AiSW 2101

Middle-Ear analyzer

Instructions for Use-EN

（The second edition）

（Please read this manual carefully before use）

Hangzhou Aisiwei Instrument Co.,Ltd

Table of contents

Usage Instructions

1. This product should be used by trained physicians.

2. Users should carefully read this instruction manual before installing and using the product.

3. The electroacoustic transducers (probe and air-conduction headphones) configured with the instrument have undergone specialized equipment calibration. The use of electroacoustic transducers other than those configured is not permitted.

4. The instrument must be used in a quiet and clean environment, away from electronic equipment with radioactive electromagnetic fields, to avoid affecting the function of the middle ear analyzer.

5. The test subject should maintain a calm state of mind during the test and understand the test procedures and precautions.

6. For instrument cleaning, please carefully follow the instructions in the "Cleaning and Maintenance" section.

7. Please keep the device documentation, purchase receipt, and original packaging materials for future maintenance and repair services. If you need after-sales services such as accessory replacement, repair, or calibration, please contact Hangzhou Asiwei Instrument Co., Ltd. or the distributor.

Warning

1. Do not perform maintenance or servicing on any components while the device is in use with a patient.

2. Do not modify this equipment without authorization from the manufacturer.

3. The use of non-original power adapters (chargers) and accessories is prohibited.

4. Before connecting this instrument to other devices with independent power supplies, ensure that the power to both devices is turned off.

5. The device must be positioned so that the plug can be easily disconnected from the power socket.

6. The device is stationary; please do not move it arbitrarily after it has been put into use.

1. PRODUCT DESCRIPTION

1.1 Operating Principle

AiSW 2101 Middle Ear Analyzer transmits a probe tone of a specific intensity into the ear canal via the probe's loudspeaker and measures the corresponding sound pressure level (SPL) in the ear canal through the probe's microphone. As variations in ear canal air pressure or middle ear muscle activity alter the acoustic compliance characteristics of the middle ear system, different SPLs can be measured at the probe under these varying conditions. By monitoring the changes in SPL through the measurement system, the acoustic compliance characteristics of the tympanic membrane and ossicular chain for sound energy transmission can be determined from the changes in the equivalent volume of air.

1.2 Product Composition Structure

The product consists of a main unit, power adapter, cable probe, air-conduction headphones, and host computer software.

1.3 Scope of application

AiSW 2101 Intended for the measurement of middle ear acoustic impedance and static pressure.

The target users include infants, children, and adults.

1.4 Software Version

Embedded software：v1.0.0.0

Host computer software：v1.0.0.0

2. MAIN TECHNICAL PARAMETERS

2.1 Work Environment

1. Environmental temperature:15℃~35℃;
2. Atmospheric pressure:98 kPa～104 kPa;
3. Relative humidity:30%～90%;
4. Power supply voltage：AC 220V，50Hz；
5. Input power：30VA。

2.2 Product Performance

The AiSW 2101 Middle Ear Analyzer complies with the technical requirements for a Type 1 acoustic immittance instrument as specified in GB/T 7341.5-2018 "Electroacoustics - Audiometric equipment - Part 5: Instruments for the measurement of aural acoustic impedance/admittance" and JJF 1771-2019 "Program of Pattern Evaluation of Impedance Audiometers (Instruments for the Measurement of Aural Acoustic Impedance/Admittance)." For detailed performance specifications, refer to Chapter 13: Technical Specifications.

2.3 Safety Index

Complies with the requirements for Class II equipment specified in GB 9706.1-2020 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance."

2.4 Packing

1）Each middle ear analyzer and its accessories shall be placed in the pearl cotton liner. The liner shall be assembled, wrapped with an inner plastic film bag for the carton, and then placed into the packaging box.

2）The packaging box shall include the accessories, packing list, product instruction manual, and certificate of quality, among others.

2.5 Transportation

The middle ear analyzer should be transported in its original packaging box. General modes of transport may be used, but the device must be protected from violent impacts, vibration, and exposure to rain or snow.

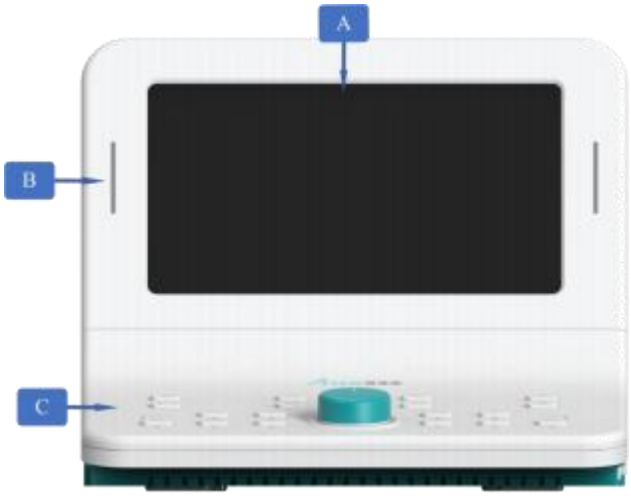
2.6 Storage

The packaged middle ear analyzer shall be stored in a clean, well-ventilated indoor environment free from corrosive gases, with a temperature range of -10°C to 50°C, a relative humidity not exceeding 90%, and an atmospheric pressure range of 86 kPa to 106 kPa.

3. STRUCTURAL AND INSTALLATION INSTRUCTIONS

3.1 Host structure

3.1.1 Front Panel



A：10 inch LCD screen

B: LED Status Indicator, available in three colors: blue, cyan, and green. Blue indicates the test ear is the left ear; cyan indicates the test ear is the right ear; and green indicates that a test is in progress.

C: Button, as illustrated in the diagram below.

Button Area Description

Icons	Key Names	Description
	Special Tests	Press to switch to the Special Tests screen.
	New Test	Press to switch to the New Session prompt screen, reminding the user to print or upload the current test data.
	Setting	Press to switch to the Settings screen.
	Delete	Deletes the currently highlighted test result.
▶ / II	Start/Stop	Press to start or stop the test.
	Switch L/R	Press to switch the test ear.
	Print	Press to switch to the print preview screen and preview the printout.
	Return	During a test, press this button to end the test. On other screens, press this button to return to the main screen.
Tymp	Tympanogram	Press to switch to the Tympanometry test screen.
Seq.	Combined test	Press to select multiple options from "Tymp, Ipsi, Contra, 0.5k, 1k, 2k, 4k, Noise". Once selected, the automatic sequence test will begin.
Contra	Contra ART	Press to select multiple options from "Tymp, Ipsi, Contra, 0.5k, 1k, 2k, 4k, Noise". Once selected, the automatic sequence test will begin.
Ipsi	Ipsi ART	Press to switch to the ipsilateral reflex threshold test screen.
±P	Pressure Compensation	Press this button to select pressure compensation.
0.5k 1k	Stimulus Freq	Press these buttons to select the pure-tone frequency required for the reflex test. The selectable frequencies are: 0.5 kHz, 1 kHz, 2 kHz, and 4 kHz.

2k 4k		
Noise	Noise Stimulus	Press this button to select broadband noise as the reflex stimulus.
	Knob	Rotate to adjust the stimulus level or switch options; press the knob to confirm.
Keypad Indicators: Some buttons have indicator lights to show that their corresponding function is active.		

3.1.2 Rear Panel

A：The calibration cavities are 0.5 ml, 2 ml, and 5 ml, respectively.；

B：Printer: For instructions on how to use the printer, refer to section 3.2.4.；

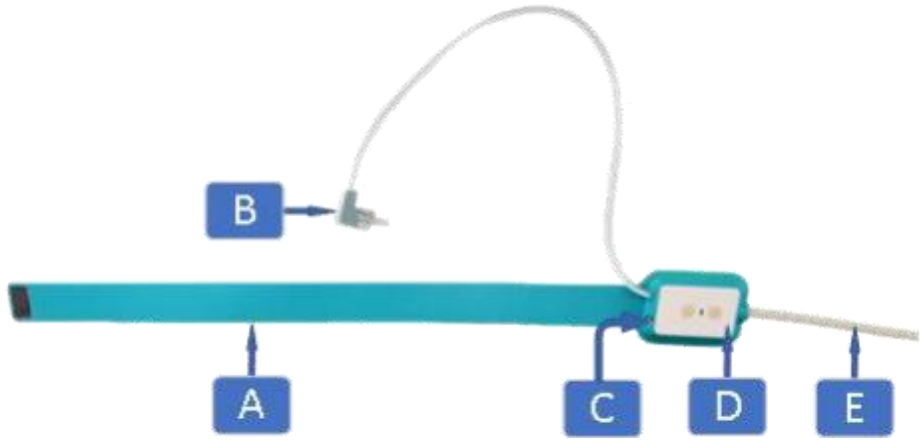
C：12V DC power input jack；

D：USB port；

E：Probe tube connector；

F：Cable connector；

3.1.3 Probe and Cable



A：Shoulder strap

B：Probe

C：Air-conduction headphone jack

D：Controller

E：Testcable

Controller Button Description

Incons	Key names	Description
	Start/Stop	Press to start or stop the test.
	Switch L/R	Press to switch the test ear.

Controller LED Indicators

Indicator Light Colors	Description
Yellow	Probe is leaking
Purple	Probe is blocked
Green	Testing

3.2 Installation

3.2.1 Plug in Power

Connect the output end of the power adapter to the power jack on the middle ear analyzer and the input end to an external power socket. To turn the device on, press the On/Off button. Once the device is on, the display screen, LED status indicators, and some function buttons will illuminate. To turn the device off, press the On/Off button.

3.2.2 Connecting Probe

The probe and cable are pre-assembled at the factory. Before use, insert the cable connector into the corresponding port on the middle ear analyzer main unit and connect the probe tube to the probe tube connector.

For contralateral reflex testing, plug the contralateral headphone into the 3.5mm headphone jack on the controller.

It is recommended to perform a daily probe check to ensure the system is functioning properly for testing.

3.2.3 Connecting PC

To connect the middle ear analyzer to a PC, the host computer software for the middle ear analyzer must be installed on the PC. The host computer software and installation instructions are stored on the included USB flash drive.

3.2.4 Printer

The built-in printer is located on the back of the middle ear analyzer main unit and is controlled from the device's keypad panel.

The method for replacing the paper roll is shown in the figure below:

Step 1: Gently release the rotating lever from the position indicated by the arrow in the figure.

Step 2: Continue to turn the lever. At this point, the platen roller will separate from the print head, opening the paper compartment cover.

Step 3: Load the paper roll and pull out a section of paper until it extends slightly past the tear bar. Ensure the paper is loaded neatly, with the smooth side facing up.

Step 4: Close the paper compartment cover and push the rotating lever back into place to reset it.

4.ACTUAL TEST

4.1 New Test

Press  to create a new test. The default screen is the Tympanometry test interface. Select the test population based on the subject: "Adult", "Child", or "Infant". After highlighting the desired test population with the cursor, fit the probe. The default screen after creating a new test is shown in Figure 4-1.

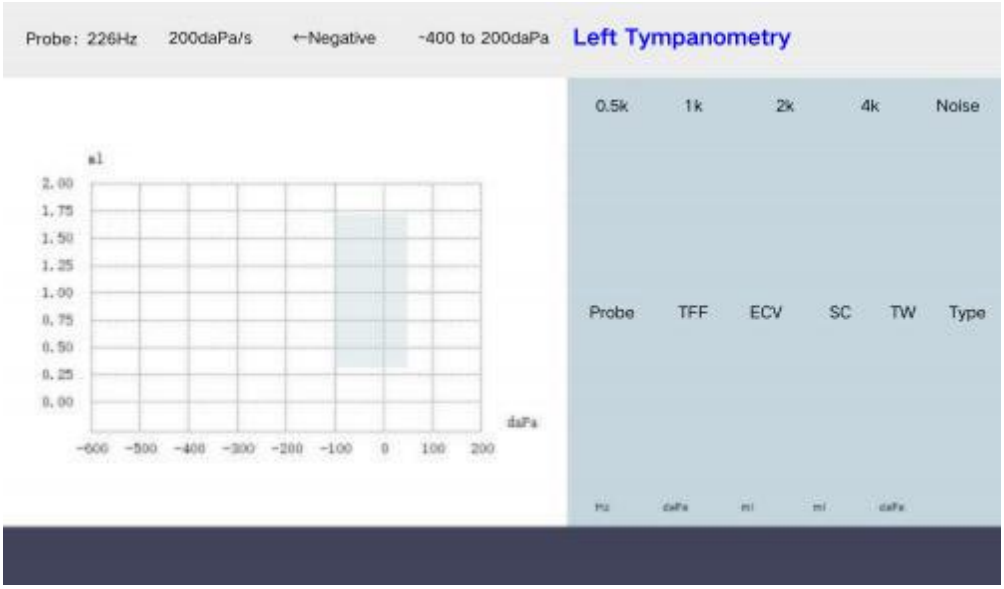


Figure 4-1 Default screen after creating a new test

4.2 Probe Placement

Select an ear tip of appropriate size for the subject and attach it to the probe. Place the shoulder strap over the shoulder on the same side as the subject's test ear. Then, insert the probe into the subject's ear. When inserting, ensure the probe fits snugly, with no air leaks and no blockage. If a leak or blockage occurs, a dialog box will appear on the screen and will automatically disappear after 3 seconds. The dialog boxes for probe abnormality alerts are shown in Figure 4-2-1 and Figure 4-2-2. The operation diagram is shown in Figure 4-2-3.

Figure 4-2-1 Probe Blockage Alert

Figure 4-2-2 Probe Leak Alert

Figure 4-2-3 Operation Diagram

4.3 Tympanogram（Tymp）

After the probe is properly fitted, press the button ▶/⏸ on the device to perform the tympanometry test according to the preset parameters. Press ⇆ to switch between the left and right test ears. The tympanometry test screen is the same as shown in Figure 4-3-1.

After the test is complete, select the test data and press the OK button. Rotate the knob to edit the data, with options including "Edit TPP" and "Change Type". After making a selection, press the knob. Rotate the knob to modify the result, and press the knob again to exit the modification mode. Once modifications are complete, move the cursor to "Save" and press the OK button to save the changes. The data editing interface is shown in Figure 4-3-1.

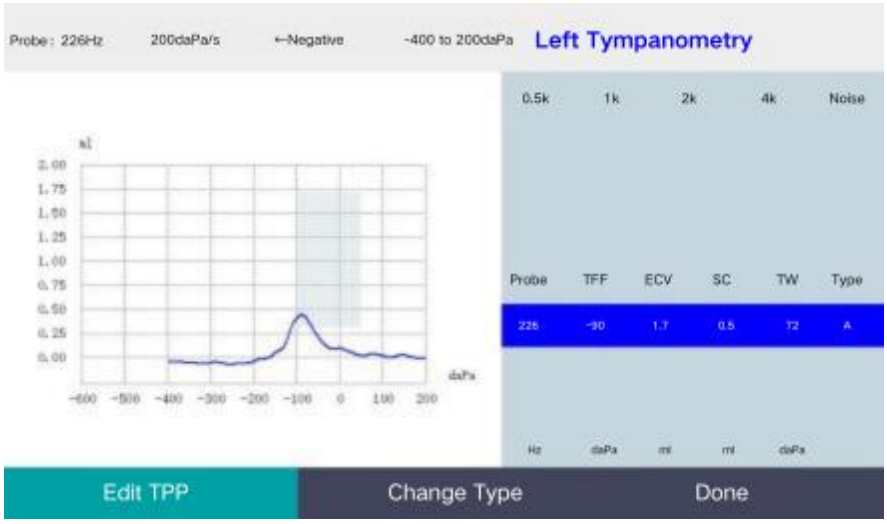


Figure 4-3-1 Tympanometry Data Editing Screen

If the subject experiences discomfort during testing, press the button ▶/⏸ on the device or the button ▶/⏸ on the probe controller attached to the shoulder strap again. The test will be interrupted, and the pump pressure will be released immediately. When the test is stopped, the results of this test will not be saved.

To delete curve data, first use the knob to select the desired curve data. Then press the button 🗑 a dialog box will appear prompting you to confirm the deletion. Follow the prompts by pressing the button 🗑 again to delete the data or pressing the button ⏏ to cancel the deletion. The data deletion confirmation screen is shown in Figure 4-3-2.

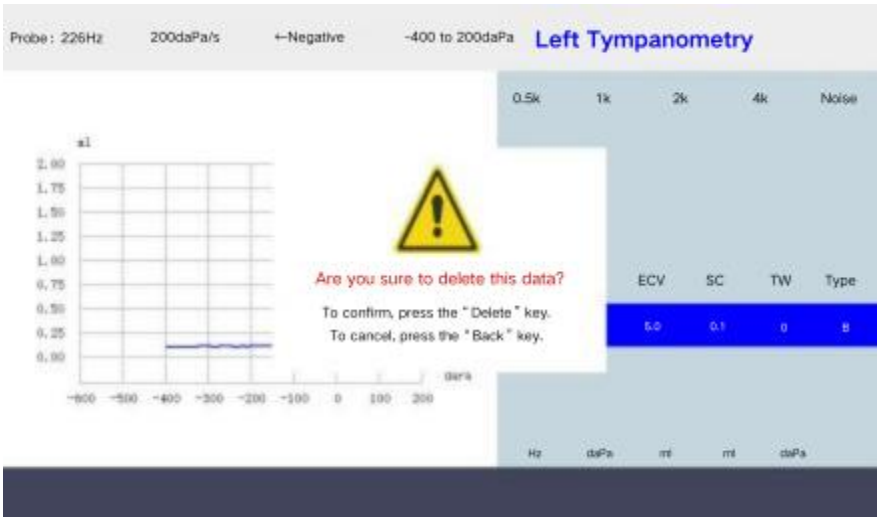


Figure 4-3-2 Tympanometry Data Deletion Prompt Screen

4.4 Manual Reflex threshold test

When the sequence test is off (i.e., the button Seq. indicator light is off), press the Ipsi or Contra button on the tympanometry screen to switch to the reflex threshold test screen, as shown in

Figure 4-4-1. Press to switch between the left and right test ears. Select the desired test frequency using the five buttons 0.5k 1k 2k 4k Noise. Move the cursor to "80 dB HL" in the lower right corner and press the knob to enter editing mode. Rotate the knob to select the test hearing level. To avoid test interruption due to high stimulus intensity levels when reaching the warning limit during automatic testing, it is recommended to set the maximum intensity to 100 dB HL. A warning message will appear when the sound intensity level exceeds the warning level (>100 dB HL)

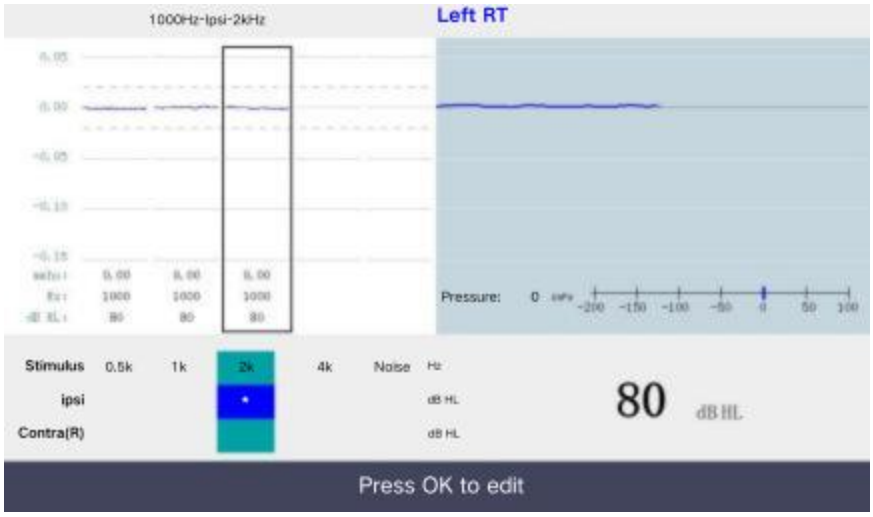


Figure 4-4-1 Left Ear Reflex Threshold Test

When manually testing the reflex threshold, the test result must be determined based on the test graph. Select the test graph and press the knob to set the current test hearing level as the threshold level. After setting, the cursor will switch to "Save". Press the knob to save the setting. The interface for editing threshold information is shown in Figure 4-4-2.

Figure 4-4-2 Reflex Threshold Editing Screen

Press Contra to switch to testing the contralateral ear. The headphones must be worn at this time.

When necessary, pressure compensation can be applied to stabilize test results: press ±P and hold the button, then turn the knob to set the desired pressure.

If the subject experiences discomfort during testing, press the button ▶/⏸ on the device or the button on the probe controller attached to the shoulder strap again. The test will be interrupted, and the pump pressure will be released immediately. When the test is stopped, the results of this test will not be saved.

To delete curve data, first use the knob to select the desired curve data. Then press the button 🗑 ; a dialog box will appear prompting you to confirm the deletion. Follow the prompts by pressing the button 🗑 again to delete the data or pressing the button ⏏ to cancel the deletion.

4.5 Combined（Seq.）

Press the button Seq. to select any combination of test items. After pressing the start button, the tests will be performed in the following order: tympanometry test, reflex threshold test, and contralateral test.

4.6 Special test

Press ⊞ to enter the special tests selection screen. This screen includes "Reflex Decay Test", "Manual Tympanometry Test", "Probe Check", and "Admittance Calibration". Selections can be made using the knob.

Figure 4-6-1 Special Tests Screen

4.6.1 Acoustic Reflex Threshold

On the Special Tests screen, select "Reflex Decay Test" and press the knob to enter the test interface. After adjusting the test hearing level, press the start test button to begin. The reflex decay test is a suprathreshold test in which the stimulus level is maintained at a high level for an extended period. Ensure there are no contraindications before performing this test.

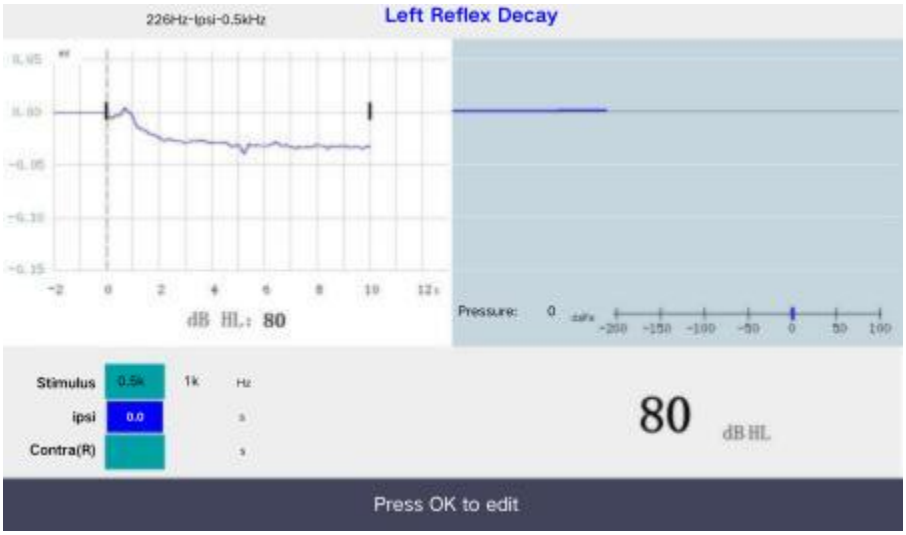


Figure 4-6-1-1 Reflex Decay Test Screen

After the test is complete, select the test data and press the OK button. Rotate the knob to edit the results. You can choose to "Adjust Half-Life Marker" or "Hide Half-Life Marker". The reflex decay editing screen is shown in Figure 4-6-1-2

Figure 4-6-1-2 Reflex Decay Editing Screen

4.6.2 Manual Tympanogram

On the Special Tests screen, select "Manual Tympanometry Test" and press the OK button to enter the test interface.

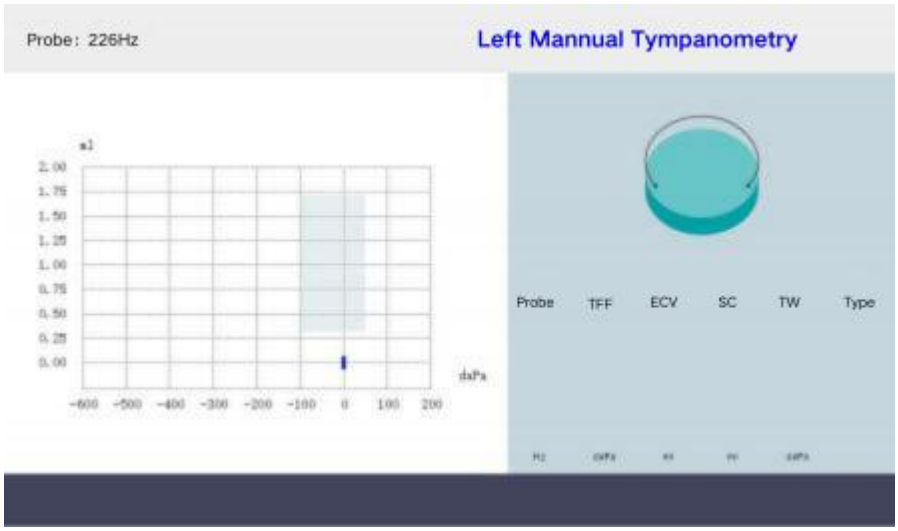


Figure 4-6-2-1 Manual Tympanometry Test Screen

Press the button ▶ / ⏸ to start the manual tympanometry test. Rotate the knob to increase or decrease the pressure. When the test starts, the curve will refresh in real-time, and the status bar at the top will display real-time information on the current pressure and compliance values. Press the button again to complete the test. The test result will be saved if the range covers at least +200 daPa; otherwise, the result will not be updated. The manual tympanometry screen during testing is shown in Figure 4-6-2-2.

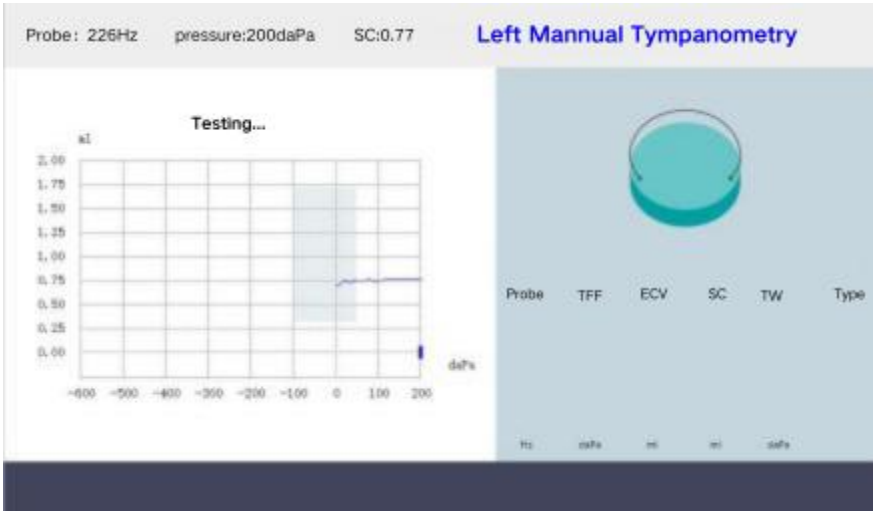


Figure 4-6-2-2 Manual Tympanometry Screen During Testing

4.6.3 Probe Test

If the testing environment changes (e.g., temperature increase) or if testing is to be conducted at a different altitude, a probe check should be performed to ensure the system is functioning correctly for testing. The specific steps for the probe check are as follows:

Before inserting the probe tip into the test cavity, use a new probe tip, or ensure that the probe tip has been cleaned and disinfected. (This is to ensure that the probe tip does not affect the test and that the test cavity is not contaminated.)

Insert the probe tip without an ear tip into the 2cc test cavity.

Select the probe check function: On the Special Tests screen, select "Probe Check" and press the OK button to enter the probe check test interface.

The control bar at the bottom of the probe check interface contains three control options: "Go to Admittance Calibration", "Start", and "Exit". These can be selected by rotating the knob. Highlight "Start" with the cursor and press the knob to begin the probe check. The probe check preparation screen is shown in Figure 4-6-3-1.

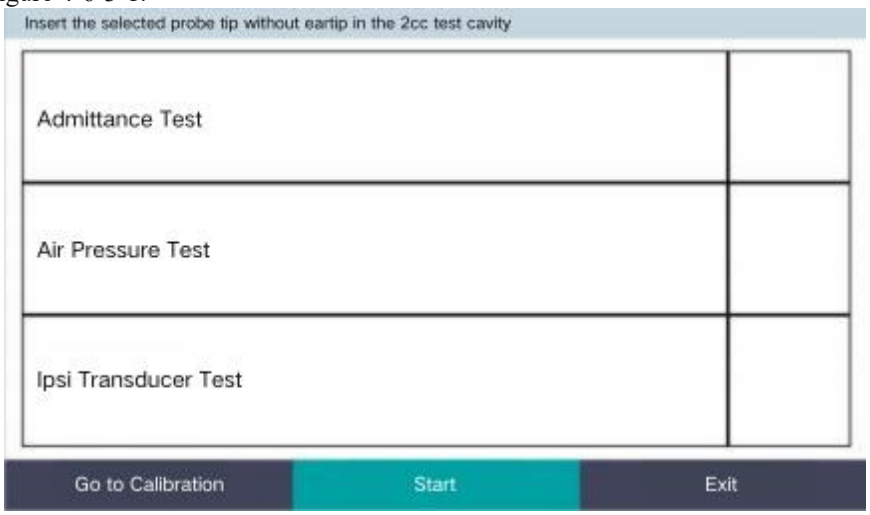


Figure 4-6-3-1 Probe Calibration Preparation Screen

During the probe check, you can press the OK button again to stop the probe check. The interface is shown in Figure 4-6-3-2.

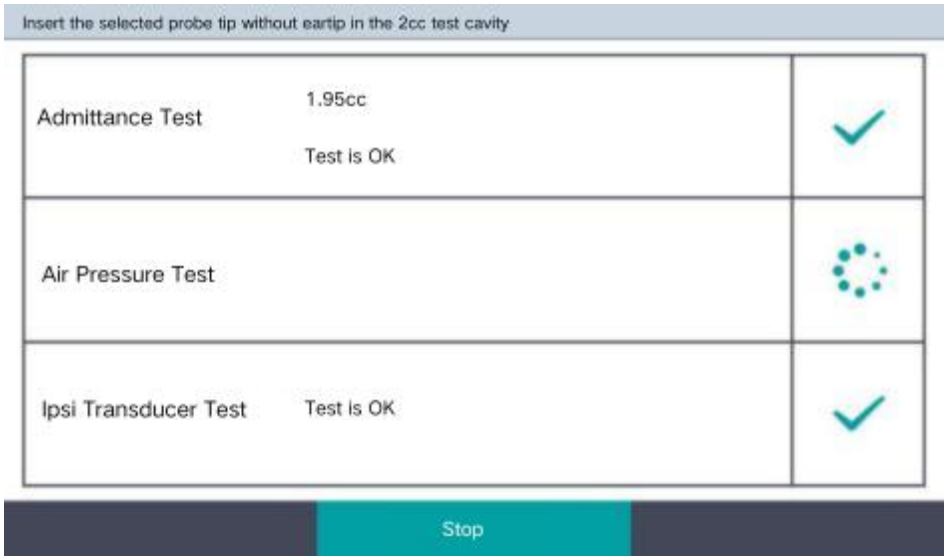


Figure 4-6-3-2 Probe Check in Progress Screen

If, after the probe check, the admittance test result is found to be out of specification (the probe admittance test is considered acceptable when the displayed value is between 1.90 cc and 2.10 cc; otherwise, it is unacceptable), you may select "Go to Admittance Calibration". For the admittance calibration procedure, refer to section 4.6.4.

If there are any doubts about the result, clean or replace the probe and press the OK button again to restart. If the test continues to fail, contact the service department for repair. The probe check complete screen is shown in Figure 4-6-3-3.

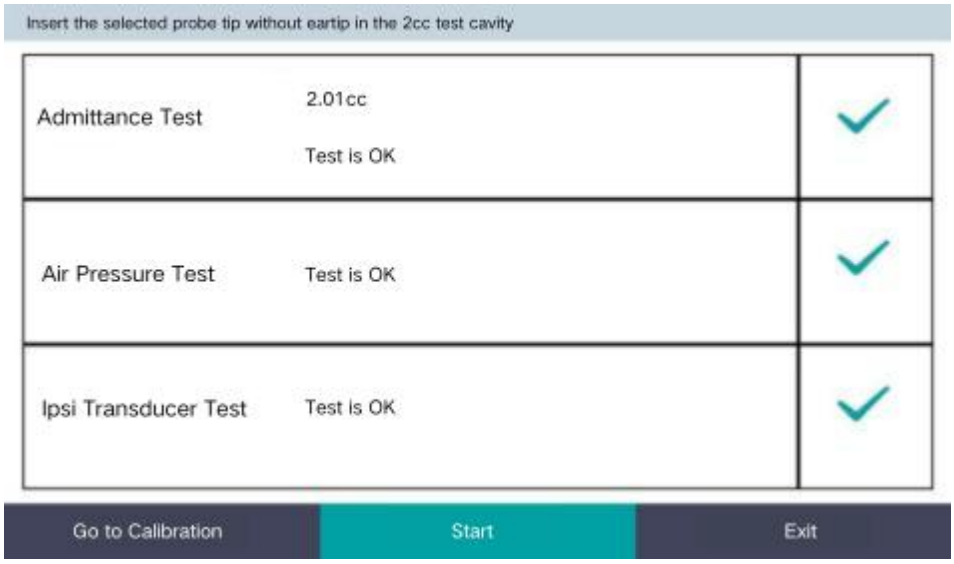


Figure 4-6-3-3 Probe Check Complete Screen

4.6.4 Admittance Calibration

On the Special Tests screen, select "Admittance Calibration" and press the knob to enter the test interface. Highlight "Start" with the cursor and press the knob to begin the admittance calibration.

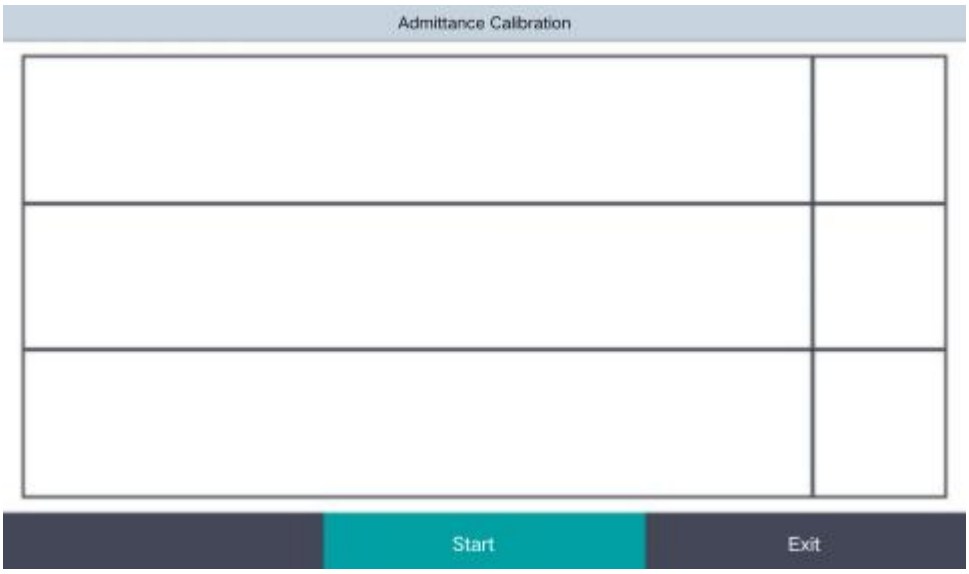


Figure 4-6-4-1 Admittance Calibration Preparation Screen

After admittance calibration begins, follow the calibration items and the prompt in the upper left corner to replace the calibration cavities one by one for calibration.

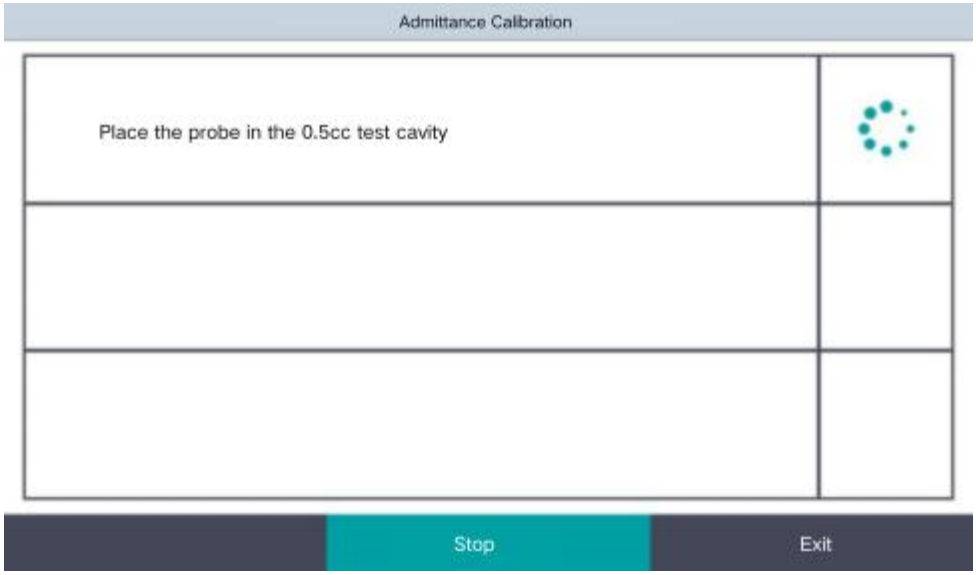


Figure 4-6-4-2 Admittance Calibration in Progress

After admittance calibration begins, if there are any doubts about the result, press the OK button again to restart. The interface is shown in Figure 4-6-4-3.

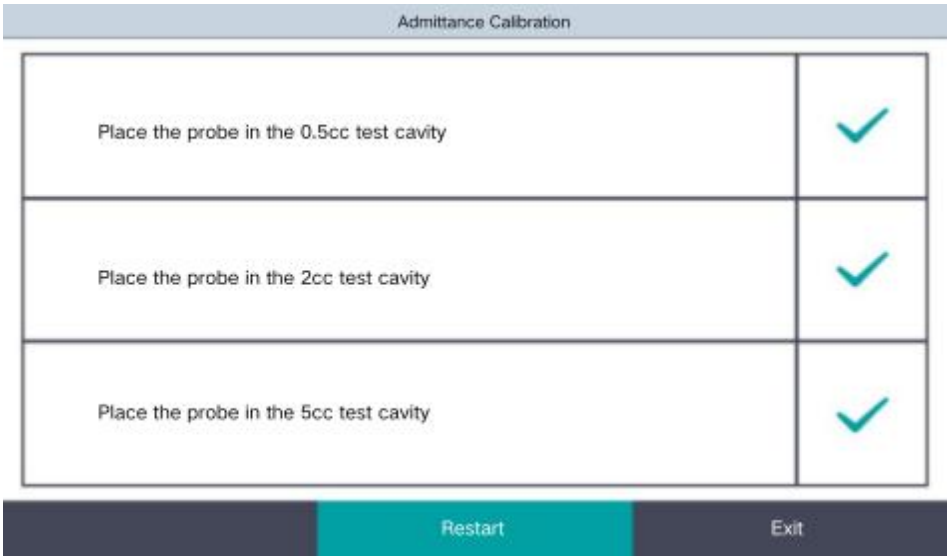


Figure 4-6-4-3 Admittance Calibration Complete

5.SETTING

Press to enter the Settings screen. The screen is divided into three columns. Rotate the knob to select a tab, press the OK button to move to the next column, and press the button to return to the previous column.

The left column displays predefined "Test Protocols" and "Device Settings options".

The middle column displays "Test Settings options".

The right column displays the specific parameter values corresponding to the selected "Test Settings option".

Figure 5-1 Setting screen

5.1 Protocol Settings Options

1）Probe tones：The probe tone frequency emitted by the probe has two options: "226Hz" and "1000Hz".

2）Protocol：Used to set whether the device performs combination testing, with two options: "On" and "Off".

3）Auto Scaling: Used to set whether the axes automatically scale according to the actual height of the curve, with two options: "On" and "Off".

4）Pump Speed：Used to set the pump speed for tympanometry testing, with five options: "50", "100", "200", "400", and "600".

5）Sweep Direction: Used to set whether the tympanometry test starts with pressurization from negative pressure or rarefaction from positive pressure, with two options: "Positive" and "Negative".

6）Tympanometry Stop Criterion: Used to set whether the curve stops plotting when the ordinate reaches 0, with two options: "None" and "Y-value reaches 0".

7）Pressure Range：Used to set the pressure range for tympanometry testing, with three options: "-200 to 200", "-400 to 200", and "-600 to 200".

8）Protocol Test Type：Used to set whether the combination test performs a simple screening or a formal diagnosis, with two options: "Screening" and "Diagnosis".

9）Baseline Compensation: Used to set whether the tympanogram is compensated downward based on the ear canal volume, with two options: "On" and "Off".

10）Scale: Used to set the vertical axis of the tympanogram, with two options: "0.0 to 2.0" and "0.0 to 6.0".

11）Gradient: Used to set whether the gradient information of the tympanometry result is expressed as pressure width or as a percentage, with two options: "Tympanic Width" and "Gradient Ratio".

12）Overwrite Existing Test Data: Used to set whether tympanometry results are automatically overwritten, with two options: "On" and "Off"

13）Step：Single-step increment for adjusting the sound pressure level on the reflex threshold interface, with three options: "1", "2", and "5".

14）Pre-Stimulus Timing for Reflex Threshold: The waiting duration before the stimulus begins in the reflex threshold test, adjustable within a range of 0.24 s to 3 s.

15）Stimulus Timing for Reflex Threshold: The duration of the stimulus in the reflex threshold test, adjustable within a range of 0.72 s to 3 s.

16）Post-Stimulus Timing for Reflex Threshold: The duration to continue waiting after the stimulus in the reflex threshold test, adjustable within a range of 0.6 s to 3 s.

17）Reflex Threshold Deflection Scale: Sets the scale of the vertical axis for the reflex threshold, with four options: "-0.15 to 0.05", "0.15 to -0.05", "-0.30 to 0.10", and "0.30 to -0.10".

18）Pre-Stimulus Timing for Reflex Decay: The waiting duration before the stimulus begins in the reflex decay test, adjustable within a range of 0.4 s to 2.0 s.

19）Stimulus Timing for Reflex Decay: The duration of the stimulus in the reflex decay test, adjustable within a range of 2.0 s to 10.0 s.

20）Post-Stimulus Timing for Reflex Decay: The duration to continue waiting after the stimulus in the reflex decay test, adjustable within a range of 0.6 s to 3 s.

21）Reflex Decay Deflection Scale: Sets the scale of the vertical axis for reflex decay, with eight options: "-0.15 to 0.05", "0.15 to -0.05", "-0.30 to 0.10", "0.30 to -0.10", "-0.6 to 0.20", "0.6 to -0.20", "-1.20 to 0.40", and "1.20 to -0.40".

22）Test Combination Selection: Options for combination testing, with five choices: "Tympanometry", "Tympanometry + Reflex Threshold", "Tympanometry + Reflex Threshold + Reflex Decay", "Reflex Threshold", and "Reflex Threshold + Reflex Decay".

23）Stimulus Selection: Selects the stimulus for the reflex threshold test, with options including "0.5 kHz", "1 kHz", "2 kHz", "4 kHz", and "Noise", available for single or multiple selection.

24）Ipsilateral/Contralateral: Selects the laterality for the reflex threshold test, with options including "Ipsilateral" and "Contralateral", available for single or multiple selection.

25）0.5 kHz Screening Level: The starting stimulus level for the 0.5 kHz reflex screening test, adjustable within a range of 70 to 100.

26）1 kHz Screening Level: The starting stimulus level for the 1 kHz reflex screening test, adjustable within a range of 70 to 100.

27）2 kHz Screening Level: The starting stimulus level for the 2 kHz reflex screening test, adjustable within a range of 70 to 100.

28）4 kHz Screening Level: The starting stimulus level for the 4 kHz reflex screening test, adjustable within a range of 70 to 100.

29）Noise Screening Level: The starting stimulus level for noise in the reflex screening test, adjustable within a range of 50 to 90.

30）Screening Increment: Indicates the number of times the stimulus level can be increased in 5 dB steps during reflex screening (provided the maximum hearing level of 100 dB HL is not exceeded), adjustable within a range of 1 to 3.

31）Threshold Criterion: Indicates the amount of admittance change required to identify a response in the reflex threshold test, adjustable within a range of 0.01 to 0.05.

32）Threshold Validation: Indicates whether further validation is performed upon reaching the reflex threshold in the reflex threshold test, with four options: "None", "Repeat", "Proceed to Next Level", and "Proceed to Next Two Levels".

33）Hearing Level Pure Tone Start Level: The starting hearing level for the pure tone stimulus in the reflex threshold test, adjustable within a range of 50 to 90.

34）Hearing Level Pure Tone Maximum Level: The maximum hearing level for the pure tone stimulus in the reflex threshold test, adjustable within a range of 90 to 120.

35）Threshold Noise Start Level: The starting hearing level for the noise stimulus in the reflex threshold test, adjustable within a range of 50 to 80.

36）Threshold Noise Maximum Level: The maximum hearing level for the noise stimulus in the reflex threshold test, adjustable within a range of 80 to 120.

37）Decay Ipsilateral/Contralateral: Selects the laterality for the reflex decay test, with options including "Ipsilateral" and "Contralateral", available for single or multiple selection.

38）Decay Stimulus: Selects the stimulus for the reflex decay test, with options including "0.5 kHz" and "1 kHz", available for single or multiple selection.

5.2 Save Protocol

After selecting a protocol and configuring the desired parameters, return to the left column. Use the knob to move the cursor to the "Save to '*'" tab and press the OK button to save the protocol. The next time the instrument is powered on, it will restore the parameters according to this configuration. The protocol save screen is shown in Figure 5-2-1.

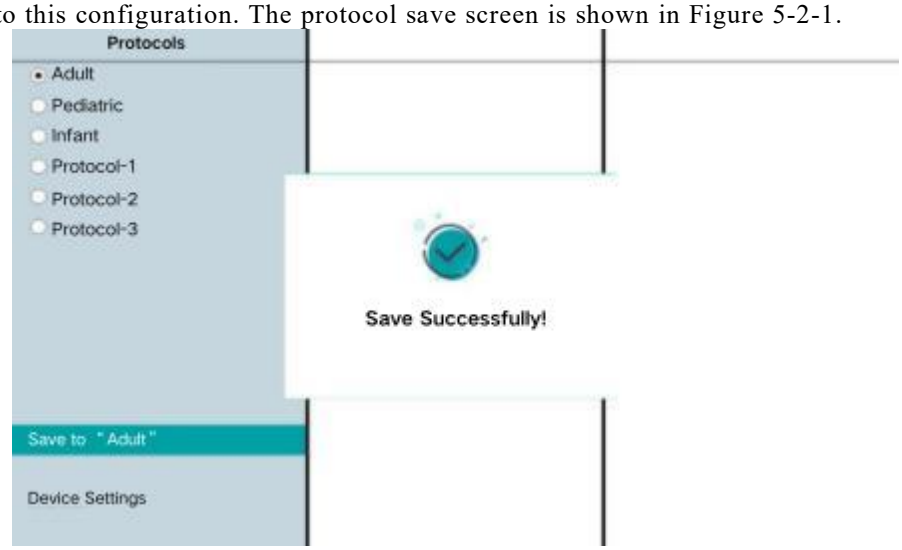


Figure 5-2-1 Protocol Save Screen

5.3 Device Settings Options

1）Admittance Calibration: After pressing the OK button, you can switch to the "Admittance Calibration" screen, as shown in Figure 4-6-4-1.

2）Probe Check: After pressing the OK button, you can switch to the "Probe Check" screen, as shown in Figure 4-6-3-1.

3）226Hz Units: When 226Hz is used as the probe tone signal, the unit of the vertical axis can be freely set. There are three options: "ml", "cc", and "mmho".

4）Time and Date: After pressing the OK button, you can switch to the "Time and Date" screen. The time can be adjusted and saved by rotating the knob and pressing the OK button, as shown in Figure 5-3-1.

Figure 5-3-1 Time and Date Screen

5）Calibration Reminder: Sets the number of days in advance to remind the user before the annual calibration is due, adjustable within a range of 0 to 60. When the admittance calibration is due, the reminder screen will appear directly upon startup. Press the OK button again to return to the normal test screen. The calibration due reminder screen is shown in Figure 5-3-2.

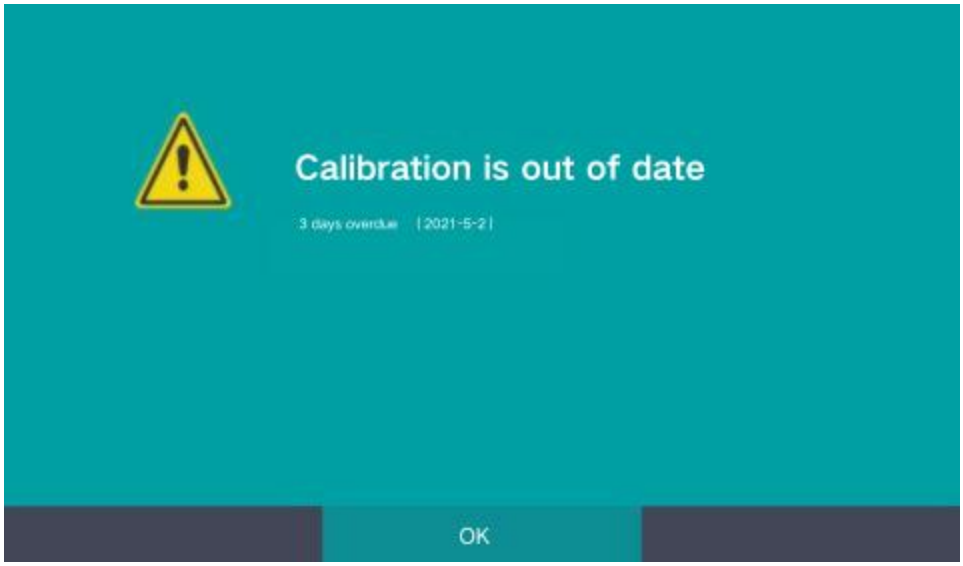


Figure 5-3-2 Admittance Calibration Overdue Reminder Screen

6）About Device: After pressing the OK button, you can switch to the "About Device" screen to view information related to the main unit. Press the OK button again to return to the Settings screen. This is shown in Figure 5-3-3.

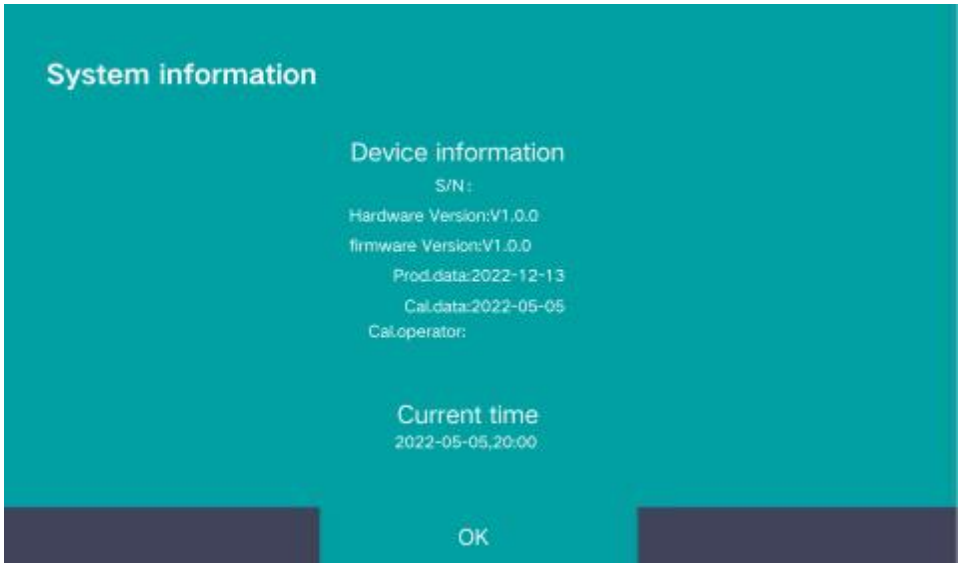


Figure 5-3-3 About Device Screen

7）Restore Factory Settings: After pressing the OK button, you can switch to the "Restore Factory Settings" screen. You can use the knob and the OK button to choose whether to restore the factory settings. This is shown in Figure 5-3-4.

Figure 5-3-4 Restore Factory Settings Screen

6.PRINT PREVIEW

From any test screen, press to enter the print preview screen. A diagram of the print preview screen is shown in Figure 6-1.

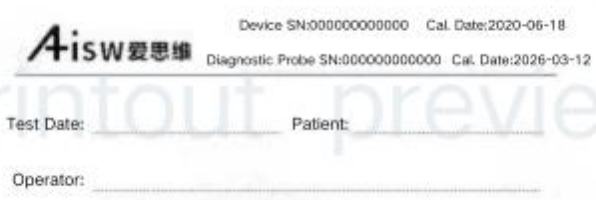


Figure 6-1 Print Preview Screen

On the print preview screen, press the OK button to start the thermal printer and print the report. If printing is not required, press the or button again to exit the print preview screen.

7.CALIBRATION

Probe Check

Changes in ambient temperature and atmospheric pressure can affect impedance measurement results. The operator should perform a probe check daily. When the probe check result deviates by more than 0.1 cm^3 , an admittance calibration should be performed.

Annual calibration is required.

Your authorized service department must perform an annual calibration of the device and probe.

8. CLEAN AND MAINTENANCE

1. The instrument should be used in a clean, quiet environment. It is recommended to perform maintenance on the instrument weekly.

2. After contralateral testing, wipe and disinfect the headphones with a medical alcohol cotton ball.

3. Always unplug the power cord before cleaning the instrument.

4. During cleaning, ensure that no liquids enter the instrument's control keys, connectors, headphones, or accessories.

5. Clean with care to prevent parts from dropping or vibrating, which could alter calibration values.

6. Acoustic transducer components are calibrated. If any acoustic transducer component is replaced, recalibration is required.

7. The probe and headphone cables are susceptible to damage from pulling. Handle with care during use and arrange for repair promptly if damaged.

8. After each use of the probe, inspect the sound bore at the probe tip. If earwax or sebum is present in the sound bore, clean it.

9. To prevent cross-infection, use a new ear tip for each new patient.

10. It is recommended to check the seal of the probe tube connection weekly to ensure a tight fit between the probe tube and the probe tube connector.

9. GENERAL PRECAUTIONS AND TROUBLESHOOTING

9.1 Contraindications

This device is not suitable for patients with the following conditions:

1. Severe infection of the external auditory canal;

2. Blockage of the ear canal;

3. Acute ear trauma.

9.2 Notice and Instructions

1. Avoid dropping accessories such as the probe to prevent altering calibration values.

2. The recommended calibration interval for this device is 1 year.

3. The normal service life of this device is eight years.

4. After the normal service life of this product has ended, please dispose of it in accordance with local environmental protection laws and regulations.

5. Do not store or operate the device in environments exceeding the temperature and humidity specifications stated in the "Storage" and "Operating Environment" technical specifications.

9.3 Simple Contraindications

9.3.1 Power not Connected

If the display screen does not illuminate after turning on the middle ear analyzer, please check if the power plug is loose and if the adapter is functioning properly.

9.3.2 Probe failure

Test abnormalities may occur due to the following issues:

1. Incorrect ear tip size;

2. Incorrect probe placement in the ear canal;

3. Probe blocked by the ear canal wall.

9.3.3 Printer out of paper

If the test results cannot be printed, please check if the printer is out of paper.

9.4 Repair and Part Replacement

Caution! This equipment should only be serviced by the device manufacturer or by service personnel from an authorized repair organization.

9.4.1 Fuse and other part Replacement

Components that may be damaged during use:

GSM36B12-P1J-12V Power Adapter: If damaged during normal use, contact the manufacturer for a replacement.

Probe: The probe is permanently connected to the device and should only be replaced or repaired by authorized service technicians.

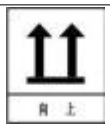
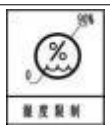
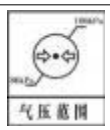
Fuse: None

9.4.2 Warrantly

The device should only be serviced by qualified technical personnel. For servicing, our company can provide circuit diagrams, component lists, and other technical documents upon request. Users may also return the device to our company for repair.

10. LABLE INSTRUCTIONS AND TERMINOLOGY EXPLANATION

10.1 Lable Notices

Explanation	
	Calss II Equipment
	Type B applied parts
	Refer to instruction manual
	Do Not Sit
	Do Not Step On
Symbols on packaging	
	Keep dry
	This way up
	Fragile, handle with care
	Maximum stacking layers: 4
	Storage temperature range:-10℃-50℃
	Storage humidity range: 0-90%
	Storage atmospheric pressure range: 86kPa-106kPa
	Do not re-use

	CPA Mark (Pattern Approval Certification)

10.2 Terminology explanation

1）**dB HL**

Hearing Level: For a specified transducer type, at a specified frequency and in a specified mode of application, the sound pressure level or vibratory force level produced by the transducer in a specified ear simulator or mechanical coupler, minus the corresponding Reference Equivalent Threshold Sound Pressure Level (RETSPL) or Reference Equivalent Threshold Force Level (RETFL).

2）**鼓室测量 Tympanometry**

Measurement of the change in acoustic immittance in the external ear canal as a function of air pressure.

3）**鼓室图 Tympanogram**

A graphical representation showing the change in acoustic immittance in the external ear canal as a function of air pressure.

4）**声反射 Acoustic Reflex**

The middle ear muscle reflex evoked by acoustic stimulation.

5）**cc**

Unit of volume measurement, expressed in cm^3.

6）**mmho**

Millimho, the unit of acoustic admittance.

7）**daPa**

daPa, the unit of air pressure measurement, where 1 daPa = 10 Pa.

8）**TPP**

Tympanometric Peak Pressure: The air pressure value corresponding to the peak of the tympanogram, expressed in daPa.

9）**ECV**

Ear Canal Volume: The ear canal volume is represented by the compliance value at +200 daPa, expressed in cm^3.

10）**SC**

Static Compliance: The static compliance is represented by the compliance value at the peak pressure point minus the ear canal volume, expressed in cm^3.

11）**TW**

Full English Name is Tympanum width.

12）**NR**

No Reflex: Full English name:No Reflection.

13）**SA**

Static Admittance: The static admittance is represented by the admittance value at the peak pressure point minus the ear canal volume, expressed in mmho.

11.WARRANTY STATEMENT

The AiSW 2101 Middle Ear Analyzer is warranted against defects in materials and workmanship for a period of 1 year from the date of purchase, provided that the instructions in this manual are followed.

If a malfunction occurs under normal use conditions as outlined in the instruction manual, please contact the warranty service provider immediately with your warranty card. Repairs will be performed free of charge during the warranty period upon presentation of the card. The warranty service provider reserves the right to refuse warranty service if the warranty card is not presented or if the warranty registration card has not been received.

During the warranty period, repairs will also be subject to a charge under the following circumstances:

1. Damage caused by human error or accident.
2. Damage resulting from unauthorized disassembly or repair by the customer.
3. Damage caused by improper use or operation.

After the warranty period expires, the company will continue to provide repair services for users, and repair fees will be charged as appropriate.

12. ELECTROMAGNETIC COMPATIBILITY DECLARATION

This product's electromagnetic compatibility shall comply with the requirements of YY 9706.102-2021 and GB/T 7341.5-2018. EMC standards are established for the safe use of medical electrical equipment. These standards stipulate that electromagnetic waves generated by the equipment must be controlled within a certain range to avoid interfering with other devices, and that the device's immunity to electromagnetic wave interference from other equipment (such as mobile phones) must also be controlled within a certain range. YY 9706.102-2021 (Clause 5.2.1) specifies that detailed information regarding the EMC environment necessary for the safe operation of the equipment must be provided to the user. The following is a description of the relevant EMC technical specifications. (For details, please refer to YY 9706.102-2021.)

When this product operates within the electromagnetic environment specified in this EMC technical documentation, its essential performance, as described in the intended use, will not be affected.

EMC (Electromagnetic Compatibility) refers to the ability to satisfy the requirements of the following two aspects:

① It does not emit electromagnetic interference noise beyond the permissible limits to other electronic devices in the vicinity. (Emission)

② It functions normally within the electromagnetic environment, including interference such as noise from other electronic devices. (Immunity) Technical Specifications Related to EMC (Electromagnetic Compatibility):

●Caution: Portable and mobile RF communications equipment may affect the normal operation of this instrument.

●Caution: The user is responsible for ensuring the electromagnetic environment of the equipment to enable the normal operation of this instrument.

●Caution: The use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

●Caution: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of the AiSW 2101 Middle Ear Analyzer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment.

●Caution: The AiSW 2101 Middle Ear Analyzer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

● Essential Performance:

Ipsilateral Mode: The probe provides a 226 Hz pure-tone probe tone, with a sound pressure level of 85 dB ± 5 dB.

Contralateral Mode: When the stimulus is presented through the contralateral headphones, the 226 Hz pure-tone probe tone provided by the probe shall still have a sound pressure level of 85 dB ± 5 dB.

13. TECHNICAL SPECIFICATIONS

Test System

Probe tone

226Hz (85dB SPL ±5dB)；

1kHz(70dB SPL ±5dB)；

THD：≤1%；

Frequency Accuracy：≤1%；

Measurement Range

Flat Tympanogram: 0.2 mL to 5 mL ± 5% or 0.1 mL (whichever is greater).

Compensated Tympanogram: 0 mL to 2 mL ± 5% or 0.1 mL (whichever is greater).

The deviation between dynamic and static measurement methods shall not exceed ±0.1 mL.

Altitude Correction

The admittance of the cavity is affected by atmospheric pressure. When the atmospheric pressure changes, the relationship between mmho and ml also changes. The following table can be used to calculate the difference.

Altitude（m）	mmho Increment（%）
0	0
500	6
1000	13
1500	20
2000	27
2500	36
3000	45

Note: The sound pressure level of the probe signal does not vary with the load volume.

The specified accuracy requires that calibration be performed at the altitude where the device is put into operation.

Acoustic Reflex

Pure-tone：500Hz 、1000Hz 、2000Hz 、4000Hz；

Frequency Accuracy： ≤ 1%；

THD：

Insert Earphones：Below 100dB HL： ≤5%

Supra-aural Headphones：Below 110dB HL： ≤2.5% ， Above 110dB HL ： ≤5%

Sensitivity: Selectable from 0.01 mL, 0.02 mL, 0.03 mL, 0.04 mL, or 0.05 mL.

Note: Artifactual changes may be displayed synchronously with the evoked stimulus!

Step：Selectable from 1dB 、2dB or 5dB；

Stimulus Level：

Minimum Hearing Level Range for Different Stimulus Signals

Stimulus Signal	500Hz～2000Hz	4000Hz	Noise
Hearing Level Range for Supra-aural Headphones (dB)	50～120	50～120	50～115
Hearing Level Range for Insert Earphones (dB)	50～100	50～80	50～90

Stimulus Level Control Accuracy: For supra-aural headphones, in the frequency range of 500 Hz to 4000 Hz, the deviation of the sound pressure level produced by the stimulus transducer from the indicated value on the stimulus level control at any setting shall be within ±3 dB. For noise stimuli, the deviation shall be within ±5 dB. For insert earphones or probe earphones, in the range of 500 Hz to 2000 Hz, the deviation shall be within ±5 dB; at 4000 Hz, it shall be within +5 dB to -10 dB.

Broadband Noise Spectrum: Within the frequency range of 500 Hz to 4000 Hz, the non-uniformity of the spectral sound pressure level relative to 1000 Hz shall not exceed ±5 dB for supra-aural headphones and shall not exceed ±10 dB for insert earphones.

Rise/Fall Time：

Rise Time/ms	"On" instant to steady-state value -1 dB	⩽100
	Steady-state value -20 dB to steady-state value -1 dB	⩾5
Fall Time/ms	Steady-state value to steady-state value -20 dB	⩽100
	Steady-state value -1 dB to steady-state value -20 dB	⩾5

Pulse Stimulus Characteristics: For pulsed stimulus signals, the rise and fall times shall not be less than 3 ms, and the interval between any two adjacent pulse signals shall not be greater than 100 ms.

On/Off Ratio and Signal-to-Noise Ratio: >70 dB SPL

Temporal Characteristics

Initial Latency/ms	5±2
Terminal Latency/ms	5±2
Rise Time/ms	30±5
Fall Time /ms	30±5
Overshoot / Undershoot	0%

Reference Equivalent Threshold Sound Pressure Level (RETSPL)

Frequency/Hz	Insert Earphones/dB	Supra-aural Headphones
500	5.5	11.5
1000	0	7
2000	3	9
4000	5.5	9.5

Pneumatic System

Pressure Range： -600daPa~ 200daPa；

Accuracy：±10daPa or ±10%， whichever is greater.

Pressure Change Rate: In a cavity volume of 0.5 cm^3 to 5 cm^3, a pressure change rate of at least 50 daPa/s shall be provided. The maximum permissible error is ±10 daPa/s

Maximum Limits：+600daPa and -800daPa

Graph Units

Graph Y-axis Unit：ml 、CC 、mmho；

Graph X-axis Unit：s 、daPa；

Display screen

Dimensions：10 inches

Resolution：1024*600

USB port connector

Type：USB Device Ports

Battery

External Power Supply： GSM36B12-P1J-12V

Output： 12V -- - 3A

Power consumption

Power Consumption：＜30VA

Warm-up time

Warm-up Time：＜5 min

Dimensions

Main unit：290mm*265mm*235mm

Probe：13mm*24mm*35mm

Probe Tube： ID 0.8mm*OD 1.9mm ， Cable Length 500mm

Weight

Main unit：3400g

Test Cable (contralateral headphone not included)）：370g

Applied part

Cable Probe

Biocompatibility

The materials of the supra-aural headphones and insert earphones that come into contact with the human body are both silicone, meeting the requirements for biological evaluation of medical devices.

Names and contents of hazardous substances in the product

Part name	Hazardous substances					
	Lead（Pb）	Mercury（Hg）	Cadmium（Cd）	Hexavalent chromium（Cr（VI））	Polybrominated biphenyls（PBB）	Polybrominated diphenyl ethers（PBDE）
Plastic housing	2mg/Kg	2mg/Kg	2mg/Kg	8mg/Kg	5mg/Kg	5mg/Kg
This table is prepared in accordance with the provisions of SJ/T 11364.						

Appendix A Guide and Manufacturer's Declaration

Table 1 Guidance and manufacturer's declaration — electromagnetic emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration — electromagnetic emissions</th></tr>
<tr><td colspan="3">The AiSW 2101 Middle Ear Analyzer is intended for use in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment—guidance</th></tr>
<tr><td>RF emissions
GB4824</td><td>Group 1</td><td>The AiSW 2101 Middle Ear Analyzer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference to nearby electronic equipment.</td></tr>
<tr><td>RF emissions
GB4824</td><td>Class A</td><td rowspan="3">The AiSW 2101 Middle Ear Analyzer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
GB17625. 1</td><td>Not Applicable</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
GB17625.2</td><td>Not Applicable</td></tr>
</table>

Table 2 Guidance and manufacturer's declaration — electromagnetic immunity

Guidance and manufacturer's declaration — electromagnetic immunity			
The AiSW 2101 Middle Ear Analyzer is intended for use in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
GB/T 17626.2 Electrostatic Discharge Immunity Test	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
GB/T 17626.4 Electrical Fast Transient/Burst Immunity Test	±2 kV power lines ±1 kV input/output lines	±2 kV power lines Not applicable	The mains power supply should be of the quality typically used in a commercial or hospital environment.
Surge GB/T 17626.5	±1 kV line to line ±2 kV line to ground	±1 kV line to line Not applicable	The mains power supply should be of the quality typically used in a commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines GB/T 17626.11	<5% UT, for 0.5 cycles (＞95% dip in UT) 40% UT, for 5 cycles (60% dip in UT) 70% UT, for 25 cycles (30% dip in UT) <5% UT, for 5 s (＞95% dip in UT)	<5% UT, for 0.5 cycles (>95% dip in UT) 40% UT, for 5 cycles (60% dip in UT) 70% UT, for 25 cycles (30% dip in UT) <5% UT, for 5 s (>95% dip in UT)	The mains power supply should be of the quality typically used in a commercial or hospital environment. If the user of the AiSW 2101 Middle Ear Analyzer requires continued operation during power interruptions, it is recommended that the AiSW 2101 Middle Ear Analyzer be powered by an uninterruptible power supply or a battery.
Power Frequency (50 Hz) Magnetic Field GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should have characteristics typical of the power frequency magnetic field level found in typical locations within a commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Table 3 Guidance and manufacturer's declaration — electromagnetic immunity

Guidance and manufacturer's declaration — electromagnetic immunity			
The AiSW 2101 Middle Ear Analyzer is intended for use in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Conducted RF GB/T 17626.6 Radiated RF GB/T 17626.3	3 V (rms) 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V（RMS） 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the AiSW 2101 Middle Ear Analyzer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** **d = 1.2** √**P** 80 MHz to 800 MHz **d = 2.3** √**P** 800 MHz to 2.7 GHz Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AiSW 2101 Middle Ear Analyzer is used exceeds the applicable RF compliance level above, the AiSW 2101 Middle Ear Analyzer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AiSW 2101 Middle Ear Analyzer. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4 Recommended separation distances between portable and mobile RF communications equipment and the AiSW 2101 Middle Ear Analyzer

Recommended separation distances between portable and mobile RF communications equipment and the AiSW 2101 Middle Ear Analyzer			
The AiSW 2101 Middle Ear Analyzer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AiSW 2101 Middle Ear Analyzer as recommended below, according to the maximum output power of the communications equipment.			
Maximum rated output power of transmitter W	**Separation distance corresponding to different frequencies of the transmitter / m**		
	150kHz～80MHz $d=1.2\sqrt{p}$	80MHz～800MHz $d=1.2\sqrt{p}$	800MHz～2.5GHz $d=2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed in the table above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Appendix B Configuration List

No.	Name	Model	Length/m	Quantity	Note
1	Power adapter	GSM36B12-P1J-12V	/	1	Ferrite Core
2	Power cord	PCD21072D75001	1	1	/
3	Air-Conduction Headphones	TDH-39P	0.5	1	/
4	Probe and cable	/	2	1	/
5	USB Cable	/	1.5	1	/
6	U Flash Drive	/	/	1	/
7	Silicone earplugs	Tapered，5.5-7.5mm，White Translucent	/	10	/
8	Silicone earplugs	Mushroom-shaped，10.0mm，7478U Light Green	/	10	/
9	Silicone earplugs	Mushroom-shaped 12.0mm，7402U Yellow	/	10	/
10	Silicone earplugs	Mushroom-shaped，14.0mm，333U Cyan	/	10	/
11	Silicone earplugs	Mushroom-shaped，16.0mm，230U Pink	/	10	/
12	Probe Assembly	AiSW 2101 Probe Tube	/	4	/
13	Instruction manual	/	/	1	/

杭州爱思维仪器有限公司

Registration Holder / Manufacturer Name: Hangzhou Asiwei Instrument Co., Ltd.

Registration Holder Address: Floor 5, Building 1, No. 37 Xianxing Road, Xianlin Subdistrict, Yuhang District, Hangzhou City, Zhejiang Province, China

Manufacturer Address: Area A, Floor 5, Building 1, No. 37 Xianxing Road, Xianlin Subdistrict, Yuhang District, Hangzhou City, Zhejiang Province, China

Medical Device Registration Certificate Number: Zhe Xie Zhun Zi 20242071993

Product Technical Requirements Number: Zhe Xie Zhun Zi 20242071993

Production License Number: Zhe Yao Jian Xie Sheng Chan Xu 20230101 Hao

Product Service Life: 8 Years

Date of Manufacture: See label

Batch Number: See label

After-sales Service Telephone: 0571-88695832

Website: www.hzaisw.com

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