

# EEG *pIR x 3*

Manual



CS10289

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## Overview

Jeff Carmen has pioneered the usage of thermal radiation from the forehead for biofeedback. The *pIR x 3* sensor array leaves no requirement out:

### 3 pIR sensors:

This unique sensor array measures not only radiation of the FPz area, but also the areas around Fp1 and Fp2.

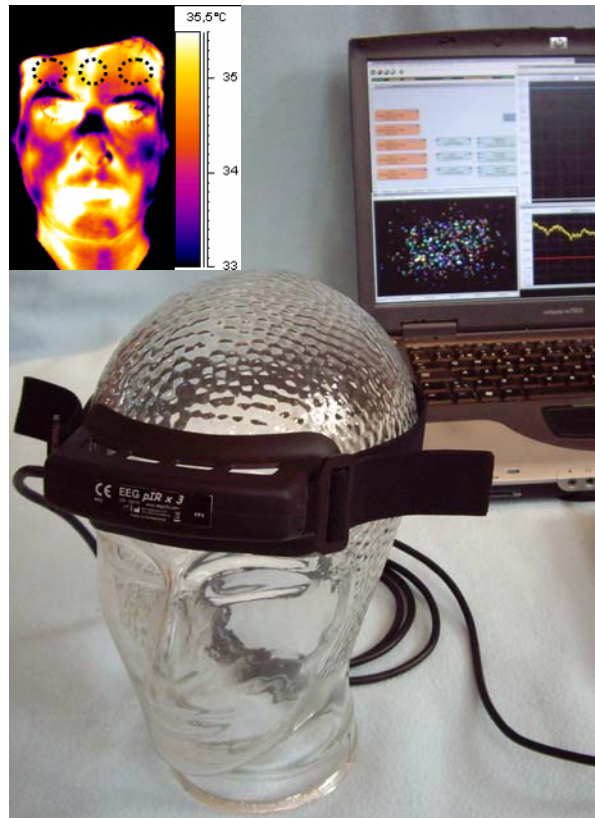
### High precision and speed:

The *pIR x 3* sensor array contains high-precision low-noise amplifiers that are mounted next to the sensors. By that, the noise level is lower allowing not only a long cable but also a resolution of 0.01°K and a reaction time as low as 0.1 seconds

### Professional design:

Your clients will appreciate the highly functional design. All materials are bio compatible and fulfill all norms for medical products.

Thanks to the internal amplifiers the long connection cable can even be made longer by an extension cord.



### General Features

- Easy to use
- High-performance design to ensure reliable pIR readings
- Interfaces directly to the EEG NeuroAmp
- Conforms to applicable norms with regard to professional medical equipment

### Technical Data

- Number of sensors: 3
- Wavelength range: 5-15µm
- Sensor field of view: 60°
- Temperature range: 29°-43°C or 84°-109°F
- Resolution: 0.01°K
- Reaction time: < 0.1 s
- Low power requirement

### Power Supply

No batteries needed- powered by EEG NeuroAmp or similar devices

# 1 Purpose

The EEG *pIR x 3* is a biofeedback sensor intended for measurement of thermal radiation of the forehead. The EEG *pIR x 3* is intended to be used only by trained professionals who can ensure sound handling practices.

This device is not intended for diagnostic purposes.

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## 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.

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# 2 Safety Instructions

## 2.1 Guidelines for Use

Please take the time to read this manual carefully before using the EEG pIR x 3 for the first time in order to familiarize yourself with its operation. This manual is part of the product and must be available anytime. Use the device only for the intended purpose (see section 2.2).

The EEG *pIR x 3* may only be used by a professional who can ensure sound handling practices.

The following table explains the warning symbols used in this manual:



**WARNING**

Denotes a probably dangerous situation that may lead to severe injury or death



**CAUTION**

Denotes a probably dangerous situation that may lead to injury






**CAUTION**

Denotes a situation that could lead to damage of the product

**NOTICE**

Warning symbol for situations that do not lead to death, injury or damage of property

Meaning of the symbols on the label of the EEG pIRx3:

 1275	Conformity symbol
	Do not dump in trash can
	Manufacturer
	Production year
	Read instruction manual / Warning, Attention

## 2.2 Indication for Use

The EEG *pIR x 3* is a biofeedback device intended for training the thermal emission from the forehead. To perform its intended function it must be used in combination with appropriate digitizing hardware as well as software and computer.

For purposes of this training task, information for feedback may be derived from one, two or three pIR sensor channels.

The EEG *pIR x 3* is intended to be used only by trained professionals who can ensure sound handling practices.

This device is not intended for diagnostic purposes.

## 2.3 Basic Regulations

Make sure that you follow the national and local regulations with regard to biofeedback.

## 2.4 Personnel and Qualification

- The therapist is responsible for the safety of use of the entire biofeedback system consisting of the EEG *pIR x 3* in conjunction with digitizing hardware, electrodes, sensors, biofeedback software, tactile feedback systems, games, etc. He or she has to make sure that the computer running the data acquisition software is capable of handling the data volume transmitted from the EEG pIR x 3 and of running all applicable software properly.
- The therapist is responsible for proper and safe biofeedback or EEG biofeedback treatment methods. He is also responsible for any adverse effects occurring during or after the biofeedback treatment.
- The EEG *pIR x 3* may only be used by a professional who can ensure sound handling practices.
- The client must be supervised at all times during the biofeedback session and must never be unattended.

## 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 agitation, anxiety, drowsiness, fogginess, spaciness, and sleep disregulation. Such adverse effects should subside promptly unless inappropriate training is continued. When employed with persons diagnosed with certain conditions such as migraine, seizure disorder, or bipolar disorder, inappropriate application may provoke rather than suppress symptom expression on a transient basis.

In particular, extended training with the instrument within a session (in excess of ten to twenty minutes) may result in the kindling of a headache in those who are susceptible to them. The sensor has only been evaluated for reinforcement at the central placement. The clinician should use appropriate caution when using customized reinforcement strategies. Laterality effects have not been fully evaluated.

The therapist is responsible for applying appropriate therapy methods. Therefore, the EEG *pIR x 3* may be used only by a professional who can ensure sound handling practices.

The manufacturer of the EEG *pIR x 3* does not assume liability for any adverse effects whatsoever caused by biofeedback therapy.

### CONTRAINDICATIONS

There are no known contraindications for the EEG *pIR x 3*.

The EEG *pIR x 3* may be applied to intact skin only. In rare cases, an allergic reaction has been observed to the material of the EEG *pIR x 3*. Proper disinfection methods must be applied.



#### WARNING

##### Entanglement or strangulation by the EEG *pIR x 3* cable

- Take care in arranging patient and sensor cable to avoid risk of patient entanglement or strangulation
- 

## 2.6 Device-related Safety Information



#### WARNING

- The EEG *pIR x 3* may not be used with a patient undergoing a treatment that involves strong electro magnetic fields or electrical signals such as defibrillation, electro-surgery or MRI. The EEG *pIR x 3* is not defibrillator-proof.
  - The EEG *pIR x 3* is not to be used either for critical patient monitoring or for diagnostic purposes.
- 

- Apply EEG *pIR x 3* to healthy skin only.

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**WARNING****Damage or electrical shock due to use of inappropriate accessories**

Accessories that are not intended for use with the EEG pIR x 3 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 EEG *pIR x 3* such as the EEG NeuroAmp.
  - Do not plug the cable of the EEG pIR x 3 into equipment unless it is meant to work with it, even if its plugs fit.
- 

**WARNING****Wrong temperature readings due to strong electromagnetic fields**

cellular phones, x-ray machines, radio thermal treatment equipment, etc. may disturb the measurement signals.

- Make sure that the recommended distances to radio wave emitters are met (see chapter 7 “Technical Data”).
- 

**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 humidity**

The EEG pIR x 3 is not to be immersed in water or other liquids.

- Do not spill liquids on the EEG *pIR x 3*.
- 

- Do not use or store the product in dusty, wet or dirty environments.
- 

**CAUTION****Injury of children or damage of product**

- 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**

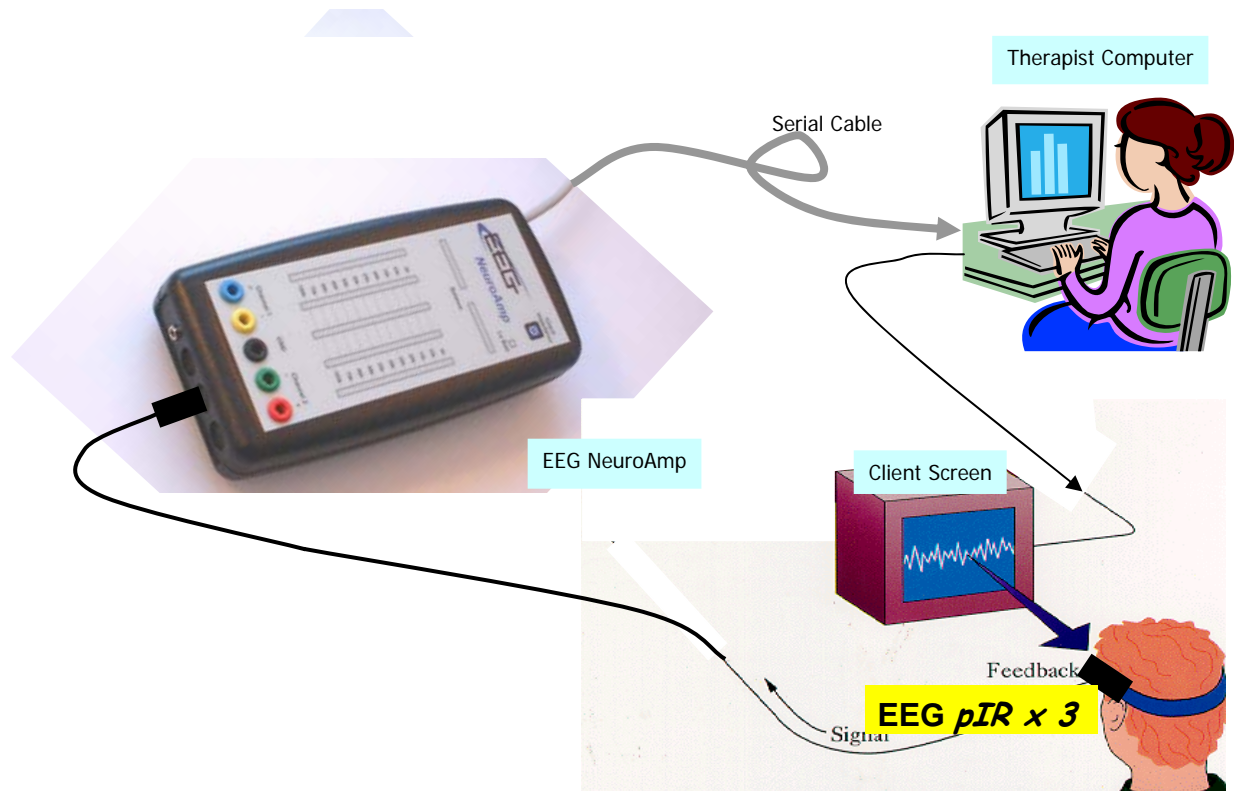
Inappropriate handling may damage the device and render the warranty invalid. Repair only by qualified personnel

- Do not attempt to open the product and repair it yourself. The manufacturer accepts no liability for any damages thus incurred
- 

- Store in its original case at up to -40 ... 70°C. Avoid condensation
-

### 3 Function

#### 3.1 Description



**Figure 1: Use of the EEG *pIR x 3* thermal sensor in a Biofeedback setting**

The EEG *pIR x 3* is an array of three pIR thermal radiation sensors (pIR = passive infrared). It contains amplifiers and signal conditioning for high signal to noise ratio and convenient interfacing.

The EEG *pIR x 3* connects directly to the EEG NeuroAmp which also provides power for the sensor amplifier and signal condition electronics.

Figure 2 shows the field of view of the three sensors.



Figure 2: Field of view of the sensor array

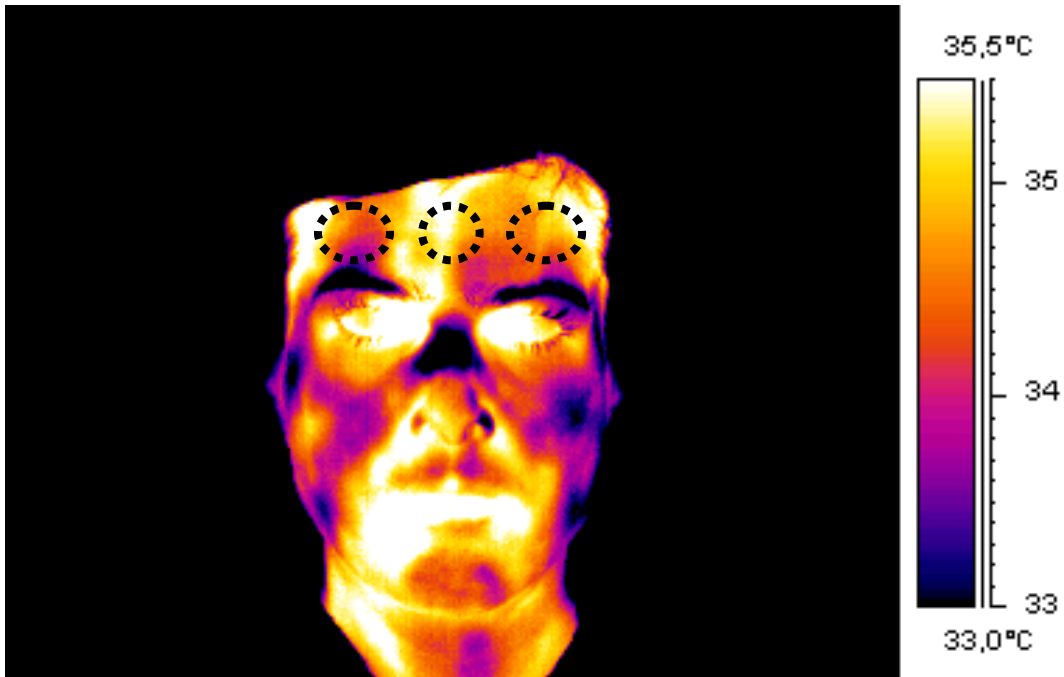


Figure 3: Typical face temperature profile



Figure 4: EEG *pIR x 3* outline

### 3.2 Electromagnetic Compliance

The EEG pIR x 3 has been tested according to IEC 60601-1-2:2001 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)
- IEC 61 000-4-8 (LF magnetic field)

No cable attached to the EEG pIR x 3 shall be longer than 3m / ten feet. The maximum length of the communications port cable with an extension cable must not exceed this limit.

### 3.3 Label

Size: 50 x 12mm



## 4 Set-Up

### 4.1 Unpacking the EEG *pIR x 3*



#### WARNING

**Death due to suffocation if packing material is swallowed**

- Store packing material out of reach of children
- 

Unpack your EEG *pIR x 3*

Please check if the unit is damaged. If so, do not use it and return it for a replacement.

### 4.2 Connection of the EEG *pIR x 3* to digitizing equipment

The EEG *pIR x 3* has a Mini-Din8 plug that connects directly to the EEG NeuroAmp. Interfacing to other digitizing equipment might be added in the future



#### WARNING

**Damage or electrical shock due to use of inappropriate accessories**

Accessories that are not intended for use with the EEG *pIR x 3* 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 EEG *pIR x 3* such as the EEG NeuroAmp.
  - Do not plug the cable of the EEG *pIR x 3* into equipment unless it is meant to work with it, even if its plugs fit.
- 

Gently plug the connector in one of the three Mini-Din8 jacks of the EEG NeuroAmp. Make sure that all eight pins of the connector look undamaged. In case a pin is bent or missing, return the product for replacement.



#### CAUTION

**Wrong signal readings if other equipment connected to the peripheral inputs of the EEG NeuroAmp**

- None of the three peripheral input jacks of the EEG NeuroAmp must be connected to any other peripheral equipment.
-

## 5 Operation

The EEG *pIR x 3* is completely remote-controlled from your biofeedback PC software and powered from the EEG NeuroAmp. No user interaction at the device is needed.

Adjust the headband such that the device sits firmly but not too tight. A too tight headband might disturb blood flow and adversely affect temperature measurements. The EEG *pIR x 3* shall be attached to the forehead such that the sensors 'see' the middle part of the forehead.

No calibration or settling times are required. After attaching the sensor to the client the measurements may start immediately.

## 6 Cleaning, Maintenance and Disposal

This product has been developed and produced with great care and should also be handled with care. If you follow these recommendations you will prevent premature expiry of the warranty and enjoy the safe use of your product for years.

### 6.1 Cleaning

Clean your EEG *pIR x 3* with a clean cloth, with a small amount of alcohol or isopropyl. The sensors must be clean, as substances on top of the sensor windows will affect the temperature readings. Use a cotton bud tintured with isopropyl or alcohol and gently clean the sensor surfaces.

The headband may be washed at 40° with soap or detergent.

### 6.2 Maintenance

There is no maintenance for the EEG *pIR x 3*. If the unit is damaged it needs to be replaced.

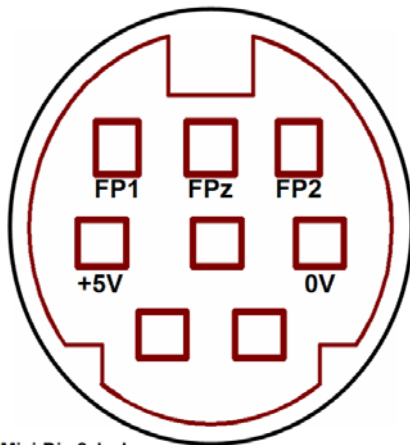
### 6.3 Disposal

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

## 7 Technical Data

Sensor array	Number of sensors	3
	Wavelength range	5-15 $\mu$ m
	Sensor field of view	60° (see Figure 2)
	Temperature range	29°-43°C or 84°-109°F
	Reaction time	< 0.15 s
	Resolution	0.01°K
Interface	Power supply	5V / 5mA
	Connector	Mini-Din8, male
	Signals	3 x 0...5V
	Mechanical interface	Flexible sensor piece with adaptable headband
Environment	Storage and Transport	Temperature: -10°C...+60°C, no condensation. Air pressure: 500 ... 1060 hPa
	Operating	Temperature: 0°C...+50°C, no condensation. Air pressure: 700 ... 1060 hPa

## 8 Plug Connection Diagram



View on Mini-Din 8 Jack

Figure 5: Connection diagram of EEG *pIR* x 3


## 9 Notes on EMC according to EN60601-1-2

<b>Guidelines and Manufacturer's Statement – Electromagnetic Emissions</b>		
The EEG pIR x 3 is intended for use in the electromagnetic environment specified below. The customer or the user of the pIR x 3 should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	The EEG pIR x 3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EEG pIR x 3 is suitable for use in all domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker IEC 61000-3-3	Not applicable	

<b>Guidelines and Manufacturer's Statement – Electromagnetic Immunity</b>			
The EEG pIR x 3 is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG pIR x 3 should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 6kV air	± 6kV contact ± 6kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / disturbance variables / burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

## Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

The EEG pIR x 3 is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG pIR x 3 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V <sub>rms</sub> 150kHz – 80 MHz	3 V <sub>rms</sub>	Portable and mobile RF communications equipment should be used no closer to any part of the EEG pIR x 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter  $d = (1.17 \text{ m/V}) * \sqrt{P}$ for 80 MHz - 800 MHz  $d = (2.33 \text{ m/V}) * \sqrt{P}$ for 800 MHz – 2,5 GHz  where P is the maximum output power rating of the transmitter in watts (W) acc. to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitter, such as base stations for radio (cellular/cordless) telephones and mobile land radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EEG pIR x 3 is to be used exceeds the applicable RF compliance levels above, the EEG pIR x 3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EEG pIR x 3.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

### Recommended safety distance between portable and mobile telecommunication devices (e.g. mobile telephones) and the EEG pIR x 3

Power rating of the HF-device in W	Safety distance depending on transmission frequency in meter		
	150 kHz – 80 MHz	80 MHz – 800 MHz	800 MHz – 2.5 GHz
0.01	0.2	0.2	0.3
0.1	0.4	0.4	0.8
1	1.2	1.2	2.4
10	4	4	8
100	12	12	24

## **10 Warranty**

The EEG pIR x 3 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 EEG Info to receive a Return Authorization. Then send the unit back by a traceable method--Neither BEE Systems nor EEG Info will be responsible for items not received. We will repair or replace your unit(s) free of charge.

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 BEE Systems LLC; 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 Systems LLC and the client and remains the exclusive property of BEE Systems LLC.

If you find any problems in the documentation, please report them to us in writing. BEE Systems LLC does not warrant that this document is error-free.