PKA 87 PC Based Screening Audiometer

LORECa Hearing Instrument

March,2014

[USER MANUAL]

PKA87 & PKA87/B User manual

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Introduction

Intended Use

The PKA87 screening audiometer is designed to be a device for screening for hearing loss. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The screening for hearing loss using this kind of audiometer depends on the interaction with the patient. “normal hearing” result should not allow for ignoring other contra indications. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist

The PKA87 audiometer is intended to be used by an audiologist, hearing healthcare professionals, or trained technicians in a quiet environment. It is recommended that the instrument be operated within an ambient temperature range of 15-35 degree Celsius (59-95 degrees Fahrenheit)

This manual describes the Diagnostic software used for PC Audiometry.

The Software allows users to working and display, store and print audiometric data.

Precautions

Notice - Be sure to use only stimulation intensities, which will be acceptable for the patient.

Notice - The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers require a recalibration.

Notice - It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognised disinfectant.

Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness

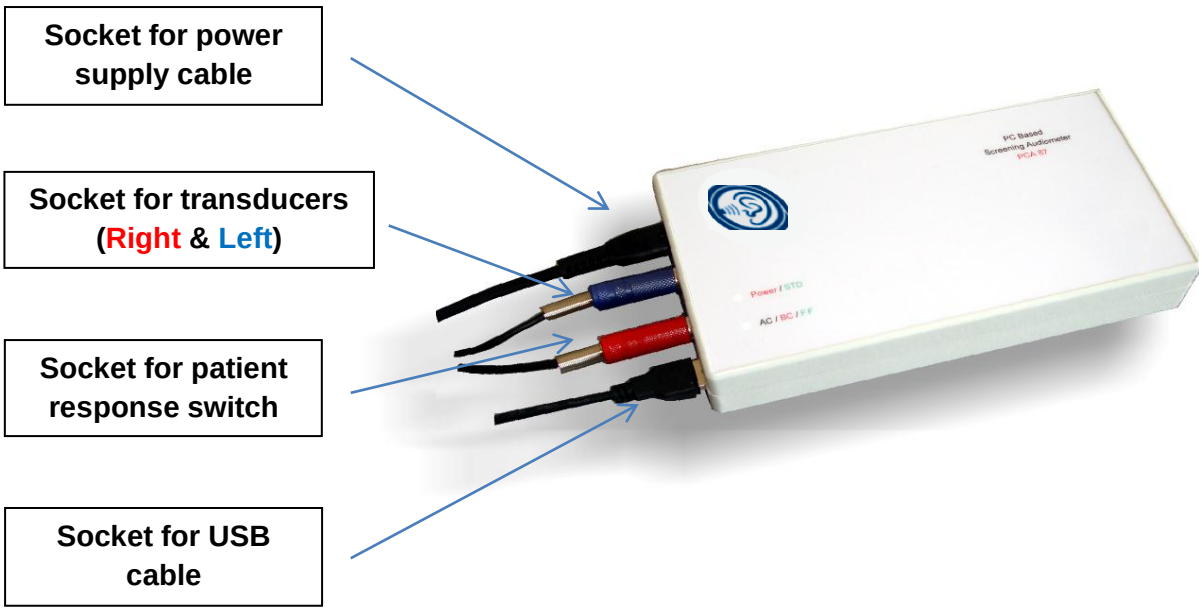
Notice - Never insert or in any way use the insert headset without a new clean non defect test tip.

Notice - Do not site the PKA87 next to a radiator or any other heat source.

Notice - In operation the instrument should not be subject to temperatures below 15C° or above 35C°.

Notice - Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Electrical Installation



System Requirements

- **Operating systems support:**
- **Windows® XP SP2 and Vista.**
- **Windows® 7 ,32 Bit**
- **PKA87/B and PKA87 uses a direct USB connection (it has built-in USB)**
- **Test measurement data support:**
- **Audiometric data: Only Air Conduction. (BC and FF are Optional)**
- **On-line/PC-operated and Patient/Session Saving in PC.**

Installation Steps

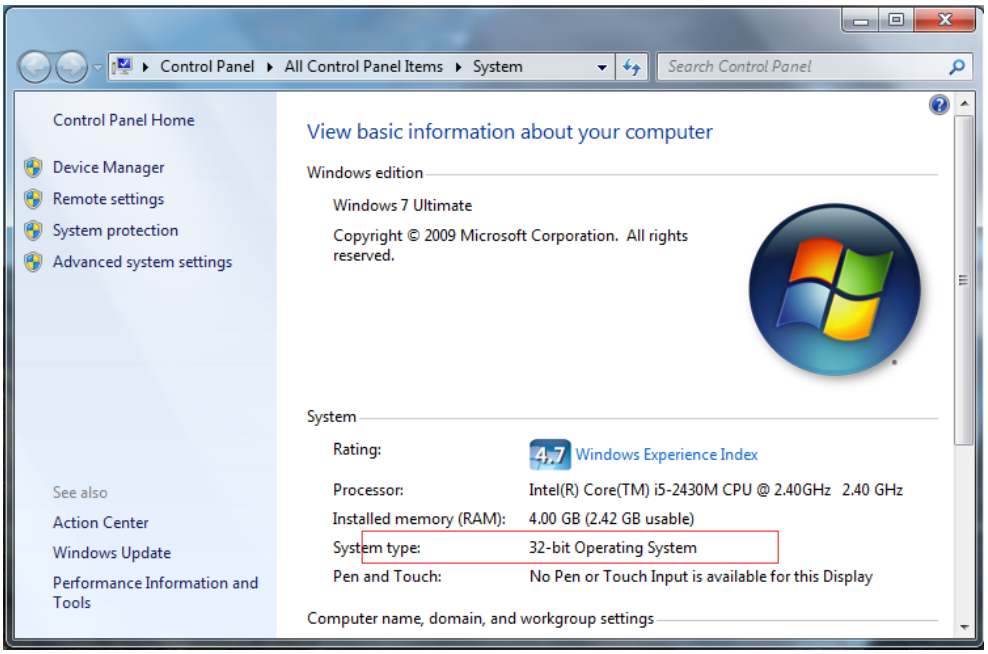
Step 1: Device Initialization

Step 2: GUI Installation

Device Initialization

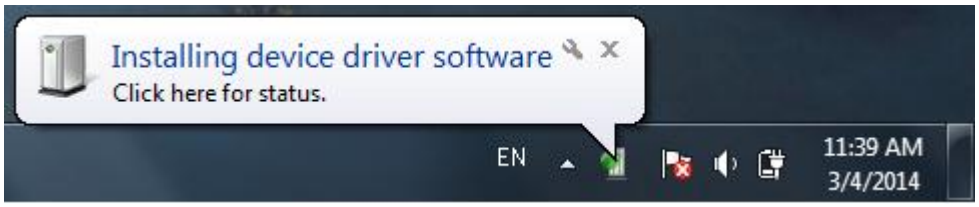
Notice: Please check for System compatibility

System type**:** **32-bit** Operating System

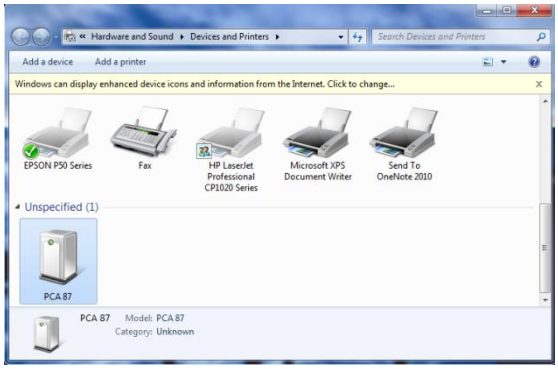


1-1- Plug in Device to the AC socket.

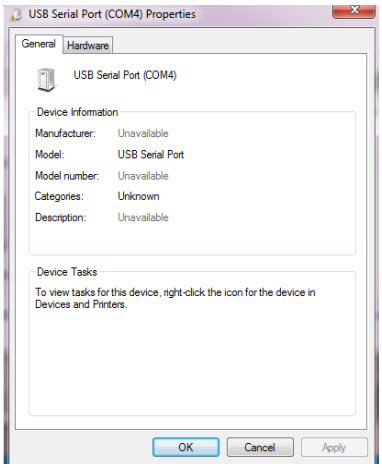
1-2- Connect the Instrument to the PC with a USB cable, the following window should appear.



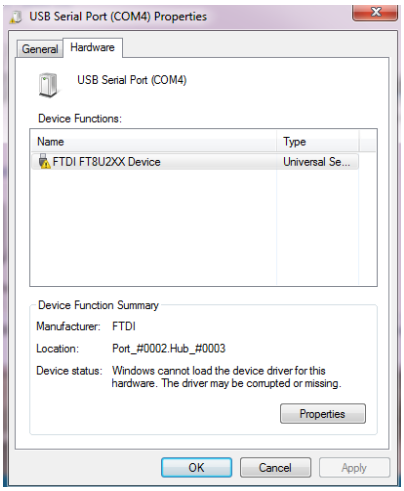
1-3- Select “**Device and Printers”** from “**Start”** menu.



1-4- Double Click on the PKA87 Icon.



1-5- Select “**Hardware”** tab and Push the “**properties”** Button.



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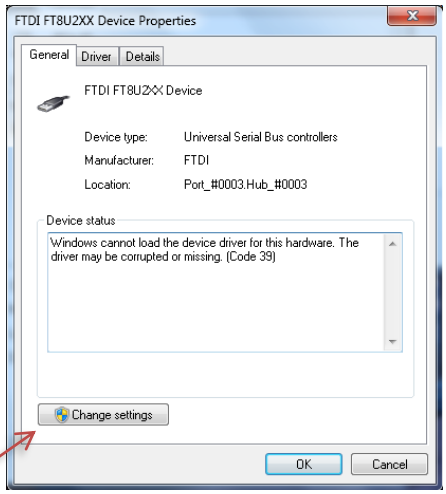
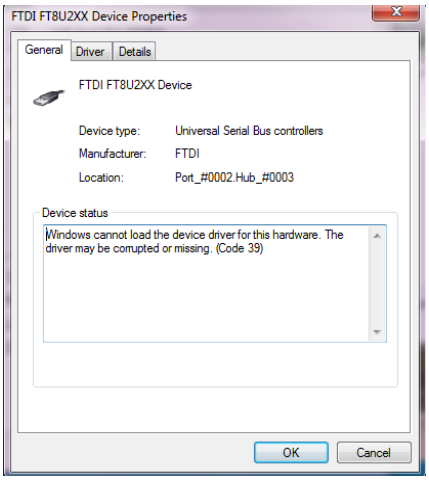
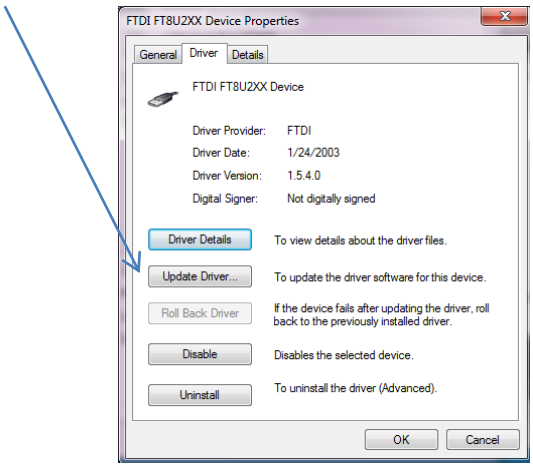


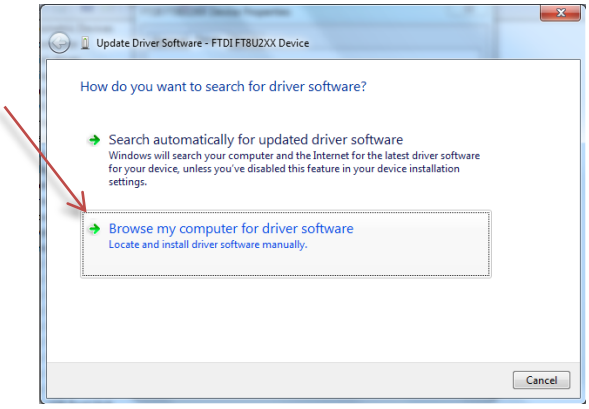
1-6- Select “**Change Settings”** and enter to the “**Driver”** Tab.



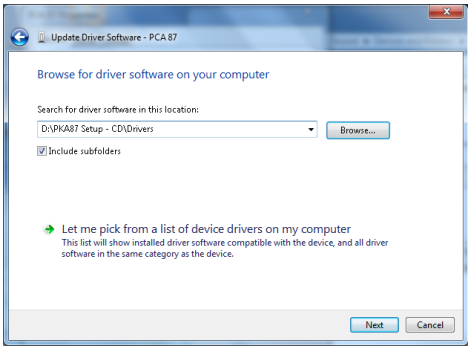
1-7- Push "**Update Driver"** button



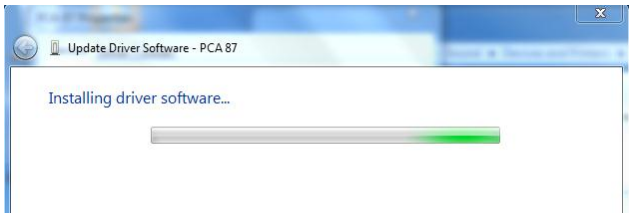
1-8- Select "**Browse my computer for driver software"** choice.



1-9- Enter address of “**Drivers”** from CD drive.

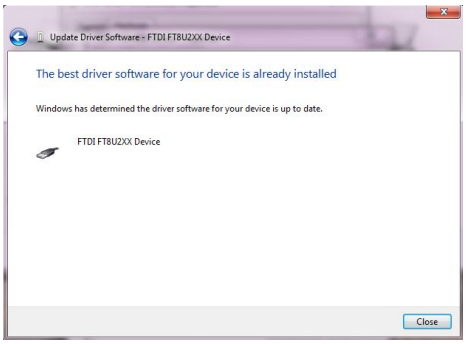


1-10- Please wait a moment.



1-11- Update driver is completed.

Close the window.

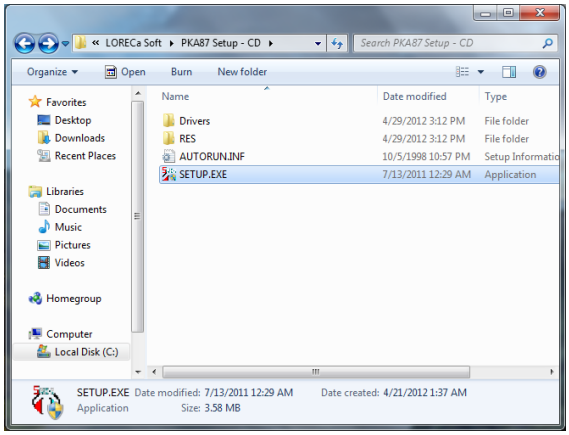


1-12- Then processed to system setup described in the next chapter.

GUI Installation

Installation of Graphical User Interface (GUI):

To install Software simply insert the installation CD run the installation file (if it does not start automatically) and following the installation:



2-1- Welcome Dialog:

Select Installation Directory.

Press Next Button.

2-2- Confirm Installation:

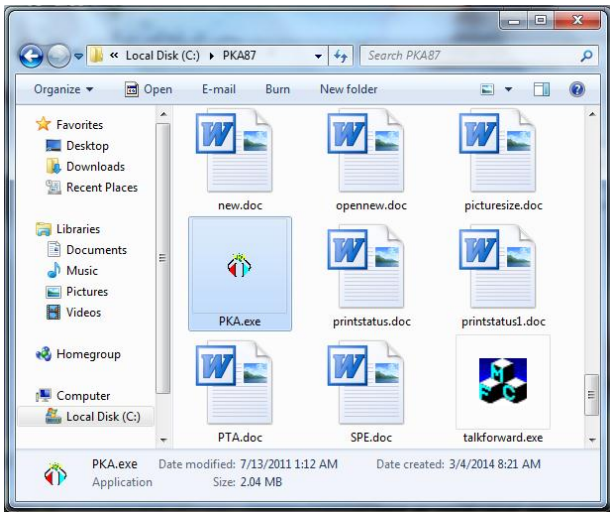
Press Next Button.

2-3- Press Setup Button

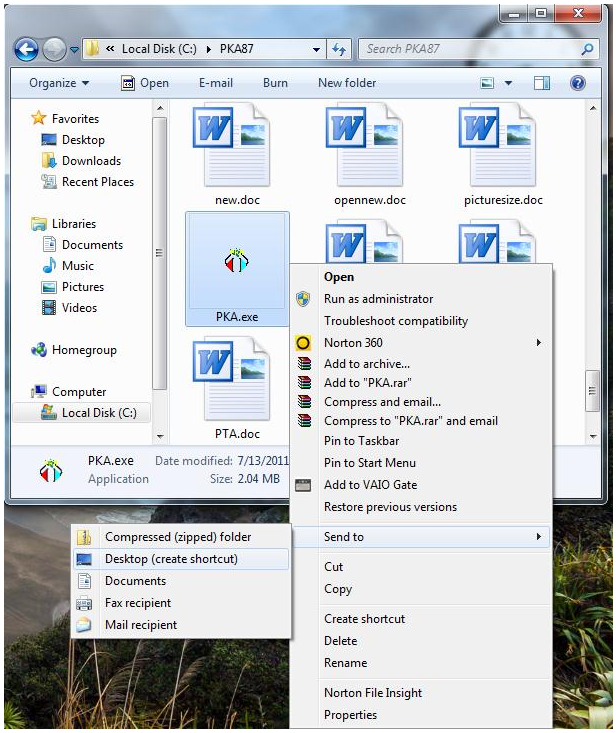
Wait for installation to complete

2-4- Installation is complete. Press “Ok”.

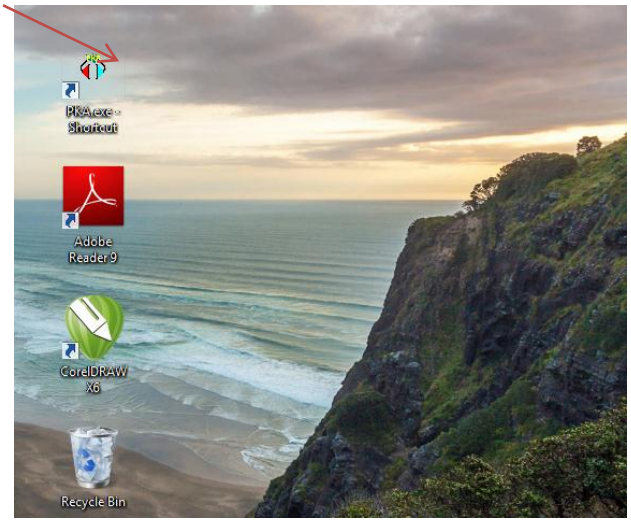
2-5- **PKA87** folder Created in the “**C**” Drive. Open this folder and select “**PKA.exe”** file.



2-6- For easy to access, Create shortcut on the Desktop.

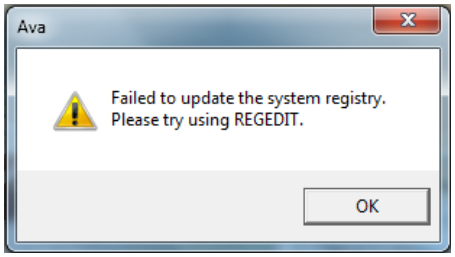


2-7- PKA87 Shortcut

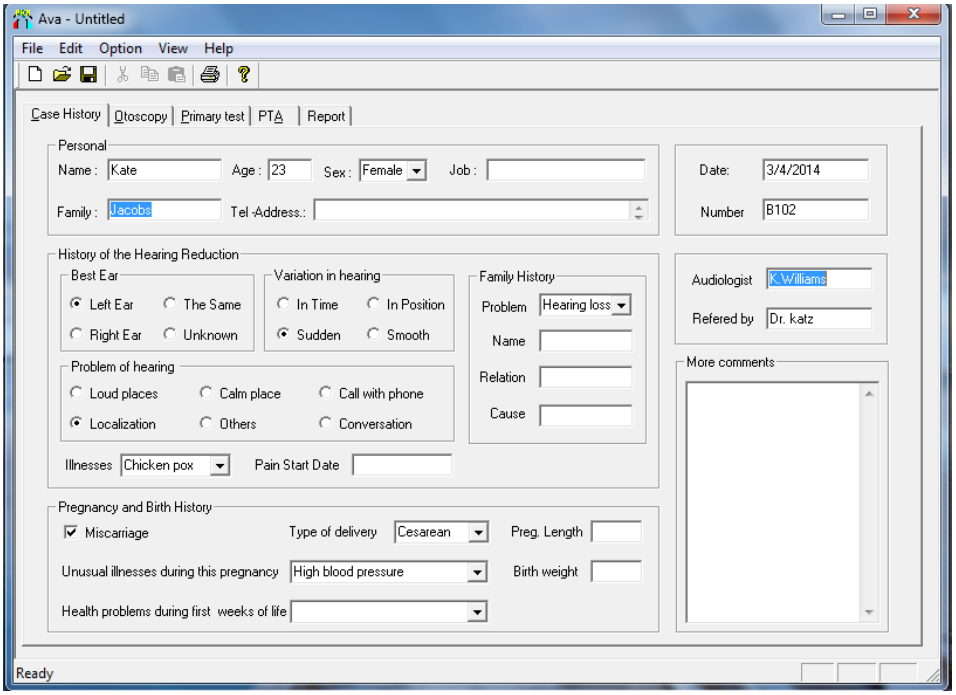


3-1 Double Click on PKA87 Shortcut

3-2 OK the window



3-3 PKA main window is open

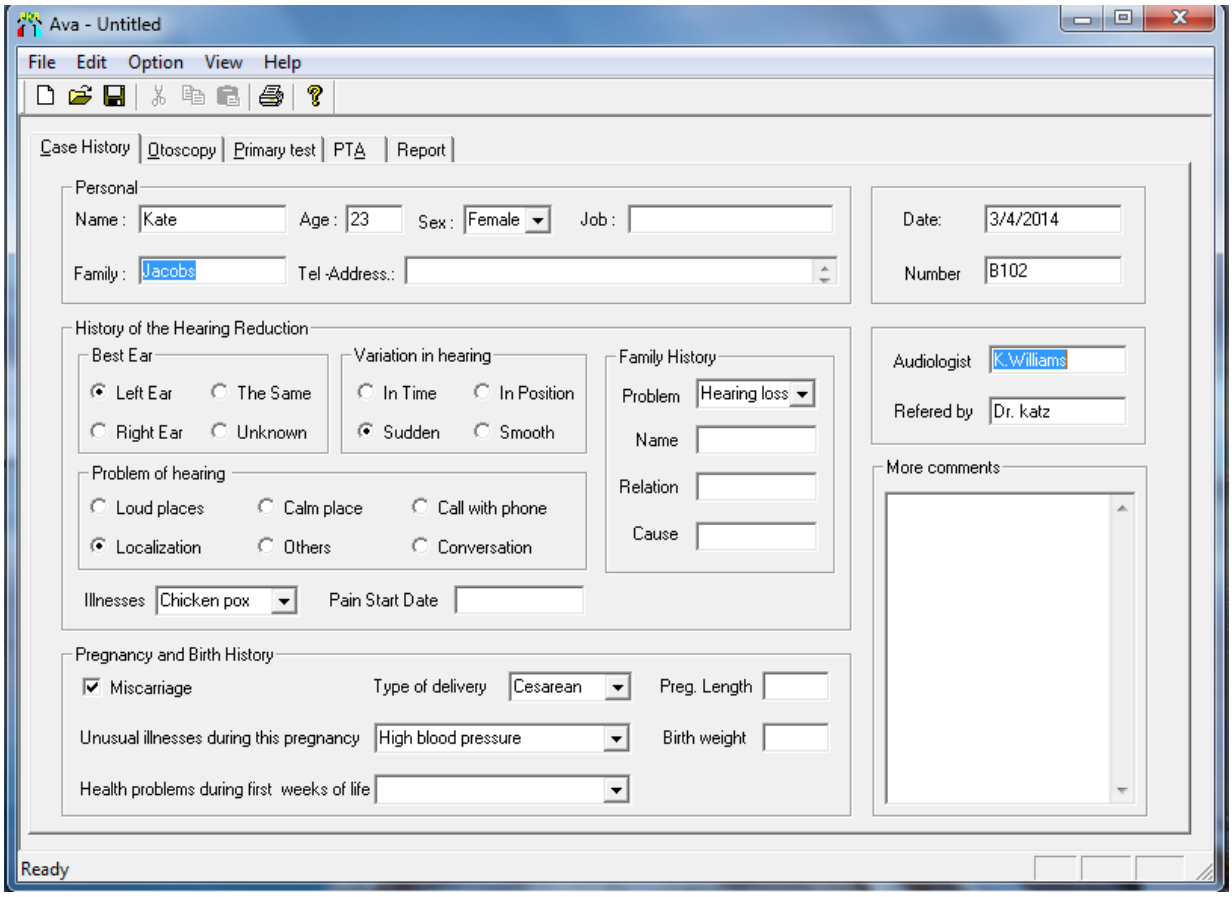


PKA window have 5 tabs for different objects.

Case History	Otoscopy	Primary test	PTA	Report

3-4 Case History | Otoscopy | Primary test | PTA | Report

Practitioner typically asks questions to obtain the following information about the patient and then Store:



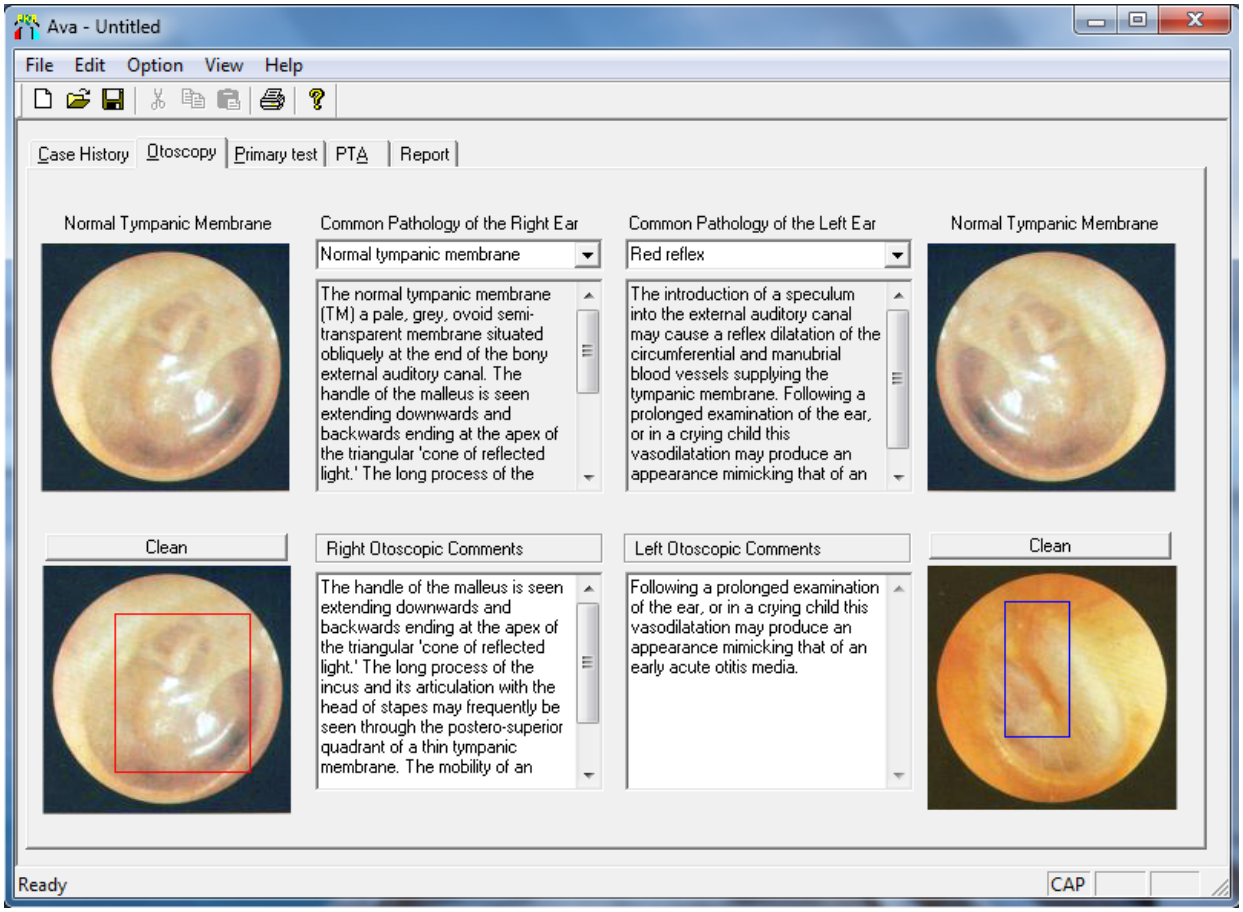
The **Case history**, especially historically of a patient is information gained by a Audiologist by asking specific questions, either of the patient or of other people who know the person and can give suitable information, with the aim of obtaining information useful in formulating a diagnosis and providing medical care to the patient. The medically relevant complaints reported by the patient or others familiar with the patient are referred to as symptoms, in contrast with clinical signs, which are ascertained by direct examination on the part of medical personnel.

Process

A practitioner typically asks questions to obtain the following information about the patient:

- Identification and demographics: name, age, ...
- The chief complaint - the major health problem or concern, and its time.
- History of the present illness - details about the complaints, enumerated in the chief complaint.
- Past medical history (including major illnesses, any previous surgery), any current ongoing illness, e.g. diabetes).
- Family diseases - especially those relevant to the patient's chief complaint.
- Childhood diseases - this is very important in pediatrics.
- Social history (medicine) - including living arrangements, occupation, number of children, drug use (including tobacco, alcohol, other Ototoxic drug use), recent foreign travel, and exposure to environmental pathogens.
- Conclusion & closure

Evaluation of Ear with a Otoscope



The otoscopic exam is performed by gently pulling the auricle upward and backward. In children, the auricle should be pulled downward and backward. This process will move the acoustic meatus in line with the canal. Hold the otoscope like a pen/pencil and use the little finger area as a fulcrum. This prevents injury should the patient turn suddenly.

- Inspect the external auditory canal.
- Evaluate tympanic membrane
    - Note the color (red, white, yellow) and translucency (transparent, opaque) and position (retracted, neutral or bulging) of the drum

- Identify the pars tensa with its cone of light, the handle and short process of malleus, and the anterior and posterior folds of the pars flaccida and position of the malleus handle..

Examination of the ear canal and tympanic membrane

The ear canal and tympanic membrane should then be examined. This may not be possible in all cases, for example, due to the absence of an ear canal, due to the presence of bandaging or when doing so might cause pain or undue discomfort. Particular care should be taken if the subject has recently undergone ear surgery, might not remain still during examination or is anxious about undergoing the procedure.

The ear canal and tympanic membrane should be examined using a device that provides appropriate magnification and illumination, has been produced for the purpose of ear examination and meets relevant safety standards, referred to hereafter as an 'otoscope'. An otoscope that employs a separate viewing screen instead of a built-in viewfinder, such as a computer monitor, will be referred to as a 'video otoscope'. Before use, the examiner shall ensure the otoscope is operational and that any relevant safety checks have been conducted.

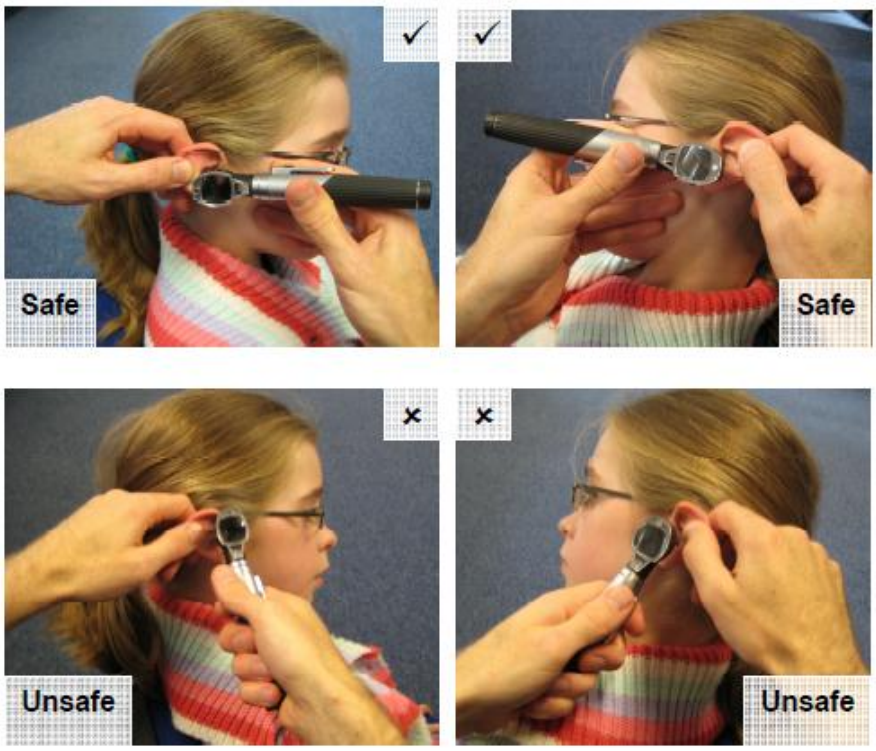
The examiner shall adopt a stable position when examining the ear using an otoscope. This involves the examiner taking necessary precautions to minimize the risk of harming the subject, or her/himself, through the loss of balance for example. For example, the examiner should not stand bent-over.

To start, the examiner shall select an appropriately sized speculum, based on the initial examination of the entrance to the ear canal and the need to obtain adequate illumination. This speculum shall then be securely, and hygienically, attached to the otoscope. The otoscope shall be held by the examiner in such a way as to enable secure bracing against the subject's head in order to avoid injuring the ear if, for instance, the subject makes a sudden movement. The upper rows of Figures illustrate examples of safe practice for otoscope.

The examiner shall then carefully guide the tip of the speculum (attached to the otoscope) into the ear canal while observing the ear (not necessarily through the viewfinder of the otoscope).

The examination of the ear canal and tympanic membrane shall be conducted carefully and safely, taking into account the size, shape, orientation and condition of the ear canal and the presence of wax or foreign bodies. It shall also take into account that the bony portion of the ear canal is especially sensitive and its surrounding skin vulnerable to trauma.

On completing the examination, the otoscope (including the speculum) shall be removed from the ear canal.

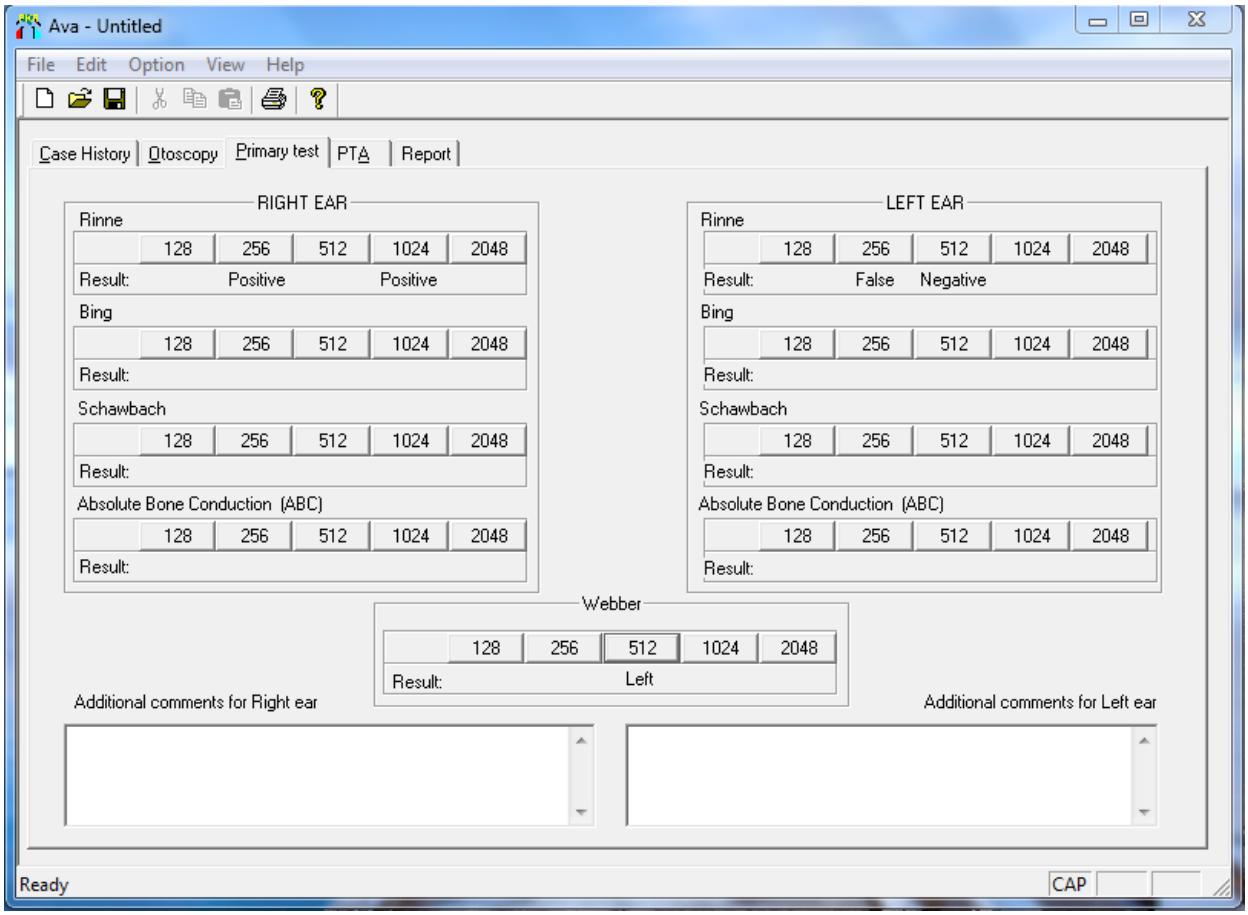


Recording, reporting and managing the findings

The examiner should note her/his observations immediately after carrying out the procedure. Depending on the circumstances, it might also be appropriate for the examiner to make a judgement as to the status of an ear, such as the presence of an abnormality or disease. It might also be necessary for the examiner to take further action, such as a referral for medical attention, in consultation with, and with the consent of, the subject.

If a printed or electronic copy of images is obtained during examination, these should be stored together with the identification details of both the subject and examiner as well as the date and time of the examination.

Evaluation of Hearing with a Tuning Fork



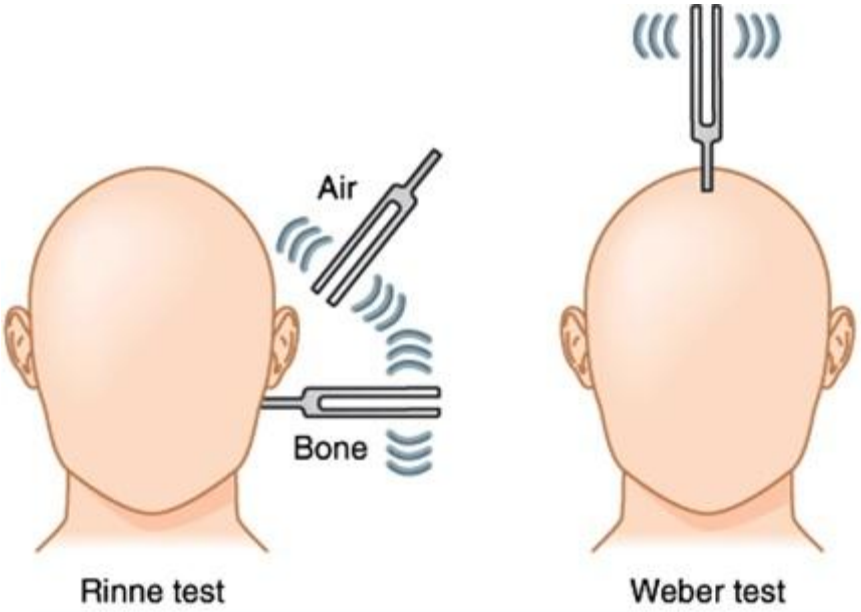
There are three types of hearing loss: conductive, sensorineural, and mixed. Differentiation between sensory (cochlear) and neural (cranial nerve VIII) sensorineural
hearing loss is important. Evaluating hearing with a tuning fork can be a useful clinical screening tool to differentiate between conductive and sensorineural hearing loss. By comparing the threshold of hearing by air conduction with that elicited by bone conduction with a 512-Hz tuning fork, one can infer the site of the lesion responsible for hearing loss. The Rinne and Weber tuning fork tests are used widely both to differentiate conductive from
sensorineural hearing losses and to confirm the audiologic evaluation results.

Weber tuning fork test

The Weber tuning fork test may be performed with a 512-Hz fork. The stem of a vibrating tuning fork is placed on the head in the midline, and the patient is asked whether the tone is heard in both ears or in one ear better than in the other. A normal result is when the patient can hear the tuning fork tone in both ears equally. An abnormal result is when the patient can hear the tuning fork tone in one ear more than the other.

Rinne tuning fork test

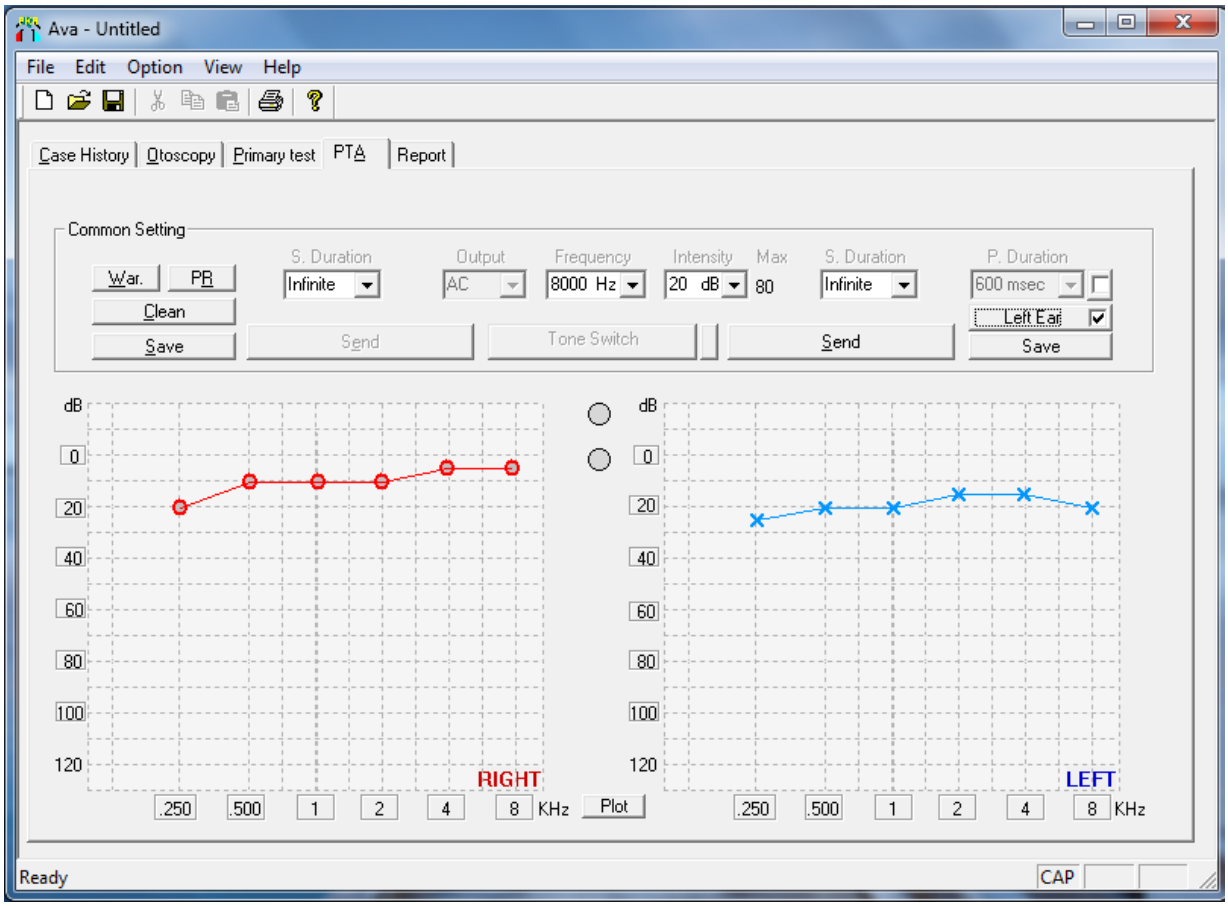
The Rinne tuning fork test is sensitive in detecting conductive hearing losses. A Rinne test
compares the ability to hear by air conduction with the ability to hear by bone conduction. The
vibrating tuning fork is held near the opening of the external auditory canal, and then the stem
is placed on the mastoid process. See figure below.
The patient is asked to indicate whether the tone is louder by air conduction or bone conduction. Normally and in sensorineural hearing loss, the tone of the vibrating tuning fork is
heard louder by air conduction than by bone conduction. However, with a 30-dB or greater
conductive hearing loss, the bone-conduction stimulus is perceived as louder than the airconduction
The combined information from the Weber and Rinne tests will tell you whether a conductive
or sensorineural hearing loss is present. However, these tests are associated with significant
false-positive and -negative responses and therefore should be used only as screening tools
and not as a definitive evaluation of auditory function.



Hearing loss	Rinne test (Conduction)	Weber test (Localization)
None	Air > bone	Midline
Sensorineural	Air > bone	Normal ear
Conductive	Bone > air	Affected ear

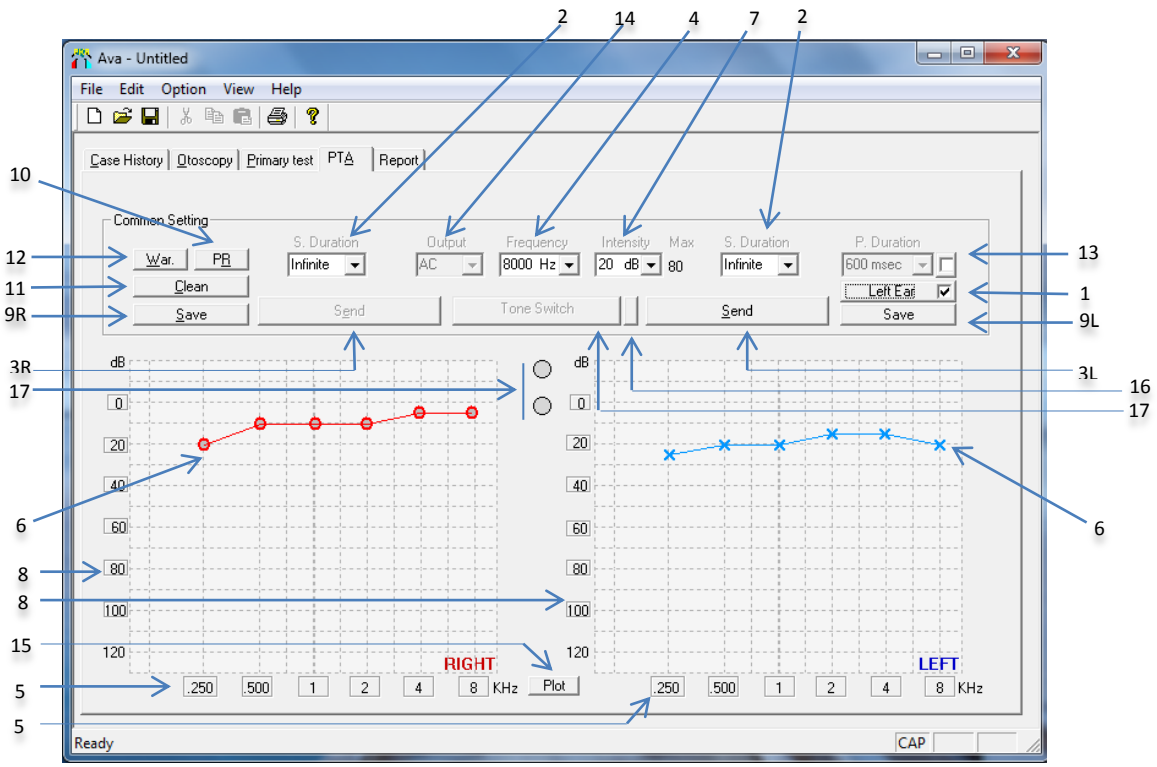
3.7 Case History | Otoscopy | Primary test | PTA | Report

Evaluation of Hearing with a Pure Tone Audiometer



3.7.1 General about Air and Bone Conduction

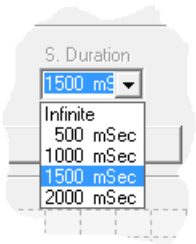
Hearing threshold levels can be determined by air conduction and bone conduction testing. In air conduction audiometry the test signal is presented to the patient via earphones. In bone conduction audiometry the test signal is presented via a bone vibrator placed on the mastoid or forehead of the patient. It is recommended to start threshold testing with air conduction first, followed by bone conduction testing. (Just PKA87/B)



3.7.2 Common Test Use

1) Select desired test ear with buttons marked “Right” or “Left” (1).

2) Select what type of presentation you wish to use either manual or automatic tones by pressing “Send Duration” (2). Manual presentation is activated each time the “Send” (3R), (3L) is pressed. Automatic will be a presentation tone each time the “Send” (3R), (3L) is pressed and interrupted Automatic (dependent by “Send Duration” Menu).



3) Select what type of presentation you wish to use either manual or reverse tones by Double Click “Send” Button (3R), (3L). Manual presentation is activated each time the “Send” (3R), (3L) is pressed. Reverse will be a continuous tone and interrupted each time the “Send” (3R), (3L) is pressed.

4) Select desired frequency with List (4) or Down of audiogram Chart Buttons (5) or direct Click on the chart (6).

5) Change intensity with (7), or Left of audiogram Chart Buttons (8) or direct Click on the chart (6).

6) Present tone by pressing the “Send” (3R), (3L).

7) Upper section of (17) is Right and Left stimulus indicators. (17)Lower part is Patient response indicator.

8) Save the threshold by pressing “Save” (9R), (9L).

Save in normally being simultaneously with Patient response.

9) Save the threshold after a question (10).

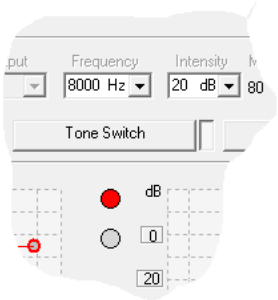
10) Delete saved point by pressing “Clean” (11).

11) If did not complete liens, between store points, press “Plot” (15).

3.7.3 Tone Switch area

Select what type of presentation you wish to use either “Send” button or “Tone Switch” area.

Click (16) button for activity “Tone Switch” area. Signal will be a presentation tone,



each time is the “Mouse Cursor” coming to the area (17).

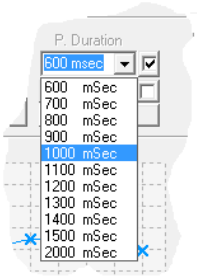
3.7.3 Tone/Warble

For pure tone testing either pure tone or warble stimulation can be selected. Warble presentation can be useful for subjects difficult to test such as children where the clinician wants to vary the stimulation. Warble tones are additionally used for free field testing. Pure tone or warble can be selected by pressing “Tone Warble” (12).

3.7.4 Pulsed Tones

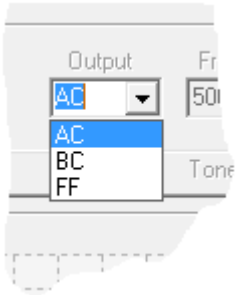
The clinician may choose to use either a single tone for each pure tone presentation or the option of pulsed tones. Pulsed tones are useful for patients with tinnitus who find it difficult to discriminate between the tone and their tinnitus.

Single or pulsed tones can be selected “Pulse” (13) and selected Pulse duration.



3.7.5 Bone Conduction

The purpose of bone conduction testing is to present the test tone directly to the cochlea via bone conduction of the skull to establish inner ear hearing thresholds. Bone Conduction testing can be selected by pressing “Output” Menu (14). (Just PKA87/B)



3.7.6 Free Field

Free field audiometry is a behavioral test obtained in a sound treated room. Free field testing is useful for a difficult to test subject like children who are too young or refuse to wear headphones. Aided thresholds are also obtained through free field testing.

Free field testing can be selected by pressing “Output” Menu (14) Right or Left according to which speaker you wish to use. (Just PKA87/B)

The menu shown below will be seen when Tone Tests is selected.

3.7.7 Manual Air Conduction Testing

Air conduction audiometry is used to establish a hearing threshold at different frequencies. The test can specify the AC loss but gives no information regarding any abnormality in the conductive mechanism or sensor neural mechanism.

3.7.8 Headphone Placement

Remove eyeglasses and earrings if possible and position the headphones over the top of the head. Place the rubber cushions so that the diaphragms are aimed directly at the opening of the ear canal. Pull the yokes of the earphones to adjust the fitting. If the cushions are not tight on the ears, the test result will show false results at lower frequencies.

3.7.9 Background Noise

Background noise can give false test results, especially at lower frequencies. The Headphone can be used with Audiocups type V3 for reducing Background Noise.

3.7.10 Instruction to Subject

Prior to threshold testing the following instructions should be given to the test subject: “You will now hear different tones at different intensities. Please press the response button every time you hear the tone and release the button when you do not hear the tone”.

3.7.11 Familiarization

Start with the subject‟s better ear at 1000 Hz. The tone should be presented at 40dB to the test ear, which should be sufficient enough to evoke a clear response from the subject. Then present a tone which is completely attenuated. If the subject does not response to a tone at 40dB, present tones 10dB higher until a response occurs. Then reduce the tone level by 20dB. In either case gradually increase the level until a response occurs. Repeat the tone presentation at the same level. If the responses are consistent, the familiarization is completed. If not, it should be repeated.

3.7.12 Threshold Determination using the Ascending Method

Manual or reversed pulses may be used. If manual pulses are used, they should be at least one second in duration.

1) Present a tone which is 10dB lower than the threshold obtained during the familiarization procedure. If the response fails, increase in 5dB steps until the subject responds.

2) Decrease by 10dB and begin another ascending level series. Continue with this until three out of a maximum of five responses at the same level occur.

Almost the same results will be obtained, when two responses out of three tone presentations occur at the same level and frequency. If less than two responses out of three (or less than three out of five) have been obtained at the same level, present a tone 10dB higher than the last response and repeat the procedure.

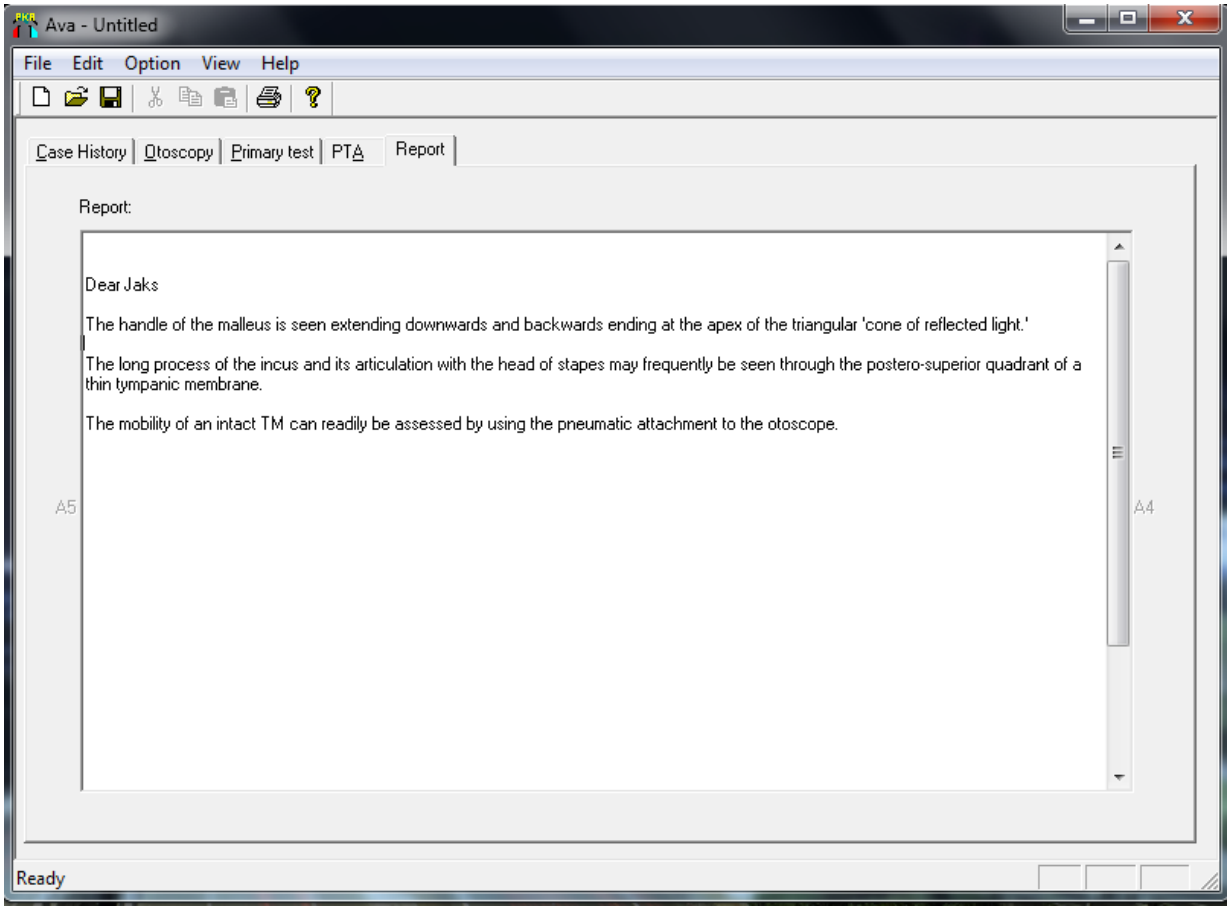
3) Proceed to the next frequency. Decrease the level by 10dB and begin another ascending level series. Continue until you get three out of five responses at the same level.

4) Repeat the familiarization procedure. If the difference is 5dB or less move on to the next ear. If the difference is 10dB or higher, repeat the test at further frequencies in the same order until agreement to 5dB or less has been obtained.

5) Proceed until both ears have been tested.

3.8 Case History | Otoscopy | Primary test | PTA | Report

Audiometry Reports



Audiometric reports should be Contain information which is meaningful to a lay person.

Audiometry Reports Contain:

we make sure all our reports contain information which is meaningful to a lay person. Alongside this, we always have an eye on the fact that reports may often be read by specialists therefore we also make sure that all the technical information they may need is also present.

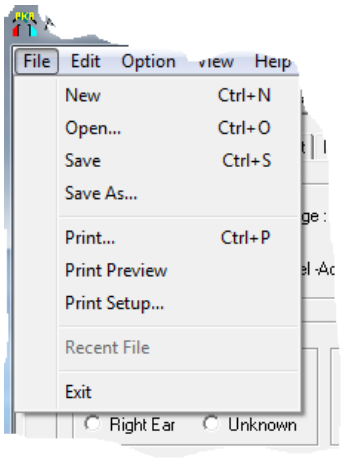
- A statistical summary of some key elements of the pre-test health questionnaires

- A list of who scored which category of result (see below for info on the category system)
- Additional detail for all referred individuals and all individuals where problems were identified, whether referred or not.
- A copy of the individual audiogram (result) for each and every attendee.

Common Setting

4.1 File menu

The **File** menu enables you to create, save, close, print, …, Audiometry resources and to exit the Workbench.



4.1.1 New (Ctrl+N)

Enables you to create new resources. Before you can create a new file, you must create a project in which to store the file.

4.1.2 Open (Ctrl+O)

Enables you to open a test file for editing - including files that do not reside in the Workspace.

4.1.3 Save (Ctrl+S)

Saves the contents of the test pages.

4.1.4 Save As

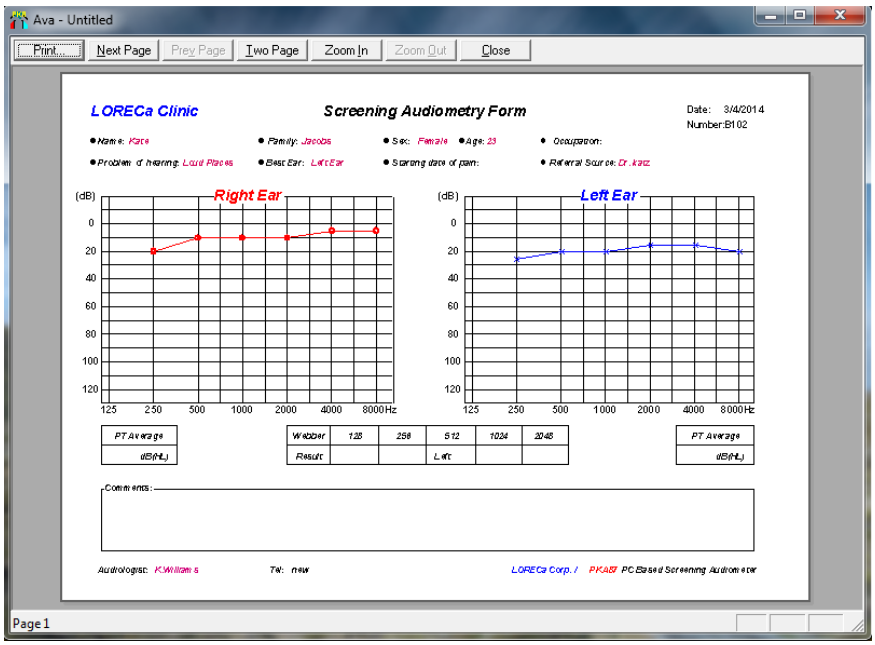
Enables you to save the contents of the active editor under another file name or location.

4.1.5 Print (Ctrl+P)

Prints the contents of the selected page.

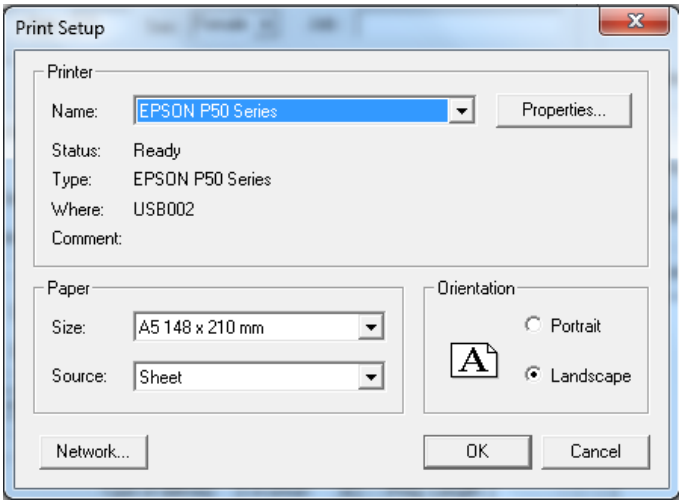
4.1.6 Print Preview

Print preview is a feature that allows audiologist to view what a printed version of the document would look like on the screen before printing a hard copy. To open the print preview feature, click the print preview option.



4.1.7 Print Setup

The Print Setup dialog box is used to select and configure your printer and final output orientation. The dialog box is used to select the paper size and orientation (landscape or portrait) used for your output.



4.1.8 Recent file

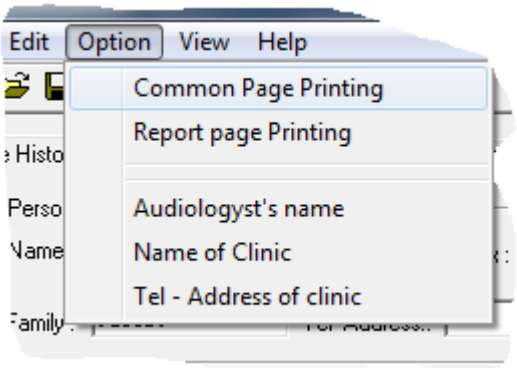
Contains a list of the most recently accessed files in the Workbench. You can open any of these files from the **File** menu by simply clicking the file name.

4.1.9 Exit

Closes and exits the Workbench.

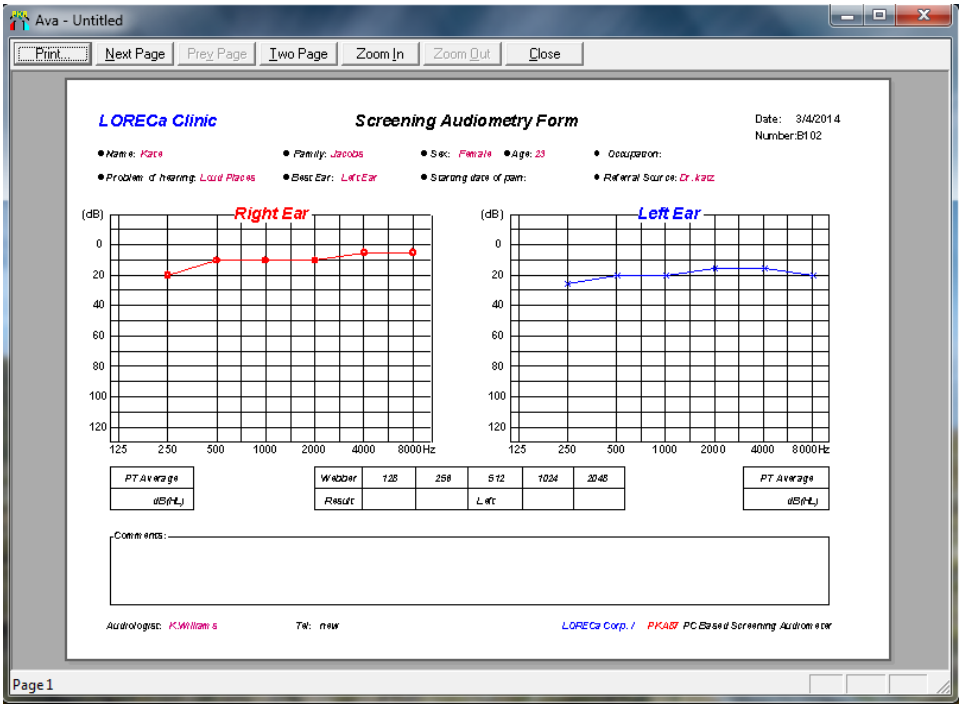
4.2 Option menu

The **Option** menu enables you to select which one print pages and to assign Header and footer of print page.



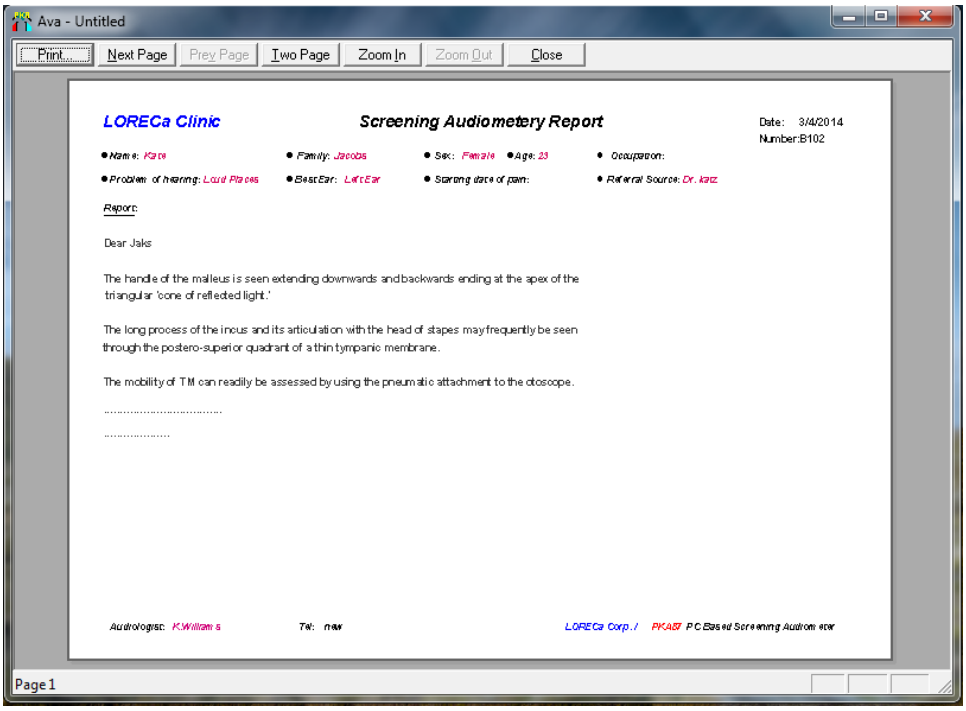
4.2.1 Common Page Printing

Setting for Print the choicest parts of all pages, except for Report page.



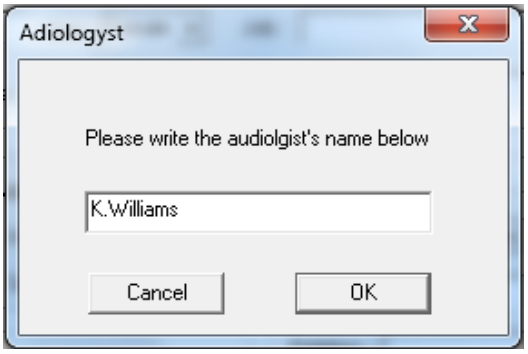
4.2.2 Report Page Printing

Setting for Print the contents of the Report page.



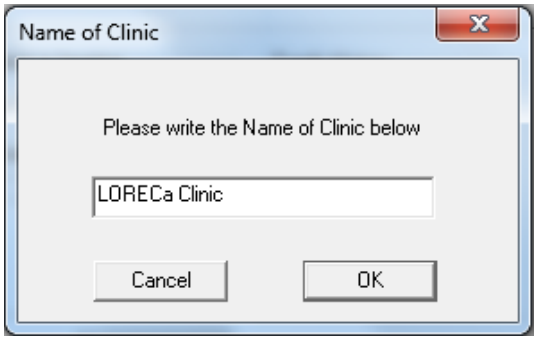
4.2.3 Audiologist Name

Enter the “audiologist name” for printing in footer pages.



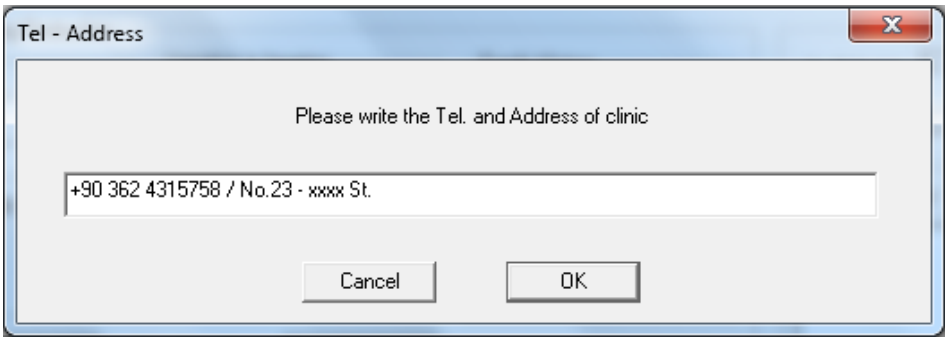
4.2.4 Name of Clinic

Enter the “Clinic name” for printing in Header pages.



4.2.5 Tel-Address of clinic

Enter the “Tel-Address of clinic” for printing in footer pages.



Shortcut keys

Main window

- You can press **Alt + F** to open the “File menu” and press **E**, **O**, or the other underlined character (Mnemonic) for the Other menu or Functions.

- Alt + F to open the “File Menu”
  - Alt + F+P “Print Menu”
  - Alt + F+V “Print Preview Menu”
  - Alt + F+R “Printer Setup Menu”

- Alt + E to open the “Edit Menu”
- Alt + O to open the “Option Menu”
- Alt + V to open the “View Menu”
- Alt + H to open the “Help Menu”

PTA tab

- Press **Alt + S** to open the “Save function” and press **C**, **S**, or the other underlined character (Mnemonic) for the other menu or Functions.

- Alt + W to active “Warble tone Function”
- Alt + R to active “Patient response dialog”
- Alt + C to active “Points cleaner”
- Alt + S to active “Save of Right ear thresholds”
- Alt + E to active “Send of right ear stimulus”

Technical Specifications

Standards :
Tone audiometer type:4
Calibration:ISO389

Channels : One channel.

Frequencies and Maximum Hearing Levels:

Hz	AC	*BC	F.F
125	*	*	*
250	80	35	60
500	100	45	80
750	100	50	80
1000	100	50	80
1500	100	50	80
2000	100	55	80
3000	100	50	80
4000	100	45	80
6000	80	*	60
8000	80	*	60

* Optional Including Bone Vibrator For this Output.

Channel 1 : Input:Tone

Output:Left,Right,Bone ,Free Field R+L.

Presentations Ch1 : Manual,
single or multiple pulses.Single and Multiple Pulse
Speed:
Programmable from 250-1000 mS in 250 mS steps.

Frequency Range: 250-8000 Hz.

Frequency Resolution: 1/2 octave steps.

Modulation: Warble:5Hz

Attenuator:
Totally Click free, 0 to 100 dB HL in 5 dB Steps.

Tone Switches:
Silent tone switches by moving Mouse.

Patient Response:
One patient response button,

Test Types:
Tone: Manual, single pulse, pulsing
(variable).

Free Field:
2x12W external amplifier and two speakers.
(Optional)

Communication:
USB Connector

Dimensions: LxWxH: 18x9.5x4 cm.

Weight: 400 gr.

Power: AC 50-60 Hz.180-240 V

Consumption: Max. 2 VA

Included Parts:
Bilsom Screening Audiometric Headset
1 Patient Response Button
Power Cable 240
USB Computer Connection Cable
PKA87 Software Program
Operation Manual
Carrying case

Options:
AP12 Built-in 2x12 watt Power Amplifier for FF
AP12 Loudspeaker
B71 Bone Conductor
Notebook (8.9” Wide LCD)

Unpacking / Inspection

Check box and contents for damage:

When the instrument is received, please check the shipping box for rough handling and damage. If the box is damaged, it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty, please contact the nearest service office. Keep the shipping material for the carrier's inspection and insurance claim.

General maintenance

The following recommendations for care and maintenance are observed:

- It is required to let the instrument go through at least one annual overhaul, to ensure that the acoustical, electrical and mechanical properties are correct. This should be made by an authorized workshop in order to guaranty proper service and repair.

- Before the connection to the mains network, be sure that the local mains voltage corresponds to the voltage labeled on the instrument. Always disconnect the power cord if the instrument is opened or by control / replacement of the mains fuses.

- Observe that no damage is present on the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load, which could involve damage.

- For maximum electrical safety, turn off the power from a mains powered instrument when it is left unused.

- Do not site the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.

- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.

- A plastic cover can be provided to protect the instrument against the accumulation of dust. The cover should only be used when the instrument is left unused with the power turned off.

- If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or something similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the mains conductor during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories.

- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.

- Great care should be exercised by the handling of earphones and other transducers, as mechanical shock may cause change of calibration.

Operating Temperature

Keep away from heat:

Do not site the PKA87 next to a radiator or any other heat source.

Operating temperature: 15C°- 35C°:

In operation the instrument should not be subject to temperatures below 15C° or above 35C°. warm-up time must be respectively prolonged.

Care and Maintenance

The performance and reliability of the PKA87 will be prolonged if the following recommendations for care and maintenance are adhered to:

Great care when handling the headset:

Great care should be exercised when handling the headset as dropping it may alter the calibration.

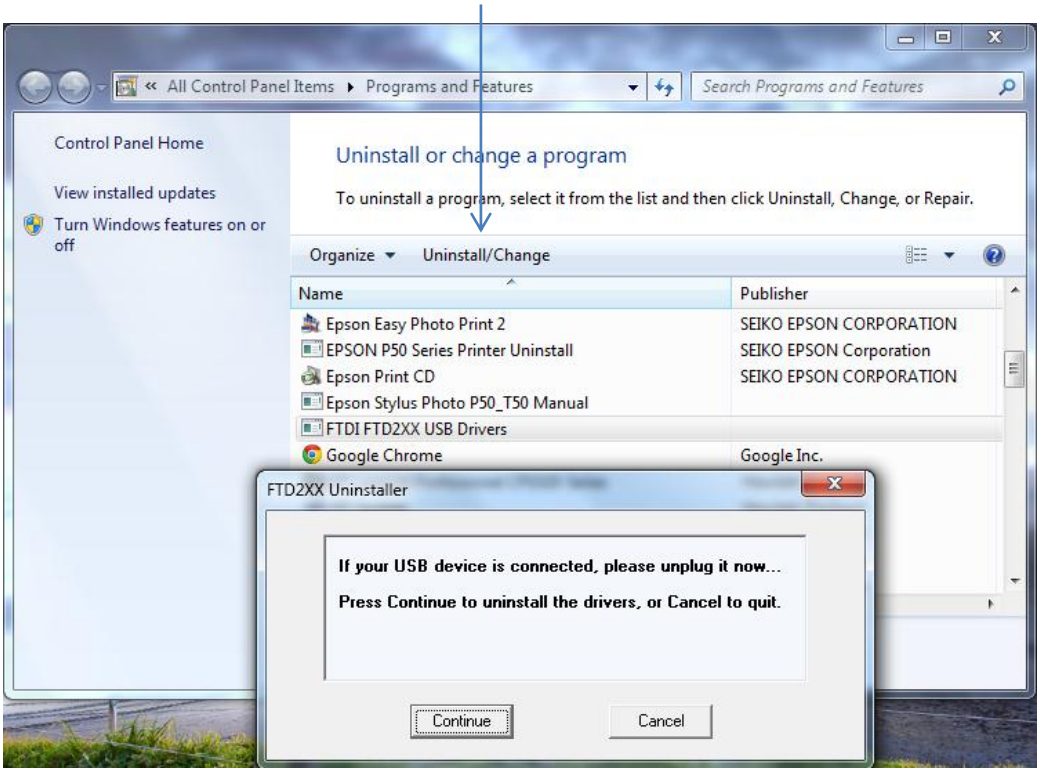
Annual calibration headset:

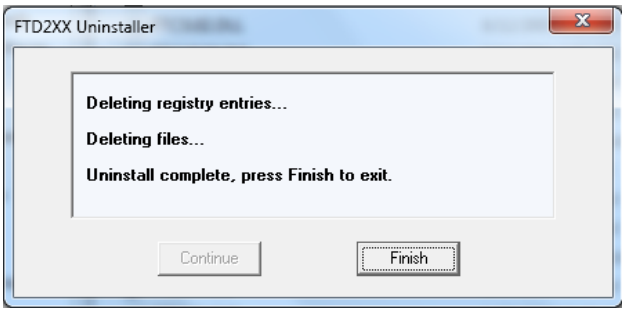
The PKA87 has been designed to provide many years of reliable service, but annual calibration is recommended. We do also recommend to calibrate the PKA87 if something drastic happens to part of it (e.g. headset is dropped).

Device Uninstall Steps

For Uninstall PKA software, Refer to following address:

- Control Panel\All Control Panel Items\Programs and Features
- Select the “FTDIFTD2XX USB Drivers”.
- Unplug USB device and then click uninstall item.





Trouble Shooting

If the red LED on the PKA87 does not light up:

Insure the connected power cable to the main power.

Your software does not start:

(The Green LED on the PKA87 does not light up)

Insure the correctly installation

Check Windows System Type (32 Bit).

Insure the connected USB cable to the PC.

Check that the power cable is securely connected to the mains.

Please uninstall and reinstall software.

Install software update point step by step.

No tones in the headphone

If no sound appears, check that the headphone is correctly connected to the phone output.

Reporting Imperfection

Inspect before connection:

Prior to connecting the PKA87 to the mains it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults:

Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of problem. In the back of this manual you will find a "Return Report" where you can describe the problem.

Please use "Return Report":

Please realise that if the service technician does not know what problem to look for he may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

INFO@LORECA.COM