Instruction for Use

CPAR

- to study human pain perception as well as sensitization of the central nervous system

nocitech
CPAR

Disclaimer:

Nocitech ApS and its affiliates shall not be liable for any injury or damage suffered by any person, either directly or indirectly, as a result of the unauthorized use or repair of CPAR. Nocitech ApS does not accept any responsibility for any damage caused to its products, either directly or indirectly, as a result of use and/or repair by unauthorized personnel.

Conformity declaration:

CE

The product complies with the directives:

- Low Voltage Directive (2014/35/EU)
- EMC Directive (2004/108/EC)
- RoHS 2 (2011/65/EU)

Customer support:

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Fredericiavej 57 A
3000 Helsingør
Denmark
Mail: ma@nocitech.com

Important Safety Notice:

CPAR is designed for research use only. Nocitech ApS does not condone the use the CPAR device for clinical medical applications. CPAR and accessories provided by Nocitech ApS are not intended for the diagnosis, mitigation, treatment, cure, or prevention of disease.

The CPAR device is a pain stimulator that is designed for biophysical measurements within pain research. Please make sure that only qualified adequately trained scientists are using the device.

1 Table of Contents

2 Introduction

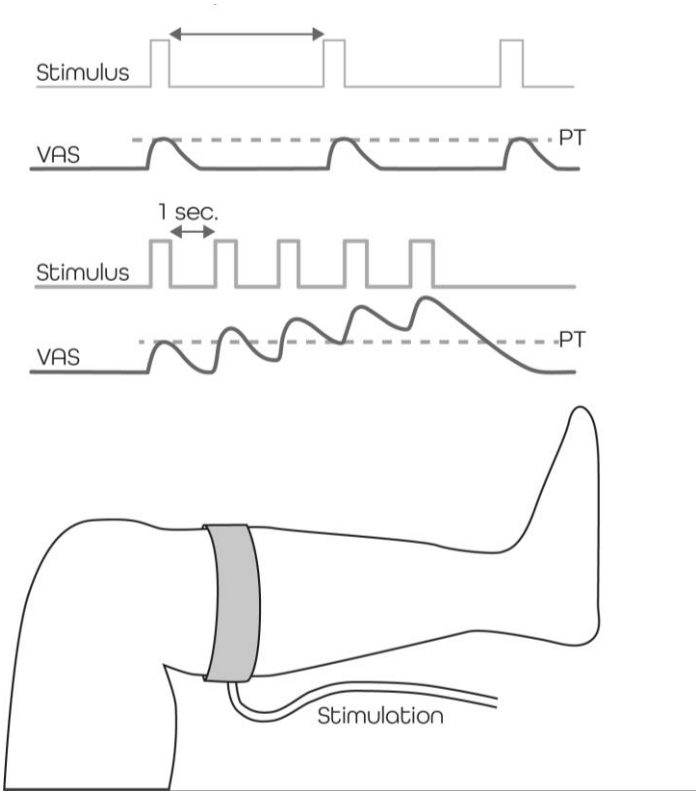
The Cuff Pressure Algometry Research (CPAR) system works by inflating a cuff/tourniquet, similar in design to those used for measuring blood pressure, around the subject's arm or leg, while the subject rates the perception of pressure on a VAS Meter. The scale on the VAS meter is typically a VAS scale with no sensation or the pain threshold at the bottom and the maximal pain/pain tolerance at the top.

The Cuff inflation is controlled by the CPAR system, such that pressure applied to subject is controlled. The system uses this to implement a series of protocols that can be used to study human pain perception as well as sensitization of the central nervous system:

Pain Detection Threshold **Pain Tolerance Threshold** **Pain Detection Limit** **Pain Tolerance Limit**	A stimulus-dependent protocol in which the pressure is linearly increased until the subject either stops the stimulation or the pressure limit for the system is reached. Pain Detection Threshold (PDT) and Pain Tolerance Threshold (PTT) are expressed in physical units (kPa) as the pressure at which the PPT and/or PTT was reached. Pain Detection Limit (PDL) and Pain Tolerance Limit (PTL) is expressed in centimetres (cm) as the VAS score reached when the PDT and PTT was reached, respectively. Depending on the definition of the PDT and PTT in a specific experiment this may either be per definition a fixed value, or a value equal to 10cm or less, depending on the instructions to the subject.

Temporal Summation

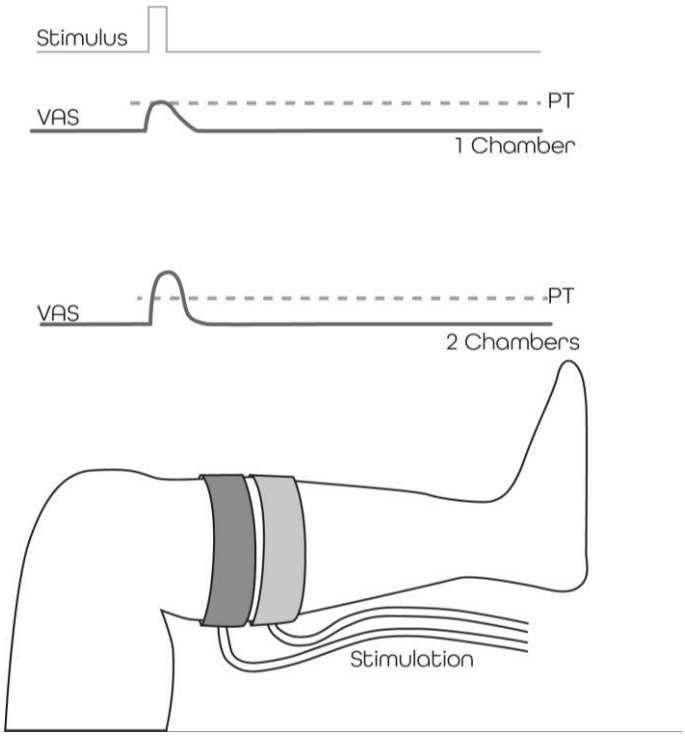
A response-dependent protocol in which pressure stimuli of the same intensity is applied repetitively while the subjects rates the pain sensation. Summation can then be seen from an increase or decrease in the pain rating during the stimuli.



The outcome measure is expressed as the VAS change over time.

Spatial Summation

Spatial summation can be performed both with response-dependent and stimulus-dependent protocols. With spatial summation the same protocol (e.g. PPT/PTT, temporal summation, etc.) is performed repeatedly with two cuffs with a different surface stimulation area (or two equally sized cuffs placed as neighbours).



The outcome measurement is either expressed as the reletive difference in between the responses to stimulations performed with two different stimulation areas.

Conditioned Pain Modulation

CPM is performed using two cuffs at two different body sites. One cuff is inflated to a constant painful or non-painful pressure stimulation, while the other is used to determine the PPT/PTT thresholds or temporal summation of pain.

The outcome measurement is compared (e.g. as the difference) to the unconditioned responses without the second cuff is expressed as either physical units (kPa) or as arbitrary unit in case of ratio comparison.

3 Intended Use

The CPAR system is intended for use by scientists within the field of neuroscience to study human pain perception.

The CPAR system is intended to be included in experimental protocols that are under ethical review/approval as potentially one out of several methods to investigate human pain perception.

4 Use limitations

The CPAR system is not to be used for the following:

- Experimental protocols where measurements from the system are used in decisions regarding a medical treatment of the experimental subject.
- Where the subjects are incapable of rating, their sensory perception using a Visual Analog Scale.
- Where subjects are incapable of stopping a stimulation.

5 Operating principle

The CPAR system uses one or more cuffs/tourniquets to apply pressure to a subjects' arm or leg. This pressure is used to evoke pressure pain that is scored on a VAS meter by the experimental subject.

6 Intended User

The intended user is a research professional within neuroscience that has a minimum training equivalent to the bachelors' level or is under close supervision of a research professional with this level of training.

7 Warnings and safety instructions

7.1 Warnings

1. Do not use the CPAR Device or VAS meter if there is visible damage to their enclosures; otherwise, the subject or experimenter may be in risk of electric shocks.

2. Do not use any cables with visible damage; otherwise, the subject or experimenter may be in risk of electric shocks.
3. Do not use the device in sessions on a single subject that are longer than one hour.
4. If the CPAR system is used outside its intended use the protection offered to the subject and experimenter by equipment may be impaired.
5. Do not use power cords with a voltage and power rating lower than the power cord rating specified in section TBD.

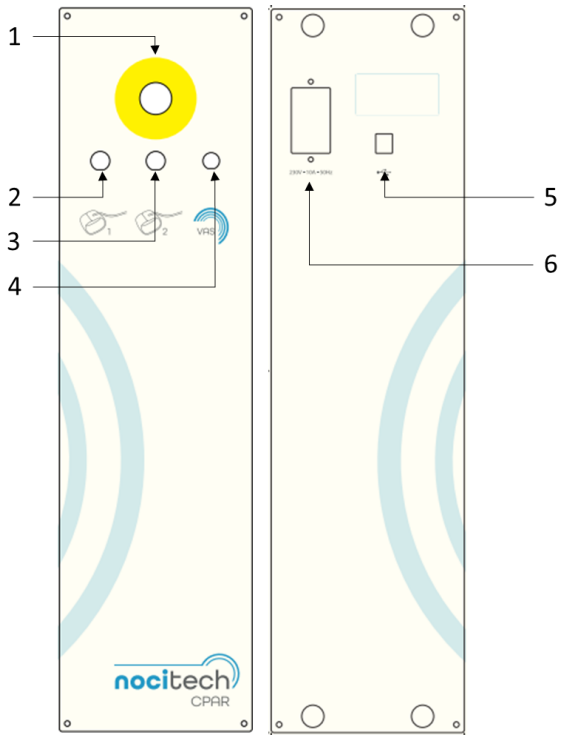
7.2 Precautions

1. When using the device, please make sure that the power cables supplying the equipment is connected to protective ground; otherwise, the subject or experimenter may be in risk of electric shocks.
2. Only use the device while the subject is sedentary; otherwise, the subject may be in risk of falls or pulling on the equipment.
3. Please make sure that the CPAR Cuffs are not placed over cables, tubes or similar; otherwise, there is a risk of local high pressures being generated that may be damaging to the skin.
4. The CPAR Cuff has a lower expected lifetime than the rest of the CPAR system and must be replaced periodically. During an experiment, please be observant if the CPAR cuff has started to leak air, which is a sure sign that it needs to be replaced.
5. Please make sure that only qualified adequately trained scientists are operating the device, or that they are closely supervised during its operation.
6. Please make sure when setting up the equipment that the emergency stop button is readily accessible to the experimenter operating the equipment.
7. Only use CPAR in lighted indoor conditions.
8. Protect all parts of the device from contact with water.
9. Do not store CPAR where temperatures may exceed: +10 to +40 C°.
10. Do not use CPAR where temperatures may exceed: +10 to +30 C°.
11. Do not transport CPAR in temperatures that may exceed: -20 °C to +60 °C
12. Do not attempt to repair or modify CPAR, as it is not designed to be serviced and/or repaired other than by the manufacturer. In case of a malfunction/technical problem please return CPAR to Nocitech ApS.

8 Product description

8.1 CPAR Device

The CPAR device contains the pressure generator and control system that is used to inflate the CPAR Cuffs and control their pressure.



(1) Emergency Stop: Activating this emergency stop button will immediately stop any pressure stimulation and vent the pressure from the CPAR cuffs.

(2) Pressure outlet for CPAR Cuff #1

(3) Pressure outlet for CPAR Cuff #2

(4) Connector for the VAS Meter

(5) USB Connector to the Control Computer

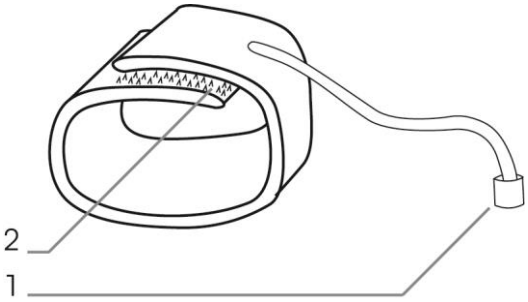
(6) On/Off Button

Operating modes:

OFF:	The device is turned off and inoperable.
IDLE:	The device is turned on without performing a pressure stimulation.
STIMULATING:	The device is performing a pressure stimulation and collecting the VAS rating from the subject.
EMERGENCY:	The emergency button has been activated; any pressure stimulation is terminated, and pressure is vented from the cuffs.

8.2 CPAR Cuff

The CPAR cuff is an inflatable tourniquet that is placed around the subjects' arm or leg, which is used to induce the pressure pain by the system.

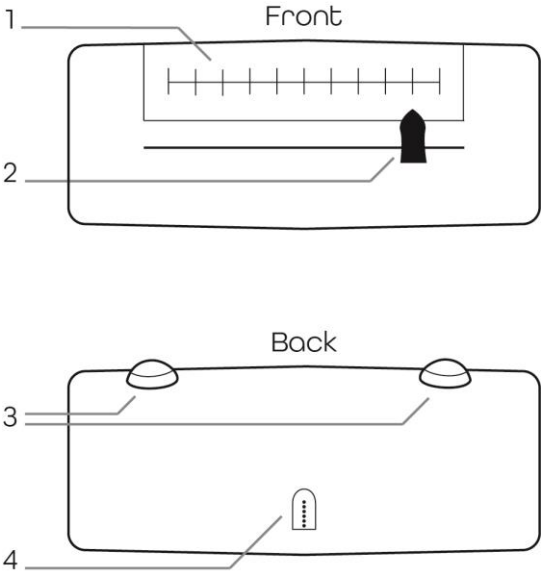


(1) Pressure connector that matches the 2 or 3 pressure outlets on the CPAR Device.

(2) Velcro band for securing the CPAR Cuff around the arm or leg of the subject.

8.3 VAS Meter

The VAS meter is used by the subjects during the pain stimulations to rate his or her pain sensation on a Visual Analog Scale (VAS).



(1) Response buttons that the subject can use to abort the stimulation or indicate a pain tolerance limit.

(2) Scale pocket; visual analog scales of the experimenters choosing can be inserted into the Scale pocket on the VAS Meter.

(3) Rating slider with which the subject can rate his or her sensation of the pain stimulation.

(4) Connector for the VAS Meter cable that connects the VAS Meter to the CPAR Device.

9 Operating the CPAR device

9.1 Running an experimental session with the CPAR system

Experimental sessions are performed with suitable control software that is designed to control the CPAR System. Nocitech provides the LabBench® software to customers that has bought a CPAR system. This software can be used to define and execute experimental protocols.

Conceptionally, running a session involves the following steps:

1. Connecting the CPAR Cuffs and VAS Meter to the CPAR Driver.
2. Turning on the CPAR Driver and starting LabBench on the computer that is connected to the CPAR device.
3. The experimenter then runs the tests in the protocol (see section 9.4).
4. When all the tests in the protocol have been run, the experimenter may end the session by closing the LabBench® software.

9.2 Donning the CPAR Cuff

The CPAR Cuffs can be donned on the subject arm or legs. CPAR Cuffs are available in different sizes from Nocitech to accommodate both legs and arms and subjects of varying size.

To don a CPAR Cuff; wrap the cuff tightly around the arm or leg and secure it with the Velcro band.

9.3 Using the VAS Meter

The VAS Meter is designed to be hold by the subject in one hand, while the other hand is used to rate his or her pain perception on the VAS slider.

Before a test can be started, the VAS slider must be set to 0cm, this is to ensure an unbiased rating of the pain perception.

A VAS rating of 10cm may depending on the parameters of the currently test (SR-Curves and Conditioning Pain Modulation) stop the pressure stimulation. The subject can always terminate the pressure stimulation by pressing one of the STOP buttons on the VAS meter.

Custom scales can be used with the VAS meter by replacing the scale in the Scale pocket of the VAS meter.

9.4 Running an experimental test

The CPAR system can perform the following tests: 1) Stimulus-Response Curves, 2) Temporal Summation, and 3) Conditioned Pain Modulation tests.

Running a test consists of the following steps:

1. Setting up the CPAR Cuffs for the test; either one cuff for Stimulus-Response Curves and Temporal Summation, or two cuffs for Spatial Summation and Conditioned Pain Modulation.
2. Instructing the subject on what to expect and how to rate the pain experience and how to terminate the test. The test may be terminated by rating 10cm on the VAS meter, and it can always be terminated by the subject by pressing the Response buttons on the VAS meter.
3. Starting the test by using the LabBench® Software. Please note that the test cannot be started if:
    a. The CPAR Device is turned off (please note that even when the CPAR Device is turned on the computer can still communicate with it, as the communication module of the CPAR Device draws its power from the computer).
    b. The VAS Meter is not connected.
    c. The VAS Meter is not set to 0cm.
    d. The compressor is running
4. The test will then run, until the subject terminates the test, the maximal pressure is reached, or the EMERGENCY button is activated.

9.5 Reacting to an emergency

At any time during a pressure stimulation the experimenter may activate the EMERGENCY button. When activated this will immediately vent the pressure in the CPAR cuff(s) and stop any pressure stimulation.

The subject may also at any time stop a pressure stimulation by pressing one of the STOP buttons on the VAS meter. Depending on the parameters of the currently running test, this may either be a normal event during the test or an abnormal termination of the test.

10 Maintenance, cleaning, storage, and disposal

10.1 Maintenance

10.1.1 CPAR Device

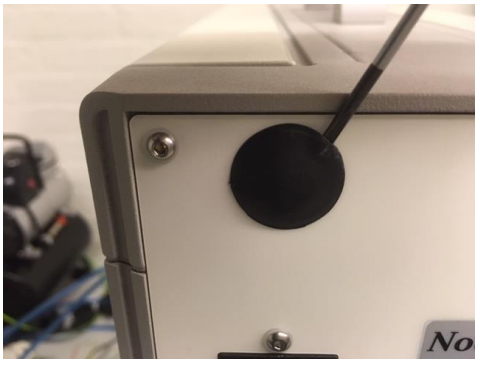
The pressure-decompression cycles within the compressor tank will over time cause water to condense. This water must periodically be drained from the tank.

- **We recommend that the water is drained from the tank and filter every 3 month or 50 hours of use.**

If this maintenance procedure is not followed the water will eventually cause the pneumatic components of the CPAR Device to be destroyed.

Procedure for draining the water from the tank and filter:

Disassembly	For getting access to the drain valves there must be access to the air tank and the filter Gently remove the rubber grommet in the left side. Top and bottom.



With a star screwdriver turn the screw counter clockwise

Turn the screw until the cover can be removed from the cabinet

The cover can now be removed by pulling the cover forward

Air tank drain

The drain valve is at the bottom of the air tank. Turn the valve screw counter clock wise. Plier might be necessary since the valve screw can be fitted very tight.

After drain tighten the valve.

WARNING

THERE MIGHT BE A VERY HIGH PRESSURE IN THE AIR TANK SO THE SCREW SHALL BE LOOSENED VERY SLOWLY.

Place cloth below the valve to absorb water.

Filter drain

The drain valve is at the bottom of the filter. Turn the valve screw counter clock wise to drain the water.

The valve should come loose without use of any tools.

Tighten the valve after drain without tools.

Place cloth below the valve to absorb water

Assembly	Before assembly connect the CPAR to the computer and turn the CPAR on. Check for any air leaks. If no leaks are found the CPAR can be assembled. Do the opposite of the disassembly instructions

Other maintenance instruction:

If the system does not operate as described in section Operating the CPAR device, it indicates that the system does not operate correctly. In that case, please contact the manufacturer.

10.1.2 CPA Cuff

The CPAR Cuff has a lower expected lifetime than the rest of the CPAR system and must be replaced periodically. During an experiment, please be observant if the CPAR cuff has started to leak air, which is a sure sign that it needs to be replaced.

10.2 Cleaning

Damp cloth with a MILD detergent may be used to wipe the outside of the CPAR Device and VAS Meter.

10.3 Storage

Store the CPAR system outside direct sunlight, accordingly to their storage temperature and humidity, as specified in section TBD.

10.4 Disposal

The CPAR system meets the requirements of guideline 2005/96/EG (used electric and electronic devices [WEEE]).

The WEEE symbol [redacted] on a part of the CPAR system or in this manual indicates that this part must not be disposed of in general waste. These parts of the CPAR system must be sent to an approved waste disposal facility, or, in case of doubt returned to the manufacturer.

11 Available articles

Item	Part Number
CPAR Cuff	PN-CPAR-80-01-001
CPAR Driver	PN-CPAR-80-02-001
CPAR VAS Meter	PN-CPAR-80-03-001
Instructions for Use	PN-CPAR-80-10-001

12 Technical description

12.1 CPAR Device

Installation category	II
Operating modes	OFF, IDLE, STIMULATING, EMERGENCY
Controls	Power On/Off EMERGENCY button

Indicators	Power On/Off (as seen on the power switch) Emergency Activated/Deactivated (as seen on the EMERGENCY button)
Pressure stimulation	0kPa – 100kPa (maximum 10 minutes)
Connectors	Front: VAS meter connector, Type REAN RT4MP: Pin #1: Output, VAS power, 5 Vdc, Max load 50 mA. Pin #2: Input, VAS score, Max input voltage 5 Vdc. Pin #3: Input, Stop button, Activated when grounded (Pin #4 Gnd), Internal pull-up resistance 10 KOhm (to 5 Vdc). NO EXTERNAL VOLTAGE MUST BE APPLIED TO THIS PIN. Pin #4: Gnd. Air pressure connectors for Cuffs. Back: IEC Main power inlet USB 2.0 Interface, Type B plug.
Power supply	220 to 240 Vac, 50 Hz.
Dimensions	589mm x 266mm x 460mm (HxWxL)
Weight	14.6 Kg.
Ingress protection	IP20
Operating temperature	+10 to +30 C° (Compressor protected against overheating)
Operating Humidity	30 to 75 % relative humidity
Storage temperature	+10 to +40 C°
Storage Humidity	30 to 75 % relative humidity
Transportation temperature	-20 °C (no humidity control) and +60 °C
Transportation Humidity	Max 93 % relative humidity. BEFORE OPERATION AFTER TRANSPORTATION CPAR MUST BE STORED IN OPERATING ENVIROMENT FOR AT LEAST 1 HOUR.
Atmospheric pressure	900mBar – 1050mBar
Acoustic noise level	Maximal SPL: 45 dB

12.2 VAS Meter

Operating modes	OFF, ON.
Controls	VAS Slider. Stop Buttons, Buttons are paralleled.
Indicators	VAS Scale.
Connectors	Rosenberger M9K702-299L. Pin #1: Input, Power supply. Pin #2: Output, VAS score, Max output is equal to power supply, Output impedance Max 10 KOhm. Pin #3: Output, VAS button, internally connected to Gnd by 39 KOhm. Connected to Gnd when buttons activated. Pin #4: Gnd Pin #5: NC Pin #6: NC
Power supply	+5 to +12 Vdc.
Dimensions	45mm x 175mm x 45mm (HxWxL)
Weight	0.155 Kg
Ingress protection	IP20
Operating temperature	+10 to +30 C°
Operating Humidity	30 to 75 % relative humidity.
Storage temperature	+10 to +40 C°
Storage Humidity	30 to 75 % relative humidity.
Transportation temperature	-20 °C (no humidity control) and +60 °C
Transportation Humidity	Max 93 % relative humidity. BEFORE OPERATION AFTER TRANSPORTATION VAS METER MUST BE STORED IN OPERATING ENVIROMENT FOR AT LEAST 1 HOUR.
Atmospheric pressure	900mBar – 1050mBar

12.3 CPAR Cuff Model VBM 20-54-522

Size	61 cm
Weight	0.45 Kg
Operating temperature	Max +60 C°
Atmospheric pressure	900mBar – 1050mBar

13 Declaration of conformity

The product complies with the directives:

- Low Voltage Directive (2014/35/EU)
- EMC Directive (2004/108/EC)
- RoHS 2 (2011/65/EU)

Manufacturer:

CPAR is a product made by the Danish manufacturer Nocitech ApS

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