Measure

# Instructions for Use

Auditdata

## Copyright notice



## Copyright © 2025, Auditdata A/S

Written in Denmark by Auditdata A/S, Denmark.

All information, illustrations, and specifications in this manual are based on the latest product information available at the time of publication.

Auditdata A/S reserves the right to make changes at any time without notice.

| Model | Product name |
|---|---|
| Primus Fitting Unit – PFU+ | Primus PFU+ (PFU+) |
| 2000 Primus Fitting Unit Pro | Primus Pro (PFU Pro) |
| 2000 Primus Audiometer Unit Ice | Primus Ice |
| 2000-1 Fitting Unit | Measure |
| 2000 Primus HIT Pro | Primus HIT Pro |

Auditdata

# 1 Introduction

This document aims to provide instructions on setting up Fitting and HIT Units as well as installing and configuring the software. It also includes essential information on safety measures, maintenance, and calibration.

The Fitting Unit is a general term combining PFU, PFU+, Primus Pro, Primus Ice, and 2000-1 FU hardware units. Please refer to the **Abbreviations and Terms** section for definitions of these units.

Up to version 4.2, the software was released under the name of Primus. The release following Primus 4.2 acquires the name Measure and the version number 6.0.

Depending on your purchased licenses, some of the modules described in this document might not be available in your version of software. Please contact your distributor to get more information on the licenses.

This document is not intended to be a complete reference. For detailed information, please refer to the Help file after installing the software.

# 2 Abbreviations and Terms

| Term | Definition |
|---|---|
| PFU | PFU stands for Primus Fitting Unit. This includes PFU, PFU+, and Primus Pro hardware units. These units are used to perform pure tone and speech measurements as well as REM and SM measurements. |
| Fitting Unit | Fitting Unit is the collective name for all fitting unit devices. |
| Primus Ice | Primus Ice is the name for Primus Audiometer Unit. This unit is used to perform pure tone and speech measurements only. |
| HIT | HIT stands for Hearing Instrument Test chamber. |
| AUD | Audiometry. |
| REM | Real Ear Measurements. |
| SM | Speech Mapping. |
| HTL | Hearing Threshold Level. Establishes the minimum level at which the client can detect the presence of a pure tone signal 50% of the time it is presented. |

| Model name | Product | Additional information |
|---|---|---|
| 2000 Primus Fitting Unit Pro | Primus Pro (PFU Pro) | PFU (Primus Fitting Unit) is the collective name for these devices: Primus Pro, Primus Ice and Primus PFU+ (2000 family of devices). |
| 2000 Primus Audiometer Unit Ice | Primus Ice | |
| Primus Fitting Unit – PFU+ | Primus PFU+ (PFU+) | |
| 2000 Primus HIT Pro (2005-1 HIT Unit) | Primus HIT Pro | Hearing instrument test unit. |
| 2000-1 Fitting Unit | Measure | 2000-1 FU stands for Type 2000-1 Fitting Unit. This Unit is in functionality very similar to the PFU and is also used to perform pure tone and speech measurements as well as REM and SM measurements.<br><br>In Measure software, the device is displayed as 2000-1 Fitting Unit (Measure Aud). |

# 3 Symbols Used

The following symbols are used in this document and/or on labelling on the device.

## Labels on Fitting Unit and HIT Unit

| | |
|---|---|
|  | Manufacturing date |
|  | Manufacturer's name and address |
|  | Disposal instructions |
|  | Serial Number |
|  | Reference Number |
|  | This device is a medical device |

## Labels only on Fitting Unit

| | |
|---|---|
|  | Type B applied parts.<br>Patient applied parts that are not conductive and can be immediately released from the patient. |
|  | Class II equipment |
|  | Follow operating instructions |
|  | Operating instructions |
|  | General warnings |
|  | CE - notified body |

## Labels only on HIT Unit

| | |
|---|---|
|  | Caution, please read the Instructions for Use and the User Manual |

CE

# 4 Compliance with Standards

Classification according Annex VIII of EU Medical Device Regulation MDR (EU) 2017/745:

| Device | Class | Rule | CE | GMDN | Basic UDI-DI |
|---|---|---|---|---|---|
| Primus Fitting Unit (all variants) | IIa | 10 | CE 0123 | 45241 | 05711781DHF2000ZC |
| 2000 Primus Audiometry Unit (Ice) | IIa | 10 | CE 0123 | 37503 | 05711781DHF2000ZC |
| 2000 Primus HIT Pro | I | 13 | CE | 41217 | 05711781DHF2000ZC |
| 2000-1 Fitting Unit | IIa | 10 | CE 0123 | 45241 | 05711781DHF2000ZC |

Note: Medical device classification may vary across different markets depending on local legislation.

All Auditdata devices covered in this manual, including the listed accessories and respective applied parts, comply with the Council Directive RoHS-II/2011/65/EU.

The Fitting System complies with the following standards:

### Safety:

- IEC 60601-1:2005+A1:2012 CSV, class 2, type B
- IEC 61010-1:2010 for HIT Unit

### EMC:

- IEC 60601-1-2:2014+A1:2020 CSV

### Audiometry:

- Tone: IEC 60645-1:2017 / ANSI S3.6:2018 Type 1
- Speech: IEC 60645-1:2017 / ANSI S3.6:2018 Type A or A-E

### Real Ear Measurement:

- IEC 61669:2015 and part of ANSI S3.46:2013

### Hearing Instrument Testing:

- IEC 60118-7:2005
- IEC 60118-15:2012
- ANSI S3.22:2009

### Medical electrical equipment

- EN 60601-1-6:2010+A1:2013+A2:2020

### Medical device software

- IEC 62304:2006+A1:2015

### Medical devices

- IEC 62366-1:2015
- EN ISO 14971:2019
- EN ISO 13485:2016

# 5 Intended Use/Indications for Use

The Fitting Unit is intended for use by professionals such as an audiologist, hearing healthcare specialist, or trained clinicians. The devices must only be used for their intended purpose as stated in this document below.

Audiometric testing should take place in a sound treated quiet environment and care should be taken to ensure optimal test conditions and safety of the client during testing.

### 2000-1 Fitting Unit , PFU and Primus Ice

- The Fitting Unit is intended for performing hearing tests.
- The Fitting Unit with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing in quiet office and sound treated environments.
- The Fitting Unit is indicated for use with both paediatric and adult age groups.
- The Fitting Unit is not indicated as a sole means of diagnostics.

### 2000-1 Fitting Unit and PFU Only

- The Fitting Unit is indicated for non-continuous real-ear measurements at the ear drum by means of noninvasive external ear canal insertion of a probe tube in quiet office environments.
- Finally, the Fitting Unit can be used to present hearing instrument related sound examples through headsets or loudspeakers.

### 2005-1 HIT Unit

- The Hearing Instrument Test Unit is intended for use by professionals such as an audiologist, hearing healthcare specialist, or trained technician.
- The Hearing Instrument Test Unit is intendent to apply sound to the hearing aid in a closed test box and obtain the acoustical output of the hearing aid in a coupler cavity equipped with a microphone.
- The Hearing Instrument Test Unit is intended to be used together with the Software to provide objective indication of the characteristics of a Hearing Aid. Visualization of the obtained coupler microphone signal is only available in the Software application.
- The Hearing Instrument Test Unit is indicated for technical quality inspection or fitting of hearing instruments with no clients involved.

# 6 Safety Instructions

⚠ PLEASE READ THE SAFETY INFORMATION COMPLETELY BEFORE USING THE FITTING SYSTEM!

## 6. 1 Applied parts

- The headsets / patient switch are only to be used with uninjured skin of the test person. The time of usage is short duration and less than 24 hours.
- Parts that come into contact with the client (that is, transducers, the handheld push-button, and the probe microphone set) should be disinfected before use.

## 6. 2 Fitting Unit

- Parts such as foam tips on insert earphones or probe tubes for real-ear measurement are not intended for reuse. Dispose of such items in a hygienic manner after each client session.
- Do not use talk forward microphone in areas where there is risk of acoustical feedback.
- The headphones supplied must not be used with any other branded equipment. Headphones from other branded equipment must not be used with the system.
- Connect only such headphones and other external devices that are approved for connection to the System.
- Probe tube measurements must be performed by trained professionals only.
- Avoid exposing the client or other persons to unnecessarily high sound pressures, as these may be damaging to hearing.
- Before applying the headphones or insert phone, inspect the patient's ear drum, ear canal, pinna and surrounding areas for lesions or other types of infection. Do not use the headphones or insert phones if any contraindications exist.
- Remove any barriers before placing the headphones or insert phones on the patient, such as jewellery or the patient's hair during the test.
- During real-ear measurements, carefully position the probe tube so as not to contact the ear drum.
- Accessory equipment connected to the analog and digital interfaces must be in compliance with the respective nationally harmonized IEC standards ( IEC 60950 for data processing equipment, IEC 60065 for video equipment, IEC 61010-1 for laboratory equipment and IEC 60601-1 3rd for medical equipment). Furthermore all configurations shall comply with MEDICAL ELECTRICAL SYSTEM in IEC 60601-1 3rd.
- Everybody who connects additional equipment to the signal inputs/outputs configures a MEDICAL ELECTRICAL SYSTEM, and is therefore responsible that the system complies with the requirements of the standard IEC 60601-1 3rd. If in doubt, consult the technical service department or your local representative.
- To comply with MEDICAL ELECTRICAL SYSTEM in IEC 60601-1 3rd the Audiometer, equipment parts and ACCESSORY, except for specified Type B applied parts, must be located outside PATIENT ENVIRONMENT, i.e. not closer than approx. 1.5 meters/5 ft.

- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  - Use of the accessory in the PATIENT VICINITY.
  - Evidence that the safety certification of the ACCESSORY has been performed.
  - In accordance to the appropriate IEC 60601-1 3rd.

# 6. 3 Fitting and HIT Units

## 6. 3. 1 Maintenance and Cleaning

- Do not modify the equipment without authorization of the manufacturer.
- Maintain a high level of hygiene and clean reusable devices which come into contact with clients between each use. See the cleaning instructions below.
- For cleaning use only a soft dry cloth dampened very sparingly with a low level disinfectant solution such as isopropyl alcohol to wipe the device. Do not allow excess solution to enter the device as this may damage internal components.
- Do not use acetone or paraffin/kerosene-based solutions, or any other harsh solvent to clean the device or its accessories. Use of such substances may be harmful to the equipment and may result in faulty operation.
- The headphones, probe microphone set, cables, connectors and other electrical accessories are not waterproof. See the Cleaning instructions for safe handling.

## 6. 3. 2 Usage

- The system with attached accessories is to be operated by qualified personnel only.
- The device is intended only as an adjunct in client assessment. It must be used in conjunction with assessment of clinical indicators and symptoms.
- The main power supply should be easily accessible for plugging/unplugging.
-  If the PC complies with IEC 60950 or with IEC 60601-1 3rd, use the USB cord to connect to the system. Do not touch the USB connector from the PC and the patient at the same time, when a IEC 60950 approved PC is used.
- The device should be directly connected to the PC and not to a USB hub.
- Do not use defective equipment. If you suspect a malfunction, contact a service representative authorized by manufacturer for inspection of the equipment.
- On a regular basis, that is, at least once a week, perform a visual inspection of the Fitting and HIT Units and their accessories for visible damages. Do not use damaged headphones or accessories with the device. During use, evaluate the test results and perform a system inspection if the results appear unreliable.
- When using the device with insert phones or probe-tube set, note that the used foam ear tips or probe tube should be disposed in a manner consistent with normal infection control procedures.
- In the event of irreparable damage to the device, dispose of it through an approved hazardous materials disposal facility in accordance with the RoHS (Restriction of the Use of

Certain Hazardous Substances) and WEEE (Waste Electrical and Electronic Equipment) regulations, or return it to manufacturer.

- Do not connect non-medical equipment unless it forms part of the medical system. There is a danger that the leakage currents may exceed their valid limits and consequently be a hazard to the client and the examiner.
- The devices should be contained in an environment according to the operational specifications, so that the temperature and humidity does not rise above dangerous measures. Refer to B.1 Technical Specification for allowed temperature, humidity, and air pressure.
- Do not expose the device to moisture. Extreme moisture can cause the device to fail or perform inaccurately.
- The devices must only be used for their intended purpose.
- All tests must be conducted in a sound treated or sound proof room with low ambient noise.
- Excessive movements should be avoided during the test, as it may interfere with the measurement and can result in wrong measurement results.
- The headset and transducers delivered with the Fitting System and reference and coupler microphones delivered with the HIT Unit are NOT intended for calibration by users. Contact your local distributor for your annual service and calibration.
- Do not pull the headphone cable. To disconnect the headphones or other accessories from the device, pull the plug.
- The examiner should take care never to touch non-medical parts of the system and the client at the same time.
- EXPLOSION HAZARD: Do not use the device in the presence of flammable substances.
- ELECTRIC SHOCK HAZARD: Do not attempt to disassemble the device. The device contains no user-serviceable items inside.
- Carefully route all the cables to reduce the possibility of entanglement or strangulation.
- Fasten the Fitting Unit on a wall, under a table or place it on a stable surface. If considered more practical, the Fitting System can also be placed inside the audiometric booth or piggyback to the HIT unit. Place the HIT Unit on a stable surface.
- Do not place the system on or near equipment that generates a strong magnetic or electrical field, as this may cause improper operation and interfere with the intended use of the device.
- If mobile multi-outlet power strips for mains power supply are in use:
  - they must comply with MEDICAL ELECTRICAL SYSTEM in IEC 60601-1 3rd
  - their rated current must not be exceeded
- Cables should be changed by properly qualified personnel only.
- Any external equipment should be connected in such a way that the Fitting Unit with connections still observes the safety requirements in IEC 60601-1 3rd.
- Conductors and wiring between the system components must be protected against mechanical damage.
- If the PC is in use and not compliant with IEC 60950 or IEC 60601-1 3rd, use optical USB connection Type OPTICIS M2-100-03 with power supply type Friwo FW7662M/05, type Friwo FW8002M/05 or optical USB connection Type IF-TOOLS; ISOUSB-BOX-PLUS; Art. No.: 14000.

- Use only with the power supply that is supplied with the system - type Friwo FW7362M/15 or type Friwo FW8030M/15.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 6. 4 HIT Unit

- The Hearing Instrument Test Unit is a laboratory equipment and must not come into contact with the patient. The hearing instrument used in the HIT Unit must NOT be connected to HIT Unit and the patient at the same time.

## 6. 5 Contraindications

- Patients unable to cooperate because of young age or other conditions cannot undergo pure tone or speech audiometry. They may need to have the auditory system tested by other methods.
- The patient shall be asked about any exposure to loud noise during the previous 24 hours, as this can cause a temporary hearing loss. If the answer is yes then it may be necessary to re-test the subject at a time when they have had no recent exposure to noise.
- Audiometry shall be preceded by otoscopic examination. Occluding wax may be removed prior to audiometry but if wax is removed the procedure shall only be undertaken by someone who is qualified and competent to do so.

# 7 Precautions

## 7. 1 Principles of Operation

### 7. 1. 1 Audiometry

- Presentation of pure tone sine wave and speech stimuli for threshold determination and supra-threshold testing within the range of 125 Hz to 16 kHz and varying intensity levels to assess client hearing levels.

### 7. 1. 2 Real Ear Measurement

- Please also note the REM standard IEC 61669 mentioned in Chapter 4. Besides technical specifications, terms and definitions, it contains additional helpful recommendations regarding the test set up, such as location of subject and tester, or location of field reference and measurement point.

  Presentation of pure tone sine wave or complex stimuli within the range of 125 Hz to 16 kHz for measurement at the ear drum by means of a flexible probe tube inserted into the ear canal. The measurement may take place with or without a hearing instrument inserted.

### 7. 1. 3 Hearing Instrument Test System

- Presentation of pure tone sine wave or complex stimuli through a loudspeaker or teleloop system within the range of 125 Hz to 16 kHz. Measurement and quality inspection of hearing instruments in a dedicated hearing instrument test chamber.

## 7. 2 Measurement Accuracy

If the accuracy of the device measurements does not seem reasonable, check the device for proper functionality. The measurement and signal presentation data, including stability, exactness and tolerances appear from the section Technical Specification.

Inaccurate measurements may be caused by factors such as:

- Excessive ambient noise in the test environment
- Excessive movements by client or operator
- Occlusion of the outer ear by hair or jewellery, or occlusion of the ear canal by objects or cerumen
- Incorrect placement of headphones, probe microphone set or free-field loudspeakers
- Incorrect headphones, loudspeakers or probe microphone set, or components such as cables, ear cushions, etc.
- Malfunction of the headphones or the device

⚠ WARNING! Use of the device in any way other than as described in this document may result in inaccurate results or injury.

## 7. 3 EMC (Electromagnetic Compatibility) Precautions

The system is suitable for use in all establishments other than domestic, but it can be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, if the following warning is taken in account:

⚠ WARNING! This system is intended for use in professional healthcare environment only and might interfere or be disturbed by nearby equipment, therefore, it may be necessary to take mitigation measures, such as reorienting, relocating or shielding the location.

Install and operate the System according to the EMC information, warnings and recommendations to prevent adverse events to the patient and operator due to electromagnetic disturbances for the expected service life time.

⚠ WARNING! Failure to comply with the precautions listed in this section may cause presenting of unwanted hearable noise or a wrong output on patients headset and therefore the possibility of wrong client response.

⚠ WARNING! Do not place the system on or near equipment that generates a strong magnetic or electrical field, as this may cause improper operation and interfere with the intended use of the device.

RECOMMENDATION: To reduce the frequency of electrical shocks through ESD, the floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

RECOMMENDATION: The quality of the mains power should be that of a typical commercial or hospital environment.

⚠ WARNING! 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.

⚠ WARNING! Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING!: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of

the System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

For more information on the conformance of the system with the EMC standard EN 60601-1-2, refer to Appendix B.

# 8 Installation and Set-Up

This installation procedure assumes that you will make a full installation. Skip irrelevant parts, if you are not going to install all the modules.

Be sure to observe the safety requirements stated in this document, both during installation and whilst using the Fitting system's instrumentation and transducers. Do not connect external devices unless they are suitable for connection to the Fitting System.

## 8. 1 Hardware Setup

**Note**: No user-serviceable parts are found inside the Fitting Unit. Do not disassemble or modify the unit!

### 8. 1. 1 Package and unpacking

#### External Inspection

Although your audiometer system parts were carefully tested, inspected and packed for shipping, immediately examine the outside of the container after receiving the instrument for any signs of damage. Notify your carrier if you observe any damage.

#### Unpacking

Carefully remove your audiometer system parts from its shipping container. If you observe any mechanical damage, notify the carrier immediately so that a proper claim can be made. Be certain to save all packing material so that the claim adjuster can inspect it as well. As soon as the carrier has completed the inspection, notify your Auditdata representative.

If the instrument must be returned to the supplier, repack it carefully (in the original container, if possible) and return it prepaid to the supplier for the necessary adjustment.

#### Package contents

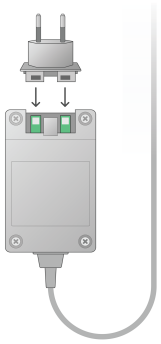
Check carefully that you have got all system parts according to the delivery note.

If any system part is missing or the delivery is not according to your order, notify your Auditdata representative immediately.

### 8. 1. 2 Fitting Unit setup procedure

1. Unpack the Fitting System and cross-check that all ordered parts (as indicated on the delivery note) are included. If any parts are missing, please contact your manufacturer for

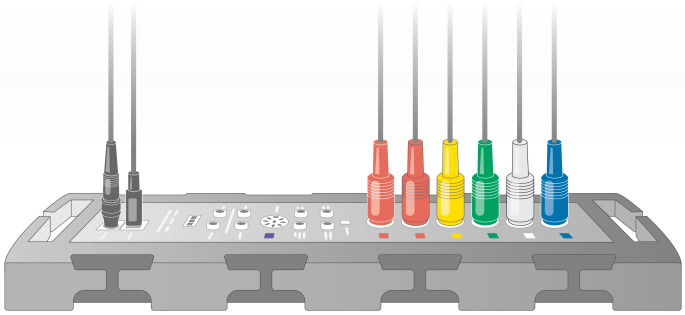
support immediately.
2. Slot the appropriate connector to your power supply.

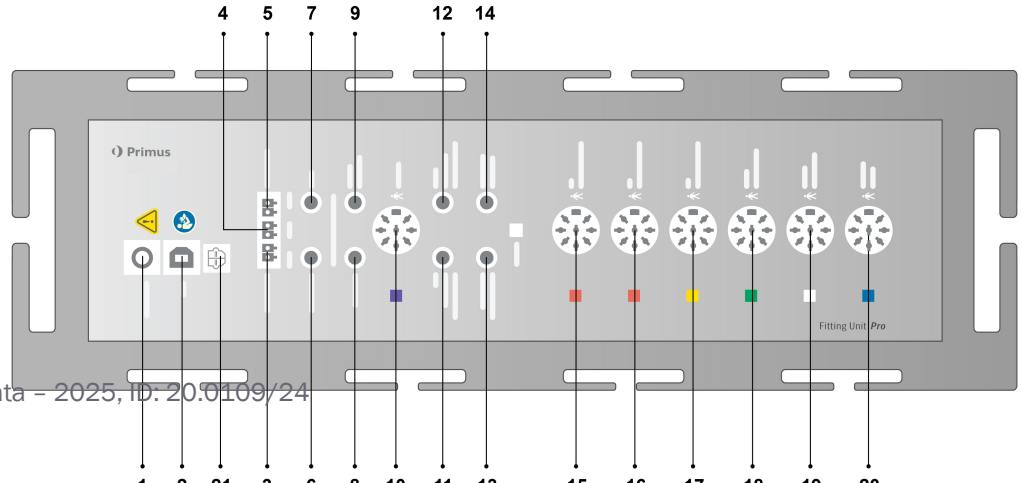


3. Fasten the Fitting Unit on a wall, under a table or place it on a stable surface. (If considered more practical, the Fitting System can also be placed inside the audiometric booth) or piggyback to the HIT unit.
4. Connect the USB cable to the inlet marked USB on the Fitting Unit.
5. Connect the other end of the USB plug into an empty slot on the operator PC.
6. Connect the power adapter to the DC inlet.
7. At the other end, connect the power plug to a power socket.

8. The plugs on the individual transducers come in specific colours, and should be plugged into the connector marked with the same colour on the Fitting Unit. The name of the connector is indicated next to the colour-marking on the Fitting Unit (see the table under the picture).

**2000 Primus Fitting Unit Pro, Primus PFU+**





| No | Table: Connectors for use in the Fitting Unit (plug/type in parenthesis) | Name on the Fitting Unit (and colour of transducer connectors if highlighted) |
|---|---|---|
| 1 | DC power adapter (pin/hole) | DC power |
| 2 | USB cable (USB type B, 2.0) | USB |
| 21 | Sony/Philips Digital Interconnect Format | S/PDIF*3 |
| 3 | Free Field Speaker, left (passive type) (Anitek, H5-02-1-0-5-0) | Left |
| 4 | Free Field Speaker, middle (passive type) (Anitek, H5-02-1-0-5-0) | Mid |
| 5 | Free Field Speaker, right (passive type) (Anitek, H5-02-1-0-5-0) | Right |
| 6-8 | Free Field Line Out (3.5 mm Stereo Mini Jack for connecting active speakers or amplifiers) | Left/Right - Rear - Sub/Mid*1*2<br>Line Out 1 - Line Out 2 - Line Out 3*3 |
| 9 | Client/Demo Headset (3.5 mm Stereo Mini Jack) | Client Headset*1*2<br>Demo Headset*3 |
| 10 | Option (DIN 8 pin) | Option*2*3 |
| 11 | Operator microphone, left (3.5 mm Stereo Mini Jack) | Left Operator Microphone |
| 12 | Operator microphone, right (3.5 mm Stereo Mini Jack) | Connector not used |
| 13 | Talk-back microphone(3.5 mm Stereo Mini Jack) | Talk Back Microphone |
| 14 | Operator headset for monitoring (3.5 mm Stereo Mini Jack) | Monitor Headset |
| 15 | Air conductor (DIN 8 pin) | Air Conductor 1*4<br>Air Conductor 2*4<br>Air Conductor 3*4 |
| 16 | Alternative air conductor (DIN 8 pin) | Air Conductor 1*4<br>Air Conductor 2*4 |

| No | Table: Connectors for use in the Fitting Unit (plug/type in parenthesis) | Name on the Fitting Unit (and colour of transducer connectors if highlighted) |
|---|---|---|
| | | Air Conductor 3*4 |
| 17 | High-frequency air conductor (DIN 8 pin) | Air Conductor 1*4<br>Air Conductor 2*4<br>Air Conductor 3 |
| 18 | Bone conductor (DIN 8 pin) | Bone Conductor |
| 19 | Client Response push button (DIN 8 pin)/Free field calibration tool (DIN 8pin) | Client Response |
| 20 | Probe microphone set (DIN 8 pin) | Primus Probe*2<br>Real Ear Probe*3*4 |

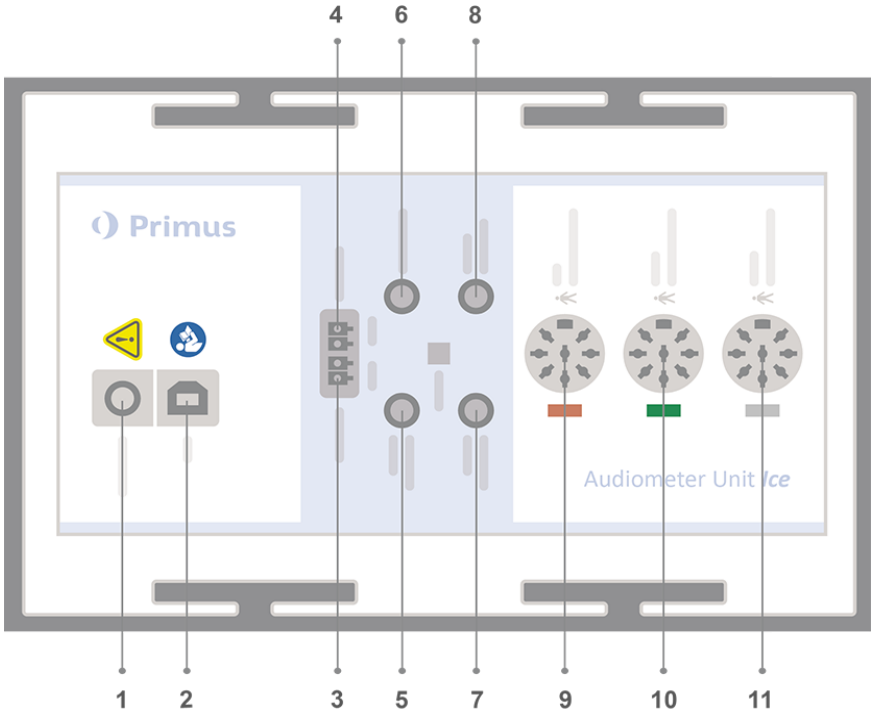
*1 This plug is only available in the PFU.

*2 This plug is only available in the PFU+.

*3 This plug is only available in the Primus Pro.

*4 Frequency above 8 kHz will be unavailable.

Primus Ice

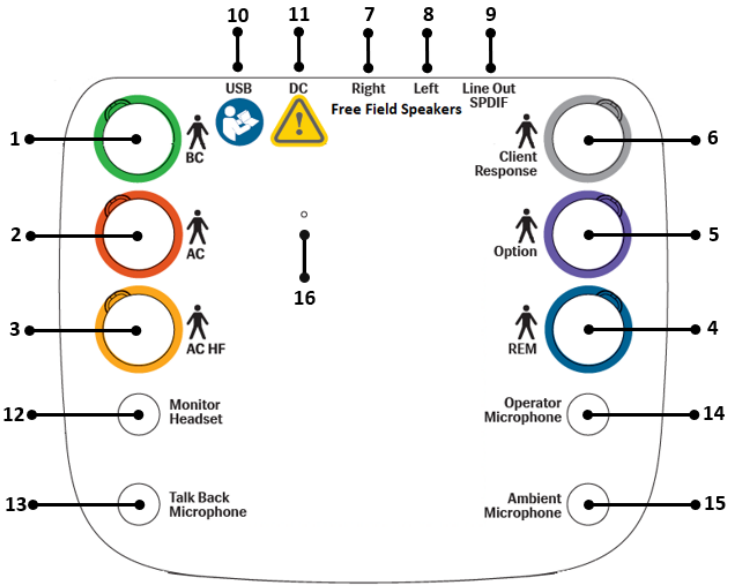



| No | Table: Connectors for use in the Fitting Unit (plug/type in parenthesis) | Name on the Fitting Unit (and colour of transducer connectors if highlighted) |
|---|---|---|
| 1 | DC power adapter (pin/hole) | DC power |
| 2 | USB cable (USB type B, 2.0) | USB |
| 3 | Free Field Speaker, left (passive type) (Anitek, H5-02-1-0-5-0) | Left |
| 4 | Free Field Speaker, right (passive type) (Anitek, H5-02-1-0-5-0) | Right |
| 5 | Operator microphone (3.5 mm Stereo Mini Jack) | Operator Microphone |
| 6 | Free Field Line Out (3.5 mm Stereo Mini Jack for connecting active speakers or amplifiers) | Line Out/Demo |
| 7 | Talk-back microphone (3.5 mm Stereo Mini Jack) | Talk Back Microphone |
| 8 | Operator headset for monitoring (3.5 mm Stereo Mini Jack) | Monitor Headset |

| No | Table: Connectors for use in the Fitting Unit (plug/type in parenthesis) | Name on the Fitting Unit (and colour of transducer connectors if highlighted) |
|---|---|---|
| 9 | Air conductor (DIN 8 pin) | Air Conductor |
| 9 | High-frequency air conductor (DIN 8 pin) | Air Conductor*1 |
| 10 | Bone conductor (DIN 8 pin) | Bone Conductor |
| 11 | Client Response push button (DIN 8 pin)/Free field calibration tool (DIN 8pin) | Client Response |

*1 Frequency above 8 kHz will be unavailable.

2000-1 Fitting Unit




| No | Table: Connectors for use in the Fitting Unit (plug/type in parenthesis) | Name on the Fitting Unit (and colour of transducer connectors if highlighted) |
|---|---|---|
| 1 | Bone conductor (Mini DIN 8 pin) | BC (Green) |
| 2 | Air conductor (Mini DIN 8 pin) | AC |
| 3 | High-frequency air conductor (Mini DIN 8 pin) | AC HF (Yellow) |
| 4 | REM probe microphone set (Mini DIN 8 pin) | REM (Blue) |

| No | Table: Connectors for use in the Fitting Unit (plug/type in parenthesis) | Name on the Fitting Unit (and colour of transducer connectors if highlighted) |
|---|---|---|
| 5 | Option (DIN 8 pin) | Option (Purple) |
| 6 | Client Response Push Button (Mini DIN 8 pin) OR<br>Free field calibration tool (Mini DIN 8 pin) | Client Response (Grey) |
| 7 | Free Field Speaker, right (passive type) (Anitek, H5-02-1-0-5-0) | Free Field Speakers, Right |
| 8 | Free Field Speaker, left (passive type) (Anitek, H5-02-1-0-5-0) | Free Field Speakers, Left |
| 9 | Free Field Line Out (3.5 mm Stereo Mini Jack for connecting active speakers or amplifiers) OR<br>SPDIF: Sony/Philips Digital Interconnect Format (toslink) | Line Out / SPDIF |
| 10 | USB cable (USB type C) | USB |
| 11 | DC power adapter (pin/hole) | DC |
| 12 | Operator headset for monitoring (3.5 mm Stereo Mini Jack) | Monitor Headset |
| 13 | Talk-back microphone (3.5 mm Stereo Mini Jack) | Talk Back Microphone |
| 14 | Operator microphone, left (3.5 mm Stereo Mini Jack) | Operator Microphone |
| 15 | Connector not used | Ambient Microphone |
| 16 | Hardware reset<br>*Note: Perform only when instructed by support or a technician.* | |

9. Connect the speakers into the speaker inlets.
10. ***Optional***: Connect the operator microphones, headset and additional freefield speakers to the appropriate sockets.
11. Make sure that all cables are routed and fastened to prevent a hazard (such as entanglement) to personnel or clients.
12. Close the Fitting Unit using the lid.

**Note:** The unit has no physical user interface (apart from the on/off lamp, which is visible through the lid itself). Hereby, in order to protect it from dust and unintended disassembly, it is recommended to keep the lid on during use.

## 8. 1. 3 2000-1 Fitting Unit Speaker Setup

The 2000-1 Fitting Unit (Measure  audiometer) includes five speaker connection options: left and right high-level speaker outputs, left and right low-level speaker outputs, and an Option connector. The high-level and low-level outputs cannot be used simultaneously, which is also indicated in the software.

### Speaker Configuration:

- **High-Level Outputs** are intended for passive speakers without built-in amplifiers.
- **Low-Level Outputs** are suitable for external amplifiers or active speakers with built-in amplifiers.
- **The Option Connector** is a single-channel high-level output that can connect to a regular passive speaker using a special cable.

### Units with serial numbers 330xxxxx

For units with serial numbers starting with 330, the low- and high-level outputs are **not** independent channels: Sound routed to the high-level output will also be routed to the low-level output.

The Option output is independent of the high-level output. However, it is **not** independent of the low-level output: Sound played on the left/right low-level output will also be output on the Option connector.

This means that a three-speaker setup is possible by connecting a pair of speakers (Left-Right) to the high-level outputs, and a third speaker to the Option output.

### Units with serial numbers 331xxxxx

For units with serial numbers starting with 331, the low- and high-level outputs are independent channels: Sound routed to the high-level output will not be routed to the low-level output.

The Option output channel is independent from the high- and low-level speaker outputs.

## 8. 1. 4 Wireless Devices Setup

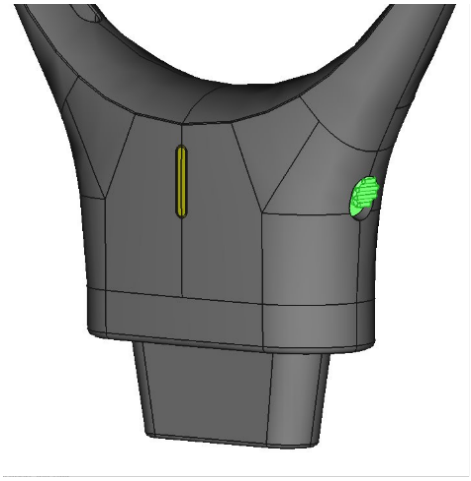
This chapter provides instructions for setting up wireless devices with the software.

### WL REM Probe

The guidelines will assist you in charging, turning on, pairing, and understanding the status indicators of these devices.

### Turning on the WL REM

The power switch is located on the left side of the REM Probe.

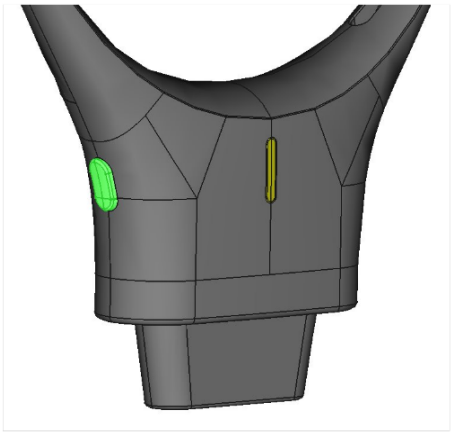


**Power ON**: Slide the switch up.

**Power OFF**: Slide the switch down.

### Pairing the WL REM

The pairing button is located on the right side of the REM Probe.



To connect your device to the fitting unit:

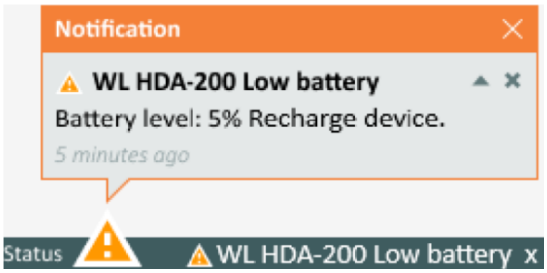
1. Ensure the fitting unit is connected to power and your PC. Ensure no other wireless REM is connected to the fitting unit.
2. Turn on the WL REM: if the switch was turned off, push it up to the "ON" position. Hold WL REM close to fitting unit.

3. Perform a long push on the button to enter pairing mode. The LED will blink blue, indicating that the device is ready to pair.
4. Once the wireless connection is set, the LED indicator will turn green.
5. The software will display a message confirming a successful connection. The status bar the software will also show the connected device's name and serial number.

NOTE: Ensure there is a clear line of sight between the WL REM and the fitting unit to maintain optimal signal strength. Barriers between the WL REM and the fitting unit may impact communication and degrade performance.

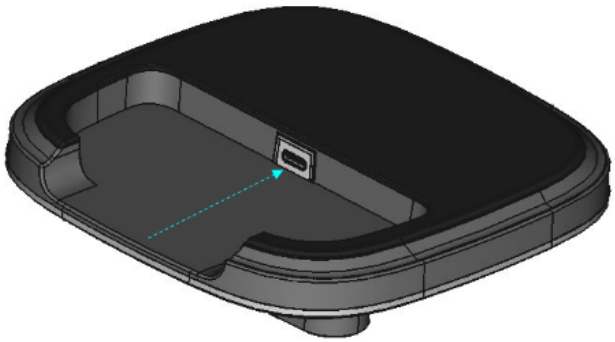
### Charging the WL REM

The software provides a battery level indicator for connected devices. When the battery is low, the LED will remain green, but a notification will appear in the software.

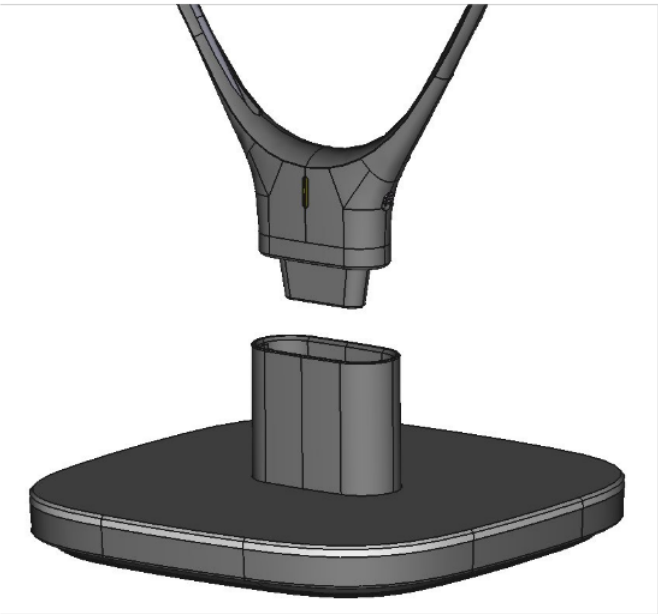



To charge the WL REM:

1. Connect the USB charger to the USB connector at the bottom of the stand charger.



Place the REM Probe in the charger stand. The LED indicator will blink red one time and will turn green again.



To find the information on the battery status, go to **Tools** > **Device Management** > **Wireless Devices** in the software.

### Sleep mode

Press & hold the button for 5 seconds to put the WL REM into sleep mode. The LED will change from green to off (no LED).

If the WL REM has not been used for some time, it will automatically enter the sleep mode. Push the pairing button to wake the device up from sleep mode.

### Disconnection and Reconnection

- Disconnection Indicator:

If the device disconnects, the LED will turn off, and a notification will appear in the software: "WL Real Ear Probe Not connected, WL Real Ear Probe S/N [xxxx] No longer connected. Please reconnect to continue use."

- Reconnection Process:

To reconnect, turn the device off and on again. It will automatically attempt to reconnect to the fitting unit.

### Status Indicators Summary

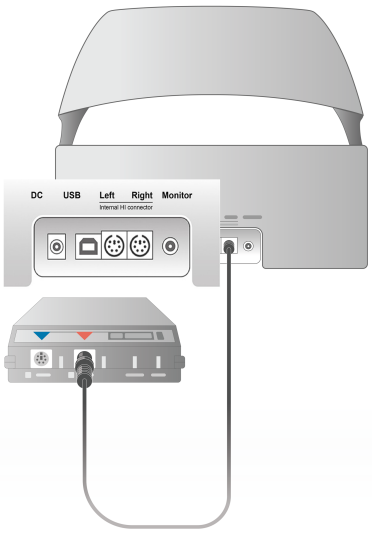
| Device Status | LED Color |
|---|---|
| Power Off/Sleep mode | No LED |
| Pairing Mode | Blinking Blue |

| | |
|---|---|
| Connected | Solid Green |
| Start charging | 1 Red Blink |
| Charging | Solid Green |

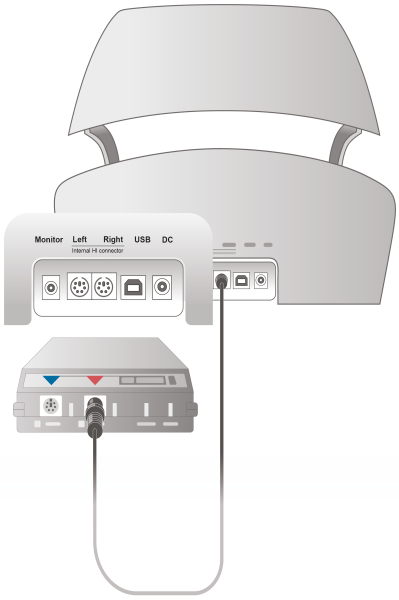
## 8. 1. 5 HIT Unit setup procedure

1. Place the HIT Unit on a stable surface.
2. Connect the USB cable to the inlet marked USB on the HIT Unit. Connect the other end of the USB plug into an empty slot on the operator PC. Connect the power adapter to the DC inlet, if performing tests are up to 16kHz.
3. To adjust hearing aid settings with HI-PRO or NOAHlink™, connect the HI-PRO box or NOAHlink™ to the appropriate INTERNAL HI CONNECTOR outlet using the extension cables provided (as shown in the picture below).

**HIT Box**



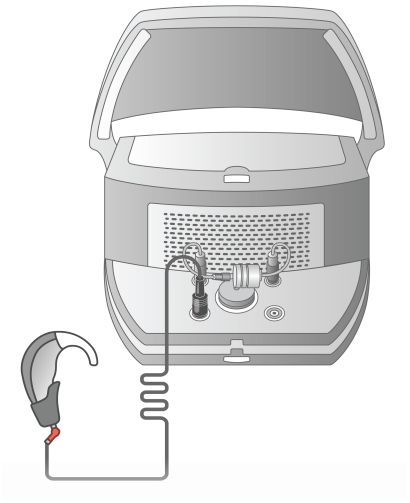

**HIT Pro**



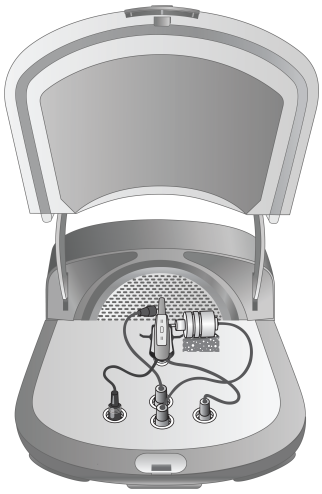

4. Plug in the hearing aid programming lead to start programming with a HI-PRO or NOAHlink™.

   **Note**: You can also connect the HI-PRO box or NOAHlink™ directly to the operator PC. The plug in the hearing aid programming leads directly to the HI-PRO box.

HIT Box

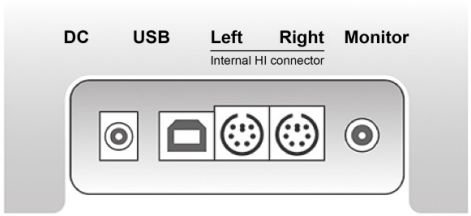


HIT Pro

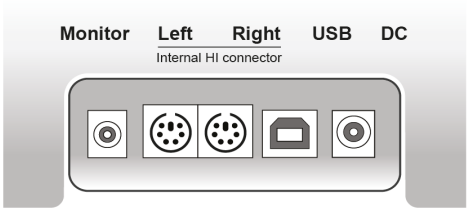


5. *Optional*: Connect a monitor headset to the MONITOR socket.

HIT Box

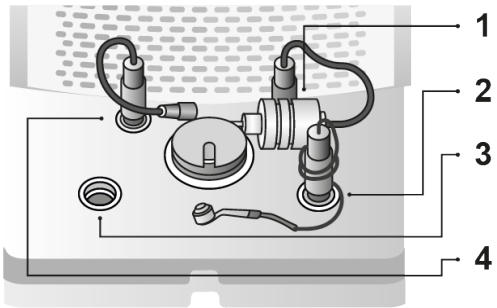



HIT Pro

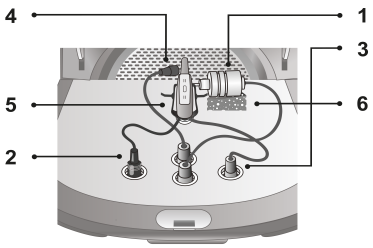



6. Plug the reference microphone, coupler and battery pill in the inlets as shown below. You can also place the necessary sponge provided to support the hearing aid. Please refer to Section 9.2, **Set up and editing for hearing instruments** in the User Manual for more information.

HIT Box




HIT Pro



| No | Name |
|---|---|
| 1 | Coupler microphone |
| 2 | Battery pill |
| 3 | Hearing aid programming lead (HI-Pro cable) |
| 4 | Reference microphone |
| 5 | Hearing aid holder |
| 6 | Coupler microphone holder |

# 8. 2 Software Installation

## 8. 2. 1 Prerequisites

If you are using NOAH, version 4.7 or higher must be installed.

## 8. 2. 2 Installation Procedure

You will receive the software installation file on a USB memory stick. Insert the USB stick into a USB slot.

To install the software:

1. Open Windows Explorer and locate the USB stick.
2. Locate the **setup_x.x.x.x.exe** file and double-click it.
3. The installation program will now guide you through the installation procedure.
4. Follow the instructions on the screen.

**Note:** You will need to install an additional driver for the Video Otoscopy module. During the installation of the software, you will be asked to allow the installation of these drivers. You must click **Install** or the installation will be cancelled.

## 8. 2. 3 Updates

When a new software version is available, you can download it from the Internet. Open Auditdata A/S' homepage, www.auditdata.com from the Support section.

# 8. 3 Installing Your License

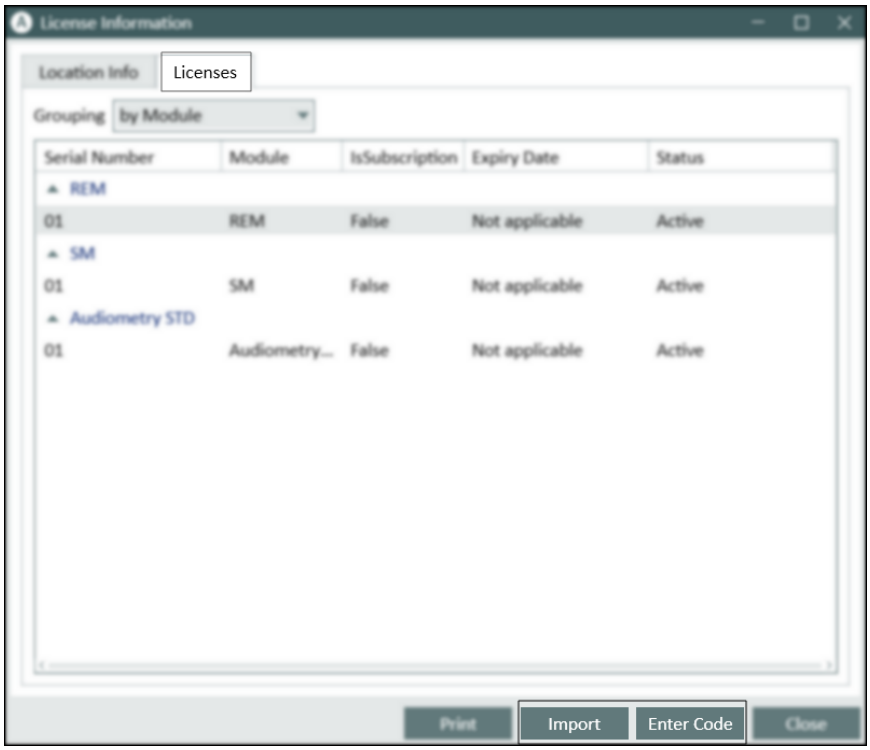
## 8. 3. 1 Cloud-based License Activation

The system automatically downloads and installs licenses from the cloud. Ensure the hardware is connected to the computer and there is an internet connection. You will see a notification once the license has been successfully added. To complete the installation, restart the application.

## 8. 3. 2 Manual license activation

If the application cannot download the license from the cloud, you can manually enter the license code:

1. Go to **Help** > **License Information** and choose the Licenses tab.
2. You have two options: **Import** and **Enter Code**.




   - Click **Import** to navigate to the location of the license file, then click **Open**.
   - If you have the license code, click **Enter Code** and enter your unique key, then click **OK**.
3. Restart the application to complete the installation of the license.

## 8. 3. 3 Calibration and Adjustments

After completing the software installation and hardware setup, proceed to calibrate the free field loudspeakers (if any) and make an initial adjustment of the attached microphones and

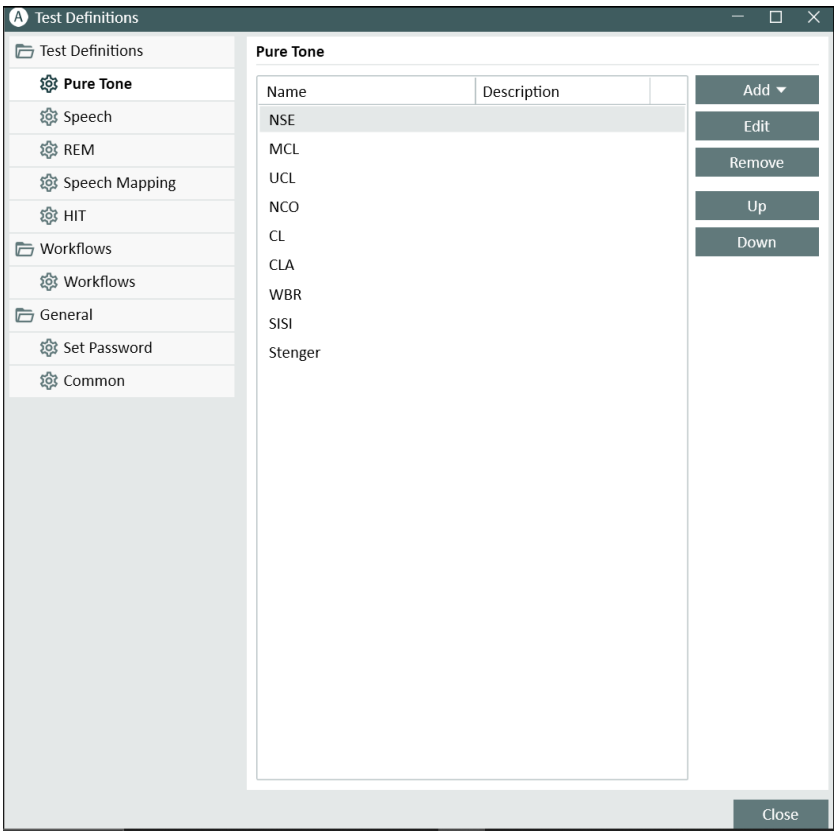
headsets. After calibration and adjustment, the system is ready for use.

To view information on connected devices and calibrations, go to **Tools** > **Device Management**.

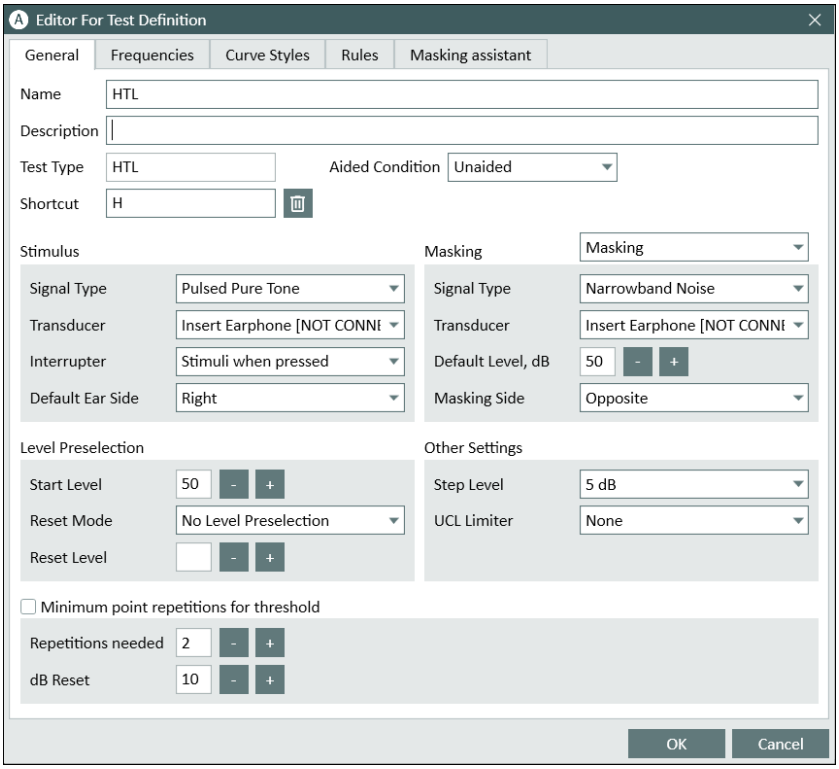
## 8. 4 Test Definitions Set-Up

Test definitions are pre-configured measurements based on the test types available within the system. You can locate them by opening **Tools** and then clicking **Test Definitions**.

Use the **Add**, **Edit** and **Remove** buttons to set up test definitions for the main modules, namely: **Audiometry**, **Real Ear Measurement**, **Speech Mapping** and **HIT**.

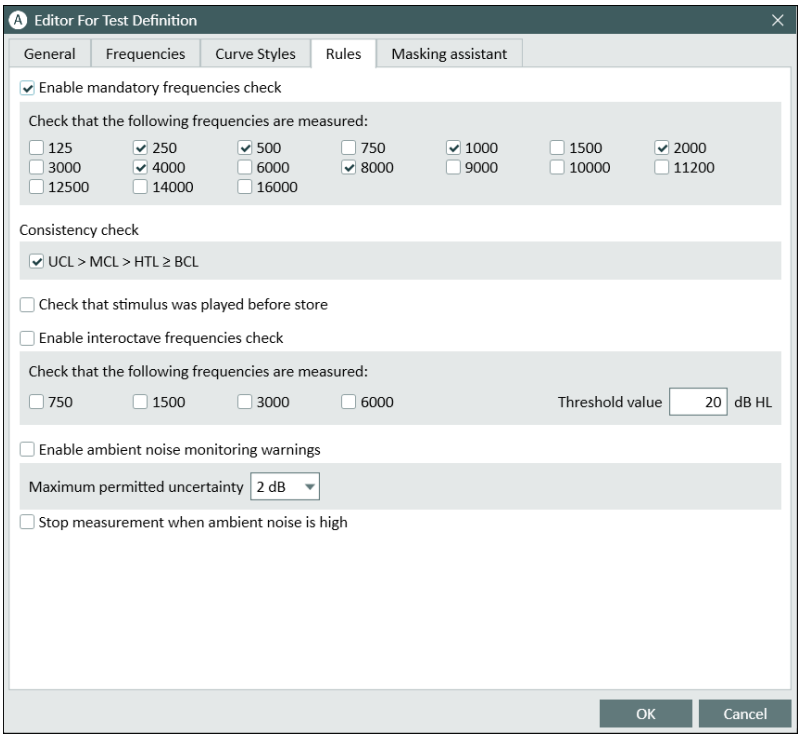



You can create and name new custom test definitions for each measurement by configuring the signal type, level, transducer, masking stimulus for each test.




It is also possible to specify the completeness criteria by checking that the selected frequencies are measured during the test.

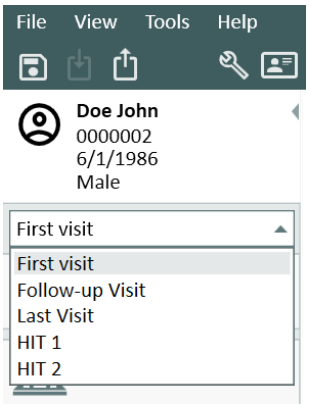
Enable consistency criteria to check whether AC and BC thresholds need to be masked. Also, check that the threshold levels are according to the following rule: UCL > MCL > AC >= BC.



More details about setting up various modules can be found in the System's Help.

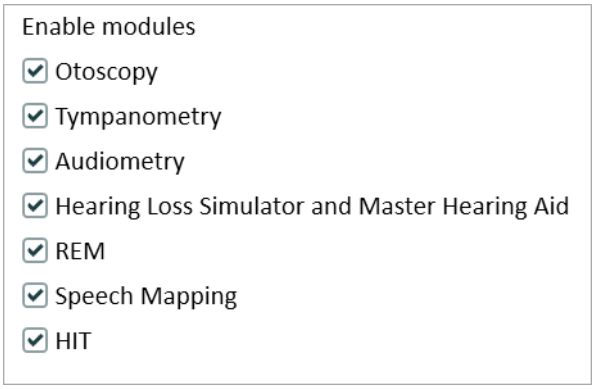
## 8. 5 Configuring Types of Visits

The Types of visits list itself is available right below the Client tab.



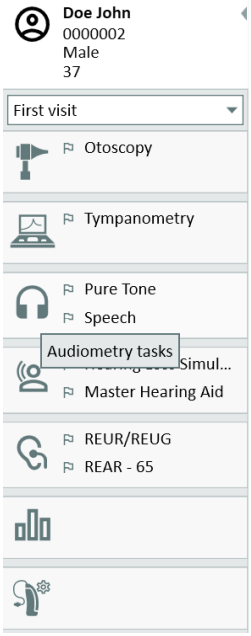

The application is shipped with a set of predefined visits. You can add, delete or edit them. To do this, open the **Tools** menu, click **Settings**, then **Workflow** in the General section, and use **Add/Delete/Edit** buttons as needed.

If you do not wish to use some of the modules, you may disable it by deselecting the check box under the **Enable modules** heading. Those modules will now not be shown in the workflow list on the main screen.




Each task group consists of relevant tasks which you can select using the arrow buttons to move to the selected tasks box to add to your workflow. Once you have selected all your tasks required, use the **Up** and **Down** button to change the order of your selected tasks.

In the main window of the application, the task groups are represented by the tabs located right below the task list.

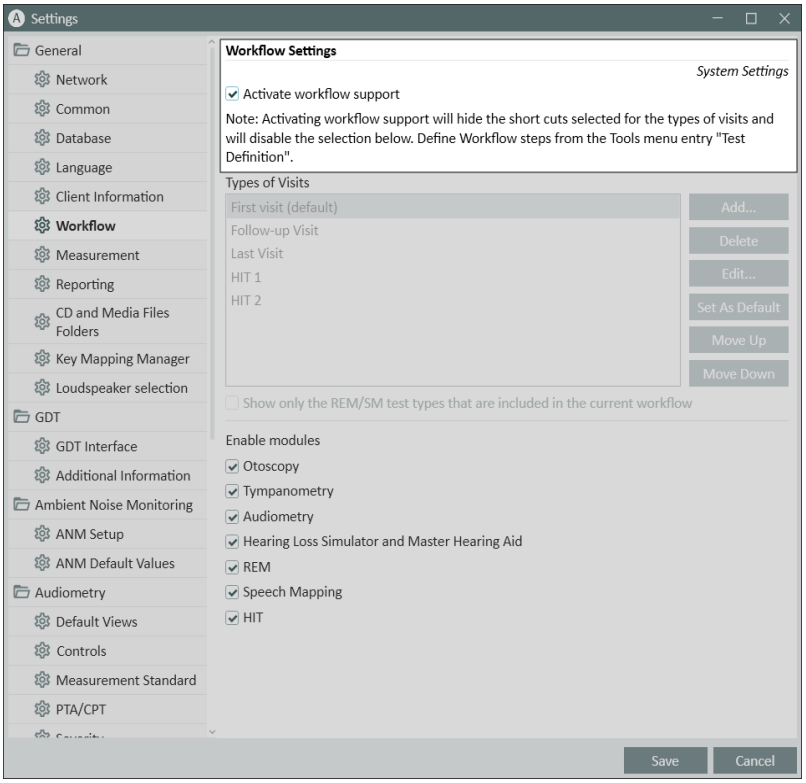



## 8. 6 Activating Workflow Support

The system includes a workflow support utility which guides you through the necessary measurements step by step. The purpose is to provide the ability to follow company defined test protocols and open the particular test steps in their predefined configuration. For each workflow step you can define type of measurement, stimulus, level, frequencies, etc. It is possible to set each workflow step as an optional or mandatory step.

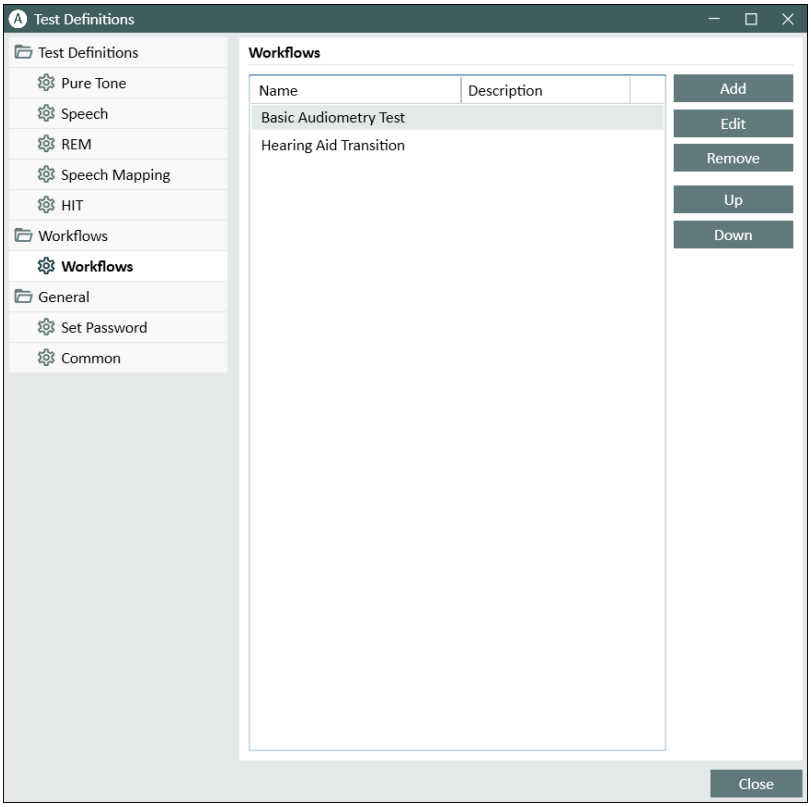
You can define as many workflows as you want depending on your needs. However, only one workflow can be activated at a time.

To enable workflow support, go to **Tools** and select **Settings** where you click the **Workflow** tab. Select the corresponding check box to activate workflow support.

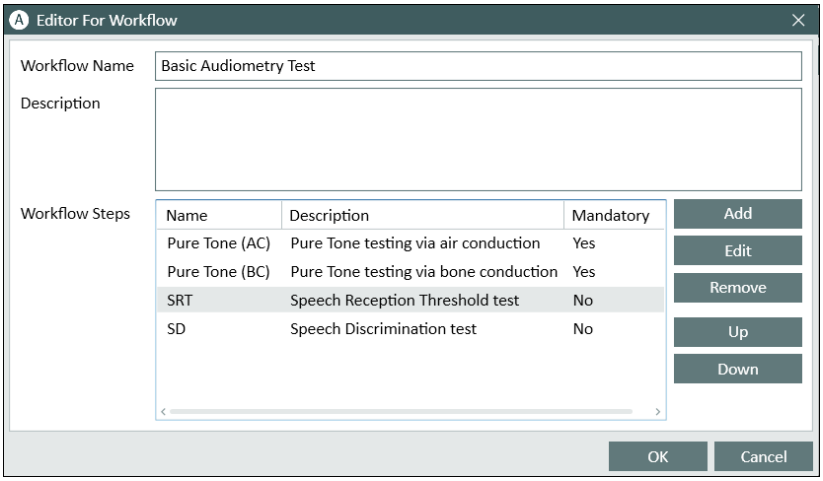



**Note:** Activating workflow support disables the types of visits functionality in the user interface.

To configure workflows, go to **Tools** -> **Test Definition**. Select a workflow entry from the list and click **Edit** to open it. Use the buttons in the right panel to add new workflows, edit existing ones or delete any workflow from the list.



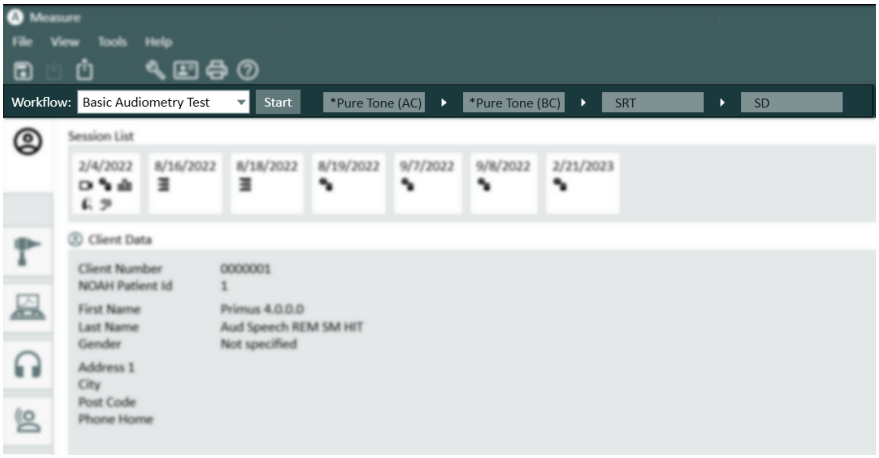

To define the steps within the workflow, click the **Edit** button to open the configuration window.




As you add the steps, you need to specify the test type, set its prospected duration and set test step as mandatory or optional.

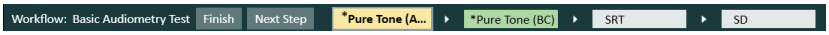
**Note:** There are three specific step types that display a message to the audiologist, prompt them to enter a note, open an external file (website or presentation), called **Display a message**, **Prompt a user to add a note**, and **Open External Link** correspondingly.

After restarting the software, you can find the workflow on the top panel of the application.




After the workflow support has been activated, click the **Start** button to begin. The first workflow step will be highlighted and after clicking on it you will be directed to the corresponding module and the preconfigured test will open up. Each step is coloured according to its state:

- Yellow - Incomplete
- Green - Done
- Red - Skipped
- Dark Grey - Active Step
- Blue - Not Done




If the criteria for the test type are not fulfilled, the application will notify you when you attempt to move to the next step. You can see what criteria was not met and make required changes to the measurement.

You must enter a reason why the criteria cannot be fulfilled or change the test to meet the criteria requirements.

**Note**: Workflows must be completed on the same day. Data cannot be modified the following day.

## 8. 7 Activating Transducers

The transducers used with the Fitting Unit need to be activated before usage. To start the activation:

1. Run the application.
2. Insert the transducer plug into the appropriate socket.
3. In the pop up window click **Activate**.
4. Your transducer is now activated.

## 8. 8 Connecting Transducers to a Sound Booth

To connect a transducer to a sound booth, please do the following:

1. Run the application and plug in the transducer into the Fitting Unit.
2. Disconnect the transducer. Do not restart the software.
3. Plug in a sound booth cable into the same plug that was used for the transducer.
4. The system will show the dialog with data from the last connected transducer.
5. Verify that the right transducer is connected.
6. You can now connect your transducer to a sound booth.

## 8. 9 Calibration of Free-Field Loudspeakers - Sound Field Calibration

Free-field loudspeakers must be calibrated before performing any audiometric testing.

The calibration of the free-field loudspeakers is only valid for the exact distance from the client's ear for which they are calibrated at.

Therefore, free-field loudspeakers should be re-calibrated if they are moved from the exact location at which they were calibrated.

For the following procedure it is assumed that the connected loudspeakers are of a high quality, particularly with respect to linearity and maximum sound pressure.

### Procedure

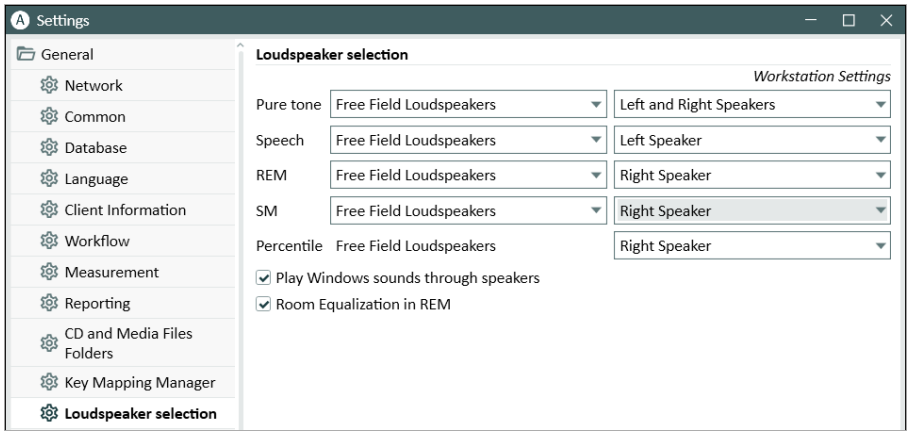
1. Place the free-field loudspeakers at a distance no further than 1 m and angle the speakers, for example at 45° or 0° azimuth from where the client's ear will be during tests. The center of the loudspeaker should be at the same height as the ear canal.

   **Note**: The calibration must be repeated if the client has moved from the original calibration distance.

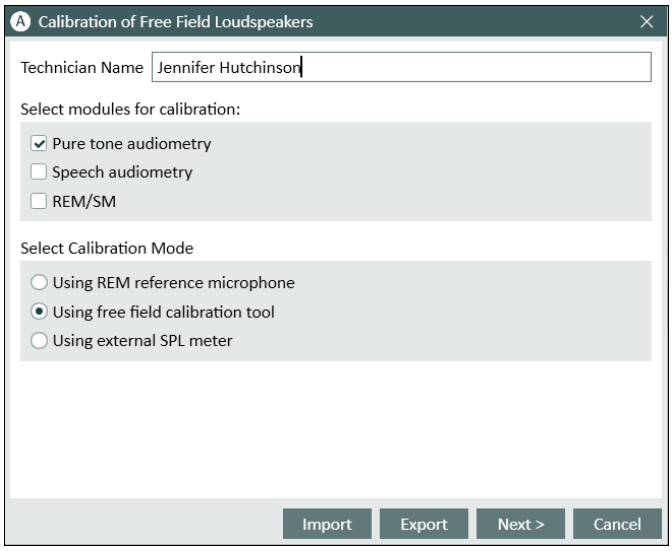
2. In the case of active loudspeakers, make sure that the volume is set to maximum.

   **Note**: Some active loudspeakers may be too sensitive and will produce distortion noise, when set at maximum volume. In that case, try to reduce the volume (if max. output can be reached) until you find a level where max. output level can still be reached and noise from the loudspeaker system is acceptable.

3. Open the Fitting System program, go to **Tools > Settings > General > Loudspeaker selection** and select the correct speaker for pure tone, speech, REM, and SM according to your setup.




4. Click **Save** to confirm the specified settings.
5. Select **Sound Field Calibration** from the **Tools** menu.
6. The window contains the history of performed calibrations. Click **Do Calibration** to start a new calibration.
   **Note**: A password is required to access this function. Enter the following password - *"primusFFcal"*.
7. In the **Calibration of Free Field Loudspeakers** dialogue box, enter the name of the technician who performs the calibration, select the module you want to calibrate and a calibration method.




   For wireless REM, ensure to select Wireless REM reference microphone dynamic option which appears if the device is connected at the start of calibration.
8. If you have selected external SPL meter, in the next Setup window, select the speakers you wish to calibrate.

Also check-mark the box at the bottom if the calibration should include the high-frequency area.

**Note**: High frequency calibration option is only available when the pure tone audiometry module is selected.

If you are using the built-in microphone, select Left or Right Probe-mic to measure the levels with.

**Note**: The REM probe microphones must be calibrated before being used to calibrate the loudspeakers.

If you are using the free field calibration tool, levels will be measured with the free field calibration microphone.

**Note**: When using the Primus Ice, you should calibrate by selecting the external SPL meter or the free field calibration tool.

9. Set the level you wish to calibrate at.
10. Select **Speech Noise- ILTASS** for signal for sound card calibration.
11. Place the SPL meter, free field calibration microphone, or Real Ear Probe at the exact location where the client's ear will be tested.
12. Observe the instructions at the top of the **Setup** window, and click the **Start** button. (You will get a warning, if any selected instruments are not connected and turned on).

    If you use the SPL meter, you will need to set the level manually, using the correction values shown in the image below. If you want to add 2 dB to the level, for example, just press +1 twice. Once you are fine with the level, click the **Next** button.
13. When using "Built-in Microphone" or free field calibration tool, and more than one speaker were selected, the procedure will continue automatically for other loudspeakers. If one or more frequencies cannot be calibrated, a warning will appear. At the end of the calibration a report will be displayed, showing any uncalibrated frequencies or levels.
14. Click **OK** to save the calibration and exit the **Loudspeaker Calibration** dialogue box.
15. By means of markings or fastening, make sure that the loudspeakers will be placed in this exact position compared to the client's location during testing.

You can import and export calibration data in the XML format using the **Import** and **Export** buttons correspondingly. After you click **Import**, locate the saved calibration XML file on your PC and click **Open**. Proceed to calibration afterwards. To export your calibration data, click the **Export** button and save the XML file to your local computer.

Use the **Print Report** button to print the calibration report.

# 8. 10 Addition of External Sound Files for Speech Audiometry and Speech Mapping

To add a new media files folder:

1. On the **CD and Media Files Folders**, click **Add** button to add a new folder with your own sound files (wav, ogg, wma) or get the files from the Cloud. The **Custom Media files Folder** window opens.
2. Specify the **Name** of the external folder.
    - If you are planning on using the speech materials from the Cloud, activate the corresponding option.
3. Select the **Folder Path** where the external folder is located.
4. Select the **CD Scheme** that corresponds to your sound files and click the **Calibrate** button.
5. Select the track or special sound which will calibrate your sound files.
6. Calibrate the selected files and click **Save** button and then **OK** to save again.

The calibration of recently calibrated file will be used for all external sound files in Speech Mapping and Speech Audiometry modules.

**Note**: Only one calibration value is available and used for all external sound files and will be applied to all transducers.

## 8. 11 Calibrating Speech CD Material

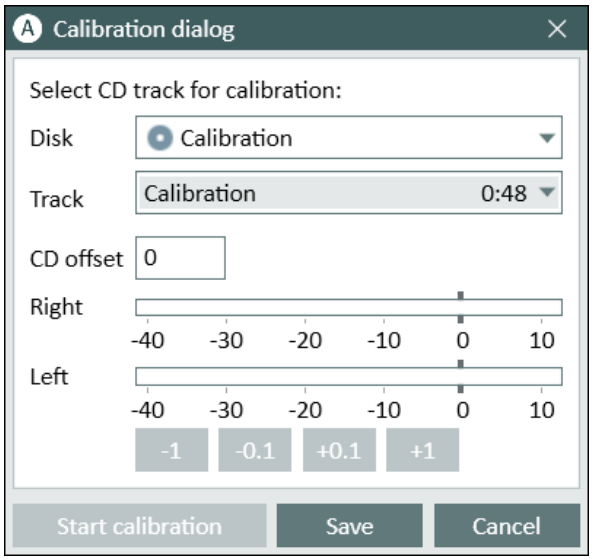
To adjust the output level for speech material:

1. Select **Settings** from the **Tools** menu.
2. In the **Settings** dialogue box, select **CD and Media Files Folders** from the General folder.
3. In **CD and Media Files Folders** Settings, click the button **Calibrate CD...** to open the **CD Calibration** window.
4. Adjust the CD Offset to the correct value in dB if the CD contains an offset value.

   The value in the field “CD Offset” has only effect on the free field speakers, but not on the transducers. It will increase or decrease the common reference output level for the sound field speakers according to the value entered. A change of the offset value does not influence the VU meter level displayed.

   **Important Note:** The required CD offset value should only be obtained in conjunction with a proper calibration equipment (sound level meter) to measure the output level of the sound field speaker.

   **Warning:** Only recorded speech material with a stated relationship with the calibration signal should be used.
5. Select the calibration track on the CD and click **Start Calibration**.




   During the calibration adjust the level so the VU meter is around 0 using the ‘+’ and ‘-’ buttons.
6. Click **Save** to save the setting and exit the dialogue box.

## 8. 12 Selecting Client and Entering Client Data

If client data has been saved in the Noah database, the client's name will appear in Noah's Patient Browser.

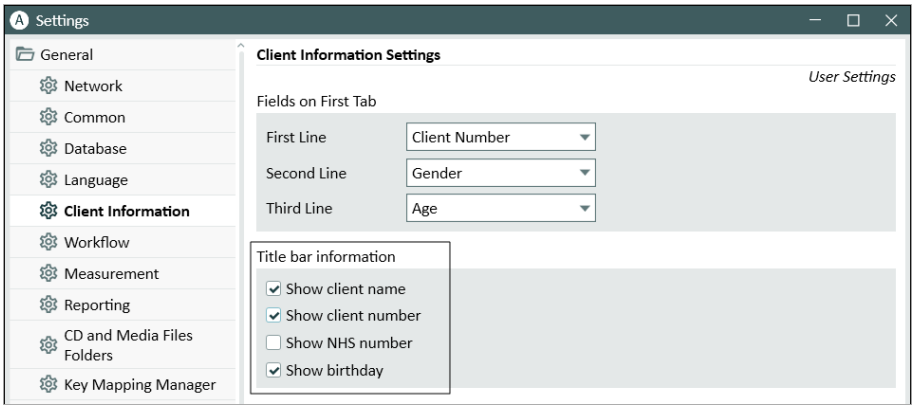
To start the program as a Noah module, you have to select the client in the Patient Browser and then click the software icon in the module list.

The application opens with the client's data displayed in the dashboard of the application.

If you need to create a client in Noah, open the Noah File menu, click **Add New Patient**, and then fill in the client data. Please note that fields marked in orange are mandatory.

If the application has been started outside the Noah system, you have to enter the client's data first. Open the **Tools** menu, click **Client Information**, and then fill in the client data.

Once you click **OK**, the client's name, date of birth and some other data will appear in the top title bar. To choose which information to display in the title bar, go to **Settings > General > Client Information** and select the appropriate checkboxes.




Alternatively, you can import client data that were previously exported from the application: open the **File** menu, click **Import Sessions** and then specify the location of the XML file with the client data.

## 8. 13 Obtaining Hearing Threshold Levels

Prior to performing audiometric measurements with your client, please ensure the following:

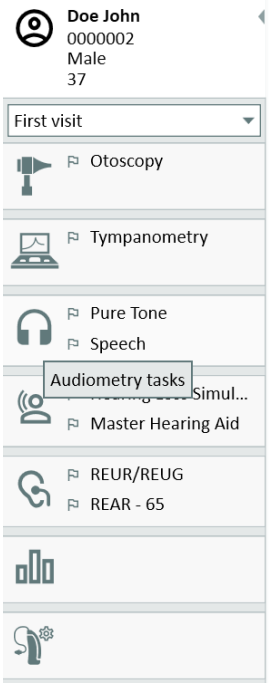
**For the client:**

1. The client has a comfortable seating in the sound-attenuating booth.
2. The appropriate testing headsets are plugged into the appropriate sockets.
3. A client response switch is connected to the CLIENT RESPONSE socket of the Fitting Unit.
4. Optionally, a microphone for the client talk-back is connected to the TALK BACK MICROPHONE socket on the Fitting Unit.

**For the operator:**

1. Optionally, a monitor headset with boom microphone can be connected to the MONITOR HEADSET socket of the Fitting Unit for talk-back monitoring.
2. Optionally, a separate microphone is connected to the OPERATOR MICROPHONE socket for talk-over monitoring.

Click on the icon on the **Audiometry tasks** tab in the application to open the Audiometry front page in the dashboard.




Click the **Pure Tone Measurement** button (Pure Tone Measurement) in the Audiometry pane of the dashboard to open the **Pure Tone Measurement** window.

Make sure that **HTL** is selected in the **Test Types** panel in the top left corner of the window.

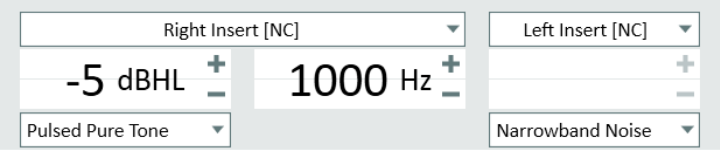

To select the **HTL** test type, simply click it. Alternatively, you can press the **T** button on the keyboard.

Check the settings on the **Measurement Controls** panel below the audiograms:

1. Select ear by means of the blue ( ) or red button ( ). Alternatively, use the **L** button on the keyboard for the left ear and the **R** button for the right ear.
2. Set frequency and amplitude by means of the "+" and "-" buttons. Alternatively, use the arrow left/right and up/down buttons of the keyboard.
3. Configure the necessary masking settings.
4. If you need to adjust the talk-over/back levels, click the **Settings** ( ) button to open this setting menu.

For a complete list of keyboard shortcuts, please refer to the Help file. To open it, go to the Help menu of the application and click **Get Help**; alternatively, press **F1** on the keyboard.

Click the **Stimulus** button, or press the spacebar on the keyboard, to present a signal to the client. When the client is capable of catching the signal of a certain frequency and level, he or she responds by using the response switch. When this happens, the colour of the **Frequency Levels** pane changes.

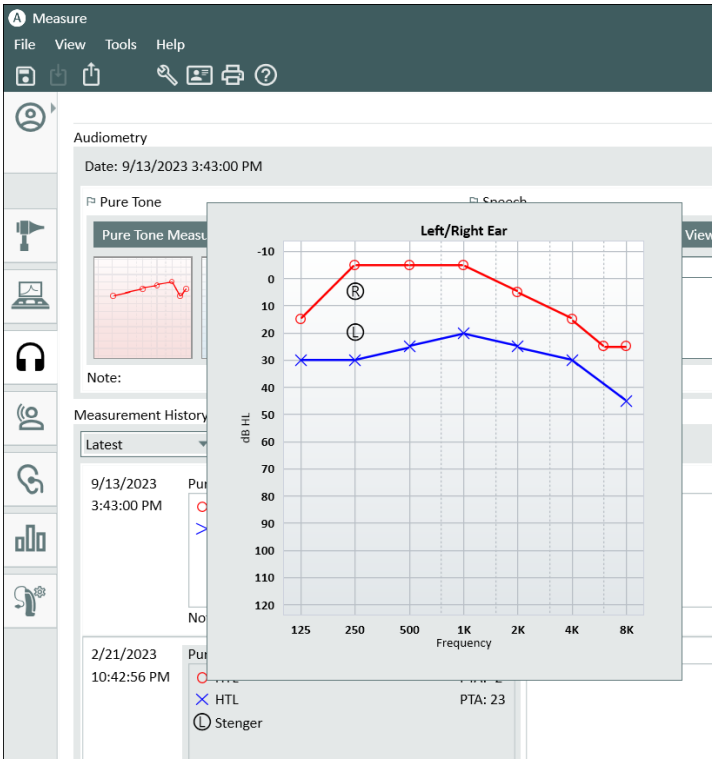



Click the **Store** button, or the **S** button on the keyboard, to mark the point in the audiogram.

Refer to the Help file for a detailed description of the procedure.

When you have obtained all required data for both ears, click **Save**—the button is active if the program is opened as a Noah module—and then **Close**, in order to save your measurement data.

After that, a corresponding item appears in the **Measurement History** pane of the dashboard. If you place the mouse pointer over the history item, the corresponding audiogram will be shown in a large format.




You can double click any measurement from the session list to display it in the workspace.

From the **Measurement History** pane, it is also possible to print a selected measurement by employing the corresponding button.

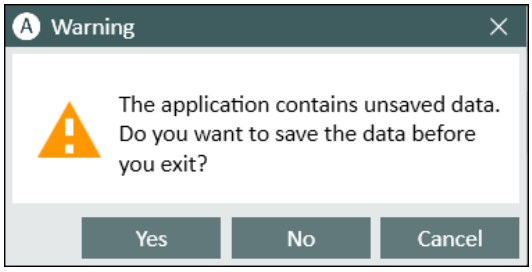
The **Print** option enables printing reports for the current or any of the older sessions. For REM, SM and HIT measurements, the only default report type will be printed. As for the Audiometry Reports, you can choose between a number of available options in the Print Options section that is accessible via **Settings > General > Reporting**.

## 8. 14 Shutdown Procedure

### Closing Application

To safely close the application:

1. Select **File > Exit** or use **Alt+F4**. If you made any measurements, the system will show the warning:




2. Click **Yes** to save the session data and close the application. Click **No** if you want to close the application without saving of data.

### Disconnecting Fitting and HIT Units

For the Unit that uses the Opto-USB cable without power DC adapter: disconnect the USB cable from the instrument and the USB power supply from the mains power outlet.

For the Unit that uses DC adapter and non-optical USB: disconnect the USB cable from the instrument and then disconnect the DC adapter both from the instrument and the mains power outlet.

For the Unit that uses non-optical USB without power DC adapter: disconnect the USB cable from the instrument.

For the Unit that uses the Opto-USB cable and power DC adapter: disconnect the USB cable and the USB power supply from the mains outlet and then the power DC adapter from the instrument and the mains power outlet.

# 9 Maintenance

## 9. 1 Annual Calibration of Headset and Transducers

The headset and transducers delivered with the Fitting System and reference and coupler microphones delivered with the HIT Unit are NOT intended for calibration by users. Contact your local distributor for your annual service and calibration.

## 9. 2 Adjustment of Common Headsets and Microphones

All calibration of the Fitting System and the transducers delivered with it has been performed by the manufacturer before shipment. The system's accessories should be re-calibrated annually

by the supplier or their appointed representatives to ensure system integrity.

However, depending on your license agreement, you may have access to perform calibrations locally. In this case, additional options such as Headphones Calibration, REM Calibration, and HIT Microphone Calibration can be done using a separate calibration tool.

# 9. 3 Regular System Checks

## 9. 3. 1 Daily Equipment Checks

Regular equipment checks ensure accurate and reliable test results. While the following guidelines provide a general procedure, always refer to official standards applicable in your region to ensure compliance with legal and clinical requirements.

Daily checks are particularly important for clinicians who frequently transport their equipment. Movement and handling can lead to subtle damage or misalignment, making routine verification essential to maintain performance consistency.

| |
|---|
| Conduct equipment checks in an environment with noise levels similar to actual test conditions to ensure accurate results. |

### Daily Equipment Check Procedure

#### Step 1: Inspect and Clean

- Examine the audiometer and all accessories for wear, dirt, or damage. Pay close attention to earphone cushions, plugs, wires, and connectors.
- Clean components. For detailed cleaning instructions, refer to Cleaning.
- Replace any damaged or worn parts before proceeding.

#### Step 2: Warm-Up

- Turn on the equipment and allow it to warm up for five minutes before use (minimum one minute).
- For rechargable devices, check the battery level and recharge if necessary.

#### Step 3: Verify Components

- Match transducer serial numbers with software records.
- Inspect all cable connections (plugs, wires, junction boxes) to ensure proper setup and stability.
- Resolve any intermittent issues before testing.

### Functional Tests

#### Step 4: Low-Level Sound Check

- Play tones at low hearing levels (10–15 dB HL) across all test frequencies.
- Verify audibility for air and bone conduction.

- Listen for noise, hum, breakthrough sounds, or tone changes when applying masking noise.

#### Step 5: High-Level Sound Check

- Set hearing levels to:
  Air conduction: 60 dB HL
  Bone conduction: 40 dB HL
- Ensure clear sound, no distortion, and proper transducer operation.

**Physical Tests**

#### Step 6: Transducer Inspection

- Check the tension of headsets and bone conduction headbands.
- Ensure that swivel joints move smoothly, neither too loose nor too stiff.
- Look for signs of wear, strain, or metal fatigue on cables and headbands.

#### Step 7: Audiometer Inspection

- Ensure no extraneous instrument noise is present when the device is idle.
- Confirm all cables and connectors are securely attached, without visible cracks or fraying.
- Verify the attachment between the audiometer and any external components, such as sound booth cables.
- Gently move cables to check for signal interruptions, which may indicate loose or damaged connections.

### 9. 3. 2 Adjusting Speech Audiometer input level

To ensure proper sensitivity levels during daily checks, it is recommended to verify the VU-meter. For this, you should play a CD calibration signal and adjust the input sensitivity to 0 dBVU.

### 9. 3. 3 Calibration of probe tube and reference microphone (in REM and SM)

Prior to real ear measurement session or when replacing the probe tube with a new one, ensure the correct probe tube calibration. If it is calibrated properly, you should see a flat curve once measuring a REUG with the probe tube still kept in the calibration position.

### 9. 3. 4 HIT box calibration

On a regular basis (e.g. once per day), check the proper coupler microphone sensitivity and calibration. The procedure is as follows:

1. Unscrew the coupler microphone body to expose the coupler microphone diaphragm.
2. Place it close against reference microphone without it touching.
3. Conduct an OSPL90 measurement, you should see a flat line at 90 dB.

## 9. 4 Inspection

On a regular basis, that is, at least once a week, perform a visual inspection of the Fitting and HIT Units and their accessories for visible damages. During use, evaluate the test results and perform a system inspection if the results appear unreliable.

## 9. 5 Cleaning

### 9. 5. 1 Disposable parts

 Parts such as foam tips on insert earphones or probe tubes for real-ear measurement are not intended for reuse. Dispose of such items in a hygienic manner after each client session.

### 9. 5. 2 Reusable parts

Maintain a high level of hygiene and clean reusable devices which come into contact with clients between each use. See the cleaning instructions below.

### 9. 5. 3 Cleaning instructions

- For cleaning use only a soft dry cloth dampened very sparingly with a low level disinfectant solution such as isopropyl alcohol to wipe the device. Do not allow excess solution to enter the device as this may damage internal components.
- Do not autoclave, pressure sterilise, or gas sterilise the device or any of its electrical accessories.
- Do not soak or immerse the device in any liquid.
- Do not use acetone or paraffin/kerosene-based solutions, or any other harsh solvent to clean the device or its accessories. Use of such substances may be harmful to the equipment and may result in faulty operation.

## 9. 6 Switching to a New Transducer

When setting up a new transducer, make sure that it is recognized by the Fitting Unit. To do so, follow the instructions:

1. Connect the Fitting Unit to the PC using the USB cable.
2. Start Measure.
3. Wait until the Fitting Unit is initialized and connected. The current connection status is displayed on the right side of the status bar at the bottom of the screen.
4. Disconnect the old transducer.
5. Connect the new transducer to the Fitting Unit.
6. In Measure, go to **Tools** > **Device Management**.
7. Review the name and serial number of the new transducer.

If the data corresponds to the new transducer, you can start using the system normally.

If the data corresponds to the old transducer, proceed with the next steps.

8. In Measure, go to **Tools** > **Refresh Transducer Data**.
9. Select the needed transducer and click **Refresh Transducer Data**.
10. The system will inform you once the process is finished. You can close the window and start using the system normally.

## 9. 7 Securing Patient Data

Protecting patient data is crucial for maintaining confidentiality and complying with legal and ethical standards. Implement the following measures to enhance data security:

1. **Enable Password Protection**: Set up strong, unique passwords for all devices and software handling patient information. This adds a critical layer of defense against unauthorized access.
2. **Implement Data Encryption**: Utilize encryption tools to protect sensitive data stored on devices. Encryption ensures that even if data is accessed without authorization, it remains unreadable.
3. **Secure Data Backups**: Regularly back up patient data to secure, access-controlled locations. Avoid using unsecured external drives or cloud services without proper encryption and security protocols.
4. **Maintain Updated Software**: Keep all operating systems, applications, and security software up to date to protect against vulnerabilities and exploits.
5. **Implement User Access Controls**: Restrict access to patient data based on user roles and responsibilities. Ensure that only authorized personnel have access to sensitive information.
6. **Utilize Secure Networks**: Ensure that data transmission occurs over secure networks. Avoid using public or unsecured Wi-Fi networks when accessing or transmitting patient information.

# 10 Troubleshooting Guide

If you have any problems with installing or running the software, please go through this guide first before contacting Support.

Please verify that the following installation prerequisites are satisfied:

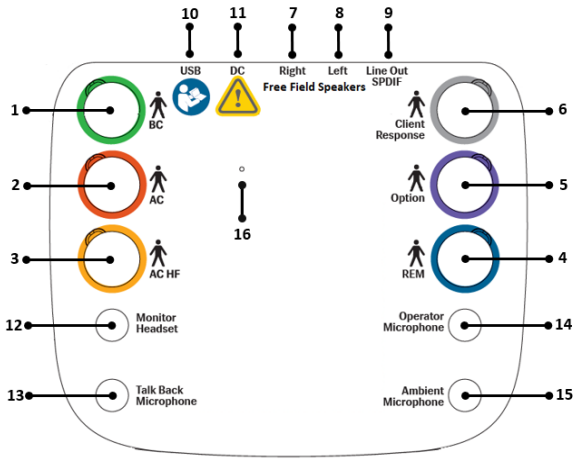
- The Fitting System software supports Windows 10, Windows 10 Anniversary Update and Windows 11 operating systems.
- Local administrator rights are required in Windows to install the Fitting System software.
- The Fitting System software supports NOAH 4 or higher.

Before starting the troubleshooting – please ensure that you do the following steps:

- Unplug the USB cables and power supply (if available) from the Fitting/HIT unit.
- Re-start the computer.
- Connect the Fitting/HIT unit to the computer using the USB cable.
- Connect the power supply to the Fitting/HIT unit, if available.
- Check that all available headsets, speaker and other accessories are connected to the Fitting/HIT unit.
- Run the Fitting System software.
- Check that the Fitting/HIT unit is connected properly:
  - In the Fitting software status bar the device is shown as Connected:
    
    
  - Power light on the Fitting/HIT unit is permanently on.

If any of the above steps failed, please refer to the below table for the solution of your problem.

| Problem | Action |
|---|---|
| Software installation problems | |
| • Setup can't be completed successfully (when running the **setup_x.x.x.x.exe**). | • Use only the supported Windows operating systems.<br>• Use the latest Windows service packs. |
| Software set-up problems | |
| • The stimulus button in the Audiogram is greyed out.<br>• At start-up of the Fitting System the "License notification" message is shown. | • The License code is not activated. Please activate the license from the help menu and follow the description for the activation of the license code. |
| Hardware connection problems | |
| • In the Fitting Software System's status bar under "AUD HW/ HIT HW" it says: "Not connected". | • Reconnect a USB cable and power supply, if available. Check that the units are connected. (See the status bar in the software).<br>• Try another USB port on the computer. |

| Problem | Action |
|---|---|
| | • Try another USB cable.<br>• If connection is done via hub/switch, connect directly to computer. |
| • No sound in headset or speakers, etc. | • Ensure that the unit is connected to the computer using the USB cable.<br>• Power light is steady on.<br>• Plug and unplug all headsets.<br>• Reconnect USB cable and power supply, if available. Check that the units are connected. (See the status bar in the software). |
| • No output from the speaker in REM. | Ensure that you have selected the correct speaker in the **Tools** > **Settings** > **General** > **Loudspeaker selection** > **REM**. Then calibrate your REM probe tube. |
| • Power light is not steady at start-up of the Fitting Software System. | • Re-start the Fitting Software System.<br>• Reconnect USB cable and power supply, if available. Check that the unit is connected. (See the status bar in the software).<br>• Check that the unit is displayed in Windows device manager under sound devices. If not, please contact support. |
| • Need to reset the instrument. | If a HW reset is required, follow these steps:<br>1. Close the software,<br>2. Disconnect all transducers, accessories, and cables from the instrument.<br>3. Locate the small reset hole on the rear of the instrument.<br>  <br><br>*16 - Hardware reset in 2000-1 Fitting Unit* |

| Problem | Action |
|---|---|
| | 4. Insert a paperclip into the hole until you feel a light click.<br>5. Hold the paperclip in place and connect the USB cable without removing it.<br>6. Wait for the instrument to blink a few times then remove the paperclip.<br>7. Restart the software.<br>*After restarting, the instrument will prompt for an update.*<br>Note: Perform only when instructed by support or a technician. |

# 11 Hotline and Technical Support

**Auditdata A/S**, Wildersgade 10B, 1408 Copenhagen, Denmark. Phone +45 70 20 31 24 support@auditdata.com

**UK** Responsible Person:
Auditdata Ltd., Staines-upon-Thames, UK. Phone +44 (0) 333 4444 212.
support@auditdata.com

**Australia** Sponsor:
Daryl Staley-Jackson, 247 Creek Ridge Road, Glossodia, NSW, 2756, Australia.
support@auditdata.com

**US:**

Auditdata, LLC, 88 Glocker Way, #352 Pottstown, PA 19465. support@auditdata.com

# Appendix A

## A.1 Declarations of Conformity

### Primus Fitting Unit+ (PFU+)

Auditdata

ID: 30.0241/09

## DECLARATION OF CONFORMITY

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT**

| | | |
|---|---|---|
| **Manufacturer name and address** | Auditdata A/S<br>Wildersgade 10B<br>1408 Copenhagen<br>Denmark | |
| **Notified Body name and address** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München | CE 0123 |
| **Product Identification** | MD Category: | Hearing Medical Diagnostic (Hardware and Software) |
| | Trademark: | Primus PFU+ |
| | Type/Model: | Primus Fitting Unit - PFU+ (PFU+) |
| | CS (Common specification) | N/A no common specification has been published |
| | SRN: | DK-MF-000011415 |
| | Basic UDI/DI: | 05711781DHF2000ZC |
| | Risk class: | IIa, rule 10 |
| | Lot/Batches/Serial number: | All issued serial numbers from 21000001 |
| **Intended purpose** | Audiometer is a device used for evaluating hearing acuity. The audiometer records the subject's responses to produce an audiogram of threshold sensitivity, or speech understanding profile. Audiometer with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing. Audiometer is indicated for non-continuous real-ear measurements (REM) at the ear drum by means of noninvasive external ear canal insertion of a probe tube. | |
| **Conformity assessment** | Annex IX (Quality system and technical documentation assessment) | |
| **EC-Certificate No.:** | G10 076081 0015 | |
| **DOC valid until** | 2029-02-18 | |

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

**Copenhagen, February 19th 2024**

Denys Lebedev, QA/RA Manager

## 2000 Primus HIT Pro

Auditdata

# DECLARATION OF CONFORMITY

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT**

ID: DN00969/06

| | | |
|---|---|---|
| **Manufacturer name and address** | Auditdata A/S<br>Wildersgade 10B<br>1408 Copenhagen<br>Denmark | |
| **Notified Body name and address** | Danish Health and Medicines Authority<br>Axel Heides Gade 1<br>2300 Copenhagen S,<br>Denmark | CE |
| **Product Identification** | MD Category: | Hearing Medical Diagnostic (Hardware) |
| | Trademark: | Primus HIT |
| | Type/Model: | 2000 Primus HIT Pro (Unit), 2005 -1 HIT Unit |
| | CS (Common specification) | N/A no common specification has been published |
| | SRN: | DK-MF-000011415 |
| | Basic UDI/DI: | 05711781DHF2000ZC |
| | Risk class: | I, rule 13 |
| | Lot/Batches/Serial number: | All issued serial numbers from 32000001 |
| **Intended purpose** | The HIT Unit is intendent to apply sound to the hearing aid in a closed test box and obtain the acoustical output of the hearing aid in a coupler cavity equipped with a microphone.<br>The HIT Unit is intended to be used together with the Software to provide objective indication of the characteristics of a Hearing Aid. Visualization of the obtained coupler microphone signal is only available in the Software application.<br>The HIT Unit is indicated for technical quality inspection or fitting of hearing instruments with no clients involved. | |
| **Conformity assessment** | Annex I, II and III | |

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

**Copenhagen, May 26th 2024**

Denys Lebedev, QA/RA Manager

## 2000 Primus Fitting Unit Pro

ID: DN01781/02

# Auditdata

# DECLARATION OF CONFORMITY

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT**

| | | |
|---|---|---|
| **Manufacturer name and address** | Auditdata A/S<br>Wildersgade 10B<br>1408 Copenhagen<br>Denmark | |
| **Notified Body name and address** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München | CE 0123 |
| **Product Identification** | MD Category: | Hearing Medical Diagnostic (Hardware and Software) |
| | Trademark: | Primus Pro |
| | Type/Model: | Primus Fitting Unit Pro (2000 Primus Fitting Unit Pro, PFU Pro) |
| | CS (Common specification) | N/A no common specification has been published |
| | SRN: | DK-MF-000011415 |
| | Basic UDI/DI: | 05711781DHF2000ZC |
| | Risk class: | IIa, rule 10 |
| | Lot/Batches/Serial number: | All issued serial numbers from 25000001 |
| **Intended purpose** | Audiometer is a device used for evaluating hearing acuity. The audiometer records the subject's responses to produce an audiogram of threshold sensitivity, or speech understanding profile. Audiometer with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing. Audiometer is indicated for non-continuous real-ear measurements (REM) at the ear drum by means of noninvasive external ear canal insertion of a probe tube. | |
| **Conformity assessment** | Annex IX (Quality system and technical documentation assessment) | |
| **EC-Certificate No.:** | G10 076081 0015 | |
| **DOC valid until** | 2029-02-18 | |

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

**Copenhagen, February 19th 2024**

Denys Lebedev, QA/RA Manager

## 2000 Primus Audiometer Unit Ice

ID: DN00625/07

# Auditdata

# DECLARATION OF CONFORMITY

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT**

| | | |
|---|---|---|
| **Manufacturer name and address** | Auditdata A/S<br>Wildersgade 10B<br>1408 Copenhagen<br>Denmark | |
| **Notified Body name and address** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München | CE 0123 |
| **Product Identification** | MD Category: | Hearing Medical Diagnostic (Hardware and Software) |
| | Trademark: | Primus Ice |
| | Type/Model: | 2000 Primus Audiometer Unit Ice |
| | CS (Common specification) | N/A no common specification has been published |
| | SRN: | DK-MF-000011415 |
| | Basic UDI/DI: | 05711781DHF2000ZC |
| | Risk class: | IIa, rule 10 |
| | Lot/Batches/Serial number: | All issued serial numbers from 26000001 |
| **Intended purpose** | Audiometer is a device used for evaluating hearing acuity. The audiometer records the subject's responses to produce an audiogram of threshold sensitivity, or speech understanding profile. Audiometer with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing. | |
| **Conformity assessment** | Annex IX (Quality system and technical documentation assessment) | |
| **EC-Certificate No.:** | G10 076081 0015 | |
| **DOC valid until** | 2029-02-18 | |

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

**Copenhagen, February 19th 2024**

Denys Lebedev, QA/RA Manager

## 2000-1 Fitting Unit

ID: DN02476/02

# Auditdata
# DECLARATION OF CONFORMITY

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT**

| | | |
|---|---|---|
| **Manufacturer name and address** | Auditdata A/S<br>Wildersgade 10B<br>1408 Copenhagen<br>Denmark | |
| **Notified Body name and address** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München | CE 0123 |
| **Product Identification** | MD Category: | Hearing Medical Diagnostic (Hardware and Software) |
| | Trademark: | Measure, Unity 4 |
| | Type/Model: | 2000-1 Fitting Unit (2000-1 FU) |
| | CS (Common specification) | N/A no common specification has been published |
| | SRN: | DK-MF-000011415 |
| | Basic UDI-DI: | 05711781DHF2000ZC |
| | Risk class: | IIa, rule 10 |
| | Lot/Batches/Serial number: | All issued serial numbers for 2000-1 FU from 33000001 |
| **Intended purpose** | Audiometer is a device used for evaluating hearing acuity. The audiometer records the subject's responses to produce an audiogram of threshold sensitivity, or speech understanding profile. The 2000-1 FU with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing. The 2000-1 FU is indicated for non-continuous real-ear measurements (REM) at the ear drum by means of noninvasive external ear canal insertion of a probe tube. | |
| **Conformity assessment** | Annex IX (Quality system and technical documentation assessment) | |
| **EC-Certificate No.:** | G10 076081 0015 | |
| **DOC valid until** | 2029-02-18 | |

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

**Copenhagen, February 19th 2024**

Denys Lebedev, QA/RA Manager

## A.2 Manufacturer


The models below are manufactured and sold by:

Auditdata A/S

Wildersgade 10B
1408, Copenhagen
Denmark
Phone: +45 70203124

www.auditdata.com

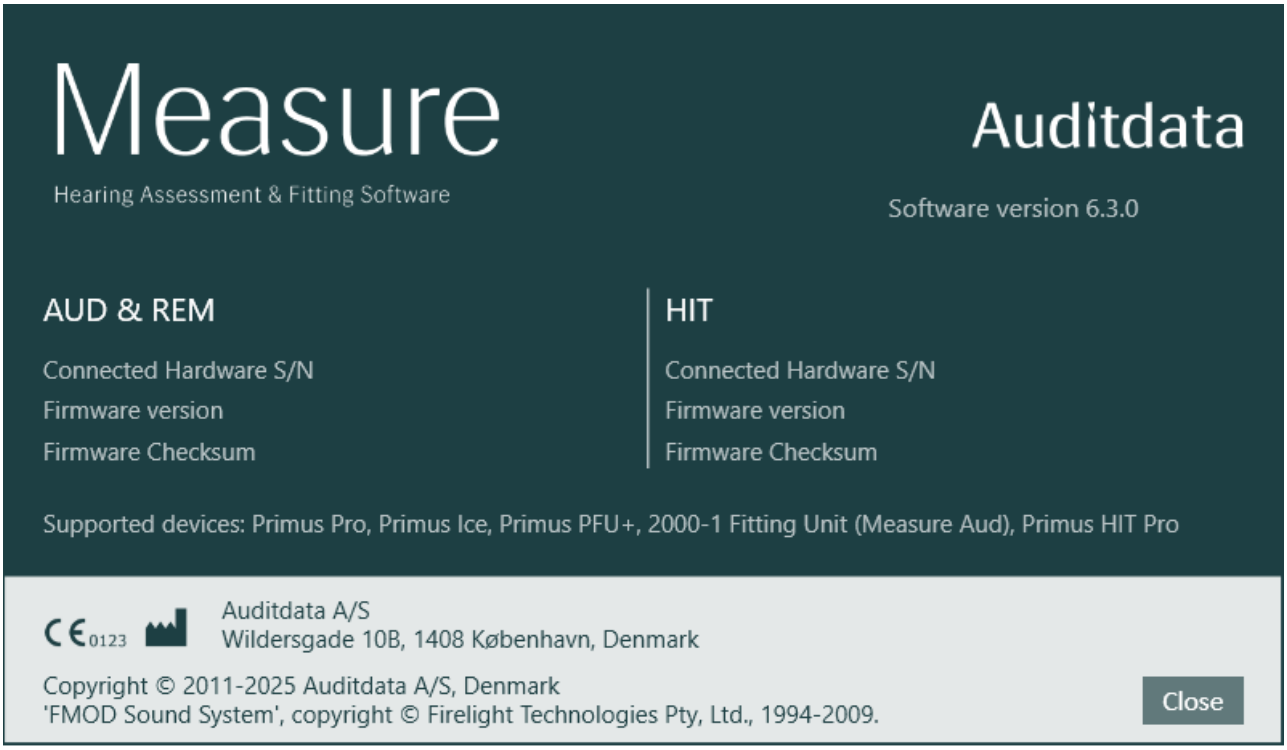
CE 0123

Primus Fitting Unit – PFU+
2000 Primus Fitting Unit Pro
2000 Primus Audiometer Unit Ice
2000-1 Fitting Unit
2000 Primus HIT Pro

# A.3 Labelling

## Label samples

Measure



# Appendix B

## B.1 Technical Specification

### B.1.1 Fitting Unit

| Item | Description | Value |
|---|---|---|
| Mechanical Data: | | |
| Primus Fitting Unit, without cover | External measures L x W x H<br>Weight | 345 x 110 x 35 mm<br>475 g |
| Primus Pro, without cover | External measures L x W x H<br>Weight | 345 x 112 x 35 mm<br>500 g |
| Primus Ice, without cover | External measures L x W x H<br>Weight | 167 x 110 x 32 mm<br>375 g |
| Primus Fitting Unit, with cover | External measures L x W x H<br>Weight | 350 x 120 x 130 mm<br>800 g |
| Primus Pro, with cover | External measures L x W x H<br>Weight | 360 x 120 x 96 mm<br>900 g |
| Primus Ice, with cover | External measures L x W x H<br>Weight | 181 x 115 x 94 mm<br>550 g |
| 2000-1 FU | External measures L x W x H<br>Weight | 142 x 142 x 55 mm<br>415 g |
| 2000-1 FU (WL), wireless | External measures L x W x H<br>Weight | 142 x 142 x 55 mm<br>450 g |
| Electrical Data: | | |
| Power supply, low power output | 5 volts USB power | max 500 mA |
| Provided power supplies for USB power in conjunction with OPTO USB cable (Type OPTICIS M2-100-03) | type Friwo FW7662M/05 | Input voltage 100-240 V, 50/60 Hz, 150 mA; output voltage 5 Vdc, 1.1 A |
| | type Friwo FW8002M/05 | Input rated 100-240 V ±10%, 50/60 Hz, 160 mA. Output rated 5 Vdc, 1.4 A |
| Provided power supplies for USB power in conjunction with USB isolation | The USB Isolator has internal power supply. | Output voltage 5 Vdc, 0.5 A |

| Item | Description | Value |
|---|---|---|
| cable Type IF-TOOLS; ISOUSB-BOX-PLUS; Art. No.: 14000 | | |
| ⚠ Provided power supplies for high power output functionality | Direct plug-in power supply, type Friwo FW7362M/15 | Input voltage 100-240 V AC, 50/60 Hz, 700 mA; output voltage 15 Vdc, 2.0 A |
| | Direct plug-in power supply, type Friwo FW8030M/15 | Input rated 100-240 V ±10%, 50/60 Hz, 300 mA. Output rated 15 Vdc, 2.0 A |
| Free-field output | w/overload protection | 2 channels, each up to 20 watts in 4 ohms *1*4*5<br>3 channels, each up to 20 watts in 4 ohms *2*3 |
| Left/Right, Sub/Mid, Rear Free Field Line Out*1*2<br>Line Out 1/Line Out 2/Line Out 3 - Free Field Line Out*3<br>Line Out/Demo Headset*4<br>Line Out*5 | 500 mV RMS | max load 16 ohms |
| Client*1*2/Demo*3 and Monitor Headset output | 500 mV RMS | max load 16 ohms |
| Operator microphone | Electret microphone powered inputs | -40 dB+/-5 dB<br>(0 dB = 1 V/pa, 1000 Hz) |
| Talk back microphone | Electret microphone powered inputs | -55 dB+/-4 dB<br>(0 dB = 1 V/pa, 1000 Hz) |
| REM Probe input | Electret microphone powered inputs | Refer to sec. B.2.2 |
| Air and Bone Conductor Outputs | For Tone and Speech:<br>3 Vrms (w. external power supply)<br>1 Vrms (USB only)<br>125 Hz – 16 kHz Frequency Range For Bone Conductor:<br>250 Hz - 8kHz Frequency Range | Max load 4 ohm |

| Item | Description | Value |
|---|---|---|
| | | |
| Calibration | Refer to a separate manual for calibration instructions.<br>Tone and Speech signals are calibrated for Max Hearing Level<br>Tolerance: +/- 3 dB (up to 8 kHz)<br>+/-5 dB (8 kHz and higher)<br>Masking signals are calibrated for Max Sound Pressure Level | |
| Client response button | Normally open contact | |
| Fuses | Autofuses | |
| **Environmental Data:** | | |
| Warm-up time | (if stored at room temperature) | 1 minute |
| Operating temperature | With wireless applied parts | 5 °C – 36 °C |
| Operating temperature | Without wireless applied parts | 5 °C – 40 °C |
| Storage temperature | | -30 °C - 70 °C |
| Humidity | | 5% - 90% |
| Air pressure (altitude) | | 70 kPa (3000 meter) to 106 kPa (-400 meter) |
| **Connectors:** | | |
| DC power | | Pin 2.5 mm/Hole 7.0 mm<br>Pin: positive supply (+)<br>Ring: negative supply (-) |
| USB 2.0 and USB 3.0 | Complies with 60601-1 3rd or IEC 60950-1 | USB-B*1*2*3*4<br>USB-C*5 |
| S/PDIF*3*5 | Optical Audio | TOSLINK connector*3<br>Optical Mini Jack 3.5 mm*5 |
| Left speaker/Middle speaker/Right speaker | Anitek, H5-02-1-0-5-0 | 2 pcs*4*5<br>3 pcs*1*2*3 |
| Line Out 1/Line Out 2/Line Out 3 - Free Field Line Out*3<br>Left/Right, Sub/Mid, Rear Free Field Line Out*1*2 | Stereo mini jack | 3.5 mm |

| Item | Description | Value |
|---|---|---|
| Line Out/Demo Headset*4<br><br>Line Out*5 | | |
| Operator and talk back microphone input | Stereo mini jack | 3.5 mm |
| Client*1*2/Demo*3 and Monitor Headset output | Stereo mini jack | 3.5 mm |
| Air conductor 1 *1*2*3*4 | DIN | 8 pin |
| Air conductor*5 | Mini-DIN | 8 pin |
| Air conductor 2*1*2*3 | DIN | 8 pin |
| Air conductor HF*5 | Mini-DIN | 8 pin |
| Air conductor 3 (high frequency)*1*2*3 | DIN | 8 pin |
| Bone conductor *1*2*3*4 | DIN | 8 pin |
| Bone conductor*5 | Mini-DIN | 8 pin |
| Client response*1*2*3*4 | DIN | 8 pin |
| Client response*5 | Mini-DIN | 8 pin |
| Option*2*3 | DIN | 8 pin |
| Option*5 | Mini-DIN | 8 pin |
| Probe*1/Real Ear Probe*2*3 input | DIN | 8 pin |
| REM Probe*5 | Mini-DIN | 8 pin |
| **Parts and Accessories*:** | **Description** | |
| AUD (in Fitting Unit) | Clinical audiometer | |
| REM (in Fitting Unit) | Real ear measurement unit | |
| Speech Mapping | Speech Mapping with Live voice and Percentile Analysis | |
| AUD/REM DC adaptor | 15 volts/2A | |
| Optical USB connection | Type OPTICIS M2-100-03<br><br>Type IF-TOOLS; ISOUSB-BOX-PLUS; Art. No.: 14000 | |
| Headset with microphone | Monitor headset w/boom microphone for operator monitoring and talk over | |
| Headset without micro- | Monitor headset | |

| Item | Description | Value |
|---|---|---|
| phone | | |
| Microphone | Table microphone for talk over or talk back | |
| Extension cord for sound attenuating booth | | |
| Loudspeaker incl. cable | Free-field loudspeaker for real ear measurement and audiometry | |
| Insert Earphones | Audiometric insert earphones | |
| Ear tips (small) | Insert ear tips for Primus Insert – small (children) | |
| Ear tips (medium) | Insert ear tips for Primus Insert – medium | |
| Ear tips (large) | Insert ear tips for Primus Insert – large | |
| Insert tube with nipples | For the Insert earphones only. Length 200 mm | |
| Probe tube guide | Probe tube stabilizer | |

*[1] Only available in the PFU.

*[2] Only available in the PFU+.

*[3] Only available in Primus Pro.

*[4] Only available in the Primus Ice.

*[5] Only available in the 2000-1 Fitting Unit.

## Applied Parts Type B

**Note:** These parts must only be replaced by identical parts delivered by the manufacturer.

| Item | Description |
|---|---|
| Insert Phone/Insert Earphone Flex | Real Ear audiometric insert earphones (Model: Realear) |
| ER-3A Insert Headset | EarTone audiometric insert earphones (Model: EarTone 3A) |
| ER-3C Insert Headset | Etymotic audiometric insert earphones (Model: Etymotic Research type 3C) |
| TDH-39 Headset | Supraaural audiometric headphone |

| Item | Description |
|---|---|
| HDA-200 Headset | Sennheiser circumaural audiometric high frequency headphone |
| HDA-280 Headset | Sennheiser standard audiometric headphone |
| HDA-300 Headset | Sennheiser circumaural audiometric high frequency headphone |
| DD45 Headset | Interacoustics supraaural audiometric headphone |
| DD450 Headset | RadioEar circumaural audiometric high frequency headphone |
| DD65 Headset | Interacoustics circumaural audiometric headphone |
| DD65v2 Headset | RadioEar circumaural audiometric headphone |
| B-71 Bone Conductor | RadioEar audiometric bone conductor |
| Client response button | Single-button response switch |
| Free field calibration tool | Free field calibration microphone |
| Real Ear Probe/REM Probe Flex | REM Probe, binaural real-ear measurement probe set |
| Wireless REM Probe | Wireless REM Probe, binaural real-ear measurement probe set |

*) **Note**: The list of Parts and Accessories is subject to change without notice.

### B.1.2 HIT - Hearing Instrument Test Unit

| Item | Description | Value |
|---|---|---|
| Indoor use | | |
| ***Mechanical Data:*** | | |
| Hearing Instrument Test Unit | External measures L x W x H | 350 x 320 x 125 mm |
| Weight | | 4.5 kgs |
| ***Electrical Data:*** | | |
| Power supply, low power | 5 volts USB power | max 500 mA |
| Provided power supplies for USB power in conjunction with OPTO USB cable (Type OPTICIS M2-100-03) | type Friwo FW7662M/05 | Input voltage 100-240 V, 50/60 Hz, 150 mA; output voltage 5 Vdc, 1.1 A |
| | type Friwo FW8002M/05 | Input rated 100-240 ±10%, 50-60Hz, 160 mA. Output rated 5Vdc, 1.4 A. |
| Provided power supplies for USB power in conjunction with USB isolation cable Type | The USB Isolator has internal power supply. | Output voltage 5 Vdc, 0.5 A |

| Item | Description | Value |
|---|---|---|
| IF-TOOLS; ISOUSB-BOX-PLUS; Art. No.: 14000 | | |
| ⚠ Provided power supplies for high power output functionality | Direct plug-in power supply, type Friwo FW7362M/15 | Input voltage 100-240 V AC, 50/60 Hz, 700 mA; output voltage 15 Vdc, 2.0 A |
| | Direct plug-in power supply, type Friwo FW8030M/15 | Input rated 100-240 ±10%, 50-60Hz, 300 mA. Output rated 15Vdc, 2.0 A |
| MAINS supply voltage fluctuations | | up to ±10 % of the nominal voltage |
| TRANSIENT OVERVOLTAGES | | up to the levels of OVERVOLTAGE CATEGORY II;<br>**NOTE 1** These levels of transient overvoltage are typical for equipment supplied from the building wiring. |
| TEMPORARY OVERVOLTAGES occurring on the MAINS supply | | 2 500 V impulse withstand voltage |
| Free-field output | w/overload protection | up to 20 watts in 4 ohms |
| Fuses | Autofuses | |
| ***Environmental Data:*** | | |
| Warm-up time | (if stored at room temperature) | 1 minute |
| Operating temperature | | 5 °C – 40 °C |
| Storage temperature | | -30 °C - 70 °C |
| Humidity | | 5% - 90% |
| Air pressure (altitude) | | 70 kPa (3000 meter) to 106 kPa (-400 meter) |
| Applicable POLLUTION DEGREE of the intended environment | | POLLUTION DEGREE 2 in most cases |
| ***Connectors:*** | | |
| ⚠ DC power | | Pin 2.5mm/hole 7.0mm<br>Pin: positive supply (+)<br>Ring: negative supply (-) |

| Item | Description | Value |
|---|---|---|
| USB 2.0 and USB 3.0 | Complies with 60601-1 3rd or IEC 60950-1 | USB-B |
| Left HI-PRO or NOAHlink™ input | 6 pin mini DIN | |
| Right HI-PRO or NOAHlink™ input | 6 pin mini DIN | |
| Monitor headset | Stereo mini jack | 3.5mm |
| ***Parts and Accessories*:*** | ***Description*** | |
| Reference microphone | Installed, Electret goose neck type | |
| Coupler microphone | Installed, Electret type | |
| Coupler | 2 cc coupler with attachments for ITE, BTE, and Body-worn Hearing Instruments | |
| Battery pills, 5 sizes | Type 5A, 10A, 312, 13 and 675 | |
| BTE tube | PVC tube for BTE Hearing Instruments. Length 25 mm | |
| ITE putty | Putty for fastening of ITE Hearing Instruments to the ITE coupler | |

***) Note:** The list of Parts and Accessories is subject to change without notice.
An updated list will always be available from our homepage: www.auditdata.com.

# B.2 Technical Data

## B.2.1 AUD system

| | |
|---|---|
| No. of channels: | Full 2 channel |
| Tone presentation: | Steady, pulsed |
| Signal types: | Pure Tone:<br>IEC 60645-3:2007<br>125 Hz - 16 kHz*<br>Accuracy within 0.2%<br>Modulated Tone:<br>125 Hz – 8 kHz<br>Triangular linear<br>10.8 Hz Repetition Rate<br>+/-10% Frequency Deviation |

| | |
|---|---|
| | (of carrier frequency) |
| Masking types: | Narrow Band Noise:<br>IEC 60645-1, 1/3 Octave filter with geometric center frequency as the audiometric TONE frequency<br>White Noise:<br>100-20000 Hz with +3 dB/octave throughout its frequency range<br><br>Speech-weighted:<br>IEC 60645,<br>125-1000 Hz +3 dB/octave ,<br>1000-6000 Hz - 9 dB/octave<br><br>Pink Noise:<br>100-20000 Hz, +/-1 dB throughout its frequency range |
| Hearing levels: | -10 dB - 120 dB HL |
| Deviation, dB: | 0.5 dB |
| Distortion: | Less than 3 % for air conduction.<br>Less than 6% for bone conduction. |

** Primus Ice supports 125 Hz - 8 kHz only.*

### B.2.2 REM system

| | |
|---|---|
| No. of channels: | 4 channel (2 probe microphone units with each a reference mic. and a probe mic.) |
| Signal types: | White noise, speech-weighted noise, and pink noise.<br>For technical specifications refer to section B.2.1. |
| Further Signals: | ISTS Signal according to IEC 60118-15,<br>Crest factor: 17<br>ISTS MPO signal |

| | |
|---|---|
| | Peak-Level: 90dB<br>SPL Frequencies: 0,5, 1, 2, 3, 4 kHz<br>On time: 250 ms<br>Off time: 250 ms<br>Rise- and fall time: 25 ms<br>ICRA Signals: (Hearing Aid Clinical<br>Test Environment Stand-ardization)<br>DSL Signals: Female “S” and “SH”<br>(Child Amplification Lab-oratory<br>National Centre for Audiology<br>Western University London, Ontario) |
| Frequency range: | 125 Hz – 16 kHz |
| Signal levels: | 50 – 90 dB SPL |
| Accuracy: | Within 4 dB |
| Signal Analysis: | Analysis type: FFT<br>Analysis bandwidth:<br>125 Hz to 16 kHz<br>Resolution: 24 bands/Octave<br>Windowing type: Hann |
| Equalization type: | Modified pressure method |
| Sensitivity, Probe Mic. | Depending on selected input range,<br>10 ranges available<br>-35 dB (0 dB = 1 V/pa, 1000 Hz) |
| Sensitivity, Reference Mic. | Depending on selected input range,<br>6 ranges available<br>-35 dB (0 dB = 1 V/pa, 1000 Hz) |
| Measurement Range | 40 dB SPL to 100 dB SPL |

### B.2.3 HIT system

| | |
|---|---|
| No. of channels: | 2 channel - One coupler micro-phone and one reference |

| | |
|---|---|
| | microphone |
| Signal types: | Pure tone, modulated tone, narrowband noise, white noise, speech-weighted noise, and pink noise.<br><br>For technical specifications refer to section B.2.1. |
| Frequency range: | 200 Hz – 16 kHz |
| Signal levels: | 40 – 100 dB SPL |
| Tolerance, dB: | +/- 1,5 dB in the frequency range 200 - 2000 Hz and +/- 2,5 dB in the frequency range 2000 - 5000 Hz and above. |
| Pure tone accuracy: | +/-2% |
| Distortion: | Less than 0,5% at 70 dB.<br>Less than 2% at 90 dB. |

### B.2.4 Insert Phone/Insert Earphone Flex

| | |
|---|---|
| Insert Phone/Insert Earphone Flex | Including Audiometric insert earphones |
| Frequency range: | 125 Hz to 8 kHz |
| Maximum output level: | Up to 120 dB HL at mid frequencies |
| Compliance: | EN 60645 and ISO 389-2 |

### B.2.5 Real Ear Probe/REM Probe Flex

| | |
|---|---|
| Real Ear Probe/REM Probe Flex | Adjustable left and right-ear hangers, each with reference and probe tube microphone |
| Frequency range: | 125 Hz to 16 kHz |
| Maximum input level for probe tube input: | 125 dB SPL with less than 3% distortion.<br>Up to 135 dB SPL |

### Wireless REM Probe

| Parameter | Value |
|---|---|
| Frequency Range | 125Hz to 16KHz |

| | |
|---|---|
| Maximum SPL | 106dB ref, 126dB probe |
| Sensitivity | -35 dB |
| Equivalent Noise Level | SNR > 62dB |
| Physical Weight | 45g |
| Dimensions (L x B x H) | 197 x 170 x 18 mm |
| Battery capacity | 250mAh 3.7V |
| Operating Temperature | 5 °C – 36 °C |
| Battery life (on one charge): | Up to 5 hours measurement |
| Operating range (Line of sight) | Recommended maximum range 5.5 meters from FU with no obstruction |
| Standards device is compliant with | ANSI S3.46, IEC 61669, EN 61669 |

## B.3 EMC Conformance Requirements

### B.3.1 EMC Classification, Standards and Test Methods

| | |
|---|---|
| **Emissions:** | EN 55011/CISPR11, Group 1, Class B |
| **Harmonic Current Emission:** | IEC 61000-3-2:2018, Class A |
| **Voltage Fluctuations and Flicker:** | IEC 61000-3-3:2013 |
| **Immunity:** | Test levels for professional healthcare environment. |
| **Enclosure Port:** | |
| Basic EMC standard | Immunity test level |
| IEC 61000-4-2 (ESD) | ± 8 kV contact, ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| IEC 61000-4-3 (rad. Fields) | 3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz<br>& Test points / frequencies according to table 9 of IEC/EN 60601-1-2 (RF wireless communications equipment):<br>385 MHz; Pulse Modulation: 18 Hz; 27 V/m<br>450 MHz, FM + 5Hz deviation: 1 kHz sine; 28 V/m<br>710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m<br>810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m<br>1720, 1845, 1970 MHz; Pulse Mod.: 217 Hz; 28 V/m |

| | |
|---|---|
| | 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m;<br>5240, 5500, 5785 MHz; Pulse Mod.: 217 Hz; 9 V/m |
| IEC 61000-4-8 (magn. Fields) | 30 A/m, 50 Hz & 60 Hz |
| **Input a.c. Power Port:** | |
| Basic EMC standard | Immunity test level |
| IEC 61000-4-4 (bursts) | ± 2 kV, 100 kHz repetition frequency |
| IEC 61000-4-5 (surges) | ± 0,5 kV, ± 1 kV, line to line |
| IEC 61000-4-6 (cond. RF) | 3 V/m, 0,15 MHz – 80 MHz, 80 % AM at 1 kHz<br>6 V/m in ISM bands between 0,15 MHz and 80 MHz |
| IEC 61000-4-11 (volt. dips) | 0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°<br>and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0° |
| IEC 61000-4-11 (volt. inter.) | 0 % UT; 250/300 cycle |
| **Patient Coupling Port:** Device has no patient coupling port | |
| **Signal Input / Output Port:** | |
| Basic EMC standard | Immunity test level |
| IEC 61000-4-2 (ESD) | ± 8 kV contact, ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| IEC 61000-4-4 (bursts) | Only applicable for patient headsets, patient client switch and speaker cables because cable length might be > 3m. |
| IEC 61000-4-5 (surges) | N/A; all SIP/SOP cables not directly connected to out-door cables. |
| IEC 61000-4-6 (cond. RF) | Only applicable for patient headsets, patient client switch and speaker cables because cable length might be > 3m. |

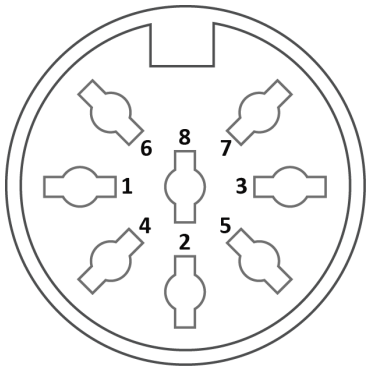
## B.3.2 Maximum permissible Cable Lengths of Accessories

| Accessory, Transducer | Maximum cable length |
|---|---|
| Power Supply (low voltage side) | 1,8 meters |
| USB cable | 3 meters |
| REM probes<br>Client response switch<br>Air conductor headsets like TDH39, DD45, DD450, | 2,5 meters (In combination with extension cable 91.0704 prolongable up to 5,5 meters) |

| | |
|---|---|
| HDA300<br><br>Bone conductor headsets like B71 | |
| Insert headsets like EAR-3A, ER-3C | 2 meters (In combination with extension cable 91.0704 prolongable up to 5,5 meters) |
| Free field calibration microphone | 3 meters |
| Table microphone (Talk back microphone) | 2,5 meters |
| Headset with microphone (Monitor headset) | 2,5 meters |
| Loudspeaker LS01 | 5 meters |
| RECD Speaker LS Mini | 2,5 meters |

# B.4 Pin Assignments Table

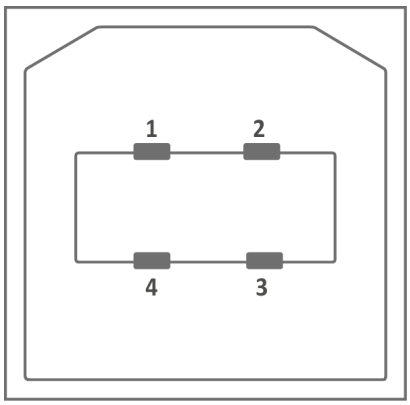
## Primus Fitting Unit

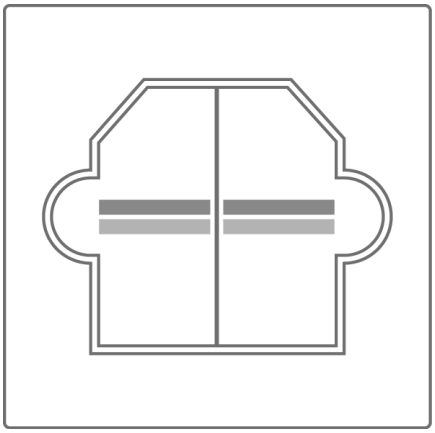
| Connector | Air Conductor 1, 2, 3 | Bone Conductor |
|---|---|---|
| Standard DIN Connector 8 pins   female | 1. Ground | 1. Output |
| | 2. Data Up/Down-load | 2. Data Up/Download |
| | 3. Ground | 3. Not Con-nected |
| | 4. Optional Micro-phone Input | 4. Not Con-nected |
| | 5. Plug Detect | 5. Plug Detect |
| | 6. Left Channel Out-put | 6. Ground |
| | 7. Right Channel Out-put | 7. Not Con-nected |
| | 8. Ground | 8. Ground |

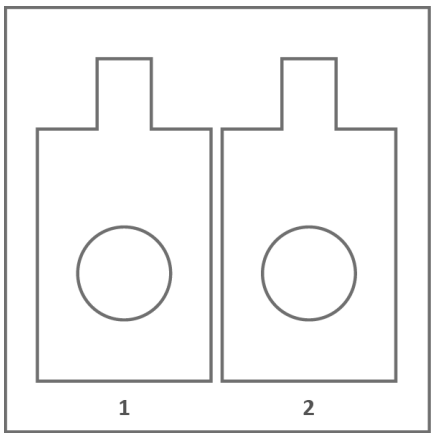
| Option*2*3 | Primus Probe*1/Real Ear Probe *2*3 | Client Response |
|---|---|---|
| 1. Secondary Micro-phone Input | 1. Ground | 1. Not Connected |
| 2. Data Up/Download | 2. Data Up/Download | 2. Logic Input (High/Low) |
| 3. Ground | 3. Ground | 3. Not Connected |
| 4. Primary Microphone Input | 4. Reference Microphone Input, Left | 4. +3.3 Vdc |
| 5. Plug Detect | 5. Reference Microphone Input, Right | 5. Plug Detect |
| 6. Speaker Output, positive | 6. Probe Microphone Input, Left | 6. Control Clock |
| 7. Speaker Output, negative | 7. Probe Microphone Input, Right | 7. Control Data |
| 8. Ground | 8. Ground | 8. Ground |

| Connector | | Client*1*2/Demo*3 Headset | Free Field: Left/Right, Rear and Sub/Mid*1*2<br>Free Field: Line out 1, Line out 2 Line out 3*3 |
|---|---|---|---|
| 3.5 mm TRS socket (mini-jack)<br>  <br> | | 1. Left Channel Output | 1. Channel 1,3,5 Output |
| | | 2. Right Channel Output | 2. Channel 2,4,6 Output |
| | | 3. Ground | 3. Ground |
| **Monitor Headset** | **Operator Micro-phone Left** | **Operator Micro-phone Right** | **Talk Back Microphone** |
| 1. Left Channel Output | 1. Input | 1. Input | 1. Input |
| 2. Right Channel Output | 2. Not Connected | 2. Not Connected | 2. Not Connected |
| 3. Ground | 3. Ground | 3. Ground | 3. Ground |

| Power supply: DC POWER JACK<br>  | 1. +15 Vdc, 2A max (Center) |
|---|---|
| | 2. Ground (Sleeve) |

| | |
|---|---|
| USB: Type B connector<br>  <br> | 1. 5 Vdc, 0.5A max |
| | 2. Data - |
| | 3. Data + |
| | 4. Ground |

| | |
|---|---|
|  | SPDIF: Toslink optical transmitter*3 |

| | |
|---|---|
| Speaker Output Right, Mid, Left   | 1. Positive<br>2. Negative |

*1 This plug is only available in the PFU.

*2 This plug is only available in the PFU+.

*3 This plug is only available in the Primus Pro.

## 2000-1 Fitting Unit

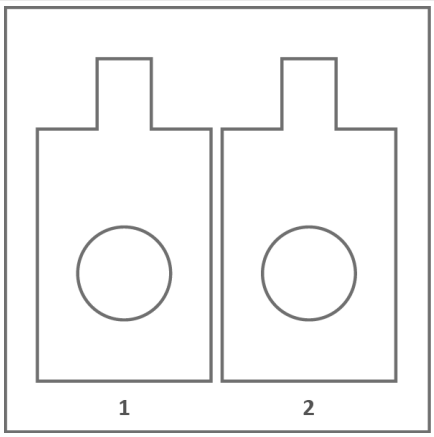
| 8-pin Mini-Din Connector Front View | Pin | Connector | | | | |
|---|---|---|---|---|---|---|
| | | AC1, AC2 | BC | Client Resp. | Option | REM Probe |
|   | 1 | Plug detect | Plug detect | Plug detect | Plug detect | Signal Ref. Mic. R |
| | 2 | Ground | Ground | +3.3VDC | Signal Coupler Mic. | Signal Ref. Mic. L |
| | 3 | Signal R | Signal | I2C Data | RECD Speaker + | Signal Tube Mic. R |
| | 4 | Data | Data | Pat. Signal | Data | Data |
| | 5 | Signal L | Signal | I2S Clock | RECD Speaker - | Signal Tube Mic. L |
| | 6 | Ground | Sig. | Ground | Ground | Ground |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | R | Ground | | Ref. Mic. | Tube Mic. R |
| | 7 | Ground | Ground | Ground | Ground Coupl. Mic. | Ground Ref. Mic. L&R |
| | 8 | Ground L | Sig. Ground | Ground | Signal Ref. Mic. | Ground Tube Mic. L |

| 3.5 mm Stereo Jack | Pin | Connector | |
|---|---|---|---|
| | | Monitor Headset, Line Out | Talk Back Microphone, Operator Microphone, Ambient Microphone |
|  | 1 (Tip) | Signal Output Left | Signal Input (Bias Voltage) |
| | 2 (Ring) | Signal Output Right | Not connected |
| | 3 (Sleeve) | Ground | Ground |

| Power Supply, DC Power Jack | Pin | Signal |
|---|---|---|
|  | Center Pin | +15VDC / max. 2A |
| | Sleeve | Ground |

| Speaker, Left and Right | Pin | Signal |
|---|---|---|

| | | |
|---|---|---|
|  | 1 | Positive Terminal |
| | 2 | Negative Terminal |

# Appendix C

## C.1 Minimum Requirements (for Software Installation)

### C.1.1 PC specifications for the connected operator PC

| | Minimum requirements | Recommended requirements |
|---|---|---|
| **Processor/clock speed** | 2 GHz | 2 GHz (or higher) multi-core |
| **System RAM** | 2 GB | 4 GB or more |
| **Free hard drive space** | 2 GB | 2 GB |
| **Operating System*** | Windows 10 and Windows 10 Anniversary Update | Windows 10 and Windows 10 Anniversary Update<br>Windows 11 |
| **Screen Resolution** | 1280 x 1024 | 1600 x 1200 |
| **Graphics Card** | XVGA | Dual monitor output |
| **CD Drive** | Required if speech test CD´s are used. | Required if speech test CD´s are used. |
| **Connection of Fitting System to PC** | USB connector 2.0 or higher | USB connector 2.0 or higher |
| **Connection of HIT System to PC (optional)** | USB connector 2.0** or higher | USB connector 2.0** or higher |

* Your OS must be up to date. All Windows updates must be installed.

** If a USB hub must be used in order to connect both units, a hub with power supply is recommended.