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Operating instructions

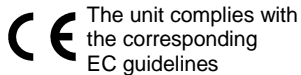


Fig. 1: 12673-00 Cobra4 Sensor-Unit Electrophysiology

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1 SAFETY PRECAUTIONS



Attention!

- Do not use the Cobra4 Sensor-Unit Electrophysiology if an attached device is connected to the mains voltage!
- Read these operating instructions carefully and completely before putting your Cobra4 Sensor-Unit into operation. Also similarly read the operating instructions for the Cobra4 measured data recording instrument that is to be used with the Sensor-Unit for measured value recording. By doing so, you protect yourself and your equipment.
- Only use the Cobra4 Sensor-Unit for the purpose that it is intended for.
- This Cobra4 Sensor-Unit is only to be operated in dry rooms in which there is no risk of explosion.
- Protect the Cobra4 Sensor-Unit from dust, moisture and vapours. Clean it with a slightly moistened, lint-free cloth. Aggressive cleaning agents and solvents are unsuitable.
- Do not attempt to open the housing of the Cobra4 Sensor-Unit.
- Take care that no liquid penetrates through the housing into the Cobra4 Sensor-Unit, as this would then be damaged.
- Only connect the data output of the Cobra4 Sensor-Unit to measurement recording instruments and measuring lines that are designed for use with it.

- Today's state of software development makes it impossible to guarantee that a product is free from faults. PHYWE Systeme GmbH & Co. KG therefore does not accept any liability for damages that result from the installation or use of this instrument.

2 PURPOSE AND CHARACTERISTICS

The Cobra4 Sensor-Unit Electrophysiology serves for wireless and cable-connected measurements of heart, eye or muscle activity by means of ECG (electrocardiography), EMG (electromyography) and EOG (electro-oculography).

The Cobra4 Sensor-Unit Electrophysiology can be connected to one of the following measured data recording instruments, as appropriate for the type of application, and transfer the data to it:

- a Cobra4 Wireless/USB-Link (12601-10) for tethered or wireless data transfer to a computer or a mobile device, and
- a handheld Cobra4 Mobile-Link 2 instrument (12620-10).

The following accessories are required for ECG, EMG and EOG measurements:

- Single measuring lines (yellow, red, green),
- Electrodes (reusable or single-use electrodes), and
- Alligator clips when single-use electrodes are used.

A list of accessories required for measurements is given in section 8 (Accessories). Only use accessories that are included in this list.

The Cobra4 Sensor-Unit Electrophysiology is neither suitable nor approved for medical purposes. It is intended exclusively for use in didactics. It is not to be used to carry out defined measurements on humans in order to make a diagnosis from the symptoms and so does not serve for the monitoring, treatment or alleviation of illnesses. It is therefore not subject to the more intensive requirements of Medical Guidelines (MPG).

3 FUNCTIONAL AND OPERATING ELEMENTS

3.1 Operating elements

The Cobra4 Sensor-Unit Electrophysiology has no manual operating elements. Operation of it is carried out via a handheld Cobra4 Mobile-Link 2 or, in the case that it is connected to a Cobra4 Wireless/USB-Link, via a computer or mobile device. The connection between the Sensor-Unit and one of the two measured data recording instruments is active as soon as it is made.

3.2 Sensor interface

Measured values can be read out from the Sensor-Unit at a maximum rate of 1 000 measured values per second (1 000 Hz). Just as all other settings, the wanted measurement frequency can be set via the instrument that has been connected to record measured values.

4 NOTES ON OPERATION

For safety reasons, the Cobra4 Sensor-Unit Electrophysiology must only be used if the attached Cobra4 measured data recording instrument is not connected to the mains voltage!

Ensure that either

- a) the Cobra4 measured data recording instrument is used in battery mode with the USB cord disconnected, or
- b) in case of a USB connection between the Cobra4 measured data recording instrument and a laptop, the latter is used in battery operating mode with the power supply disconnected, or
- c) in case of a USB connection between the Cobra4 measured data recording instrument and a commercially available PC or laptop with the power supply connected, the latter are operated via an isolation transformer that is not earthed.

Otherwise do not use the Cobra4 Sensor-Unit Electrophysiology, also not when the measured data recording instrument is charged via a USB power supply (e.g. 07932-99)!

We recommend operation with the Cobra4 Wireless/USB-Link (12601-10) in wireless mode.

Together with the particular transmission instrument (Cobra4 Mobile-Link 2 or Cobra4 Wireless/USB-Link), the Cobra4 Sensor-Unit Electrophysiology fulfils the technical requirements compiled in the current European Community Guidelines. The product characteristics justify the CE-mark.

Use of this instrument is only permissible under the supervision of qualified staff in a controlled electromagnetic environment of research, teaching and training facilities (schools, universities, institutes and laboratories).

Such an environment is one in the vicinity of which the use of radio emitters such as mobile phones is forbidden. Individual leads that are connected must not be longer than 2 m. The instrument can be so influenced by electrostatic charges and similar electromagnetic phenomena (HF, bursts, indirect lightning discharges, etc.) that it no longer works within the given specifications.

The following measures reduce or eliminate the effect of such disturbances:

Avoid fitted carpets; ensure potential equalization; experiment on a conductive, earthed pad; use screening, screened cables. Do not allow the use of high frequency emitters (radio equipment, mobile phones) in the immediate vicinity.

5 HANDLING

This section describes how to use the Sensor-Unit and record data. To avoid failure or improper operation, please read carefully through this section.

5.1 Putting into operation



For operation of some Cobra4 interfaces, PHYWE software is eventually required. Please make sure that the current version is installed on your device. Therefore read the operating instructions of the Cobra4 interface you want to use.

Connect the Cobra4 Sensor-Unit Electrophysiology to one of the Cobra4 measured data recording instruments by means of the click-catch 15-pin plug connector. Connect the three colour-coded single measuring lines (article no. 12673-01) to the Sensor-Unit as shown on the front plate of the Sensor-Unit (plus, minus, ref.). The Cobra4 Sensor-Unit is now immediately ready to use, as the voltage for it is supplied by the measured data recording instrument.

Further information on the control of the measured data recording instruments is to be found in their operating instructions.

Procedure using the software *measure*

Select the desired type of measurement, ECG, EOG or EMG in *Cobra4 measure* as follows: Double click on “voltage *U*” under the “Electrophysiology” entry in the navigation window. The “Channel voltage *U*” window now opens. Select here the “Settings” tabulator (see Fig. 2) and click on the wanted type of measurement.

The gauge electronics adjusts to the zero line as soon as connection of the measuring electrodes to the Sensor-Unit has been made. During this transient oscillation phase, no values are measured even if you have started measurement. Further information on the steering of measured value recording is given in the operating instructions of the respective measurement recording instruments.

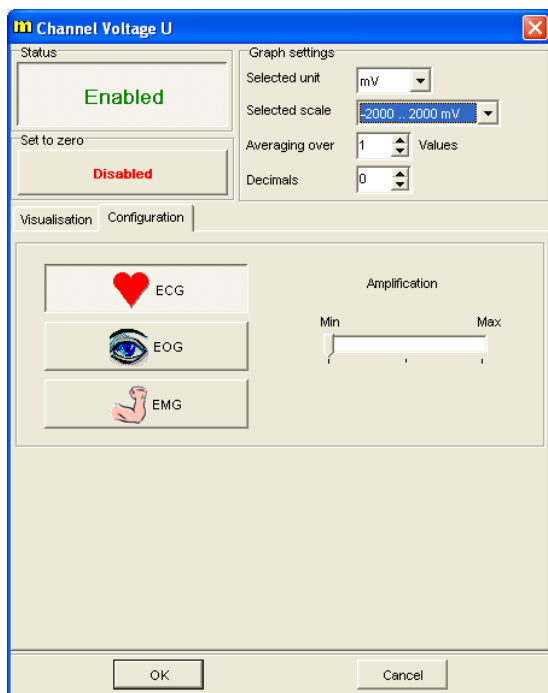


Fig. 2: “Channel voltage *U*” window.

5.2 ECG

Either reusable electrodes or single-use electrodes can be used for ECG.

When a measurement is being made, it will be influenced by even slight muscle activity. A relaxed sitting or lying position is therefore necessary during measurement. When sitting, lay the hands on the thighs.

When the three ECG reusable electrodes (article no. 65981-01) are to be used, prepare a 1 % potassium chloride solution. Cut paper towels to areas of 3 cm x 8 cm, wet these small sheets with the potassium chloride solution and then position them as wetted paper contacts between the ECG reusable electrodes and the skin.

Now use the rubber bands to fasten one each of the three reusable electrodes to the inner sides of the two wrists and directly above the ankle on the inner side of the left lower leg. Plug the 2 mm thick ends of the three colour-coded single measurement lines in the electrode sockets according to the assignment shown in the display. You can now start measurement.

The single-use electrodes (article no. 12559-01) have the advantage that they can be stuck directly onto the skin without the need for any preparatory measures. When they are to be used, first fit the alligator clips (article no. 12673-02) to the single measurement lines, stick the single-use electrodes on the skin at the positions described above, but without the paper contacts etc., and clamp the alligator clips to the loose ends of the single-use electrodes.

5.3 EMG

Either reusable electrodes or single-use electrodes can be used for EMG.

When three EMG reusable electrodes (article no. 65981-02) are to be used, use electrode cream (article no. 65981-05) to improve the contact between skin and electrodes.

Use adhesive plaster to fasten the three reusable electrodes to the muscles to be measured. Elbow or calf muscles are suitable for this. Position the reusable electrodes at a sufficient distance from each other one below the other. Now plug the 2 mm thick ends of the three colour-coded single measurement lines in die sockets of the EMG reusable electrodes from above to below in the following succession: yellow, red, green. You can now start measurement.

The single-use electrodes (article no. 12559-01) have the advantage that they can be stuck directly onto the skin without the need for any preparatory measures. When they are to be used, first fit the alligator clips (article no. 12673-02) to the single measurement lines, stick the single-use electrodes on the skin at the positions described above, but without the paper contacts etc., and clamp the alligator clips to the loose ends of the single-use electrodes.

5.4 EOG

The three EMG reusable electrodes (article no. 65981-02) are also used for elektro-oculography. Use electrode cream (article no. 65981-05) to improve the contact between skin and electrodes as in EMG measurements.

Use adhesive plaster to fasten the reusable electrodes to the following positions in the eye area; to an ear lobe (green single measurement line), alongside the left eye (yellow line) and alongside the right eye (red line). Now plug the 2 mm thick ends of the three colour-coded single measurement lines into the sockets of the EMG reusable electrodes. You can now start measurement.

Single-use electrodes (article no. 12559-01) could also be used but reusable electrodes are better suited to this application, because their smaller area allows them to be more exactly positioned. If single-use electrodes are to be used, fit the alligator clips (article no. 12673-02) to the single measurement lines, stick the single-use electrodes on the skin at the positions described above and clamp the alligator clips to the loose ends of the single-use electrodes.

6 TECHNICAL DATA

(typical for 25 °C)

Operating temperature range 5–40 °C
Relative humidity < 80 %

With plug sockets for 3.5 mm jack plugs for single measurement lines with assignment identification.

Operation using three separate and screened measurement lines.

Galvanic separation with 4 000 V (protection class 2)

Measurement mode: Long-term measurement with 1 000 Hz sampling rate

Signal filter:

ECG-Filter 0.03 Hz...20 Hz
EMG-Filter 80 Hz...5 000 Hz
EOG-Filter 0.03 Hz...10 Hz

Data throughput rate: 1 000 Hz

Dimensions:

Housing dimensions (mm) approx. 62 x 110 x 35
Weight approx. 190 g

7 SCOPE OF SUPPLY

The extent of delivery comprises:

- Cobra4 Sensor-Unit Electrophysiology 12673-00
- Operating instructions

8 ACCESSORIES

Refer to sections 5.1 to 5.4 for the use of the individual accessories.

Single measurement lines, colour-coded (3/pack)	12673-01
ECG-Reusable electrodes, 8 cm x 3 cm (3/pack)	65981-01
EMG-Reusable electrodes (3/pack)	65981-02
Electrode cream (tube, 100 g)	65981-05
Single-use electrodes (100/pack)	12559-01
Alligator clips for single-use electrodes (3/pack)	12673-02

9 WARRANTY

We guarantee the instrument supplied by us for a period of 24 months within the EU, or for 12 months outside of the EU. Excepted from the guarantee are damages that result from disregarding the Operating Instructions, from improper handling of the instrument or from natural wear.

The manufacturer can only be held responsible for the function and technical safety characteristics of the instrument, when maintenance, repairs and alterations to the instrument are only carried out by the manufacturer or by personnel who have been explicitly authorized by him to do so.

10 WASTE DISPOSAL

The packaging consists predominately of environmentally compatible materials that can be passed on for disposal by the local recycling service.



Should you no longer require this product, do not dispose of it with the household refuse.

Please return it to the address below for proper waste disposal.

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11 SYMBOL DESCRIPTION



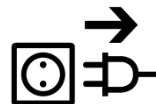
Caution!
Potentially harmful situation
(damage of property)
Generally dangerous spot
Follow operating instructions



Note
Important device information
Follow operating instructions



Equipment type BF
Patient leakage currents, isolation, creepage distance and clearance have been tested based on DIN EN 60601-1 for medical electrical equipment.
However this instrument must not be used in defined human measurements for diagnosis of a state of disease.



Unplug when in use!
For safety reasons, the Sensor must only be used if the attached Cobra4 measured data recording instrument is not connected to the mains voltage!