Neurosteer - User Manual

The Device

The fBASe™ is a non-invasive, wearable EEG sensor for continuous brain monitoring. The hardware and software modules facilitate the capture and labeling of electrophysiological data as well as enable reviewing the processed data in real time. The device is composed of an electrode-patch, sensing hardware and a cloud-based computerized interpretation that provides reading of the electrophysiological activity.

A medical grade 3-electrode patch is attached to the user's forehead and includes dry gel for optimal signal transduction at minimal discomfort. The electrodes are located at F1 and F2 and a reference electrode at Fpz. The signal sampled is the differential between Fp1 and Fp2 which provide a simpler form of measuring cerebral asymmetry. The electrode patch is disposable and showed no evidence of causing cell lysis, toxicity, or skin irritation upon testing. The Signal acquisition and transmission module includes signal amplification and filtering, analog to digital conversion, BLE communication, battery, battery charger and power management.

Detailed system overview: The signal acquisition and transmission module include: (1) a low noise instrumentation amplifier with an amplification of 100 (AD8429). This includes all protections to protect the patient and the circuit. (2) An 18-bit Analog to Digital converter (AD7982). The device runs at a high sampling rate of 32 kHz and the result averaged to increase the number of effective bits and improve the signal to noise ratio. (3) A low energy Bluetooth 4.2 module (CYBLE-222014-01 EZ-BLE). This is a standard low energy Bluetooth module which transmits in low energy the information collected by the sensor to the device which relays the data to the cloud via cellular or Wi-Fi communication.

Sensor Operation

1

1. Skin preparation – wipe the forehead with an electrode prep-pad or alcohol wipe.
2. Open the electrode package and remove the electrode sticker so that the adhesive foam is exposed.
3. Place the electrode strip on the forehead, 1cm above the eyebrows. The middle electrode should be located between the eyebrows. Make sure the electrode is in full contact with the skin (image 1).

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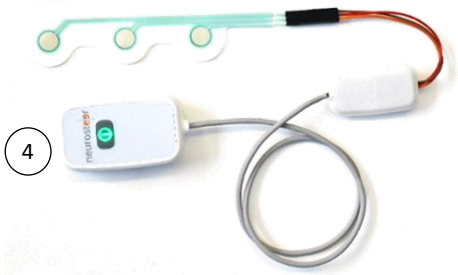
4. Locate the black connector located in the edge of the electrode patch (image 2).
5. The white sensor is composed of the box, a wire and a black connector array (with 3 pins) in the edge of the wire.

3



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6. Attach the electrode patch connector to the device connector array. Make sure the 3 pins are all inserted at the in the proper manner when making the connection (image 3).
7. Press the ON/OFF button on the sensor for 3sec, a blinking red light will appear. The light indicated that the device is turned on.
8. When the device is connected to the system, a green light will appear. Only when the green light is on, the device is transmitting information (image 4).
9. To disconnect the system: unplug the black connectors between the electrode patch and the sensor and press the sensor's ON/OFF button for 3 seconds. The sensor is turned off when the light in the ON/OFF button turns off. The electrode patch is disposable, remove it from the forehead carefully and dispose of it.
10. Battery Charge: Do not charge the device while monitoring. The battery should last up to 14 hours when fully charged. To charge the sensor, connect the charger at the charging socket located on the right side of the device. When the device is charging, a red light will appear in the ON/OFF button.

Monitor operation

1. Plug-in the monitor.
2. Select the desired sensor from the list of sensors that appears on screen.
3. The monitor home screen will appear when the sensor is connected, presenting 3 biomarker graphs and additional details of the recoding (e.g. subject's name, monitor description, battery levels etc.).
4. Choose biomarkers of interest by pressing the biomarker graph. Three different biomarkers can be presented on the screen at once.
5. To disconnect the sensor, press the red disconnect button located on the upper right side of the screen. This will terminate the current recording session.
6. To disconnect the monitor, plug it out. This monitor doesn't operate on battery power.
7. Several indications and alerts will appear on screen when a technical problem arises:
    i. Indication of the sensor's battery level: the battery icon on screen presents the battery levels in percentage and is color coded. When the battery level is low, the battery icon will turn red and start blinking. At that point the sensor should be removed for charging.
    ii. Indication of internet connection: when the internet connection is down, an error will appear on screen. The error screen will be presented until the connection is restored.
    iii. Indication of Bluetooth connection: when Bluetooth connection is down, an error will appear on screen. The error screen will be presented until the connection is restored.
    iv. Indication of poor recording quality: when the electrode patch is not properly located on the subject's forehead or when the connector array is not linked well, an error will appear on screen. The error screen will be presented until recording quality is restored. When a "check electrode" error is presented, remove the electrode patch and clean the forehead skin with an alcohol-wipe. Then, set the electrode back on the forehead. Make sure the connector array is properly linked.
    v. Monitor service malfunction: when the monitor service is down, an error will appear on screen until service is restored. Restart the monitor by plugging our and plugging in again. If the problem is not fixed, contact Neurosteer support.

Activity Presentation

Signal processing together with machine learning and big-data mining render it possible to extract very detailed Brain Activity Features (BAF) from the EEG signal collected with the device. These featured give rise to over 120 brain activity channels related to different functional neural networks. These include functions such as executive, emotional and cognitive components, which correspond to cognitive states, awareness, sustained attention and focus, as well as emotional states including stress, anxiety, positive/negative mindsets, and excitement levels. The representation is based on a functional separation (decomposition) algorithm which processes the EEG data in real time. The processed data creates a two-dimensional information matrix, which can translate brain activity into a heat color map, to represent the progress of the magnitude of different functions of brain activity in time. Each feature is associated with a distinct time/frequency pattern that is unique to a specific functional neuronal network. The decomposition of the EEG signal into several networks enables a much finer brain activity analysis compared to the classical bandwidth features such as Alpha-Delta. The presentation of the activity using the heat map shows the intensity of the activity in each channel in real time (see image 5, blue represents lower activity and red represents higher activity). The chart provides a demonstration of both cognitive load (upper and middle segments) and emotional load (lower segments). The columns in the representation are consecutive time frames (each column represents one second).

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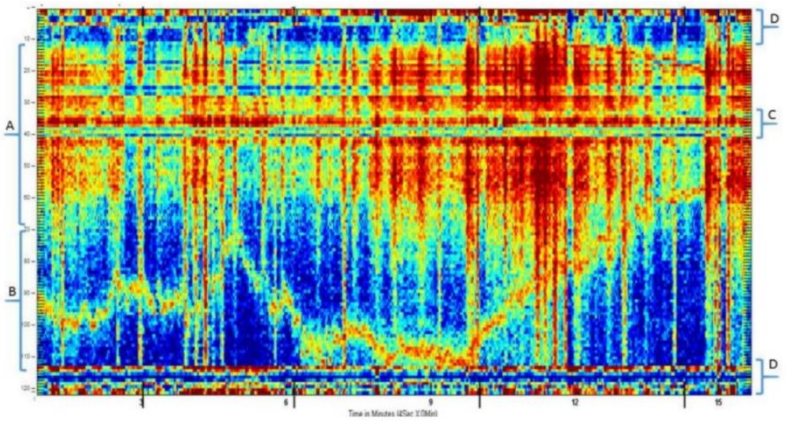

A - features that are active (less blue) during cognitive tasks.

B – features that are active as a response to emotional stimulation, e.g. while watching a movie. We term them the emotional features.

C – features that are active during decision-making and strong awareness. They can be turned on or off under some meditations and in general appear to be missing (not active) in subjects that are in a minimally conscious or unresponsive wakefulness.

D – features that indicate extreme emotions, such as stress or extreme happiness.