ELECTRONICA MEDICAL
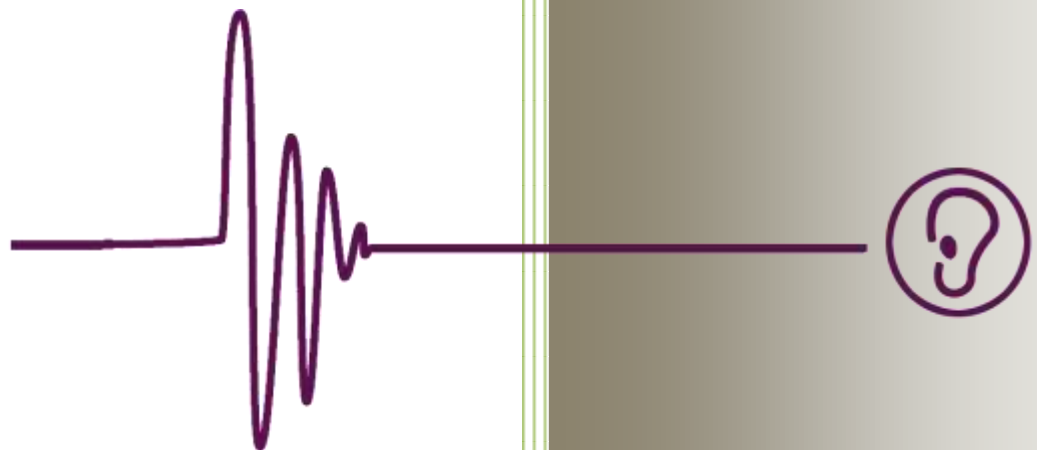by Electronica Technologies

600M Software

plus audiometer console

User manual

CONTENTS

1. Presentation

You have made a good choice.

The audiometer 600M uses air conduction to screen for hearing loss. The tone is presented through speakers in the headphones worn by the patient.
With the 600M software, the practitioner can choose the frequency, the level of hearing, the side to send the sound and the type of sound and also perform automatic audiometric tests, combining performance and timeframe optimal. A patient response return wire, equipped with a push button, allows the patient to signal to the audiometer that he has heard the sound.
The device is used with a standard circumaural headphone or with a high performance audiometric headphone, depending on model.

600M software is part of the computer-controlled audiometer.

It is a pure-tone air-conduction type-4 audiometer (Standard: EN 60645-1).

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

This documentation is also available online on our websites. You may retrieve a paper copy of the document by submitting a request as described on the accompanying sheet in the case.

The complete audiometer set includes the following components:
- Audiometer console
- USB cable
- Patient response return wire
- Headphone (not interchangeable without a technical calibration procedure)
- USB memory key containing the 600M software, the installing of the software and this user manual
- Transport case containing the above components.

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

To meet safety and regulatory requirements for electromagnetic compatibility, the microcomputer used must comply with the conditions of the following directives:
- 2014/30/EU EMC Directive
- 2014/35/EU Low Voltage Directive

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

See the product literature on the USB key for instructions on installing the software.

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

This product, which is very easy to use, requires a minimum knowledge of the PC-based Windows environment. If this is not the case, we invite you to contact your IT manager or IT consultant.

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
- Windows 10 –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".
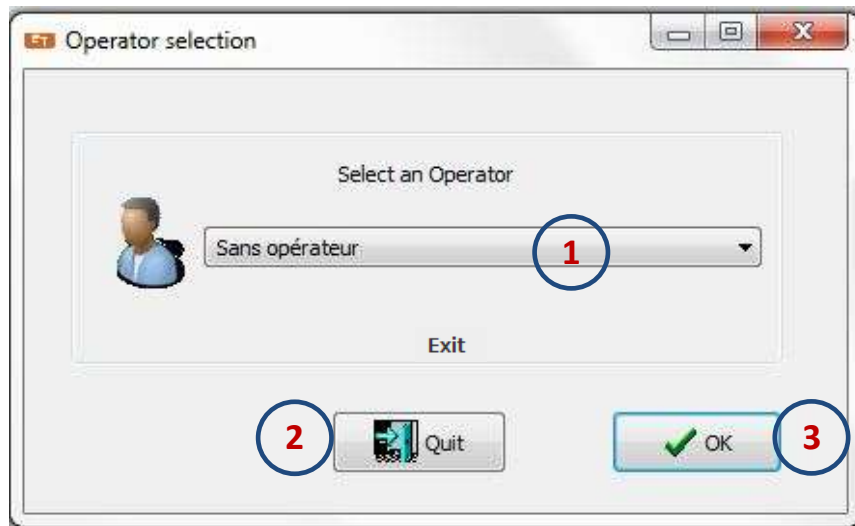
1) Dropdown list, used to select the operator
2) Quit button, to close the software without connecting
3) OK button, to validate the operator selected

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 start point 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.
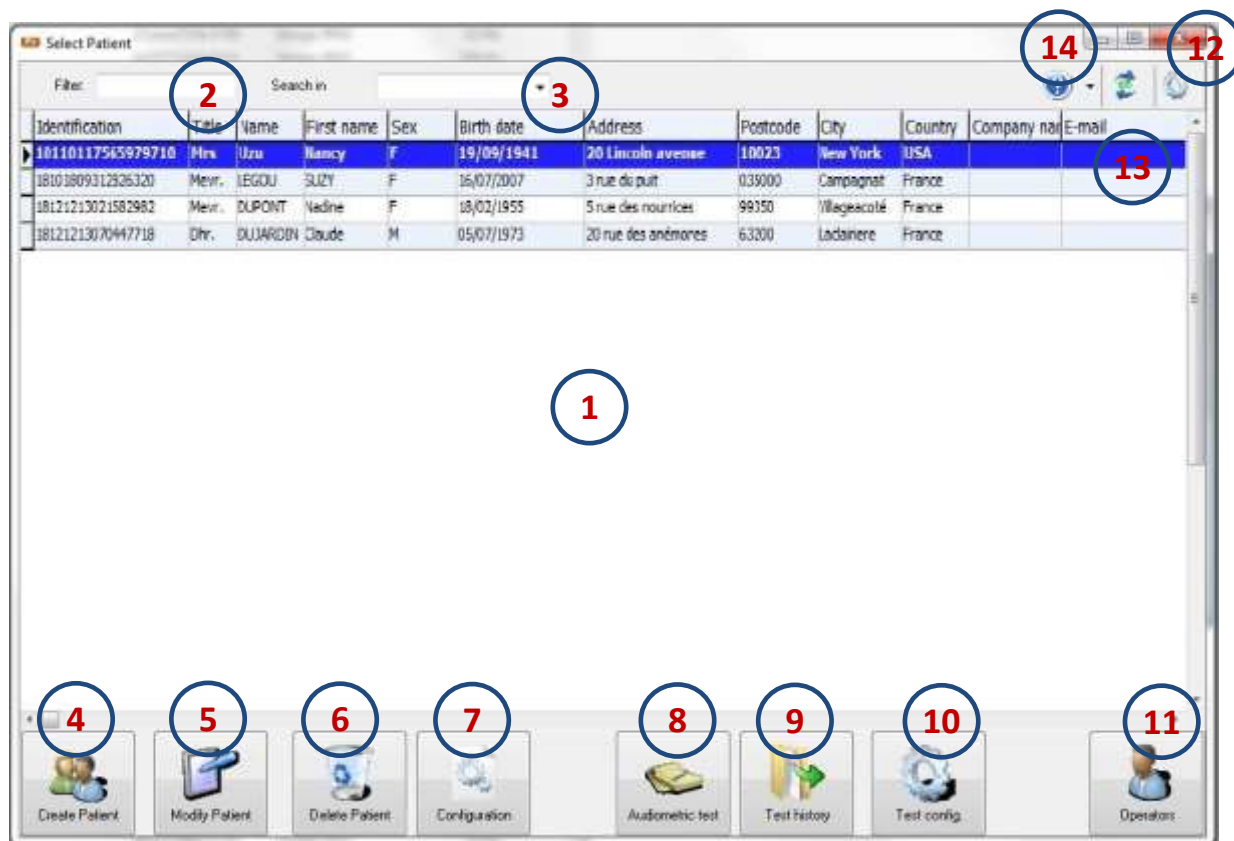
3) **Select search column**.

4) **Create a new patient records file**: see page Create/Modification of patient sheet

5) **Modify highlighted patient record**: see page Create/ Modification of patient sheet

6) **Delete the highlighted patient record**

7) **Visual display configuration:** hide/show the columns in table 1: see page
    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 Tests configuration

11) **Create/Modify operator** see page Operator accounts.

12) **General software configuration** (other than test configuration) see page
    General configuration

13) **Merge/synchronize** with pre-compiled databases
    See page Merge/Synchronize database.

14) **Help menu** see page 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

Configuration

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

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

Operators

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.
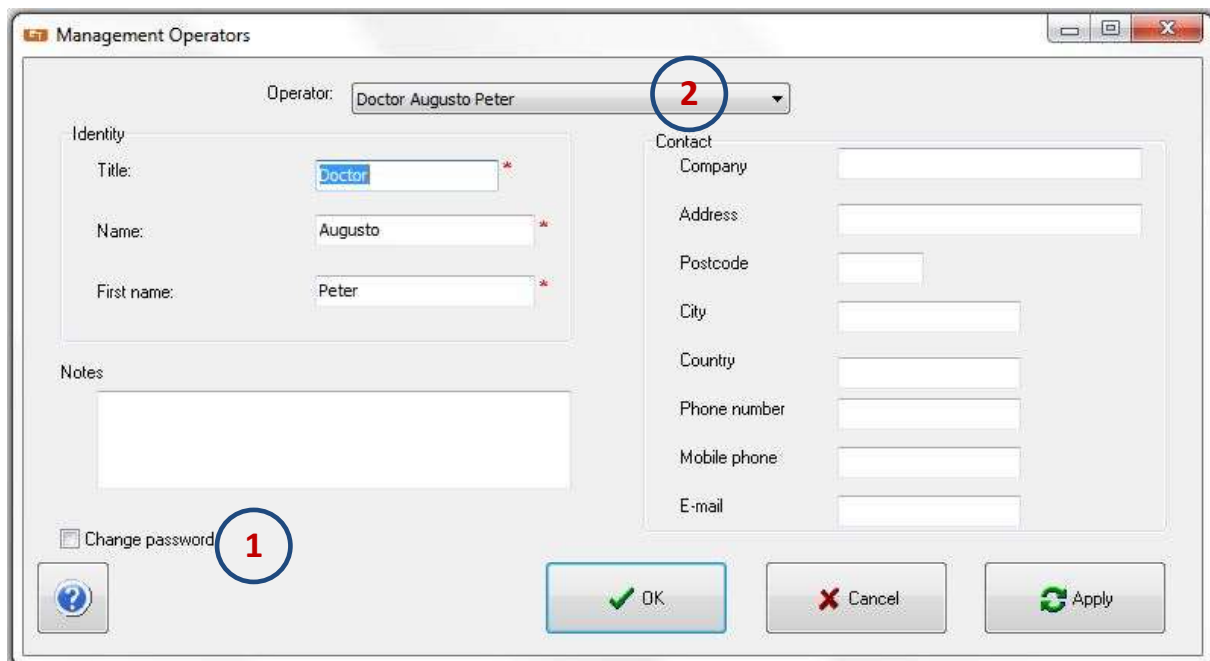
Obligatory fields are flagged with a red asterisk.

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 [icon] , at top-right of the main window takes you to the general configuration menu.

The general configuration window looks like this:
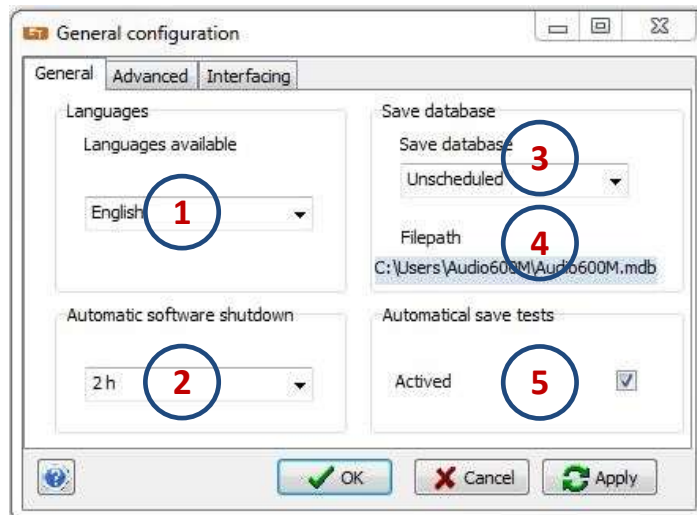
Under the "General" tab

1) Selection of the current language version
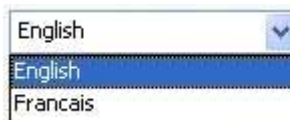
2) A drop-down list used to programme the software to shut down automatically after a scheduled time-lapse. This function is disabled while running audiometric tests. The programmable time-lapse options are: disabled (---), 15 min, 30 min, 1 hour or 2 hours.
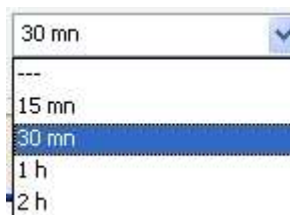
3) Database backups
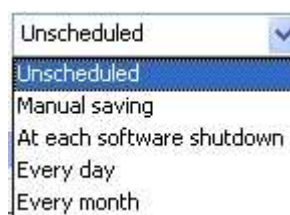
Backups can be performed either manually or automatically, and there are several backup options available.

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)

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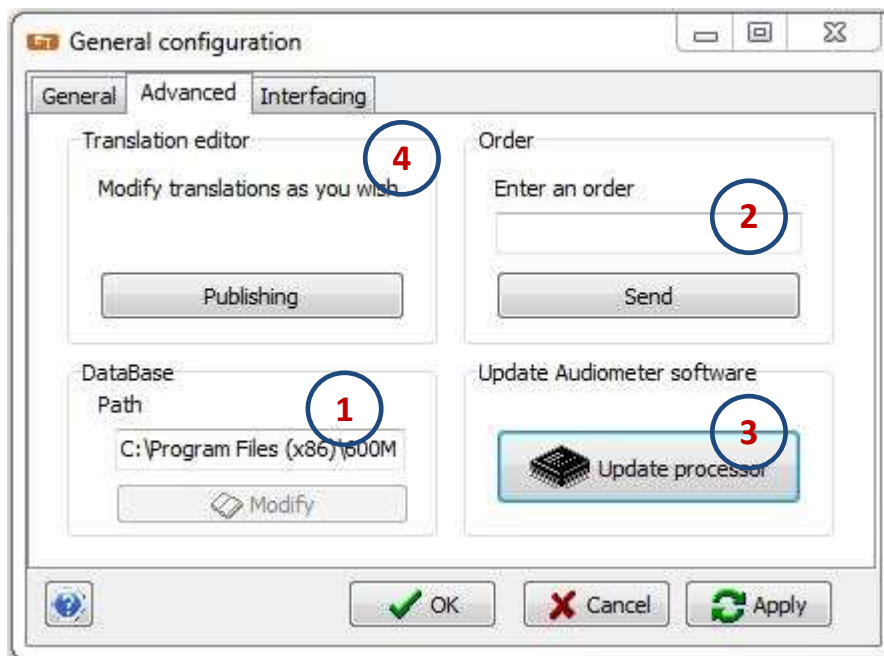
1) Software functionality activation
2) Programme diagnostics command lines (manufacturer only)
3) Update the audiometer software (manufacturer only)
4) Software text-output publishing (see page 14)

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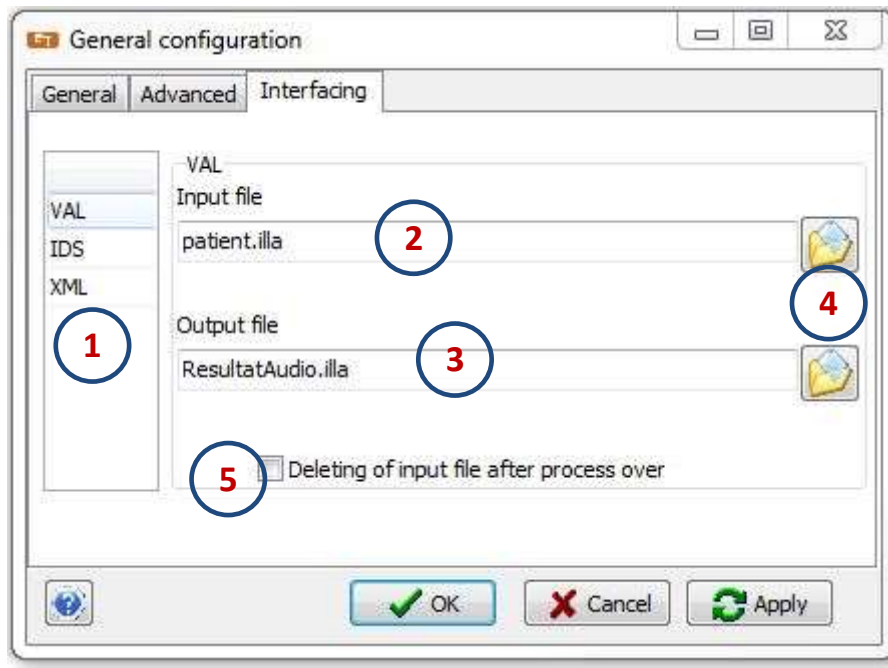
This tab provides configuration options for interfacing the 600M software with other clinical database software.

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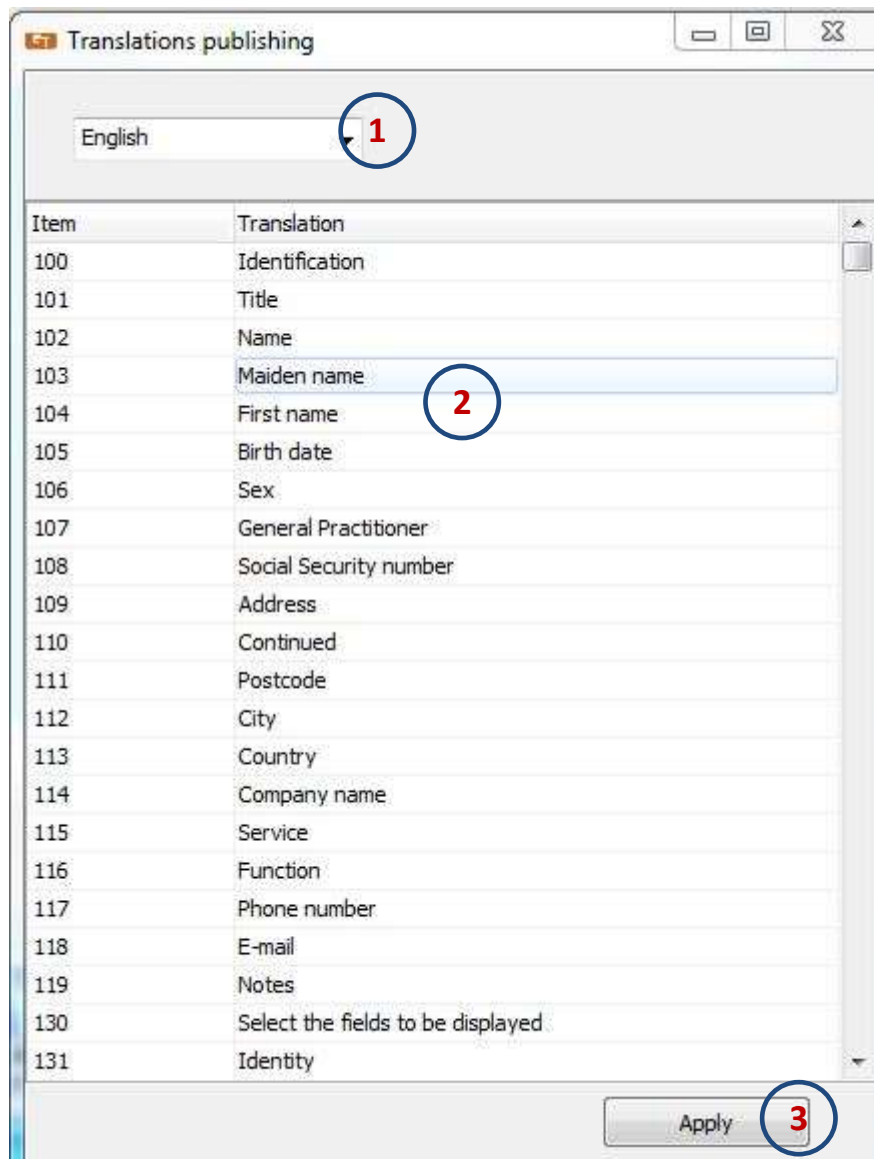
1) Selection of the text-output translation file to show and to modify
2) Editable text (in the right-hand column only)
3) Instantly apply the modifications (would be lost if this button is not pressed)

Merge/synchronize database

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

Clicking the [db] button at top-right of the main window takes you to this menu.
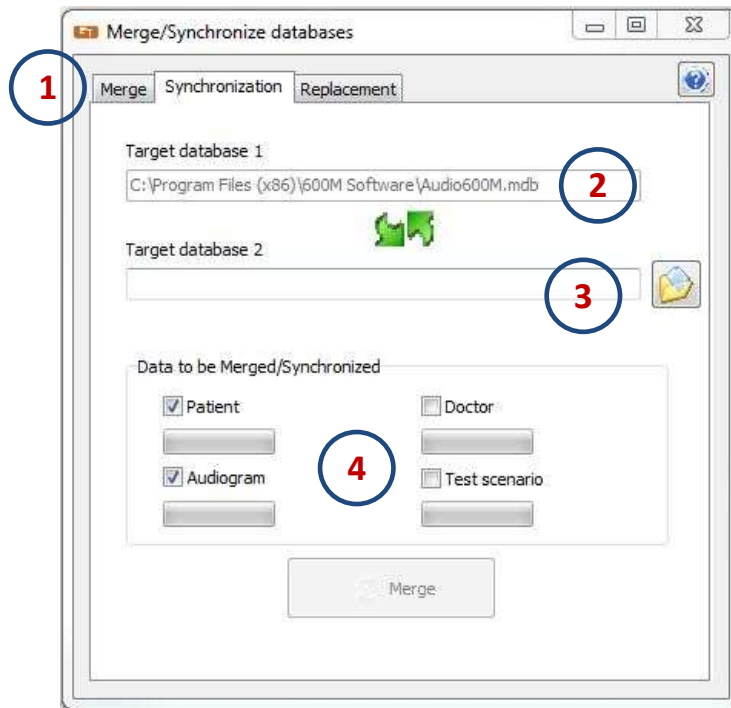
1) There are 3 different options available:
   - Merge: Additional inputs entered in the database that field n°3 are added to the database currently in use (field 2) — no entries get deleted. This is a one-way mode.
   - Synchronize: all the additional data inputs in each database are added to the other database. This is a two-way mode.
   - Replace: The current database is <u>deleted</u> 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
> On Windows 10, right click on the Windows flag icon and then click file explorer.

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
> In Windows 10 all 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   This button opens up other
Windows Help   options
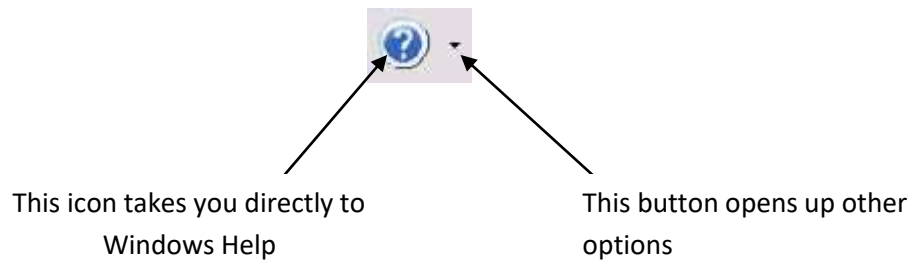
The other options opened by the drop-down arrow are:

Windows Help

Help

User guide(PDF) ◄──────── This user manual

About... ◄──────── About the 600M software
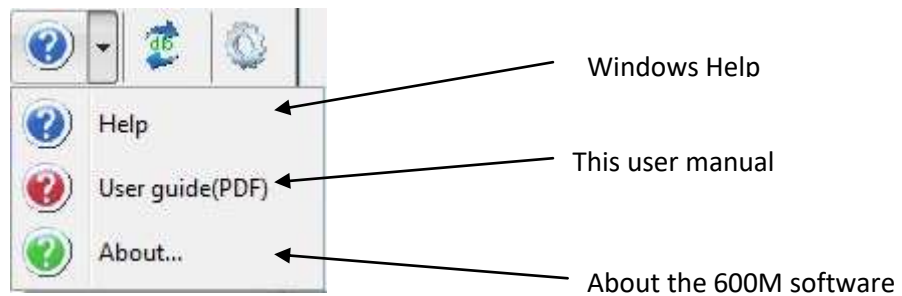
Tests configuration

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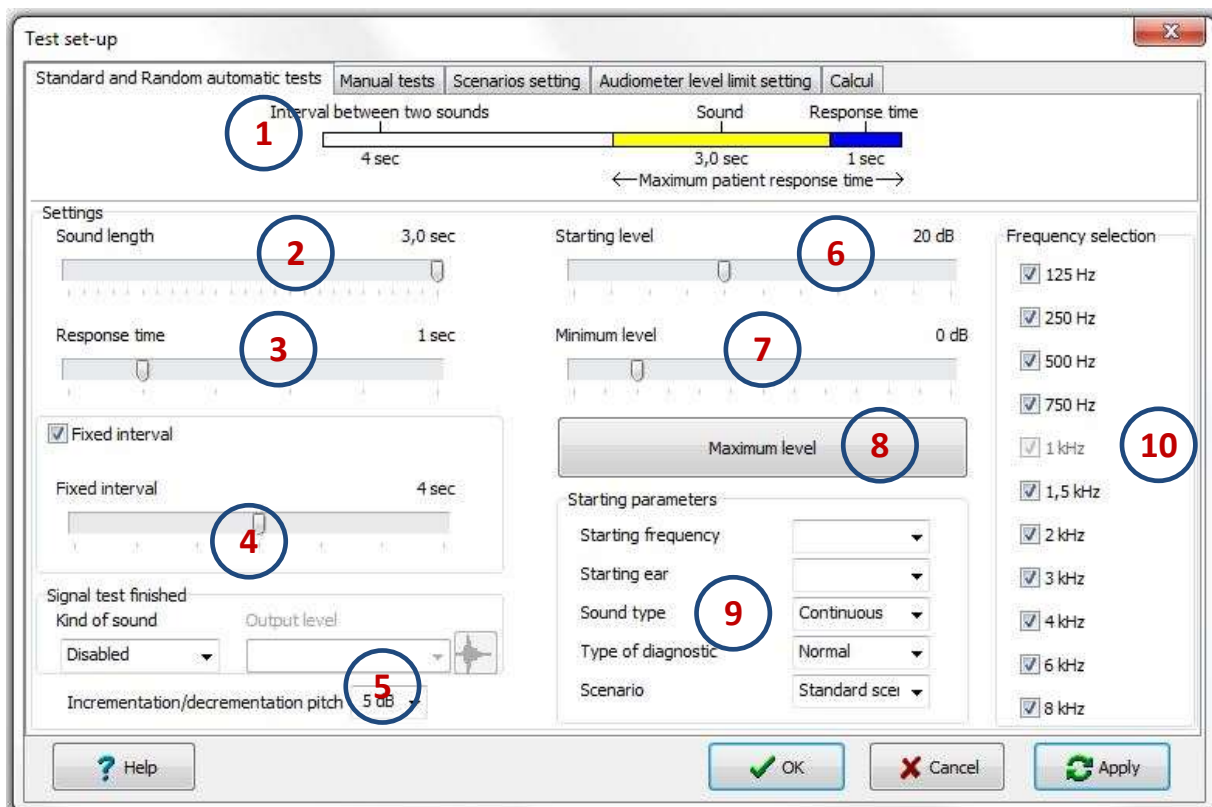
1) Graphic representing the input data: in 2, 3 and 4.
2) Sound duration (continuous or pulsed) in an automatic test, settable from 0.5 to 3 seconds.
3) Extra time allowed to the patient to respond once the sound has stopped (2), settable from 0 to 5 seconds.

4) Interval time between two sound exposures:

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

☑ Fixed interval

Fixed interval   3 sec
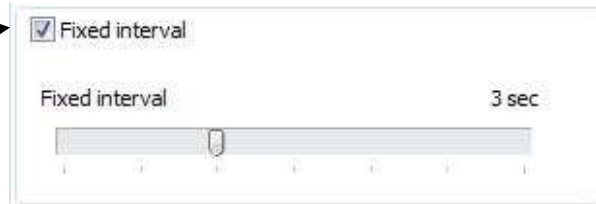
Adjustment of fixed inter-sound time interval (from 1 to 7 seconds)

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

☐ Fixed interval

Random interval maximum   3 sec

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

5) Increment/decrement 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
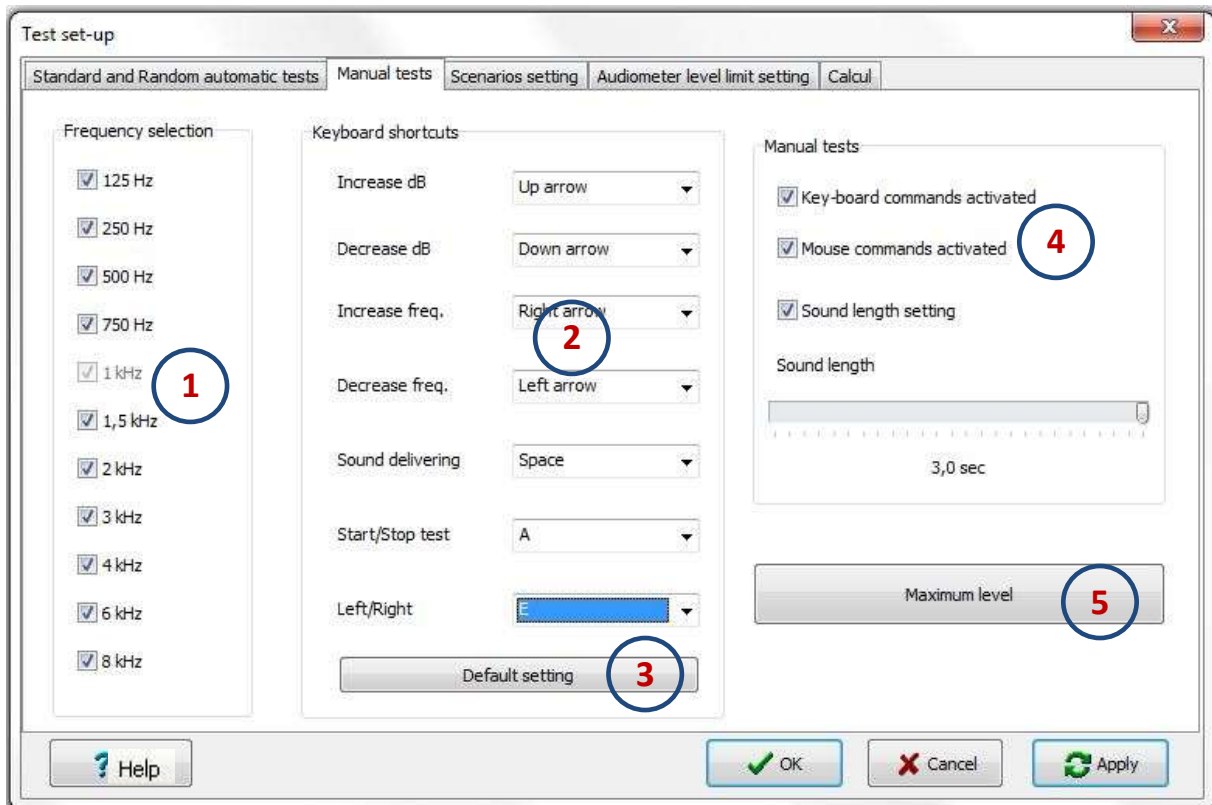
1) Frequencies testable. The 1kHz frequency is compulsory.
2) Keyboard shortcuts configuration (no matter to use capital or small letters), if enabled (point 4).
3) Default factory keyboard shortcut settings
4) Configuration of test control mode:
   ▪ Manual test control enabled (handles both manual 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'.
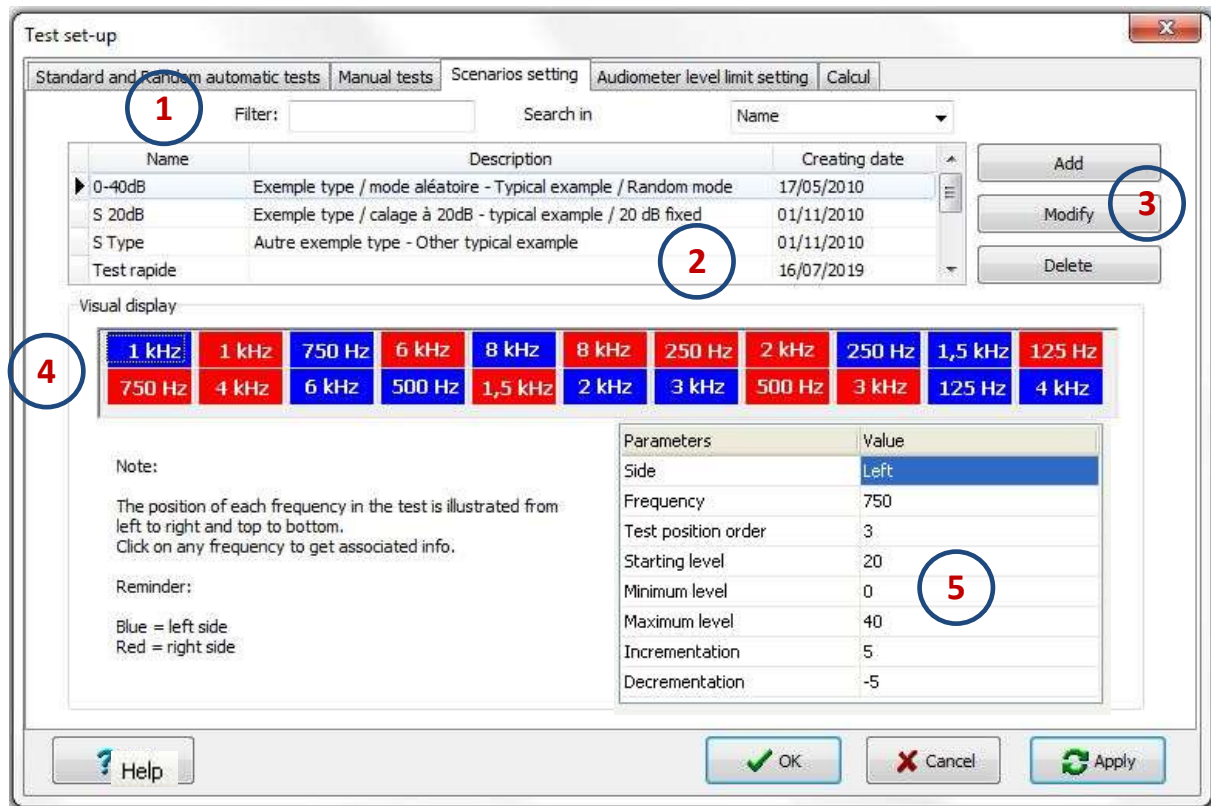
1) Scenario quick-search: only shows scenarios for which the name of description contains the wordtext entered
2) Recap of the scenarios already created (shown as filtered). The columns can be repositioned, and you can click on the column headings to choose between ascending-order or descending-order 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 increment if the patient does not respond
   - ➢ Sound level decrement 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
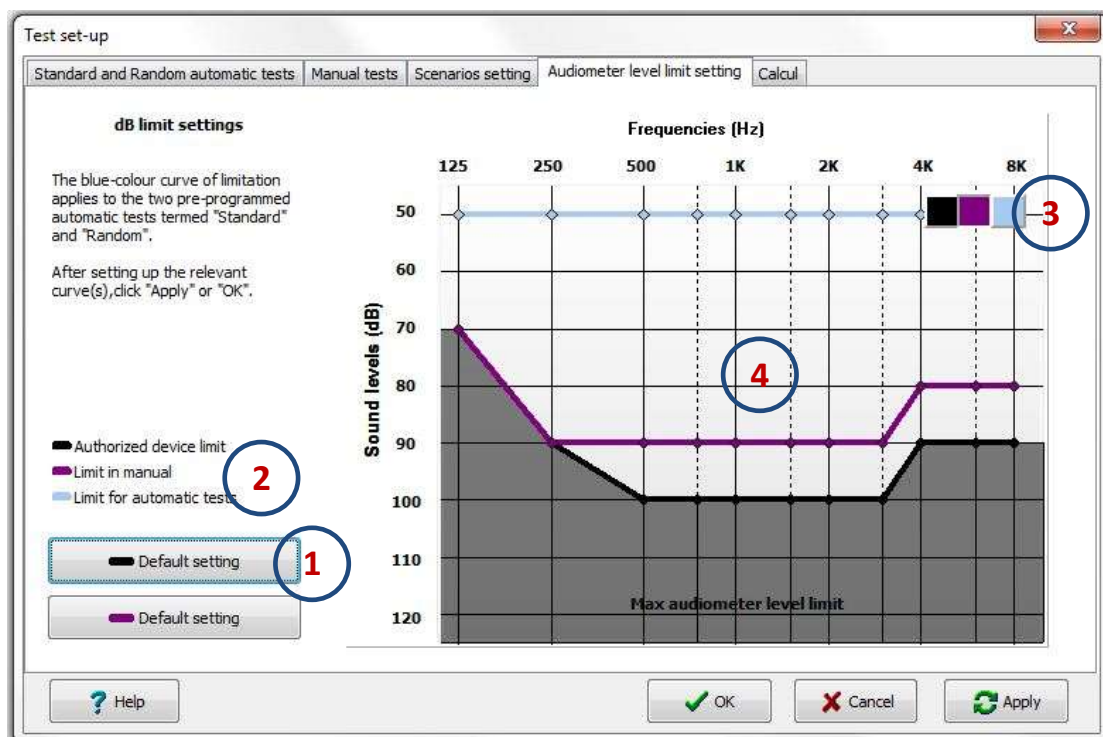
1) Default factory setting for the black and purple curves (absolute maximum sound levels and alert threshold in manual test mode)

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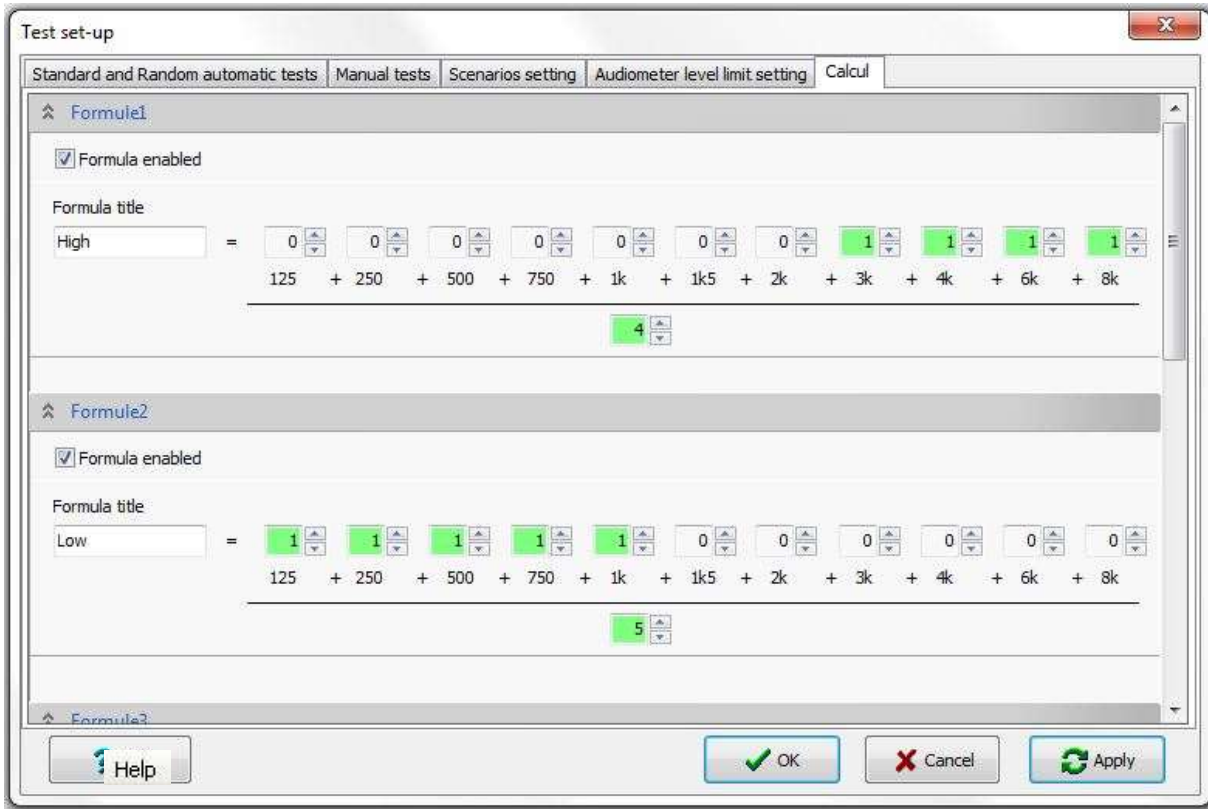
There are 5 configurable calculation formulae. All 5 are configurable in the same way.

Current name of the formula

Enable formula: the formula
will be visible in the test results

Multiplier factor to be
integrated for each
individual frequency

Division factor applied across
the full calculation
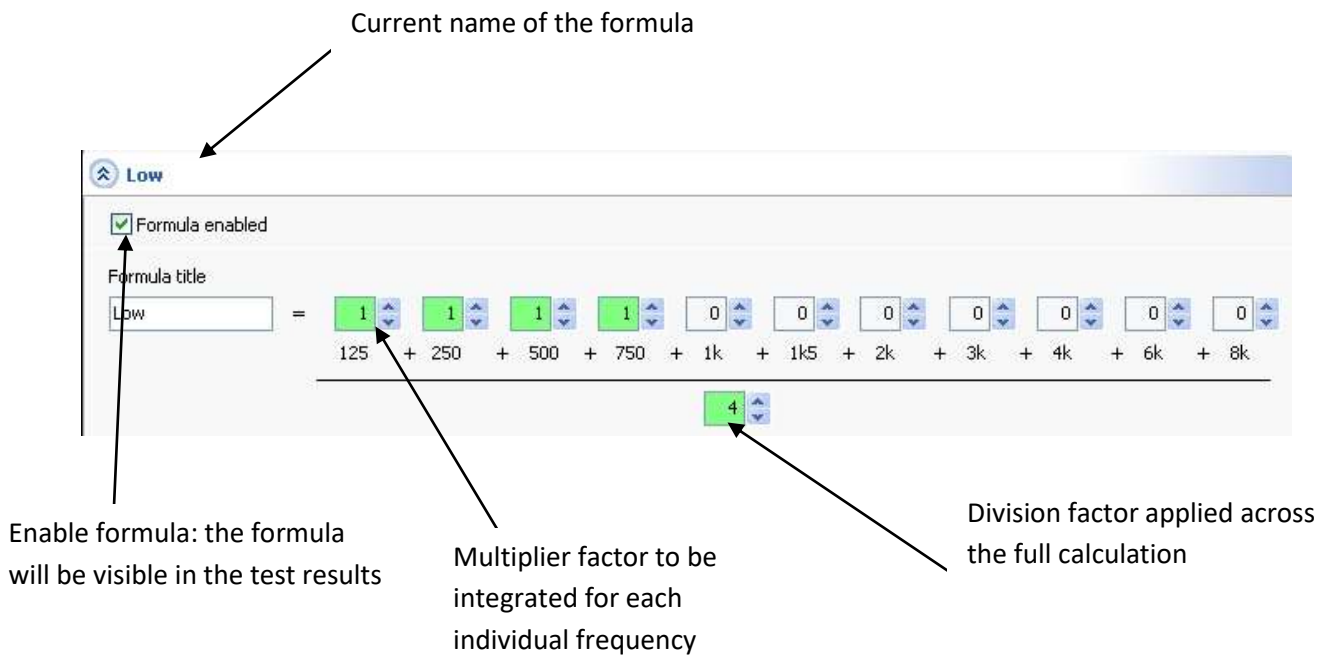
The multiplier factors are limited to 100.

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.
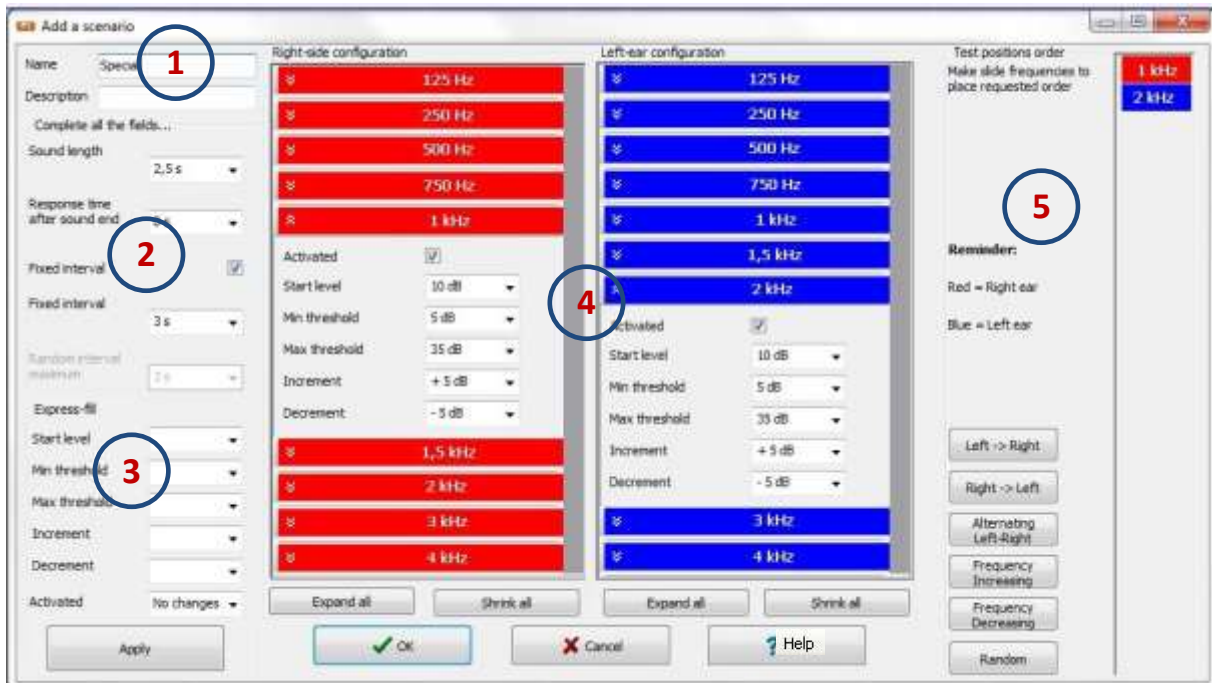
1) Name and description of the scenario

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 → **Complete all the fields…**

Sound length → 2,5 s

Extra time allocated for replying after sound duration → Response time after sound end → 0 s

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

Fixed interval → 3 s

Random interval maximum → 3 s

➢ Express-fill all the frequency fields

Express-fill

Start sound level (from 0 to 70 dB) → Start level

Minimum sound level (from -10 to 60 dB) → Min threshold

Maximum sound level allowed (from 10 to 80 dB) → Max threshold

Increment

Sound level increment when patient does not respond → Increment

Decrement

Sound level decrement when patient responds → Decrement

Actived → No changes

Selection or not of all the frequencies

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

Apply

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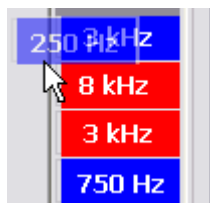
If you place the cursor over any frequency you will get a short recap of its settings.
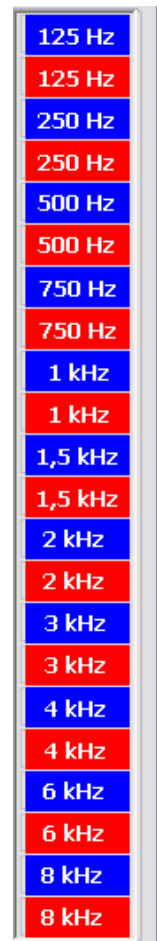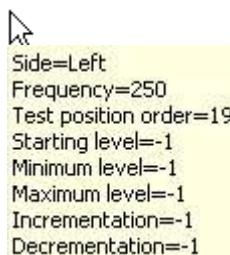
Audiometric tests history

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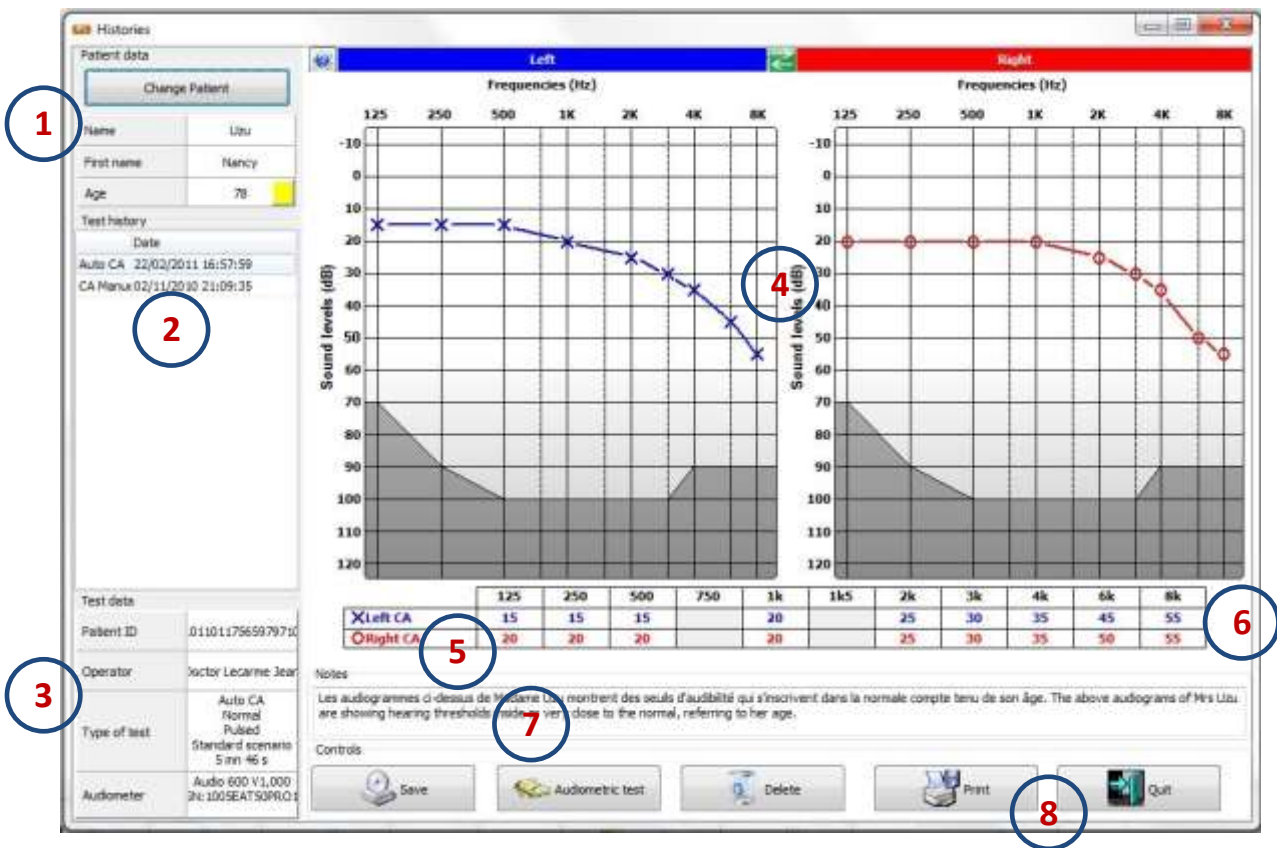
1) Recap of the patient record, giving name, family name, and age.

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
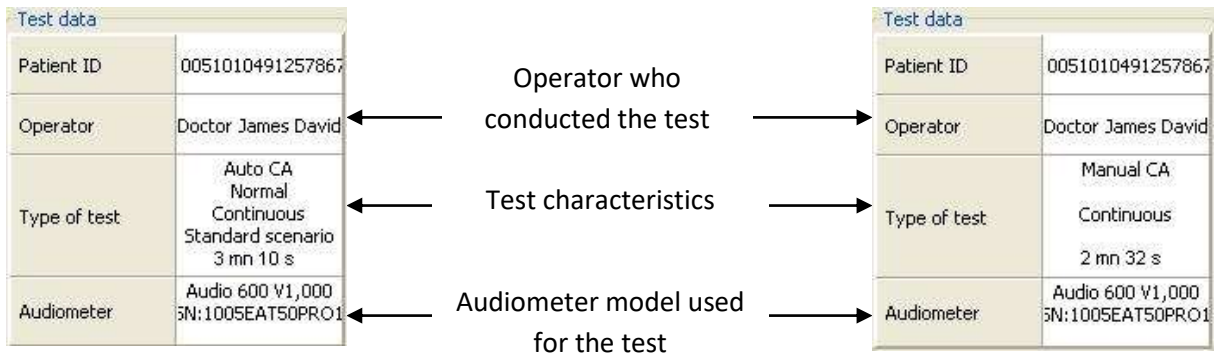
Test characteristics:

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)

	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

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
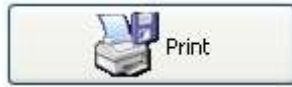
Print

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

Clicking on [Print] 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
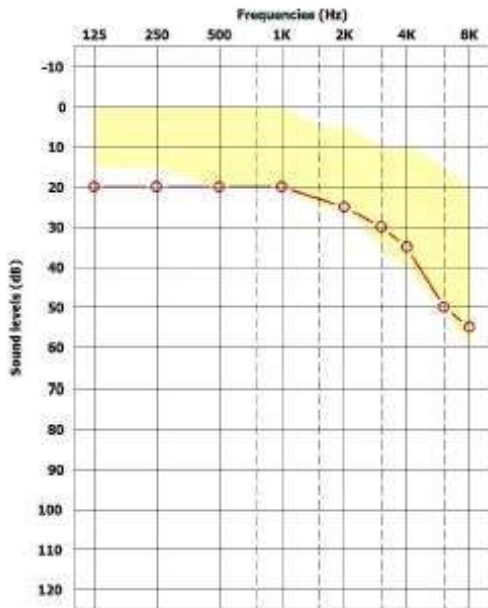
Right ear
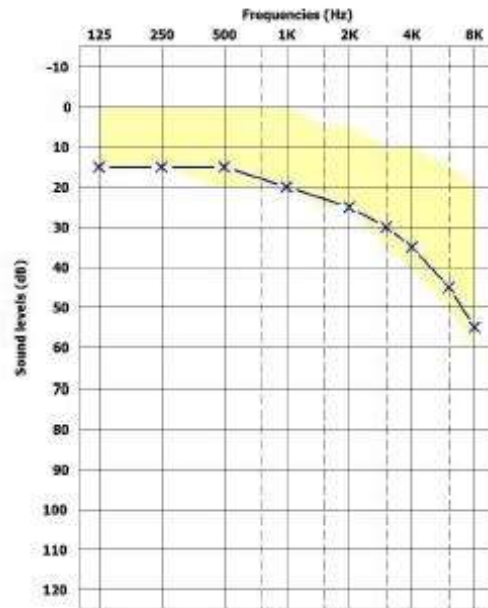
Left ear

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

Audiometric tests

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

Audiometric test

This will bring up the following window:
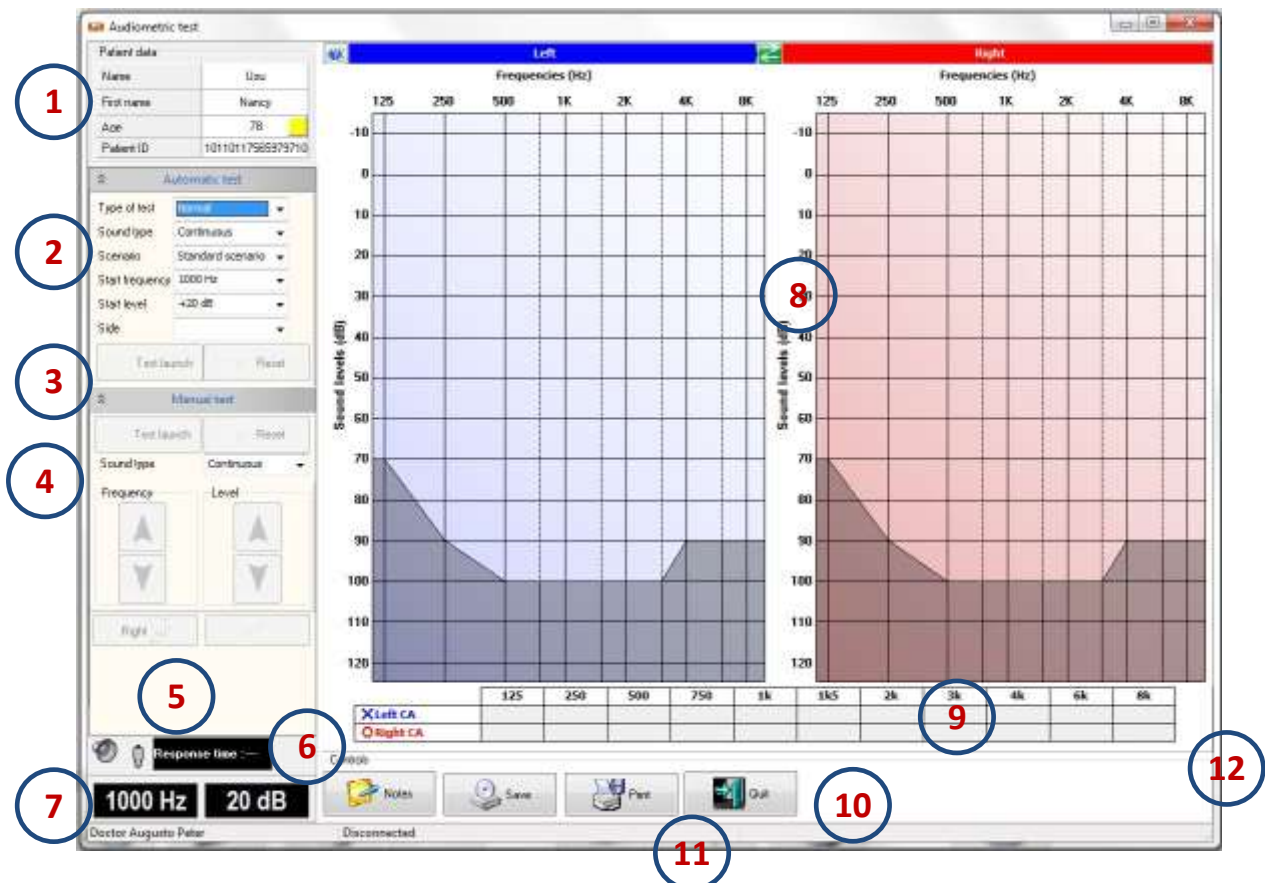
1) Recap of the patient data

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 Calculations configuration)

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.
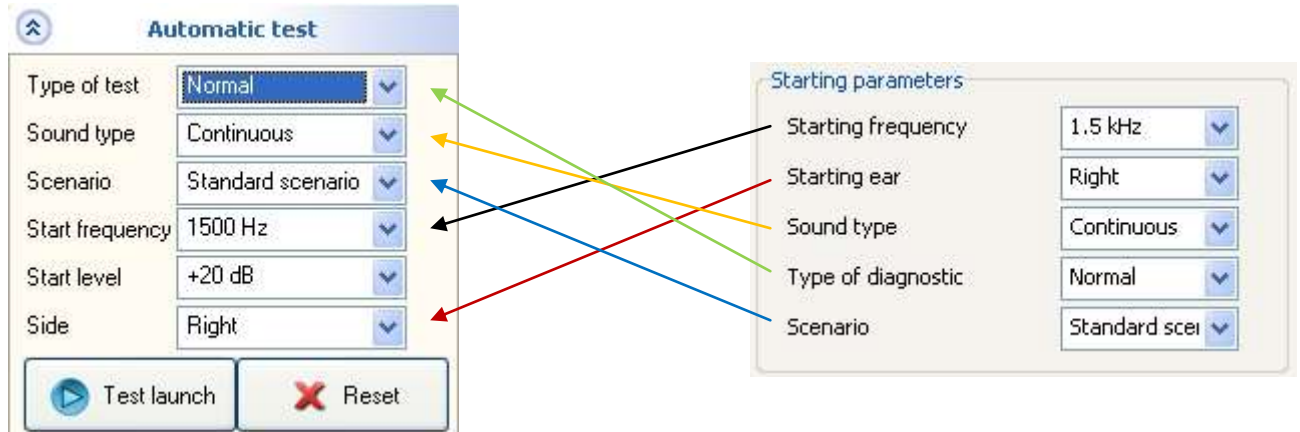
Type of test: choice between Standard and Hughson-Westlake
Sound format: choice between "Continuous" and "Pulsed"
Scenario: choice between standard scenario, random scenario, and the custom scenarios created
Starter frequency: the test sequence will kick off with this frequency. Only applies to pre-programmed (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 pre-programmed test:

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

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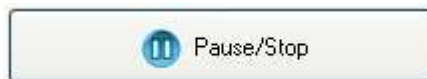
It is equally possible to completely stop the test at this particular point. This test will have to be saved manually, by clicking on "Save".

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.
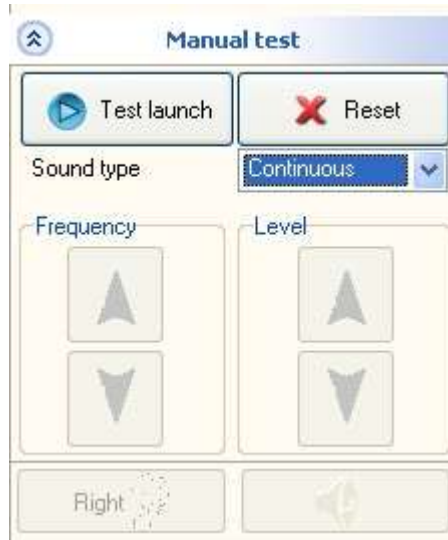
Sound type: continuous or pulsed

Launching the manual test activates the control panel.

Pause button

Frequency control

Sound level control

Ear-side control

Deliver the sound
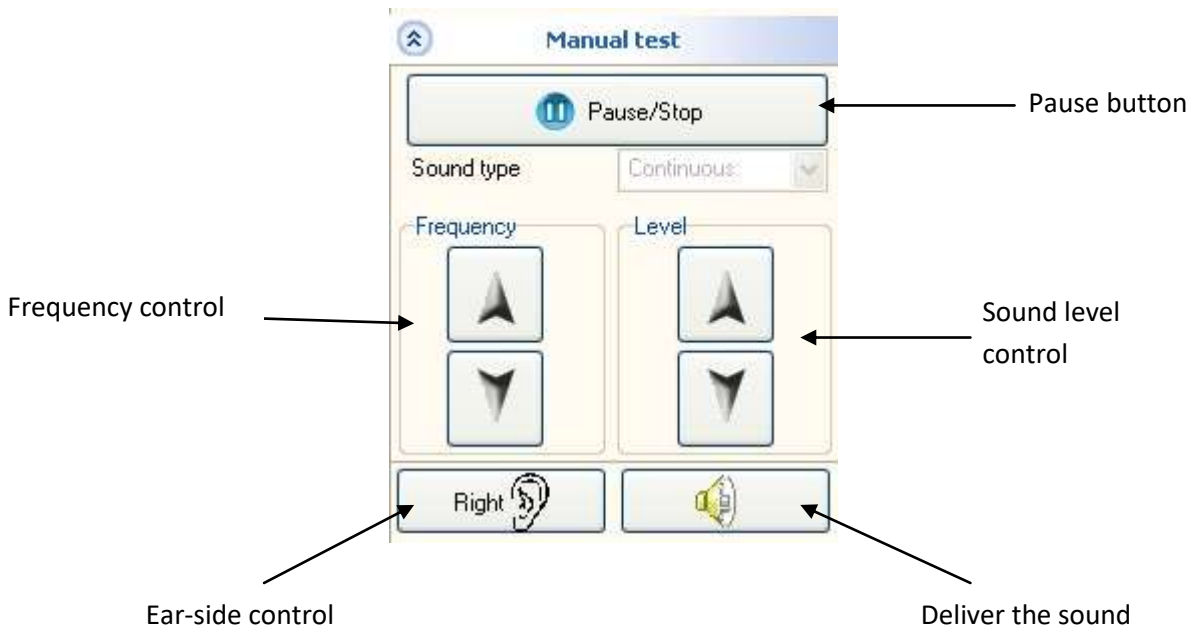
There are three control methods for a manual test:
- using the control panel (above)
- using the keyboard (via the shortcuts stipulated in the manual tests configuration tab)
- using the mouse, by clicking directly on the audiogram

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:

No sound emitted   The patient response button is not pressed   No patient feedback response timeframe
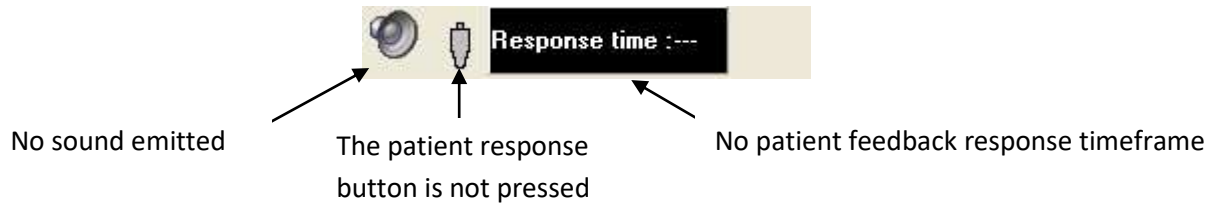
If the patient squeeze-button is pressed in (during the test or not), the panel icon changes to this:

The patient response switch is pressed
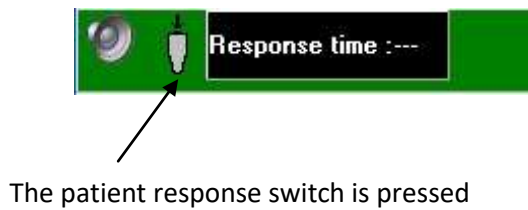
While sound is being emitted, the speaker becomes an animated icon:

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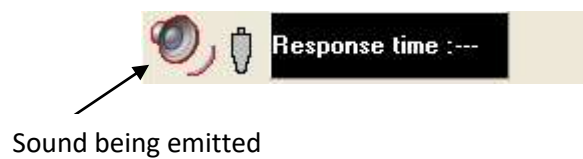
If the patient squeeze-button is pressed before sound is emitted, the panel shows the caution sign:

caution sign

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

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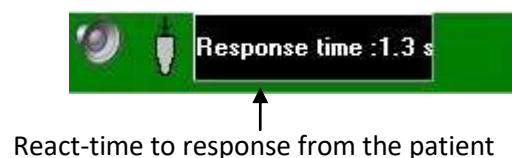
In manual mode, the operator needs to wait for the patient to release the button (panel switches to grey) before moving on to the next test.

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

Infobar 11 (at the bottom of the window):

| Doctor James David | Audio 600 V1,000   SN:1005EAT50PROI | |

Operator running the session

Audiometer peripheral connected

Audiometer status
In white if there is nothing to report

Audiometer status changes through the following sequence

| Sound being emitted |

| Waiting for Patient response | Time added on by the configuration

| Waiting time between two sounds: 4,0 s | Pause interval before the next sound

| Waiting for squeeze-button to be released | 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.

500 Hz	+40 dB	Response time ::0,7 s
500 Hz	+45 dB	Response time ::1,8 s
1000 Hz	+50 dB	Response time ::---
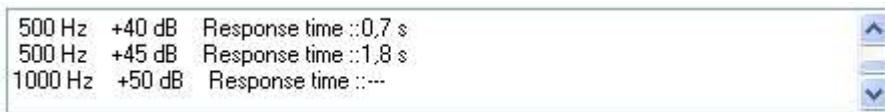
'Routine' diagnostic

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.
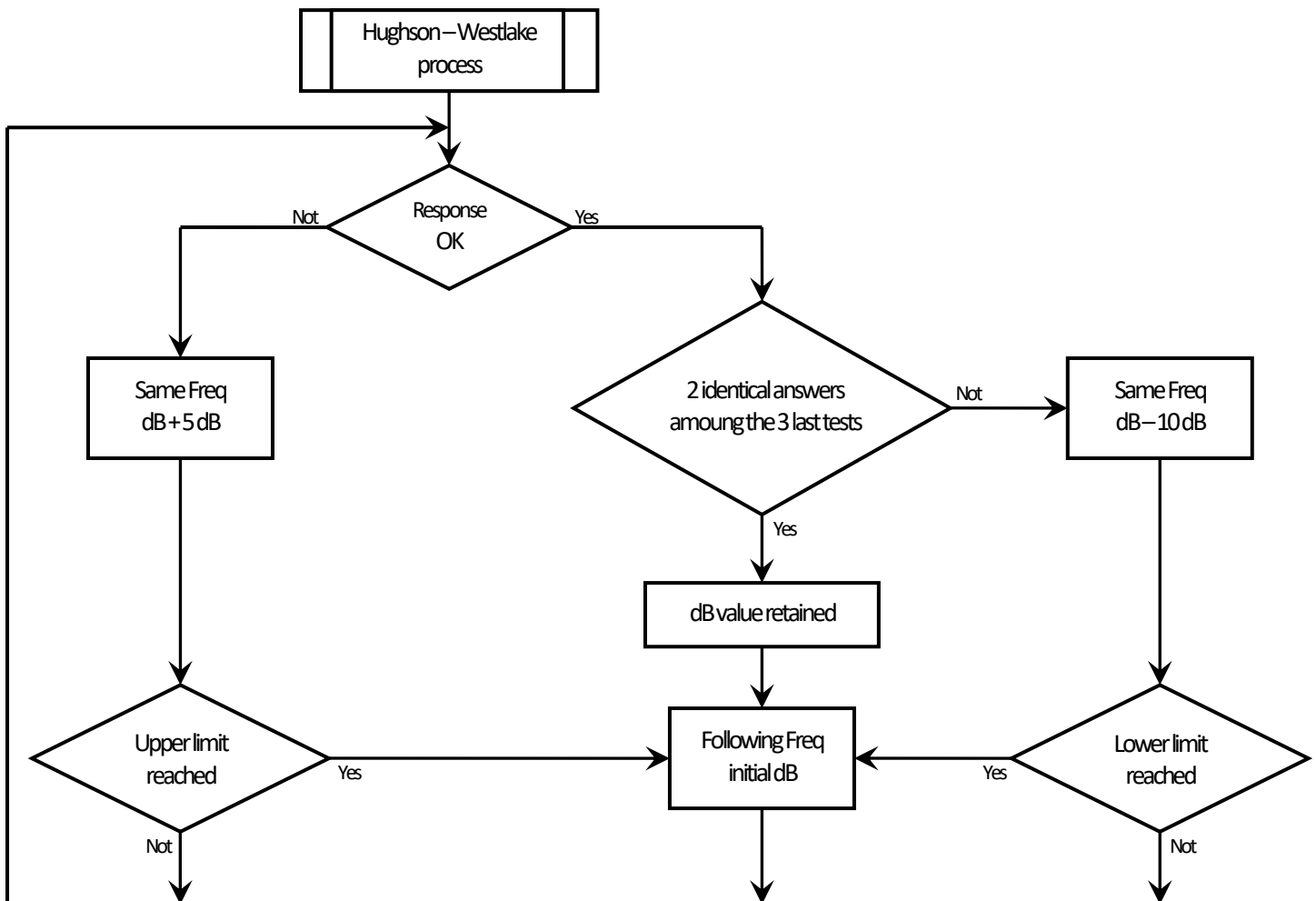
Decrement and increment are set by default at -10dB and +5dB, respectively.

Uninstalling the software

Quit the 600M software.

Open "Configuration Panel" (starting menu).

Use the menu for uninstalling programs and select the program to be uninstalled:600M Software.

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.

4. Technical datasheet

General: Type-4 pure-tone audiometer, conform to standard EN 60645-1:2017.
                                                    Air conduction

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

                                                    Electrical safety
                                                    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 +/- 0.25 V

Computer connexion   USB connector

Audio output: On stereo jack 3.5 mm with standard headphones
                                                     2 x mono jack 6.35 mm (1/4 inch) with high performance audiometric headphones

Contact pressure: Standard headphones: 10N +/-2N
                                                    High performance audiometric headphones: 8.8N +/- 0.5N

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

Calibration: Individual on a specific air conduction calibration bench (according to ISO 389-1)

Operating environment: Storage temperature: -10° to 60°C
                                                    Working temperature range: 15° to 35°C
                                                    Relative humidity: in the range 30% to 90%
                                                    Atmospheric pressure: in the range 98 kPa to 104 kPa

Patient response wire: Removable connection via a 1.2 meter lead /a 3.5 mm jack

Electrical isolation: 4000V, in compliance with NF EN 60601-1(USB/Headphone)

Pre-heat: Less than 5 seconds

Status light: blue LED

Dimensions: 150 x 92 x 29 mm (audiometric console)
                                                    L= 310- l=280-H=100 mm (complete box)

Weight: about 1.5 Kg (complete box)

5. Regulatory specification

Usage environment

For use in a professional health care facility (medical practice)

For use in a home-based care settings (school, office etc.).

CE marking

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

$$C \, \epsilon$$
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.

6. Electromagnetic compatibility

In exceptional cases, if the audiometer is exposed to strong discharges of static electricity or if it is exposed to a very intense electromagnetic environment, it may cease to function and may not be able to generate the sounds for which it was designed.   This kind of error does not compromise the basic safety of the device. This state will result in a total lack of response (no communication with the computer, no sound generation). If this should occur, simply unplug the USB cable briefly and then reconnect the USB cable.

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

Warning

This device should not be used in close proximity to other devices and should never be stack on top of another device, as this may cause it to malfunction.   If this kind of arrangement is necessary, it is important to observe this device and other equipment to ensure proper functioning.

Warning

Use of accessories, transducers and cables other than those provided by the manufacturer of this device may cause increased electromagnetic emission or decreased immunity of this device and hence may result in improper functioning.

Warning

Portable radiofrequency communication devices (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any component of the 600M audiometer, including cables specified or supplied by the manufacturer. Otherwise, the performance of these devices may be impaired.

7. Precautions for use

The 600M audiometer must be placed on a table in a stable position to prevent it being dropped, which could damage the device or affect its proper functioning. When not being used longer term, it should be kept stored in its case.

The audiometer is intended to function only with the accessories delivered (headphone, patient response switch, USB cable). Using accessories other than those delivered with the audiometer or distributed by the manufacturer may cause electromagnetic immunity degradation and device malfunction.

However, a standard USB cable may be used but should never exceed 2 metres in length.

The audiometer 600M is calibrated with the headphone delivered with the audiometer. Using any² other headphone (even if it has an identical reference) may distort the measurements (headphone and audiometer share exactly the same last four digits in the serial number)

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

Before testing a different patient, double-check the contact surface between headphone and patient to make sure there is no asperity that could inconvenience him. 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) making sure no liquids are allowed to get into the headphone.

The audiometer 600Mmust only be used in a temperated, dry environment. No liquids must penetrate the accessories (carry-case, headphone, patient response switch).

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 who is responsible for its disposal.

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. The user must have the skills necessary for operating the device and interpreting the results. If this is not the case, please contact the distributor of the audiometer or an organisation that provides training to improve your audiometry knowledge.

The operator must make sure that the patient is able to assimilate the instructions given to him, before performing the audiometric test and implementing them, taking into account his level of understanding (age, intellectual ability…)

Please check to ensure that the device and its accessories show no signs of impacts or deterioration of any kind that may cause it to malfunction.

To give optimal performance, the patient must be seated in a very quiet room where environmental noise is less than 35 dB.

In order to remove any ambiguity regarding the consistency of the patient's response, it is recommended to perform several times the same test at representative frequencies / levels. These provisions also cover operating disturbances resulting from electromagnetic disturbances

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

The patient should be informed how to respond. To indicate that he has heard correctly, he must press the patient response button. Run a preliminary test using the pushbutton to check it is working properly.
Optimal threshold determination hinges on the patient first being familiar with the audiometer tone.

Before each installation of the computer-audiometer set, the user should verify proper functioning of the audiometer (in particular, proper connection of the connectors should be checked).
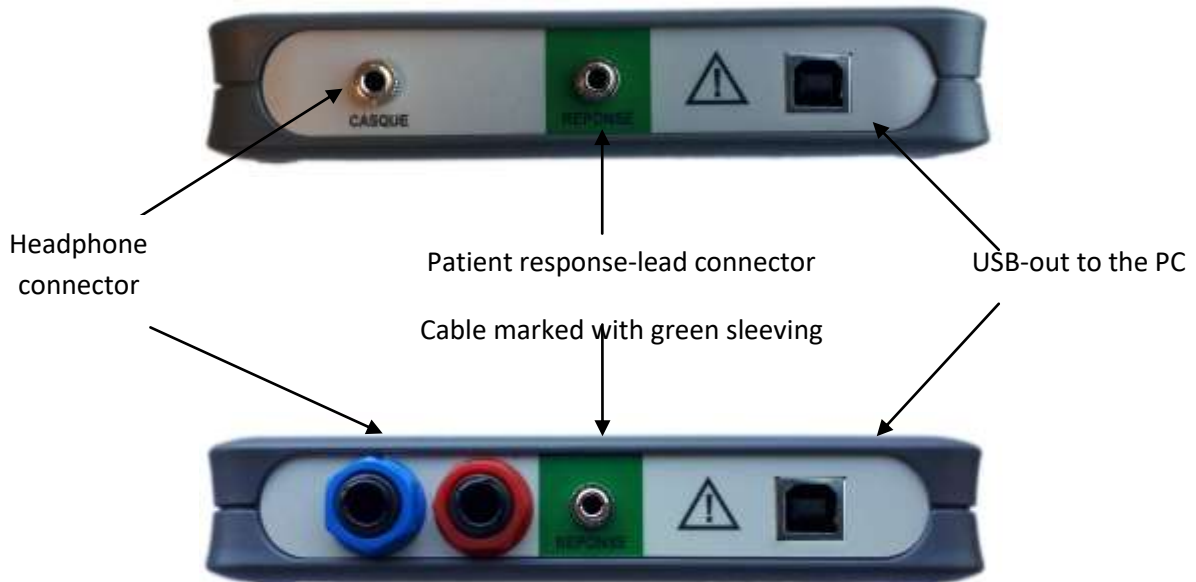
To avoid any background noise during a test, use of a computer with a silent mouse or with a touchpad is recommended.

As with any software, it is advisable to make any arrangements necessary for saving files and the database (see the paragraph on "General Configuration").

8. Audiometer box

Connections

Above: stereo jack 3.5mm model (standard headphones)
Below: 2x mono jack 6.35mm model (high performance headphones)

⚠️ Operators are urged to plug the headphone into the console underline before the patient puts the headphone 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 properl
Impossible to run a test — the buttons remain greyed-out	➢ Double-check the PC-to-audiometer connection
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
The software throws up a "Checksum Error" message before launching a test	➢ Unplug then reconnect your audiometer
No tone in the headphone	➢ Check if the headphone is properly connected ➢ Check if that the sound level is high enough to be audible
The patient-response controller does not work	➢ Check if the controller is plugged into the right socket (should be in the central connector)
Chaotic headphone tone (sound too strong, erratic, etc.)	➢ Get in touch with the After Sale Service
The interface between headphone and patient is damaged:	➢ Think to replace the headphone cushions
The printout function does not work	➢ Install Acrobat Reader or any other pdf reader

If the error continues, please contact the supplier's customer service department.

10.   Maintenance

Never open up the device. There is no reason for anyone other than a manufacturer-approved technician to attempt to conduct repairs.

It is recommended to achieve some good running tests (refer to standard ISO 8253-1 to know all the test procedures)

•   Routine check and subjective tests , with the headphone, every weeks and / or before use

•   Calibration by the manufacturer every 3 years

The audiometer can be cleaned with a soft cloth that you may dampen in soapy water, making sure no liquids are allowed to get into the device.

11.   Warranty

Thank you for purchasing the audiometer 600M. In the event of any claim made under warranty, please check the following terms and conditions:

- Electronica Technologies warrants this equipment to remain free from operating defects throughout the warranty period. If the equipment or accessories, sold with the audiometer, proves defective at some point during the warranty period, it will be repaired free-of-charge by Electronica-Technologies. The product must not be modified or used for purposes other than those provided for in these instructions. Any intervention or different use would totally release the manufacturer's responsibility.

- This warranty extends to a 3 YEARS period, starting from the purchasing date of the audiometer. The costs of sending and returning the equipment are the responsibility of the customer.

- This warranty does not cover:

        - The periodic calibration
        - The replacement of parts following normal wear.
        - The defects caused by modifications made by the user.

- The warrantied repair service does not cover damages or defects coming from:

        - Misuse, excessive use, or any abnormal operations or conditions of audiometer use in contradiction with the terms of the user manual.
        - Any repairs performed by anyone who has not been authorized to do so by the audiometer manufacturer.
        - Any use of parts that are not compatible with the audiometer (Headphones, etc…)

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