Ethics Committee of Nanjing Hospital of Chinese Medicine

Ethics Review Report for Biomedical Research/Medical New Technology Involving Human Subjects

Ethics Committee of Nanjing Hospital of Chinese Medicine
KY2022004

Project Title	Early Warning and Supportive Intervention for Mild Cognitive Impairment in Older Adults from a Family Perspective
Principal Investigator	Xiujun Guo, Yamei Bai (Department of Nursing)
Research Unit	Nanjing Hospital of Chinese Medicine
Review Method	Expedited Review
Review Committee Members	Yang Zhao
Review Materials	1. Ethics Review Application Form for Scientific Research Project / Medical Technology 2. Project Abstract / Application Form 3. Informed Consent Form or Application for Waiver of Informed Consent 4. Others
Review Content	1. Ethical Norm Requirements [✓] Conform [ ] Not Conform 2. Investigator and Scientific Requirements [✓] Conform [ ] Not Conform 3. Protection of Participants' Rights and Interests [✓] Conform [ ] Not Conform 4. Risk Control and Ethical Handling Measures [✓] Conform [ ] Not Conform 5. Requirements of Fairness and Justice [✓] Conform [ ] Not Conform 6. Evaluation of Technical Effectiveness [✓] Conform [ ] Not Conform
Review Comments	1. According to the "Measures for the Ethical Review of Biomedical Research Involving Human Subjects" issued by the National Health and Family Planning Commission of China, as well as the ethical principles of the "Declaration of Helsinki" and the "International Ethical Guidelines for Biomedical Research Involving Human Subjects" promulgated by the Council for International Organizations of Medical Sciences, this ethics committee has reviewed and approved the conduct of the study entitled Early Warning and Supportive Intervention for Mild Cognitive Impairment in Older Adults from a Family Perspective. 2. In the event of a serious adverse event, it must be promptly reported to the ethics committee. 3. Any modification to the protocol or informed consent form, or any change of the principal investigator, must be promptly reported to the ethics committee for re-review and may only be implemented after approval.
Review Date	2022.02.18
Approval Date	2022-02-18

Note: Translated from the original Ethics Review Report (Approval No.: KY2022004) issued by the Ethics Committee of Nanjing Hospital of Chinese Medicine. Provided for submission reference only.

Report Number: GRGST.TF-IM2526701-T05V1.0

Software Test Report

Software Name: Cognitive Assessment System Based on Wearable Multimodal Signals

Version: V1.0.0

Test Category: Project Acceptance Test

Commissioning Unit: Southeast University

Report Date: June 20, 2025

Note: The content presented here is translated from the original Chinese inspection report (Report No.: GRGST.TF-IM2526701-T05V1.0). The translation is provided for supplementary submission purposes only.

Guangdian Metrology & Testing Group Co., Ltd.

Software Testing Technical Service Order

Broadcasting and Metering Testing Group Co., Ltd. Test Results Report

Tested Product Name	Cognitive Assessment System Based on Wearable Multimodal Signals
Tested Product Version	V1.0.0
Test Item Unique Identifier	IM2526701
Applicable Standard	GB/T25000.51-2016 "Systems and Software Engineering - Systems and Software Quality Requirements and Evaluation (SQuaRE) Part 51: Quality Requirements and Test Guidelines for Ready-to-Use Software Products (RUSP)"
Test Type:	Functional
Test Results:	For version V1.0.0 of the Cognitive Assessment System Based on Wearable Multimodal Signals, 16 test items were organized and analyzed, and 16 test cases were designed and executed, all of which were functional test cases. In the first round of testing, all 16 test cases passed without identifying any software issues (defects).
Test Conclusion:	After testing, all 16 functional test cases of the Cognitive Assessment System Based on Wearable Multimodal Signals were passed. The system's functionality meets the requirements outlined in the software testing service commission form, is fully functional, provides accurate data, and meets user needs. The conclusion of this test is: Passed.

1. Purpose

The purpose of this test is to verify whether the wearable multi-modal signal-based cognitive assessment system complies with the specified technical requirements, in accordance with:

- GB/T 25000.51-2016 (*Systems and Software Engineering — Systems and Software Quality Requirements and Evaluation (SQuRE) — Part 51: Requirements for Quality of Ready-to-Use Software Products (RUSP) and Test Instructions*)
- *Software Testing Technical Service Commissioning Form*

2. Reference Documents

The documents referenced for this test are listed in Table 1.

Table 1 Reference Documents

No.	Name	Version	Source
1	GB/T 25000.51-2016 *Systems and Software Engineering — Systems and Software Quality Requirements and Evaluation (SQuRE) — Part 51: Requirements for Quality of Ready-to-Use Software Products (RUSP) and Test Instructions*	2016	General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China
2	*Software Testing Technical Service Commissioning Form*	V1.0	Southeast University
3	*Software Test Plan for Wearable Multi-modal Signal-Based Cognitive Assessment System*	V1.0	GRG Metrology & Test Group Co., Ltd.
4	*Software Test Description for Wearable Multi-modal Signal-Based Cognitive Assessment System*	V1.0	GRG Metrology & Test Group Co., Ltd.
5	*Software Test Report for Wearable Multi-modal Signal-Based Cognitive Assessment System*	V1.0	GRG Metrology & Test Group Co., Ltd.

3. Testing Process

3.1 Test Object

The software can run on Android tablets, developed using the Java language. It is applied in active health cognitive function screening and related fields, with functionalities including:

- Real-time acquisition and analysis of multi-modal physiological and behavioral signals
- Cognitive function assessment based on 8 types of physiological and behavioral signals
- Implementation of 12 cognitive function evaluation schemes

3.3.2 Hardware Configuration

The hardware configuration for this test project is shown in Table 2.

Table 2 Hardware Configuration

No.	Hardware Component/Firmware Name	Configuration	Quantity	Purpose
1	Development Host	i9-13900KF/64G DDR5/2TB NVMe SSD	1 set	Software development environment
2	Android Tablet	Android 11 or above	1 set	Software runtime environment
3	Self-developed Wearable Signal Monitoring Module	Wearable wireless ECG-respiration-activity sensor module, wearable wireless photoplethysmography (PPG) sensor module, portable high-frequency ECG sensor module, microphone, camera	1 set	Supporting hardware sensors

3.3.3 Software Configuration

The software configuration for this test project is shown in Table 3.

Table 3 Software Environment Configuration

No.	Software Name	Version	Purpose
1	Wearable Multi-modal Signal-Based Cognitive Assessment System APP	V1.0.0	Software under test
2	Android OS	Android 13 (API 33)	Software runtime environment
3	Android Studio	Flamingo 2022.2.1 Patch 2	Development IDE
4	Java JDK	JDK 17	Development environment
5	XML	Layout Inspector	UI development
6	Windows OS	Windows 10	Development operating system
7	Git	2.37.4	Version control

3.3.4 Test Equipment and Tools

The test equipment and tools for this test project are shown in Table 4.

Table 4 Test Equipment and Tools

No.	Name/Version	Identifier	Source
1	Laptop	GRGSTHD-BX1-2214	GRG Metrology & Test Group Co., Ltd.

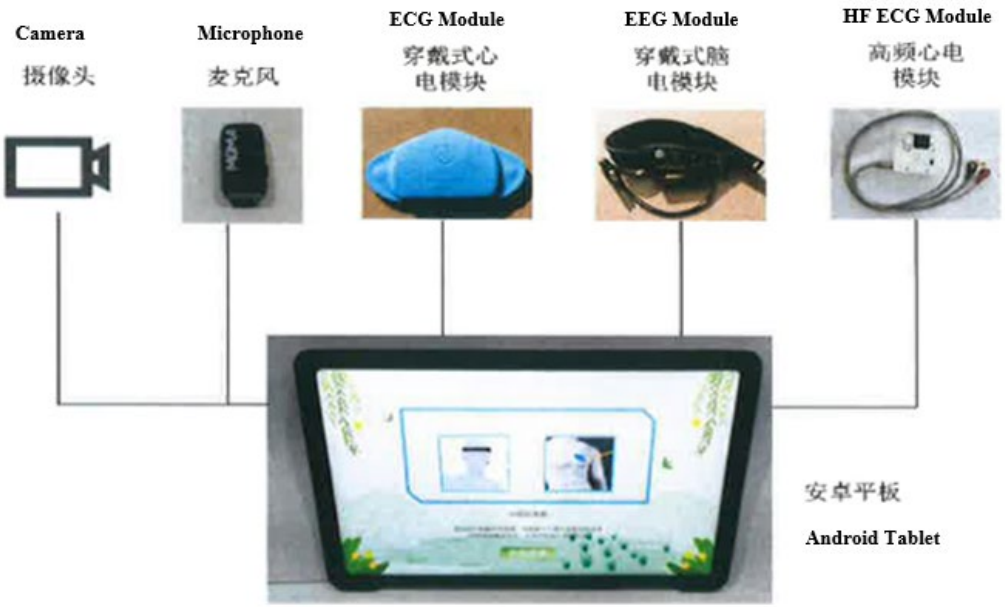
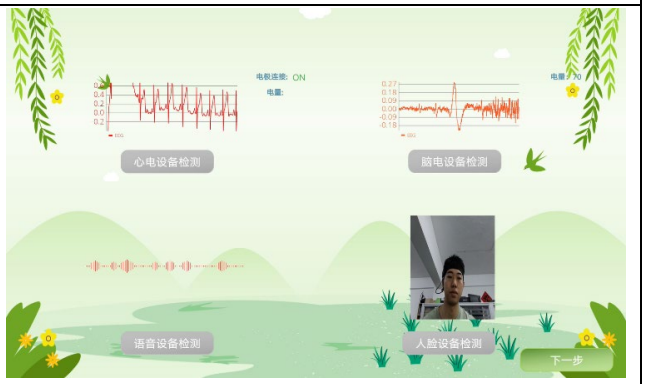


Figure 1. Topology of the Test Environment

Project Test List

<table>
<tr><td colspan="2">Product Name</td><td>Cognitive Function Assessment System Based on Wearable Multi-Modal Signals</td></tr>
<tr><td colspan="2">Test Item</td><td>Description</td></tr>
<tr><td rowspan="3">Real-time Acquisition and Analysis of Multi-Modal Physiological and Behavioral Signals Based on Wearable Devices</td><td>Bluetooth Communication</td><td>The software connects to the wearable physiological monitoring module via Bluetooth communication technology, enabling automatic device search, connection, and data communication.</td></tr>
<tr><td>Signal Acquisition</td><td>  </td></tr>
<tr><td>Real-time Display and Saving</td><td>  </td></tr>
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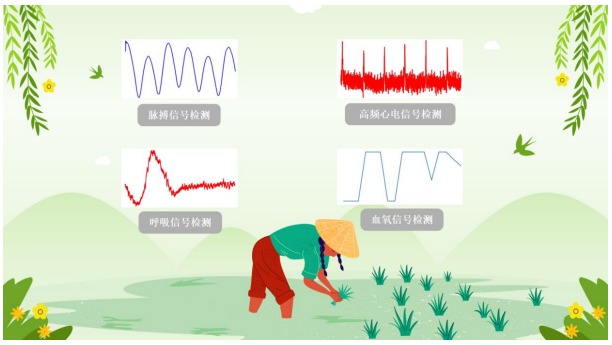
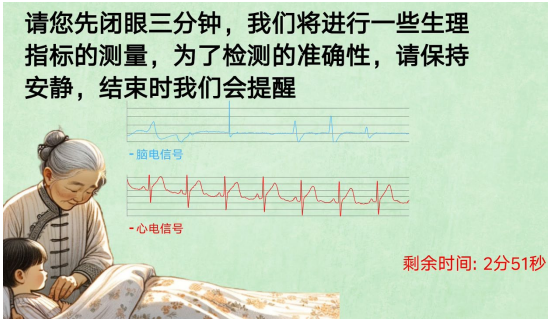
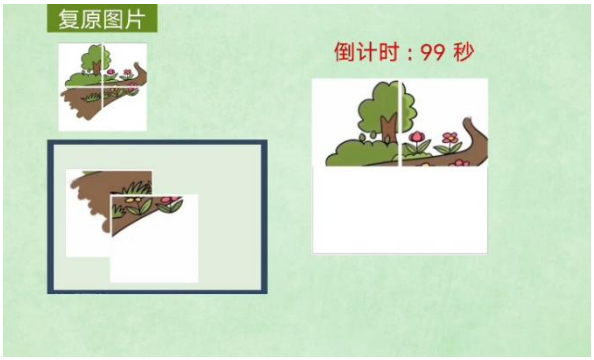
		
	Signal Feature Analysis	Through in-depth feature analysis of the acquired multi-modal signals, the system can extract key signal features, providing a scientific basis for cognitive function assessment.
Cognitive Function Assessment Schemes (Total 12)	Scheme 1: Resting State	•**Test Steps:** Check whether the system supports acquisition of baseline physiological signals, including EEG and ECG, during a resting-state task. Participants are instructed to close their eyes for three minutes and remain quiet to ensure accurate measurements. •**Test Results:** The system successfully acquired synchronized resting-state EEG and ECG signals with stable baseline patterns and minimal noise interference. •**Test Conclusion:** Passed. Resting-state signals can be reliably collected, providing a valid physiological baseline for subsequent cognitive tasks. 
	Scheme 2: Image Observation	•**Test Steps:** Present complex images and instruct participants to identify target objects within the scene. Eye-tracking and EEG are recorded simultaneously to evaluate attention allocation. •**Test Results:** The system accurately captured eye movement paths, fixation points, and EEG activity, reflecting visual

		attention distribution and response speed. **•Test Conclusion:** Passed. The system supports evaluation of selective attention based on synchronized physiological and behavioral signals. 
	Scheme 3: Object Categorization	**•Test Steps:** Display random tool images and ask participants to state the name and classify each as a cleaning or repair tool. Record voice, EEG, and reaction time. **•Test Results:** The system recorded speech responses, classification accuracy, and completion time, with EEG features reflecting decision-making processes. **•Test Conclusion:** Passed. Reasoning and decision-making ability can be effectively evaluated. 
	Scheme 4: Scene Description	**•Test Steps:** Show a complex image and instruct participants to verbally describe the scene within one minute. Record speech, language fluency, and EEG activity. **•Test Results:** The system successfully captured voice signals, vocabulary diversity, sentence complexity, and pause frequency, together with EEG correlates of expressive

		language. **•Test Conclusion:** Passed. Expressive language ability can be reliably assessed. 
	Scheme 5: Calculate	**•Test Steps:** Present a shopping scenario with sequential price subtraction tasks. Participants calculate remaining money after each purchase and input the answers. **•Test Results:** The system recorded arithmetic accuracy, response latency, and associated EEG/ECG features during calculation tasks. **•Test Conclusion:** Passed. The system can evaluate arithmetic ability and decision-making under working memory load. 
	Scheme 6: Attention Counting	**•Test Steps:** Display a sequence of dynamic images containing butterflies. Participants count the total number and report their answer afterward. **•Test Results:** The system captured attention-related EEG activity, behavioral accuracy, and response times, reflecting sustained attention and interference resistance.

		•**Test Conclusion:** Passed. Attention resource allocation and maintenance ability can be effectively assessed. 
	Scheme 7: Object Recall	•**Test Steps:** Present tools and ask participants to recall whether each was shown in the earlier classification task. •**Test Results:** The system recorded recognition accuracy and response times, with EEG features reflecting episodic memory retrieval. •**Test Conclusion:** Passed. The system supports evaluation of delayed recall and memory consolidation. 
	Scheme 8: Emotion Understanding	•**Test Steps:** Show emotional film clips (e.g., sad scenes) while recording subjective emotion ratings and physiological signals (EEG, ECG, HRV). •**Test Results:** The system successfully collected synchronized physiological signals and self-reported emotion scores, showing sensitivity to emotional empathy. •**Test Conclusion:** Passed. Emotional response and empathy assessment can be effectively implemented.

		
	Scheme 9: Drawing Execution	•**Test Steps:** Ask participants to draw two non-overlapping five-pointed stars and write the date and day in the corner. •**Test Results:** The system recorded handwriting performance and evaluated spatial planning, line smoothness, and error corrections. •**Test Conclusion:** Passed. Executive control functions such as planning, motor control, and monitoring can be reliably assessed. 
	Scheme 10: Date Orientation	•**Test Steps:** Ask participants to provide the current date (year, month, day, and weekday). •**Test Results:** The system recorded accuracy and response time, reflecting temporal orientation ability. •**Test Conclusion:** Passed. The system can effectively evaluate orientation to time.

		
	Scheme 11: Puzzle Task	•**Test Steps:** Present a fragmented image and ask participants to place missing pieces into the correct positions. •**Test Results:** The system measured accuracy and completion time, reflecting visuospatial construction and integration speed. •**Test Conclusion:** Passed. The system can reliably assess visuospatial construction ability. 
	Scheme 12: Target Search	•**Test Steps:** Show dynamically appearing sheep in grid positions. Participants memorize their locations and recall them after disappearance. •**Test Results:** The system recorded memory accuracy and response speed, with EEG features reflecting working memory capacity. •**Test Conclusion:** Passed. Working memory and attention refresh efficiency can be effectively evaluated.

Note: The software function item list may include 1–3 levels of sub-functions as needed.

China National Accreditation Service for Conformity Assessment (CNAS), International Mutual Recognition Testing, CNAS L17653

Inspection Report

Report No.:	CTG2410290729E_SR135AB
Product Name:	Wearable Multi-Modal Physiological Signal Acquisition Device
Brand:	N/A
Model:	BIO-M7
Applicant:	Southeast University
Address:	Sipailou, Xuanwu District, Nanjing City

Note: The content presented here is translated from the original Chinese inspection report (Report No.: CTG2410290729E_SR135AB). The translation is provided for supplementary submission purposes only.

Summary of Inspection Results

No.	Inspection Item	Result	Conclusion
1	Product Component Assembly: The device supports ECG, EEG, respiratory, and blood oxygen modules. Each module can be connected and securely fixed.	Qualified	Passed
2	Product Hardware: The device can record ECG and EEG signals simultaneously with a maximum sampling rate of 250 Hz.	Qualified	Passed
3	Product Electrical Safety: Leakage current ≤ 0.25 μA; complies with safety standards.	Qualified	Passed
4	Functional Test: The device supports synchronized acquisition of multimodal physiological signals including EEG, ECG, respiratory, high-frequency ECG, pulse, blood oxygen, voice, and facial expression signals.	Qualified	Passed

Fig1. Sample Image