Claims

1. An auricular neurostimulation device (electrode assembly) (1) that is wireless and wearable by a user and is configured to provide concurrent bilateral neurostimulation of the Auricular Branch of Vagus Nerve (ABVN) of the user's ears, wherein,

   -the auricular neurostimulation device (1) is wireless comprising of at least one electrode contact (2) positioned to the cymba conchae for administering electrical stimulation exclusively to the nerve ramifications of the ABVN; **characterized in that**

   -the auricular neurostimulation device (1) is structured in the form of a wireless earbud, integrating a compact design (6) that avoids full obstruction of the user's ear canals (5) or avoids inhibition of the user's auditory perceptions wherein,

   -the at least one electrode contact (2) is positioned on the neurostimulation device (1) ear-mold that encompasses the ABVN anatomical region,

   -a conduction sensor, designed within the ear-mold, and

   -a compacted faceplate design (6) encapsulated with all electrical components on a Printed Circuit Board (PCB) connected to the holding portion of an infinity shape ('figure of eight') (3), that generates the electrical pulses to carry out ABVN stimulation.

2. The auricular neurostimulation device (electrode assembly) (1) according to claim 1 where in the at least one electrode contact (2) is made of biocompatible materials and biocompatible polymers for adaptation to user's ears for comfort, secure wear providing accurate positioning and contact to the stimulation areas.

3. The auricular neurostimulation device (electrode assembly) (1) according to claim 1 for ABVN stimulation, comprising at least one electrode contact (2) and an infinity-shaped ('figure of eight') holding portion (3) designed to hold the

neurostimulation device (electrode assembly) (1) at the ear of the user, wherein the at least one electrode contact (2) is connected to the holding portion of the infinity shape (‘figure of eight’) (3) via a connecting portion (4), and wherein the connecting portion is inclined relative to the vertical center line (y-axis) of the infinity holding portion (3) at an angle of about 10° to 40°; wherein the holding portion (3) and the connecting portion (4) are manufactured from materials of similar hardness with a Shore hardness in the range of 60 Shore A to about 90 Shore A, and wherein the holding portion (3) is largely manufactured from a relatively soft material, and the connecting portion (4) as well as a section of the holding portion adjoining the connecting portion can be manufactured from materials of different hardness, with the relatively hard material preferably being inserted, embedded, or sunk into the relatively soft material.

4. The auricular neurostimulation device (electrode assembly) (1) according to claim 1, characterized in that a cable associated with at least one electrode contact (2) extends along or within the holding portion of the infinity shape (‘figure of eight’) (3), and that the at least one electrode contact (2) and the infinity shape (‘figure of eight’) holding portion (3) are arranged such that the access to the auditory canal of the user is not completely blocked and does not impede the auditory perception of the user when the neurostimulation device (electrode assembly) (1) is arranged in the ear; wherein a lower portion of the holding portion of the infinity shape (‘figure of eight’) forms a ring, and an additional full circle ring may be attached to the inner part of the lower portion (5), allowing further support for the neurostimulation device (electrode assembly) (1) to be secured into the ear of the user.

5. The auricular neurostimulation device (electrode assembly) (1) according to claim 1, wherein the electronic circuit comprises of:

   -a central circuit for generation of stimulation patterns;

   -a voltage amplifier that can modulate the potential difference supplied by a battery;

-a charger circuit;

-a circuit for detection of impedance;

-a battery that is rechargeable.

6. An auricular neurostimulation system comprising: a bilateral wireless neurostimulation device (1) and a controller unit (8), wherein the controller unit recharges an internal battery of the neurostimulation device when placed into the controller unit; and where the stimulation data performed by the neurostimulation device (1) is collected by the controller unit (8) and is sent to a dedicated cloud-based platform, and wherein the auricular neurostimulation system further includes at least one external input mechanism for inputting feedback data by the device user to the controller unit (8), for estimating levels of hemoglobin and oxyhemoglobin within the user's circulation, and using this data to calculate heart rate, heart rate variability (HRV), breath rate, breathing phases, autonomic nervous system parameters such as sympathovagal balance, or movement activity or muscle response (i.e., electromyography (EMG)), or a combination thereof.

7. The auricular neurostimulation system according to claim 6, wherein the controller unit (8) has a PCB electronic circuit configured to do one or more of the following:

-perform wireless control of ABVN neurostimulation;

-generate synchronized or unsynchronized bilateral wireless ABVN neurostimulation;

-generate stimulation patterns with variable duration, intensity, frequency of bursts and pulses, number of pulses per burst, pulse width, and pulse delays;

-generate of stimulation patterns synchronized with the autonomic nervous system such as sympathovagal balance, and/or parameters relating to movement activity or muscle response i.e. electromyography (EMG), of the user;

-conduct wireless data transfer with external devices;

-conduct battery recharge of neurostimulation devices; and

-detect appropriate skin contact for sufficient neurostimulation conduction.

8. The auricular neurostimulation system according to claim 6, characterized in that it incorporates a multitude of stimulation protocols tailored for bilateral ABVN neurostimulation, where the intensity of the electrical current, pulse width, and pulse frequency is variable; and the stimulation protocols are based on rectangular, bi-phasic symmetrical waveforms, wherein the stimulation protocols applied through the neurostimulation device (1) are personalized for each user according to therapeutic requirements, and wherein an electrical voltage difference applied to any electrodes is measured in real-time to provide metrics of impedance of the contact electrodes to the skin.

9. The auricular neurostimulation system comprising a neurostimulation device (1) according to claim 6 further comprises: a smartphone having a smartphone application; where the controller unit (8) and a connection to the smartphone application in the smartphone allows data transfer to an external cloud; and where the user can use the smartphone application to interact with the neurostimulation device.

10. The auricular neurostimulation system according to claim 6, having at least one input device for inputting feedback data by the device user, characterized in that the neurostimulation system has memory in which the feedback data are stored, and in that the neurostimulation system has a controller unit (8) that is suitable to set one or more parameters of a stimulation pulse delivered by the neurostimulation device (1) based on the feedback data or to propose parameters of stimulation (a stimulation protocol) delivered by the neurostimulation device (1) for selection by the device user, wherein the feedback data stored in the memory

are either individual to the user or not individual to the user, but rather to all the neurostimulation system users for a specific/ or related disease of a majority of users.

11. The auricular neurostimulation system according to claim 10, characterized in that the memory is either an integral component of the neurostimulation system or is arranged as an external device component, with at least a 2-point communication link from the input controller unit (8) to the memory, wherein the neurostimulation device (1) is wireless, and the neurostimulation system controller unit (8) is portable and has a size similar to that of a smartphone; wherein the neurostimulation system has one or more sensors by means of which one or more user parameters and/or external parameters can be detected, and in that the controller unit (8) is configured also to set one or more parameters of a stimulation pulse or pulses delivered by the wireless neurostimulation device (1) based on the user parameters and/or on the external parameters or to propose the parameters of the stimulation pulse delivered by the electrode for selection by the device user.

12. The auricular neurostimulation system according to claim 6, characterized in that the neurostimulation device (1) having at least one electrode (2) for generating a stimulation pulse wirelessly, with the neurostimulation system having at least one detection means that is configured to detect one or more parameter values, with the neurostimulation system having a controller unit (8) that is suitable to set one or more parameters of the stimulation pulse delivered by the wireless neurostimulation device (1) based on the detected parameter value or values; wherein the parameter or parameters whose values are measured by the at least one detection means are user parameters or external parameters, wherein the user parameter is the physiological signals of the user such as heart rate, that can be determined by means of an ECG sensor, a parameter relating to breathing, or a parameter relating to the autonomic nervous system such as sympathovagal balance, or a parameter relating to movement activity or muscle response i.e. electromyography (EMG), of the user or a combination of any of the aforesaid parameters.

13. The auricular neurostimulation system according to claim 12, characterized in that the controller unit (8) is configured to control the neurostimulation device (1) wirelessly such that the parameter value detected by means of the at least one detection means is adjusted to a desired value or to a desired value range by means of the stimulation pulse.

14. The auricular neurostimulation system according to claim 11, characterized in that the controller unit (8) is configured to coordinate the stimulation pulse or pulses with periodically occurring physiological processes, in particular neuro-physiological processes of the user.

15. The methods for operating the auricular neurostimulation system of claim 10 comprising the following steps of:

a. Prior to stimulation:

- creating a user account on the system via a smartphone application with the user entering personal data;

- assigning a suitable stimulation protocol depending on the user's profile based on data groups and statistical studies;

- having the user log into the mobile application to establish a connection with the auricular neurostimulation device through scanning the device QR code, which facilitates the assignment of the device's serial number with the user account;

b. After completion of stimulation:

- storing any session data (including date, time, stimulation duration, stimulation parameters and user's physiological metrics) in the auricular neurostimulation system controller unit (8);

-recharging any batteries of the auricular neurostimulation with return to the neurostimulation system controller unit;

- transmitting the data of each stimulation session from the neurostimulation system controller unit (8) to the mobile application, wherein the data is then sent to the cloud for analyses;

- storing the user data sessions in a cloud based platform;

- wherein an algorithm systematically processes all user-specific data such that a more suitable or adopted stimulation protocol may be provided based on the user’s profile, and wherein the platform will send the values to the application, so that the optimized or personalized stimulation protocol can be selected.