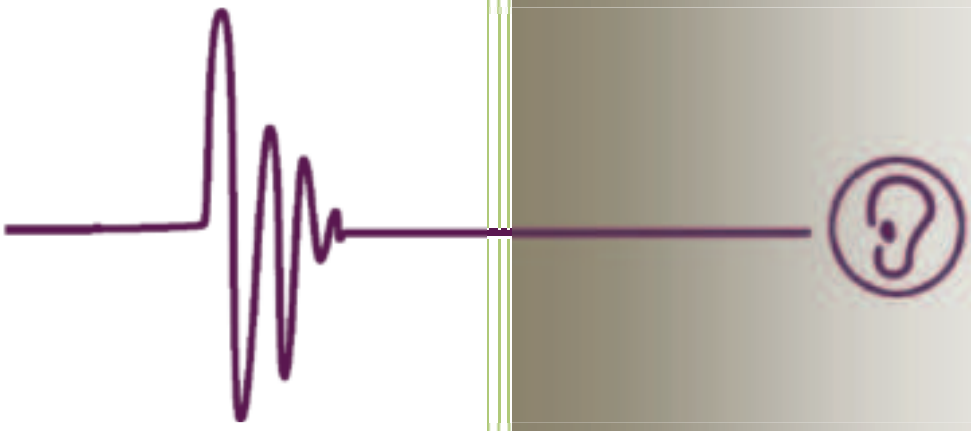
ELECTRONICA
TECHNOLOGIES

600M Software

plus audiometer console

User manual



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CONTENTS

1. Presentation

You have made a good choice.

600M software is part of a computer-controlled audiometrics platform. It enables you to automate high-performance, timeframe-optimized, audiometric testing routines.

This document provides a walk-through on running and using the software and on the technical features of the audiometer console.

Your audiometric testing kit comprises the following components:

- Audiometer console
- USB cable
- Patient feedback peripheral
- Stereo headset (not interchangeable without a technical calibration procedure)
- CD containing the 600M software plus this user manual

This software is designed to run on any desktop PC or laptop — even notebooks.

The audiometer console is powered directly by your computer's USB port.

See the product literature on the CD for instructions on installing the software.

Upon receipt of the equipment, it must check the condition and contents of the bag and the operation of the audiometer.

If problems all must be returned to the seller in its original packing it is advisable to keep to facilitate the repackaging and so the protection of all.

Any redirection must be accompanied by the enclosed return form (at end of document) in order to facilitate the identification and resolution of problems.

Note: The illustrations and images featured in this document are not contractually binding

2. Minimum system requirements

Hardware requirements:

- PC with 1-GHz processor or faster
- 50 MB of available hard-disk space
- 1 GB of RAM
- Screen display resolution: 1024 x 600 pixels or better
- 65536 colours (16-bit)
- 1 free USB port

OS platform support:

- Windows XP (home edition or professional)
- Windows Vista x86 (32-bit) — all versions
- Windows Vista x64 (64-bit) — all versions
- Windows 7 x86 (32-bit) — all versions
- Windows 7 x64 (64-bit) — all versions
- Windows 8 x86 (32-bit) — all versions
- Windows 8 x64 (64-bit) — all versions

Acrobat Reader required for printouts and file-saves.

3. The 600M software — Getting started

Run the 600M software from the start menu or by clicking on a desktop shortcut.

Login

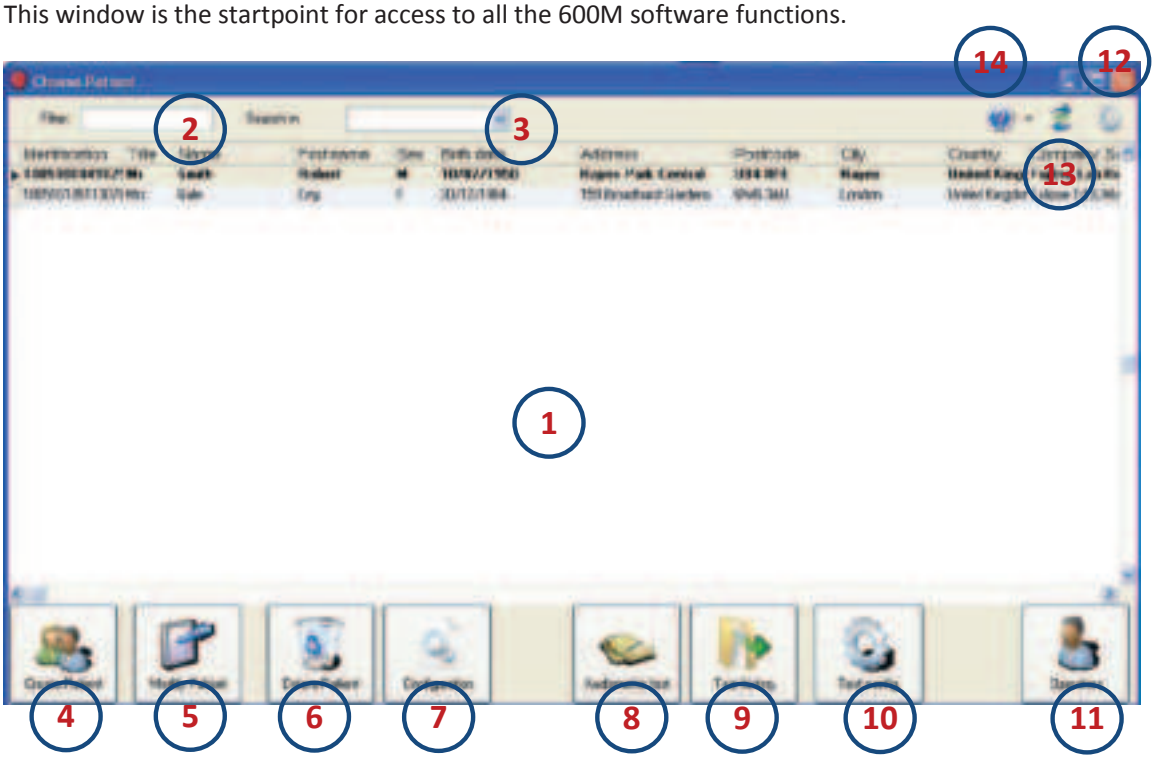
First you will see a splash screen image, after which the following "Login" window prompts you to select an operator. The first time you run the programme, the default choice selected is "No operator".

1) Dropdown list, used to select the operator
2) Quit button, to close the software without connecting
3) OK button, to validate the operator selected

Once the operator has been selected, you may see a password prompt if the operator was created with password-login.

Patient display / main window

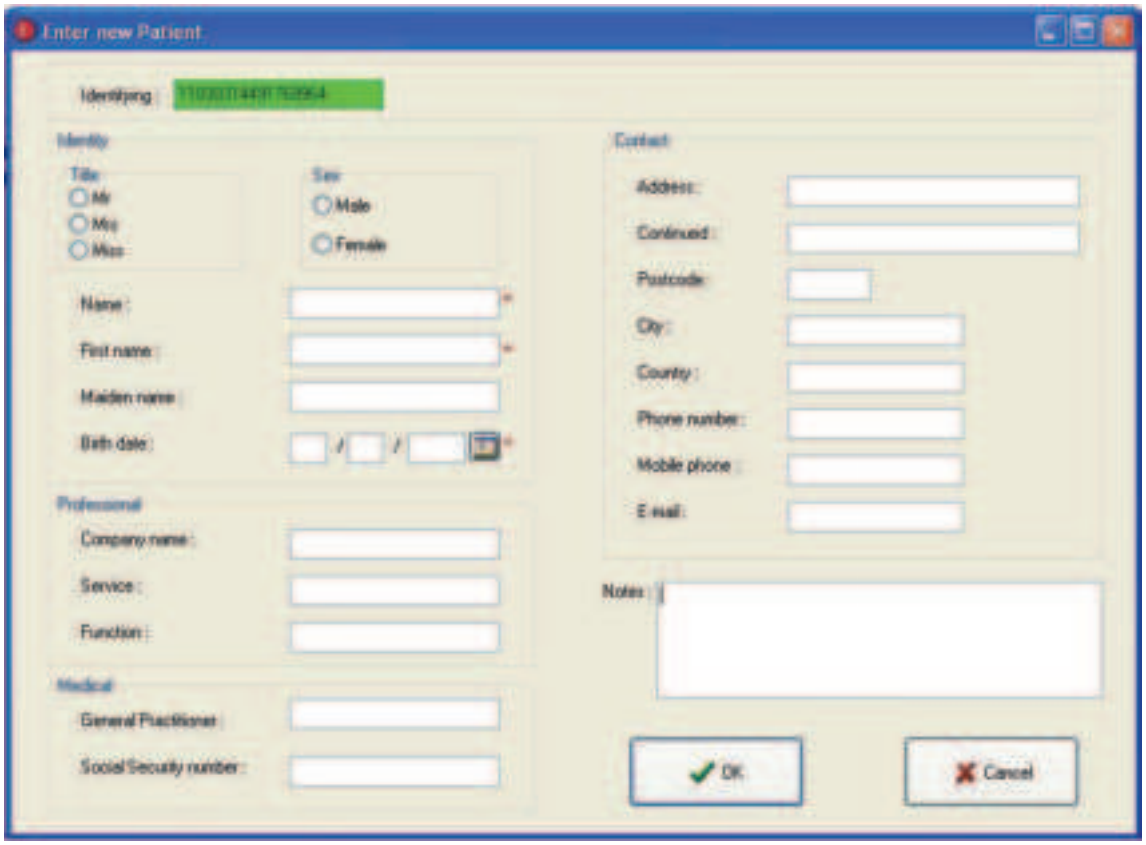
This window is the startpoint for access to all the 600M software functions.



1) **Display patient data**: the information displayed can be reconfigured using button 7. Column order is repositionable simply with a simple mouse drag. Column data can also be sorted in ascending or descending order simply by clicking on the target column.
2) **Search filter**: For filtering the field given in a searchbox 3 — will only return data containing the words entered.
3) **Select search column**.
4) **Create a new patient records file**: see page 7 (Create/Modification of patient sheet)
5) **Modify highlighted patient record**: see page 7 (Create/ Modification of patient sheet)
6) **Delete the highlighted patient record**
7) **Visual display configuration:** hide/show the columns in table 1: see page 8 (Visual display configuration)
8) **Run audiometric test**: to run an audiometric test on the patient highlighted.
9) **Audiometric tests history**: Show the audiometric tests history of the patient highlighted.
10) **Audiometric tests configuration** see page 18 (Tests configuration)
11) **Create/Modify operator** see page 9 (Operator accounts).
12) **General software configuration** (other than test configuration) see page 11 (General configuration)
13) **Merge/synchronize** with pre-compiled databases
    See page 15 (Merge/Synchronize database).
14) **Help menu** see page 17 (Help)

Create/Modification of patient sheet

Clicking either of the buttons above will bring up the following window.



When creating a new patient record, the **only** compulsory fields are those flagged with a red asterisk. The ID number is generated automatically, and is not operator-editable.

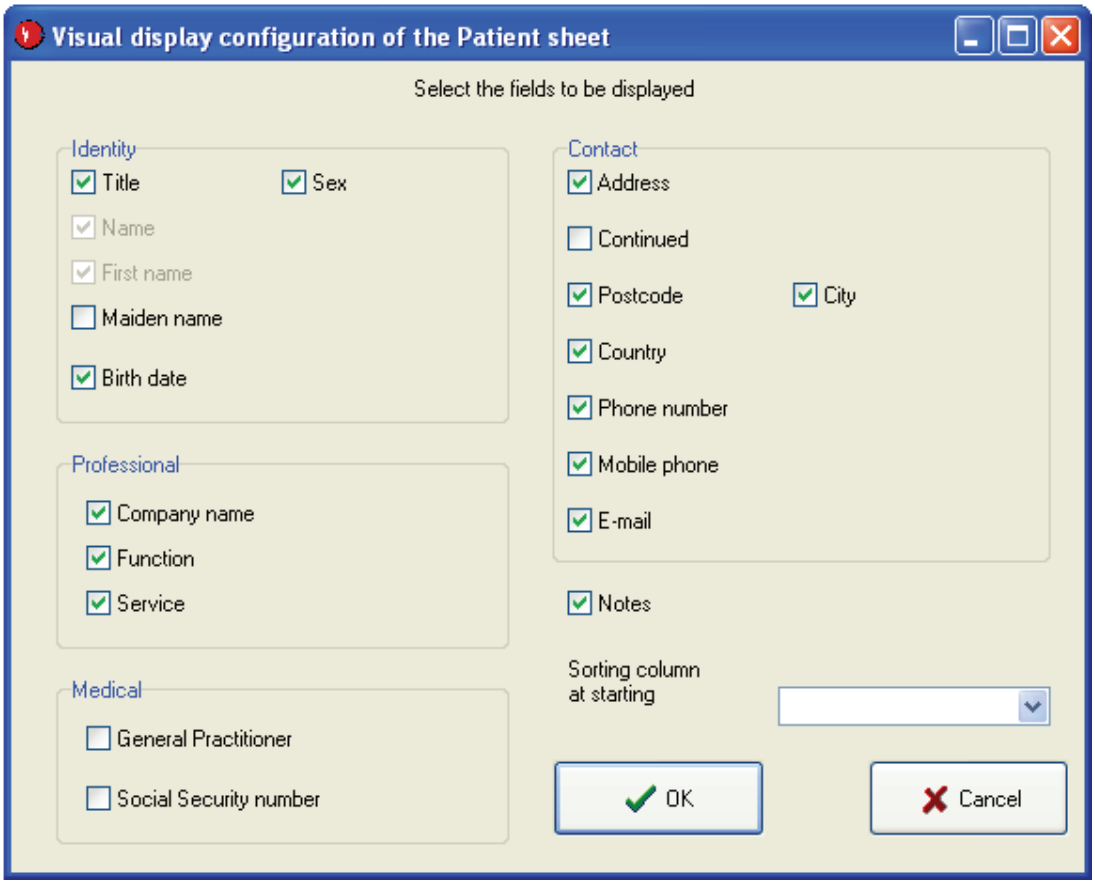
Clicking the icon next to date of birth opens up a calendar that can be used to select date of birth.

Both the create patient record and the modification patient record modes open this same window.

Visual display configuration

To hide or show columns in the data visualization window, simply click on the button above (flagged as button 7 on page 6)

This brings up the window below, in which you simply check or uncheck the boxes for the relevant columns.

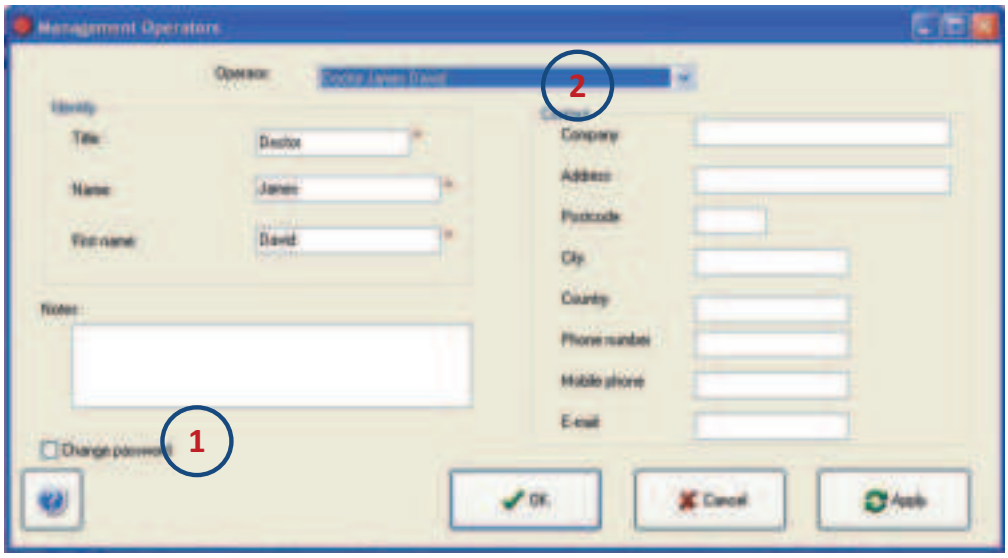


The name and family name ID fields cannot be hidden.

Field 1 selects the column, which is automatically sorted into alphabetical order each time the 600M software is rebooted.

Operator accounts

Clicking this button opens up the following window, which provides options for creating/modifying/suppressing operators. The operator who opened the software session is displayed as default operator.



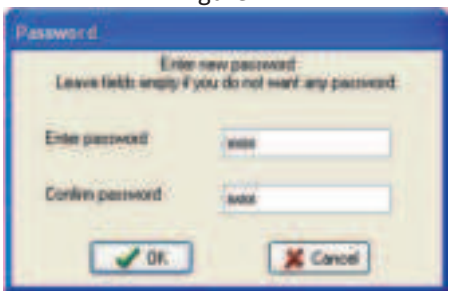
Obligatory fields are flagged with a red asterisk.

Field information is easy to change — just edit the field(s) you want to change, then click 'OK' or 'Apply changes'.

If you need to create or change a password, just check box 1 then click 'OK' or 'Apply changes'. If a password has already been registered, you will be prompted to enter it here (Figure 1), then asked to enter a new password and a password confirmation (Figure 2). If there was no previous password registered, you will jump directly to the window asking for the new password (Figure 2).

Figure 1

Figure 2



To create a new operator, select the create new operator option in the drop-down menu (n°2).

All the fields will start empty. You have to complete at least all the fields flagged with a red asterisk.

Once this data has been entered, click 'OK' or 'Apply changes', which will take you to new password prompt window (Figure 2). If you do not want to enter a password at this stage, simply leave the two fields blank, and click 'OK'.

To delete an operator (other than the operator who opened the current session), click on the operator drop-down list (marked '2'), select the operator you want to delete, and click on 'Delete' button at bottom-left of the window.

Whenever you come to create new operators, you are advised to delete the default operator named "No operator".

General configuration

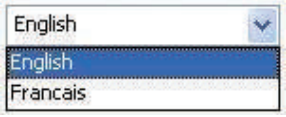
Clicking button 12  , at top-right of the main window takes you to the general configuration menu.

The general configuration window looks like this:

There are three tabs (see 5) that open up two configuration levels.

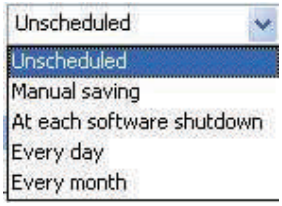
Under the "General" tab

1) Selection of the current language version



2) A drop-down list used to programme the software to shut down automatically after a scheduled time-lapse. This function is disabled while running audiometric tests. The programmable time-lapse options are: disabled (---), 15 min, 30 min, 1 hour or 2 hours.

3-4) Database backups



Backups can be performed either manually or automatically, and there are several backup options available.

The options available under automatic backup are:

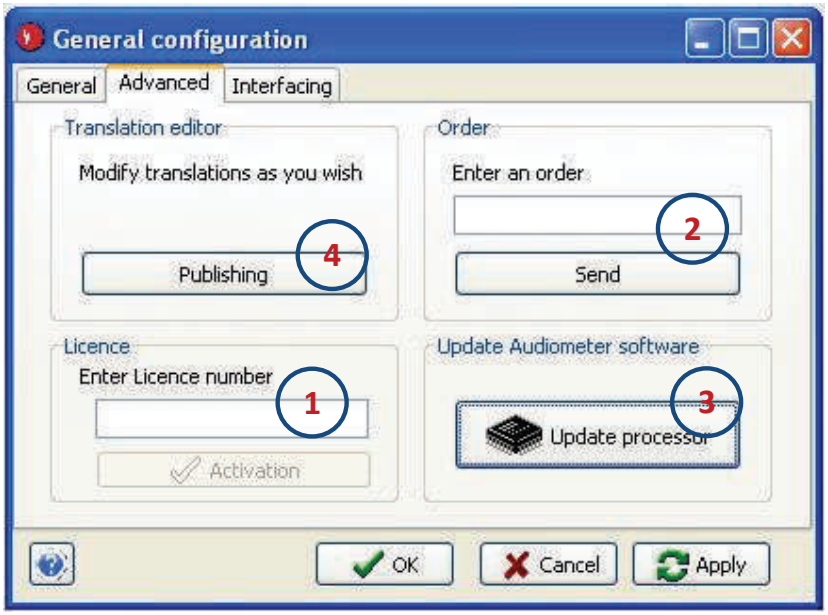
- At each shutdown of the software
- Every day (at the 1st programme run of the day)
- Every month (at the 1st programme run of the month)

Configure the backup target directory by clicking the cream-coloured field (flagged '4').

When performing manual backups, the files are saved when you configure the backup target directory.

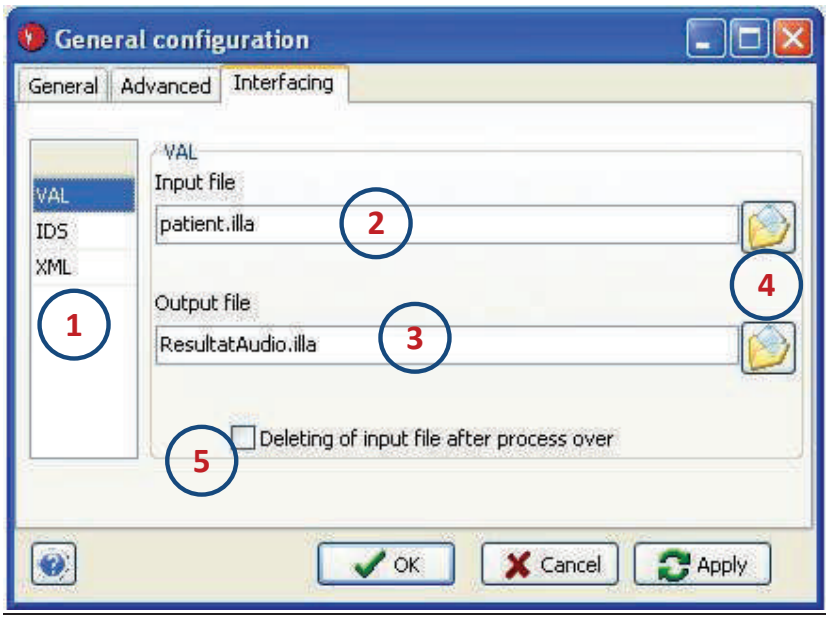
5) Enabling automatic test file-saves means you do not have to make a manual backup each time a test is completed (note that manual test procedures will remain unaffected).

Under the "Advanced" tab



1) Software functionality activation
2) Programme diagnostics command lines (manufacturer only)
3) Update the audiometer software (manufacturer only)
4) Software text-output publishing (see page 14)

Under the "Interfacing" tab



This tab provides configuration options for interfacing the 600M software with other clinical database softwares.

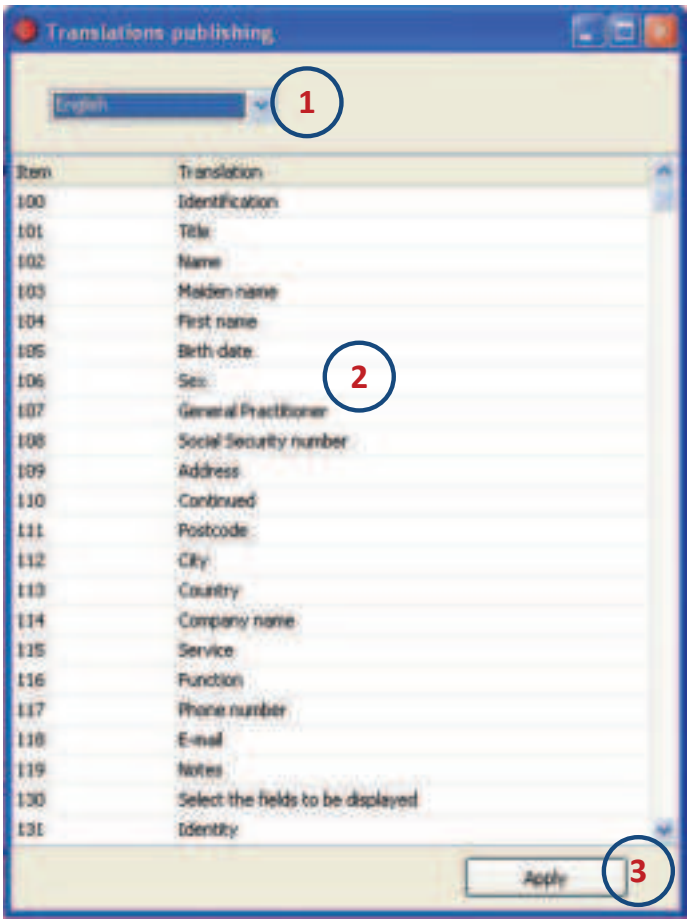
In interfacing mode, you can only run one audiometric test, and once completed, the 600M software will not store any trace of this test and corresponding patient data.

Before running an audiometric test in interfacing mode, you first have to configure the test under the "Tests configuration" menu.

1) List of supported software interfaces
2) Interfacing input file (including patient record data)
3) Interfacing output file (result of the test)
4) Buttons providing a graphic filepath input format
5) Check this box if you want 600M software to delete the input file after processing

Advanced configuration: publishing text-output translations

To get to this menu, go to the "General configuration" menu then to the "Advanced" tab.

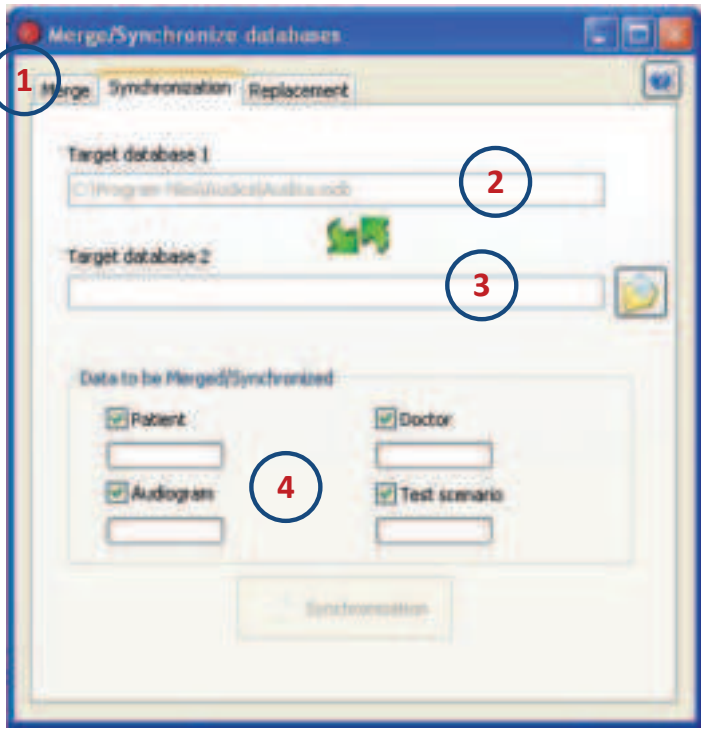


1) Selection of the text-output translation file to show and to modify
2) Editable text (in the right-hand column only)
3) Instantly apply the modifications (would be lost if this button is not pressed)

Merge/synchronize database

The 600M software uses a database file (with the .mdb file extension) found in the application directory.

Clicking the  button at top-right of the main window takes you to this menu.



1) There are 3 different options available:
    - Merge: Additional inputs entered in the database that field n°3 are added to the database currently in use (field 2) — no entries get deleted. This is a one-way mode.
    - Synchronize: all the additional data inputs in each database are added to the other database. This is a two-way mode.
    - Replace: The current database is deleted and replaced by the database that field 3 includes.
2) Data filepath currently in use
3) Database with what it will be proceeded for the coming operation.
4) Database fields that will be merged/synchronized:
    - Patient: involves the patient file records
    - Audiogram: involves the patient test records
    - Doctor: involves the operators
    - Test scenario: involves test scenarios that have already been scripted

Replacement of databases:

This specific mode is used to replace the current database with a new database. All the current data will be lost. If you make a mistake, it remains possible to backtrack using the following procedure.

Quit the 600M software.

Open a file explorer.
In XP, Start > My Computer
In Windows 7 and Vista, Windows logo, Computer.

Navigate to the application directory.
In XP, the by-default directory is: C:\Program Files\600MSoftware
In Windows 7 and Vista 32-bit versions: C:\Programmes\600MSoftware
In Windows 7 and Vista 64-bit versions: C:\Programmes (x86)\ 600MSoftware

Delete the file named "Audio600M.mdb".

Navigate to the "Old" directory, which is a directory created automatically by the replacement operation process.

Mouse over file named "Bdddd-mm-yyyy_hh_minmin_ss.old" (where the second dd is the day of the replacement operation, mm the month, yyyy the year, hh the hour, minmin the minutes, and ss the seconds), and right-click to "Copy".

Navigate back to the application directory.

Right-click and "Paste".

Rename "Bdddd-mm-yyyy_hh_minmin_ss.old" as Audio600M.mdb. Validate the alert prompt.

The old file has now been restored.

Reboot the 600M software.

Help

Get to the help menu by clicking on the  button.

This icon takes you directly to Windows Help

This button opens up other options

The other options opened by the drop-down arrow are:

Windows Help

This user manual

About the 600M software

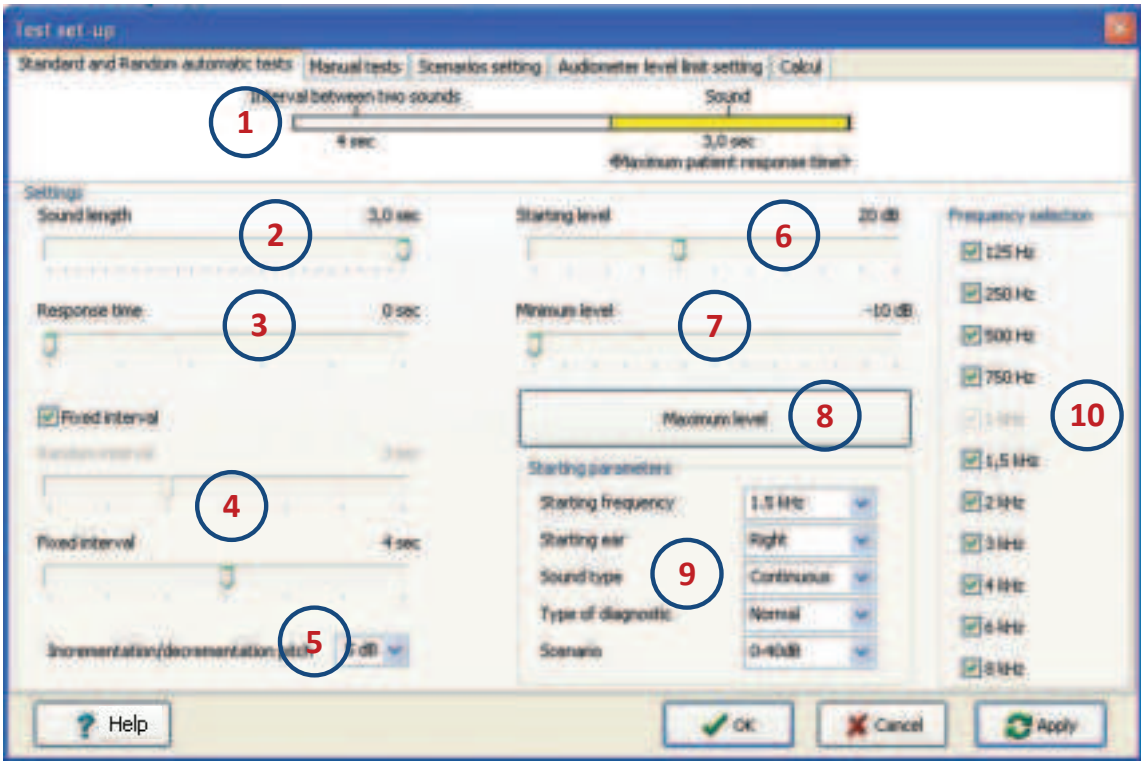
Tests configuration

This menu is available through button 10 of the main window.

Several configuration tabs are available:

- Settings for pre-programmed automatic tests (standard routine and random-sequence automatic tests)
- Settings for manual tests
- Scenario programming
- Settings for maximum sound levels and security levels
- Calculation of hearing losses

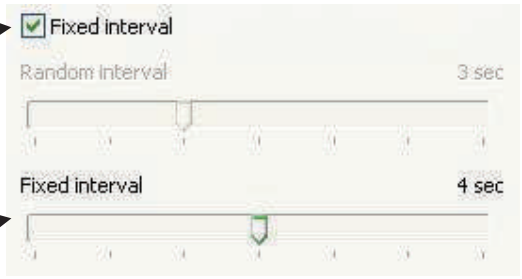
Automatic standard-routine and random-sequence test settings



1) Graphic representing the input data: in 2, 3 and 4.
2) Sound duration (continuous or pulsed) in an automatic test, settable from 0.5 to 3 seconds.
3) Extra time allowed to the patient to respond once the sound has stopped (2), settable from 0 to 5 seconds.
4) Interval time between two sound exposures:

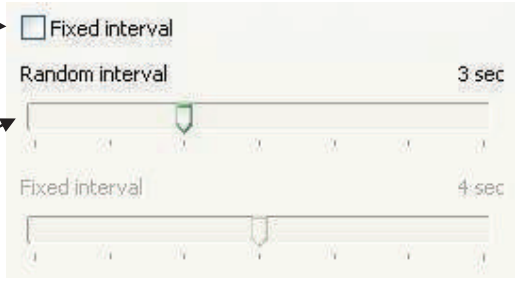
If this box is checked, the inter-sound time interval remains fixed.

Adjustment of fixed inter-sound time interval (from 1 to 7 seconds)



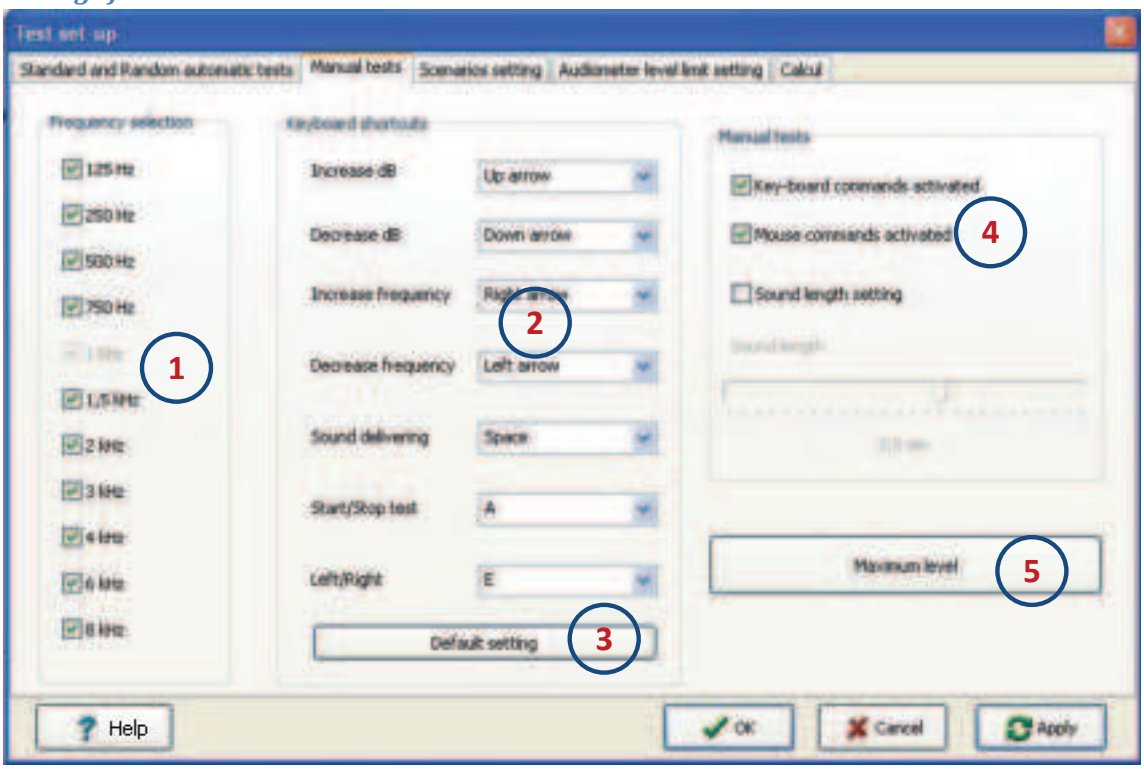
If left unchecked, there will be a random time interval between two sounds (min. 1 sec, max. as per the setting below)

Max. random inter-sound time interval (from 1 to 7 seconds max.)



5) Incrementation/decrementation pitch during automatic test. After a sound sending, if the patient does not press the response button, sound level increases by this value. If the patient does respond, sound level is dropped by this value (increments available: 5, 10, and 15 dB).
6) Start sound level for all frequencies and for both ears: the switch to next frequency starts at this level (value in the range 0 to 50 dB).
7) Minimum sound levels: the test on frequency is considered completed if the patient still responds to this level — the test then switches to the next frequency (value in the range -10 to 50 dB).
8) Maximum sound levels: the test on frequency is considered completed if the patient still does not respond to this level — the test then switches to the next frequency (value in the range 50 dB to the peak audiometer volume). Leads to the "Audiometer limit settings" tab. See Max. setting.
9) Starter settings: the following settings can also be set by default while the test window is on-screen:
    - Start frequency
    - Start ear
    - Sound format
    - Diagnostic type
    - Scenario
10) Frequencies to be tested. The 1kHz frequency is compulsory.

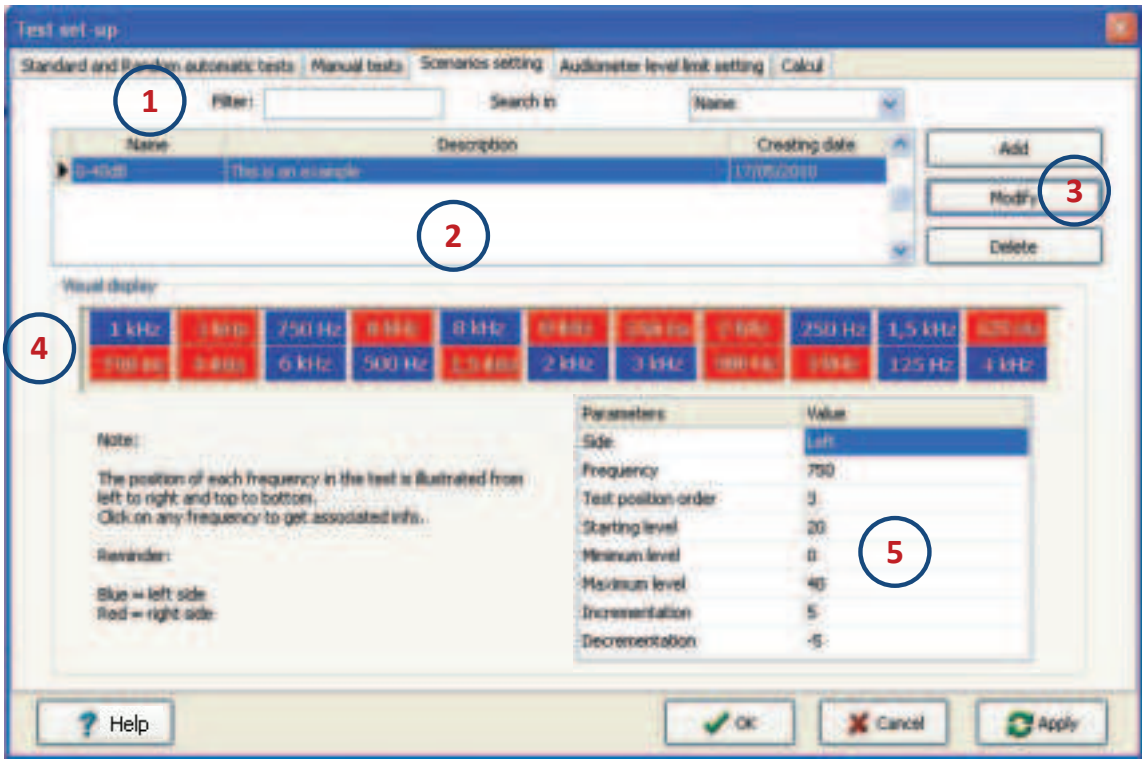
Settings for manual tests



1) Frequencies testable. The 1kHz frequency is compulsory.
2) Keyboard shortcuts configuration (no matter to use capital or small letters), if enabled (point 4).
3) Default factory keyboard shortcut settings
4) Configuration of test control mode:
   - Manual test control enabled (handles both manual inputs simultaneously):
     - mouse-command control
     - keyboard-command control
   - Automatic or manually-set sound duration
     - ➢ If this box is checked, timeframe is settable from 0.5 to 3 seconds
     - ➢ If this box is left unchecked, sound timeframe is two seconds
5) Setting the alert threshold (see Max. setting)

Scenario scheduling

The 600M software is capable of creating its own automatic tests, so-called 'test scenarios'.

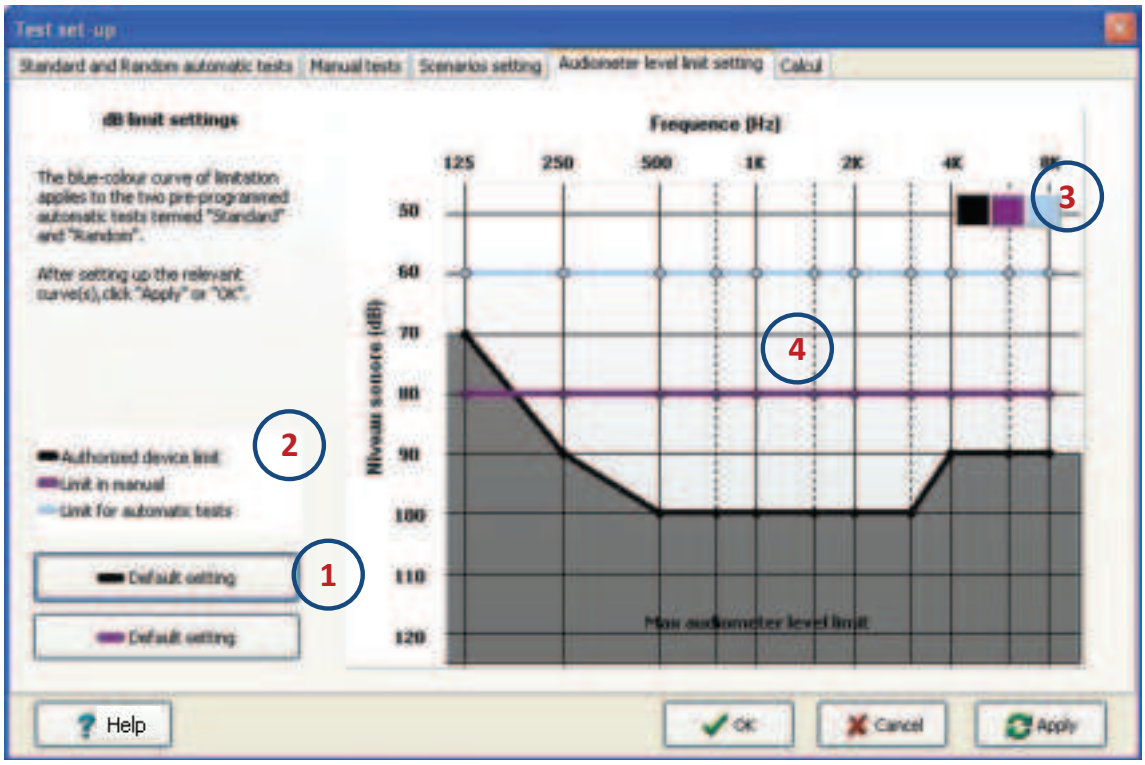


1) Scenario quick-search: only shows scenarios for which the name of description contains the wordtext entered
2) Recap of the scenarios already created (shown as filtered). The columns can be repositioned, and you can click on the column headings to choose between ascending-order or descending-order column content display.
3) There are three options: add a new scenario, modify a scenario (see Create scenarios), or delete a scenario
4) Visual illustration of the order in which the frequencies will be delivered. Clicking on a frequency button displays in the table '5' associated data
5) Shows the test frequency parameters:
    - Right or left ear
    - Test frequency (in Hz)
    - Position in the test order (from 1 to 22)
    - Starter level of the test for the above-specified frequency
    - Minimum level of the test for the specified frequency
    - Maximum level of the test for the specified frequency
    - Sound level incrementation if the patient does not respond
    - Sound level decrementation if the patient responds

Audiometer limit settings

There are 3 possible maximum sound levels:

- Maximum sound levels for automatic tests (excluding scenarios), sky-blue curve
- Maximum sound levels before prompting for confirmation – overrun alert (manual testing mode only), purple curve
- Absolute maximum sound levels (all tests included), black curve



1) Default factory setting for the black and purple curves (absolute maximum sound levels and alert threshold in manual test mode)
2) Key to the curves
3) Choice selectable between three settings curves
4) Graphic visualization of the maximum sound levels:
   - Maximum sound level in automatic-mode tests (blue curve)

     This curve only applies for pre-programmed automatic tests (excluding test scenarios). It is used to select the maximum sound level for each frequency featuring in an automatic test (the test will stop at this level if the patient has still not given a response).
   - Maximum sound level before prompting for confirmation (purple curve)

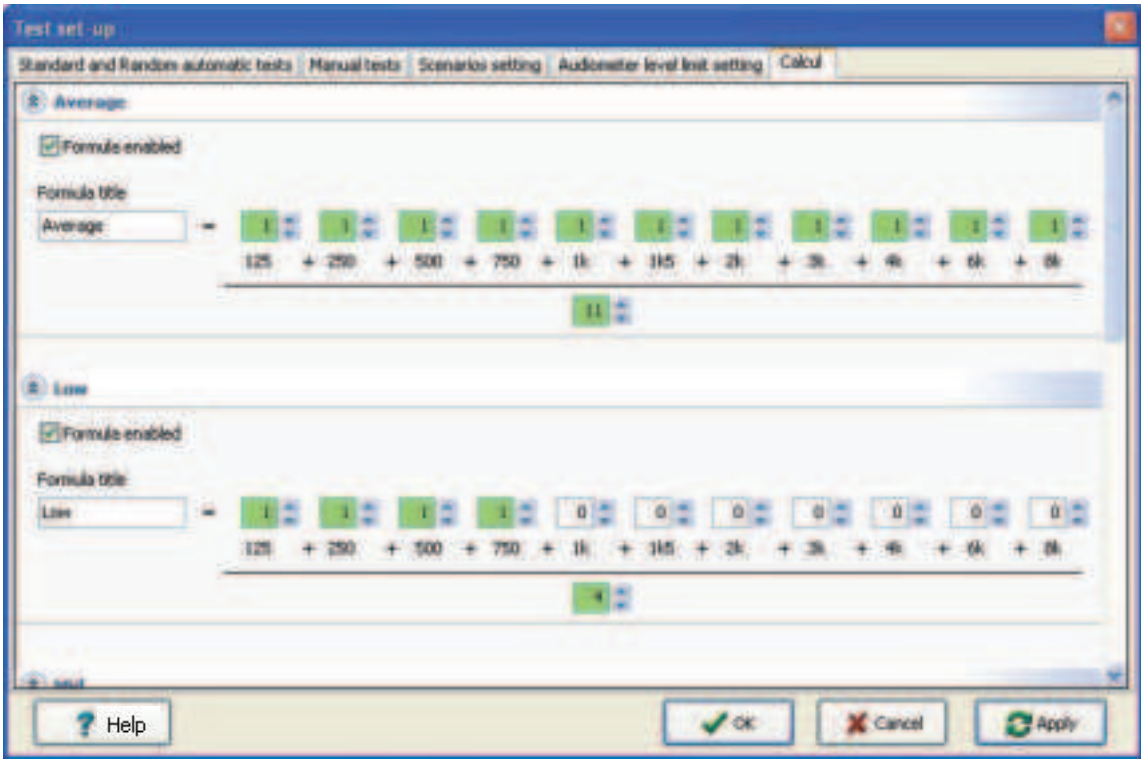
     This curve is designed to protect the patient against potential discomfort caused by procedural errors in a manual test. However, if this curve is configured to the peak possibilities of the audiometry set-up, then an alert prompt will still come

up on screen if the system asks for a level of 100 dB or higher (as stipulated in standard EN 60645-1).

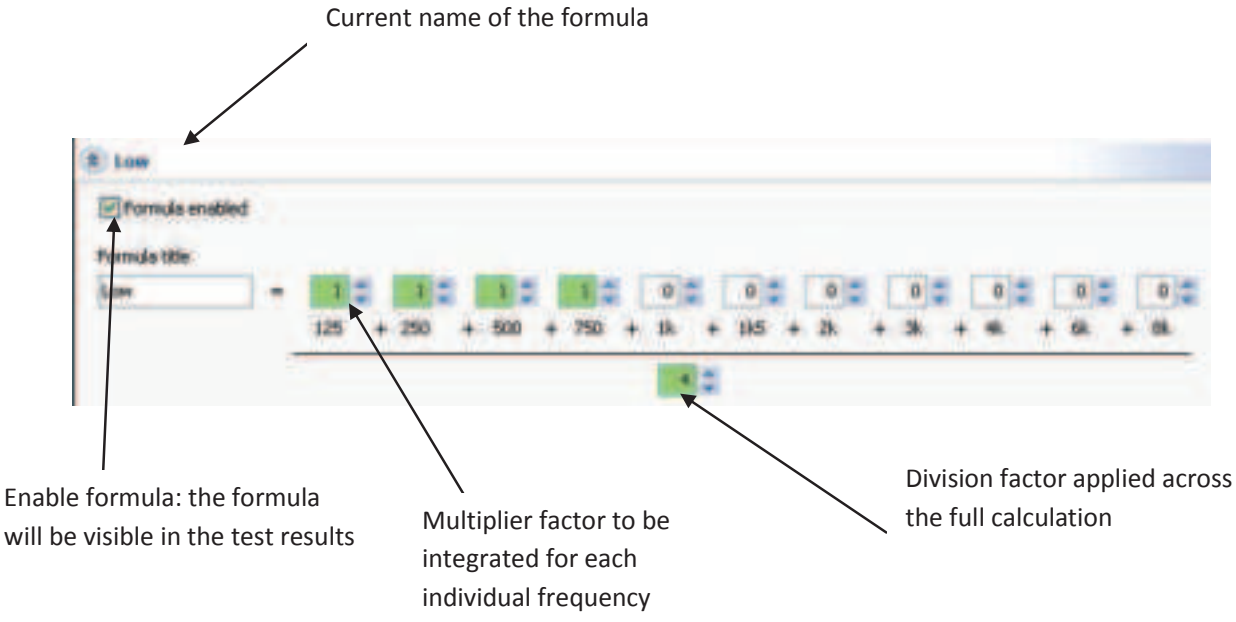
- Absolute maximum sound levels (black curve): this curve represents the absolute maximum sound levels permissible, all tests included. The default setting matches with maximum capacities of the audiometer.

To change these levels, select the curve in field 3 (the cursor will adopt the same colour as the curve selected), then just click on the level and frequency you want to re-set.

Calculations configuration



There are 5 configurable calculation formulae. All 5 are configurable in the same way.



The multiplier factors are limited to 100.

The results calculated by the formulae are visible in the audiometric tests, audiometric tests history, and printout windows.

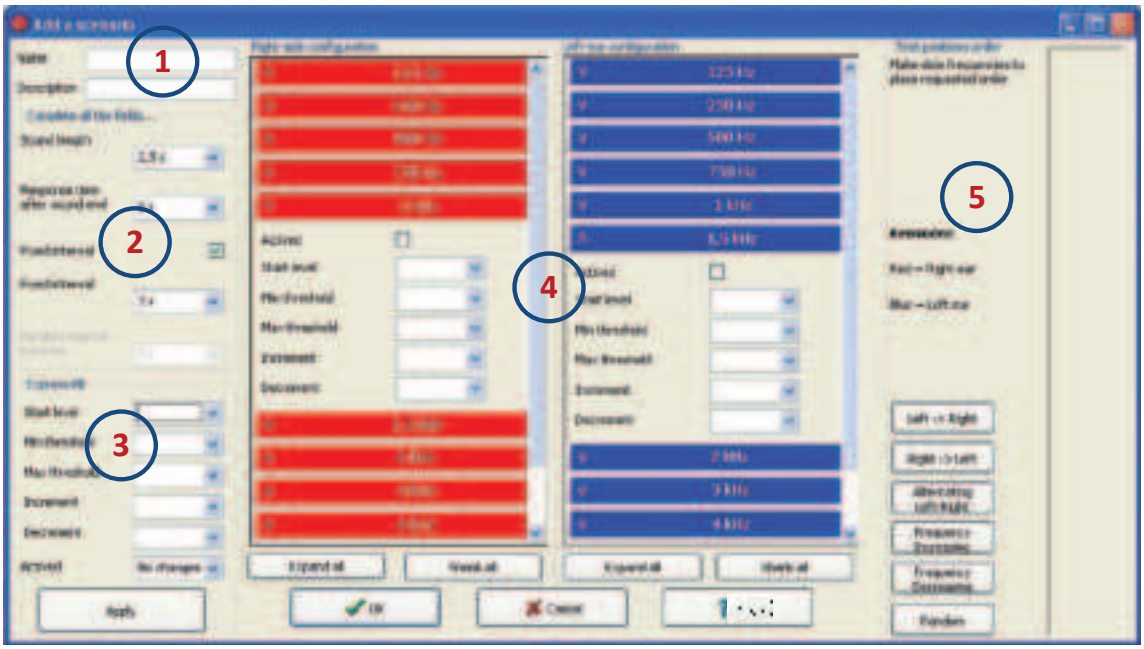
	Average	Low	Mid	High	Perso
Left CA	25,5 dB	21,3 dB	20,0 dB	35,0 dB	27,0 dB
Right CA	28,6 dB	21,3 dB	22,5 dB	41,3 dB	31,0 dB

Note that if there is no patient feedback response for a particular frequency, then no calculation will be done.

Create and modify scenarios

Test scenarios enable the operator to build a custom-tailored, automated audiometric test.

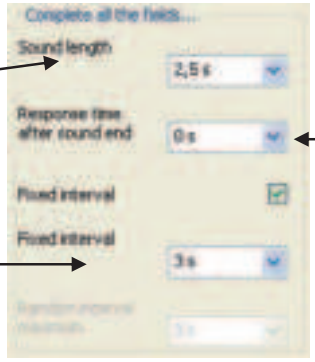
Scenarios are created and modified in the "Tests configuration" menu.



1) Name and description of the scenario
2) Sound exposure parameters
3) Quick-create scenario function
4) Recap of the data inputs entered
5) Chronological order of the test frequencies

The recommended sequence of steps for creating a scenario is as follows:

- Enter a name (compulsory), and a description (optional)
- Define the sound exposure parameters

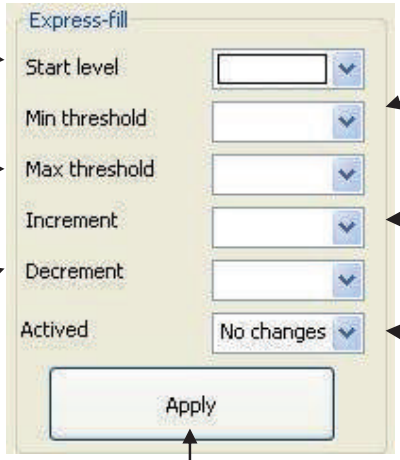


Sound duration

Extra time allocated for replying after sound duration

Time interval before the next sound pulse (fixed if the box is checked, random with maximum if the box is left unchecked)

- Express-fill all the frequency fields



Start sound level (from 0 to 70 dB)

Minimum sound level (from -10 to 60 dB)

Maximum sound level allowed (from 10 to 80 dB)

Sound level incrementation when patient does not respond

Sound level decrementation when patient responds

Selection or not of all the frequencies

Using the "no change" option will make sure earlier activations remain unchanged

Applies the settings entered above to all the frequencies

Since all the settings entered above will replace all previous configurations, you are strongly advised to complete these settings right at the start.

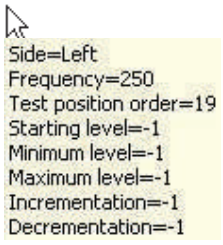
- The table in the middle also gives you options for modifying each frequency one by one.

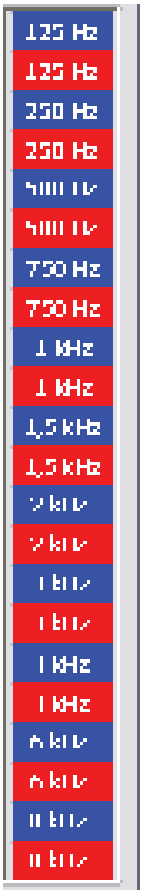
It features the same parameter settings as the express-fill box.
Red for the right ear, blue for the left ear.
Each enable/disable operation modifies the frequencies sequence highlighted in '5'.

- When settings for each frequency are fixed, then you simply enter the test time-course sequence.

  The frequency order sequence can be changed by a sliding (with the left mouse button) to the new position in the order.

  If you place the cursor over any frequency you will get a short recap of its settings.

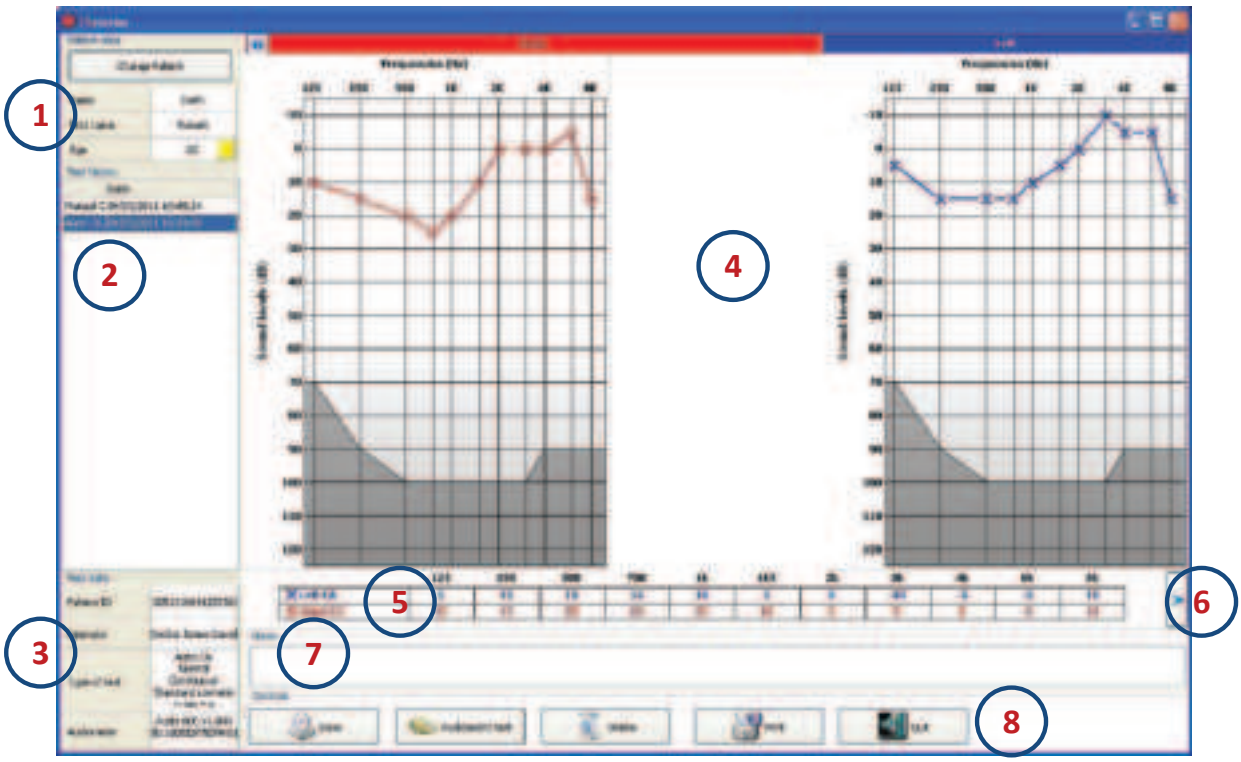




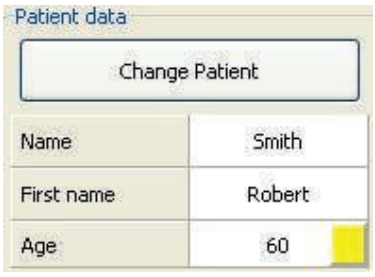
Audiometric tests history

To get a test history for a patient, select the patient from the list, then click on the Tests History button or double-click on the selected patient row.

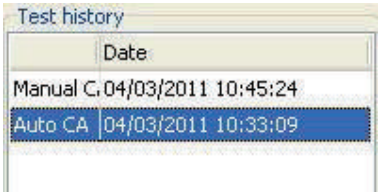
You will get a screen that looks like this.



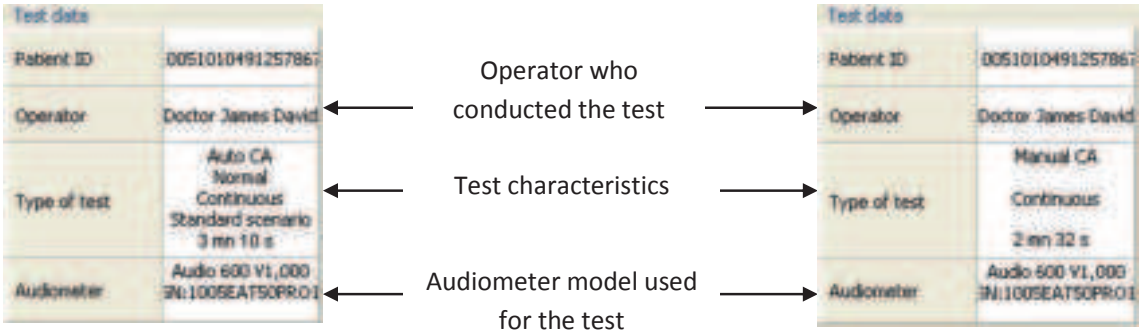
1) Recap of the patient record, giving name, family name, and age.



2) List of tests already run, listed from the most recent back to the oldest, giving type of test (manual or automatic), and the timestamp.



3) This table recaps some of the test informations



Test characteristics:

1st line:	Automatic or Manual
2nd line:	type of diagnostics: normal or according to Hughson-Westlake technique (in automatic mode)
3rd line:	type of sound delivered, "Continuous" or "Pulsed"
4th line:	name of the scenario used (in automatic mode)
5th line:	test duration, in minutes and seconds.

Audiometer characteristics:

1st line:	audiometer model plus its version (not to be confused with the 600M software version)
2nd line:	audiometer serial number

4) Graphical representation of the test results (audiogram)

5) Results expressed in table format

6) Button for toggling to test results expressed in calculation format (hearing losses)

See Calculations configuration for the formulae used.

7) Shows notes and comments concerning test, it is possible to complete them on this history window.

8) Command buttons

The operations are as follows (from left to right):

- Save: only saves added notes and comments
- Audiometric test: run a new audiometric test
- Delete: delete this test
- Print test history as a .pdf file (requires Acrobat Reader)
- Quits the tests history and go back to the patient records window

Print

Requires Acrobat Reader
Adobe Reader is available as a free download from:
http://get.adobe.com/fr/reader/

Clicking on 

will open Acrobat Reader with the page required.

This button is found in the "Tests History" window as well as in the "Audiometric test" window

The operator is free to save or print the test.

See following page for an illustrative example printout.

The printout page features all the information given in the tests history as well as the date and time of the printout (shown at bottom-right).

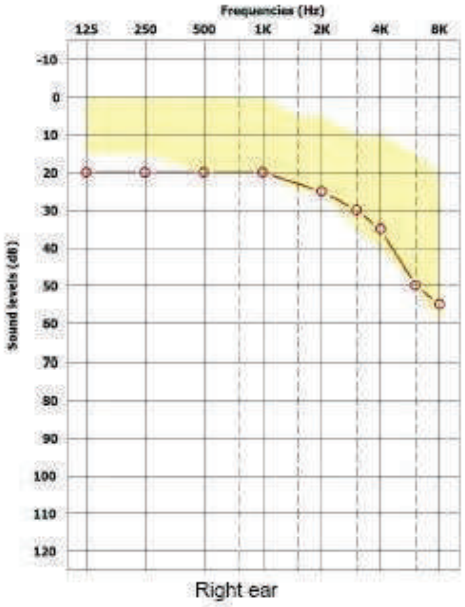
ELECTRONICA Technologies

Doctor Jean Lecarme

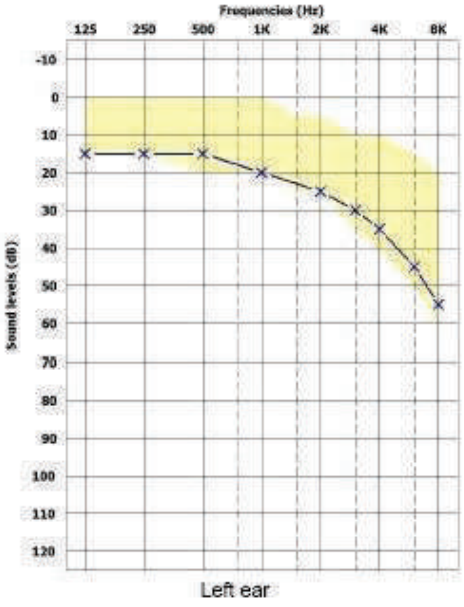
Patient data	Uzu Marie
Birth date	19/09/1941
Age	69
Company name	
ID	10110117565979710

Date of the test:	22/02/2011 16:57:59
Duration:	5mn 46s
Type of test	Auto CA Normal Pulsed Standard scenario

Audiometer	
Type:	Audio 600 V1,000
Serial number:	1005EAT50PRO1
Calibrated on:	18/05/2010



Right ear



Left ear

Frequencies (Hz)	125	250	500	750	1k	1k5	2k	3k	4k	6k	8k
Left CA	15	15	15		20		25	30	35	45	55
Right CA	20	20	20		20		25	30	35	50	55

Calculation

	PAM	IPA
Left CA	20,0 dB	36,7 dB
Right CA	21,3 dB	38,3 dB

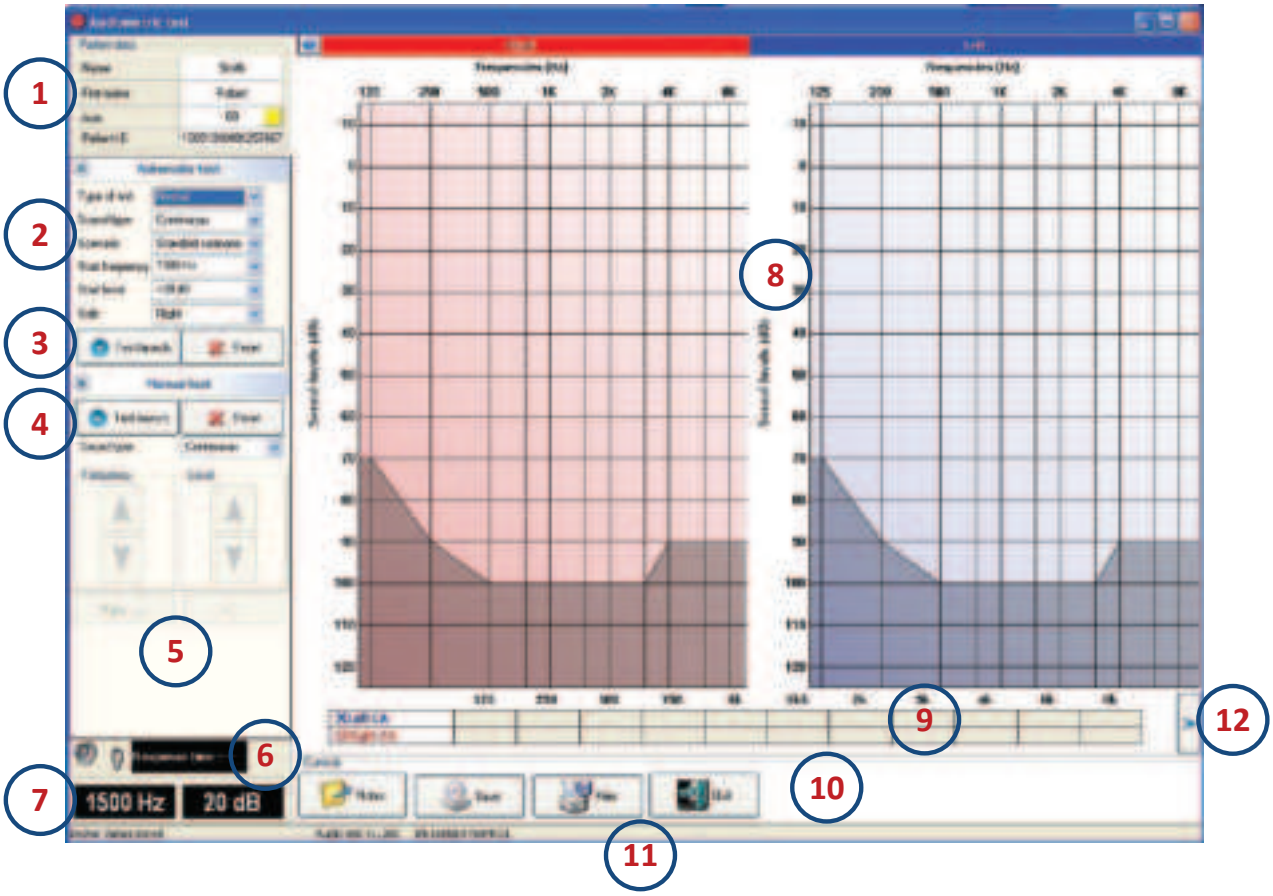
Notes

600M software 22/02/2011 17:03:58

Audiometric tests

This menu is available in the patient records window and in the tests history window, by clicking this button:

This will bring up the following window:



1) Recap of the patient data
2) Automatic audiometric test configuration
3) Button that launches an automatic test
4) Button that launches a manual test
5) Control panel for a manual test
6) Audiometer status

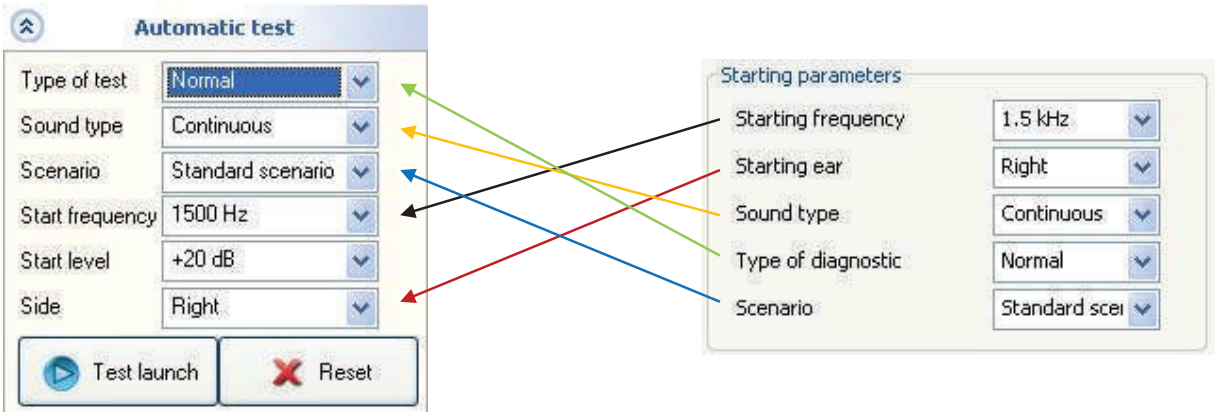
7) Current frequency and sound level
8) Real-time developped audiogram
9) Real-time results of the test currently running
10) Command buttons
11) Infobar giving operator and audiometer data
12) Button that opens up access to the calculation results, once one or more formula have been configured (see page 24)

Automatic test

Before an automatic test can be launched, it has to be configured with zone 2 of the tests page.

When the page is brought up on-screen, it is configured with the parameter settings featuring in the test configuration menu under the automatic tab.

The configured parameters quickly set up the most commonly-used test, thus eliminating the need to make unnecessary adjustments.



Type of test: choice between Standard and Hughson-Westlake
Sound format: choice between "Continuous" and "Pulsed"
Scenario: choice between standard scenario, random scenario, and the custom scenarios created
Starter frequency: the test sequence will kick off with this frequency. Only applies to pre-programmed (standard and random) scenarios
Start levels: start-off sound level for each frequency (only applies to pre-programmed scenarios)
Side: choice between left or right ear (applies to pre-programmed tests).

When these parameter settings have been configured, the test can be launched by clicking on "Test launch".

A box will appear at bottom-right of the screen, showing the timeline of the tested frequencies, with a small cursor indicating where the test is up to.

This digital timing box features a test sequence. The sequence shown above is for a "standard" pre-programmed test.

Routine standard of a standard preprogrammed test:

1 kHz → 1.5 kHz →2 kHz →3 KHz →4 kHz →6 kHz →8 kHz →1 kHz →750 Hz →500 Hz →250 Hz →125 Hz

The start of the sequence jumps to whichever start-off frequency has been set. For each of these frequencies, each ear is tested one after the other.

Under a random scenario, all the above frequencies are shuffled into random order — the only common denominator is the start-off frequency with the ear side.

The frequencies tested are the frequencies configured in the "Test configuration" menu under the "Standard-routine and random-sequence automatic tests" tab.

When the test is over, if general configuration is set to manual backup mode, a message box appears with a prompt asking whether to save the test. Otherwise, the message simply informs that the test has finished.

It is possible to pause mid-test — just click the Pause button.

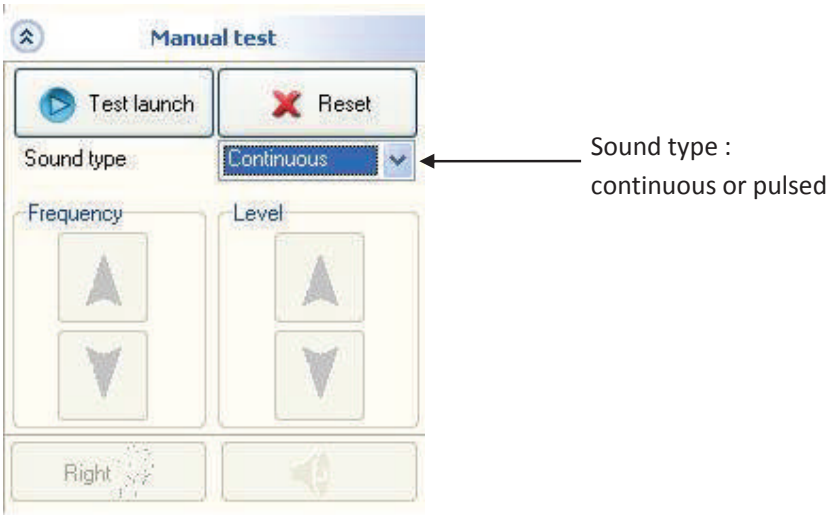
It is equally possible to completely stop the test at this particular point. This test will have to be saved manually, by clicking on "Save".

The test can also be restarted from the beginning, by clicking on "Reset". Note, though, that if you use the reset button, the test being run will be lost, and without a warning message.

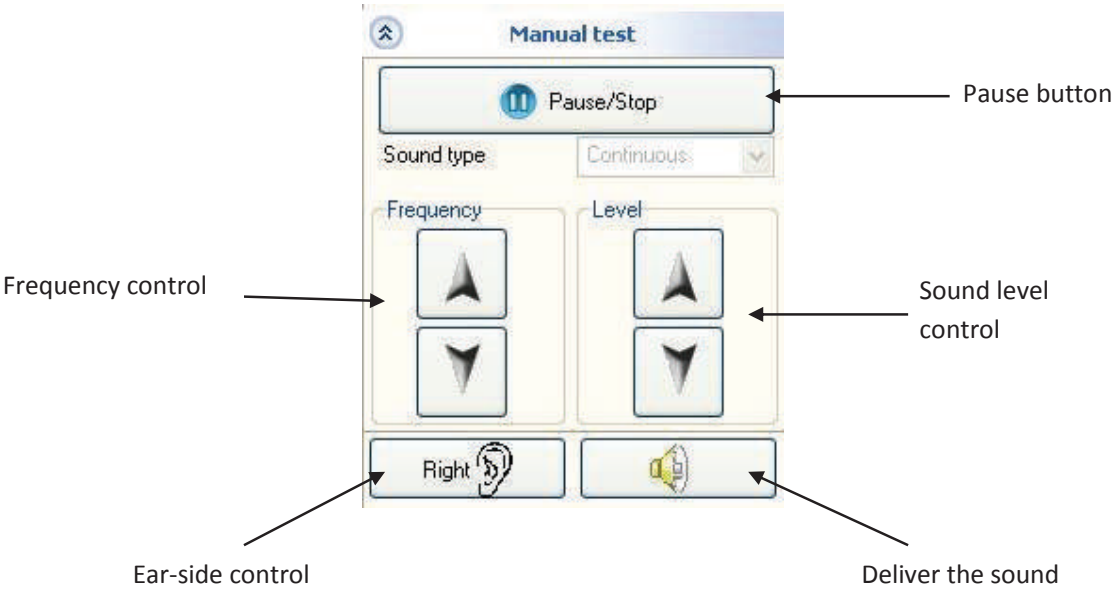
To continue the test, just click on "Restart". The level being tested when the sequence was paused will be re-emitted.

Manual test

No pre-configuration is needed before starting a manual test, and you can select between continuous or pulsed sound at any time.



Launching the manual test activates the control panel.



There are three control methods for a manual test:

- using the control panel (above)
- using the keyboard (via the shortcuts stipulated in the manual tests configuration tab)
- using the mouse, by clicking directly on the audiogram

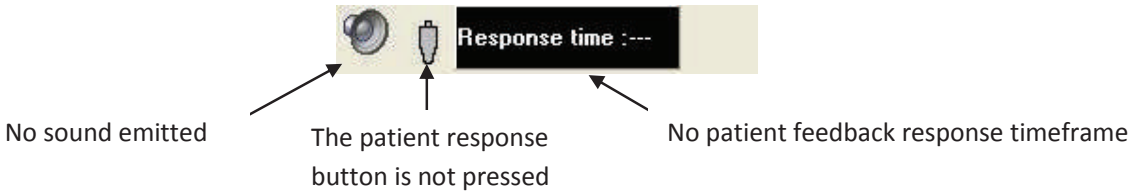
The mouse and keyboard commands can be disabled from within the test configuration window.

During test roll-out

During test roll-out, several indictors are visible:

Panel 6 (see page 34): audiometer status

While there is no sound generated and no action on the audiometer, the panel looks like this:



If the patient squeeze-button is pressed in (during the test or not), the panel icon changes to this:

While sound is being emitted, the speaker becomes an animated icon:

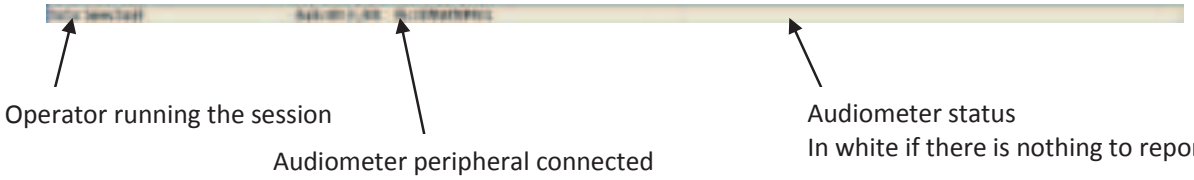
If the patient squeeze-button is pressed before sound is emitted, the panel shows this caution sign:

Example of a normal patient response — the operator can register the response:

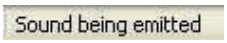
In manual mode, the operator needs to wait for the patient to release the button (panel switches to grey) before moving on to the next test.

In automatic mode, 600M waits for the patient to release the response button.

Infobar 11 (at the bottom of the window):



Audiometer status changes through the following sequence



Time added on by the configuration

Pause interval before the next sound

Waiting for the patient to release the squeeze-button

In manual mode, a box at bottom-right shows the test results history logging frequency—hearing level as well as patient react-time to response.

'Routine' diagnostic

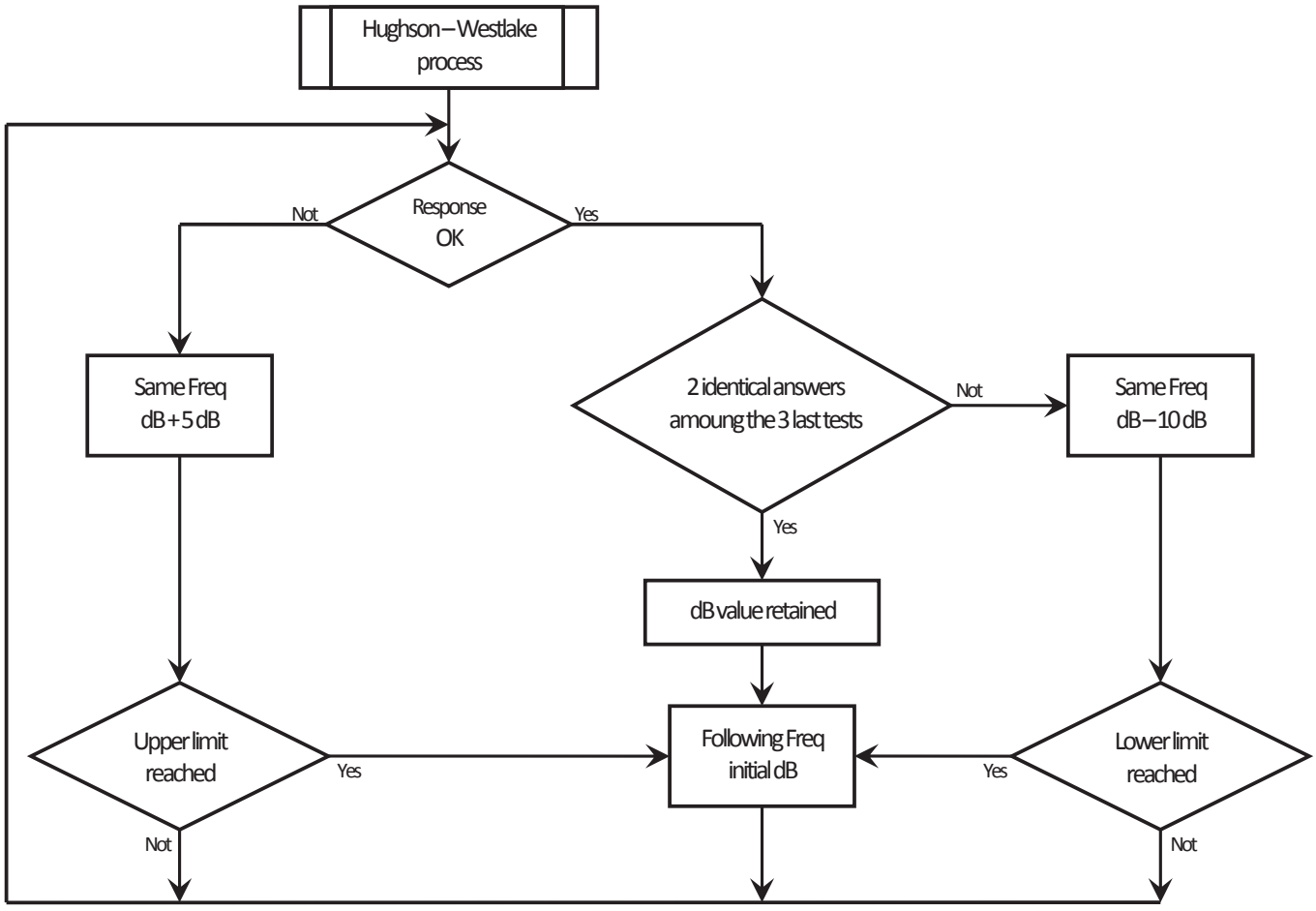
The 1st sound for the specified frequency is emitted.

If the patient shows no response, sound level is incremented until it becomes just audible to the patient. This audible sound threshold is recorded, and the next test is lined up.

If the patient responds to the 1st sound, the sound level is decremented until it becomes inaudible. The level of the last sound heard is the level recorded.

"Hughson-Westlake" diagnostic

This screening method runs through the algorithm below. The patient's hearing threshold recorded corresponds to the sound level that triggered two of the patient's last three responses.



Decrementation and incrementation are set by default at -10dB and +5dB, respectively.

4. Uninstalling the software

Quit the 600M software.

Open “Configuration Panel” (starting menu).

Use the menu for uninstalling programms and select the programm to be uninstalled: EasyAudio.

The software has now been suppressed from your computer.

Validate the message boxes.

The software has now been uninstalled from your computer.

Certain files have not been deleted — you need to navigate through a Windows file explorer to remove them manually. They include log files (*.log), the "old" database directory, and the last .pdf files saved (reportxx.pdf) as part of the last print-and-backup operations.

5. Technical datasheet

General: Type-4 pure-tone audiometer, conform to standard EN 60645-1. Air conduction

Classification: Group 1, class B (EN 60601-1-2: 2002)

Type B. 

Maximum sound levels (HLdB):

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
dB	70	90	100	100	100	100	100	100	90	90	90

The sound levels are expressed in HLdB, i.e. Hearing Level in decibels. This is what is known as a compensated curve, where “0 dB” for each of the frequencies corresponds to the minimum hearing threshold of an otologically healthy subject (definition according to standard EN 60645-1). The sound levels can be adjusted in 5dB steps.

Power supply: directly via the USB connection (1 m long cable supplied)
5 V +/- 0.2 V

Frequency precision tolerance: +/-2%

Tone presentation: Its pure sinusoidal digital management.
Select channel (left / right) with PC software interface.

Audio output: On stereo jack 3.5 mm.

Calibration: Air conduction calibration, in compliance with standards ISO 389-1 and ISO 389-8

Operating environment: Storage temperature: -10° to 60°C
Working temperature range: 15° to 40°C
Relative humidity: in the range 30% to 90%
Atmospheric pressure: in the range 98 kPa to 104 kPa

Dimensions and weight: 150 x 92 x 28mm-160 grams (one audiometer)
L= 310- l=280-H=100 mm- 1.2Kg (complete suit case)

Patient responder: 3.5 mm plug-in audio jack
Cable length: 1.20 m

USB/Headset electrical isolation: 4000 V, in compliance with NF EN 60601-1

Pre-heat: Less than 5 seconds

Status light: blue LED

6. Regulatory specification

CE marking

Electronica Technologies is certified for medical CE marking by LNE / G-MED (France)

CE
0459

Product origin

Device designed and manufactured in France by:

« Electronica -Technologies, ZA de la Tour, 03200 ABREST France »

First « CE » marking obtained in 2014.

Electromagnetic compatibility

In rare cases, the audiometer may stop working if it is exposed to heavy surges of static electricity. If this happens, simply unplug then re-connect the audiometer.

If this does not resolve the problem, contact your Distributor.

Guidance and manufacture´s declaration – electromagnetic emission		
The Audiometer 600M is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer 600M should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 600M audiometers use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 600M audiometers are suitable to be used in all establishments, different than the domestic promises and those directly connected with the public low voltage power supply network, feeding domestic use buildings.
Harmonic emissions IEC 61000-3-2	Not Applicable	
fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacture´s declaration – electromagnetic immunity			
The audiometer 600M is intended for use in the electromagnetic environment specified below. The customer or the user of the audiometer 600M should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-5	± 2 kV for power supply Lines ± 1 kV for input/output lines	± 2 kV for power supply Lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycle 70 % *U*T (30 % dip in *U*T) for 25 cycle <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycle 70 % *U*T (30 % dip in *U*T) for 25 cycle <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the audiometer 600M requires continued operation during power mains interruptions, it is recommended that the audiometer 600M be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacture´s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The audiometer 600M is intended for use in the electromagnetic environment specified below.
The customer or the user of the audiometer 600M should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601
Test level</th><th>Compliance
level</th><th>Electromagnetic environment
–
guidance</th></tr>
<tr><td>Conducted RF

IEC 61000-4-6

Radiated RF

IEC 61000-4-3</td><td>3 Vrms

150 kHz
to 80 MHz

3 V/m

80 MHz
to 2,5 GHz</td><td>3 Vrms

150 kHz
to 80 MHz

3 V/m

80 MHz
to 2,5 GHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the audiometer 600M, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

d=0,35√P

d=0,35√P 80 MHz to 800 MHz

d=0,7√P 800 MHz to 2,5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b].

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Audiometer 600M is used exceeds the applicable RF compliance level above, the Audiometer 600M should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the audiometer 600M.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</td></tr>
</table>

7. Precautions for use

The audiometer 600M is calibrated designed to work in tandem with the headset delivered with the kit (headset and audiometer share exactly the same last four digits in the serial number). Using any other headset may distort the measurements.

Always make sure that you only test tones at an intensity level that is acceptable for the patient.

Using accessories other than those delivered as part of the device kit or distributed by the manufacturer may cause device damage or malfunction.

Operators are advised not to use the device if it is too close to other electronic equipment. If this kind of situation is unavoidable, you should run checks to verify that the audiometer works properly under the conditions encountered.

As well, using wireless communications terminals can also interfere with the audiometer's operational performance. The "Technical datasheet" section carries useful information on minimal distances.

The operator must not simultaneously touch the patient and the USB connector.

Before testing a different patient, double-check the surface interface between headset and patient to make sure there is no asperity capable of causing injury. This surface area should also be cleaned between patients to avoid spreading contamination. (Recommended cleaning agents include: Linget'Anios, Biohit Proline Biocontrol or any other similar product).

The other parts of the device can be cleaned with a soft moistened cloth that you can damp in soapy water, making sure no liquids are allowed to get into the device.

The 9900-series audiometer must only be used in a temperated, dry environment. No liquids must penetrate the accessories (carry-case, headset, patient feedback lead).

When the audiometer 600M has reached the end of its useful life, do not throw it in the bin. It should be returned to the retailer to be disposed of properly.

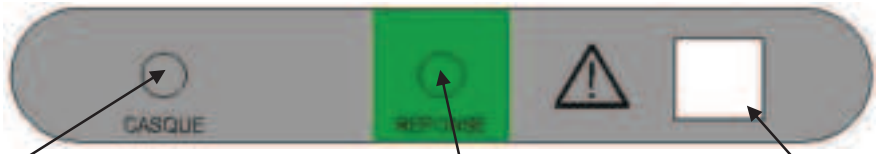
The audiometer is a screening tool designed to be used by doctors, nurses or other healthcare professionals. Under no circumstances may it override the medical diagnosis carried out by a specialist.

To give optimal performance, the patient must be seated in a very quiet room where environmental noise is less than 20 dB.

The headset shall be adjusted to fit with the patient's head perfectly. Make sure the headset is fitted with the left and right earphones correctly-placed. Patients who wear glasses should remove them for the test.

8. Audiometer box

Connections



Headset connector

Patient response-lead connector

USB-out to the PC

Cable marked with green sleeving

Operators are urged to plug the headset into the console before the patient puts the headset on his head.

Light emitting diode

A LED on the front face indicates the status of the PC link.

It flags three different statuses:

- Standby mode: the 600M software is not running.
- Active mode: 600M software is running, but not in test mode.
- Test mode: a test is in progress.

Standby mode: LED off for 7.5 seconds, then on for 0.25 seconds
Active mode: LED off for 3.5 seconds, then on for 2 seconds
Test mode: LED off for 0.1 seconds, then on for 7.5 seconds

Pictograms

The pictograms featuring on the console ID tag have the following signification:

See user manual

Electronics equipment — to be disposed of properly

Class B device (EN 60601-1)

Manufacturer - name and address

9. Operating incidents

Problem encountered	What to do ?
The blue LED does not come on.	➢ In standby mode, the LED does not come on. Wait 10 seconds and see whether it has still not blinked on ➢ Double-check that the PC-to-audiometer USB cable is properly connected ➢ Check if the PC is running properly ➢ Get in touch with the After Sale Service
Impossible to run a test — the buttons remain greyed-out	➢ Double-check the PC-to-audiometer connection ➢ Get in touch with the After Sale Service
The test launch buttons remain greyed-out	➢ The system is not connected to an audiometer ➢ There is a problem with the USB cable — replace the cable ➢ A different audiometer is connected ➢ Unplug then reconnect your audiometer ➢ Get in touch with the After Sale Service
The software throws up a "Checksum Error" message before launching a test	➢ Unplug then reconnect your audiometer ➢ Get in touch with the After Sale Service
No tone in the headset	➢ Check if the headset is properly connected ➢ Check if that the sound level is high enough to be audible ➢ Get in touch with the After Sale Service
The patient-response controller does not work	➢ Check if the controller is plugged into the right socket (should be in the central connector) ➢ Get in touch with the After Sale Service
Chaotic headphone tone (sound too strong, erratic, etc.)	➢ Get in touch with the After Sale Service
The interface between headset and patient is damaged:	➢ Think to replace the headset cushions
The printout function does not work	➢ Install Acrobat Reader or any other pdf reader

10. Warranty

See your distributor's general terms and conditions of sale.

If you would have to return an audiometer, don’t forget to fill and to attach the "Device return sheet" (next page).

- This warranty does not cover:
  - Calibration control checks.
  - The replacement of parts following normal wear.
  - Defects caused by alterations made by the user.

- The warrantied repair service does not cover damage or defects issued from:
  - Misuse, excessive use, or any abnormal operations or conditions of audiometer use in contradiction with the conditions outlined in the user manual.
  - Any repairs performed by anyone who has not been authorized to do so by the audiometer manufacturer.
  - Any use of accessory parts that are not compatible with the audiometer (other headsets, etc.).

To get the best use of this audiometer, the customer is strongly advised to carefully read the user manual.

	DEVICE RETURN SHEET	1/1
	Audiometer 600M	

Company: _____

Address: _____

_____

Postcode: _____

Telephone: _____

Fax: _____

E-mail:_____

Contact person: _____

Audiometer returned for: ☐ Periodical checking

☐ Repair

Description of the problem/defect:

_____
_____
_____
_____

Return the device to the distributor or retailer in its original packaging, along with all the original accessories.

Serial number: _____