Instruction for Use

LabBench CPAR+

- to study human pain perception and
sensitisation of the central nervous system.

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Disclaimer:

Inventors' Way ApS and its affiliates shall not be liable for any injury or damage suffered by any person, either directly or indirectly, due to the unauthorised use or repair of CPAR+. Inventors' Way ApS does not accept any responsibility for any damage caused to its products, either directly or indirectly, due to use and/or repair by unauthorised personnel.

Conformity declaration:

CE

The product complies with the directives:

- EMC Directive (2004/108/EC)
- RoHS 2 (2011/65/EU)

Customer support:

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Niels Jernes Vej 10
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Denmark

Mail: help@labbench.io

Important Safety Notice:

LabBench CPAR+ is designed for research use only. Inventors' Way ApS does not condone the use of the LabBench CPAR+ device for clinical/medical applications. LabBench CPAR+ and accessories provided by Inventors' Way ApS are not intended to diagnose, mitigate, treat, cure, or prevent disease.

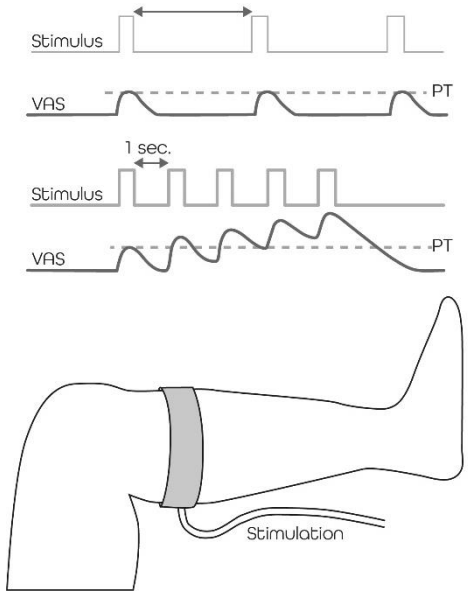
The LabBench CPAR+ device is a pain stimulator designed for biophysical measurements within pain research. Please ensure that only qualified, adequately trained scientists use the device.

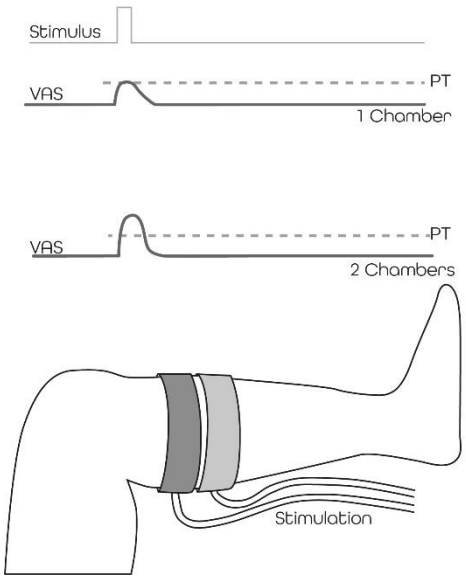
1 TABLE OF CONTENTS

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 medical treatment of an experimental subject.
- Where human subjects are incapable of rating, their sensory perception with a visual analog scale.
- Where human subjects are incapable of stopping the stimulation.

5 OPERATING PRINCIPLE

The CPAR+ system uses one or more cuffs/tourniquets to apply pressure to a subject's 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 of training equivalent to the bachelor's level or is under close supervision of a research professional with this level of training.

7 WARNINGS AND SAFETY INSTRUCTIONS

8 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 at risk of electric shocks.
2. Do not use any cables with visible damage; otherwise, the subject or experimenter may be at risk of electric shocks.
3. Do not use the device in sessions on a subject longer than one hour.
4. If the CPAR+ system is used outside its intended use, the protection offered to the subject and experimenter by the equipment may be impaired.

9 PRECAUTIONS

1. When using the device, please make sure that the power supply 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.

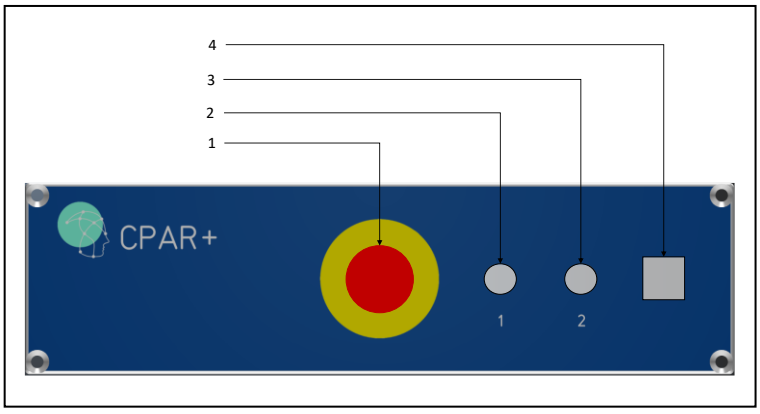
5. Please ensure that only qualified, adequately trained scientists are operating the device or that they are closely supervised during its operation.
6. Please make sure when setting up the equipment that the emergency stop button is readily accessible to the experimenter operating the equipment.
7. 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 Inventors' Way ApS.
13. Do not install the device close to magnetic field generators.

10 PRODUCT DESCRIPTION

11 CPAR+ DEVICE

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

Front



(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 a Response Device

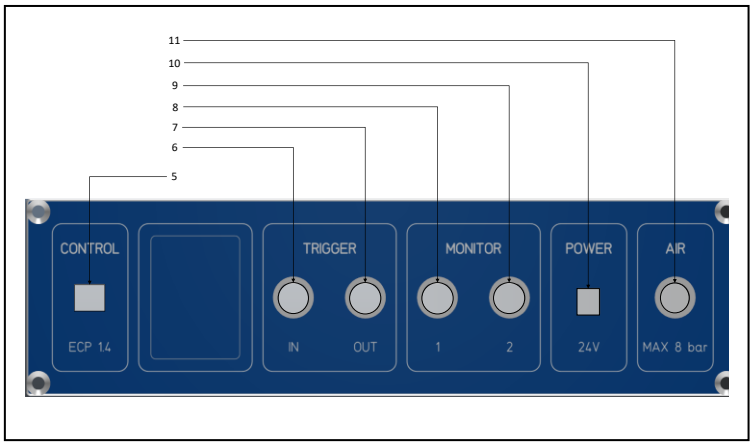
(5) USB Connector to the Control Computer

(6) Trigger IN signal

(7) Trigger OUT signal

(8) Monitor signal pressure regulator #1

Back



(9) Monitor signal pressure regulator #2 (ONLY FUNCTIONAL ON CPAR+ DUO)

(10) Power supply connector

(11) Air supply

Operating modes:

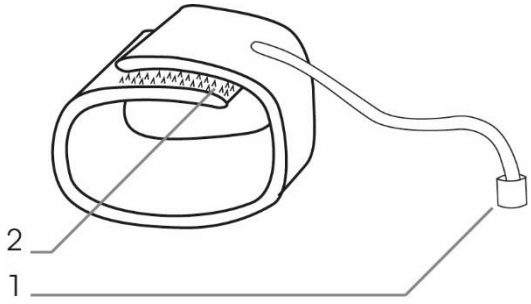
IDLE:	The device is turned on without performing a pressure stimulation.
STIMULATING:	The device is performing a pressure stimulation and collecting the data from the Response Port. It could be VAS rating from the subject.
EMERGENCY:	The emergency button has been activated; any pressure stimulation is terminated, and pressure is vented from the cuffs.

12 CPAR+ UNO

The CPAR+ UNO variant has one internal pressure regulator. The pressure can be routed to one of the two pressure outlets.

13 PRESSURE CUFF

Pressure cuffs 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 pressure outlets on the CPAR+ Device.

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

14 RESPONSE PORT

Various devices can be connected to the Response Port. Examples shown below.

(1) LabBench BUTTON; The subject can use a LabBench BUTTON to abort the stimulation or indicate a pain detection or tolerance threshold.

(2) LabBench SCALE; The subject can rate his or her pain sensation on a visual analog scale.

The Response Port is an open standard, and the operator can connect other devices than those provided by Inventors' Way ApS. Connected equipment must comply with the Response Interface protocol.

15 OPERATING THE CPAR DEVICE

This section provides a conceptual view of how to perform experimental procedures with the LabBench CPAR+ device. For detailed instructions on how to design and execute experimental protocols with the device, please refer to the LabBench Book or the LabBench MATLAB Toolbox.

16 RUNNING AN EXPERIMENTAL SESSION WITH THE CPAR SYSTEM

Experimental sessions are performed with the LabBench® software. This software can be used to define and execute experimental protocols.

Conceptionally, running a session involves the following steps:

1. Connecting the Cuffs and Response Device to the CPAR+ device.
2. Turning on the CPAR+ 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.

17 DONNING THE CPAR CUFF

The cuffs can be donned on the subject arm or legs. Cuffs are available in different sizes from Inventors' Way or 3rd party distributers of surgical cuffs to accommodate both legs and arms and subjects of varying size.

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

18 USING A RESPONSE DEVICE, VISUAL ANALOG SCALE

If a LabBench SCALE is connected, it is designed to be held by the subject in one hand while the other hand is used to rate his or her pain perception on the rating slider.

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

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

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

19 RUNNING AN EXPERIMENTAL TEST

Running a test consists of the following steps:

1. Setting up the 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 not powered (please note that even when the CPAR+ Device is not powered, the computer can still communicate with it, as the communication module of the CPAR+ Device draws its power from the computer).
    b. The LabBench SCALE or LabBench BUTTON is not connected (except when response is disabled).
    c. The rating slider on the LabBench SCALE is not set to 0cm (except when response is disabled).
    d. The supplied air pressure is too low.
4. The test will run until the subject terminates the test, the maximal pressure is reached, or the EMERGENCY button is activated.

If a fault occurs at any time during an experiment; LabBench will inform you of the nature of the fault in its user interface and how to correct it.

20 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 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 LabBench SCALE or LabBench BUTTON. 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.

21 MAINTENANCE, CLEANING, STORAGE, AND DISPOSAL

22 MAINTENANCE

23 CPAR+ DEVICE

The CPAR+ driver does not require regular maintenance. We recommend a visual inspection of all input/output connections every 3 months or 50 hours of use.

Other maintenance instructions:

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

24 CUFF

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

25 CLEANING

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

26 STORAGE

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

27 DISPOSAL

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

The WEEE symbol ▬ 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.

28 AVAILABLE ARTICLES

Item	Part Number
LabBench CPAR+ DUO	PN-CPA-80-01-001-001
LabBench CPAR+ UNO	PN-CPA-80-02-001-001
LabBench SCALE	PN-PRS-80-01-001-001
LabBench BUTTON	PN-BTN-80-01-001-001

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29 TECHNICAL DESCRIPTION

30 CPAR DEVICE

Installation category	II
Operating modes	IDLE, STIMULATING, EMERGENCY
Controls	EMERGENCY button
Indicators	Emergency Activated/Deactivated (as seen on the EMERGENCY button)
Pressure stimulation	0kPa – 100kPa (maximum 10 minutes)
Connectors	Front: Response Connector, Type 10P10C: For a specification of this port, please refer to LAB-10-008-DOC Interface Design Description (RESPONSE). Air pressure connectors for Cuffs. Back: 24 VDC power supply port, DC socket 5.5mm (2.5mm centre pin) Centre pin positive. USB 2.0 Interface, Type B plug. Cuff 1 Monitor out, 1 – 5V (0 – 100Kpa). Min load 100 kOhm Cuff 2* Monitor out, 1 – 5V (0 – 100Kpa) Min load 100 kOhm Trigger IN TTL signal (0V or 5V). Impedance 10 kOhm Trigger OUT TTL signal (0V or 5V). Impedance 50 Ohm Air pressure inlet, 2 – 8 bar. **AIR PRESSURE EXCEEDING 8 BAR MAY CAUSE SEVERE DAMMAGE TO THE CPAR+**
Power supply	24 Vdc, max input power 48 Watt
Dimensions	80mm x 297mm x 210mm (HxWxL). Ex. Connectors
Weight	3 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 CPAR+ MUST BE STORED IN OPERATING ENVIROMENT FOR AT LEAST 1 HOUR.
Atmospheric pressure	900mBar – 1050mBar
Acoustic noise level	Maximal SPL: 45 dB
Recommended USB cable (Supplied)	AMP-Connectivity, PN 1487588-1

31 DECLARATION OF CONFORMITY

The product complies with the directives:

- EMC Directive (2004/108/EC)
- RoHS 2 (2011/65/EU)

Manufacturer:

CPAR is a product made by the Danish manufacturer Inventors' Way ApS

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