Operator's Manual – CNAP™ Monitor 500

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

CE 0408

according to the European standard for medical devices 93/42/EWG, annex IX
as amended by 2007/47/EC

The product starting with the serial number 0500-0917-xxxx was voluntarily tested according to
UL 60601-1:2003, CAN/CSA C22.2 No.601.1-M90

This manual refers to the following configuration:

Hardware:	CNAP™ Monitor 500i and CNAP™ Monitor 500at (note that only the CNAP™ Monitor 500at comes with a functional analog output port)
Software:	"Version 3.7.x" – with CNAP™-PPV extension for the types CNAP™ Monitor 500i/at+PPV

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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 patients.

STOP

The STOP icon indicates important security-relevant information:

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

CAUTION

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

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

NOTE

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

NOTE:
- Use the graphics on the CNAP™ controller to determine the correct finger cuff size.
- If the size of a patient'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	Setting
Brightness	Regulates the brightness of the TFT-display	**20(20)100, Auto**

2 General information

2.1 Warnings

- The CNAP™ Monitor 500 is not designed for intracardial use.
- Do not connect the device's air connectors to an intravascular system!
- Do not use the oscillometric cuff on patients 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 a 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 patient'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, patient 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 (blue fingers). Check the monitoring area frequently and discontinue the continuous blood pressure measurement and remove all air connectors immediately in case of any signs of reduced blood circulation.
- 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 patient/test subject at a time. Never measure two or more patients at the same time, applying only one device!
- Please pay attention to the precautions regarding electromagnetic compatibility (see chapter 15.3 – Electromagnetic compatibility).
- In perioperative settings, the CNAP™ Monitor 500 is not to be used without additional ECG monitoring for independent patient monitoring.
- Warnings regarding CNAP^{TM}-PPV are listed separately in chapter 11.1.

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 patients 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 liquids 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 confusion entailing possible serious consequences.
- Medical devices like the CNAP™ Monitor 500 are to be operated only by accordingly trained persons who can guarantee the 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 has to check and control the due condition, operational reliability and functional safety of the device.
- Before connecting any cables to a patient, 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 or hoses 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 (approx. 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 patients' safety. Notes and precautions of particular importance are highlighted by the following symbols:  ,  ,  (see chapter 1 – About this manual).
- In order to ensure the device's faultless functioning, accuracy of measurement and immunity of interference as well as the patients' 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 a company authorized by CNSystems. 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 programs and labels mentioned in this manual are reserved to CNSystems Medizintechnik AG.
- Never touch the AUX, Ethernet and USB interfaces together with the patient.
- All devices that get connected to the AUX, Ethernet and USB interfaces must meet EN 606950-1 standard.

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 the longest. If it is not possible to obtain a continuous blood pressure signal, it is, in most cases, caused by a vasopathy. 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 either, please check if the labeling on the CNAP™ double finger cuff (symbol) is on the side of the back of the hand.
- 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.
- During NBP measurements or venous stasis, the graphic display of the blood pressure waveform may be physiologically influenced.

- **Limitations:** In certain cases, a continuous blood pressure measurement is not reliable and/or not possible:

  - Weak signal shown through indicator: low PI ≤ 1 on the CNAP™ Monitor 500 (see chapter 3.7 - PI)
  - Reduced peripheral blood flow (peripheral shock, hypothermia, extreme centralization, extreme hypothermia)
  - Arterial vascular diseases (arteriosclerosis, Raynaud’s syndrome, endarteritis obliterans, collagenosis, extremely advanced vascular diseases PAOD)

- NBP limitations (see below)

NBP:
- Under the following conditions there might be a decrease in accuracy of the oscillometric blood pressure measurement:
  - weak pulse
  - arrhythmia
  - patient movement artifacts
  - tremor artifacts
  - respiratory artifacts

2.3 Disposal

Packaging 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 CNAP™ Monitor 500 is intended for the non-invasive continuous measurement and display of blood pressure (blood pressure waveform, beat-to-beat numerics, systolic, diastolic and mean pressures), and pulse rate in hospitals, clinical institutions, medical practices and outpatient settings. Furthermore, the display of alarms can be set for the parameters of blood pressure and pulse rate. The CNAP™ Monitor 500 is to be used for adults and pediatric patients from the age of 4 years and is to be operated by medical professional staff.

The derived measurement Pulse Pressure Variation (CNAP™-PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The CNAP™-PPV measurement has been validated only for adult patients.

3 Introduction

3.1 General information

The CNAP™ Monitor 500 is suitable for monitoring in **Adult** and **Pediatric** patients (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 connected with other patient monitoring systems (**BP Wave Out** analog output port for CNAP™ blood pressure waveform) and other devices (USB, Ethernet).

NOTE:

- Upon production of the CNAP™ monitor the models, "500i", "500at" and "500i/at+PPV", are differentiated. While the CNAP™ monitor "500i" resembles the basic device configuration for use of blood pressure monitoring (i.e. operating theatres, intensive care units), the CNAP™ monitor "500at" in addition enables the "AUX (analog output port)" for transferring the analog blood pressure waveform to other devices.
- The CNAP™ Monitor 500i/at+PPV has the additional feature to measure the Pulse Pressure Variation (PPV) for hemodynamic optimization of patients.

3.2 System components

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

1. CNAP™ Monitor 500
2. CNAP™ hardware (CNAP™ double finger cuff, CNAP™ controller, CNAP™ cable)
3. NBP cuff

3.2.1 CNAP™ Monitor 500

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: Patient connectors

① Thermal printer

② Mains power port

③ USB connector: software updates

④ Ethernet connector

⑤ AUX: analog output port (only functioning with the CNAP™ Monitor 500at)

Illustration 3: Printer, interface, power supply

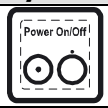
① Holding device channel (optional)

② Type plate

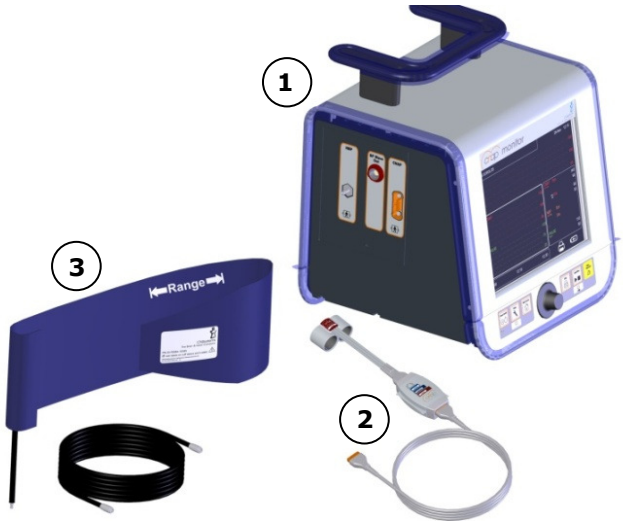
Illustration 4: Back view

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, Appandix IX in the changed version 2007/47/EG, annex IX as amended by 2007/47/EC
14		• Recycle damaged sealed lead gel battery
15		• Caution: see accompanying documents
16		• Separate disposal of electric and electronic appliances
17		• Protection class II

3.2.2 CNAP™ hardware



① CNAP™ Monitor 500

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 different colored hood.

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

Illustration 6: CNAP™ finger cuffs

3.2.2.2 CNAP™ controller

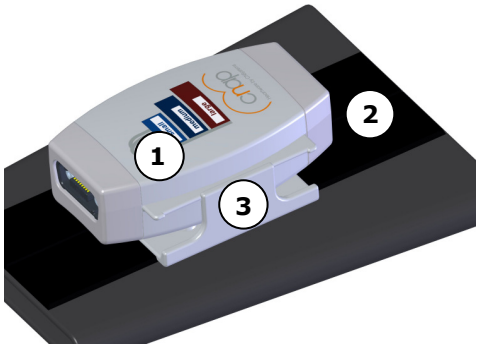


Illustration 7: CNAP™ controller

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 patient's forearm by means of the CNAP™ forearm fixing cuff with a Velcro fastener.
- ③ The fixture for CNAP™ controller connects the CNAP™ forearm fixing cuff mechanically to the CNAP™ controller. The fixture for CNAP™ controller needs to be setup-up centrally (see also illustration 18).

3.2.2.3 CNAP™ cable

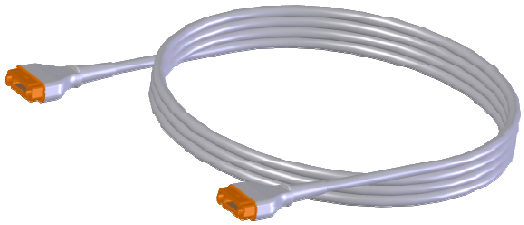


Illustration 8: CNAP™ cable

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

3.2.3 NBP cuff

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

Illustration 9: NBP cuff

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

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.

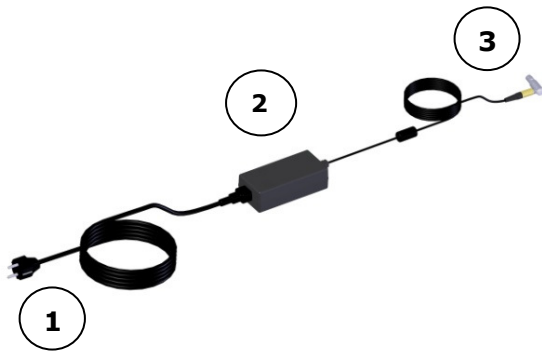
3.3.1 Mains operation

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. When the CNAP™ Monitor 500 is connected to the mains power supply, the integrated sealed lead gel battery is recharged as well. 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 color	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 shutdown within 15 minutes

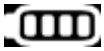
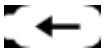
In addition, a low battery charge status (5 minutes of remaining operation time on battery) is indicated by the status message **MU: Battery Low**, a depleted battery by **MU: Battery Depleted** on the TFT-display (see battery status below). For security reasons, the measurement is stopped with a depleted battery and the monitor is shut down automatically.

STOP:
- Damaged or time-worn batteries might considerably reduce the 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:
- Total discharge may damage the battery. Therefore charge the battery at every opportunity.
- Immediately charge the battery with a battery charge status ≤ 25%, or as soon as possible and for at least 5 hours at ≤ 50%.
- Extreme temperatures might impair your battery performance. For optimal operability, charge and use the battery at temperatures < 35°C (95°F).
- In the case of infrequent use, charge the battery at least every 3 weeks for at least 5 hours.
- In order to guarantee a long product lifetime, preferably use the CNAP™ Monitor 500 in mains operation.
- 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%.
- During display of a status message or alarm, the battery symbol will be faded out – however, a critical battery status can be seen through the LED color being orange or red.

Battery status

Symbol	Battery charge status	Resulting measure
	• Battery charge status 100%	
	• Battery charge status 50%	• Switch to mains operation via power adapter as soon as possible
	• Very low battery charge status (< 25%), battery operation still possible	• Immediately switch to mains operation via power adapter • Printing deactivated • Current print job cancelled • Technical alarm **MU: Battery Low**
	• Battery depleted, operation possible for 5 minutes at most; monitor is switched off	• Immediately switch to mains operation via power adapter • Technical alarm **MU: Battery Depleted** • Current measurement discontinued, monitor switched off automatically
	• Battery malfunction, acoustic technical alarm signal	• Call a service technician (CNSystems)
	• Battery is being charged while running on mains power	
	• Fully charged while running on mains power	

3.4 First steps

3.4.1 Power On/Off

The ***Power On/Off*** key 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 ***Power On/Off*** key 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 splash 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

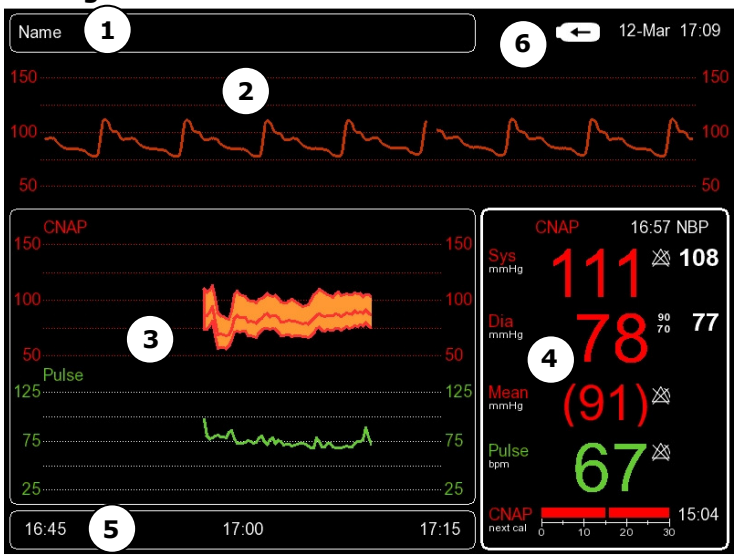
The CNAP™ Monitor 500 is switched off by pressing the ***Power On/Off*** key located on the front side of the device for 2 seconds.

CAUTION:
- The ***Power On/Off*** key 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 the operator to access all menus.

Arrangement of the screen:



① **Patient 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 ***Main Screen*** key 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:** Manual display of the **Setup Patient** dialog to continue measurement (see chapter 5.1 – Patient entry) if this is not displayed automatically. **Stop:** Stop measurement (CNAP or NBP).
6	***Alarm Pause/Off***	Alarm functions control: Press Alarm Pause/Off key once: set alarm reminder Press Alarm Pause/Off key twice: set alarm pause Press Alarm Pause/Off key three times: re-activate alarm function

CAUTION:

- The ***Start/Stop*** key controls stop of CNAP™ measurements. In case of an active NBP measurement, the operator first stops the NBP measurement by pressing the ***Start/Stop*** key once. Only pressing the ***Start/Stop*** key for a second time will stop the active CNAP™ measurement.
- The start function of the ***Start/Stop*** key is limited to display the **Setup Patient** dialog for continuing the measurement. When applying the finger cuff, the patient setup dialog is displayed automatically.

3.4.4 Menu navigation – click-wheel control

The monitor's click-wheel control enables the operator to select menus and settings 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.

Illustration 15: Click-wheel control

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 **on** to **off**).
3. Wheeling the click-wheel control – drop-down list appears.

3.4.5 Menu selection

Menus can be accessed 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 – Menu navigation – click-wheel control).

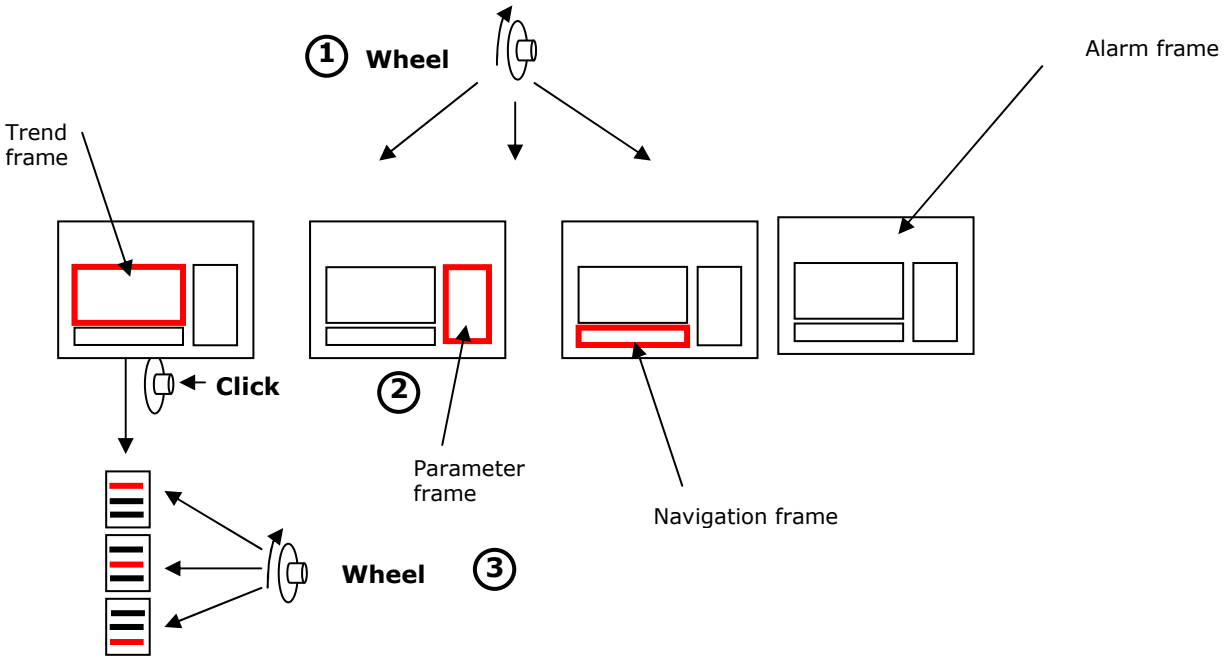


Illustration 16: Menu selection

3.5 Patient setup

Illustration 17: Patient-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. **Patient setup:**

   a) Choose the correct CNAP™ double finger cuff size by means of the graphic on the CNAP™ controller. If a patient'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 make it impossible to switch them accidentally.
   c) Equip the patient 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 outside of the patient's arm. Fasten the CNAP™ controller to the patient's forearm by means of the fixing cuff (with a Velcro fastener) and make sure that the hand with the CNAP™ double finger cuff is placed at heart level (see illustration on the side).

3. **Putting on the NBP cuff:**

   a) Make sure that only NBP cuffs authorized by CNSystems are used and that you apply the correct size to the patient (Child, Small Adult, Adult, Large Adult).
   b) Place the blood pressure cuff on the patient's upper arm, preferably contralaterally, at 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 patient side of the CNAP™ Monitor 500.

4. **Starting the measurement:**

   d) New entry of patients:
   Selecting the functions **New Patient - Adult Defaults** or **New Patient - Pediatric Defaults** starts a new measurement automatically – previous measurements will be deleted. Detailed patient data input can be performed at a later time via the **Alarm frame** in the **Patient Data** menu.

   e) Use current patient data:
   When selecting the option **Use Current Patient Data**, all patient data is maintained. To continue a measurement, press the ***Start/Stop*** key as the **Setup Patient** dialog is not displayed automatically. After selection of the option **Use Current Patient Data**, the measuring process starts automatically.

STOPP:

- Please be aware that CNAP™ finger cuffs as well as CNAP™ Cuff Controller needs to be setup without tension. The fixation of CNAP™ Cuff Controller is to be setup centrally (see illustration below). This obviates tension during a measurement due to dislocation of the patient which can disturb the CNAP™ measurement significantly.

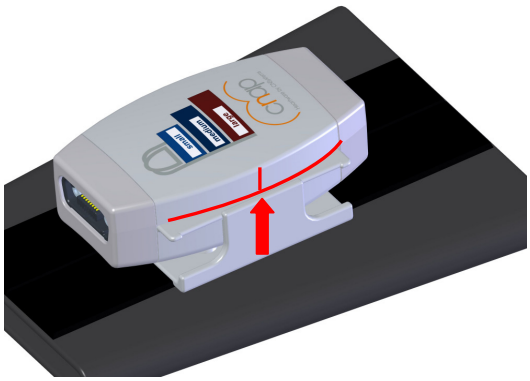


Illustration 18: CNAP™- Controller-Fixation

3.6 Timer

The timer displays the CNAP™ change of finger and/or NBP measurements following within the next 30 minutes (calibration measurements), thus making the following measurement-related interruptions of continuous blood pressure perceptible and allowing adequate time management (see below).

All **next calibration** measurements within 30 minutes will be graphically displayed and are color coded (continuous bar graph display).

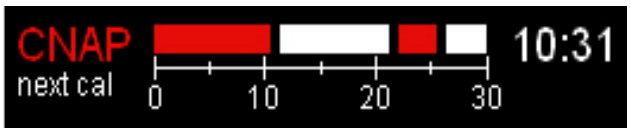
- Red = long interruption of measurement: CNAP™ change of finger (+ NBP measurement).
  The red bar always refers to a completely new calibration of CNAP™ change of finger (+NBP measurement) resulting in a longer interruption of continuous blood pressure of approx. 90 seconds.

- White = short interruption of measurement: NBP measurement
  The white bar always refers to an independent NBP measurement of shorter duration of approx. 45 seconds.

The immediate **next calibration** is displayed with **CNAP** or **NBP** to the left next to the bar graph display and numerically as a countdown (mm:ss) to the right of the bar graph display.

Example 1:

The immediate next interruption is a CNAP™ change of finger (+ NBP measurement) in 10:31 minutes, followed by another NBP measurement in approx. 21 minutes, a CNAP™ change of finger (+ NBP measurement) in 25 minutes and another NBP measurement in more than 30 minutes.



Example 2:

The immediate next interruption is an NBP measurement in 10:47 minutes, followed by another CNAP™ change of finger (+ NBP measurement) in approx. 15 minutes and another NBP measurement in more than 30 minutes.

NOTE:

- The timer is only displayed during active measurement (with available CNAP values) at the bottom of the **Parameter frame**.
- A manual **NBP: Start** resets the NBP timer: this means a reset of the NBP countdown to **NBP: Cal Interval** set in the **Parameter** menu.
- A manual **CNAP: Change Finger** resets the CNAP timer. In addition, also a reset for the NBP is carried out as soon as the NBP is triggered by CNAP. This means a reset of both the CNAP and the NBP countdown to the **CNAP: Cal Interval** and **NBP: Cal Interval** set.

TIME MANAGEMENT:

Example: As next calibration a CNAP™ change of finger (+ NBP measurement) will be in 5:00 minutes; however, continuous blood pressure will probably be essential at this time.

- **Option 1: Delay interruption**
  The user delays the next calibration by increasing the **CNAP: Cal Interval** in the **Parameter** menu to max. 60 minutes. This option does not apply if the **CNAP: Cal Interval** has already been set to 60 minutes.

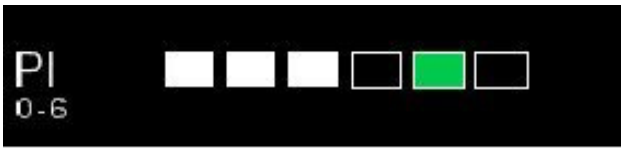
- **Option 2: Anticipate interruption**
  The user immediately starts a manual **CNAP: Change Finger** in the **Parameter** menu. This CNAP Change Finger resets both timers at the time of triggering CNAP or NBP. With **CNAP: Cal Interval** of 30 minutes, the subsequent interruption would only be in 30 minutes, provided the **NBP: Interval** has not been set with a shorter interval.

  Option 1 and option 2 apply analogously to the NBP if this is planned as the next calibration.

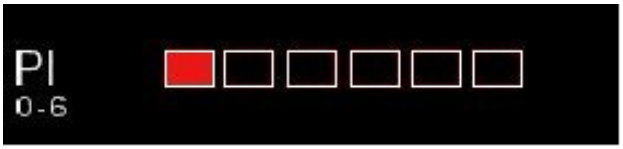
3.7 Perfusion Index

The Perfusion Index (PI) describes the signal quality of perfusion in the finger artery in the CNAP™ cuff on a scale from 0 (no signal) to 6 (very good signal). The currently found PI is shown on the screen as a white bar. The maximum value that was found during the calibration phase is marked with a green rectangle in the bar graph (see example 1). Patients with a very bad peripheral blood circulation can be identified by means of a very low PI ≤ 1. Also a red rectangle at the very left position in the bar graph is displayed (see example 2). Such a case involves the risk of a CNAP™ interruption due to insufficient peripheral circulation, i.e., in the course of measurement it could fail temporarily or completely. The red rectangle will disappear if a PI > 1 will be found.
During measurement, a temporary, too low signal quality will be displayed with the technical error message **CNAP: Artefact.** If the signal quality is insufficient for more than 10 seconds, particularly during the initialization phase, the technical error message **CNAP: Check Cuff – Low Light Signal** will be displayed. A further NBP measurement by means of the CNAP™ Monitor 500 remains unaffected by this.

Example 1: current PI = 3, maximum found = 5 – good signal quality



Example 2: current PI ≤ 1 - bad signal quality



NOTE:
- The Perfusion Index will only be displayed during the initialization phase (until NBP measurement - **NBP: triggered by CNAP**).

NOTE:
- The reason for a low light signal may be
  - insufficient peripheral circulation
  - or a misplaced CNAP™ finger cuff.

  Before starting a new measurement the position of the finger cuff must be checked.

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 setting for the user interface	**EN, DE, FR, ES, IT**
Date	Date setting	**YYYY/MMM/DD** e.g. 1970/MAR/10
Time	Time setting	**hh:mm:ss**
Record	Sets data recording on the USB	**Off, User, Debug**

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

4.2 Measurement settings

Menu item	Description	Settings
NBP: Mode	Refer to the description of the NBP Modes in the following paragraphs.	**Auto, Intelligent, Manual**
NBP: Interval	Setting of time interval [min] for automatic NBP measurements	**Off, 5(5)30, 45, 60**
CNAP: Cal Interval	Setting of intervals [min] for automatic change of signal source in the CNAP™ double finger cuff	**5(5)60 min**
Audio Trend...	Setting of source and volume of audio trend	Submenu
Display...	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 8.4 Print Options)	Submenu
Parameter Averaging	Averaging of displayed numeric parameters [sec]	**Off, 5, 10, 15 beats**
Patient Category	Presetting of patient category as a focus in the **Setup Patient** dialog	**Adult, Pediatric**

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.
- All settings can be changed to factory settings in the **Service** menu (see chapter 4.3 – Service settings.

The following table gives an overview of the three different NBP modes:

NBP Mode	Timed NBP	CNAP™ Change Finger	NBP Used for Calibration
Manual	Yes	NBP Calibration	• timed or manual • always used for calibration
Auto	Yes	NBP Calibration	• timed or manual • triggered if difference > 25mmHg for > 45 seconds • always used for calibration
Intelligent	No	Calibration to previous CNAP™ values	• triggered based on internal criteria • NBP used for calibration if difference > 13mmHg

4.2.1 NBP Mode – Manual

For the manual NBP mode a NBP measurement is triggered after each change finger event and at predefined NBP intervals.
The CNAP signal will always be calibrated to the NBP values.

4.2.2 NBP Mode – Auto

For the automatic NBP mode a NBP measurement is triggered after each change finger event and at predefined NBP intervals.
Also if a difference in the CNAP values compared to the last NBP measurement of more than 25 mmHg for over 45 seconds occurs, a NBP measurement is triggered.
The CNAP signal will always be calibrated to the NBP values.

4.2.3 NBP Mode - Intelligent

In NBP Mode "Intelligent" the automated triggering of NBP measurements is restricted to situations when the blood pressure based on CNAP changes excessively.
In the case that NBP measurements are triggered automatically, CNAP is calibrated newly upon differences of more than 13 mmHg between CNAP and NBP values.
After a subsequent change finger no NBP measurement will be triggered.

NOTE:
- In the intelligent NBP mode no automatic NBP measurements (timed NBP measurements in fix intervals) are triggered. The settings "NBP: interval" in the parameters and measurement menu are deactivated in this mode.

NOTE:
- An automatically triggered NBP measurement may be canceled by pressing the start/stop button once during the NBP measurement.
- A manually NBP or change finger measurement is possible any time during the measurement.
- A manually triggered NBP or change finger measurement will always lead to a calibration of the CNAP signal.

CAUTION:
- Before interventions with expected haemodynamic instabilities perform a manual NBP calibration.
- Following a relocation of the patient or repositioning of the arm make sure that the position of the finger cuff has not changed (mechanically). If so please initiate a change finger. In all other cases initiate a NBP measurement.

4.3 Service settings

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

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 patient categories (**Adult, Pediatric**) within the limits of factory settings. The alterations will be used for each new measurement. The operator/user can also restore factory settings.	Submenu
Log...	Lists technical alarms by means of language-independent error codes	Submenu
Function Tests ...	Function tests of the modules IBP analog output, printer and CNAP/NBP	Submenu
Advanced...	Menu for software update	Submenu

4.4 Feature activation

Starting with software version 3.6 the basic features of the CNAP™ Monitor 500 can be extended with a license key. The following features can be activated on the monitor:

- Additional AUX analog out port (the monitor type is changed to 500at)
- CNAP™-PPV (the monitor type is changed to 500i/at+PPV)

The additional features can be activated by entering a valid license key in the menu **Setup/Monitor/Device Features/License Key**. The license keys for activating features can be purchased from the local distribution partner or directly at CNSystems.

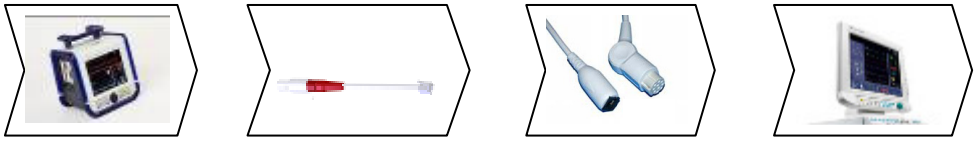
NOTE:
- After activation of CNAP™-PPV with a license key the feature is disabled per default. The parameter can be enabled per default (via menu entry **Setup/Measurement/PPV**) or only for the current measurement in the menu **Parameters/PPV**.

4.5 BP Wave Out (patient monitors)

4.5.1 BP Wave Out configuration

Similar to the BP waveform obtained from an invasive catheter (e.g. radial artery), the CNAP registered blood pressure waveform can be interfaced to patient 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). As can be seen from the graphics below, the CNAP™ Monitor 500 can also be connected with the patient monitor by **a)** CNAP™ Transducer Cable and **b)** IBP Interface Cable (see also chapter 15.2 - Connections).

CNAP™ Monitor 500 | Transducer Cable | Interface Cable | Patient Monitor



CAUTION:
- In order to connect the CNAP™ Monitor 500 to another patient monitor with invasive BP port, the following 2 compatible cables are needed (see compatibility list below):
- CNAP™ Transducer Cable: suitable for the different patient monitors and available in 4 colors (grey, blue, red, yellow). The cable is connected to the CNAP™ Monitor 500 (patient side) and enables access to the CNAP™ blood pressure waveform using an RJ11 6P4C connector. The compatible CNAP™ Transducer Cable is a component for the CNAP™ Monitor 500 and is only available from CNSystems Medizintechnik AG.
- IBP Interface Cable: connects the IBP port of a patient monitor to the RJ11 6P4C connector of the CNAP™ Transducer Cable. Selected IBP Interface Cables (e.g. Abbott IBP catheter) are also available from CNSystems Medizintechnik AG.

Unlike the analog output port (see chapter 4.5 - Interfaces), the CNAP™ blood pressure waveform signal via the "BP Wave Out" is standardized. Its sensitivity always amounts to 5 µV/V/mmHg. The bridge voltage on the CNAP™ Monitor 500 depends on the supply voltage the patient monitor provides.

If, for example, the supply voltage is 4 V, the sensitivity will be calculated as follows: 5 µV/V/mmHg x 4 V = 20 µV/mmHg

4.5.2 Compatibility list

Make	Type	Transducer Cable		Interface Cable
Siemens	SC 9000XL, SC 9000, SC 8000, SC 7000	20-FFKA-01200	○	20-HHKA-01201
Dräger	SC 7000	n/a		20-HHKA-01202
GE	Marquette	20-FFKA-01201	●	20-HHKA-01214
	Marquette Solar8000M	20-FFKA-01200	○	20-HHKA-01214
Spacelabs	n/a	n/a		20-HHKA-01215
Mindray	Beneview T5	20-FFKA-01202	●	20-HHKA-01216
Philips	Intellivue M8008A	20-FFKA-01200	○	20-HHKA-01218
	Intellivue MP50	20-FFKA-01203	●	20-HHKA-01218
	Intellivue MP70	20-FFKA-01203	●	20-HHKA-01218
Datex	AS/3	20-FFKA-01200	○	20-HHKA-01230
	S/5	20-FFKA-01200	○	20-HHKA-01230
HP	Viridia	20-FFKA-01202	●	HP/Abbot

4.5.3 Zeroing

After having connected the CNAP™ Monitor 500 and the patient monitor using a) the CNAP™ transducer cable and b) the IBP interface cable (see 4.4.1 - BP Wave Out configuration), zeroing must be performed:

a) Zeroing without active measurement:
Before and after an active measurement (without displayed CNAP values), zeroing is activated **automatically** (a zero signal is output). Zeroing can be immediately performed on the patient monitor.

b) Zeroing during active measurement:
During an active measurement (with displayed CNAP values), zeroing is inactive; however, it can be activated **manually** in the **Parameter** menu:

1. CNAP™ Monitor 500: Activate zeroing via **IBP: Zeroing Start**
2. Patient monitor: Performing the zeroing process
3. CNAP™ Monitor 500: Deactivate zeroing via **IBP: Zeroing Stop**

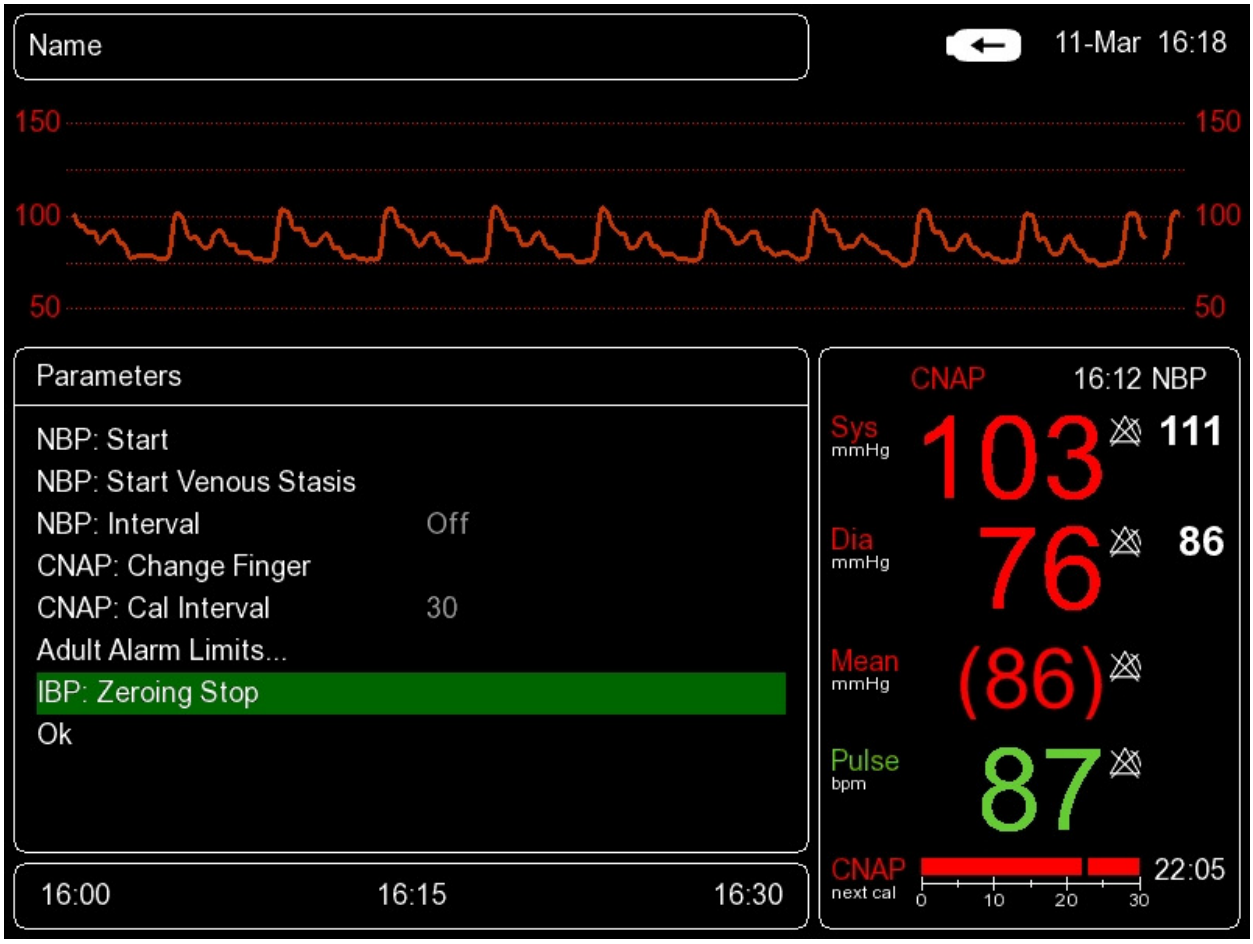


Illustration 19: Parameter menu: IBP: Zeroing

NOTE:

- Usually a patient monitor will report successful zeroing (must be within ± 32 mmHg), e.g. by signaling "zero completed, offset is xx mmHg".
- If you don't deactivate **IBP: Zeroing Stop** and leave it on **Stop**, the pressure signal on the patient 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 patient 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 hospital regulation (but at least once a day). Plus, zeroing should be performed if there is any doubt as to the accuracy of obtained recordings and in the event of a new connection of the transducer to the monitor.

NOTE:

- Blood pressure values obtained by means of CNAP™ and invasively obtained reference values (e.g. radial measurement) may differ for the following reasons:
  a) Difference in beat detection
  b) Different settings for **Parameter Averaging** (see chapter 4.2 – Parameter Averaging menu item)
  c) Physiological differences due to different measuring positions (e.g. left-right, brachial-radial)
  d) During the initialization of CNAP measurement, at the start of measuring or change of finger, the non-calibrated and then the measured blood pressure signal will be displayed (blood pressure waveform – see illustration 20 below). In order to avoid misinterpretation, the scale of the blood pressure waveform will be blanked in the meantime.

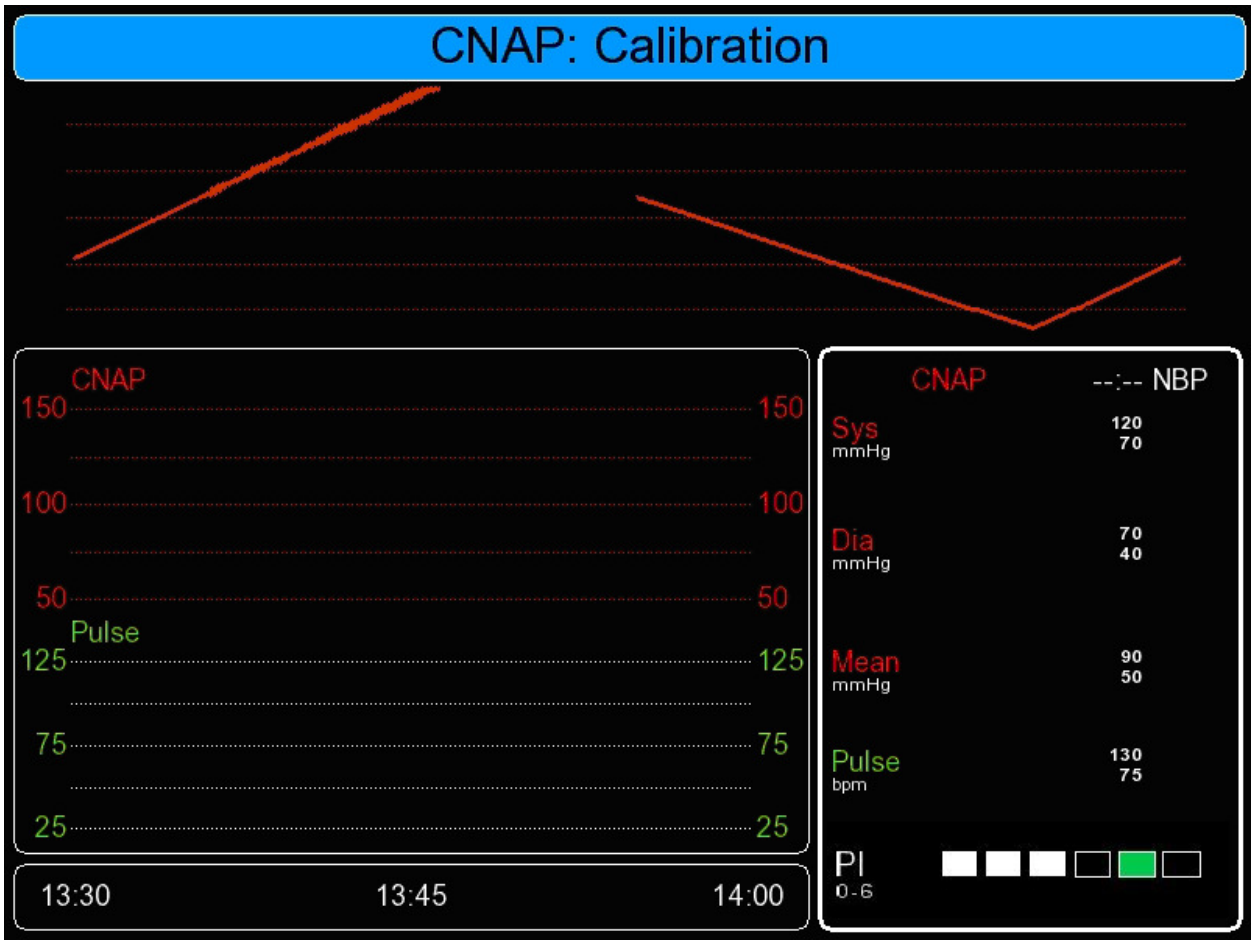


Illustration 20: CNAP calibration

4.6 Interfaces (optional)

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

4.6.1 AUX Analog Out (analog output port)

The AUX Analog Out (analog output port) is only available for the CNAP™ Monitor 500at. The corrected CNAP™ blood pressure waveform is available from the device's analog output port (see chapter 15.2 - Connections).

4.6.2 Ethernet

The Ethernet port is restricted for service perposes only.

4.6.3 USB

In addition to service functions such as software updates, the USB port serves for data recording on a USB flash drive, provided that **Record** for data recording has been activated in ***Setup*/Monitor** (**CSV File** or **Advanced**). The settings for **Record** cannot be changed during a measurement.

NOTE:
- Only USB flash drives formatted with FAT32 are supported by the CNAP™ Monitor 500 for data storage and software updates.
- Recording data as CSV files is an optional feature. If the entry **CSV File** in the menu **Setup | Monitor | Record** is not visible this feature is not available on your device. To activate optional features read the description in chapter 4.4.

CAUTION:
- Don't connect any input devices or devices with high power consumption to the USB port. Only USB flash drives are supported.

STOP:
- Because of a possible influence on the patient safety it's not allowed to connect USB hard drives or any other devices using external power supplies to the CNAP™ Monitor 500.

NOTE:
- If the shutdown procedure of the CNAP™ Monitor 500 is interrupted by releasing the ***Power On/Off Button*** to early, the error message "No USB Stick Attached" may occure even if the USB media is placed correctly. In this case the USB media must be reconnected to mount the device correctly.

Procedure for activating data recording on the USB device:

1. Prepare a USB stick with the following specifications:
   - 'Corsair Flash Voyager' 4GB recommended
   - Writable
   - FAT32 formatted (not NTFS)
   - Old data deleted

2. Turn off the CNAP™ Monitor 500

3. Connect USB stick

4. Turn on the CNAP™ Monitor 500

5. Open the monitor menu in ***Setup*/Monitor** and select one of the following settings for recording:

Setting	Use	Parameters	Capacity
CSV File	Clinical focus: Data storage in the CSV format (comma separated values)	CNAP™ (wave form and beat-to-beat values), NBP, pulse rate, time, interventions, measurement parameters	approx. 10 MB/h (4GB = 400h)
Advanced	Additional storage of measurement data in PDP file format (for internal use only)	Further technical parameters	approx. 180 MB/h (4GB = 22h)

6. Back to ***Main Screen***

7. Check if the USB stick properties are displayed in the top right of the screen.

S: USB connected A: Available, free capacity in MByte U: Stored capacity	

In the event of failed activation, status messages will be displayed (see 13.1.1 – Status Messages).

5 Management of patient data

Immediately after a patient has been connected to the CNAP™ Monitor 500 and the setup process has been performed correctly (see chapter 3.5 - Patient setup), the **Setup Patient** dialog for selecting the patient category opens automatically. After selecting the correct patient category, the measurement starts automatically.

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 patient data is a prerequisite of essential importance. Entering the respective patient category, for instance, results in the subsequent adjustment of alarm limits as well as of the NBP cuff inflation pressure.

5.1 Patient entry

Patient entry and use of current patient data is done via the setup patient dialog appearing on the main screen immediately after a new patient has been set up with the CNAP™ double finger cuff.

NOTE:
- The **Setup Patient** dialog will be displayed automatically if a new patient is measured or if the CNAP™ double finger cuff was not applied for ≥ 5 seconds. In case the **Setup Patient** dialog is not displayed automatically despite correct application of the CNAP™ double finger cuff (detection error) or if the measurement is continued, it is displayed by pressing the ***Start/Stop*** key.

Illustration 21: Setup Patient Dialog

There are 2 ways for setup a patient before starting a measurement:

a) New Patient:

Selecting the functions **New Patient – Adult Defaults** or **New Patient – Pediatric Defaults** automatically sets the respective patient category (adult, pediatric). Presetting of the focus on **New Patient – Adult Defaults** or **New Patient – Pediatric Defaults** can be defined in ***Setup*/Measurement/Patient Category**. As soon as a category is selected, measurement starts automatically.

b) Use Current Patient Data (continue):

The **Use Current Patient Data** option can be selected in the **Setup Patient** dialog provided that a patient category has already been defined (current patient data is being used). After confirming the **Use Current Patient Data** option, the measurement will automatically continue with a new initialization phase.

NOTE:

- While the **Setup Patient** dialog is displayed, it is not possible to complete further patient data (e.g. name, gender) in the **Patient Data** menu (see chapter 5.2 - Editing of patient data). In such a case, the **Patient Data** menu will only be accessible again after selection of a patient category.

5.2 Editing of patient data

At any given time – except during the display of the **Setup Patient** dialog – you can enter detailed patient data by using the click-wheel control to select the **Alarm frame** on the main screen and to open the **Patient Data** menu.

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

STOP:

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

NOTE:

- Before applying the CNAP™ finger cuff and during a measurement, the **Patient Data** menu can be selected via the **Alarm frame.**
- If, before starting a measuring process, you want to enter additional patient data, you have to do this before applying the finger cuff. By selecting the **Use Current Patient Data** option in the **Setup Patient** dialog, the currently input patient data will be used.

5.3 Discharge

As a rule, patient data needs to be deleted when a measurement in a new patient is performed:

The **Discharge** function

- deletes all information in the **Patient Data** menu,
- deletes all trends of data from the monitor,
- deletes all entries of the **Alarm History.**

After having stopped the measuring process, patient data can be deleted in 2 ways:

a) **Patient Data** menu:

Open the **Patient Data** menu by using the click-wheel control to select the **Alarm frame** on the main screen. Select **Discharge** and confirm your selection in the input dialog.

b) Setup of a new patient:

Immediately after a new patient has been set up with the CNAP™ double finger cuff and the device's self-test has been performed, the **Setup Patient** dialog appears on the main screen. Select **New Patient – Pediatric Defaults** or **New Patient – Adult Defaults** and confirm your choice in the input dialog. This will result in the deletion of any previous patient data.

NOTE:

- In order to avoid loss of patient data, all required data and entries must be printed before discharging (=deleting patient data) a patient.
- **Discharge** can only be made after the measurement has stopped.
- After **Discharge,** even before leaving the **Patient Data** menu, new patient data can be entered for the next patient. In such a case, this patient data will be used in the following **Setup Patient** dialog by selecting **Use Current Patient Data.**

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 three stars **(***)**, 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).
- Physiological alarms are deleted:
  - by **Discharge,**
  - by stopping the measurement using ***Start/Stop***,
  - by the next NBP measurement.
- Physiological alarms triggered by a single NBP measurement will be saved until the next NBP measurement.

STOP:
If several alarms are activated at the same time:
- The alarm signals will be displayed alternately in intervals of 5 seconds in the **Parameter 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 will be accompanied by an acoustic signal,
- New alarms and technical malfunction alarms will be displayed immediately.

6.1 Visual alarm signals

Alarm signals are displayed visually in the **Alarm frame** and the **Parameter frame,** directly in the main screen. In the **Parameter frame**, only those parameters are visually marked which exceed the defined alarm limits.

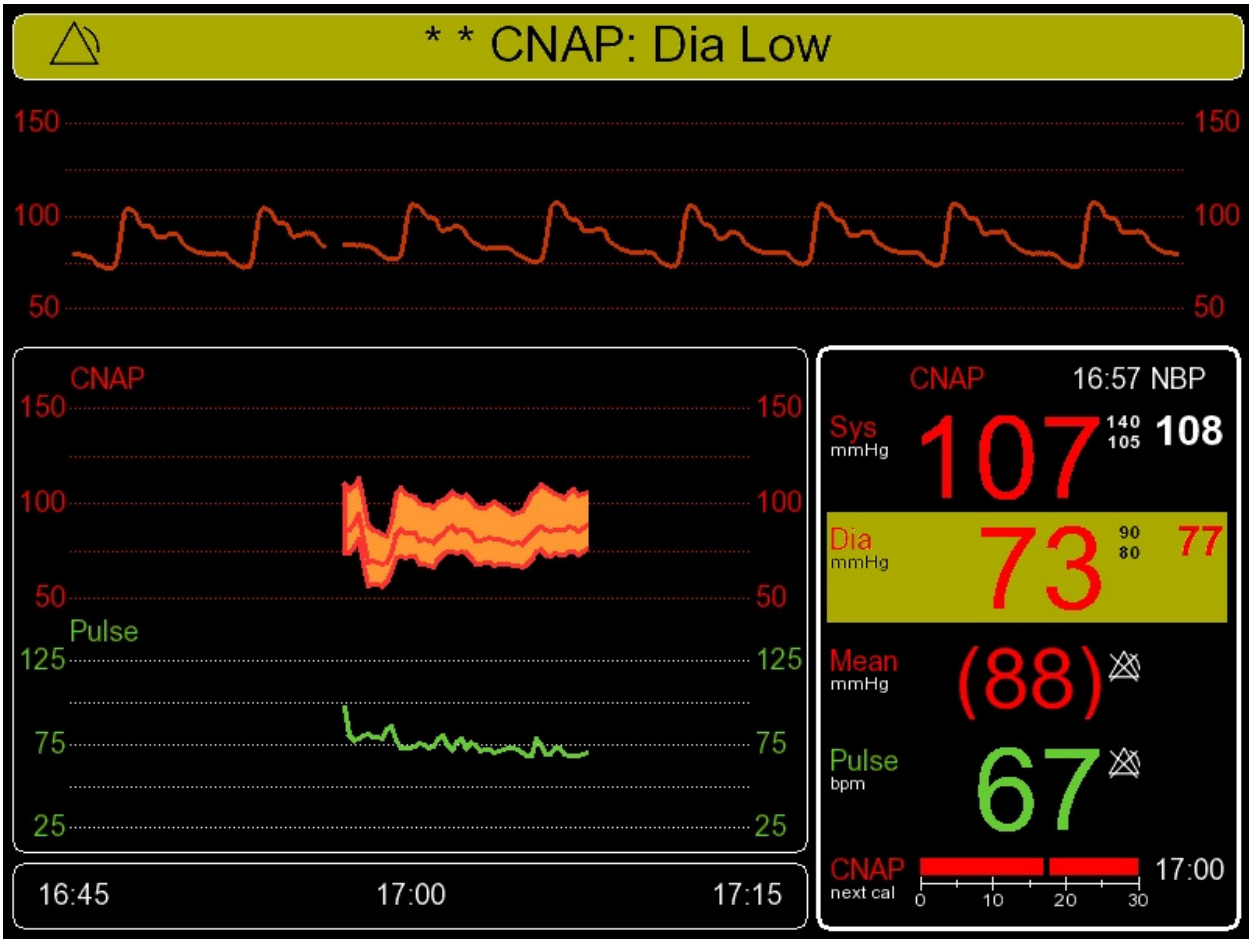


Illustration 22: Visual alarm signals

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

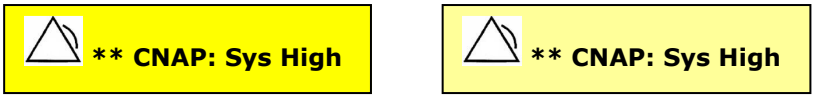


Illustration 23: Alarm frame – alarm conditions

Parameter frame:

- Background color: YELLOW – Physiological alarms (medium priority)
  WHITE - Technical malfunction alarms (low priority)
  BLUE - Status messages
- Flashing parameters which are exceeding the alarm limits
- Numeric values: unchanged during physiological alarms, blanked during technical malfunction alarms by 3 stars (***).

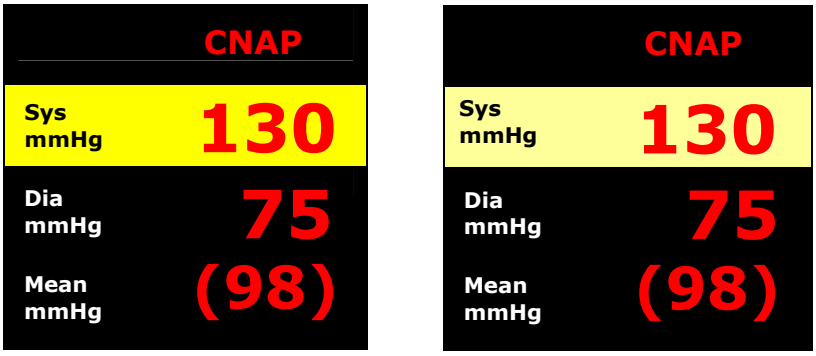


Illustration 24: Parameter frame – alarm conditions

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 ***Alarm Pause/Off*** key.

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 or has been turned off, alarms might be missed which could constitute a possible danger for patients!

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 alarms), 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, 3 min**

NOTE:
- During measurements, an alarm reminder setting may be entered in the **Parameter** menu by using the click-wheel control to open the **Parameter frame**. The settings are saved by confirming with ***Alarm Pause/Off***.
- The alarm reminder operator setting may be set in the **Alarm defaults** menu, which is opened from the **Service** menu by using the click-wheel control.

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 patient 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 timeout**

NOTE:
- Pausing alarms is only possible if no physiological alarms are activated.
- During measurements, **Alarm Pause** setting changes will only become active with the next activated alarm pause, i.e. after restart of the alarm system (see chapter 6.3.3 – Reactivation of paused alarms) and reactivation of paused alarms by pressing ***Alarm Pause/Off*** twice.
- 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 **Alarms 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 physiological 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 **Alarms Off** will appear next to the measured value in the **Parameter frame** (refer to chapter 6.1 – Visual alarm signals).

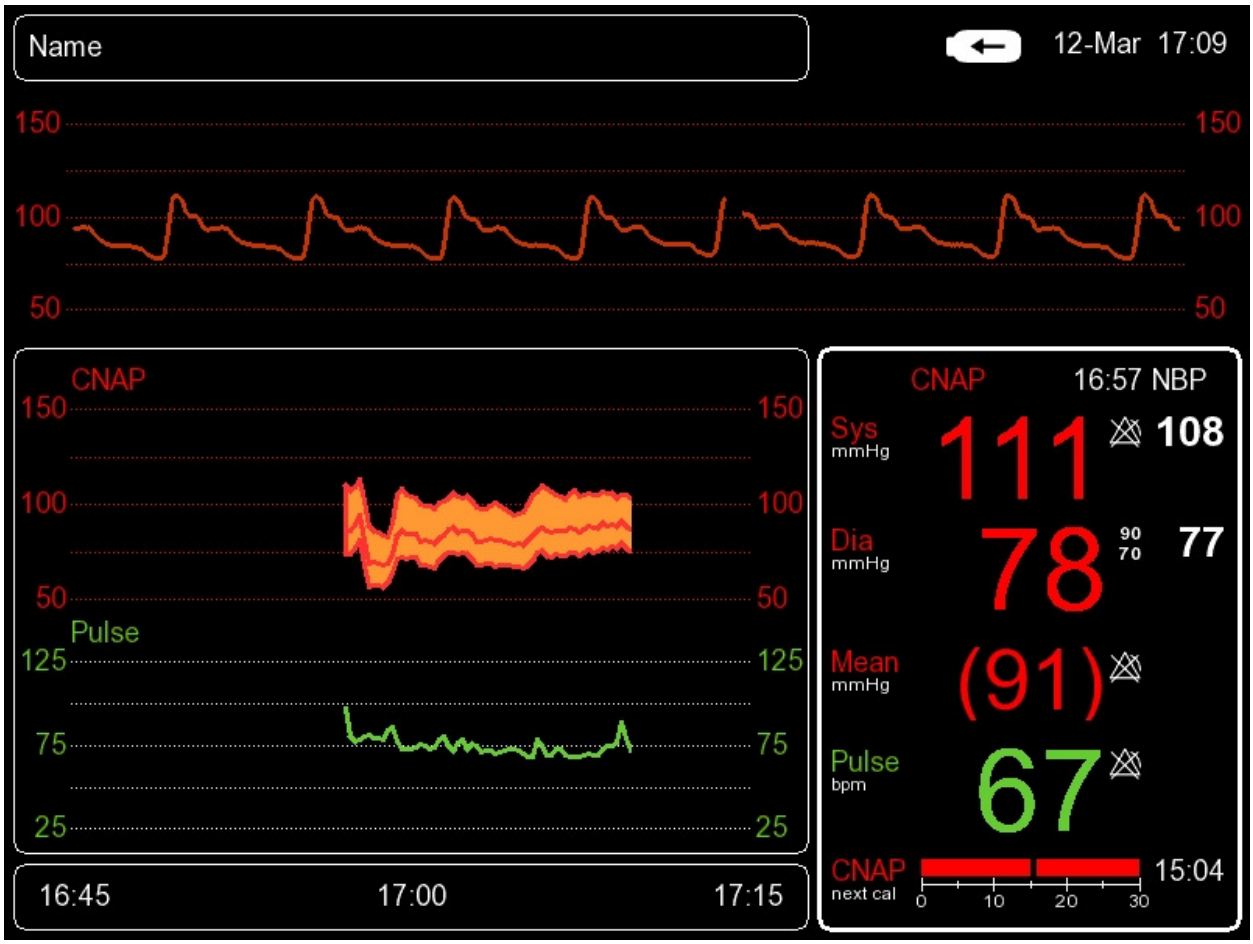


Illustration 25: Parameter frame – alarm limits

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 Limits** menu (see chapter 6.4.2 – Alarm setup).

6.4.2 Alarm setup

The **Alarm Limits** menu, which is opened from the **Parameter frame** by means of the click-wheel control, 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; upper, lower**
Dia	Alarm limits for diastolic blood pressure	**On, Off; Upper, Lower**
Mean	Alarm limits for mean blood pressure	**On, Off; Upper, Lower**
Pulse	Alarm limits for pulse rate	**On, Off; Upper, Lower**
Alarm Volume	Volume settings for alarms, 20 – 100%	**20(20)100**
Alarm Reminder	Function to set alarm reminders (see chapter 6.3.1 – Acknowledgement of alarms - Audio Off, Audio Pause)	**Off, 1 min, 2 min, 3 min**
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 configured in the factory settings never leave the physiological area.

Sys, Dia, Mean, 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 patient category. Thus, be sure to enter the correct patient category before starting a measurement.
- 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 configuring individual user settings or restoring factory settings can be found in the CNAP™ Monitor 500 "Service manual for users".

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 patients.

6.4.3 Auto limits

By means of the function **Auto limits,** the operator is able to adjust alarm limits to a specific patient. 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 patient data is deleted or new patient 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/Dia/Mean/Pulse ± 20mmHg
- **Wide:** currently measured value Sys/Dia/Mean/Pulse ± 30mmHg
- **Cancel:** return to **Alarm limits** menu without changing the alarm limits
- **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
dBP [mmHg]	30	50	245	35	90	250
mBP [mmHg]	35	60	250	40	110	255
Pulse [bpm]	30	50	195	35	110	200

- Alarm limits (PEDIATRIC):

	Lower limits			Upper limits		
Parameter	Lower limits	Defaults	Upper limits	Lower limits	Defaults	Upper limits
sBP [mmHg]	40	70	175	45	120	180
dBP [mmHg]	30	40	165	35	70	170
mBP [mmHg]	35	50	170	40	90	175
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 configuring individual user settings or restoring factory settings can be found in the CNAP™ Monitor 500 "Service manual for users".
- 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!

6.5 Alarm history

The **Alarm History** is displayed directly on the main screen 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 priority)
- 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 check the functional reliability 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.** Check the functional reliability of the alarm system during start-up of the monitor 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.	Flashing 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.	Flashing 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.	Flashing CNAP™ values, alarm message and acoustic alarm signal
CNAP: Sys Low **CNAP: Dia Low** **CNAP: Mean Low**	Medium**	CNAP™	Measured CNAP™ pressure value falls below lower alarm limit. In addition, "Sys", "Mean", "Dia" indicates which parameter has fallen below the alarm limit.	Flashing CNAP™ values, alarm message and acoustic alarm signal
CNAP: Pulse High	Medium**	CNAP™	Pulse rate (CNAP™) exceeds upper alarm limit.	Flashing CNAP™ values, alarm message and acoustic alarm signal
CNAP: Pulse Low	Medium**	CNAP™	Pulse rate (CNAP™) falls below lower alarm limit.	Flashing CNAP™ values, alarm message and acoustic alarm signal

NOTE:
- All technical malfunction alarm messages of the CNAP™ Monitor 500 or its components can be 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 graphic as well as numeric trends. The display of a list of physiological alarms is optional.

NOTE:

- The recorded parameters **Sys, Mean, Dia** and **Pulse** 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 report:** The setup 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 – Printing).

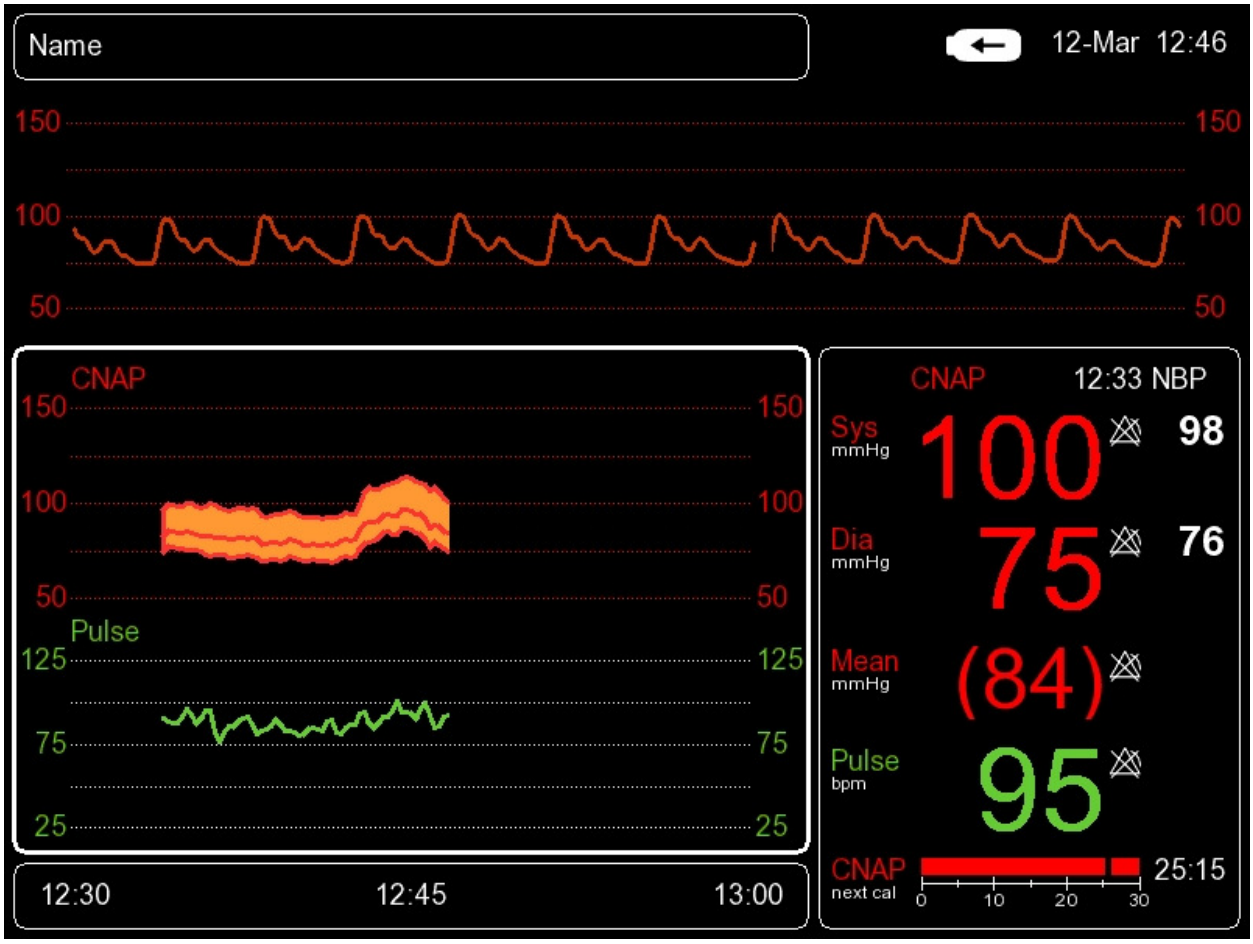


Illustration 26: Trend frame

7.1 Trend – the menu for display options

The **Trend (Display Options)** menu, 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: **Graphical** or **Numeric** display or **Alarm History**	**Graphical, 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** on the main screen, including three **Trend Display** options:

- **Graphical:** graphic trend of measured parameters, displayed on a time axis
- **Numerical:** numeric trend of measured parameters in adjustable time limits
- **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 **Trend frame** on the main screen and access the **Trend Display** menu item.

7.2.2 Graphic trend

The **Graphic Trend Display** allows a graphic view of the following parameters on a time axis:

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

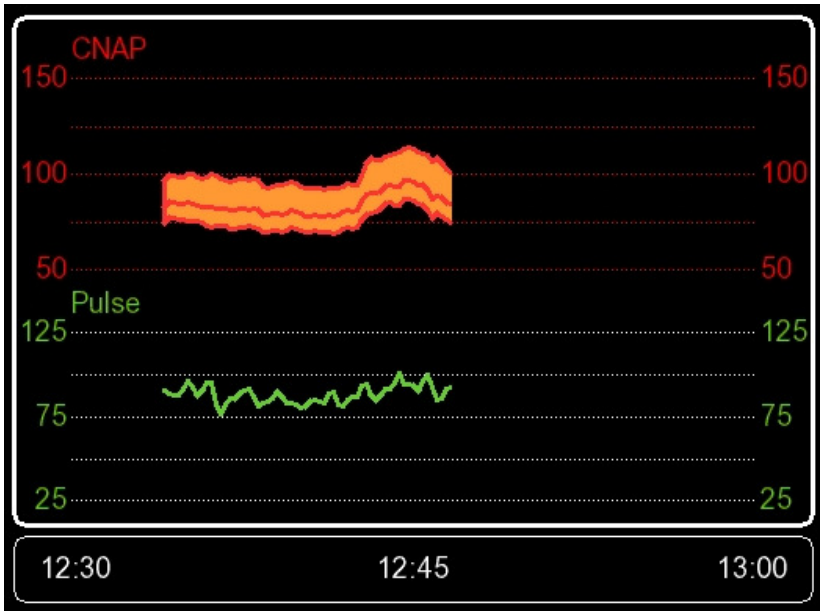


Illustration 27: Graphic Trend Display

NOTE:
- The **Graphic Trend Display** can be adjusted by changing the following scales: **BP Scale, Pulse Scale** and **Time Scale.**
- The displayed data dialog 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 **BP Scale** menu item which is located in the **Trend** menu. 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 blood pressure amplitude	**40*, 100**, 200*** mmHg**

Example:

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

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

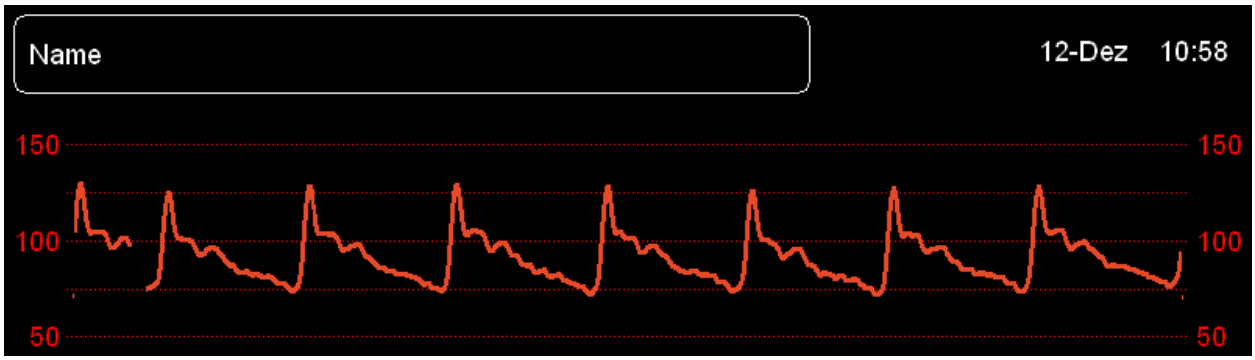


Illustration 28: Example of BP scale

NOTE:
- The scaling of the CNAP™ blood pressure waveform occurs analogously with the scaling of the CNAP™ trends.

PULSE SCALE:

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

Menu item	Description	Settings
Pulse Scale...		
Pulse Mean	Setting of expected mean pulse rate	**20(10)240 bpm* 50(25)200 bpm** 100(50)150 bpm***

Menu item	Description	Settings
Pulse Amplitude	Setting of expected 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 **Time scale** menu item which is located in the **Trend** menu.

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

NOTE:
- Time scales of **Graphic Trend Display** 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. Therefore, it is essential to make sure before starting the measuring process that the monitor's system clock is showing the correct time.

7.2.3 Numeric trends

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

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

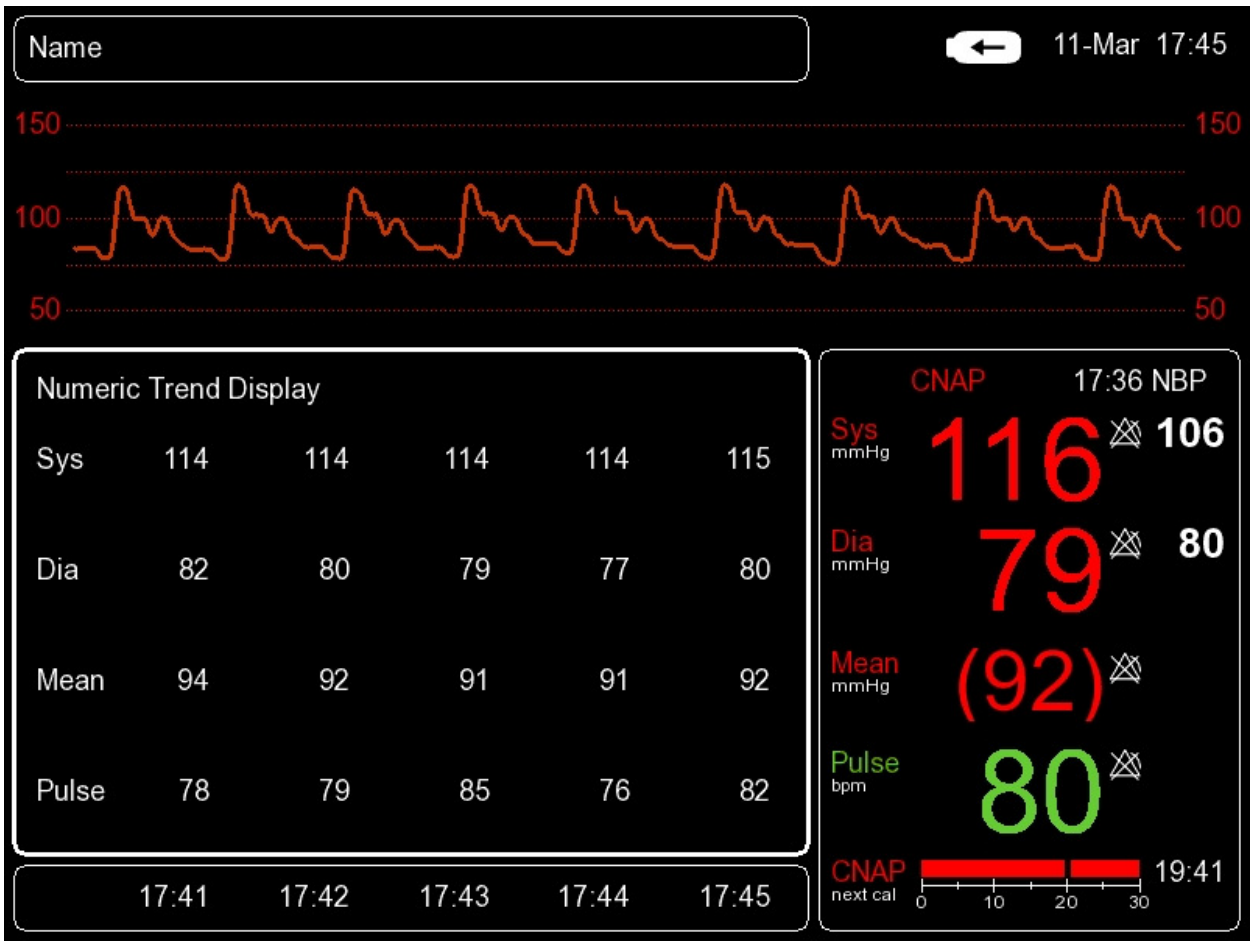


Illustration 29: Numeric Trend Display

NOTE:

- The **Numeric Trend Display** can be configured by adjusting **Time Scale** from the **Trend** menu.
- The displayed data dialog can be adjusted by means of the click-wheel control in **Time Scale** in the **Navigation frame**, which also determines the amount of data to be printed.

TIME SCALE:

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

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

NOTE:
- The time scale of the **Numeric Trend Display** 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. Therefore, it is essential to make sure before starting the measuring process 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

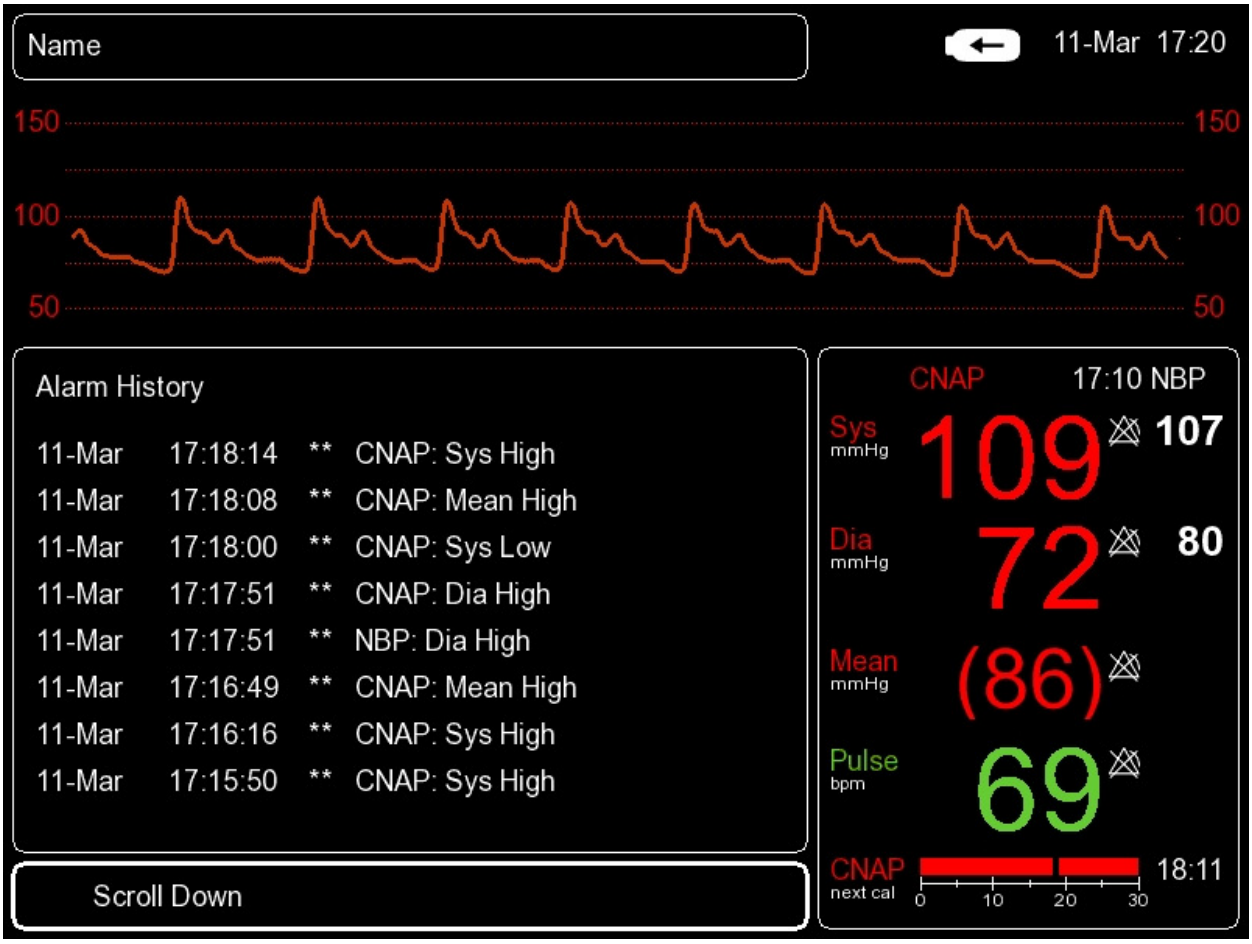


Illustration 30: Alarm History with entries

NOTE:
- The **Alarm History** includes the entire list of the last reported alarms (up to 100 entries). Therefore, **Time Scale** cannot be selected.

STOP:
- The deletion of patient data irretrievably deletes all connected recordings, including the parameters **Sys, Mean, Dia** and **Pulse** as well as the **Time Scale** (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.

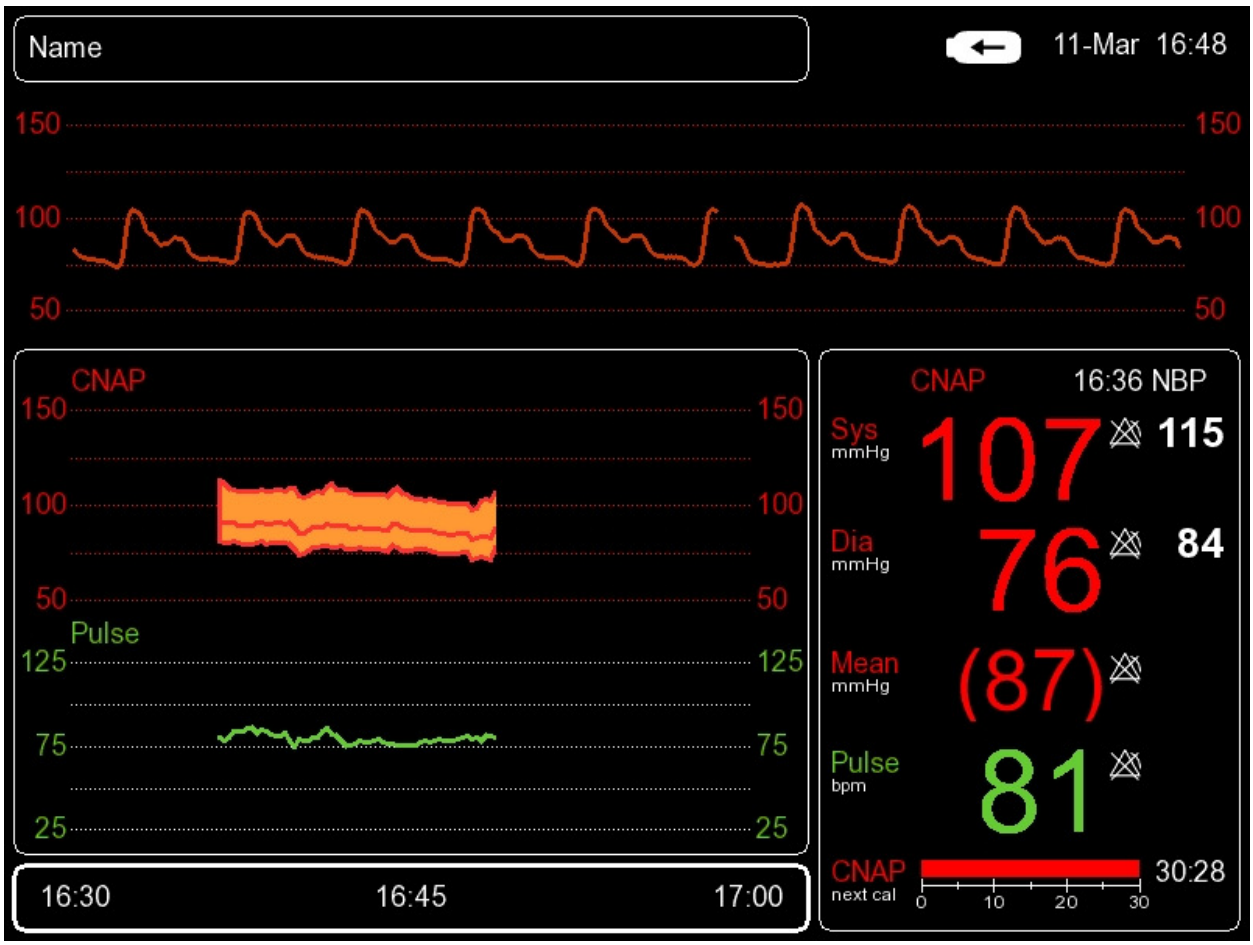


Illustration 31: Navigation frame including time specification

7.2.6 Interventions

During a measurement it is possible to mark a specific event with a graphical marker called intervention. These interventions can be set manually at any time during a measurement or automatically for system events (e. g. CNAP change finger, NBP measurement).

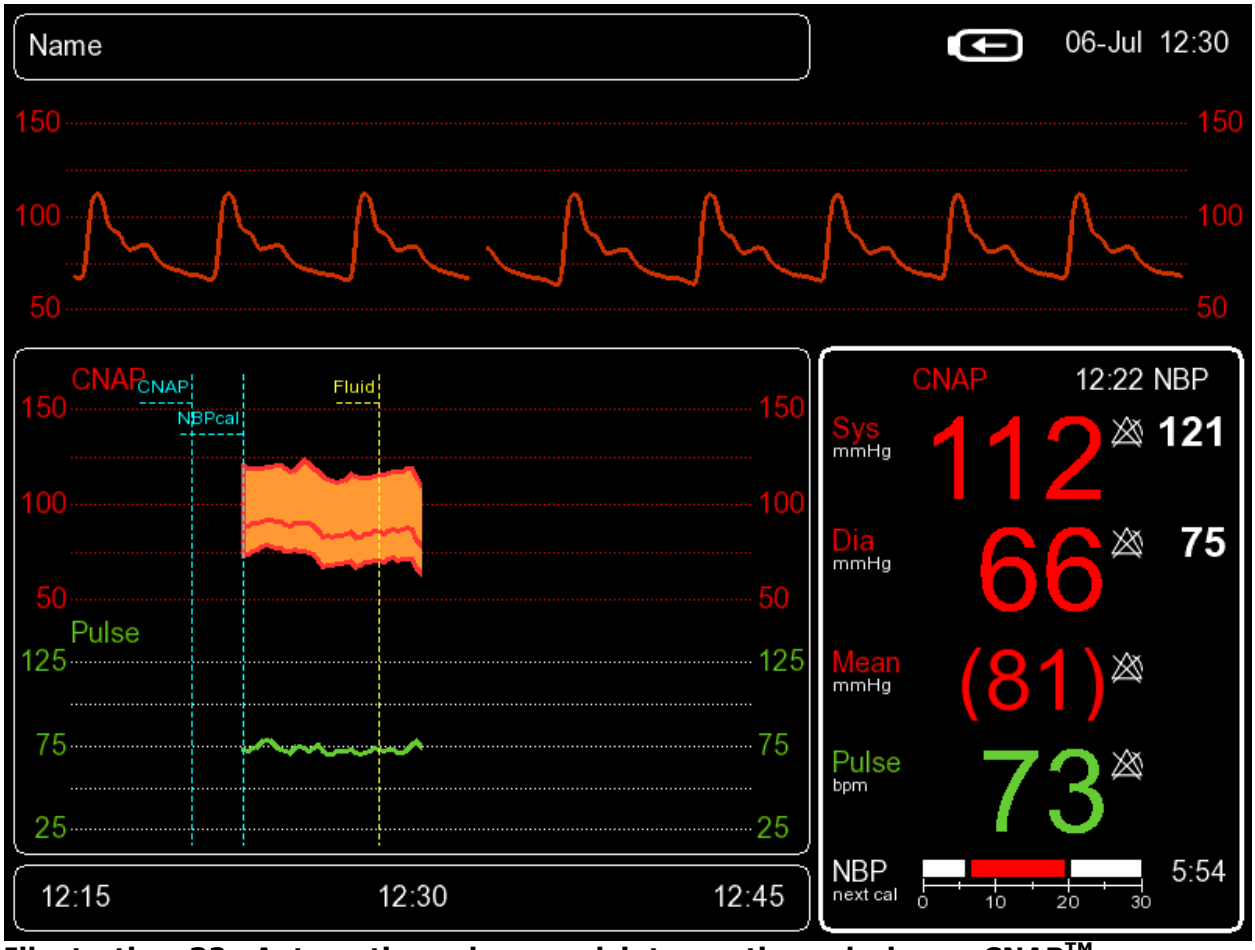


Illustration 32: Automatic and manual interventions during a CNAP™ measurement

7.2.6.1 Automatic interventions

In the menu **Setup | Measurement | Display Options | Auto Interventions** the setting of automatic interventions in the trend view can be activated or deactivated.

The marker of an automatic intervention is displayed in cyan (see illustration 32).

If this option is active (default) an intervention is set in case of one of the following events.

Label	Description	Event
CNAP	Start of measurement, manual or automatic change finger.	Begin of CNAP™ measurement or CNAP™ change finger
NBPcal	NBP measurement with subsequent calibration of CNAP values.	End of NBP measurement

Label	Description	Event
NBPman	Manually triggered NBP measurement.	End of NBP measurement
NBP	NBP measurement with no calibration of CNAP™ values (only possible in NBP mode intelligent).	End of NBP measurement

7.2.6.2 Manual Interventions

A manual intervention can be set by the user any time during a measurement. To set an intervention open the menu **Display Options | Interventions...** from the trend frame and select a marker from the list.

The marker of a manual intervention is displayed in yellow (see illustration 32).

The labels for the customer defined interventions are changed in the menu **Setup | Measurement | Display Options | Custom Interventions**.
Also the Order of the Interventions can be changed in the menu **Setup | Measurement | Display Options | Intervention Order** by changing the position number for each entry.

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

a) Depending on how long the operator presses ***Print*** he/she can select either **Snapshot Report** or **Trend Report**:

- **Snapshot Report:** Press Print once for a short time. The blood pressure curve is printed.
- **Trend Report:** Press Print for longer than 0.5 seconds. **Trend Report** is printed by corresponding to the data displayed in the **Trend frame.**

NOTE:
- The duration of a **Snapshot Report** is limited to 20 seconds. **Snapshot Delay** settings are edited in ***Setup*/Measurement/Print Options/Snapshot Delay.**

b) The way recordings are displayed in the **Trend frame (Graphical, Numerical, Alarm History)** automatically determines the selected **Trend Report**:

- **Graphic Trend Report:** **Graphical** (see chapter 8.3 - Print reports)
- **Numeric Trend Report:** **Numerical** (see chapter 8.3 - Print reports)
- **Alarm History Report:** **Alarm History** (see chapter 8.3 - Print reports)

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

NOTE:
- A **Print On Alarm Report** due to physiological alarm is printed automatically if **Print On Alarm Report** is activated in ***Setup*/Measurement/Print Options/Print On Alarm**. 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 tasks will be cancelled immediately for safety reasons.

8.2 Canceling print reports

In order to cancel print tasks, press ***Print*** once.

8.3 Print reports

The CNAP™ Monitor 500 offers a range of predefined **print reports.** All **print 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)

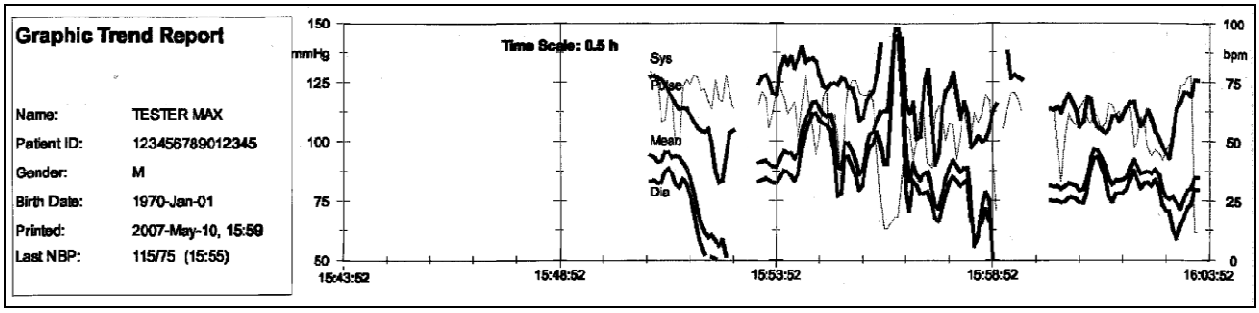


Illustration 33: Graphic Trend Report

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	15:50:58
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 34: 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 35: 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)

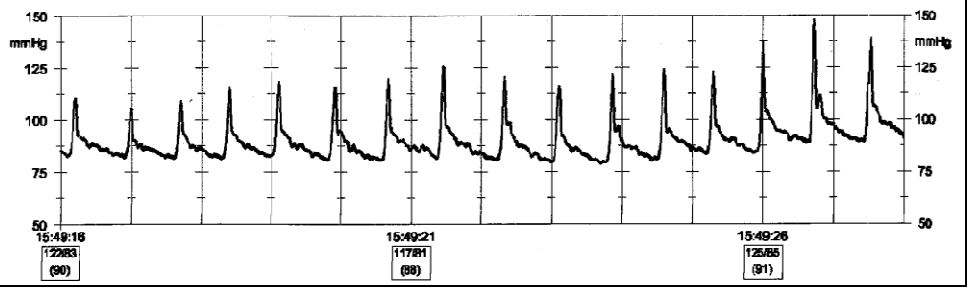


Illustration 36: Snapshot report

NOTE:

- **Alarm History Report:** The currently selected alarm as well as the 15 preceding alarms will be printed.
- **Snapshot Report:** In the case of multiple alarms, a separate snapshot for each alarm will be printed (last 10 seconds before to 3 seconds after the alarm).
- All reports are uniformly in English.

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. The measured IR signal – similar to a pulse oximeter – helps to measure the blood volume in the finger, which is kept constant by means of CNAP: beat to beat a counter pressure in the finger cuff is built up, which fluctuates between the systolic and diastolic blood pressure.

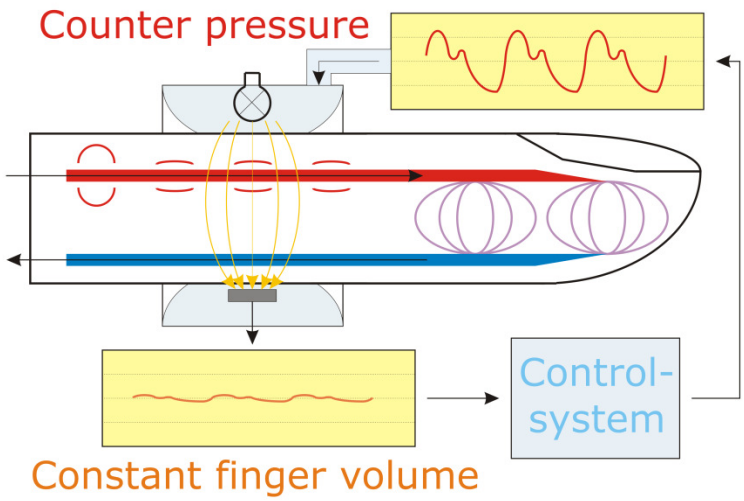


Illustration 37: CNAP™ Technology

By means of NBP cuff (oscillometric blood pressure measurement), the relatively measured blood pressure in the finger is calibrated to absolute blood pressure values (to the pressure of a big artery at heart level), thus ensuring absolute accuracy. The NBP cuff can be placed on the patient's upper arm either on the same or on the other arm as the CNAP™ 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 approx. 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 heart level, will have immediate influence on the absolute values of blood pressure readings. To compensate these physical effects (hydrostatic height), recalibrate the CNAP™ measurement by triggering a single NBP measurement (see chapter 10.6 - NBP options).

9.2 Safety precautions

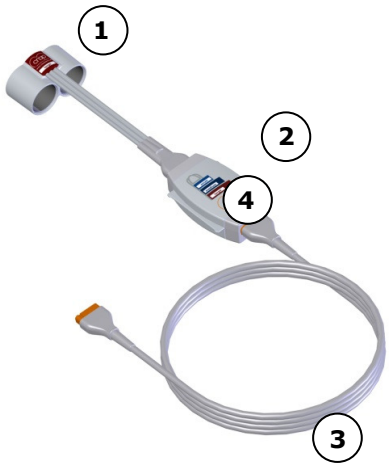
CAUTION:
- Do not use CNAP™ and NBP in patients with vascular prostheses!
- CNAP™ is designed for the concurrent measurement of only one patient at a time.
- Be sure to follow local regulations regarding storage of the CNAP™ Monitor 500, its accessories and packing material.
- Keep the CNAP™ Monitor 500 out of reach of children!
- The CNAP™ blood pressure waveform is calibrated by means of oscillometric 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.
- Never connect the device's air connectors to an intravascular system!
- Regularly inspect the patient's 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 in a finger during measurement, immediately discontinue the measurement process by pressing ***Start/Stop*** on the front panel of the CNAP™ Monitor 500.
- 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 wear. Any faulty parts are to be replaced immediately.
- Check 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™ measurement. To avoid mechanical damage to the CNAP™ finger cuff, remove all objects (e.g. rings) from the patient's fingers before measuring.

STOP:
- The operating environment for CNAP™ hardware has to comply with the directions regarding ambient temperature, relative humidity and atmospheric pressure.
- 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).
- In some cases, CNAP measurement is not suitable (see chapter 2.2.2 – Limitations).

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

Illustration 38: 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.

Illustration 39: Patient-setup

Start/Stop a measurement (refer to chapter 3.5 – Patient 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 make 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 a 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 (refer to chapter 10 – NBP).
- As soon as you have selected a category in the **Setup Patient** dialog, the CNAP™ measurement will start automatically

NOTE:
- The ***Start/Stop*** key is primarily intended to stop the CNAP™ measurement and the NBP measurement. In addition, the ***Start/Stop*** key serves to display the **Setup Patient** dialog manually if it was not automatically displayed upon start of measurement. After selecting a patient category in the **Setup Patient** dialog, the CNAP™ measuring process starts automatically.
- 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:
  - Sys
  - Dia
  - Mean
  - Pulse
- Numeric blood pressure values:
  - Sys
  - Dia
  - Mean
  - Pulse

9.4.1 Blood pressure waveform

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

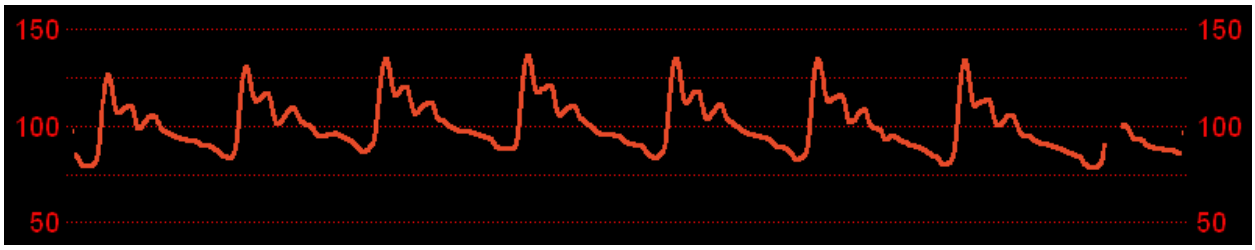


Illustration 40: CNAP™ blood pressure waveform

NOTE:
- The mean and amplitude scales of the CNAP™ blood pressure waveform are set in the **Trend** menu (see chapter 7 – Trends).
- The signal speed of the CNAP™ blood pressure waveform is set to 12.5 mm/sec 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.

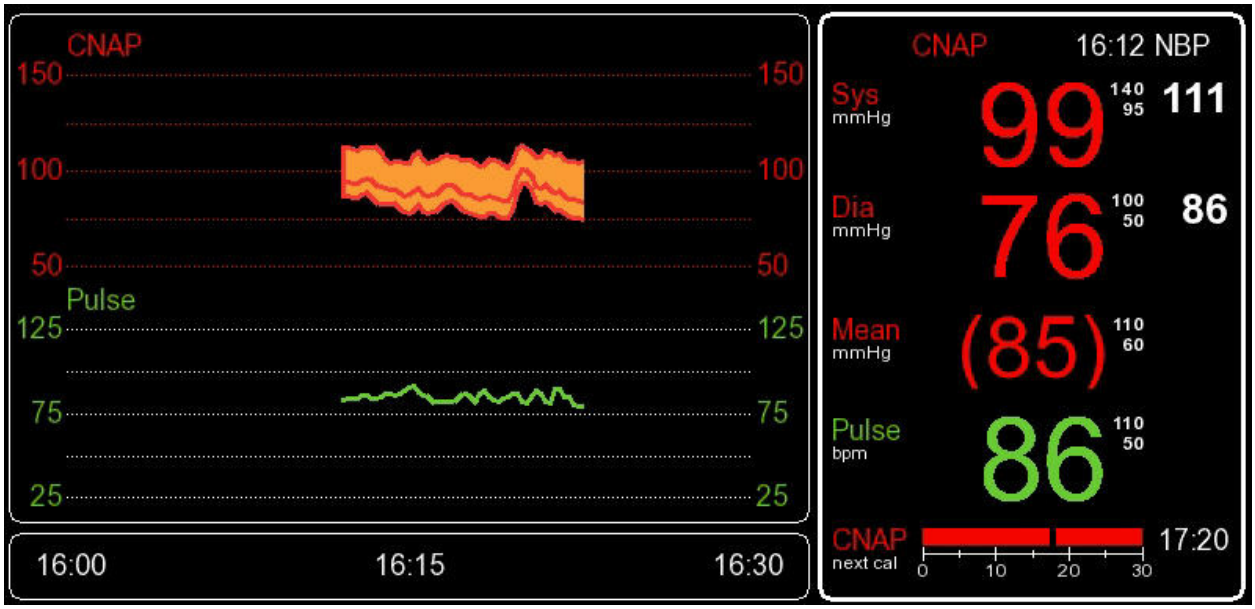


Illustration 41: Graphic Trend and numeric values

NOTE:
- The mean and amplitude scales for CNAP™ trends, CNAP™ and pulse are set in the **Trend** menu (see chapter 7 – Trends).

9.4.3 Numeric values

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

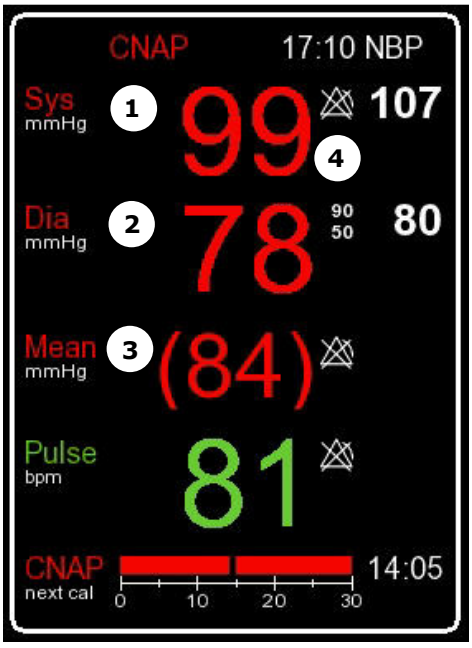


Illustration 42: Parameter frame

① Systolic blood pressure

② Diastolic blood pressure

③ Mean blood pressure

④ Alarm limit settings

9.5 CNAP™ options

Parameter menu:

Menu item	Description	Settings
NBP: Start/Stop	Start/Stop of a single NBP measurement	
NBP: Start/Stop Venous Stasis	Start/Stop of venous stasis	
NBP: Interval	Setting of time interval for automatic NBP measurements [min]	**Off, 5(5)30, 45, 60**
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)60 min**
Pediatric/Adult Alarm Limits...	Setting of alarms for the parameters Sys, Dia, Mean, Pulse	Submenu
IBP: Zeroing Active **IBP: Zeroing Start/Stop**	Active zeroing for interface to external patient monitors before and after an active CNAP measurement (available CNAP values). Zeroing, which can be activated/deactivated manually, for interface to external patient monitors during an active CNAP measurement.	

Measurement menu:

Menu item	Description	Settings
NBP: Mode	Automatic or manual NBP measurement at changes of >=25 mmHg compared with the last NBP.	**Auto, Intelligent, Manual**
NBP: Interval	Setting of time interval for automatic NBP measurements [min]	**Off, 5(5)30, 45, 60**
CNAP: Cal Interval	Setting of automatic change of signal source in CNAP™ double finger cuff [min]	**5(5)60 min**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Display Options...	Submenu to adjust display settings	Submenu
Print Options...	Submenu to set print options	Submenu
Parameter Averaging	Averaging of display parameters	**Off, 5, 10, 15**
Patient Category	Presetting of the focus on Adult or Pediatric for new patient setup	**Adult, Pediatric**

NOTE:
- Interruptions due to CNAP change of finger are displayed by means of red countdown bars in the **Parameter frame** (see chapter 3.6 – Timer).
- Adjustments in the **Parameter** menu alter only the current measurement. In a new measurement, they are transcribed by the defaults in the **Measurement** menu.
- Settings performed in the **Measurement** menu, however, alter both the current as well as future measurements and are transcribed by factory settings upon reset.

9.6 CNAP Values During Calibration

For a number of applications it can be useful to display CNAP™ values during an ongoing NBP calibration. I. e. to avoid false physiological alarms on patient monitors connected over the BP Wave Out or AUX Analog Out interface – especially for centralized monitoring as used in ICUs – it is mandatory to provide a blood pressure curve even during calibration.

Activate the option **CNAP Values During NBP** in the menu **Setup | Measurement | Display Options**.

The following Table gives an overview how values are displayed in different states of operation.

Measurement State	CNAP™ Monitor 500		Interfaces: BP Wave Out / AUX Analog Out	
	CNAP™ Values During NBP		CNAP™ Values During NBP	
	Off	On	Off	On
No measurement	Blank	Blank	Zero	Zero
Measurement	CNAP values	CNAP values	BP waveform	BP waveform
NBP measurement	Blank	CNAP values	Zero	BP waveform
Venous stasis	Blank	CNAP values	Zero	BP waveform
Start of measurement	Blank	Blank	Zero	Zero
CNAP change finger	Blank	Blank	Zero	Rectangular signal calibrated to Sys/Dia-values

In case of a subsequent change finger, the signal on the BP Wave Out / AUX Analog Out interface is a rectangular curve with minimum, maximum values and frequency resembling the last valid systolic and diastolic beat values and pulse rate.

CAUTION:
- When using an ipsi-lateral setup (CNAP™ finger cuff and NBP cuff on the same arm) the blood flow to the fingers will be constricted during the NBP measurement and venous stasis. Therefore the displayed signal and beat values are influenced by the NBP cuff.

NOTE:
- To avoid influence of the NBP measurement on the CNAP™ measurement a contralateral setup can be used if applicable.

NOTE:
- The CNAP™ Monitor 500 generates a rectangular signal on the BP Wave Out interface during a subsequent change finger event. This signal contains no information about the physiological condition of a patient and is used as a calibration signal until the calibration phase is finished.
- The rectangular calibration signal may trigger false positive alarms on patient monitors, when connected to the BP Wave Out or AUX Analog Out interface.

10 NBP

10.1 General information

NBP (Non-Invasive Blood Pressure) uses the oscillometric 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 (brachial artery) 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 and Dia.

NOTE:
- When a measurement process is started on the CNAP™ Monitor 500, a NBP measurement is also triggered automatically.
- However, it is also possible to trigger an NBP measurement manually at any time during measurement – except during display of the **Setup Patient** dialog (see chapter 10.6 – NBP options).
- NBP measuring interval can be pre-set in the **Measurement** menu for every new measurement and can be adapted via the **Parameter** menu during a measurement.
- Inflation pressure of the NBP cuff is determined by the selected patient category (see chapter 5.1 – Patient entry). During NBP measurement, it is graphically and numerically displayed as a bar at the bottom of the **Parameter frame** (see illustration 42 below).
- Interruptions due to NBP measurements are displayed as white countdown bars in the **Parameter frame** (see chapter 3.6 - Timer).
- During an NBP measurement, neither venous stasis nor manual change of finger can be performed.

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 put on the same arm as the CNAP™ double finger cuff (ipsilaterally) or on the other arm (contralaterally).

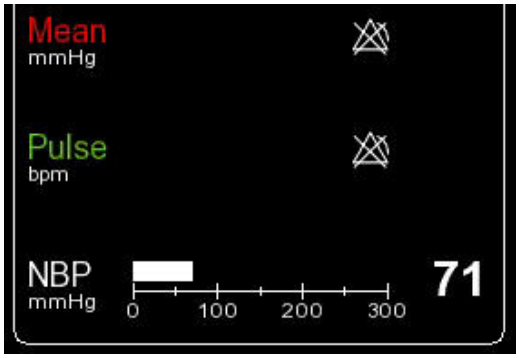


Illustration 43: NBP measurement

10.2 Venous stasis

Venous stasis to support punctures of intravenous lines can be performed by means of the NBP cuff. After putting on the NBP cuff, venous stasis can be started by selecting **NBP: Start Venous Stasis** in the **Parameter** menu at any time. During venous stasis, the **NBP: Start Venous Stasis** status message is displayed (see illustration below). Depending on the selected patient category, the NBP cuff is inflated to constant pressure levels of **80mmHg** for adults and **60mmHg** for pediatric patients.

NOTE:

- During venous stasis, the cuff inflation pressure is graphically displayed as a bar at the bottom of the **Parameter frame** (analogous to the NBP measurement, see chapter 10.1 – General information).
- Until the target pressure of 80/60mmHg is reached, the pressure is displayed numerically to the right of the bar.
- After the target pressure has been reached, the numeric display of pressure is replaced by the time remaining until automatic stop of venous stasis (see illustration 43 below).
- Venous stasis can be performed for max. 2 minutes. If venous stasis is not terminated prematurely by selecting **NBP: Stop Venous Stasis** manually, it will stop automatically after 2 minutes. In case it was performed during an ongoing CNAP measurement, it will be continued afterwards automatically.
- Numeric display of continuous blood pressure is not available during venous stasis; however, the blood pressure waveform will continue to be displayed (without scale).
- Venous stasis cannot be performed while the **Setup Patient** dialog is displayed.
- Neither manual NBP nor manual change of finger can be performed during venous stasis.

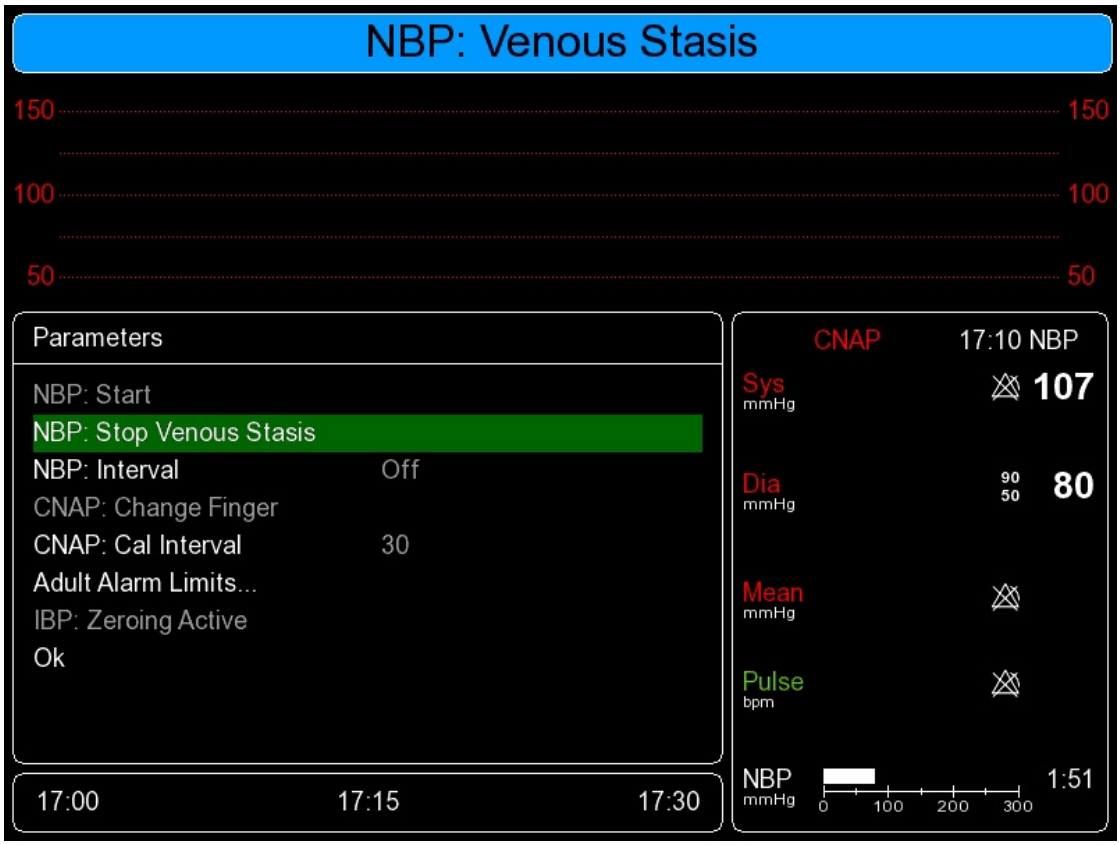


Illustration 44: Venous stasis

10.3 Safety precautions

STOP:

- **Patient category:** Make sure to select the correct patient category before starting a measurement (see chapter 5.1 – Patient entry). The higher adult levels of inflation pressure of the NBP cuff, excess pressure limits or measuring time for instance, must never be used for pediatric patients!
- **Intravenous infusion lines:** Never put on an NBP cuff to a limb already connected to an intravenous infusion line or an intra-arterial 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 drepanocythemia or from cutaneous lesions, or in patients where cutaneous lesions are to be expected.
- **Unsupervised measurements**: Patients with severe blood coagulation dysfunction may develop haematoma on the limb where the NBP cuff has been inflated. In these cases, carefully consider the pros/cons of frequent unsupervised blood pressure measurements.
- **Interference by external devices:** Results of NBP recordings are not to be used if the measured oscillometric pulse has been influenced by other devices or techniques (e.g. 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 measurements, be sure to choose the right size of the upper arm cuff. Selecting the wrong size or incorrect attaching of the cuff may cause significant inaccuracies of recordings!
- In case of longer monitoring, 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.

10.4 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

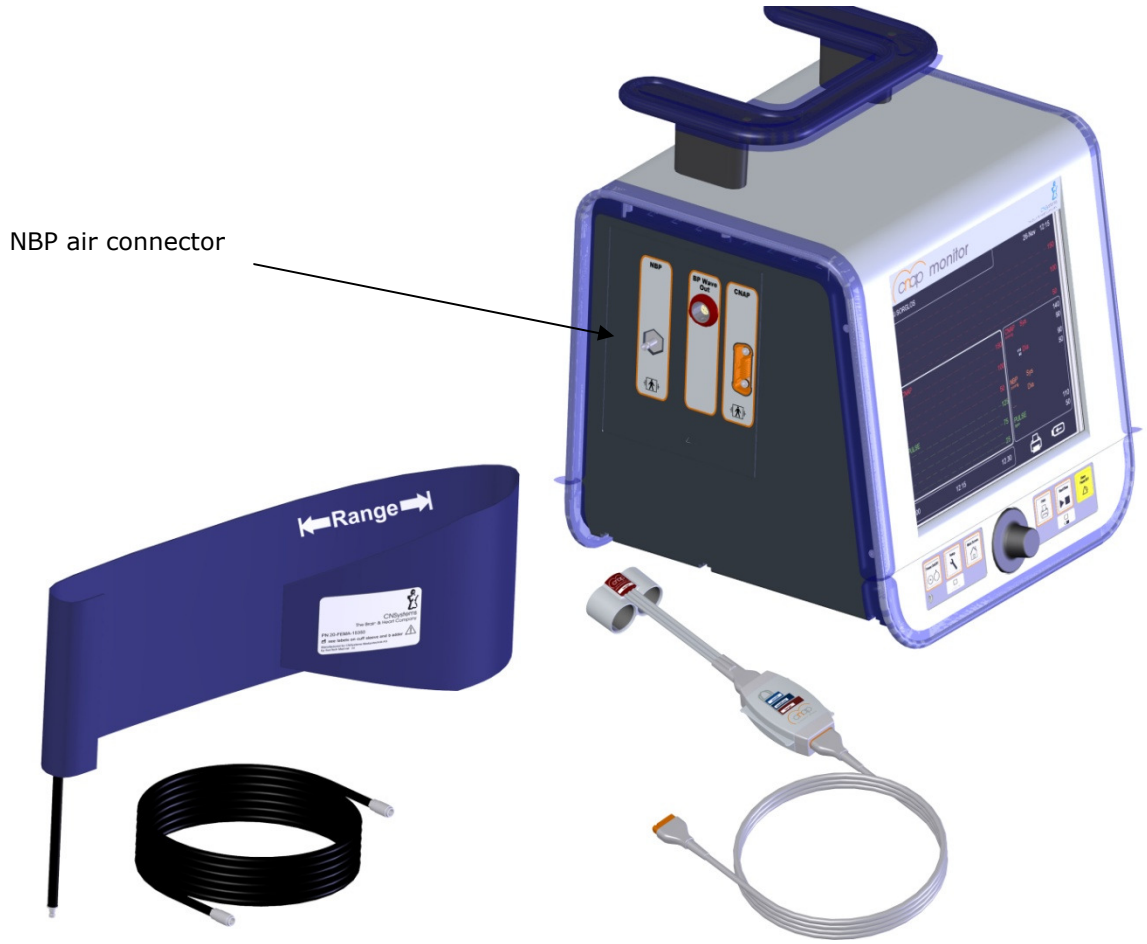


Illustration 45: CNAP™ Monitor 500 with NBP air connector

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 NBP cuff sizes are available:

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

2. Attach 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 attach 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 (color, temperature, sensitivity of limb) around the cuff on a regular basis. Should any signs of alterations to the skin or decreased blood supply be noticeable, immediately change arm 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:

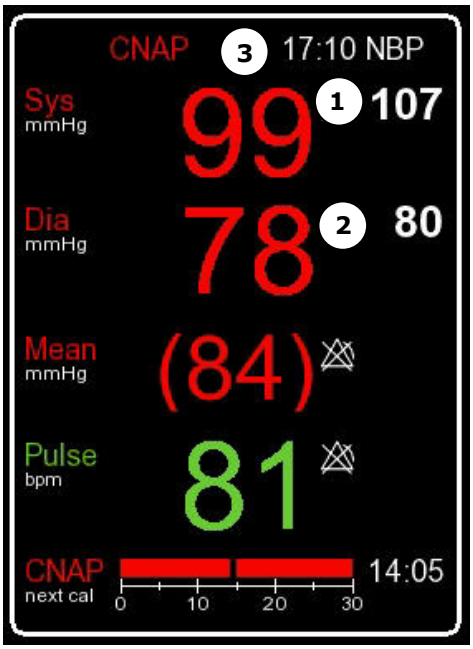
   a) The start of a CNAP™ measurement also automatically starts an NBP measurement. NBP measurements are performed after the calibration phase of the CNAP™ Monitor 500 or automatically in defined time intervals. To set the desired time intervals, access either the **Parameter** menu or the **Measurement** menu.

   b) Starting a single measurement by using the click-wheel control to access the **Parameter** menu.

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

10.5 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 46: Parameter frame

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

10.6 NBP options

Parameter menu:

Menu item	Description	Settings
NBP: Start/Stop	Start/Stop of a single NBP measurement	
NBP: Start/Stop Venous Stasis	Start/Stop venous stasis	
NBP: Interval	Setting of time interval for automatic NBP measurements [min]	**Off, 5(5)30, 45, 60**
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)60**
Pediatric/Adult Alarm Limits...	Setting of alarms for the parameters Sys, Dia, Mean, Pulse	Submenu
IBP: Zeroing Active **IBP: Zeroing Start/Stop**	Active zeroing for interface to external patient monitors before and after an active CNAP™ measurement (available CNAP values). Zeroing, which can be activated/deactivated manually, for interface to external patient monitors during an active CNAP measurement.	

Measurement menu:

Menu item	Description	Settings
NBP: Mode	Refer to the description of the NBP Modes in chapter 4.2f.	**Auto, Intelligent, Manual**
NBP: Interval	Setting of time interval for automatic NBP measurements [min]	**Off, 5(5)30, 45, 60**
CNAP: Cal Interval	Setting of automatic change of signal source in CNAP™ double finger cuff [min]	**5(5)60**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Display Options...	Submenu to adjust display settings	Submenu
Print Options...	Submenu to set print options	Submenu
Parameter Averaging	Averaging of display parameters	**Off, 5, 10, 15**
Patient Category	Presetting of the focus on Adult or Pediatric for new patient setup	**Adult, Pediatric**

NOTE:

- Adjustments in the **Parameter** menu alter only the current measurement and are transcribed by defaults **in the Measurement** menu when a new measurement is started.
- Settings performed in the Measurement menu, however, alter both the current as well as future measurements and can be transcribed by the operator or factory settings from the Service menu.

11 Pulse Pressure Variation (PPV)

CNAP™-PPV is a dynamic, non-invasive indicator for hemodynamic optimization of patients. The PPV values are calculated directly from the non-invasive CNAP™ blood pressure curve.

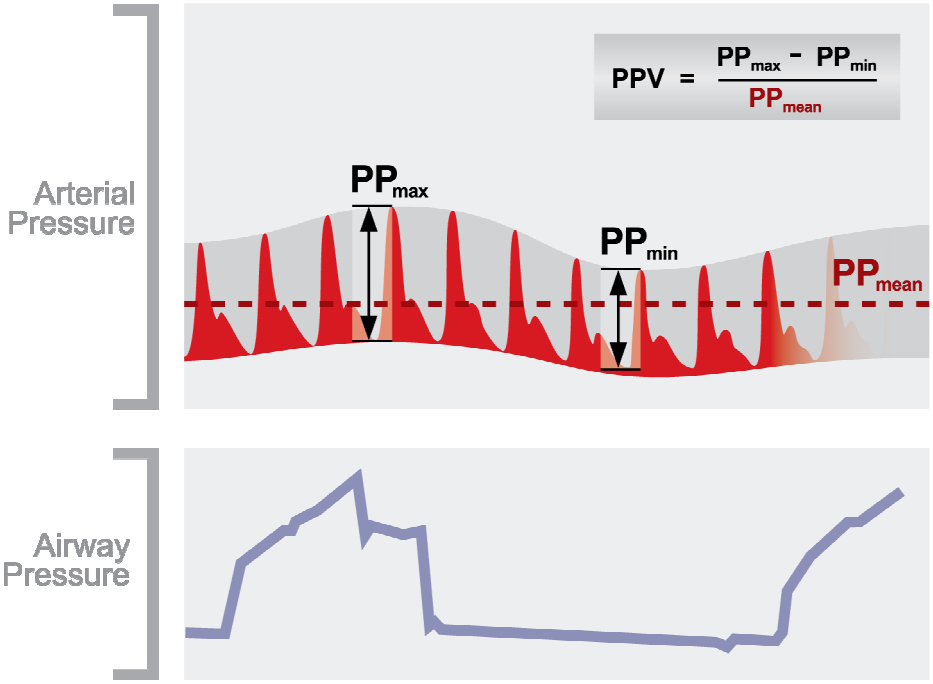


Illustration 47: Pulse Pressure Variation (PPV)

11.1 Warnings

- The clinical value of the derived CNAP™-PPV information must be determined by a physician. According to recent scientific literature, the clinical relevance of PPV information is restricted to sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia.
- The monitor calculates CNAP™-PPV from CNAP beat-to-beat values. The circumstances under which the calculation of a PPV value is clinically meaningful, appropriate and reliable must be determined by a physician.
- To get accurate values for the CNAP™-PPV it is absolutely necessary to fulfill the following pre-conditions:
  - at respiration rates > 8 rpm
  - mechanical ventilation with tidal volumes > 8 ml/kg
  - mechanical ventilation with PEEP < 5 cmH2O
  - no open chest surgery
- For patients with acute right ventricular dysfunction (“cor pulmonale”) CNAP™-PPV may lead to inaccurate values.
- The CNAP™-PPV measurement has been validated only for adult patients.

11.2 Performing CNAP™-PPV measurements

The measurement of CNAP™-PPV (Pulse Pressure Variation) is activated for the types CNAP™ Monitor 500i+PPV and CNAP™ Monitor 500at+PPV. The activation of the CNAP™-PPV parameter with a license key is described in chapter 4.4.

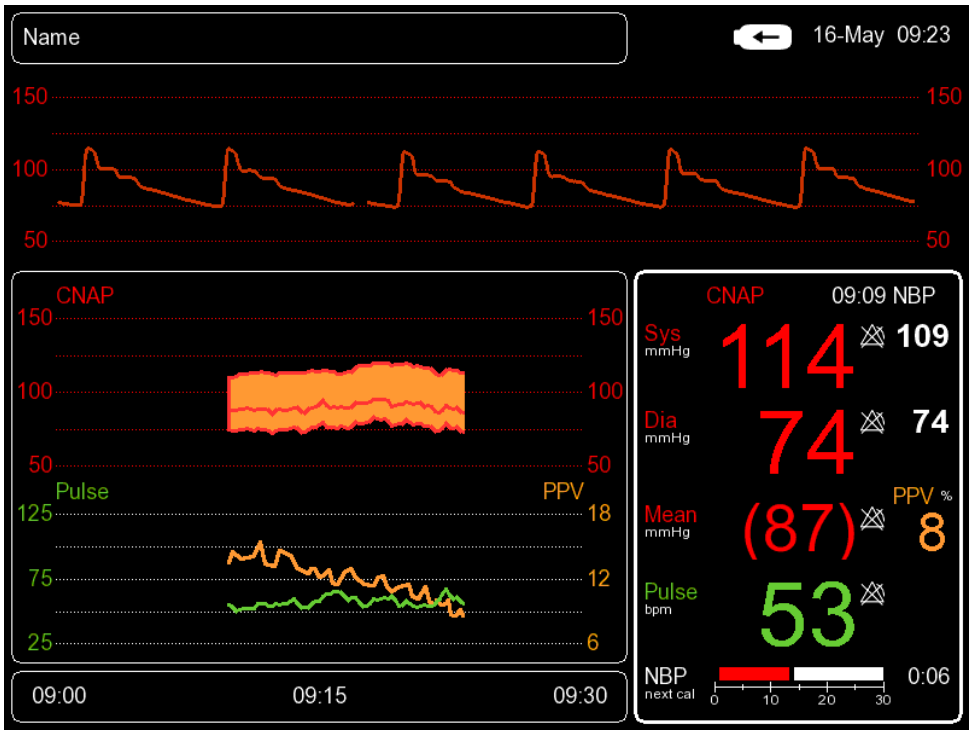


Illustration 48: Display of the CNAP™-PPV during a measurement

In the default configuration of the monitor the measurement of CNAP™-PPV is disabled. The parameter can be enabled only for the current measurement in the menu **Parameters/PPV** or as a default for all measurements in the menu **Setup/Measurements/PPV**.

Stop:

- Before considering a measurement with CNAP™-PPV one must be sure that the preconditions for an accurate PPV measurement are fulfilled. The warnings regarding CNAP™-PPV are listed in chapter 11.1.

After the initialization phase of the CNAP™ Monitor 500 the value of the CNAP™-PPV (orange) is displayed in the parameter field on the display of the monitor (see illustration 47).

Under the following circumstances no CNAP™-PPV values are displayed:

- No valid CNAP™ values are available (during initialization phase of CNAP™)
- During the initialization of the PPV-Algorithm (takes at least three breathing cycles)
- Artifacts or arrhythmia in the CNAP™ signal.
- After a technical alarm regarding the CNAP™ subsystem has occurred.

12 Cleaning and disinfection

Only use disinfectants and detergents recommended by CNSystems Medizintechnik 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 should contact the hospital hygiene department. This particularly applies for the effectiveness of disinfectants and detergents against hepatitis B and HI viruses. The operator is to follow the regulations of the respective hospital and country.

12.1 General precautions

The CNAP™ Monitor 500 including all its components and accessories 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 Medizintechnik AG, they are to be decontaminated.

CAUTION:
- Always dilute detergents and disinfectants 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 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 with a moist cloth (water), then dry surfaces with a 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.

12.2 Cleaning

In order to clean any part of the device use a lint-free cloth, moist with warm water (max. 40° C), and soap, diluted non-caustic detergents, tensides or detergents containing ammonia or alcohol. Do not use strong solvents like dimethylketone or trichloroethylene. Do not dip the device, any part of the device or any accessories (especially not the 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.

12.3 Disinfection

CAUTION:
Disinfectant agents: Never mix different kinds of disinfecting solutions (e.g. bleaching agents and ammonia), 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 disinfectants listed below:

Disinfectant	Concentration
Glutaraldehyd	3.4%
n-Alkyl/Alkohol	0.28% - 8%
Hypo-chlorite	0,55%
Succindialdehyd/ Alkohol	11%
Alkohol Spray/ Wipe	10%
Orthophthal-aldehyd	0,55%
Propan-1-ol	< 50%
Propan-2-ol	< 50%

Common brands:

- Cidex® Plus
- Theracide®
- Gigasept® FF
- Cidex® OPA
- Schülke - Microcid® AF Liquid
- ECOLAB - Indicidin® Liquid
- B.Braun – Meliseptol®
- BODE – Bacillol® plus

13 Technical alarms and status messages

Besides physiological alarms, the CNAP™ Monitor 500 displays technical malfunction alarms (white) and device status messages (blue) in the **Alarm frame**.

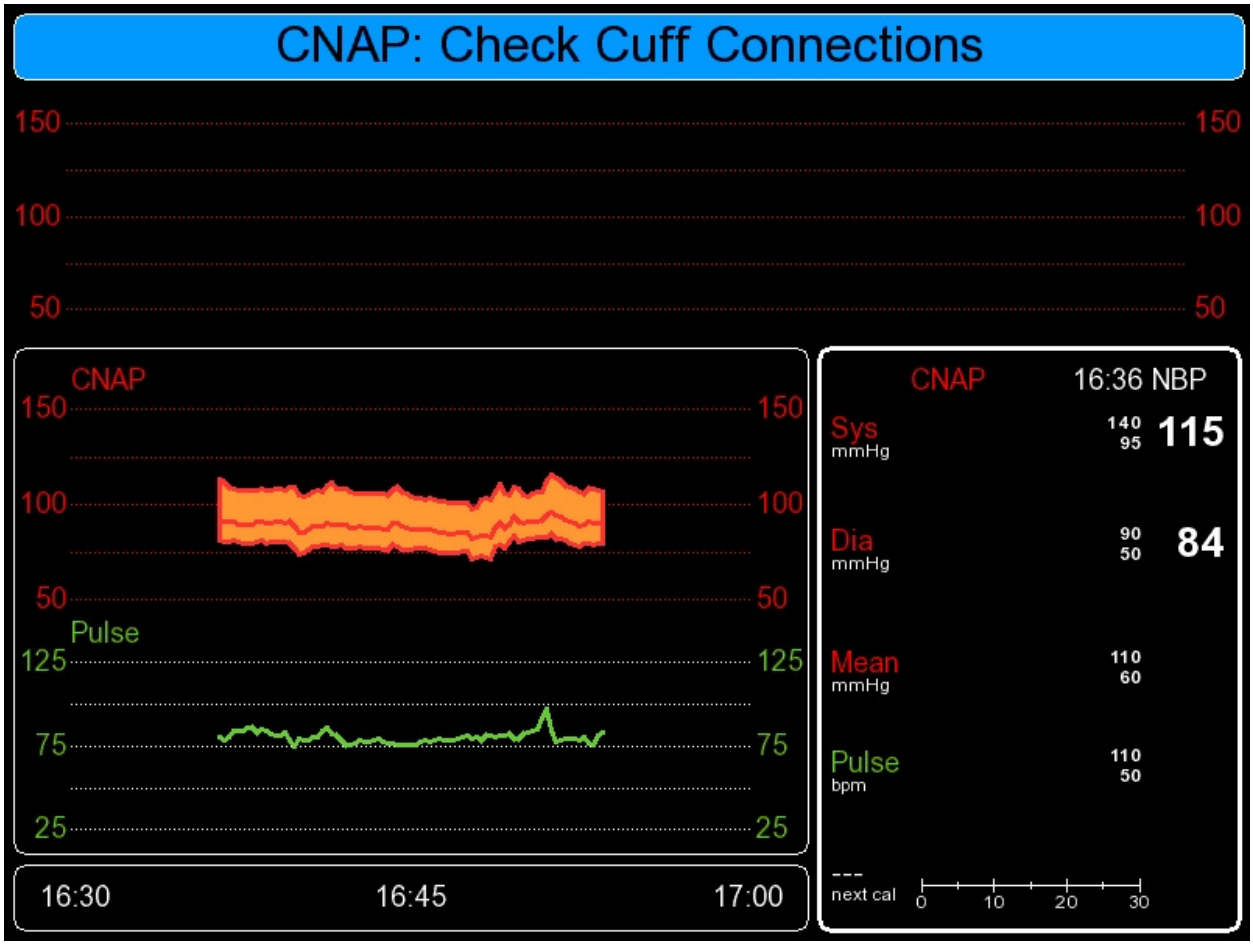


Illustration 49: Status messages

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 will find the password for the service menu in the CNAP™ Monitor 500 "Service manual for users".

13.1 Main unit

13.1.1 Status messages

Message	Possible cause	Measures
MU: No USB Stick Attached	– No USB stick connected	– Connect USB stick and reboot CNAP™ Monitor 500
MU: USB Stick Full	– USB memory full	– Connect USB with free storage capacity and reboot CNAP™ Monitor 500
MU: USB Stick Write Error	– USB stick not recognized	– Activate and deactivate the Record setting in Setup. Use compatible USB stick.

13.1.2 Technical alarms

Message	Priority	Possible cause	Measures
MU: Fatal Error – Contact Service	Low *	– Internal error; CNAP™ monitor must not be used for further measurements	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
MU: CNAP Failure	Low *	- Failure in CNAP™hardware	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
MU: NBP Failure	Low *	- Failure in NBP hardware	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
MU: IBP Failure	Low *	- Failure in IBP component	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
MU: Battery: Low	Low *	– Very low battery charge status (< 25%), battery operation still possible	– Switching to mains operation via power adapter recommended
MU: Battery: Depleted	Low *	– Battery depleted, operation possible for 15 minutes at most	– Immediately switch to mains operation via power adapter
MU: Battery: Shutdown	Low *	– 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
MU: Memory Full – Dis-	Low *	– Internal memory is full (as a result of long measuring	– Discharge patient

Message	Priority	Possible cause	Measures
charge Patient		periods without discharging)	– Start new measurement

13.2 BP Wave Out (IBP)

13.2.1 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.

13.2.2 Technical alarms

Message	Priority	Possible cause	Measures
IBP: Fault	Low *	– Internal controller problem	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
IBP: Transmission Fault	Low *	– Interface problem	– In case of persistent error, contact service
IBP: EEPROM RW Error	Low *	– I/O memory chip defective	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
IBP: Iso Board Fault	Low *	– Isolation board failure	– In case of persistent error, contact service
IBP: Iso Board Bridge Voltage	Low *	– Bridge voltage > 10V (BP Wave Out)	– Disconnect CNAP™ transducer cable – Check bridge voltage range of patient monitor (refer to chapter 4.4) – In case of persistent error, contact service

13.3 Printer

13.3.1 Technical alarms

Message	Priority	Possible cause	Measures
PRINTER: Out of Paper	Low *	– Printer is out of paper	– Replenish paper
PRINTER: Fault	Low *	– Hardware problem: ○ Excess temperature ○ Internal voltage supply error	– Problem will be solved automatically – In case of persistent error, contact service
PRINTER: Failure	Low *	– Hardware problem – Interface problem	– Contact service
PRINTER: Communication Error	Low *	– Interface problem	– Problem will be solved automatically – In case of persistent error, contact service

13.4 CNAP™

13.4.1 Status messages

Message	Possible cause	Measures
CNAP: Check Connections	– CNAP™ controller is not connected	– Check connection of CNAP™ controller
CNAP: Check Cuff 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 CNAP™ finger cuff
CNAP: Initializing...	– System self-test	– n.a.
CNAP: Controller Not Calibrated	– CNAP™ controller is not calibrated	– Replace CNAP™ controller – Contact service (CNAP™ controller)
CNAP: Put Fingers in Cuff	– CNAP™ self-test successful; CNAP™ is ready for patient setup and measurement	– Patient setup
CNAP: Calibration...	– CNAP™ calibration phase in progress	– Wait for end of calibration

Message	Possible cause	Measures
CNAP: Calibrating NBP	– NBP measurement to calibrate CNAP™ blood pressure is in progress	– Wait for end of NBP measurement
CNAP: Artefact	– CNAP™ blood pressure is not within physiological measuring range – Low signal amplitude in CNAP™ double finger cuff – Interference because of third party measuring devices – CNAP™ hardware is ringing due to artifacts	– Check and eliminate 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 lifecycle, 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

13.4.2 Technical alarms

Message	Priority	Possible cause	Measures
CNAP: Fault – Reservoir Pressure	Low *	– Air reservoir blocked or faulty pressure offset	– Disconnect and reconnect CNAP™ controller – In case of persistent error, contact service
CNAP: Fault – Zero Offset Controller	Low *	– Zero offset of CNAP™ controller faulty	– In case of persistent error, contact service for faulty CNAP™ controller
CNAP: Fault – Initial Pressure	Low *	– Pressure could not reach threshold upon initialization	– Check CNAP™ cables and connectors – In case of persistent error, contact service
CNAP: Fault – Pump/Tubing/Valve Leaky	Low *	– Leakage detected upon initialization	– Check CNAP™ cables and connectors

Message	Priority	Possible cause	Measures
			– In case of persistent error, contact service
CNAP: Failure – Valve Blocked/Leaky	Low *	– Valve blocked or leaky	– Disconnect CNAP™ hardware – In case of persistent error, contact service for faulty CNAP™ controller
CNAP: Failure – Reservoir Overpressure	Low *	– Pressure exceeded 450mmHg for more than 10 sec in CNAP™ air reservoir	– Disconnect CNAP™ hardware – Reboot CNAP™ monitor – In case of persistent error, contact service
CNAP: Failure – Cuff Overpressure Left	Low *	– Pressure exceeded 330mmHg for more than 10 sec in left CNAP™ finger cuff	– Disconnect CNAP™ hardware – Reboot CNAP™ monitor – In case of persistent error, contact service
CNAP: Failure – Cuff Overpressure Right	Low *	– Pressure exceeded 330mmHg for more than 10 sec in right CNAP™ finger cuff	– Disconnect CNAP™ hardware – Reboot CNAP™ monitor – In case of persistent error, contact service
CNAP: Cuff Cannot Deflate/Blocked	Low *	– CNAP™ finger cuff cannot be deflated	– Replace CNAP™ double finger cuff – In case of persistent error, contact service
CNAP: Check Cuff – Low Light Signal	Low *	– Low light signal in CNAP™ finger cuff (PI too low)	– Check patient for low peripheral blood flow – Check size of CNAP™ double finger cuff – Check setup of CNAP™ double finger cuff – Check proper optical path in CNAP™ double finger cuff
CNAP: Check Cuff – Ambient Light	Low *	– Ambient light interferes with CNAP™ double finger cuff	– Reduce ambient light – Check setup of CNAP™ double finger cuff
CNAP: Check Cuff – Timeout On Calibration	Low *	– 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 of CNAP™ dou-

Message	Priority	Possible cause	Measures
			ble finger cuff – Improve peripheral blood flow (e.g. warm patient's hand)
CNAP: Cuff Fault – Overpressure	Low *	– Pressure exceeded 330mmHg for more than 2 sec in CNAP™ finger cuff	– Check CNAP™ double finger cuff for patient movement – Disconnect and reconnect CNAP™ hardware – In case of persistent error, contact service
CNAP: Cuff Fault – Light Sensor Left	Low *	– Light sensor in left CNAP™ finger cuff defective	– Check proper optical path in CNAP™ double finger cuff – Check influence from ambient light – In case of persistent error, replace CNAP™ double finger cuff
CNAP: Cuff Fault – Light Sensor Right	Low *	– Light sensor in right CNAP™ finger cuff defective	– Check proper optical path in CNAP™ double finger cuff – Check influence from ambient light – In case of persistent error, replace CNAP™ double finger cuff
CNAP: Cuff Fault – Memory	Low *	– Memory chip in CNAP™ double finger cuff defective	– Replace CNAP™ double finger cuff
CNAP: Cuff Fault – Unlicensed	Low *	– CNAP™ double finger cuff is not licensed for CNAP™ Monitor 500	– Check for permutation with equipment from third party devices
CNAP: Finger Cuff Expired	Low *	– CNAP™ cuff has reached end of life-cycle, thus providing low quality of measurement – it must be replaced immediately	– Replace CNAP™ double finger cuff immediately – Order new CNAP™ double finger cuff in corresponding size
CNAP: Cuff Fault – Leakage Left	Low *	– Leakage in left CNAP™ finger cuff	– Check connections of CNAP™ hardware – Replace CNAP™ double finger cuff (check with other cuff size) – In case of persistent error,

Message	Priority	Possible cause	Measures
			replace CNAP™ double finger cuff
CNAP: Cuff Fault – Leakage Right	Low *	– Leakage in right CNAP™ finger cuff	– Check connections of CNAP™ hardware – Replace CNAP™ double finger cuff (check with other cuff size) – In case of persistent error, replace CNAP™ double finger cuff
CNAP: Cuff Failure – Inflation Timeout	Low *	– 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	Low *	– 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	Low *	– CNAP™ controller is not licensed for CNAP™ Monitor 500	– Check for permutation with equipment from third party devices

13.5 NBP

13.5.1 Status messages

Message	Possible cause	Measures
NBP: Terminated	– User has stopped current NBP measurement	– n.a.
NBP: Fault	– Checksum error occurred	– Start new NBP measurement – In case of persistent error, contact service
NBP: Single Measurement	– User has triggered a single NBP measurement	– n.a.
NBP: Automatic Measurement	– Timed NBP measurement (NBP: Interval)	– n.a.

Message	Possible cause	Measures
NBP: Checking CNAP	– NBP check measurement as CNAP™ blood pressure changed more than 25mmHg within one minute (compared with last NBP measurement)	– n.a.
NBP: Venous Stasis	– Venous stasis is performed	– n.a.

13.5.2 Technical alarms

Message	Priority	Possible cause	Measures
NBP: Weak Or No Signal	Low *	– Weak or no oscillometric signal	– Check position and fit of NBP cuff – Make sure cuff is placed directly on the skin
NBP: Artefact	Low *	– Artifact/irregular oscillometric signal	– Check position and fit of NBP cuff – Avoid artifacts (e.g. movement) – Check for proper NBP cuff size – Check ECG for sinus rhythm
NBP: Exceeded Retry Count	Low *	– 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	Low *	– 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 proper NBP cuff size
NBP: Blocked Line	Low *	– 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

Message	Priority	Possible cause	Measures
			– cuff
NBP: Leakage	Low *	– NBP cuff or air hose leaking 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 proper NBP cuff size
NBP: Safety Timeout	Low *	– Safety time limit exceeded	– Check position and fit of NBP cuff – Avoid artifacts (e.g. movement) – Check for proper NBP cuff size – Start new NBP measurement
NBP: Overpressure	Low *	– Overpressure in NBP cuff	– Check for proper 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	Low *	– Voltage supply exceeds limits or other hardware problem	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
NBP: Autozero Failure	Low *	– Autozeroing has failed	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
NBP: Out Of Range Failure	Low *	– Measuring transducer out of measuring range	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
NBP: ADC Failure	Low *	– Analog/digital converter out of measuring range	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service
NBP: Calibration Failure	Low *	– Faulty EEPROM calibration data	– Reboot CNAP™ Monitor 500 – In case of persistent error, contact service

14 Appendix A – Glossary

A

AC Alternating current
Ah Ampere-hour

B

BP Wave Out Interface to patient monitors (CNAP™ blood pressure waveform)
bpm Beats per minute
BSA Body surface area (m²)

C

CNAP™ Continuous non-invasive arterial pressure

D

Dia or diastolic Diastolic blood pressure

H

h Hour
Hz Hertz

L

LED Light-emitting diode

M

Main Screen Monitor main screen (can be accessed 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

P

PPV Pulse pressure variation

S

Sys or systolic Systolic blood pressure
Sec Second

T

TFT Liquid crystal display

V

V Volts

14.1 Illustrations

15 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.

15.1 CNAP™

Items	Number
CNAP™ cable (2.5 m)	20-FEKA-10041
CNAP™ controller	21-FHCN-16705
CNAP™ double finger cuff "small"	20-FVMA-15420
CNAP™ double finger cuff "small", Extended Lifecycle	20-FVMA-15420E
CNAP™ double finger cuff "small", Maximum Lifecycle	20-FVMA-15420M
CNAP™ double finger cuff "medium"	20-FVMA-15520
CNAP™ double finger cuff "medium", Extended Lifecycle	20-FVMA-15520E
CNAP™ double finger cuff "medium", Maximum Lifecycle	20-FVMA-15520M
CNAP™ double finger cuff "large"	20-FVMA-15620
CNAP™ double finger cuff "large", Extended Lifecycle	20-FVMA-15620E
CNAP™ double finger cuff "large", Maximum Lifecycle	20-FVMA-15620M
Fixture for CNAP™ controller	21-FEZU-15401
CNAP™ forearm fixing cuff (Velcro fastener)	20-FEMA-05705

15.2 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

15.3 Printer

Item	Number
Thermal paper	20-HVZU-00258

15.3.1 Paper recommendation

CNSystems Medizintechnik AG recommends using 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 plasticisers, oil, hand lotion or cream, etc. This results in your prints being readable and storable for a longer time. If stored properly, KANZAN guarantees archivability of at least 7 to 10 years when using this kind of paper. High quality non-topcoated thermal papers like this are also resistant to the influence of external substances like oil, grease or water.

In addition, the characteristics of this high quality paper positively influences the product lifetime of your thermal printer. The characteristics of the above-mentioned KANZAN paper regarding chemical composition, thickness, surface texture ..., have material influence on the print head 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 print head 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 printer’s economic lifespan as this can cause damage or staining of the print head.

15.4 Connections

Items	Number
BP Wave Out: CNAP™ transducer cable	20-FEKA-01201
BP Wave Out: IBP interface cable (to patient monitor)	Contact r the authorized dealer of your patient monitor
AUX: Analog Out connector	20-FEKA-01100

15.5 Additional Features

Items	Number
Option PPV "unlimited"	21-HHCS-02200
Option PPV "500"	21-HHCS-02250
Option PPV "200"	21-HHCS-02220
Option PPV "100"	21-HHCS-02210
Option PPV "50"	21-HHCS-02201
Upgrade 500i to 500at	21-HHCS-02100

15.6 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™ Cart	21-FHGW-05500
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

16 Appendix C – Technical specifications

16.1 CNAP™ Monitor 500

CNAP™ Monitor 500	
Physical properties	
Dimensions (H x W x D)	280 x 270 x 250 mm
Weight	7.5 kg (16.6 lbs) including components and accessories necessary 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	3 A
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)
Relative humidity	Operation: 30% - 85%, non condensing Storage: 20% - 95%, non condensing, wrapped
Atmospheric pressure	Operation: 647 - 1059 hPa Storage: 500 - 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
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

16.1.1 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 (H x W x D)	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
Earth leakage current	< 500 µA
Operability	Continuous

16.1.2 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 shock	Type BF

16.1.3 NBP - non-invasive blood pressure

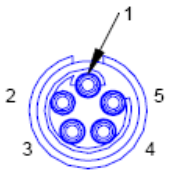
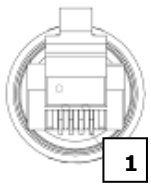
NBP - non-invasive blood pressure	
Parameter classification	Sys, Dia [mmHg]
Measuring method	Oscillometric: diastolic value for phase 5 Korotkoff
Measuring range	Sys: ADULT 40 - 260 mmHg PEDIATRIC 40 - 160 mmHg Dia: ADULT 20 - 200 mmHg PEDIATRIC 20 - 120 mmHg
Heart rate indication range	40-200 bpm
Inflation pressure at start	ADULT: 160 mmHg PEDIATRIC: 120 mmHg
Clinical accuracy	Meets ANSI/AAMI SP10:1992 and 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

16.1.4 Printer

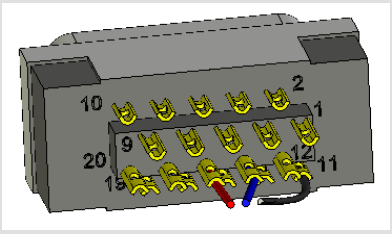
Printer	
Type	Integrated thermal paper printer
Width	58mm
Roll diameter	60mm

16.2 Connections

BP Wave Out		
Bridge supply voltage from other monitor to CNAP	2 - 10 VDC	
Input current max @10V	1.3mA	
Sensitivity	5 µV/V/mmHg	
V_{out} bridge excitation voltage from CNAP to other monitor	V_{in}*5*10^{-6}*Pressure [mmHg]	
PIN configurations	**CNAP Monitor (BP Wave Out)**	**Transducer Cable (RJ11 6P4C)**
		
V_{in}– neg. bridge supply voltage from other monitor to CNAP	1	4
V_{out}+ pos. bridge excitation voltage from CNAP to other monitor	2	2
V_{out}– neg. bridge excitation voltage from CNAP to other monitor	3	3
V_{in}+ pos. bridge supply voltage from other monitor to CNAP	4	1
N/A	5	-

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
Sampling 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
Resolution Impedance	12bit	12bit
Isolation (1sec)	4 KVDC min.	4 KVDC min.
Isolation (>1sec)	1.5 KVDC min.	1.5 KVDC min.

NOTE:
- When configuring the interface cable for the AUX analog out connector, insert a 10-100nF ceramic capacitor between ground and signal pin to reduce noise.



PIN configuration:
- **ground (schwarz): Pin 11**
- **channel 1 (rot): Pin 16**
- **channel 2 (blau): Pin 14**

16.3 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 arrangement of devices.
Only original CNSystems Medizintechnik AG 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 electromagnetic 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 ensure it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidelines
RF emissions 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 60601-1-2:2001+A1:2006

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 ensure 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 60601-1-2:2001+A1:2006

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 ensure 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 to 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 d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, 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 60601-1-2:2001+A1:2006

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 transmitting 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
For transmitters whose maximum rated power output values are not listed in the above list, the minimum distance can be calculated depending on the transmitting frequency and rated power output 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 60601-1-2:2001+A1:2006

16.4 Recurrent inspections

The time intervals for the recurrent inspections of the CNAP Monitor 500 as well as the extent of the work is defined as follows:

- Every 12 months: Safety control (SC)
- Every 24 months: Metrological control (MC)
- Every 24 months: Maintenance (Servicing)

16.4.1 Safety control (SC)

The SC is performed according to IEC 62353 and includes the following activities:

- Visual inspection of the device
  - damages,
  - hygienic condition and
  - safety relevant labeling (labels, signs)
- Mechanical inspection (enclosure, handholds, mounts)
- Functional technical inspection and check
- Overall assessment
- Safety test including leakage current measurement acc. EN 60601-1
- Calibration of NBP module
- Documentation including: safety protocol, inspection sticker, shipping documents

16.4.2 Metrological control (MC)

The MC is performed according to EN 62353 and includes the following activities:

- Adjustment and calibration of the following components:
  - CNAP™ Controller
  - CNAP™ Modul
  - NBP Modul
- Function technical inspection and check
- Overall assessment
- Safety inspection including current measurement according to EN 60601-1
- Documentation including: safety protocol, shipping documents

16.4.3 Maintenance

The maintenance includes the following activities:

- Exchange of the following components:
  - CNAP™ pump
  - Battery
  - CNAP™ controller cable
- Service of seals
- Test measurement
- Documentation including: safety protocol, inspection sticker, shipping documents
- Packing and shipment (standard delivery) from CNSystems to the customer.

NOTE:

- The MC and maintenance is always performed by CNSystems Medizintechnik AG or through a certified service partner.

16.5 Standards

The CNAP™ Monitor 500 meets the following standards:

1. ÖVE EN60601-1:1990 + AC:1994
2. ÖVE EN 60601-1-2:2001 + A1:2006
3. ÖVE EN 60601-1-4:1996 + A1:1999
4. ÖVE EN 60601-1-6:2004
5. ÖVE EN 60601-2-30:2000
6. ÖVE EN 60601-1-8:2004 + A1:2006
7. ÖNORM EN 1060-1:1995 + A2:2009
8. ÖNORM EN 1060-3:1997 + A2:2009
9. ANSI/AAMI DF2:1996
10. ANSI/AAMI DF39:1993
11. ANSI/AAMI SP10:2002

16.6 Declaration of conformity

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Web: http://www.cnsystems.at

cnsystems

Konformitätserklärung

Declaration of Conformity

CE-CNS-20120604-01

Produktspezifikation / *product details:*

Produktbezeichung /*product name:*	Continuous non-invasive blood pressure measurement equipment
Type / *type:*	CNAP® Monitor 500at CNAP® Monitor 500at+PPV CNAP® Monitor 500i CNAP® Monitor 500i+PPV
Systemkomponenten/*system components:*	CNAP® Monitor 500, CNAP®-controller, CNAP®-cable, Fixture for CNAP®-controller, CNAP®-forearm fixing cuff CNAP®-double finger cuff "small", "medium", "large"
Software Version:	3.7
Klassifizierung nach RL 93/42/EWG, Anhang IX in der geänderten Fassung der 2007/47/EG ***Classification according 93/42/EEC, annex IX as amended by 2007/47/EC***	IIb

Konformitätsbewertung / *assessment details:*

Benannte Stelle / *notified body* TÜV AUSTRIA SERVICES GMBH

Konformitätsbewertungsverfahren / *Conformity assessment procedure*

Nach RL 93/42/EWG, Anhang II / *according 93/42/EEC, annex II*

Zertifikate / *certificates*

Zertifikatsnr.:/ *Certificate No.:* TÜV-A-MT-1/10/Q034

Angewandte Normen / *used standards:*

EN 60601-1:1990 + AC:1994
EN 60601-1-2:2001 + A1:2006
EN 60601-1-4:1996, + A1:1999
EN 60601-1-6:2004
EN 60601-2-30:2000
EN 60601-1-8:2004 + A1:2006
EN 1060-1:1995 + A2:2009
EN 1060-3:1997 + A2:2009
ANSI/AAMI DF2:1996
ANSI/AAMI DF39:1993
ANSI/AAMI SP10:2002

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte und das zugehörige Zubehör den Anforderungen der Richtlinie 93/42/EWG in der geänderten Fassung der 2007/47/EG entsprechen. Die Produkte werden mit dem CE-Kennzeichen und der Kennnummer 0408 versehen.

We declare under sole responsibility that the products and the dedicated equipment described above are in compliance with directive 93/42/EEC as amended by 2007/47/EG. The products are CE-marked with the number 0408.

Gültig bis / *valid until*: 06/2016

Graz, 04.06.2012

DI. Walter Habenbacher, ppa