CortiVision Sp. z o.o.
Name: PHOTON CAP
model: C20

Instruction Manual

(Version 2023.1.1)

Cortivision sp. z o.o.
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Product information

Product name: PHOTON CAP
Model: C20

Manufacturer: Cortivision sp. z o. o. based in Lublin (address: al. Warszawska 47, 20-803 Lublin) entered into the Register of Entrepreneurs kept by the Lublin-Wschód District Court, 6th Commercial Division of the National Court Register, under the number KRS 0000778384, REGON 382891891, NIP 7123384349.

Device parameters:
Technology: near infrared spectroscopy of solid light using the modified Beer-Lambert law.
Light sources: up to 16 LEDs with wavelengths of 760 nm and 850 nm.
Detectors: up to 10 SiPD detectors.
Sampling frequency: up to 86 Hz (depending on the number of channels).
Battery operation: at least 6 hours.
Communication with the recording device: Wireless communication protocol.
As part of product improvement, we reserve the right to make changes to its design and appearance.

FCC compliance:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
And:
This device complies with the safety requirements for RF exposure for portable use conditions in accordance with FCC rule part 2.1093

If you wish to know more about the compliance of our products with regulations please visit our website: www.cortivision.com/certification.

Safety information

Before starting work with the device, please read the instructions carefully. If you have any questions, please contact Cortivision sp. z o. o. (support@cortivision.com).

Cortivision sp. z o. o. is not responsible for any loss or damage resulting from failure to comply with the following rules and failure to comply with the operating instructions.

Safety tips:

1. Before use, make sure that all components of the device are connected in accordance with the operating instructions.
2. The device may only be operated by adults who have read the manual beforehand.
3. In the event of damage to the device components, it is absolutely necessary to turn off the power supply and contact Cortivision sp. z o. o.
4. The device and its accessories should be protected against the action of water and other liquids, the possibility of mechanical damage and the influence of extreme weather conditions.
5. The device is not adapted to work in a high magnetic field, e.g. in the immediate vicinity of magnetic resonance imaging (MRI).
6. The device and accessories should be maintained and cleaned in accordance with the information provided in the user manual. Do not use chemicals with a composition other than that specified in the manual.
7. Elements in contact with the body of the tested person should be disinfected before each subsequent use (according to the information contained in the instructions).
8. Elements of the device that come into contact with the body of the tested person (e.g. optodes, cap) should be applied carefully and gently to avoid the possibility of scratching or injury.
9. Do not repair the device yourself, open its casing or replace any element with parts other than those provided by Cortivision sp. z o. o.
10. This product is not authorised for use as a critical component in life support systems nor for diagnosis or medical use purposes. The manufacturer designed this product for research purposes only.

Environmental protection

Each user makes a significant contribution to the protection of the environment. The product and its packaging contain materials that should be reused. The reprocessing of waste reduces its quantity and contributes to the protection of the natural environment. It is possible only with the involvement of users who will hand over waste equipment for recovery and reuse.

The **packaging** should be disposed of in accordance with the principles of waste segregation. Local options for separate collection of waste should be used.

Devices marked with this symbol must not be disposed of with ordinary household waste. Therefore, the PHOTON CAP C20 device, including accessories, should not be mixed with normal household waste. Elements of the PHOTON CAP C20 system should be disposed of in accordance with national regulations for the management of used electronic equipment.

Cortivision sp. z o. o. at the customer's request, accepts the return of used devices and accessories and takes care of their disposal. For this purpose, a request for collection of waste equipment should be submitted by sending a message to info@cortivision.com.

The user may independently hand over the device for disposal at a selective electronic waste collection point. Information on collection points accepting waste equipment free of charge can be obtained from the local government administration.

1. Description of the set

Cortivision PHOTON CAP C20 is a scientific device - wireless near infrared spectroscope (NIRS) for the functional measurement of the haemodynamic response of the brain designed for research purposes. The device enables non-invasive monitoring of oxy-, doxy haemoglobin levels in selected areas of the cerebral cortex, thanks to a set of infrared light emitters and detectors. The set includes:

1. Amplifier with wireless communication module (Fig. 1.).
2. A splitter with infrared light emitters and detectors with the IMU (inertial measurement unit) module (Fig. 2).
3. A cap for attaching optodes in the 10-5 standard (Fig. 3.).
4. Wires (Fig. 4. and Fig. 5.).
5. Transport case (Fig. 6.).

The individual elements of the set and additional accessories are presented in subchapters 1.1 to 1.5. Please note that the colours of some elements may slightly vary from those in the photos.

1.1. Amplifier

Fig. 1. The PHOTON CAP amplifier: 1. Plastic casing, 2. Diode , 3.Diode , 4. Diode , 5 Diode , 6. Ribbon cable socket, 7. Battery charging socket, 8. Two-position switch of the device, 9. Fastening band.

The Cortivision PHOTON CAP C20 amplifier shown in Figure 1 allows you to connect infrared light emitters and detectors (see 1.2) and send the processed signal via wireless communication to the recording software (CortiView). The amplifier contains a built-in lithium-ion battery with a capacity of 2000 mAh, powered by the charging socket (Fig. 1.7). The device status is communicated by means of four LEDs informing about: the current battery charging mode (Fig. 1.2); starting the power supply of the device (Fig. 1.3); establishing wireless communication (Fig. 1.4) and the detected error or the need to calibrate the IMU module (Fig. 1.5). There is a band on the back of the device that allows it to be mounted on the forearm (Fig. 1.9).

1.2. Detectors and emitters

Fig. 2. Detectors and emitters: 1. Infrared light detectors, 2. Dual-band infrared light emitters (LEDs), 3. Short channel emitters, 4. Common electrode, 5. Splitter with IMU module, 6. Ribbon cable.

PHOTON CAP enables the connection of an optode beam consisting of ten infrared light detectors (Fig. 2.1) and sixteen emitters in the form of LEDs emitting light with a length of 760 nm and 850 nm (Fig. 2.2. and Fig. 2.3). Four LED emitters are dedicated to building the short channel montages (Fig. 2.3). The bundle also includes one grounding electrode (Figure 2.4). The optodes and grounding electrode are connected to the amplifier through a splitter(Fig. 2.5) and a ribbon cable (Fig. 2.6). The splitteris additionally equipped with an IMU (inertial measurement unit) module, which includes an accelerometer and a gyroscope (Fig. 2.5).

1.3. Caps

Fig. 3. Cap: 1. Holes for mounting optodes, 2. Optode mounts, 3. Chinstrap.

Cortivision PHOTON CAP uses the so-called "10-5 system"[1], which is an extension of the EEG electrode positioning standards known as "10-20 system"[2] and "10-10 array"[3]. In the 10-5 system, the distance between the 128 possible optode localization points corresponds to 10 or 5 percent of the distance between the imaginary extreme points on the skull. Emitters and detectors should be placed in predetermined holes (Fig. 3.1), using the mounts included in the kit (Fig. 3.2). The size of the cap is selected individually on the basis of the examined person's head circumference and the chinstrap (Fig. 3.3) can be secured against displacement during signal recording.

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[1] Oostenveld, R., Praamstra, P. (2001). The five percent electrode system for high-resolution EEG and ERP measurements. *Clinical neurophysiology, 112*(4), 713-719.
[2] Jasper, H. H. (1958). The ten-twenty electrode system of the International Federation. Electroencephalogr. *Clinical neurophysiology., 10*, 370-375.
[3] Chatrian, G. E., Lettich, E., Nelson, P. L. (1985). Ten percent electrode system for topographic studies of spontaneous and evoked EEG activities. *American Journal of EEG technology, 25*(2), 83-92.

1.4. Wires

Elements of the PHOTON CAP system uses two types of cables: battery charging cable (Fig. 4.) and a flat cable to connect the optode splitter with the amplifier (Fig. 5.).

Fig. 4. Charger and charging cable (1.8 m)*: 1. USB plug for connection to the socket on the charger, 2. Charger, 3. Micro USB plug for connection to the socket on the amplifier.
* Use only the cable that is supplied with the device. The use of another cable is not allowed.

Fig. 5. Flat cable: 1. Plug to be connected to the socket in the distributor, 2. Plug to be connected to the socket on the amplifier.

Fig. 6. Transport case.

1.5. Additional accessories

Additional accessories, available for purchase together with the PHOTON CAP C20 device.

Fig. 7. Pressure cap PCAP-COV-XX. 1. Velcro for attaching the chinstrap (Fig. 3.1).

Fig. 8. PCAP-LB light blocking overlay to be placed on the PCAP-COV-XX pressure cap (Fig. 6).

Fig. 9. Fixing the amplifier on a forearm.

Fig. 10. Holders for PCAP-H30 optodes, set of 30 pieces.

2. Preparing the system for startup

2.1. Transport and storage

The PHOTON CAP C20 System should be transported in a protective case attached to the set and protected against the effects of extreme environmental conditions. The device is not waterproof and is not adapted to work in conditions of high sun exposure, dust, high humidity and temperature below 0°C and above 40°C.

When the device is not used intensively, it is best to store the system components in a protective case, away from heat sources (e.g. heaters) and the possibility of contamination or damage.

2.2 Preparation for activation

Before first use, you must charge the amplifier by plugging the charger cable (Figure 4). The LED will be blue while in charging mode. It takes approximately 6 hours to fully charge the battery.

Before each subsequent use, check the battery level in the CortiView program ("CortiView- user manual").

The battery in the amplifier's housing enables uninterrupted operation in mobile mode for about 6 hours. The battery is not interchangeable.

2.3. Connecting elements of the set

Step 1. Using the flat cable (Fig. 5) connect the splitter with optodes and the amplifier.

Step 2. The previously charged amplifier is turned on by sliding the Two-position switch of the device (Fig. 1.8). The LED will turn blue on the housing of the amplifier.

Step 3. (During first time use) On the computer on which the signal will be recorded, install the CortiView application, start Wireless communication protocol communication, pair the device with the computer, and then check if the device name is displayed in the program window (see: "CortiView - user manual").

Step 4. On the computer where the signal will be recorded, start the CortiView application. The LED will turn blue on the housing of the amplifier.

Step 5. PHOTON CAP C20 is ready to start recording.

3. Description of operation

3.1. Research environment

An intense natural or artificial light source may cause infrared radiation to penetrate the device's detectors and cause disturbances in the recorded signal. For this reason, it is best to record with the lights off, the windows covered and away from devices emitting infrared light (e.g. radiators in industrial cameras). If the place where the tests will be conducted does not allow for the elimination of the above-mentioned factors, the PCAP-LB light blocking insert (Fig. 7) and/or additional shields blocking the possibility of light from outside reaching the detectors on the subject's head should be used.

The PHOTON CAP C20 amplifier connects to the CortiView software via Wireless communication protocol communication. Make sure that the distance between the amplifier and the computer used to record the signal does not exceed the range of the Wireless communication protocol connection, i.e. about 10 m.

3.2. Preparation of the test person

Step 1. First, choose a cap the size of which corresponds to the circumference of the person's head. The head circumference is measured using a tailor's tape measure, drawing a line low over the ears, eyebrows and the bone thickening on the edge of the occipital bone of the skull (Fig. 11). Before deciding to choose a cap, we ask the test person to put it on his head. The cap, after fastening the chin, must not move loosely on the head or compress the scalp. The ears should pass freely through the openings on the sides.

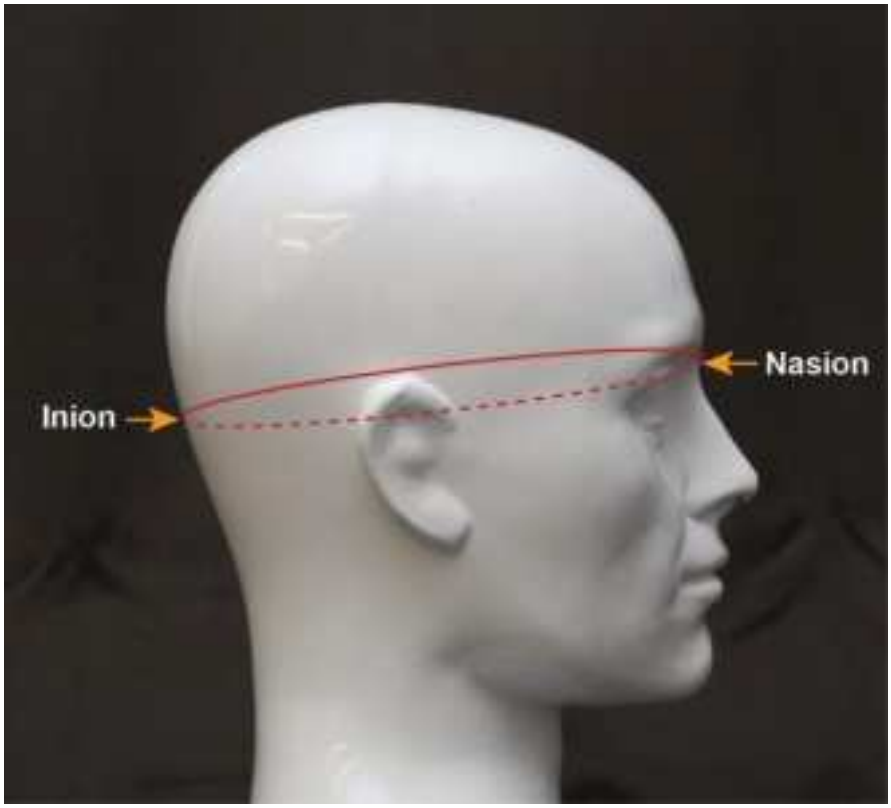

Fig. 11. Place of measuring the head circumference of the examined person.

Step 2. In the selected cap, we place holders for emitters and detectors in places where we want to record brain activity. There are many methods of determining the points where optodes should be placed. One way is to use software to help determine the assembly of optodes by selecting the structures listed in popular brain atlases[4] . Place the optodes in the mounted holders (Fig. 12.).

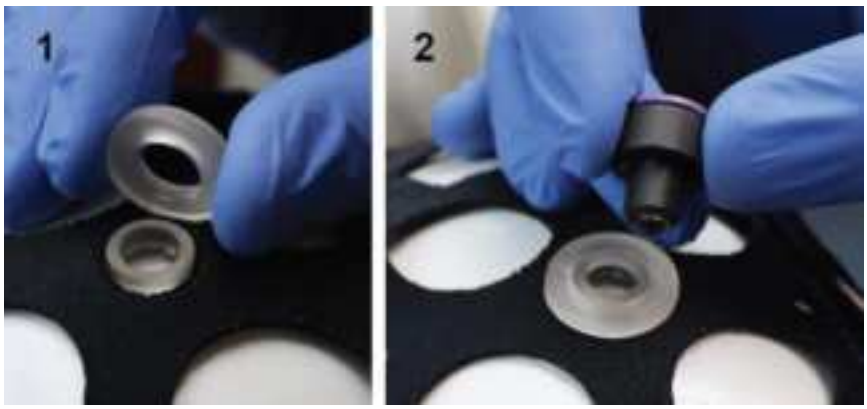

Fig. 12. 1. Mounting of the optode holders, 2. Placing optodes in appropriate holders.

[4] Morais, G. A. Z., Balardin, J. B., Sato, J. R. (2018). fNIRS optodes' location decider (fOLD): a toolbox for probe arrangement guided by brain regions-of-interest. *Scientific reports, 8(*1), 1-11.

Step 3. Using a tailor's measure, we measure the distance from the point between the eyebrows of the test subject (nasion) and the farthest point of the back of the skull (inion) (Fig. 13.1). We divide the obtained value by 10 and measure, using the same measure, from the point of the nasion, towards the centre of the head (Fig. 13.2). For example, if the distance through the centre of the subject's head was 35 cm, then we measure a distance of 3.5 cm from the point between the eyebrows, towards the centre of the head. We mark the measured point with a dermatograph, for example.

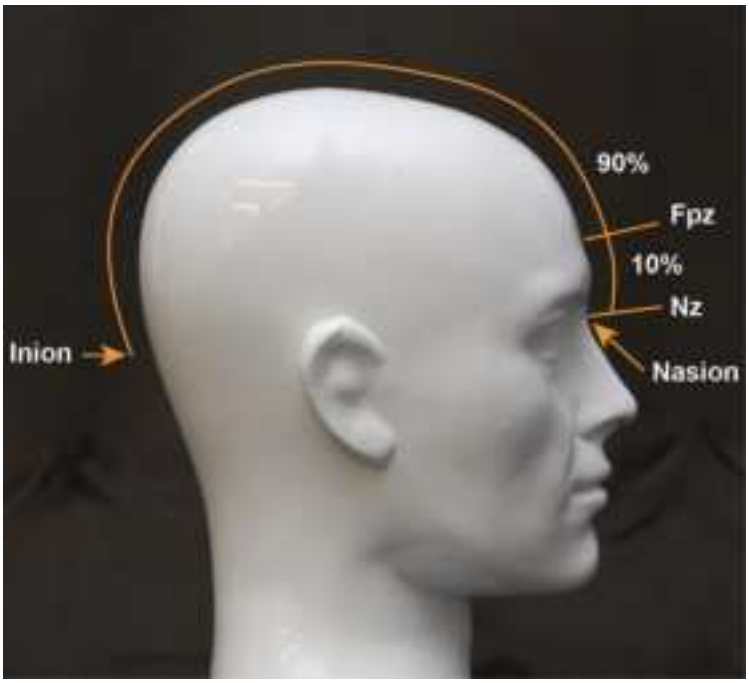

Fig. 13. Determining the reference point on the subject's head (FPz).

Step 4. The cap with mounted optodes and the grounding electrode is put on the head of the examined person in such a way that the point marked as FPz coincides with the point marked in Step 3. Then fasten the chinstrap in such a way as to prevent the cap from moving on the head. Using, for example, cotton buds, carefully brush the hair from under each optode so that it touches the skin on the head.

Caution:

- If the EEG signal is simultaneously recorded during fNIRS recording, make sure that the applied gel, paste or conductive fluid does not come into direct contact with the optodes.
- If virtual reality (VR) goggles are used to present stimuli during fNIRS recording, it should be checked that no part of the goggles causes the optodes to shift or tighten during the test.

Step 5. Using the CortiView software, we control the signal quality on individual channels ("CortiView - user manual") and if it is unsatisfactory, we check again whether the optodes accurately touch the scalp. Additionally, the cap with optodes can be fitted with the PCAP-COV-XX pressure cap (Fig. 7.) and the PCAP-LB light blocking cap (Fig. 8.) to improve the fit of the cap to the head and reduce the influence of external lighting.

Step 6. We start and end the recording of the signal using the CortiVision View program ("CortiView - user manual").

Step 7. After completing the registration: turn off the power to the amplifier, disconnect the splitter and amplifier, and remove the cap with optodes from the subject's head. Elements in direct contact with the body of the tested person should be cleaned before the next registration (Subsection 3.3. Disinfection and maintenance).

3.3. Disinfection and maintenance

After removing the optodes and handles, the cap can be washed by hand with the addition of ECOLAB® Sekuspet® Plus liquid according to the manufacturer's instructions.

Parts of the optodes in contact with the scalp should be disinfected by wiping with a cotton pad soaked in the ECOLAB® Sekuspet® Plus liquid solution according to the manufacturer's instructions.

Clean the other elements of the PHOTON CAP C20 set by wiping their surface with a dry cloth.

4. Support

4.1. Online support

In the event of any difficulties, they should be reported directly to the manufacturer, Cortivision sp. z o. o. to the e-mail address support@cortivision.com.

4.2. Warranty Coverage Information

§1. Cortivision sp. z o. o. (hereinafter referred to as the Manufacturer) grants a 12-month warranty for each device, the warranty period starts from the moment the device is delivered to the Buyer.

§2. The Manufacturer undertakes to remove the defects arising during the warranty period and recognized by the Manufacturer free of charge within the shortest possible time, but not longer than 30 days from the date of notification by the Buyer of the defect. In the event of a defect, the removal time of which will require a longer period, the Manufacturer will agree with the Buyer a longer period of defect removal.

§3. The Buyer is responsible to report the defect within 7 working days from its detection in writing or, for example, by sending an email to the Manufacturer's e-mail address. service@cortivision.com

§4. The warranty period of a given device, if the Manufacturer recognizes a significant defect, is extended by the time counted from the date of notification of the damage to the date of its removal. The warranty period for parts and components replaced or repaired during service work is 12 months.

§5. Liability under this warranty covers physical and legal defects arising from causes inherent in the device and only on the condition that the device is used in accordance with its intended purpose and the operating conditions specified in the manual.

§6. The warranty does not cover defects arising in connection with:

a) improper maintenance, operation, storage of the device,

b) mechanical, chemical and thermal damage resulting from improper use of the device or deliberate damage to the device by the Buyer or third parties and causing a defect in it,

c) damage to the device resulting from random events, force majeure factors, e.g. fire, flood, lightning,

d) defects caused by the Buyer's actions

§7. The warranty covers only, at the discretion of the Manufacturer, replacement of the device, replacement of components / elements of the device with new ones or free removal / repair of defective parts or components that turned out to be defective.

§8. The warranty is valid within the territory of the United States.

§9. Information about the Manufacturer’s service centre:

CortiVision sp. z o.o.

Al. Warszawska 47, 20-803 Lublin, Poland support@cortivision.com