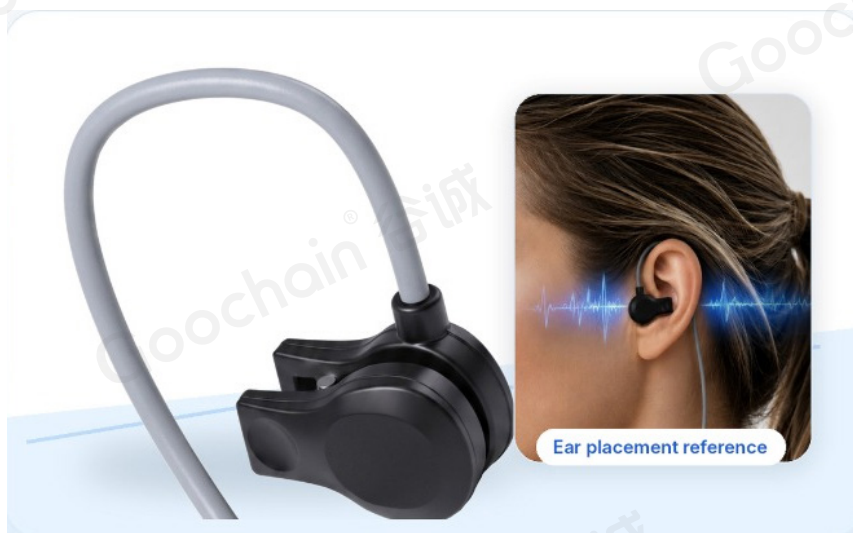




VAGUS NERVE STIMULATION EAR CLIP ELECTRODE

taVNS / tVNS Ear Clip Electrode Finished Product Specification

OEM / ODM Support for Custom Connectors, Cables,
Packaging and Private-Mold Development

Document No.: GC-SPEC-A01
Product Model: FG-MED-00080
Product Name:
taVNS / tVNS Vagus Nerve Stimulation Ear Clip Electrode
Version No.: V1.0
Effective Date: 2026-07-08
Prepared / Reviewed / Approved:
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Note: This specification applies to the FG-MED-00080 taVNS / tVNS Ear Clip Electrode finished product and covers its technical parameters, material requirements, test standards, acceptance criteria, packaging and storage requirements, and precautions for use.

This product is a passive ear-contact electrode assembly. Two conductive silicone contacts clamp onto the tragus and transmit low-voltage, low-current electrical stimulation signals from the connected stimulation device.

The final regulatory classification and intended use shall be determined by the customer's finished-device definition and the applicable regulations of the target market.

1 Basic Product Information

Product Name	taVNS / tVNS Vagus Nerve Stimulation Ear Clip Electrode	Product Model	FG-MED-00080
Material Code	FG-MED-00080	Product Type	Tragus-Clamping Bipolar Conductive Silicone Electrode
Product Category	Electrode Assembly for Neuromodulation Devices / Auricular Electrical Stimulation Devices	Product Attribute	Passive Conductive Connection Assembly
Electrode Structure	2-Pole Conductive Silicone Contact Structure	Intended Contact Area	Tragus, or the ear-clamping area defined in the finished-device instructions for use
Compatible Devices	Goochain vagus nerve stimulation devices and other-brand devices that meet the interface, electrical parameter and safety requirements	Standard Connector	DC 2.35 mm Safety Male Plug
Standard Cable Length	1200 ± 30 mm (1.2 m)	Optional Connectors	USB Type-C, 3.5 mm Audio, magnetic connector, or customer-specified connector
Standard Color	Black Ear-Clip Body + Medical Gray Flexible Cable	Customization Support	OEM / ODM, Connector, Cable Length, Color, Logo, Packaging and Private-Mold Development

2 Product Function and Compatibility

- This product connects a taVNS / tVNS stimulation device to the skin-contact area of the tragus and transmits low-voltage, low-current electrical stimulation signals from the device.
- The two conductive silicone contacts form separate contact surfaces on opposite sides of the tragus. Together with the ear-clip structure, they provide stable clamping and reliable electrical contact.

- The standard configuration includes a DC 2.35 mm safety male plug and a 1.2 m cable, suitable for desktop, hand-held and portable stimulation devices.
- The product is compatible with Goochain tVNS stimulation devices. It may also be used with third-party devices whose connector dimensions, pin assignments, electrical output and safety requirements are compatible.
- This product does not contain a power supply, stimulation waveform generator or software control module. It shall not be used independently as a diagnostic, therapeutic or rehabilitation device.

TRAGUS POSITIONING

Designed primarily for tragus placement, with a contoured structure that follows the shape of the ear for repeatable wearing.

BIPOLAR CONDUCTIVE SILICONE

The two contact surfaces use conductive silicone to provide a soft feel and stable signal transmission.

OPEN DEVICE COMPATIBILITY

Compatible with Goochain and third-party stimulation devices, subject to verification of the connector, polarity and finished-device safety.

◆ Built for Daily Wellness Routines ◆



- Comfortable Skin Contact
- Stable Signal Transmission
- Lightweight Fit
- Long-Lasting Durability

3 Appearance and Structure

3.1 Appearance and Color

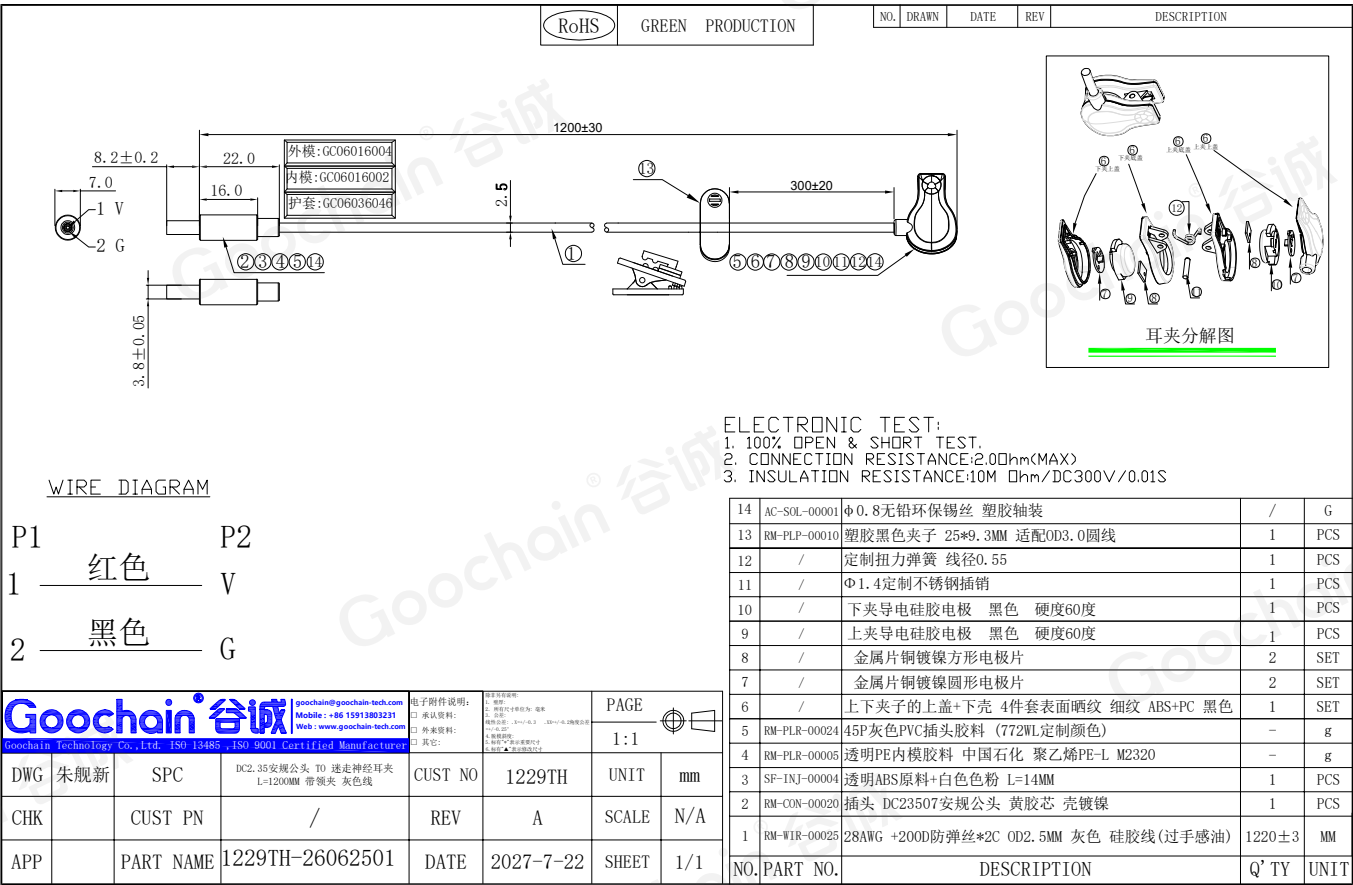
- The standard ear-clip housing is matte black with a fine-textured surface. It shall be free from visible scratches, sink marks, flash, deformation and color variation.
- The contact section consists of two black conductive silicone contacts. The surfaces shall be smooth and soft, with no bubbles, cracks, powder shedding or detachment.
- The standard cable is medical gray or light gray. The cable jacket shall be smooth and free from cuts, crushing, exposed conductors or visible contamination.
- Product color, logo, cable color, connector color and packaging style may be customized according to the customer-approved sample or color standard.

Precision Stimulation Connection



Multi-Angle Product Views

3.2 Product Construction



3.3 Assembly Requirements

- The ear clip shall open and close smoothly and maintain stable clamping force. The two conductive silicone contacts shall be securely assembled with the housing and internal conductive structure.
- Strain relief shall be provided at the cable-to-clip connection. Pulling and bending shall not cause conductor breakage, intermittent contact or other electrical failure.

4 Material Requirements and Environmental Compliance

4.1 Main Material Requirements

Item	Material Requirement	Quality Requirement
Conductive Silicone	Black skin-contact-grade conductive silicone; Shore A 60 ± 5; conductive filler uniformly compounded	No odor, burrs, bubbles, cracks, powder shedding or localized insulating spots
PCB / Conductive Plate	FR-4 PCB or metal conductive part; according to the engineering drawing	No cold solder joints, oxidation, exposed copper or looseness
Cable	Multi-stranded oxygen-free copper with silicone, TPE or PVC jacket	Flexible and bend-resistant; no jacket damage, exposed copper or odor
Ear-Clip Housing	ABS+PC, matte black with fine texture	No sink marks, deformation, flash, color variation or contamination
SR Strain Relief	TPE or silicone	No short shots, cracking or detachment

4.2 Conductive Silicone and Skin-Contact Requirements

- The conductive silicone shall be soft and suitable for skin contact. No hard spots, burrs or sharp edges are permitted in the area that contacts the tragus.
- The conductive filler shall be evenly distributed throughout the effective contact area. Impedance consistency shall be maintained between production lots, with no localized insulating gaps.
- After the adhesive-tape test, the conductive silicone surface shall show no visible powder shedding, particles, surface delamination or separation of the conductive material.
- Materials in direct contact with the skin are recommended to undergo cytotoxicity, skin irritation and skin sensitization testing in accordance with the applicable requirements of ISO 10993.

4.3 Environmental and Export Documentation



RoHS
Certified



FCC
Certified



Recyclable
Materials



CE
Certified



UKCA
Certified



WEEE
Certified

Environmental compliance and export documentation shall be provided according to the specific customer project, purchase order requirements and available test reports.

Where registration of the finished medical device is required, the customer shall complete finished-device verification and regulatory submission in accordance with the applicable requirements of the target market.

5 Device Compatibility and Limitations of Use

- This product may be used with Goochain tVNS stimulation devices and compatible third-party stimulation devices.
- Before connecting the product to a third-party device, verify the connector dimensions, pin assignments, output waveform, output voltage and current, current-limiting protection, and finished-device safety requirements.
- This specification defines only the structure, materials, electrical connections and quality requirements of the electrode assembly. It does not constitute evidence of therapeutic efficacy or clinical performance of the finished device.

6 Core Technical Parameters

Parameter	Specification	Test Condition / Method	Remarks
Electrode Type	Tragus-clamping bipolar conductive silicone electrode	Normal temperature and pressure	Intended for tragus contact
Contact Configuration	Two conductive silicone contacts positioned on opposite sides of the tragus	Visual inspection and drawing verification	Forms a bipolar stimulation circuit
Intended Contact Area	Tragus, or the ear-contact area specified in the finished-device instructions for use	Wearing verification	Do not use outside the area specified by the finished-device manufacturer
Conductive Contact Size	Approx. 8.0 × 8.0 mm per contact	Vernier caliper	Engineering drawing shall prevail
Effective Conductive Area	≥0.48 cm² per contact	Microscope measurement or drawing calculation	Insulating borders are excluded
Conductive Impedance	80–350 Ω	1 kHz, 0.5–1 V small signal	Recommended lot consistency: within ±20%
Cable Specification	28AWG × 2C, OD 2.5 ± 0.2 mm	Caliper and continuity test	Customizable
Standard Cable Length	1200 ± 30 mm (1.2 m)	Measuring tape	Other lengths available
Standard Connector	DC 2.35 mm safety male plug	Mating test	Optional Type-C, 3.5 mm or customized connector
Continuity	100% continuity; no short circuit, open circuit or miswiring	Continuity tester	100% finished-product inspection
Insulation Resistance	≥10 MΩ	Measured at 500 VDC	Cable insulation test
Dielectric Strength	AC 1500 V / 1 min; no breakdown	Dielectric withstand-voltage tester	Confirm according to finished-device safety requirements
Connector Mating Life	≥1,000 cycles	Insertion and withdrawal tester	Connector end
Flex Life	≥3,000 cycles	Cable flex tester	No conductor breakage or jacket damage at the SR
Clamping Durability	≥500 effective uses	Simulated clamping-cycle test	Calculated at 20 minutes per use
Operating Conditions	5–40°C; 10%–90% RH, non-condensing	Temperature and humidity test	Normal operating environment
Storage Conditions	–20–60°C; 5%–95% RH, non-condensing	Controlled storage environment	Keep away from direct sunlight and corrosive substances

Note:Conductive contact dimensions, effective conductive area, structural tolerances and pin assignments shall be governed by the approved engineering drawing, BOM, customer-approved sample or other mutually confirmed document.Where the customer-approved standard is more stringent than this specification, the customer-approved standard shall take precedence.

7 Connector Definition and Production Process

7.1 Standard DC 2.35 mm Pin Assignment

- Product wiring shall strictly follow the approved engineering drawing, wiring table or customer approval document. Miswiring, reversed polarity, short circuits, open circuits, cold solder joints and false solder joints are not permitted.
- If the customer’ s device uses a different connector or pin assignment, the customer-approved interface drawing and approved sample shall take precedence.
- All finished products shall undergo 100% testing for continuity, short circuits, open circuits, polarity and critical im-pedance.

7.2 Production Process Control Requirements

No.	Process	Intended for tragus contact
1	Cable Cutting	Standard length: 1200 ± 30 mm. No crushing, scratches, jacket damage or exposed conductors
2	Stripping	Strip dimensions shall follow the process specification. No broken strands, conductor damage or inconsistent lengths
3	Soldering	Follow the wiring diagram. Solder joints shall be full, with no cold joints, false joints, solder bridges, solder spikes or heat damage
4	Molding	SR, inner-mold and outer-mold dimensions shall comply with the drawing. No short shots, material overflow, bubbles, color contamination or flash
5	Assembly	Assemble the ear clip, conductive silicone and conductive parts according to the SOP. No missing, incorrect or reversed parts
6	Electrical Test	Perform 100% testing for continuity, short circuits, open circuits, polarity and impedance

8 Test Standards and Methods

8.1 Finished-Product Performance Tests

Test Item	Test Method	Acceptance Criteria
Impedance Test	Digital LCR meter; 23°C ± 5°C; 40% ± 10% RH; 1 kHz; 0.5-1 V small signal. Place the two conductive surfaces flat against each other under a pressure of 50-100 g/cm². Take three readings and calculate the average	80-350 Ω; recommended within-lot variation: within ±20%
Visual Inspection	Inspect the ear clip, conductive silicone, cable, SR, connector and packaging under normal lighting at a distance of 30-40 cm	No flash, bubbles, damage, contamination, sink marks, deformation, exposed copper or oxidation
Dimensional Inspection	Use a vernier caliper, measuring tape, profile projector or microscope to inspect the contact surfaces, cable length, connector and critical structural dimensions	Must comply with the engineering drawing. Where no tolerance is specified, critical appearance dimensions shall be controlled within ±10%
Continuity and Polarity	Use a continuity tester or multimeter to check continuity, short circuits, open circuits, polarity and contact misalignment	100% continuity. No short circuit, open circuit, miswiring or intermittent contact
Pull Test	Apply a steady axial force using a force gauge: ≥20 N at the ear-clip end and ≥25 N at the connector end; hold for 5 seconds	No detachment, conductor breakage, loose solder joint or intermittent contact
Bend Test	Bend the ear-clip SR and connector SR 45° in both directions for at least 3,000 cycles	No conductor breakage, short circuit, jacket damage, SR cracking or continuity failure
Clamping Durability	Use a fixture to simulate tragus clamping for 20 minutes per cycle, for a total of 500 cycles	No significant loss of clamping force, no conductive silicone detachment and no abnormal impedance
Environmental Conditioning	Condition at 5°C and 40°C for 24 hours each. Condition at 23°C and 90% RH, non-condensing, for 48 hours. Return to room temperature before retesting	No deformation, cracking, tackiness, oxidation, corrosion, continuity failure or conductivity degradation

8.2 Biocompatibility Testing

- Conductive silicone materials in direct contact with the skin are recommended to undergo third-party testing based on the regulatory requirements of the customer's target market and finished device.
- The recommended test items include cytotoxicity, skin irritation and skin sensitization.
- The test results should comply with the applicable requirements of ISO 10993 or the regulatory registration requirements of the customer's finished device.

9 Quality Acceptance Criteria

Item	Acceptance Criteria
Sampling Rate	Randomly inspect 10% of each lot, with a minimum sample size of 30 pcs. If one defective unit is found, double the sample size. If any defect is found during the doubled inspection, quarantine the entire lot for review
100% Inspection Items	Continuity, short circuits, open circuits, polarity and critical impedance shall be inspected on 100% of finished products
Mandatory Acceptance Items	Appearance, structural assembly, conductive silicone, critical dimensions, impedance, cable reliability, connector performance and packaging labels shall comply with this specification
Defect Criteria	Continuity failure, reversed polarity, out-of-range impedance, conductive silicone detachment, abnormal clamping, damaged cable jacket, exposed conductors, loose or oxidized connectors, and incorrect labels shall be classified as defects

10 Quality Acceptance Criteria

10.1 Packaging and Storage Requirements

Item	Requirement
Inner Packaging	Each set shall be individually packed in a PE bag, pearlescent bag or customer-specified packaging. The cable shall be coiled naturally and shall not be forcibly folded or compressed
Inner Carton	Pack 50 pcs per inner box, or according to the customer's purchase order. The outer label shall indicate the model, lot number, quantity, date and inspection status
Outer Carton and Transportation	The outer carton shall provide moisture, compression and vibration protection. Avoid rain, severe impact, heavy pressure and prolonged exposure to high temperatures during transportation
Storage Conditions	Store at -20°C to 60°C and 5%-95% RH, non-condensing. Keep away from direct sunlight, strong magnetic fields and corrosive chemicals
Shelf Life	12 months in unopened original packaging. Products exceeding the shelf life shall be reinspected for appearance, continuity, impedance and critical performance

10.2 Precautions for Use

- Before use, confirm that the ear clip, conductive silicone contacts, cable and connector are complete and undamaged. Ensure that the product is connected to the correct device interface.
- Clamp the product onto the tragus or other ear-contact area specified in the finished-device instructions for use. Stop using the product immediately if significant discomfort occurs.
- Do not pull the cable when removing the product. Do not immerse, disassemble, cut, modify or clean the product with corrosive solvents.

11 Notes and Revision History

- This specification applies to the GC-A11 taVNS / tVNS Vagus Nerve Stimulation Ear Clip Electrode finished product.
- This product is a passive electrode connection assembly. It does not contain a power supply, battery, stimulation circuit, software algorithm or treatment-parameter control function.
- Any requirements not covered in this specification shall be governed by the mutually approved engineering drawings, approved samples, purchase agreement, quality agreement and applicable industry standards.