OMNI C&S, Inc.
288 Digital-ro, Guro-gu, Seoul, Korea

Manual

Model Name : neuroNicle FX2

Product Code : OCW-H10

1. Intended use

By using 2 channels of EEG sensors and 1 PPG sensor, the headset type device measures brain waves of prefrontal lobe and pules wave and displays each waves form.

2. Indications

- Autonomic Nervous System Function Test
- Heart Rate Variability Test
- Epilepsy, status epilepticus

3. Instructions for use

- Read the manual before use and be familiar with the usage and precautions.
- Do not place liquids that may spill around the device and affect the equipment.
- It is used in an environment that provides stability to the patient in order to measure accurate information.
- Turn on the power by pressing the power switch for more than 2 seconds.

- Wear the device on your head. At this time, check whether the EEG sensors are in good contact with the forehead, and check if the hair does not overlap with the sensor.

- Fix the earlobe electrode to the right earlobe.

- Make a Bluetooth connection between the device and the host device.
- EEG and pulse waves are monitored in the software.

4. Storage condition

- After use, wipe the metal electrode clean and store it in a place that is not inclined, except for a place with dust, liquid, temperature, moisture and humidity that exceed the usage range.
- Storage temperature: -10 ~ 50 ℃
- Storage Humidity: 15 ~ 90 %RH

5. Shelf life

- N/A

6. Contraindications

- Labeling and advertising that may cause false, exaggerated, misuse, etc. for purposes other than the purpose of use are prohibited.
- Do not use with a defibrillator.
- Do not use with a high-frequency electrosurgical device because there is a risk of burns.
- If you experience any abnormality while using the product, stop using it immediately.

7. Warnings

- Do not arbitrarily disassemble or modify the product, and immediately stop using the product if any abnormality is found.
- When using multiple devices interconnected, there is a risk of leakage current, so seek guidance from a technical expert.

8. Precautions

- Be careful when using in damp or wet places.
- Be careful when using it in places where it may be affected by strong external shocks or malfunctions by other medical devices.

9. Specification

No	Item	Content	
1	Measuring signal	EEG: 2 Channels, PPG: 1 Channel	
2	Measuring method	EEG: Mono-polar(Reference electrode attached to right earlobe) PPG: Transmissive optical pulse driving method	
3	Power	3.7V Li-Polymer battery (300mAh)	
4	Charging time	About 2 Hours (500mA USB port)	
5	Usage time	More than 7hrs(continuous use)	
6	Weight	Less than 67g	
7	Dimension	Height 150mm / Width 130mm / Depth 20mm	
8	Temperature.(Normal operation)	10 ℃ ~ 40 ℃	
9	Temperature.(Storage)	-40 ℃ ~ 70 ℃	
10	Bluetooth	Bluetooth version	Bluetooth Spec. V3.0

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FCC Information

This device complies with part 15 of the FCC Results. Operation is subject to the following two conditions :
(1) This Device may not cause harmful interface, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for CLASS B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try correct the interference by one or more of the following measures:

1.1. Reorient or relocate the receiving antenna.
1.2. Increase the separation between the equipment and receiver.
1.3. Connect the equipment into an outlet on a circuit different from that to which receiver is connected. 1.4. Consult the dealer or experienced radio/TV technician for help.

WARNING
“Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment”.

“CAUTION : Exposure to Radio Frequency Radiation.
Antenna shall be mounted in such a manner to minimize the potential for human contact during normal operation. The antenna should not be contacted during operation to avoid the possibility of exceeding the FCC radio frequency exposure limit.

“This was approved under a Limited Modular Approval, and because the module has no shielding, each other host which is not identical in construction/material/configuration would have to be added through a Class II Permissive Change.”

Contains FCC ID: X3ZBTMOD4

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FCC Information

2.8 Label and compliance information
Grantees are responsible for the continued compliance of their modules to the FCC rules. This includes advising host product manufacturers that they need to provide a physical or e-label stating “Contains FCC ID” with their finished product. See Guidelines for Labeling and User Information for RF Devices – KDB Publication 784748.
Explanation:The host system using this module, should have label in a visible area indicated the following texts: "Contains FCC ID: Contains FCC ID: X3ZBTMOD4".

For all Class A Digital Devices, a statement like the following is needed:
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

For all Class B Digital Devices, a statement like the following is needed:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

OEM INTEGRATION INSTRUCTIONS:
This device is intended only for OEM integrators under the following conditions:
The module must be installed in the host equipment such that 20 cm is maintained between the antenna and users, and the transmitter module may not be co-located with any other transmitter or antenna. The module shall be only used with the internal on-board antenna that has been originally tested and certified with this module. External antennas are not supported. As long as these 3 conditions above are met, further transmitter test will not be required.
However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed (for example, digital device emissions, PC peripheral requirements, etc.). The end-product may need Verification testing, Declaration of Conformity testing, a Permissive Class II Change or new Certification. Please involve a FCC certification specialist in order to determine what will be exactly applicable for the end-product.

Requirement per KDB996369 D03

2.2 List of applicable FCC rules
List the FCC rules that are applicable to the modular transmitter. These are the rules that specifically establish the bands of operation, the power, spurious emissions, and operating fundamental frequencies. DO NOT list compliance to unintentional-radiator rules (Part 15 Subpart B) since that is not a condition of a module grant that is extended to a host manufacturer. See also Section 2.10 below concerning the need to notify host manufacturers that further testing is required.3
Explanation: This module meets the requirements of FCC part 15C(15.247), part 15E(15.407)

2.3 Summarize the specific operational use conditions
Describe use conditions that are applicable to the modular transmitter, including for example any limits on antennas, etc. For example, if point-to-point antennas are used that require reduction in power or compensation for cable loss, then this information must be in the instructions. If the use condition limitations extend to professional users, then instructions must state that this information also extends to the host manufacturer's instruction manual. In addition, certain information may also be needed, such as peak gain per frequency band and minimum gain, specifically for master devices in 5 GHz DFS bands.
Explanation: The EUT has a Chip Antenna, and the antenna use a permanently attached antenna which is not replaceable.

2.4 Limited module procedures
If a modular transmitter is approved as a "limited module," then the module manufacturer is responsible for approving the host environment that the limited module is used with. The manufacturer of a limited module must describe, both in the filing and in the installation instructions, the alternative means that the limited module manufacturer uses to verify that the host meets the necessary requirements to satisfy the module limiting conditions.
A limited module manufacturer has the flexibility to define its alternative method to address the conditions that limit the initial approval, such as: shielding, minimum signaling amplitude, buffered modulation/data inputs, or power supply regulation. The alternative method could include that the limited module manufacturer reviews detailed test data or host designs prior to giving the host manufacturer approval.
This limited module procedure is also applicable for RF exposure evaluation when it is necessary to demonstrate compliance in a specific host. The module manufacturer must state how control of the product into which the modular transmitter will be installed will be maintained such that full compliance of the product is always ensured. For additional hosts other than the specific host originally granted with a limited module, a Class II permissive change is required on the module grant to register the additional host as a specific host also approved with the module.
Explanation: Clear and specific instructions describing the conditions,
limitations and procedures for third-parties to use and/or integrate the module into a host device (see Comprehensive integration instructions below).
Resolve:
Installation Notes:
1) The host product should supply the regulated power of DC 3.7 V.
2) Make sure the module pins correctly installed.
3) Make sure that the module does not allow users to replace or demolition

Requirement per KDB996369 D03

2.5 Trace antenna designs
For a modular transmitter with trace antenna designs, see the guidance in Question 11 of KDB Publication 996369 D02 FAQ – Modules for Micro-Strip Antennas and traces. The integration information shall include for the TCB review the integration instructions for the following aspects:
layout of trace design, parts list (BOM), antenna, connectors, and isolation requirements.
a) Information that includes permitted variances (e.g., trace boundary limits, thickness, length, width, shape(s), dielectric constant, and impedance as applicable for each type of antenna);
b) Each design shall be considered a different type (e.g., antenna length in multiple(s) of frequency, the wavelength, and antenna shape (traces in phase) can affect antenna gain and must be considered);
c) The parameters shall be provided in a manner permitting host manufacturers to design the printed circuit (PC) board layout;
d) Appropriate parts by manufacturer and specifications;
e) Test procedures for design verification; and
f) Production test procedures for ensuring compliance.
The module grantee shall provide a notice that any deviation(s) from the defined parameters of the antenna trace, as described by the instructions, require that the host product manufacturer must notify the module grantee that they wish to change the antenna trace design. In this case, a Class II permissive change application is required to be filed by the grantee, or the host manufacturer can take responsibility through the change in FCC ID (new application) procedure followed by a Class II permissive change application.
Explanation: Yes, The module with trace antenna designs, and This manual has been shown the layout of trace design, antenna, connectors, and isolation requirements.

2.6 RF exposure considerations
It is essential for module grantees to clearly and explicitly state the RF exposure conditions that permit a host product manufacturer to use the module. Two types of instructions are required for RF exposure information: (1) to the host product manufacturer, to define the application conditions (mobile, portable – xx cm from a person's body); and (2) additional text needed for the host product manufacturer to provide to end users in their end-product manuals. If RF exposure statements and use conditions are not provided, then the host product manufacturer is required to take responsibility of the module through a change in FCC ID (new application).
Explanation: This module complies with FCC RF radiation exposure limits set forth for an uncontrolled environment, This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body." This module is designed to comply with the FCC statement, FCC ID is: X3ZBTMOD4.

2.7 Antennas
A list of antennas included in the application for certification must be provided in the instructions. For modular transmitters approved as limited modules, all applicable professional installer instructions must be included as part of the information to the host product manufacturer. The antenna list shall also identify the antenna types (monopole, PIFA, dipole, etc. (note that for example an "omni-directional antenna" is not considered to be a specific "antenna type")).
For situations where the host product manufacturer is responsible for an external connector, for example with an RF pin and antenna trace design, the integration instructions shall inform the installer that unique antenna connector must be used on the Part 15 authorized transmitters used in the host product. The module manufacturers shall provide a list of acceptable unique connectors.
Explanation: The EUT has a Chip Antenna, and the antenna use a permanently attached antenna which is unique.

2.9 Information on test modes and additional testing requirements
Additional guidance for testing host products is given in KDB Publication 996369 D04 Module Integration Guide. Test modes should take into consideration different operational conditions for a stand-alone modular transmitter in a host, as well as for multiple simultaneously transmitting modules or other transmitters in a host product.
The grantee should provide information on how to configure test modes for host product evaluation for different operational conditions for a stand-alone modular transmitter in a host, versus with multiple, simultaneously transmitting modules or other transmitters in a host.
Grantees can increase the utility of their modular transmitters by providing special means, modes, or instructions that simulates or characterizes a connection by enabling a transmitter. This can greatly simplify a host manufacturer's determination that a module as installed in a host complies with FCC requirements.
Explanation: Top band can increase the utility of our modular transmitters by providing instructions that simulates or characterizes a connection by enabling a transmitter.

Requirement per KDB996369 D03

2.10 Additional testing, Part 15 Subpart B disclaimer
The grantee should include a statement that the modular transmitter is only FCC authorized for the specific rule parts (i.e., FCC transmitter rules) listed on the grant, and that the host product manufacturer is responsible for compliance to any other FCC rules that apply to the host not covered by the modular transmitter grant of certification. If the grantee markets their product as being Part 15 Subpart B compliant (when it also contains unintentional-radiator digital circuity), then the grantee shall provide a notice stating that the final host product still requires Part 15 Subpart B compliance testing with the modular transmitter installed.
Explanation: The module without unintentional-radiator digital circuity, so the module does not require an evaluation by FCC Part 15 Subpart B. The host shoule be evaluated by the FCC Subpart B.

Requirement per KDB 996369 D01

This module support Bluetooth 2402 MHz ~ 2480 MHz which compliance with part 15.247 And all test items have been tested.

Test plan (For Host incorporating the approved 2.4 GHz BT module)
- Transmit output power according to FCC Part 15 Subpart C, paragraph 15.247(b)(3) – with limits: 21 dBm at antenna port
- Spurious unwanted emissions according to FCC Part 15 Subpart C, paragraph 15.247(d) – with limits according to FCC 15.209 within bands listed in FCC 15.205.
- Test methods shall be in accordance to ANSI C63.10 (2013):
i. Section 6.5 for emissions below 1 GHz
ii. Section 6.6 for emissions above 1 GHz.
iii. Section 6.10 for band-edges
iv. Section 7.8.5 for fundamental power
- Place the Product on the turn platform within the anechoic chamber.
- Position the measurement antenna on the antenna mast at a distance of 3 meters from the Product.
- Set the transmitter to operate in continuous mode at low, mid and top channels, with modulation BDR DH5 1Mbps (worst case scenario).
- Rotate the turn platform 360 degrees.
v. Gradually raise the antenna from 1 to 4 meters.
vi. Purpose: Maximize emissions and verify compliance with Quasi-peak limits below 1 GHz and Peak/Average limits above 1 GHz; and compare with the appropriate limits as outlined in ANSI C63.10 and appropriate FCC Part 15 Subpart C rule parts.
- Initial scan: Cover frequency ranges from 30 MHz to 1 GHz.
vii. Subsequent scan: Change measurement setup for above 1 GHz measurements.
- Verify fundamental emission levels, according to FCC 15.247(b)(3) within the pass band 2400–2483.5 MHz.
viii. Check band edges within restricted bands at 2390 MHz and 2483.5 MHz and check for Harmonics above 4.8 GHz - according to 15.247(d).
ix. Verify Spurious Emissions against quasi-peak, peak and average limits.