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Product Name: Combination Sensor

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It can be useful in terms of therapy to measure not only the EEG but also other physiological parameters and to provide feedback based on them. A device that does exactly this is the Combination Sensor. It’s highly functional housing contains three different sensors with measuring amplifiers, which allow for the precise and low-noise measurement of three physiological parameters. The Combination Sensor has the following properties:

3-in-1 Sensor:
The unique sensor arrangement measures the Galvanic Skin Response (GSR), the skin temperature and the heart rate of the patient.

High Precision and Speed:
The Combination Sensor contains highly precise amplifiers with an excellent signal-to-noise ratio. These are right next to the sensors themselves, which allows for an even better signal even when using a long cable to connect to the EEG NeuroAmp®.

Professional Design:
Your clients will appreciate the highly functional design. The Combination Sensor can easily be attached to a single finger. All materials are biocompatible and fulfill the strict regulations for medical devices. Thanks to the internal amplifiers, the roughly two-meter-long cable can even be extended by extension cables with minimal effect on the measurements.

General Properties
- Easy to use.
- Functional design to allow for quick and reliable measurements.
- Direct interface to the EEG NeuroAmp®.
- Complies with all applicable regulations for medical devices.

Technical Data
- Number of sensors: 3
- GSR sensor range: 0.2-100µMho
- Temperature sensor range: 20-40°C, Time constant: 60s
- Heart rate: Optical measurement using 940nm and 660nm at the fingertip. Rate: 62 measurements/s

Power Supply
No batteries required – Power supplied by EEG NeuroAmp®
1 Indications for Use

The Combination Sensor is a biofeedback sensor to measure GSR, skin temperature and heart rate. GSR and skin temperature are not measured in absolute values. The purpose is to measure trends. The Combination Sensor may only be used by trained professionals who can ensure safe handling. The Combination Sensor can only be used in conjunction with the EEG NeuroAmp®. The device is not intended for diagnostic purposes or for patient monitoring.

Notice

US Federal Law restricts this device to sale by, or on order of, a physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.

2 Safety Notices

2.1 Usage

Please take your time to read these instructions carefully and become familiar with the functions of the Combination Sensor. These instructions are part of the product and must be stored in such a way that they are available anytime. Please only use the device for purposes outlined in Chapter 2.2, Indications for Use.

The Combination Sensor may only be used by trained personnel.

The following table explains the warning symbols used in these instructions:

- **WARNING**: Points out potentially dangerous situations that may lead to severe injury or death.
- **CAUTION**: Points out potentially dangerous situations that may lead to injury.
- **CAUTION**: Points out situations that could lead to damage to the device.
- **NOTICE**: Points out a situation that does not lead to death, injury or damage of property.
2.2 Intended Purpose

2.2.1 INTENDED USE
The Combination Sensor is a biofeedback sensor to measure GSR, skin temperature and heart rate. GSR and skin temperature are not measured in absolute values. The purpose is to measure trends. The Combination Sensor may only be used by trained professionals who can ensure safe handling. The Combination Sensor can only be used in conjunction with the EEG NeuroAmp®.

The device is not intended for diagnostic purposes or for patient monitoring.

2.2.2 USER POPULATION
The Combination Sensor may only be used by trained professionals who can ensure safe handling.

2.2.3 CONTRAINDICATIONS
There are no known contraindications for the Combination Sensor.

The Combination Sensor may only be used on intact skin. The skin may not be injured and may not be compromised in its physiological function. In rare cases, allergic reactions to the material of the Combination Sensor were observed. The strap of the Combination Sensor may not be applied too tightly. Blood flow to the finger must be sufficient at all times.

For disinfection, please follow the method outlined in chapter 6.1.

2.2.4 TARGET PATIENT POPULATION – MEDICAL CONDITIONS
The device can be used on adult and pediatric patients. The finger must be long enough to fit adequately into the Combination Sensor. The device is used on patients undergoing neurofeedback therapy in order to serve the therapist as an indicator for the relaxation state of the patient by monitoring trends.
2.2.5 ENVIRONMENT
The Combination Sensor may be used in professional healthcare facilities, such as physician offices. It is not intended for use in home healthcare environments or in special environments, such as heavy industry or HF surgical environments.

2.2.6 DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION
For device description and principles of operation, please see chapter 3.

2.3 Basic Regulations
Make sure that you follow the national and local regulations with regard to the use of this device as well as biofeedback.

2.4 Personnel and Qualification
- The therapist is responsible for the safety of the entire biofeedback system, consisting of the Combination Sensor and other hardware, sensors and software, tactile feedback systems, animations, etc. The therapist is also responsible for ensuring that the computer on which the data recording software runs is powerful enough to process the data volume provided by the Combination Sensor quickly enough that all software that build upon this data can be run without additional delay.
- The therapist is responsible for the correct and safe biofeedback treatment. The therapist is responsible for possible side effects, which appear during or after biofeedback treatment.
- The Combination Sensor may only be used by trained personnel.
- The patient may not be left unsupervised at any point during the treatment.

2.5 Personal Safety Information

ADVERSE EFFECTS
No adverse effects are known for the device itself. However, in case biofeedback therapy is performed by inexperienced or careless practitioners, it may cause unwanted effects, such as those associated with inappropriate activation, including tiredness, drowsiness, restlessness, and sleep dysregulation. Another unwanted effect that can occur is headaches. Such adverse effects should subside promptly unless inappropriate training is continued. The signals of the Combination Sensor do not control the feedback animations of the patient software, they are only displayed on the therapist screen.

The therapist is responsible for applying appropriate therapy methods. The Combination Sensor may therefore be used only by a professional who can ensure sound handling practices.

The manufacturer of the Combination Sensor does not assume liability for any adverse effects whatsoever caused by biofeedback therapy.

Notice
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.
WARNING
Entanglement or Strangulation by the cable of the Combination Sensor
• The patient and the cable should always be arranged in a way that it is not possible for the patient to become entangled or strangled by the cable.

2.6 Device-related Safety Information

WARNING
• The Combination Sensor may not be used with a patient undergoing a treatment that involves strong electromagnetic fields or electrical signals such as defibrillation, HF-surgery or MRI. The Combination Sensor is not defibrillator-proof.
• The Combination Sensor may not be used for monitoring or diagnosing patients.
• The Combination Sensor must be applied to healthy skin only. The skin must be undamaged and not impaired in its physiological function.
• The band must always be loose enough to allow sufficient blood flow through the finger. Otherwise, false data could be measured.
• Please note that nail varnish on the fingernail can lead to false heart rate values.
• The strap on the Combination Sensor must consist of biocompatible materials. Use the included medically approved Kinesiotape.
• For hygienic reasons, use a new strap for each new patient.

WARNING
Damage or electrical shock due to use of inappropriate accessories
Accessories that are not intended for use with the Combination Sensor may damage the product, impair performance, breach the regulations or even cause electrical shocks. Inappropriate use may have dangerous consequences or at least damage the device and render the warranty invalid.
• Only use the Combination Sensor with devices that are intended for use with it, such as the EEG NeuroAmp®.
• Do not plug the cable of the Combination Sensor into devices which are not intended for use with the Combination Sensor, even if the connectors fit.

WARNING
Incorrect measurements due to strong electromagnetic fields
Mobile phones, x-ray machines, high frequency therapy devices or other devices, which radiate electromagnetic radiation, can influence and falsify the signals.
• Make sure that the recommended distances to radio wave emitters are met (see chapter 9 “Notes on EMC”).
• The function of Combination Sensor could be degraded by exposure to electromagnetic disturbances exceeding the limits defined in chapter 9. This would be noticed by distorted signals. In this case take care to eliminate the electromagnetic disturbances before continuing operation.
WARNING
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Combination Sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION
Damage due to electrostatic discharge
Take anti-ESD measures such as anti-static mats or a humidifier to condition hot, dry air.

- The unit is not susceptible to electromagnetic disturbances below IEC 60601-1-2 immunity test levels, as long as the connection cable including extension cables is not longer than three meters.

CAUTION
Damage due to water or moisture
The Combination Sensor may not be submerged in water or other liquids.
- Do not pour liquids over the Combination Sensor and avoid situations where the Combination Sensor comes into contact with liquids.

- The Combination Sensor should not be used or stored in dusty, moist or dirty environments.
- Please check the sensors on the Combination Sensor for contamination regularly. The sensors must be kept clean, because particles on the sensor surface may influence the measurements. Use a cotton swab or tissues moisturized with Isopropanol or rubbing alcohol to carefully clean the sensors.

CAUTION
Injury to children or damage to the device
- Store the unit out of reach of children to prevent them from injuring themselves or others and to avoid damage to the product.

CAUTION
Damage by inappropriate handling or repair attempts
Inappropriate handling may damage the device and render the warranty invalid. Repair only by qualified personnel.
- Do not attempt to open the product and repair it yourself. The manufacturer accepts no liability for any damages thus incurred.

- The Combination Sensor should be stored in its original packaging in a dry place, at which the temperature lies between -10°C and +60°C. Storage locations at which condensation of water out of the air may occur are to be avoided.
3 Function

3.1 Description

The Combination Sensor consists of an arrangement of three sensors to measure Galvanic Skin Response, skin temperature and heart rate (see Figure 2). It contains amplifiers and signal processing electronics, which allow for an excellent signal quality as well as the use of a long, easy to handle connection cable. The signals of the Combination Sensor do not control the feedback animations of Cygnet, they are only displayed on the therapist screen.

Figure shows a detail image of the Combination Sensor, which can be attached to a finger with the strap opened. To do this, one finger (preferably the index finger on the left or right hand) is placed on the Combination Sensor so that the fingertip lays in the indent in the front of the sensor, and the strap fastened around it (see Fehler! Verweisquelle konnte nicht gefunden werden.). Please make sure that the Combination Sensor is attached firmly, but that the strap is still loose enough to allow sufficient blood flow to the finger.

The Combination Sensor can be connected directly to the EEG NeuroAmp®. Please make sure that the Combination Sensor is connected only to the rightmost socket on the EEG NeuroAmp® (see Figure 4). The EEG NeuroAmp® supplies power to the amplifiers and signal processing electronics.

During measurements, the patient should avoid moving the finger. The hand should be laid on the thigh or a table.
Figure 2: Detail image of the Combination Sensor with the localization of the three individual sensors. For the sake of clarity, most of the finger strap is cropped.

Figure 3: Combination Sensor is attached by the finger strap to the left index finger.
Figure 4: Connection of the Combination Sensor cable to the rightmost socket on the EEG NeuroAmp®. The Combination Sensor only functions when connected to this specific socket.

3.2 Electromagnetic Compliance

The Combination Sensor was tested according to the IEC 60601-1-2 and complies with:

- IEC / CISPR 11, Class B (RF emission)
- IEC 61 000-4-2 (Electrostatic Discharge - ESD)
- IEC 61 000-4-3 (RF susceptibility)
- IEC 61 000-4-6 (RF asymmetric)

The Combination Sensor should not be connected to a cable with a total length of over 3 meters. This maximum length also applies to the serial interface cable in connection with an extension cable.
4  Set-Up

4.1 Unpacking the Combination Sensor

**WARNING**
Death due to suffocation if packing material is swallowed
- Store packing material out of reach of children

Unpack your Combination Sensor.
Please verify that the device is not damaged. If the device is damaged, please return it for a replacement.

4.2 Enabling the Combination Sensor

Before use, please check if the Combination Sensor is enabled in the software. If you want to switch between disabled and enabled, the data acquisition must be stopped. It cannot be done during a running session.

*Figure 5: Enabling the Combination Sensor*
4.3 Connecting the Combination Sensor to the digitizing unit

The Combination Sensor has a Mini-Din8 plug, which plugs directly into the EEG NeuroAmp®. Please make sure to only plug the Combination Sensor into the rightmost socket on the EEG NeuroAmp® (see Figure 4). Interfaces to other digitalization units might be added in the future.

---

**WARNING**

**Electrical shock or damage due to use of inappropriate accessories**

- Accessories that are not intended for use with the Combination Sensor may damage the product, impair performance, breach the regulations or even cause electrical shocks. Inappropriate use may have dangerous consequences or at least damage the device and render the warranty invalid.
- Use only in conjunction with equipment that is intended for use with the Combination Sensor such as the EEG NeuroAmp®.
- Do not plug the cable of the ComiSensor into equipment unless it is meant to work with it, even if its plugs fit.

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Before connecting the Combination Sensor to the EEG NeuroAmp®, please verify that all eight pins on the plug (Mini-Din8) are intact. If a pin is offset, bent, or missing, please return the device for a replacement.

Carefully plug the Combination Sensor into the rightmost socket on the EEG NeuroAmp®. If the device is plugged into any other socket, it is no longer functional, meaning that measurement signals can no longer be transmitted to the digitalization unit.

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**CAUTION**

**Incorrect measurements if other peripheral devices are connected to the EEG NeuroAmp®.**

- When the Combination Sensor is connected to the EEG NeuroAmp®, only the following additional bio/neurofeedback devices and sensors may be connected: one EEG pIRx3 sensor on the middle input sockets and/or one tactile Neurofeedback device on any of the free input sockets. If any other devices are connected to the EEG NeuroAmp® while the Combination Sensor is connected, this may lead to malfunction in the Combination Sensor.
5 Operation

The Combination Sensor is controlled entirely by the Biofeedback/Neurofeedback software on the computer and powered by the EEG NeuroAmp®. No user interaction with the device is necessary.

In order to attach the Combination Sensor to the finger, cut off a 10cm-long piece of the tape that comes with the sensor. Remove the white foil on the back. Insert the band through the latch of the sensor and wrap the band around finger and sensor. The sensor should be attached to a finger firmly, but still loosely enough to allow sufficient blood flow through the finger. If the strap is too loose or too tight, this will affect measurement results. It does not matter which hand or finger is used for measurement. The thumbs are not useful for measurements.

The finger and hand on which the sensor is measuring should be moved as little as possible during the session to avoid interfering with the measurement. To support this, the hand could be placed on a table or on the thigh during the measurement (s. Figure 6)

The Combination Sensor does not require a settling time or calibration. Measurements can begin immediately after the sensor has been attached to the finger.

Figure 6: During measurements, the finger and sensor should be held as still as possible

Check proper function of the Combination Sensor before starting a session with your patient by starting the clinician software on your computer. The graph display of the clinician screen must show data acquisition.
5.1 Interpretation of the measured data

Figure 7 shows the recorded sensor data. The HRV (Heart Rate Variability - first diagram) and the Stress Index (last diagram) are calculated according to established methods described in the literature.

All displays can be zoomed in or out by clicking on “+” or “−”. The position of the curves can be adjusted by clicking on the arrows. Furthermore, every display, except the EEG Trend display, can either be set in manual or automatic mode to align the graph.
5.1.1 Definition HRV

HRV is defined as the deviation of the current heart rate from a completely rhythmic sequence. The numerical value displayed as HRV corresponds to the Min / Max interval of the heart rate in a defined time slot.

In general, a higher value indicates that the heart is able to change the time between two heartbeats depending on physical or psychological stress and therefore react flexibly to varying challenges.

5.1.2 Definition Stress Index

The stress index calculated in the last diagram is used in space medicine and originates from Prof. Baevsky. In a broader sense, this is the mathematical description of a histogram. The only measure on which the calculation is based is the R-R interval. This indicates the time interval between two consecutive heartbeats.

In order to achieve statistical relevance, value windows of approximately 120s are required. This is why no stress index is displayed at the start of the measurement. As soon as a value appears, the 120s computation window is continuously shifted and results can be produced continuously.

The small window below the blue control panel shows the determined heartbeats in the form of a sawtooth characteristic. This diagram is a good indication whether the sensor is detecting correct data for the heartrate measurement. If a (relatively) continuous signal is not seen here, then it should be checked if the sensor is attached correctly to the finger.
6 Cleaning, Maintenance, Storage and Disposal

Great care was taken to develop and produce this device, and it should be handled with just as much care. If you follow these instructions carefully, you avoid the premature expiry of the warranty and enjoy the safe use of your product for years.

6.1 Cleaning and Maintenance

For disinfecting your Combination Sensor we recommend the disinfectant wipes Incidin Wipes Premium. These are moistened with the disinfectant Incidin Foam. Other wipes that are compatible with Incidin Foam can be used alternatively.

To clean the Combination Sensor, rub across the area that has been in contact with the finger of the patient with the soaked disinfectant tissue, twice clockwise and twice anticlockwise. Particular care must be taken to press the wipe into the pits of the Combination Sensor and wipe these parts thoroughly. Discard the cloth after this procedure and spray Incidin Foam again onto the above mentioned critical parts and leave it there for at least 5 minutes. The surfaces must remain moist within this 5-minute time period.

The finger strap is exchanged for each new patient and discarded after the session.

Please check the sensors regularly for dust and dirt and clean the sensors carefully, if needed, with a cotton ball or soft cloth with alcohol or isopropanol. Otherwise the accuracy of measurement will be adversely affected.

No maintenance is required for the Combination Sensor. If the unit is damaged, please return it for a replacement.

6.2 Storage

The Combination Sensor should be stored in its original packaging in a dry place, at which the temperature lies between -10°C and +60°C. Storage locations at which condensation of moisture out of the air may occur are to be avoided.

6.3 Disposal

Dispose of the unit as an electronic device in accordance with any applicable local, state and federal laws and regulations.
7 Technical Data

<table>
<thead>
<tr>
<th>Sensors</th>
<th>Number of sensors</th>
<th>4</th>
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<tbody>
<tr>
<td>Skin resistance</td>
<td>0.2 – 100µMho, Umax 2.5V, Imax 2.5µA</td>
<td></td>
</tr>
<tr>
<td>Heart rate</td>
<td>Optical measurement using 940nm and 660nm</td>
<td></td>
</tr>
<tr>
<td>Temperature range</td>
<td>20°- 40°C or 68°-104°F</td>
<td></td>
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<tr>
<td>Measurement rate</td>
<td>62 samples/s</td>
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<td>Time constant (Temp)</td>
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<th>Power Supply</th>
<th>5V / 5mA</th>
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<td>Plug</td>
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</tr>
<tr>
<td>Signals</td>
<td>3 x 0...5V</td>
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<tr>
<td>Mechanical Interface</td>
<td>Sensor housing with cable</td>
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<table>
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<tr>
<th>Environment</th>
<th>Storage and Transport</th>
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<tbody>
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<td>Operation</td>
<td>Temperature: -10°C...+50°C, no condensation, air pressure: 700 ... 1060 hPa</td>
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8 Plug Diagram

![View on Mini-Din 8 Jack](image)

Figure 8: Connection diagram of the Combination Sensor
### Guidelines and Manufacturer’s Statement – Electromagnetic Emissions

The **Combination Sensor** is intended for use in the electromagnetic environment specified below. The customer or the user of the Combination Sensor should assure that it is used in such an environment.

<p>| | |</p>
<table>
<thead>
<tr>
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<tr>
<td>RF emissions CISPR 11</td>
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<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
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<td>Harmonic emissions IEC 61000-3-2</td>
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<tr>
<td>Voltage fluctuations / flicker</td>
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### Guidelines and Manufacturer’s Statement – Electromagnetic Immunity

The **Combination Sensor** is intended for use in the electromagnetic environment specified below. The customer or the user of the Combination Sensor should assure that it is used in such an environment.

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<th>IEC 60601 test level</th>
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<td>± 8kV contact</td>
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<tr>
<td></td>
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<td>±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge</td>
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<td>Radiated RF IEC 61000-4-3</td>
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<td>Electrical fast transient / disturbance variables / burst IEC 61000-4-4</td>
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<td>Surge IEC 61000-4-5</td>
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<td>Not applicable</td>
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<tr>
<td>Conducted disturbances IEC 61000-4-6</td>
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<td>3 V: 0,15 MHz – 80 MHz</td>
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<td>6 V: IMS Bands</td>
<td>6 V: IMS Bands</td>
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## IMMUNITY to proximity fields from RF wireless communications equipment

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<td>1 720</td>
<td>1 700 - 1 990</td>
<td>GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS</td>
<td>Pulse modulation</td>
<td>2</td>
<td>0,3</td>
<td>28</td>
</tr>
<tr>
<td>1 845</td>
<td></td>
<td></td>
<td>Pulse modulation</td>
<td>217 Hz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 970</td>
<td>2 400 - 2 570</td>
<td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td>
<td>Pulse modulation</td>
<td>2</td>
<td>0,3</td>
<td>28</td>
</tr>
<tr>
<td>2 450</td>
<td></td>
<td></td>
<td>Pulse modulation</td>
<td>217 Hz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 240</td>
<td>5 100 - 5 800</td>
<td>WLAN 802.11 a/n</td>
<td>Pulse modulation</td>
<td>0,2</td>
<td>0,3</td>
<td>9</td>
</tr>
<tr>
<td>5 500</td>
<td></td>
<td></td>
<td>Pulse modulation</td>
<td>217 Hz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 785</td>
<td></td>
<td></td>
<td>Pulse modulation</td>
<td>217 Hz</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE**: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- **a)** For some services, only the uplink frequencies are included.
- **b)** The carrier shall be modulated using a 50% duty cycle square wave signal.
- **c)** As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
10 Warranty

The Combination Sensor is guaranteed to be free from defects in material and workmanship for one year from the date of purchase.

In the unlikely event that repair is necessary within the warranty period, call BEE Medic to receive a Return Authorization. Then send the unit back by a traceable method -- Neither BEE Group AG, nor BEE Medic will be responsible for items not received. We will repair or replace your unit(s) free of charge if repair during the warranty period is necessary.

This warranty does not apply to damage incurred through accident, alteration, or abuse, nor to damage created by static electricity. Do not use this equipment in a dry, static-prone area unless using an anti-static mat or anti-static spray on carpeted areas.

We may refuse to honor this warranty if the unit has been opened or unauthorized repair attempts are detected.

We accept no liability for accidental damage or for consequential damages, including, for example lost profit, downtime, damage or replacement of devices or property from a breach of the warranty.

11 Copyright Notice

This hardware contains proprietary embedded software code, which is the property of the BEE Group; it is provided under a license agreement containing restrictions on use and disclosure and is also protected by copyright law. Reverse engineering of the software or the hardware is prohibited.

Due to continued product development the embedded software may change without notice. The information and intellectual property contained herein is confidential between BEE Group and the client and remains the exclusive property of BEE Group.

If you find any problems in the documentation, please report them to us in writing. BEE Group does not warrant that this document is error-free.
12 Declaration of Conformity

EG-Konformitätserklärung
(gemäß EG-Richtlinie 93/42/EWG, Anhang II, Abschnitt 3 vom Juni 1993)
Declaration of Conformity
(according to MDD 93/42/EEC, annex II, chapter 3 dated June 1993)

Corscience GmbH & Co. KG
Hartmannstr. 65
91052 Erlangen, GERMANY

erklärt in alleiniger Verantwortung, dass (declares under its sole responsibility that)
das Produkt (the product)

EEG NeuroAmp & Software Cygnet V2.0 & Software ERPRec V2.0
 gültig für / valid for

UDI-DL: 042513419000016 mit / with SN 6600-9600
UDI-DL: 042513419000023 mit / with SN 4000-4200
UDI-DL: 042513419000047 mit / with SN 001-900
UDI-DL: 042513419000081 mit / with SN 070 - 400
UDI-DL: 042513419000078 mit / with SN 001 - 200
UDI-DL: 042513419000085 mit / with SN 001 - 100
UDI-DL: 042513419000092 mit / with SN 001 - 200
UDI-DL: 042513419000030 mit / with Version 2.0
UDI-DL: 042513419000153 mit / with Version 2.0

auf das sich diese Erklärung bezieht, mit to which this declaration relates, is in
folgender Richtlinie übereinstimmt:

Bewertungsverfahren nach EG-Richtlinie Evaluation procedure according to MDD
für Medizinprodukte 93/42/EWG, Anhang II, annex II, chapter 3
Klassifizierung nach Richtlinie 93/42/EEC, Anhang IX:
Aktives Medizinprodukt der Klasse Ila

Gemäß §9 Medizinproduktegesetz wurde Classification according to MDD
dieses Produkt aufgrund der Erfüllung 93/42/EEC, annex IX:
der Grundlegenden Anforderungen nach Active medical device class Ila
Richtlinie 93/42/EEG, Anhang I mit der Corresponding to §9 German medical
CE-Kennzeichnung versehen.

Medcert GmbH
Pilatuspool 2
20356 Hamburg
Germany

Erlangen, 2018-07-25

Dr.-Ing. Claudius Moor
(Management)

GC00032_Doc