monitor 500, its accessories and packing material.
- Keep the CNAP™ Monitor 500 out of reach of children!
- The CNAP™ blood pressure waveform is calibrated by means of an additional NBP measurement. If the accuracy of the NBP measurement is affected by artifacts (weak pulse, irregular pulse, artifacts from patient movement or tremor, or respiratory artifacts), this may also affect and reduce the accuracy of values measured by the CNAP™ Monitor 500.
- The use of technical surgical devices might cause interference and reduce the quality of CNAP™ recordings.
- Do not ever connect the device's pneumatic connectors to an intravascular system!
- Regularly inspect concerned patient limbs during measurement to avoid possible lasting damages caused by prolonged impairment of the patient's blood circulation! In case of any signs of total arterial compression, immediately discontinue the measurement process by pressing **Start/Stop** on the front panel of the device.
- Pain or strong feelings of discomfort are in no way normal and are not a part of CNAP™ measurements! Should a patient report any of these feelings, stop the measurement process immediately!
- Before connecting any cables to a patient, visually inspect all components for damages or wearout. Any faulty parts (e.g. cables or plugs) are to be replaced immediately.
- Control the correct positioning of the CNAP™ double finger cuff regularly during measurement. Make sure that the cuff is not positioned on the finger joints.

NOTE:

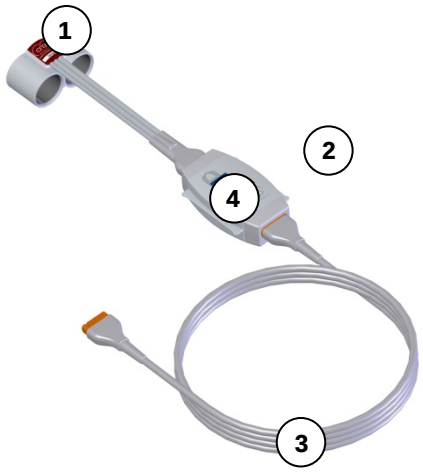
- Avoid compressing the air hoses or reducing their diameter in any way (e.g. by bending the cables) as this could impair the quality of the CNAP™ measuring signals. To avoid mechanical damage to the finger cuffs, remove all objects (e.g. rings) from patient fingers before measuring.

STOP:

- The operating environment for CNAP™ hardware has to comply with the directions regarding ambient temperature, relative humidity and atmospheric pressure (see chapter 14 – Appendix C – Technical specifications).
- Take care to ensure regular and sufficient air circulation around the CNAP™ Monitor 500 by placing the device accordingly (e.g. do not cover it with sheets or blankets).

9.3 Setup

The CNAP™ hardware consists of the following components:



① CNAP™ double finger cuff

② CNAP™ controller

③ CNAP™ cable

④ Graphics to select correct finger cuff size

Abbildung 34: CNAP™ hardware

NOTE:
- CNSystems recommends placing the CNAP™ double finger cuff on the index and the middle finger of a patient. In rare cases – if necessary – the CNAP™ double finger cuff may also be placed on the middle and the ring finger. Thumb and little fingers are not suited for CNAP™ blood pressure measurement.
- The use of a too big/too small CNAP™ double finger cuff may result in faulty blood pressure recordings.

Start / stop a measurement (refer to chapter 3.4 – Quick setup):

- Choose the correct size of a CNAP™ double finger cuff by means of the graphics on the upside of the CNAP™ controller (refer to chapter 3.2.3 CNAP™ controller).
- Assemble the CNAP™ hardware by connecting the CNAP™ double finger cuff, the CNAP™ controller, the CNAP™ cable and the CNAP™ Monitor 500. All the plugs and connectors are designed so as to making it impossible to switch them accidentally.
- Equip the patient with the CNAP™ hardware: The CNAP™ double finger cuff is placed on the proximal joints of the index and middle fingers. Make sure that the cuff cables run along the upper side of the patient's arm.
- Fasten the CNAP™ controller to the patient's forearm by means of the fixing cuff (with Velcro fastener).
- Place the NBP blood pressure cuff on the patient's upper arm (calibration for CNAP™) contralaterally, or, if necessary, on the same arm as the double finger cuff.
- Start the CNAP™ measurement by pressing Start/Stop on the front side of the device.

Illustration 35: Subject setup

NOTE:

- The key **Start / Stop** starts or stops both a CNAP™ measurement as well as the calibration process by means of the NBP measurement.
- A current NBP measurement can be stopped without interfering with a concurrently performed CNAP™ measurement by pressing **Start / Stop**. Pressing the same key a second time also stops the CNAP™ measurement

9.4 View features

CNAP™ determines the following blood pressure values which are displayed directly in the **Main screen** of the CNAP™ Monitor 500:

- Blood pressure waveform (morphology)
- Blood pressure trends:
  - o Sys
  - o Mean
  - o Dia
  - o Pulse
- Numeric blood pressure values:
  - o Sys
  - o Mean
  - o Dia
  - o Pulse

9.4.1 Blood pressure waveform

The CNAP™ blood pressure waveform is displayed directly in the **Main screen.**

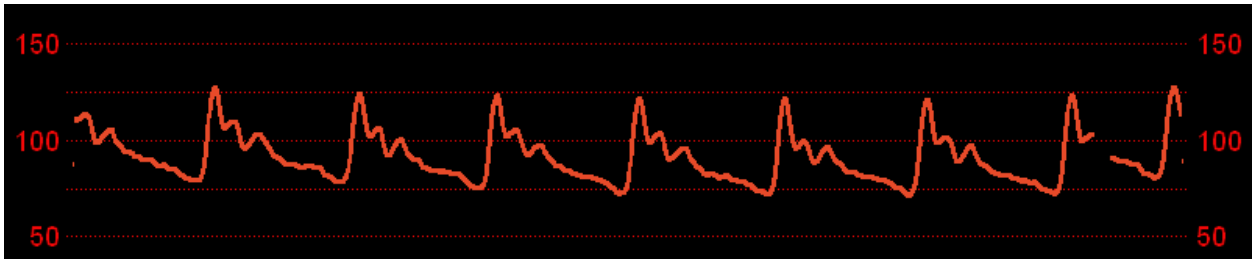


Illustration 36: CNAP™ blood pressure waveform

NOTE:
- The scale of the CNAP™ blood pressure waveform is configured in the same way as the scale of the CNAP™ trend. It is set in the **Menu trend** (see chapter 7 – Trends).
- The signal speed of the CNAP™ blood pressure waveform is set to 12,5 mm/s and cannot be adjusted in any way.

9.4.2 Trend view

The CNAP™ blood pressure trend is displayed in the **Trend frame** directly in the **Main screen** of the CNAP™ Monitor 500. It enables both graphic as well as a numeric view of blood pressure trends.

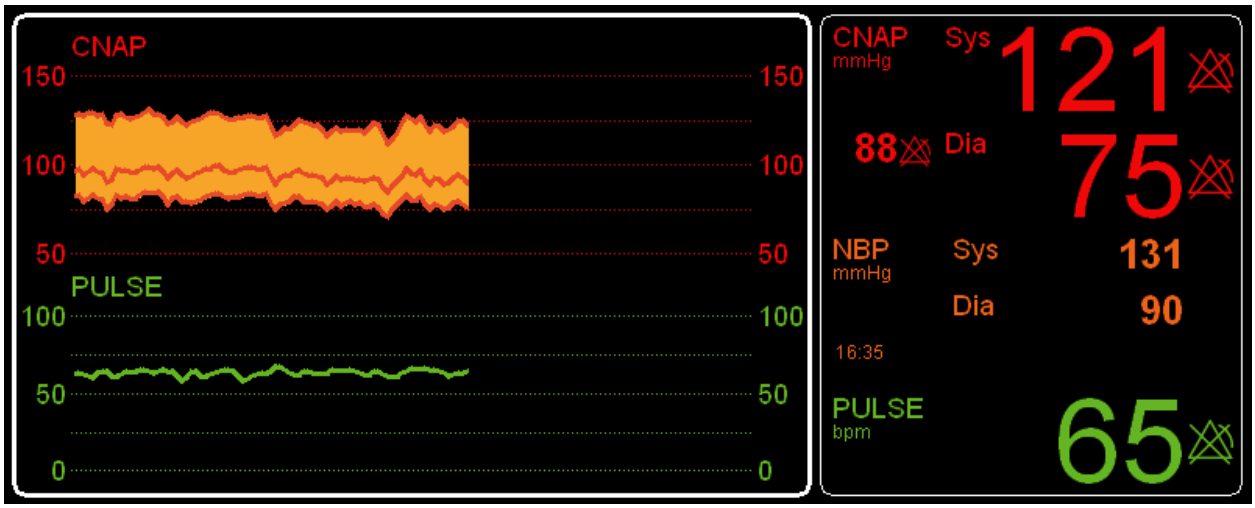
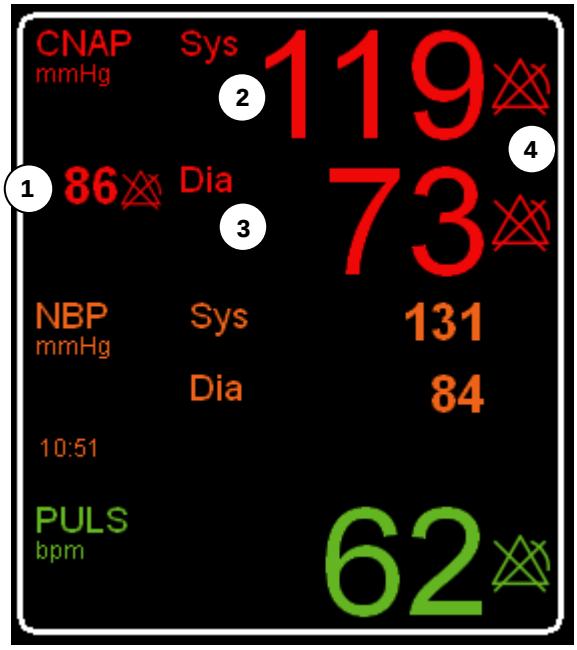


Illustration 37: Graphic trend and numeric values (parameter frame)

NOTE:
- Scales for CNAP™ trends and the CNAP™ blood pressure waveform are set by means of the click-wheel control in the menu **Trend**. Amplitude scales are set likewise for the CNAP™ blood pressure waveform and the CNAP™ trend (see chapter 7 – Trends).

9.4.3 Numeric values

The CNAP™ parameter box displays the current blood pressure parameters **Sys**, **Mean**, **Dia** and **Pulse**:



① Mean blood pressure

② Systolic blood pressure

③ Diastolic blood pressure

④ Alarm limit settings

Illustration 38: Parameter frame

9.5 CNAP™ options

Parameter menu:

Menu item	Description	Settings
CNAP: Change Finger	Change of signal source in CNAP™ double finger cuff	
CNAP: Cal Interval	Setting of automatic change of signal source in CNAP™ double finger cuff [min]	**5(5)60min**
NBP: Start	Start of a single NBP measurement	
	Setting of time interval for automatic NBP measurement [min]	**off, 5(5)30, 45, 60min**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Alarms...	Setting of alarms for the parameters Sys, Mean, Dia, Pulse	
IBP Zeroing	Zeroing for interface to other patient monitors	**on, off**

10 NBP

10.1 General information

NBP (Non-Invasive Blood Pressure) uses the oscillimetric method to determine a patient's blood pressure on a non-continuous basis. To achieve this, the NBP module is integrated into the CNAP™ Monitor 500. Blood pressure measurement is conducted by means of a NBP cuff (available in 4 sizes) which is placed around the patient's upper arm and connected to the CNAP™ Monitor 500 on the left side of the monitor (see chapter 3 – Introduction). For measurement purposes, the pressure in the NBP cuff is controlled by the NBP module. The cuff pressure is first increased above systolic blood pressure and decreased step by step. The pulsations in the NBP cuff provide the basis for deriving the blood pressure values Sys, Mean and Dia.

NOTE:

- When a measurement process is started on the CNAP™ monitor, a NBP measurement is also triggered automatically.
- However, it is also possible to trigger an NBP measurement manually at any time during measurement (see chapter 10.5 – NBP options).
- NBP measuring interval is pre-set in the menu **Setup / Measurement** for every new measurement and can be changed via the menu **Parameters** for the current measurement only.
- Inflation pressure of the NBP cuff is determined by the selected patient category (see chapter 5.1 – Input of patient data).

NOTE:

- The CNAP™ blood pressure waveform is calibrated by means of an oscillometric NBP measurement. If the accuracy of the NBP measurement is affected by artifacts (e.g. weak pulse, irregular pulse, artifacts from patient movement or tremor, or respiratory artifacts), this may also affect and reduce the accuracy of blood pressure values measured by the CNAP™ Monitor 500.
- An NBP cuff can be donned on the same arm as the CNAP™ double finger cuff (ipsilaterally) or on the other arm (contralaterally).

10.2 Safety precautions

STOP:

- **Patient category:** Make sure to select the correct patient category before starting a measurement (see chapter 5.1– Input of patient data). The higher adult levels of inflation pressure, excess pressure limits or measuring time, for instance, must never be used for pediatric patients!
- **Intravenous infusion lines:** Never don a NBP cuff to a limb already connected to an intravenous infusion line or an intraarterial catheter. The inflation of the cuff might result in the infusion solution being caught up or even cause tissue damage to the punctured area.
- **Cutaneous lesions:** Never perform NBP measurements in patients suffering from drypanocytemia or from cutaneous lesions, or in patients where cutaneous lesions are to be expected.
- **Unsupervised measurements**: Patients with severe blood coagulation dysfunction may develop hematoma where the NBP cuff has been inflated. In these cases, carefully consider the pros/cons and the necessity of frequent unsupervised blood pressure measurements.
- **Interference by external devices:** Results of NBP recordings are not to be used if the measured oscillometric pulses have been influenced by other devices or techniques (e.g. counterpulsation or contrapulsation).
- **Interpretation:** NBP recordings are to be interpreted only by a physician or medical professional staff.
- **Limitations of NBP measurements:** NBP recordings may be inaccurate or even impossible under the following conditions:
  - lack of detectable regular arterial blood pressure
  - arrhythmia
  - strong and persistent patient movement (e.g. tremor or convulsions)
  - rapid blood pressure fluctuations
  - severe shock or hypothermia with reduced peripheral blood flow
  - obesity, as adipose tissue in the limbs muffles arterial oscillations

NOTE:

- In order to ensure the accuracy of NBP measurings, be sure to choose the right size of the upper arm cuff. Selecting the wrong size or incorrect donning of the cuff may cause significant inaccuracies of recordings!
- In case of longer monitorings, be sure to inspect the correct blood supply of the patient's limbs on a regular basis.
- The NBP cuff is made of latex free and skin friendly synthetic material.

10.3 Setup

The NBP hardware consists of the following components:

- NBP cuff (Child, Small adult, Adult, Large adult)
- NBP module (integrated into the CNAP™ Monitor 500)
- NBP air connector

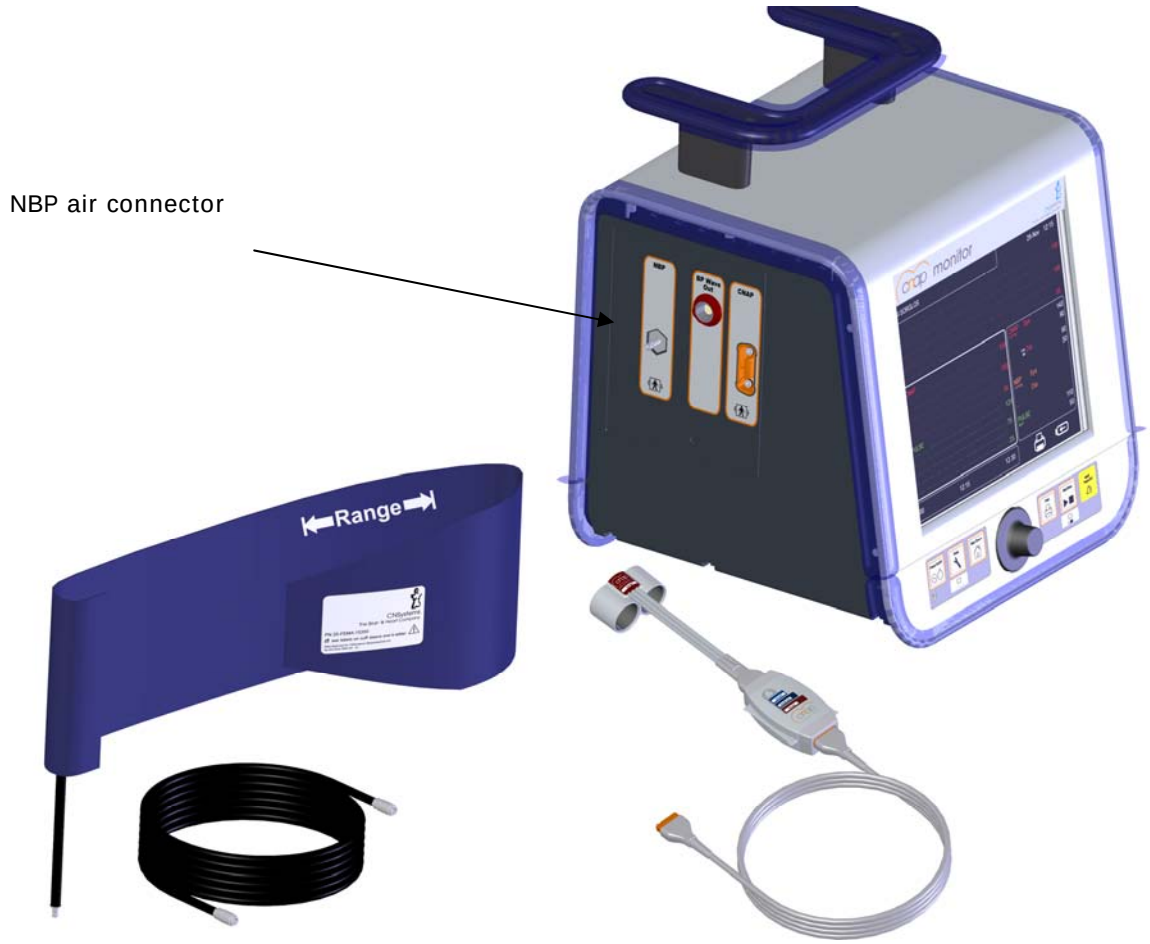


Illustration 39: CNAP™ Monitor 500 with NBP air connector

Start / Stop a measurement:

1. Make sure you are using an NBP cuff authorized by CNSystems and make sure to use the correct size.

NOTE:
- The width of the cuff should be between 37% and 47% of the circumference of the patient's limb. The inflatable part of the cuff should be at least 80% of the respective extremity.
- The following cuff sizes are available:

Size	Arm circumference (cm)
Child	12 - 19
Small Adult	17 -25
Adult	23 - 33
Large Adult	31 - 40

2. Apply the NBP cuff on the upper arm of the patient at heart level. The marker on the NBP cuff should be directly above the brachial artery.

NOTE:
Do not fix the cuff too tightly around the limb as this might cause problems during inflation and deflation of the cuff and lead to ischemia of the extremities. Be sure to inspect the patient's skin (colour, temperature, sensitivity of limb) around the cuffs on a regular basis. Should any signs of alterations of the skin or decreased blood supply be noticeable, immediately change arms or stop the blood pressure measurement altogether.

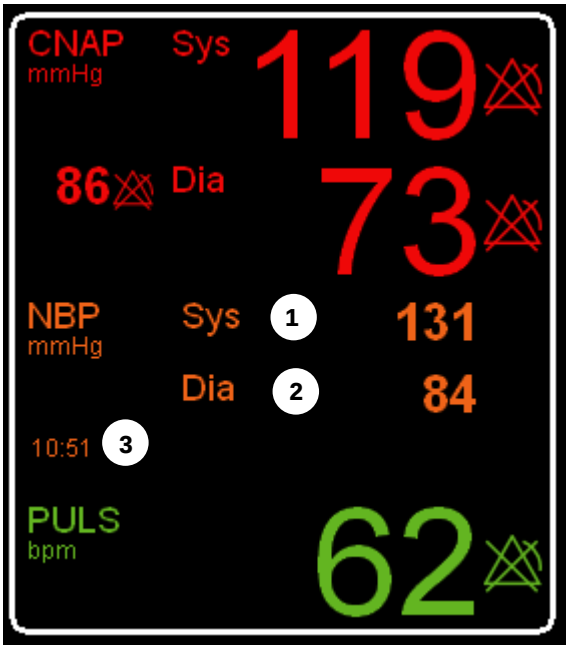
3. Connect the NBP cuff with the NBP air connector on the left side of the CNAP™ Monitor 500.

4. There are 2 ways to start an NBP measurement:
   a) The start of a CNAP™ measurement also automatically starts an NBP measurement. NBP measurements are performed after the calibration phase of the CNAP™ measurement or automatically in defined time intervals. To set the desired time intervals, acces either the menu **Parameter** or the menu **Measurement**.
   b) In order to start a single measurement, use the click-wheel control to access the menu **Parameter**.

NOTE:
- The NBP measurement serves to calibrate the CNAP™ blood pressure measurement at the height of the heart.

10.4 View features

By means of NBP the blood pressure values Sys and Dia are determined and displayed in the Parameter frame of the CNAP™ Monitor 500.



① Systolic blood pressure

② Diastolic blood pressure

③ Time of last NBP measurement

Illustration 40: Parameter frame

NOTE:

- The **Parameter frame** always displays the most recent NBP values as well as the time of measurement.

10.5 NBP options

Parameter menu:

Menu item	Description	Settings
CNAP: Change Finger	Change of signal source in CNAP™ double finger cuff	
CNAP: Cal Interval	Setting of NBP calibration interval for CNAP™ measurement	**5(5)60min**
NBP: Start	Start of a single NBP measurement	
NBP: Interval	Setting of time interval for automatic NBP measurement for the current CNAP™ recording only	**off, 5(5)30, 45, 60min**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Alarms...	Setting of alarms for the parameters Sys, Mean, Dia, Pulse	
IBP Zeroing	Zeroing for interface to other patient monitors	**on, off**

Measurement Setup:

Menu item	Description	Settings
CNAP: Cal Interval	Setting of NBP calibration interval for CNAP™ measurement	**5(5)60**
NBP: Interval	Pre-set time interval for automatic NBP measurement for each new CNAP™ recording	**off, 5(5)30, 45, 60**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Display Options...	Submenu to adjust display settings	
Print Options...	Submenu to set print options	
Parameter Averaging	Averaging of display parameters	

NOTE:

- Adjustments in the menu **Parameter** alter only the current measurement and are transcribed by **Defaults** when a new measurement is started.
- Settings performed in the menu **Measurement**, however, alter both the current as well as future measurements.

11 Cleaning and disinfection

Only use disinfectants and detergents recommended by CNSystems Medizintechnic AG to clean or disinfect the device and its accessories. CNSystems warranty does not cover any damage caused by the use of unsuitable cleaning agents or methods.
The warranty of CNSystems does not apply to the effectiveness of the mentioned cleaning agents and methods for the purpose of infection prevention and control. When in doubt, the operator is to contact the hospital hygiene department. This particularly applies for the effectivity of disinfectants and detergents against hepatitis B and HI viruses. The operator is to follow the regulations of the respective hospital and country.

11.1 General precautions

The CNAP™ Monitor 500 including all its components and accesssories are to be kept clean and free of dust.
After cleaning and disinfecting the devices, they must be thoroughly inspected before use.
If any components show signs of wear or damage, these components must not be used for patient measurements!
Before sending devices and components back to CNSystems they are to be decontaminated.

CAUTION:
- Always dilute detergents according to manufacturers' instruction, or use in the smallest possible concentration.
- No liquid must ingress the CNAP™ Monitor 500.
- Do not dip instruments, device parts or components in liquid.
- Do not pour any liquid directly on the device.
- Do not let residues of detergents or disinfectants air-dry on any parts of the device. Wipe them off with a cloth moist with water, then dry the instruments with a clean cloth.
- Never use scouring agents or abrasive detergents (e.g. steel wool or silver polish).
- Do not use bleaching agents!
- Wipe off detergents and disinfectants with a moist cloth (water), then dry surfaces with clean cloth.

STOP:
- No liquid must be spilt on any part of the CNAP™ Monitor 500. In case this should happen, carefully dry device/accessory. If in doubt whether liquid has ingressed the device, do not start up the instrument. Contact technical staff or a service partner of CNSystems Medizintechnik AG.

11.2 Cleaning

In order to clean any part of the device use a lint-free cloth, moisted with warm water (max. 40° C), and soap, diluted non-caustic detergents, or ammoniac-/ alcohol- containing tensides or detergents. Do not use strong solvents like dimethylketone or trichloroethylene. Do not dip the device, any part of the device or any accessories (especially not any hoses) into liquid.
As the screen of the CNAP™ Monitor 500 is easily scratched, be particularly careful when cleaning it.
No liquid must enter the CNAP™ Monitor 500, so be sure to not spill any liquid directly on the monitor.
No liquid must enter the connectors of the CNAP™ Monitor 500 or the CNAP™ controller, so take care not to wipe over, but rather around, the connectors when cleaning them.

CAUTION:
- Be particularly careful when cleaning or disinfecting the insides of the CNAP™ double finger cuffs. Wipe them carefully in order to avoid any damage.

11.3 Disinfecting

CAUTION:
- **Disinfecting agents**: Never mix different kinds of disinfectant agents (e.g. bleaching agents and ammoniac), as this might result in the production of dangerous gases!
- **Internal hospital regulations:** Disinfect the product in accordance with your own hospital regulations in order to avoid long-term damage of any kind.

The device is to be cleaned before disinfection. Find recommended detergents and disinfectants listed below:

Disinfectant	Glutar-aldehyde	n-Alkyl/ Alcohol	Succindial-dehyde/ Alcohol	Alcohol Spray/ Wipe	Orthophthal-aldehyd
Concentration	3.4%	0.28% -8%	11%	10%	0,55%
Common brands	Cidex Plus	Theracide	Gigasept FF	Microzid AF Liquid	Cidex OPA

12 Technical alarms and status messages

Despite physiological alarms the CNAP™ Monitor 500 displays technical malfunction alarms (white) and device status messages (blue) in the “Alarm Frame”:

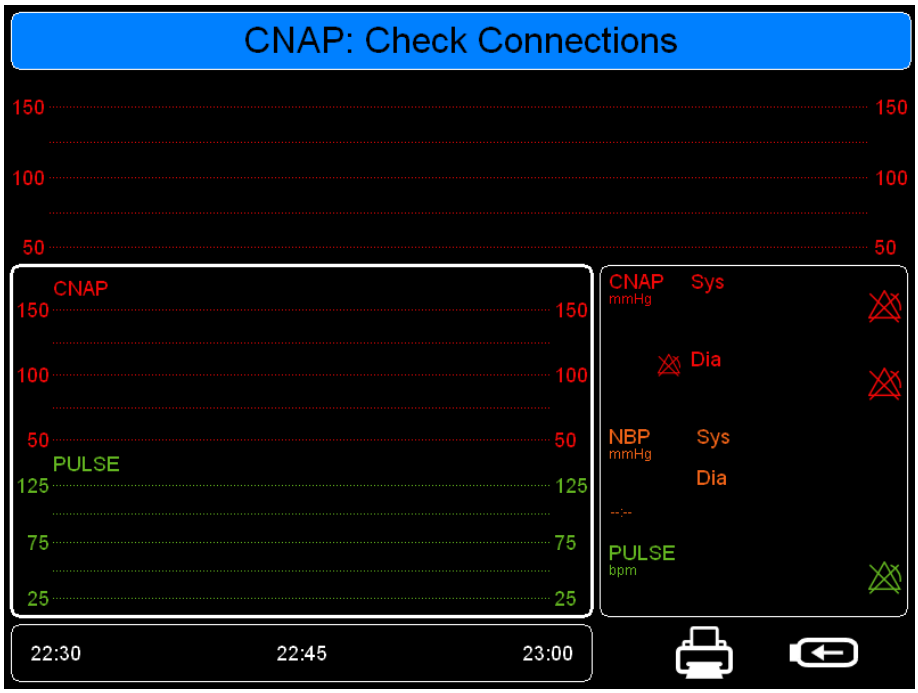


Illustration 41: Status Message

The following documentation lists all technical alarms and device status messages that may occur during the use of the CNAP™ Monitor 500.

NOTE:

- In case you require service support for your CNAP™ Monitor 500 please report the exact technical alarm to the service partner.
- A complete list of technical alarms including error code, time- and date of appearance is available from the Log menu located in the Service Menu. You find the password for the service menu in the CNAP™ Monitor 500 "Instructions for service".

12.1 Main unit

12.1.1 Technical alarms

Message	Possible cause	Measures
MU: Fatal Error – Contact Service	- CNAP™ monitor must not be used for further measurements	- Reboot CNAP™ monitor - In case of persistent error, contact service
MU: CNAP Failure	- Failure in CNAP™ hardware	- Reboot CNAP™ monitor - In case of persistent error, contact service
MU: NBP Failure	- Failure in NBP hardware	- Reboot CNAP™ monitor - In case of persistent error, contact service
MU: IBP Failure	- Failure in IBP component	- Reboot CNAP™ monitor - In case of persistent error, contact service
MU: Battery: Low	- Very low battery charge status (< 25%), battery operation still possible	- Switching to mains operation via power adapter recommended
MU: Battery: Depleted	- Battery depleted, operation possible for at least 15 minutes	- Immediately switch to mains operation via power adapter
MU: Battery: Shutdown	- Battery depleted, operation possible for 5 minutes at most; monitor is switched off	- Immediately switch to mains operation via power adapter - Current measurement discontinued, monitor switched off automatically

12.2 BP Wave Out (IBP)

12.2.1 Status messages

Message	Possible cause	Measures
IBP: Connected	- "BP Wave out" is connected to patient monitor	- Perform zeroing (refer to chapter 4.4) - Make sure to disable zeroing when calibration is complete
IBP: Disconnected	- "BP Wave out" is disconnected from patient monitor	- n.a.

12.2.2 Technical alarms

Message	Possible cause	Measures
IBP: Fault	- Internal controller problem	- Reboot CNAP™ monitor - In case of persistent error, contact service
IBP: Transmission Fault	- Interface problem	- In case of persistent error, contact service
IBP: EEPROM RW Error	- I/O memory chip defective	- Reboot CNAP™ monitor - In case of persistent error, contact service
IBP: Iso Board Fault	- Isolation board failure	- In case of persistent error, contact service
IBP: Iso Board Bridge-Voltage	- Bridge-voltage (BP wave out) exceeds 10V	- Disconnect IBP transducer cable - Check bridge-voltage range (refer to chapter 4.4) - In case of persistent error, contact service

12.3 Printer

12.3.1 Technical Alarms

Message	Possible cause	Measures
PRINTER: Out Of Paper	- Printer is out of paper	- Replenish paper
PRINTER: Fault	- Hardware problem - Excess temperature - Internal voltage supply error	- Problem will be solved automatically - In case of repeated messages, contact service
PRINTER: Failure	- Hardware problem - Interface problem	- Contact service
PRINTER: Communication Error	- Interface problem	- Problem will be solved automatically - In case of repeated messages, contact service

12.4 CNAP™

12.4.1 Status messages

Message	Possible cause	Measures
CNAP: Check Connections	- CNAP™ controller is not connected	- Check connection of CNAP™ controller
CNAP: Check Cuff **CNAP: Connections**	- CNAP™ double finger cuff is not connected	- Check connection of CNAP™ double finger cuff
CNAP: Check Cuff	- No finger in inactive cuff (before CNAP: Change Finger)	- Put finger in cuff
CNAP: Initializing	- System Self-test	- n.a.
CNAP: Controller Not Calibrated	- CNAP™ controller is not calibrated	- Replace CNAP™ controller - Contact service for calibration of CNAP™ controller
CNAP: Put Finger In Cuff	- CNAP™ has passed self-test and is ready for measurement	- Patient setup
CNAP: Calibration	- CNAP™ calibration phase in progress	- Wait for measurement
CNAP: Calibrating	- NBP measurement to calibrate CNAP™ blood pressure is in progress (end of calibration phase)	- Wait for end of NBP measurement
CNAP: Artifact	- Pressure is not within physiological	- Check and eliminate

Message	Possible cause	Measures
	measuring range - Low signal amplitude in CNAP™ double finger cuff - Interference because of third party measuring devices - CNAP™ hardware is ringing due to artifacts	influence from third party measuring devices - Avoid artifacts (e.g. movements) - Check CNAP™ cables and connectors - Check CNAP™ double finger cuff - Replace CNAP™ double finger cuff and cable
CNAP: Cuff Expiring	- CNAP™ cuff is reaching end of life-cycle, thus providing low quality of measurement	- Replace CNAP™ double finger cuff
CNAP: Cuff Ambient Light	- Ambient light interferes with CNAP™ double finger cuff	- Reduce ambient light (i.e. brightness, switch off, …) - Check setup of CNAP™ double finger cuff

12.4.2 Technical Alarms

Message	Possible cause	Measures
CNAP: Check Connection	- Leakage in CNAP™ hardware	- Check connections of CNAP™ hardware
CNAP: Fault – Reservoir Pressure	- Air reservoir blocked or faulty pressure offset	- Disconnect an reconnect CNAP™controller - In case of persistent error contact service
CNAP: Fault – Zero Offset Controller	- Zero offset of CNAP™controller faulty	- In case of persistent error, contact service for faulty CNAP™controller
CNAP: Fault – Initial Pressure	- Pressure could not reach threshold upon initialization	- Check connections of CNAP™ cable - In case of persistent error message, contact service
CNAP: Fault – Pump/Tubing/Valve Leaky	- Leakage detected upon initialization	- Check connections of CNAP™ cable - In case of persistent error, contact service

Message	Possible cause	Measures
CNAP: Failure – Valve Blocked/Leaky	- Cuff pressure exceeded 450mmHg for more than 10sec in CNAP™ air reservoir	- Disconnect CNAP™ hardware - In case of persistent error, contact service for faulty CNAP™controller
CNAP: Failure – Reservoir Overpressure	- Pressure exceeded 450mmHg for more than 10sec in air reservoir	- Disconnect CNAP™ hardware - Reboot CNAP™ monitor - In case of persistent error, contact service
CNAP: Failure – Cuff Overpressure Left	- Pressure exceeded 330mmHg for more than 10sec in left CNAP™ finger cuff	- Disconnect CNAP™ hardware - Reboot CNAP™ monitor - In case of persistent error, contact service
CNAP: Failure – Cuff Overpressure Right	- Pressure exceeded 330mmHg for more than 10sec in right CNAP™ finger cuff	- Check connections of CNAP™ controller - Reconnect CNAP™ controller - In case of persistent error, contact service
CNAP: Cuff Cannot Deflate/Blocked Line	- CNAP™ finger cuff cannot be deflated	- Replace CNAP™ double finger cuff (check with other cuff size) - In case of persistent error, contact service
CNAP: Check Cuff – Low Light Signal	- CNAP™ detected low signal in measuring finger	- Check for low perfusion - Check size of CNAP™ double finger cuff - Check setup (positioning) of CNAP™ double finger cuff - Check proper optical path in CNAP™ double finger cuff
CNAP: Check Cuff – Ambient Light	- Ambient light interferes with CNAP™ double finger cuff	- Reduce ambient light (i.e. brightness, switch off, …) - Check setup of CNAP™ double finger cuff

Message	Possible cause	Measures
CNAP: Check Cuff – Timeout On Calibration	- Missing NBP calibration - Signal quality insufficient during the calibration cycle (max. 5min) -	- Check NBP for proper setup and measurement - Check size of CNAP™ double finger cuff - Check setup (positioning) of CNAP™ double finger cuff - Warm patient´s hand before measurement
CNAP: Cuff Fault – Overpressure	- Pressure exceeded 330mmHg for more than 2sec in CNAP™ finger cuff	- Check CNAP™ double finger cuff for patient movement (i.e. repositioning) - Disconnect and reconnect CNAP™ hardware - In case of repeated error, contact service
CNAP: Cuff Fault – Light Sensor Left	- Light sensor in left CNAP™ finger cuff defective	- Check influence from ambient light - In case of persitent error, replace CNAP™ double finger cuff
CNAP: Cuff Fault – Light Sensor Right	- Light sensor in right CNAP™ finger cuff defective	- Check influence from ambient light - In case of persitent error, replace CNAP™ double finger cuff
CNAP: Cuff Fault – Memory	- Memory chip in CNAP™ double finger cuff defective	- Replace CNAP™ double finger cuff
CNAP: Cuff Fault – Unlicensed	- CNAP™ double finger cuff is not licensed for CNAP™ Monitor 500	- Check for permutation with equipment from 3rd party devices
CNAP: Cuff Fault – Safety Shutdown	- CNAP™ double finger cuff cannot provide suffient quality for further measurement	- Replace CNAP™ double finger cuff immediately - Order new CNAP™ double finger cuff in corresponding size
CNAP: Cuff Fault – Leakage Left	- Leakage in left CNAP™ finger cuff	- Check connections of CNAP™ hardware - Replace CNAP™ double finger cuff (check with other cuff size): o In case of persistent error contact service

Message	Possible cause	Measures
		o In case of non-persistent error, replace defective CNAP™ double finger cuff
CNAP: Cuff Fault – Leakage Right	- Leakage in right CNAP™ finger cuff	- Check connections of CNAP™ hardware - Replace CNAP™ double finger cuff (check with other cuff size): o In case of persistent error, contact service - In case of non-persistent error, replace defective CNAP™ double finger cuff
CNAP: Cuff Failure – Inflation Timeout	- Inflation of CNAP™ finger cuff exceeded time limit	- Disconnect CNAP™ hardware - Reboot CNAP™ monitor In case of persistent error contact service
CNAP: Controller Fault – Memory	- Memory chip in CNAP™ controller defective	- Disconnect and reconnect CNAP™ controller - In case of persistent error, contact service for faulty CNAP™controller
CNAP: Controller Fault – Unlicensed	- CNAP™ controller is not licensed for CNAP™ Monitor 500	- Check for permutation with equipment from 3rd party devices

12.5 NBP

12.5.1 Status messages

Message	Possible cause	Measures
NBP: Terminated	- NBP measurement was stopped from the user	- n.a.
NBP: Fault	- Checksum error occurred	- Take new NBP - In case of persistent fault, contact service
NBP: Single Measurement	- User has triggered a single NBP measurement	- n.a.
NBP: Automatic Measurement	- Timed NBP measurement (NBP: Interval)	- n.a.
NBP: Checking CNAP	- NBP is triggered to confirm BP trend (CNAP™ differs more than 25mmHg for more than 1min from last NBP	- n.a.

12.5.2 Technical alarms

Message	Possible cause	Measures
NBP: Weak Or No Signal	- Weak or no oscillometric signal	- Check position and fit of NBP cuff - Make sure cuff is placed directly on the skin
NBP: Artifact	- Artifact/irregular oscillometric signal	- Check position and fit of NBP cuff - Avoid artifacts (e.g. movement) - Check for proper NBP cuff size
NBP: Exceeded Retry Count	- In spite of numerous retries, no measurement possible	- Avoid artifacts (e.g. movement) - Check position and fit of NBP cuff - Make sure cuff is placed directly on the skin - Check for proper NBP cuff size
NBP: Measurement Timeout	- Time limit for measurement has been exceeded	- Avoid artifacts (e.g. movement) - Check position and fit of NBP cuff - Make sure cuff is placed directly on the skin - Check for right NBP cuff size

Message	Possible cause	Measures
NBP: Blocked Line	- Blocked line / air hose	- Make sure that NBP air hose is not bent, or twisted too tight - Make sure patient is not lying on NBP cuff or air hose - Check position and fit of NBP cuff
NBP: Leakage	- NBP cuff or air hose leaky or loose	- Check NBP air connections (e.g. for damages, loose fit) - Check NBP cuff for leakage - Check position and fit of NBP cuff - Check for right NBP cuff size
NBP: Safety Timeout	- Safety time limit exceeded	- Check position and fit of NBP cuff - Avoid artifacts (e.g. movement) - Check for right NBP cuff size - Start new NBP measurement
NBP: Overpressure	- Overpressure in NBP cuff	- Check for right NBP cuff size - Make sure NBP air hose is not bent, or twisted too tight - Check position and fit of NBP cuff - Make sure patient is not lying on NBP cuff or air hose
NBP: Hardware Fault	- Voltage supply exceeds limits or other hardware problem	- Reboot CNAP™ monitor - In case of persistent error, contact service
NBP: Autozero Failure	- Autozeroing has failed	- Reboot CNAP™ monitor - In case of persistent error, contact service
NBP: Out Of Range Failure	- Measuring transducer out of measuring range	- Reboot CNAP™ monitor - In case of persistent error, contact service
NBP: ADC Failure	- ADC out of measuring range	- Reboot CNAP™ monitor - In case of persistent error, contact service
NBP: Calibration Failure	- faulty EEPROM calibration data	- Reboot CNAP™ monitor - In case of persistent error, contact service
NBP: Terminated By User	- User has stopped current NBP measurement	n.a.

13 Appendix A - Glossary

A

AC	Alternating current
Ah	Ampere-hour

B

BP Wave Out	Interface to subject monitors (CNAP™ blood pressure waveform)
bpm	Beats per minute
BSA	Body surface area (m^2)

C

CNAP™	Continuous noninvasive arterial pressure

D

Dia or diastolic	Diastolic blood pressure

H

h	Hour
Hz	Hertz
IBP	Invasive blood pressure

L

LED	Light-emmitting diode
LCD	Liquid crystal display

M

Main Screen	Monitor main screen (can be accessed to from any menu via pressing **Main Screen** fixed key)
Mean	Mean arterial blood pressure
min	Minute
mm/sec	Millimeters per second
mmHg	Millimeter of mercury
msec	Millisecond

N

NBP	Non-invasive blood pressure = oscillometric blood pressure measurement
Parameter	Monitored biosignal (e.g. pulse rate, blood pressure)
Pulse	Pulse rate

S

Sys or systolic	Systolic blood pressure
Sec	Second

V

V	Volts

13.1 Illustrations

14 Appendix B – Accessories

STOP:
In order to ensure operational reliability, functional safety as well as patients' safety, only original CNSystems Medizintechnik AG accessories and replacement parts are to be used.

14.1 CNAP™

Items	Number
CNAP™ cable (2.5 m)	20-FEKA-10041
CNAP™ controller	21-FHCN-16705
CNAP™ double finger cuff “small“	21-FVMA-15420
CNAP™ double finger cuff “medium“	21-FVMA-15520
CNAP™ double finger cuff “large“	21-FVMA-15620
Fixture for CNAP™ controller	21-FEZU-15401
CNAP™ forearm fixing cuff	20-FEMA-05705

14.2 NBP

Items	Number
NBP cuff „Child“ (12 – 19 cm)	20-FEMA-15150
NBP cuff ”Small Adult“ (17 – 25 cm)	20-FEMA-15250
NBP cuff „Adult“ (23 – 33 cm)	20-FEMA-15350
NBP cuff ”Large Adult“ (31 – 40 cm)	20-FEMA-15450
NBP extension hose	20-FEKA-05050

14.3 Printer

Items	Number
Thermal paper	20-HVZU-00258

14.3.1 Paper recommendation

CNSystems Medizintechnik AG recommends to use the following paper with your CNAP™ Monitor 500: Kanzan KPR 540.

In comparison with standard thermal paper for POS or fax, this high quality paper is characterized by a considerably higher degree of resistance against substances, i.e. alcohol, grease, PVC or plasticizers, oil, hand lotion or cream, etc. This results in your prints being readable and storable for a longer time. If stored properly, Kenzan guarantees archivability of at least 7 to 10 years when using this kind of paper. High quality non-topcoated thermal papers like this are suitable for all uses where the influence of external substances like oil, grease or water can be excluded as much as possible.

In addition, the characteristics of this high quality paper positively influences the product lifetime of your thermal printer. The characteristics of the above KANZAN paper regarding chemical composition, thickness, surface texture ..., have material influence on the printhead as well as the printer mechanism. The use of papers with lower dynamic sensitivity requires a higher level of energy transfer of the printer, while papers with a rougher surface lead, among others, to increased abrasion or mechanical strain. All these parameters automatically entail a considerable reduction of your printhead product lifetime.

For these reasons, only use the recommended paper brands or a thermal paper marked as top-quality by the manufacturer. However, when using other paper brands, CNSystems Medizintechnik AG cannot guarantee for the printers economic lifetime as this can cause damage or staining of the printhead.

14.4 Connections

Items	Nummer
BP Wave Out: CNAP™ transducer cable	20-FEKA-01201
BP Wave Out: IBP interface cable (to subject monitor)	contact BIOPAC
AUX: Analog Out connector	20-FEKA-01100

14.5 Other accessories

Items	Number
External mains adapter	20-FEKA-01010
Power cord for low power devices	20-HEKA-01011
Power cord British Standard	20-HEKA-01012
Power cord USA	20-HEKA-01013
CNAP™ Monitor mount	21-FEZU-15202
Operator's Manual German	21-FHZU-10001
Operator's Manual English	21-FHZU-10002
Operator's Manual French	21-FHZU-10003
Operator's Manual Italian	21-FHZU-10004
Operator's Manual Spanish	21-FHZU-10005

15 Appendix C – Technical specifications

15.1 CNAP™ Monitor 500

CNAP™ Monitor 500	
Physical properties	
Dimensions	280 x 270 x 250 mm (11 x 10.6 x 9.8 in.)
Weight	7,5 Kg (16.6 lbs) including components and accessories neccessary for operability of device
Battery	Sealed lead gel, operating time ≥ 2h (fully charged battery, normal conditions)
NBP cuff	Latex free
Electrical properties	
Nominal voltage	18 VDC ±10%
Nominal current	3A
Operability	No time-limit if powered by external mains adapter, at least 2h if on battery-operation (fully charged battery)
Environmental conditions for operation	
Temperature	Operation: 10°C - 40°C (50°F - 104°F) Storage: 0°C - 40°C (32°F - 104°F)
Humidity	Operation: 30% bis 85%, non condensing Storage: 20% bis 95%, non condensing, wrapped
Altitude	Operation: 647 bis 1059 hPa Storage: 500 bis 1059 hPa
User interface	
Controls	Fast access keys, click-wheel control
Alarming	Physiological alarms: medium priority Technical alarm messages: low priority
Screen	
Type	TFT-LCD
Size	200 x 150 mm (7.8 x 5.9 in.)
Display	170 x 128 mm (6.6 x 4.9 in.); 8.4 inch diagonally

CNAP™ Monitor 500	
Resolution	800 x 600 pixel
Color resolution	16 Bit
Trend memory	
Data memory	24 h, based on a mean heart rate of 90
Data resolution	Beat-to-beat

15.1.1 External mains adapter

External mains adapter	
Type	PDM60US18 (XP Power)
Connectors	IEC mains power plug, DC-connector for CNAP™ Monitor 500
Cooling system	Convection cooling
Dimensions	119 x 60 x 32 mm (4.6 x 2.3 x 1.2 in.)
Weight	0,650 kg (1.44 lbs)
Nominal voltage	100 – 240 VAC
Power frequency	~50/60 Hz
Power output	18 V, 3,3 A
Safety class	Class II with functional earth
Earth leakage current	< 500 µA
Operability	Continuous

15.1.2 CNAP™ - continuous non- invasive arterial pressure

CNAP™ - continuous non-invasive arterial pressure	
Parameter classification	Sys, Dia, Mean [mmHg] Pulse [bpm]
Measuring range	Sys: 40 - 250 mmHg (5,3 – 33,3 kPa) Dia: 30 - 210 mmHg (4 - 28 kPa) Mean: 35 - 230 mmHg (4 – 30,6 kPa)
Heart rate indication range	20-200 bpm
Accuracy	±5 mmHg (0,6 kPa)
Display resolution	1 mmHg (0,1 kPa)
Inflation pressure	Typ.: 120 mmHg (16 kPa) Min.: 30 mmHg (4 kPa) Max.: 300 ±10 mmHg (41,3 kPa ±1,3 kPa)
Excess pressure limit	300 ±10 mmHg (40 kPa ±1,3 kPa) Response time: < 3 sec. Deflation time: < 15 sec
Protection against electric	Type BF

CNAP™ - continuous non-invasive arterial pressure	
shock	

15.1.3 NBP – non-invasive blood pressure

NBP – non-invasive blood pressure	
Parameter classification	Sys, Dia [mmHg]
Measuring method	Oscillometric: diastolic value oscillometric: diastolic value for phase 5 Korotkoff
Measuring range	Sys: ADULT 40 - 260 mmHg PEDIATRIC 40 - 160 mmHg Dia: ADULT 20 - 200 mmHg PEDIATRIC 20 - 120 mmHg
Heart rate indication range	40-200 bpm
Inflation pressure at start	ADULT: 160 mmHg PEDIATRIC: 120 mmHg
Clinical accuracy	Meets ANSI/AAMI SP10:1992 und 2002
Accuracy of pressure recording	± 3mmHg between 0 - 300 mmHg at operating temperatures of 0 – 50°C
Calibration interval for pressure recording	12 months
Atmospheric pressure	no influence on accuracy of measurement
Measuring time	max. 130 s (ADULT)
Max. inflation time	50 s
Max. cuff pressure	300 mmHg
Automatic deflation after	180 s
Protection against electric shock	Type BF

15.1.4 Printer

Printer	
Type	Integrated thermal paper printer
Width	58mm
Roll diameter	60mm

15.1.5 Product configuration

Product configuration: CNAP Monitor 500i versus CNAP Monitor 500at	
CNAP Monitor 500i	CNAP Monitor 500at
CNAP finger blood pressure	CNAP finger blood pressure
NBP upper arm BP	NBP upper arm BP
8,4'' LCD screen	8,4'' LCD screen
Thermal printer	Thermal printer
BP-Wave Out	BP-Wave Out
Ethernet	Ethernet
USB	USB
	AUX Analog Out

15.2 Connections

BP Wave Out	
Sensor bridge voltage	2 - 10V (external monitor)
Sensitivity	5 µV/V/mmHg
BP Wave Out: CNAP™ transducer cable	0,3m; connector RJ11 6P4C (e.g. Abbott IBP catheter)

AUX (analog output port)		
	Channel 1	Channel 2
Voltage range	+-12 V	+-12 V
Reference	0 / 5 V (0 / 500 mmHg)	-5 / +5 V (0 / 500 mmHg)
Sensitivity	100 mmHg/V	50 mmHg/V
Samling frequency	100 Hz	100 Hz
Output Offset	+/- 50 mV	+/- 50 mV
Output Accuracy	5%	5%
Output Internal Resistor	100 Ohm	100 Ohm
Output Current	max 2 mA	max 2 mA

15.3 Electromagnetic compatibility

Medical electric devices have to comply with special safety regulations regarding EMC (electromagnetic compatibility). Please keep in mind the respective precautions in this operator's manual before installing and operating the CNAP™ Monitor 500. Also, pay attention to the fact that portable and mobile HF-communication devices (e.g. mobile phones) may interfere with medical electric devices.
The CNAP™ Monitor 500 must not be placed immediately beside or stockpiled with other devices. If there is no other way but to operate the CNAP™ Monitor 500 immediately beside or stockpiled with other devices, the CNAP™ Monitor 500 must be closely observed to ensure its normal operability within this arrangment of devices.
Only original CNSystems Medizintechnik Austria accessories and power cords are to be used with this device! Authorized accessories and replacement parts are listed in "Appendix B – Accessories" in this operator's manual. Using third party manufacturer accessories may result in increased emission or in decreased functional immunity of the CNAP™ Monitor 500.
As electric and magnetic fields may interfere with the functional reliability of the device, avoid using the CNAP™ Monitor 500 close to devices emitting powerful electromagnetic fields, e.g. x-ray equipment, diathermy applications or magnetic resonance tomographs.

Guidelines and manufacturer's declaration – electromagnetic emissions		
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment as specified below. The customer or operator of the CNAP™ Monitor 500 is to assure it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidelines
R F emmissions CISPR 11	Group 1	The CNAP™ Monitor 500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CNAP™ Monitor 500 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	NA	

Table 201 from EN 60601-1-2:2003

Guidelines and manufacturer's declaration – electromagnetic immunity			
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment as specified below. The customer or operator of the CNAP™ Monitor 500 is to assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wooden, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4-	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power supply quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the CNAP™ Monitor 500 requires continued operation during power mains interruptions, it is recommended that the CNAP™ Monitor 500 be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Table 202 from EN 60601-1-2:2003

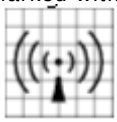
Guidelines and manufacturer's declaration – electromagnetic immunity			
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment as specified below. The customer or operator of the CNAP™ Monitor 500 is to assure that it is used in such an environment.			
Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile RF communication equipment should be used no closer to any part of the CNAP™ Monitor 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-	3 V_{rms} 150 kHz to 80 MHz	3 → $V1$ in V	$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz bis 2,5 GHz	3 → $E1$ in V/m	$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ for 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, **a** should be less than the compliance level in each frequency range.**b** Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CNAP™ Monitor 500 is used exceeds the applicable RF compliance level above, the CNAP™ Monitor 500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CNAP™ Monitor 500.		
b	Above the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.		

Table 204 from EN 60601-1-2:2003

Recommended separation distance between portable and mobile RF-communication devices and the CNAP™Monitor 500			
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment with controlled RF disturbances. The customer or operator of the CNAP™ Monitor 500 can avoid electromagnetic disturbances by complying with the minimum distance between portable or mobile RF-communication equipment (transmitter) and CNAP™ Monitor 500, depending on the power output of the communication equipment as specified below.			
Rated power output of the transmitter W	Separation distance depending on the transmit-frequency m		
	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	800 MHz to 2,5 GHz $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
The maximum rated power output values of transmitters that are not listed in the above list can be calculated by means of the respective formula, whereas the maximum rated power output is P in watts (W) according to the specification of the manufacturer.			
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Table 206 from EN 60601-1-2:2003

15.4 Standards

The CNAP™ Monitor 500 meets the following standards:

- ÖVE EN60601-1+A1+A2+A12+A13:1996
- ÖVE EN 60601-1-2:2003
- ÖVE EN 60601-1-4:1996 +A1:1999
- ÖVE EN 60601-1-6:2004
- ÖVE EN 60601-1-8:2004+A1:2006
- ÖVE EN 60601-2-30:2000
- ÖNORM EN 1060-1:1995
- ÖNORM EN 1060-3:1997+A1:2005
- ANSI/AAMI SP10:2002

15.5 Declaration of conformity

CNSystems Medizintechnik AG
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CNSystems
The Brain & Heart Company

Konformitätserklärung

Declaration of Conformity
CE-CNS-20080424

Produktspezifikation / *product details:*

Produktbezeichung / *product name*	Continuous non-invasive blood pressure measurement equipment
Type / *type*	CNAP™ Monitor 500at CNAP™ Monitor 500i
Software Version	2.9
Klassifizierung nach RL 93/42/EWG, Anhang IX *Classification according 93/42/EEC, annex IX*	IIb

Angewandte Normen / *used standards:*

EN 60601-1+A1+A2+A12+A13:	1996	EN 1060-1+A1:	1996
EN 60601-1-2+A1:	2003	EN 1060-3:	2006
EN 60601-1-4+A1:	1999	EN ISO 14971:	2007
EN 60601-1-6:	2005		
EN 60601-1-8:	2007		
EN 60601-2-30:	2001		

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den Anforderungen der Richtlinie 93/42/EWG entsprechen. Die Produkte werden mit dem CE-Kennzeichen und der Kennnummer 0408 versehen.

We declare under sole responsibility that the products described above are in compliance with directive 93/42/EEC. The products are CE-marked with the number 0408.

Gültig bis / valid until: 10/2010

Graz, 24.04.2008

Dr. Jürgen Fortin
Geschäftsführer / CEO