시점확인본 진본 2018-06-11 16:39:34 KST 정부시점확인센터



Jane No. 16-4837

# Medical device manufacturing certificate

(Business license number: No. 1431)

| | | | |
|---|---|---|---|
| Division | [ √ ] Manufacturing / [ ] Importing | [ √ ] Item / [ ] Item Category | |
| Designation (Product name, item name, model name) | • Laxtha, Co., Ltd<br>• EEG (Electroencephalogram)<br>• neuroNicle FX2 | Classification number (class) | A26150.01 (2) |
| Shape and structure | Enclosure | | |
| Raw materials | Same as previous certification | | |
| Manufacturing method | Same as previous certification | | |
| Performance | Same as previous certification | | |
| Purpose of use | Enclosure | | |
| How to use | Same as previous certification | | |
| Precautions for use | Same as previous certification | | |
| Packaging unit | Same as previous certification | | |
| Storage method and period of use | Storage Method: Same as previous certification, Period Use: Same as previous certification | | |
| Test standard | Article 10-05-20180335-0197 (2018.06.04)<br>Korea Testing & Research Institute for Chemical Convergence | | |
| Manufacturer (importer) information | • Laxtha Co., Ltd.<br>• Manufacturer: Same as above<br>• 4F, 106 Techno2ro, Yoosung-gu, Daegeon-si, South Korea | | |
| Permit condition | N/A | | |
| Location | 4F, 106 Techno2ro, Yoosung-gu, Daegeon-si, South Korea | | |
| Note | | | |

In accordance with Articles 6 and 15 of the “Medical Devices Act” and Articles 6, Paragraphs 2 and 34 of the Enforcement Rules of the same Act, it is implied as above.

11 June, 2018

**Head of Medical Device Information Technology Support Center**

(Omission of seal)



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(The back page)

## Changes and dispositions, etc.

| Date (YYYY-MM-DD) | Contents |
|---|---|
| 2016-11-02 | Initial permission |
| 2018-06-11 | Purpose of use (changes the purpose of use according to the pulse rate monitor combination) |
| 2018-06-11 | Shape and structure - principle of action (change of principle of action according to pulse rate monitor combination) |



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## Shape and structure - working principle.

This product is a combination of an EEG(electroencephalograph), a pulse meter, and a pulse rate meter, and is measured according to the following principle.

The EEG differentially amplifies the buffer output signal between the measurement electrodes (CH1, CH2) and the reference electrode (REF) and obtains the EEG signal for each channel. The signal band of each channel EEG signal is determined through a high-pass filter, a notch filter, and a low-pass filter, and a signal gain is determined through an amplifier for adjusting the signal level.

The pulse wave meter non-invasively irradiates light (LED) to peripheral blood vessels and detects the light passing through tissues using a photodiode to measure the amount of light absorbed by biological tissues. The amount of light absorption is synchronized with the heartbeat and fluctuates according to the mechanical properties of blood vessels. The device detects these fluctuations, amplifies and filters the signal. The pulse rate monitor digitizes and displays the pulse rate value using the pulse wave measured by the pulse wave meter. These analog signals are converted to digital through ADC and transmitted to the corresponding device through Bluetooth communication.



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## Shape and Structure - Appearance

[1] neuroNicle FX2

1. External Picture

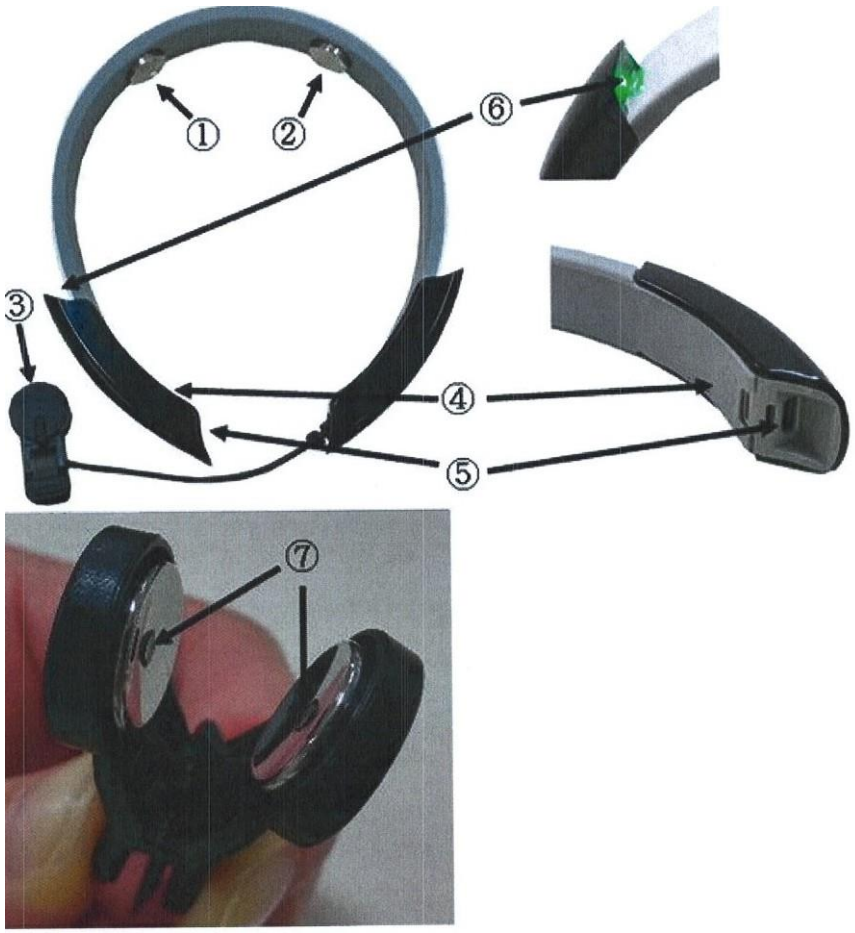




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## 2. Appearance description



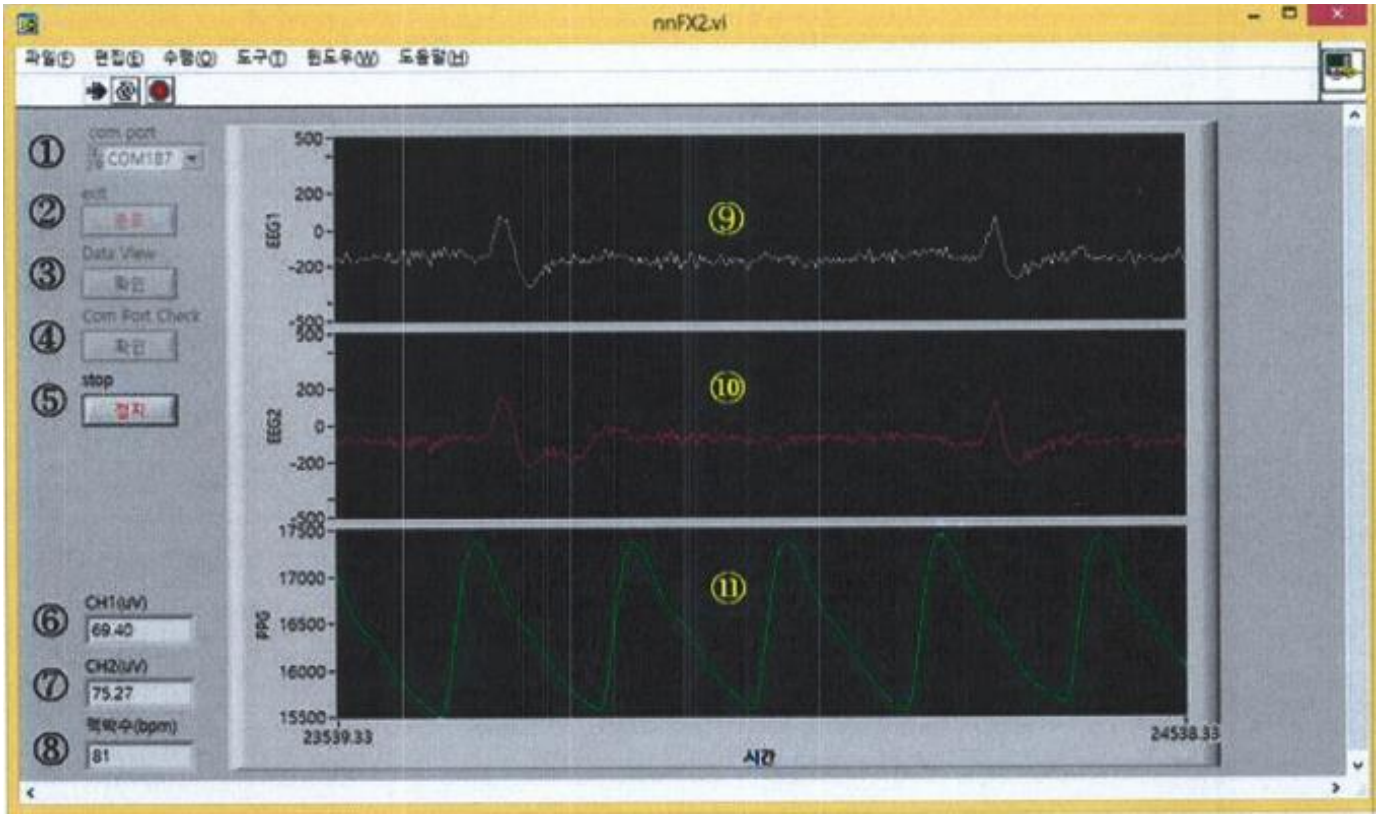

| No | Designation name | Description |
|---|---|---|
| 1 | Measuring electrode_CH1 | CH1 electrode attached to Fp1 (left side of forehead) |
| 2 | Measuring electrode_CH2 | CH2 electrode attached to Fp2 (right side of forehead) |
| 3 | Reference/ground electrode | Reference/ground electrode attached to the right earlobe |
| 4 | Power button | Power button for ON/OFF of device |
| 5 | Charging terminal | USB port for charging |
| 6 | LED | LED for providing status information |
| 7 | Light sensor | Optical sensor for pulse wave measurement |



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3. Software display screen




| No | Major Functions | Function Description |
|---|---|---|
| 1 | COM Port | Indicates a list of COM ports. |
| 2 | EXIT | Disconnect COM port |
| 3 | Data View | Start EEG monitoring |
| 4 | Com Port Check | COM port connection |
| 5 | Stop | Stop waveform monitoring |
| 6 | Ch1 amplitude display | Ch1 amplitude display |
| 7 | Second amplitude display | Ch2 amplitude display |
| 8 | Pulse rate display | Pulse rate display |
| 9 | Ch1 waveform | Ch1 Displays the wave form. |
| 10 | Ch2 waveform | Ch2 EEG waveform is displayed. |
| 11 | Pulse wave waveform | Display pulse wave waveform. |



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## 4. Components

### 4.1 micro 5pin USB cable for charging



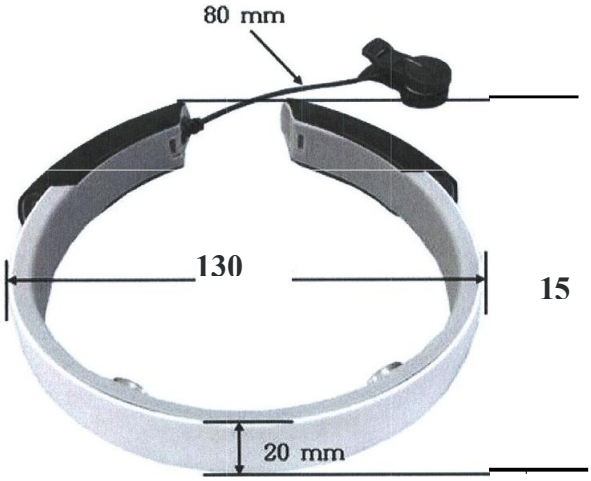


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## Shape and Structure – Dimensions

1. Main Body
   - Width: 130mm
   - Vertical: 150mm
   - Height: 20mm
   - Cable Length: 80mm
   - Weight: 67g




2. Components

   2.1 micro USB cable
   - Length : 50 cm
   - Weight : 18 g
   -





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## Appearance and Structure - Characteristics

1. How it works

   For the 2-channel EEG signal, each channel signal is obtained by differentially amplifying the buffer output signal between the control electrodes (CH1, CH2) and the reference electrode (REF). For each channel signal, a signal band is determined through a high-pass filter, a notch filter, and a low-pass filter, and a signal deviation is determined through an amplifier for adjusting the signal level. These analog signals are converted to digital through ADC and transmitted to the corresponding device through Bluetooth communication.

2. Electrical Ratings

   Use internal power (rechargeable battery): Lithium Polymer 3.7V 300mAh

3. Protection type and degree of protection for rating

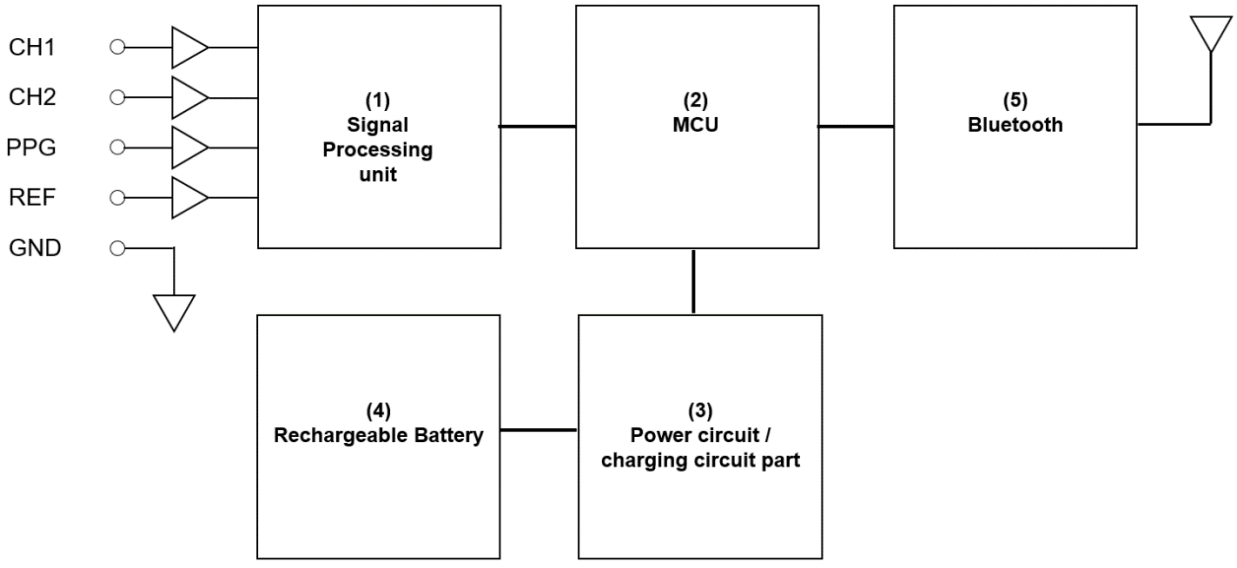
   Internal power type device, BF type mounting part

4. Safeguards

   - Built-in overcharge protection circuit

   - If the device is not worn, it automatically turns off after 1 minute.

5. Operation Schematic




(1) Signal processing unit

- It consists of an amplifier that adjusts the signal level of each signal and a filter that



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adjusts the signal band. HPF, Notch, LPF are equipped.

(2) MCU

- Convert analog signal to digital.

(3) Power circuit, charging circuit part

- Receives power from the rechargeable battery and supplies necessary power to the circuit part.
- Check the state of charge of the rechargeable battery and charge it when the battery capacity is insufficient.

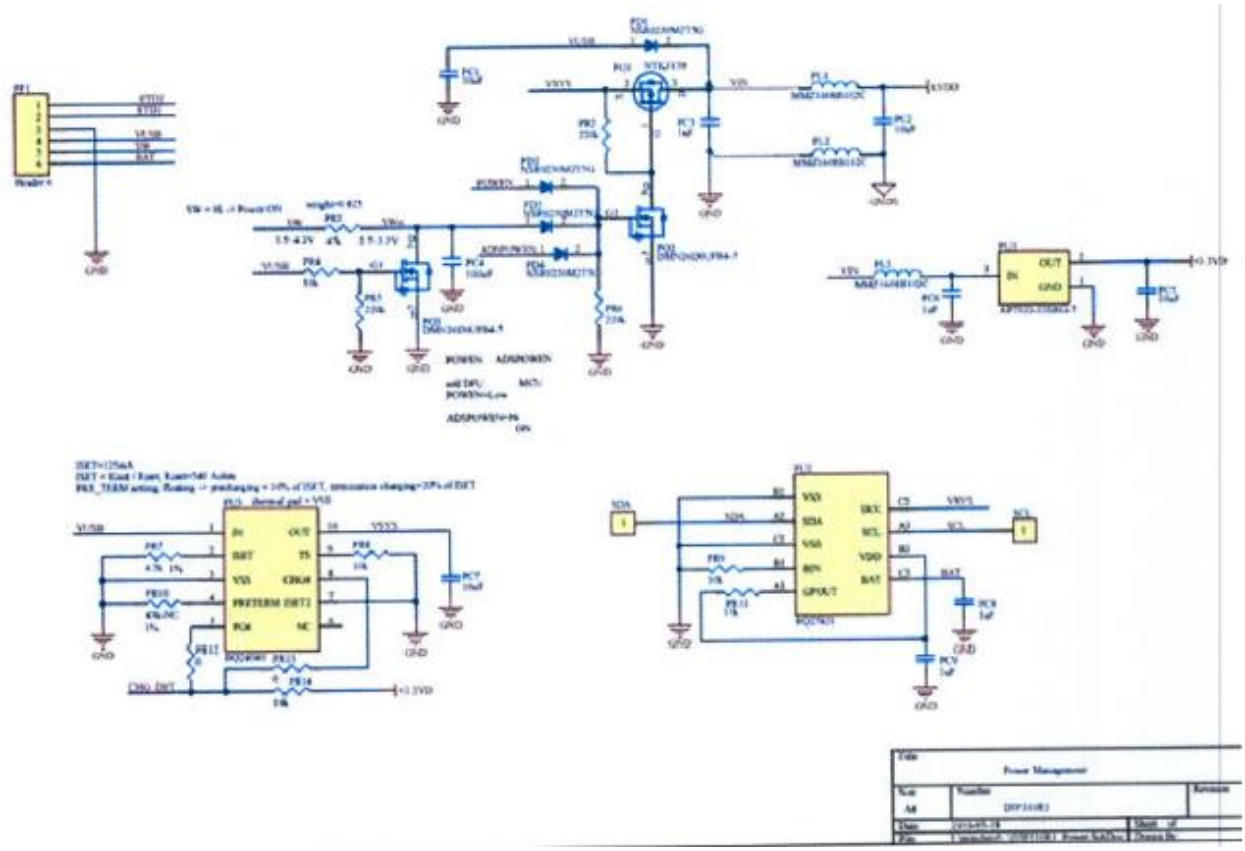
(4) Rechargeable battery

- It is a Lithium Polymer Battery and has a capacity of 3.7V 300mAh.

(5) Bluetooth

- Send output data to the corresponding terminal using Bluetooth communication.

6. Electrical circuit diagram of the insulation part



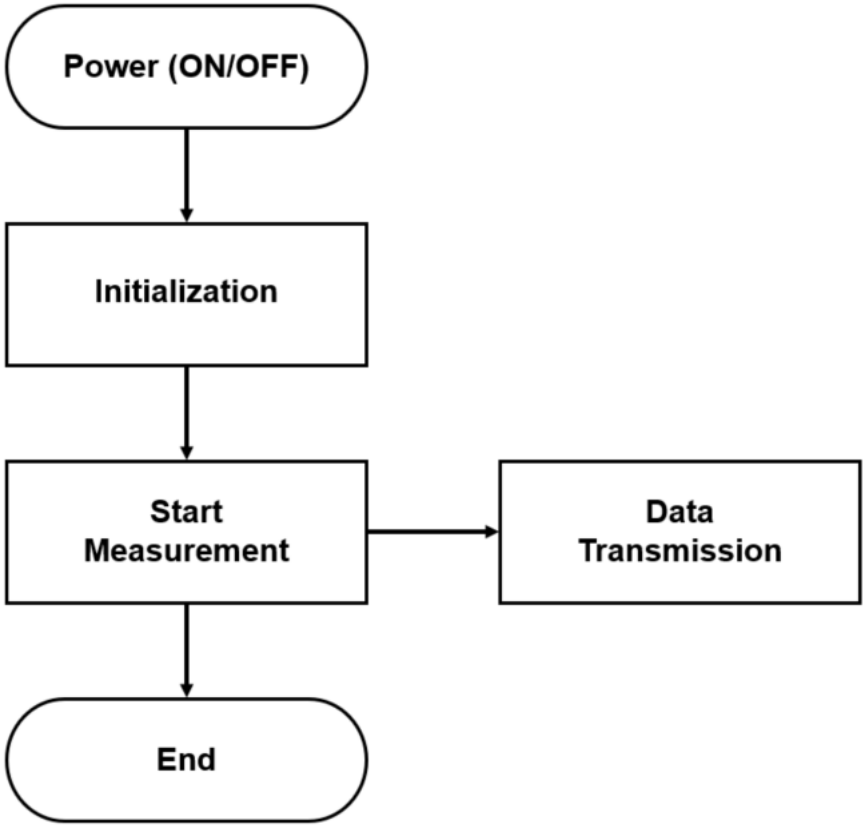


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7. Software Algorithms and Functions

(1) Internal Software




| No | Procedure | Procedure description |
|---|---|---|
| 1 | Initialization | Initialize all variables and functions of the equipment to a measurable state. |
| 2 | Start Measurement | It processes the patient's vital signs. |
| 3 | Data Transmission | The measurement results are transmitted through a communication protocol that can be connected to the equipment. |



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## Purpose of use

(1) EEG: A device that records electrical activity signals in the brain by attaching two or more electrodes to the patient's head.

(2) Pulsemeter: A device that measures the pulse rate in the human body and displays the pulse wave.

(3) Pulse Rate Monitor: A device that measures the number of times per minute or for a certain period when the blood is pushed to the origin of the aorta by the contraction of the heart and the pressure change in the blood vessel is transmitted to the peripheral direction.



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