Directions for Use

Single use

Device Name: Disposable Non-invasive EEG Sensor

Model: see label

CE

℞ Only Caution: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

Specifications:
AC impedance: ≤3ＫΩ (10Hz), DC offset voltage: ≤100mV, internal noise: ≤150μV(peak-peak),
Simulated defibrillation overload recovery:
1) 5 seconds after discharges, the electrode pair's polarization potential value≤100mV,
2) during 30-sec interval following polarization potential measurement, the rate of change≤±1mV/s.
AC impedance after simulated defibrillation: ≤3ＫΩ
Bias current tolerance: ≤100mV
Temperature limit: Operating: +5°C～+40°C; Storage/Transportation: -10°C～+40°C
Humidity limitation(Operating/Storage/Transportation): 0～80%RH, non-condensing
Hyperbaric pressure limitation(Operating/Storage/Transportation): 86kPa～106kPa
Applicalbe population：Adult（B-BIS-4A）, Pediatric（B-BIS-4P）

Description:
The sensor consists of electrodes, lead wire and connector.

Intended use:
The sensor is a single patient use, disposable device. It is intended to be used with a monitoring device to non-invasive detects and transfers patients' electroencephalograph (EEG) and electromyography (EMG) signals.

Caution:
Do not use if the sensor is dry. To avoid dry out, do not open the packaging bag unless using it immediately. Due to intimate skin contact, reuse may pose risk of infection. If skin rash or other unusual symptom happens, stop use and remove it. Limited to short-term use (maximum of 24 hours). After removal, slight redness of skin may be seen and will disappear within a short period of time.

Instructions for use:
1) Wipe the forehead with normal saline and dry it with gauze.
2) Tear the packaging bag along V type notch and take out the sensor.
3) Remove the plastic sheets on the back of the electrodes and paste the electrodes on the forehead correctly as follows according to **Figure 1**.
   • number 1 at center of forehead, about 5cm above the bridge of nose
   • number 4 directly above eyebrow
   • number 3 on temple, between corner of eye and hairline
4) Press around the sensor probe to make sure it is firmly attached.
5) Press 1, 2, 3 and 4 firmly for 5 seconds to ensure that the probes are contact with the skin well.
6) Insert the sensor's connector into the interface of extension cable of monitoring device and proceed to monitor.
   Note: In order to minimize twisting of the sensor, fasten the connection point between the sensor and cable using with tape and/or relieving cable strain.
7) Remove the sensor after use and then clean the skin using water.

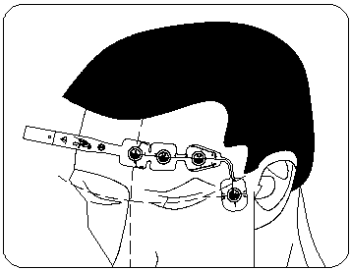

Figure 1

Warning:
1) The sensor is designed for use with specific monitors, the operator is responsible for checking the compatibility of the monitor, sensor and cable before use since incompatible components can result in degraded performance.
2) The sensor is intended for used by professional health care provider.
3) Do not apply the sensor on the position of wrinkle, scar, wound and inflammation.
4) The sensor should be used with caution in patients with skin allergic.
5) Do not immerse the sensor in water or cleaning solutions for cleaning or disinfection. Do not use radiation and steam for disinfection. Any cleaning or disinfection or sterilization methods may result in a bio-incompatibility, infection or failure risks to the patient.
6) Do not use the sensor during MRI scanning. Conducted current may cause burns.
7) In order to reduce the hazard of burns during use of brain stimulating devices place stimulating electrodes far from the sensor and make sure that the sensor is placed correctly according to the instructions for use.
8) Do not change or modify the sensor otherwise those changes or modifications will affect its performance or precision.

Disposal

Waste electrical and electronic equipments must be disposed of in accordance with the local applicable regulations, not with domestic waste.

Statement:
The patient-contacting materials used in this sensor have been tested for biocompatibility.

The following symbols may appear on the product or product's labeling:

Refer to instruction manual/ booklet	Single use Do Not reuse	Contains no natural rubber latex	Non sterile packaging	Medical device
Temperature limitation	Humidity limitation	Model number	Date of Manufacture	Unique Device Identifier

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