

# ALFA RHYTHM LTD

## Clinical test summary of Alfa Rhythm devices

Preliminary testing of the devices showed that the devices stand out in their ability to cause the brain to mimic the frequencies which operate on it, creating brain waves of different wavelengths and types, in the tow devices detailed below.

1. TCD3) - delta and theta (3Hz),
2. TCD9,13 - alpha (9 and 13 Hz),
3. TCD 23 - beta (15 and 23 Hz),

### **Preliminary tests:**

#### **TCD3 (3 Hz)**

This device was found to balance the brain waves frequencies, which relieve the pressure and tension, and enables the patient to feel relaxed and need to sleep. Using a frequency of 1-3 Hz for 10-30 minutes the device managed to activate theta waves and balanced their power.

Eight volunteers were tested in the preliminary tests. Two of the volunteers tested have slept during the test.

The results show that using the device activates and balances the dynamic wave

#### **TCD9,13 (9 and 13 Hz)**

The TCD 9,13 device helps balance the brain waves and leaves the patient in an alpha state: alert, calm and focused.

This device provides the patient an optimal effect, allowing the patient to decide and desire to be in that state, while sharpening his senses and enhancing his functionality. This device emits rapid frequencies of 9 Hz or 13 Hz.

The TCD 9,13 device was tested in 11 volunteers, using 9 and 13 Hz. Its goal is to balance alpha waves. By testing this device for 10 - 30 minutes there was significant change of the wave power at the frequency used by the device.

#### **3. TCD23 (23 Hz)**

This device emits rapid frequencies at 23 Hz.

The TCD 23 device was tested in 4 volunteers, using 23 Hz frequency. The goal of this device is to balance and activate beta and alpha waves. Testing this device in volunteers for 10 - 30 minutes showed there was significant change of the wave power at the frequency used by the device itself.

Four hours after using the the TCD23 device all volunteers reported that they felt more focused and calm.

The results show that using the device activates and balances producing of the

# ALFA RHYTHM LTD

what called the dynamic wave, in our case beta and alpha waves.

## **Conclusions:**

The transcranial devices of this disclosure help people to master their brain waves according to their needs to reach an optimal state by reducing or increasing the individual power of the waves.

Without wishing to be bound by theory, the inventors assume that the change of the energy (power) of the wave is an efficient marker for measuring the effect of the devices

The above examples show that using the device of 3 Hz frequency causes change of wave power, helping the patient to relax and sleep.

Using the device of 9-13 Hz causes changing of the alpha wave energy and also the theta and delta, assisting the patient to become more active and focused and also relaxed.

Using the device of 23 Hz causes changes of the beta and alpha wave energy and also the theta and delta, assisting the patient to become more active and more focused.

All results show that positive effects of the devices was reported by all volunteers allowing them to obtain the desired effect.

Devices of different sizes can be made to treat pediatric, adolescent and adult patients. The device may use a plurality of electrotherapy emitters and include an adjustable frame/framework (e.g., a scaffold, holder, arm, gantry, or the like) to hold the one or more parts in position on an individual's head, during its application. The frame may include preset locking positions for holding the parts in position, to target the brain regions. In one embodiment of the present invention, the device is a hat or a cap worn by a patient where the cap has a plurality of bioelectric emitters that make up an array. The cap is made of any fabric such as a cloth fabric or synthetic polymer mesh.. The emitters are affixed to the cap to make an array of emitters across the whole head of the patient. The cap is worn on the head of the patient where the emitters can produce desired electric pulses upon desire.

The device can be used to enhance or improve physiological functions including, but not restricted, to concentration, sleep, alertness, memory, speech, motor function, physical performance, cognitive function, intelligence. The pulses generated by the present device to different regions of the brain are preferably synchronized together to promote coherence across the brain.

Such modifications and changes do not depart from the true spirit and scope of the present invention. Unlike many existing transcranial stimulation systems which are very crude, the present device is structured for ease of use through a noncumbersome, light-weight and easy to use design.

For the primary motor cortex and primary visual cortex (small sections of the total brain surface), proper positioning is established by the elicited response: muscle contractions when stimulating the primary motor cortex; illusory lights (phosphenes)

# ALFA RHYTHM LTD

when stimulating the primary visual cortex. In both of these areas, the effects are very sensitive to emitter position and orientation.

The step of positioning the transcranial electrotherapy device may comprise positioning a plurality of electrotherapy emitters outside of the subject's head directed to the target brain region so that the principal direction of current in at least one of the emitters is transverse to the anterior-posterior axis of the subject's head.

In experiments conducted on a group of adults, an EEG (electroencephalography) device was utilized for measurement during a period of 2 minutes to determine the changes in the state of alertness and creativity before and after exposure to above device frequencies.

The results obtained clearly indicate that subjects' brain has reacted according to our expectations, i.e., creation of brain waves with frequencies similar to those intentionally exposed to, having most subjects maintain these brain waves for a 3 hours period since the actual stimulation. Based on experimental results, the devices of the present invention provide a method to arouse brain waves over a range of frequencies, designed to cure a variety of physical and mental deficiencies as well as bolster mental potency and efficiency.

Without wishing to be bound by any specific theory, we presume that the brain replicates and recreates the same frequencies it is exposed to, through interaction with the transcranial electrotherapy device.

In an embodiment, there are provided devices which can be used by any individual, irrespective of age, self-determine the chosen frequency according to predetermined goals.

Based on the above, the appliance may assist school and college students, as well as individuals who are in need of a calmed alertness level, enabling them to cope and solve complex tasks and problems in their everyday lives.

The devices of the present invention may be used to stimulate deep regions of the brain while maintaining a high field intensity as compared to superficial regions without significant side-effects.

The principles and operation of a system for transcranial electric stimulation according to the present disclosure may be better understood with reference to the drawings, Figures, charts and accompanying descriptions.

The invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

The devices are designed for self use according to the following characteristics:

1. Its dimensions enable it to be portable and light-weight for mobile and immediate use.

# ALFA RHYTHM LTD

2. The power necessitated for its functionality is based on 3-9 volt batteries, making it:
  - a. Safe compared to other instruments.
  - b. Adaptable for domestic use.
  - c. Accessible to a wider range of uses: children, adolescents as well as adults.
3. Diversity of frequencies (optionally low to high frequency in one device, using a designated switch) is in accordance with the purpose of using the device:
  - a. As a health care appliance designed for healing/alleviating emotional, psychiatric and mental issues such as stress, lack of focus, anxiety, to name a few.
  - b. As a mental booster appliance designed to hone the mental skills such as focus, remembering ability, vigor, creativity and alertness.

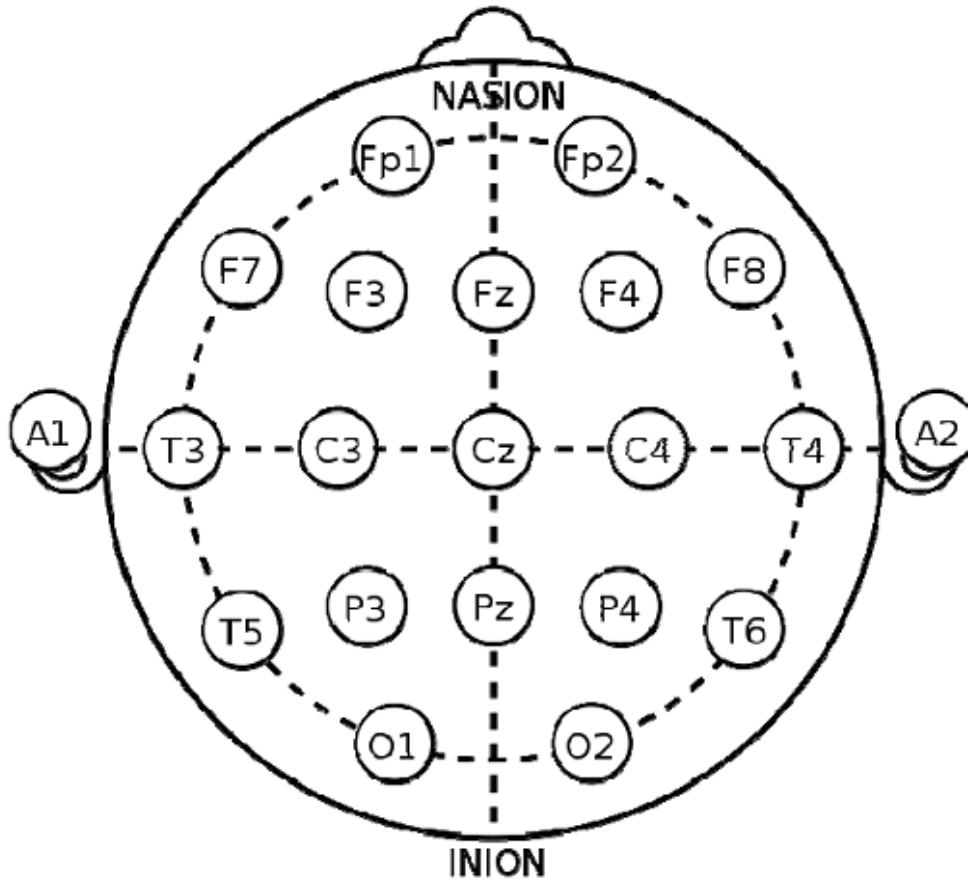
Electrical emitters must be oriented such that they will produce a considerable field in a direction tangential to the surface, which should also be the preferable direction to activate the neurons under consideration.

In devising the instant devices, great care has been exercised to avoid unwanted side-effects. Thus, for example, if the electrical field is too strong, it can cause pain, epileptic seizures, or other complications. Therefore, it is important to maximize deep region stimulation without causing a large electrical field to accumulate at surface areas. This can be accomplished by summation of electrical impulses, a concept which will be described further hereinbelow.

A device may include a housing and an electrically conductive core in the emitter unit having a base and an outwardly projecting extension portion. The device can be placed in various orientations around the skull, while effectively inducing electric fields within the body of a subject.

In the four Examples below, the skull location used for the measuring electrodes was FC5. The FC5 location is according to the International 10-20 system. The "10" and "20" refer to the fact that the actual distances between adjacent electrodes are either 10% or 20% of the total front-back or right-left distance of the skull.

# ALFA RHYTHM LTD



The letters F, T, C, P and O stand for frontal, temporal, central, parietal, and occipital lobes, respectively. Note that there exists no central lobe; the "C" letter is used only for identification purposes. A "z" (zero) refers to an electrode 375 placed on the midline. Even numbers (2,4,6,8) refer to electrode positions on the right hemisphere, whereas odd numbers (1,3,5,7) refer to those on the left hemisphere. In addition, the letter codes A, Pg and Fp identify the earlobes, nasopharyngeal and frontal polar sites respectively.

Two anatomical landmarks are used for the essential positioning of the EEG electrodes: first, the nasion which is the distinctly depressed area between the eyes,

# ALFA RHYTHM LTD

just above the bridge of the nose; second, the inion, which is the lowest point of the skull from the back of the head (see above drawing) and is normally indicated by a prominent bump.

FC means that the location is between F and C on the above 385 drawing, and 5 is an odd number which means that the location is on the left side.

An emitter includes at least one core or a plurality of cores which may be composed of any electrically conductive material, such as metal. Particular embodiments have cores made of copper, aluminum, or other electrically conductive material.

In one embodiment of the present invention, a different type of spatial summation is contemplated. Rather than focusing on a single point, several points along a neuronal structure can be stimulated, causing a net result depolarization at an even lower electrical field strength. This type of spatial summation can be termed morphological line spatial summation.

In an embodiment, there is provided a transcranial electrotherapy brain stimulator, comprising an emitter including at least one core comprising a highly saturable material having an electrical saturation of at least 10 Kilocoulomb, electrodes, and a battery activated electric pulse generator unit connected to the emitter unit.

In another embodiment, there is provided a transcranial electrotherapy brain stimulator wherein emitting at a fixed frequency between 0.5 Hz and 30 Hz.

In yet another embodiment, there is provided a transcranial electrotherapy brain stimulator wherein emitting at a fixed frequency selected from the group comprising 3 Hz, 9 Hz, 13 Hz, 15Hz and 23 Hz.

In an embodiment, there is provided a transcranial electrotherapy brain stimulator, wherein its electric core is comprised of a plurality of adjacent cores.

In another embodiment, there is provided a method of treatment, healing or alleviating cerebral conditions, emotional, psychiatric and mental issues of an individual in need thereof for stress, lack of focus, anxiety, depression, nervousness, anxiety, restlessness or agitation, using a transcranial electrotherapy brain stimulator of this invention for 10-30 minutes.

In an embodiment, there is provided a method of treatment of an individual in need thereof for increasing the mental capability of the brain such as alertness, focus, concentration, remembering ability, vigor and creativity by electrically stimulating the brain with a transcranial electrotherapy brain stimulator of this invention for 10-30 minutes.

In another embodiment, there is provided a transcranial electrotherapy brain stimulator of this invention, wherein safe, lightweight and user friendly for domestic and independent use, by adults and children.

In an embodiment, there is provided a transcranial electrotherapy brain stimulator of this invention, wherein activated by standard 3-9 Volt batteries.

# ALFA RHYTHM LTD

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art.

## **EXAMPLES**

The Examples below detail the operation of the devices of this invention, equipment, measurements and clinical results.

### **Equipment**

#### **TCD devices**

Volunteers were treated with one of the three devices of this invention, emitting at 3Hz (TCD3), 9Hz or 13 Hz (TCD9,13) or 23 Hz (TCD23). The transcranial devices (TCD) of this disclosure were placed on the skull of the volunteers so that they are in contact with skull positions AF3 (left forehead) and AF4 (right forehead). See also Fig. 1-3.

#### **EEG measurements**

Baseline EEG measurements were taken for 2-3 minutes before the TCD treatment for each volunteer, using the EPOC™ neural headset device produced by the EMOTIV company (see also Stage 1 below).

#### **General Procedures and Measurements**

A group of 24 volunteers aged 16-80 were treated for 10-30 minutes with each 465 one of the three devices of this invention, emitting at 3Hz (TCD3), 9Hz or 13 Hz (TCD9,13) or 23 Hz (TCD23). The transcranial devices (TCD) of this invention were placed on the skull of the volunteers so that they are in contact with skull positions AF3 (left forehead) and AF4 (right forehead). See also Fig.1-3.

The volunteers complained before the treatment of at least one disorder, selected from the group comprising insomnia, ADHD, epilepsy, 470 lack of focus, calmness, attentiveness, alertness and concentration.

#### **Stage 1 – Baseline EEG measurements**

Baseline EEG measurements were taken for 2-3 minutes before the TCD treatment for each volunteer, using the EPOC™ neural headset device produced by 475 the EMOTIV company.

The EPOC™ device has 14 electrodes, placed at various skull locations. The Examples 1-4 below (one Example for each TCD emitting frequency) use only the FC5 electrode EEG readings for calculations and charting, as this skull location seems to be the most reliable. All the charts below detail only the EPOC™ FC5 electrode 480 readings. All other 13 EPOC™ electrode EEG readings are not depicted in the charts. The charts also indicate the intersection between the FC5 EEG readings trace and the TCD device's emitting wavelength. This intersection indicates the power of the EEG signal at the TCD device wavelength, before and after TCD treatment.

#### **Stage 2 – TCD device treatment**

In this stage, the TCD device (TCD3, TCD9,13 or TCD23) was applied on the

# ALFA RHYTHM LTD

volunteer's head as depicted in Fig. 1-3 so as the device's two electrodes are placed at skull positions AF3 (left forehead) and AF4 (right forehead) and the device was activated by pressing the activation button. The treatment was continued for 10-30 minutes.

## **Stage 3 – Post-treatment EEG measurements**

Following the volunteer's treatment with the proper TCD device, posttreatment EEG readings were taken for 2-3 minutes using using the EPOC™ neural headset device produced by the EMOTIV company. As with the baseline measurements, the charts below detail only the EPOC™ FC5 electrode readings. All 495 other 13 EPOC™ electrode EEG readings are not depicted in the charts. The charts also indicate the intersection between the FC5 EEG readings trace and the TCD device's emitting wavelength. This intersection indicates the power of the EEG signal

at the TCD device wavelength, after TCD treatment. These readings were compared to the baseline EEG readings. Readings different from baseline EEG readings were interpreted as a positive sign for the effect of the transcranial device.

The EPOC™'s device EEG readings were processed using Fast Fourier Transform (FFT) calculations using the MATLAB computing language.

## **Example 1 – TCD3 device – 3Hz**

The post-treatment EEG measurement chart at the FC5 electrode (Fig. 4) shows that the power at the 3 Hz frequency was changed by the TCD3 treatment as compared to the EEG before treatment (Fig. 5).

As a result of the TCD3 treatment the volunteers reported the need to sleep.

## **Example 2 – TCD9,13 operated at 9 Hz**

The post-treatment EEG measurement chart at the FC5 electrode (Fig. 6) shows that the alpha wave power at the 9 Hz frequency was changed by the TCD9 treatment as compared to the EEG before treatment (Fig. 7).

## **WHAT WAS THE EFFECT OF 9 HZ ON THE VOLUNTEERS?**

## **Example 3 – TCD9,13 operated at 13 Hz**

The post-treatment EEG measurement chart at the FC5 electrode (Fig. 8) shows that the alpha wave power at the 13 Hz frequency was changed by the TCD13 treatment as compared to the EEG before treatment (Fig. 9).

As a result of the TCD13 treatment the volunteers reported being focused and relaxed.

## **Example 4 –TCD23 – 23 Hz**

The post-treatment EEG measurement chart at the FC5 electrode (Fig. 10) shows that the beta wave power at the 13 Hz frequency was changed by the TCD23 treatment as compared to the EEG before treatment (Fig. 11).

As a result of the treatment with TCD23 all volunteers reported being more focused and active.



# ALFA RHYTHM LTD



**Fig. 1** - Backview illustrative embodiment of a transcranial 580 electrotherapy brain stimulator device



**Fig.2** – Front view of an illustrative embodiment of a transcranial 585 electrotherapy brain stimulator device

# ALFA RHYTHM LTD



Fig.3 – Backview

illustrative embodiment of an electrotherapy brain stimulator device, showing the on/off button and the two electrodes for the forehead of the patient.

## EEG Measurement Charts

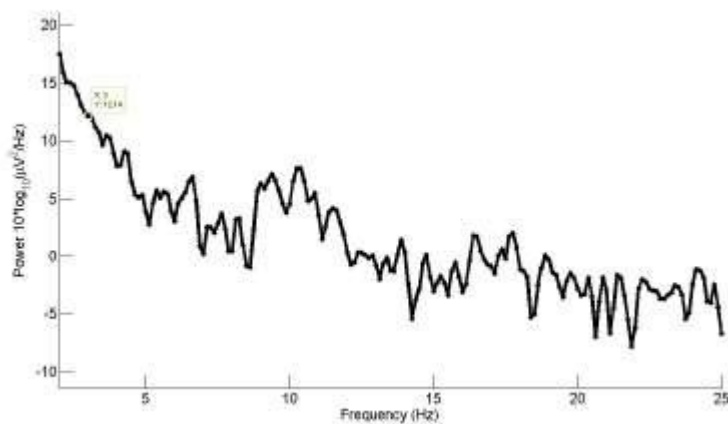
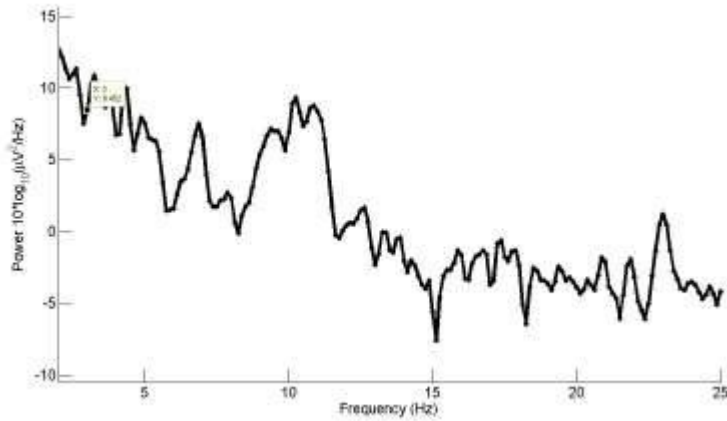


Fig. 4 – EEG measurement chart at FC5 electrode after TCD3 treatment

# ALFA RHYTHM LTD



25  
595

Fig. 5 – EEG measurement chart at FC5 electrode before TCD3 treatment

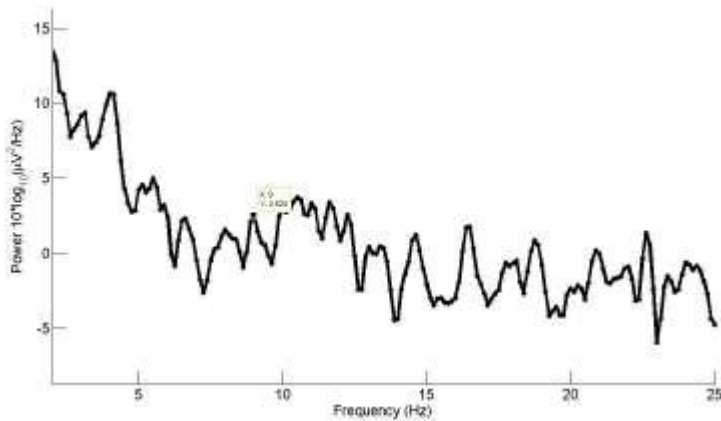


Fig. 6 – EEG measurement chart at FC5 electrode after TCD9 treatment  
600

# ALFA RHYTHM LTD

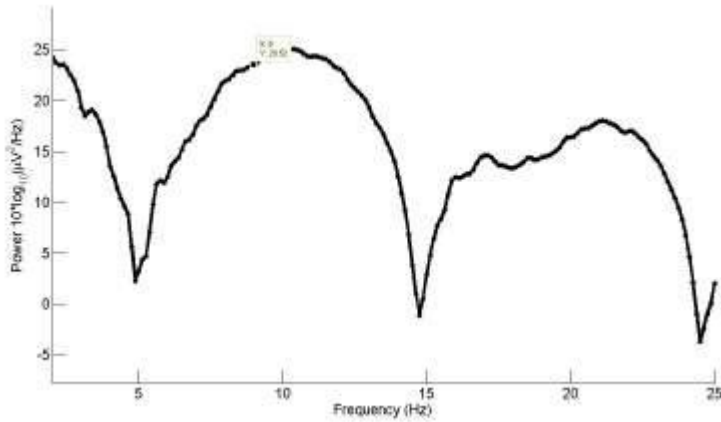


Fig. 7 – EEG measurement chart at FC5 electrode before TCD9 treatment

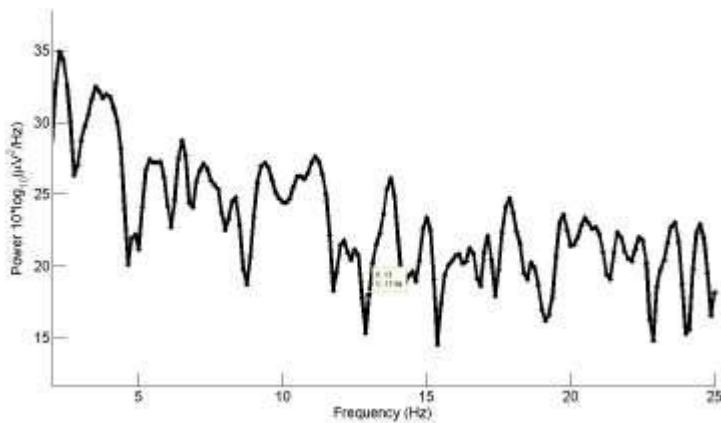


Fig. 8 – EEG measurement chart at FC5 electrode after TCD13 treatment

# ALFA RHYTHM LTD

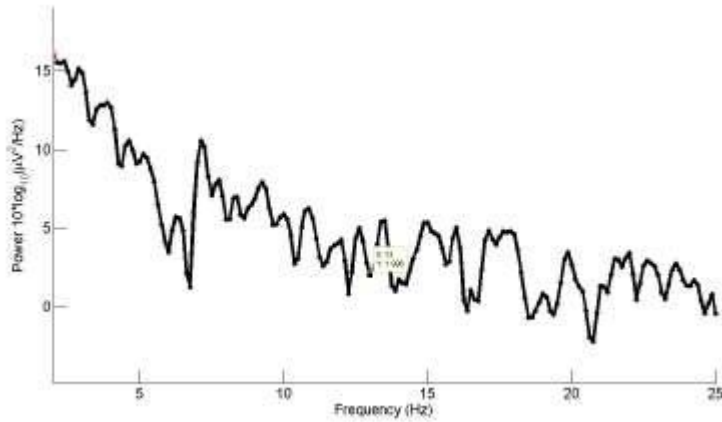
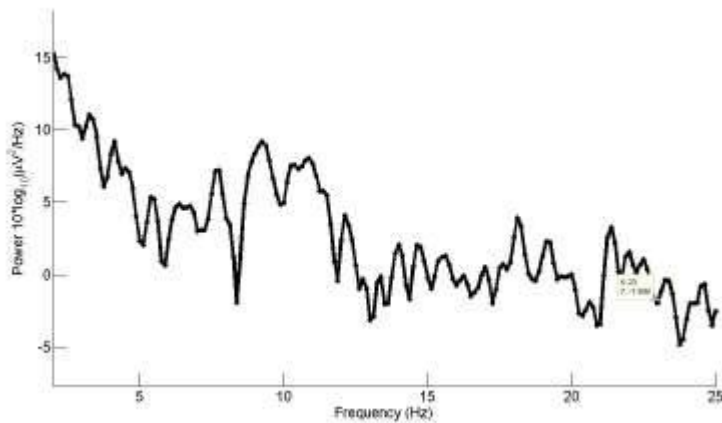


Fig. 9 – EEG measurement chart at FC5 electrode before TCD13 treatment.



27  
Fig. 10 – EEG measurement chart at FC5 electrode after TCD23 treatment

# ALFA RHYTHM LTD

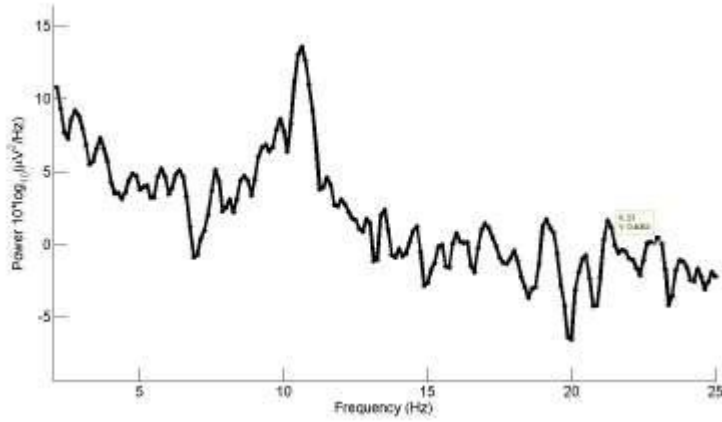


Fig. 11 – EEG measurement chart at FC5 electrode before 620 TCD23 treatment