



820M Software

And its audiometric case

Instructions for use

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1. Introduction

Congratulations on your choice.

The 820M software is part of a computer-controlled audiometer. It allows audiometric tests to be performed automatically, combining performance with optimal duration.

This document explains the operation and use of the software, as well as the features of the audiometric box.

It is also available online on our website. A paper version is available upon request in accordance with the procedure explained on the accompanying sheet in the case.

The complete audiometric set consists of the following parts:

- Audiometric case
- USB cable
- Patient response device
- Stereo headphones (not interchangeable without technical calibration process)
- USB memory stick with the 820M software and installation software, and this manual
- Transport case containing the above elements.
- A bone transducers with its support arch

The software can be used on a desktop PC, or on a laptop (including notebook).

To meet the safety and regulatory requirements for electromagnetic compatibility, the microcomputer used must comply with the following directives:

- 2014/30/EC EMC Directive
- 2014/35/EU Low Voltage Directive

The audiometric box is powered directly from the computer's USB port.

To install the software, refer to the document attached to the USB stick.

Upon receiving the equipment, it is advisable to check the condition and contents of the case as well as the operation of the audiometer.

In the event of a problem, the unit must be returned to the seller in its original packaging, which should be kept in order to make repackaging easier and help protect the unit.

This product, very simple to use, requires a minimum knowledge of the Windows environment that runs on a PC. If this is not the case, you are asked to contact your IT manager or your IT representative.

Note: The images illustrating this document are not contractual.

2. Minimum requirements

Physical configuration:

- PC with at least 1GHz processor
- 50 MB free hard disk space
- 1 GB of RAM (RAM)
- Minimum screen resolution: 1024 x 600 pixels
- 65536 colours (16 bit)
- 1 free USB port

Supported operating systems:

- 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

Requires Acrobat Reader or equivalent to view the "pdf" files generated by the software.

This can be downloaded from the following address:

<http://get.adobe.com/reader/>

3. Using the software

Launch the 820M software via the "Start" menu, or with the icon on the desktop.

3.1. First launch

When the software is first launched, a form asks you to create a new operator.

This step is essential to use the software. For security reasons, it is preferable to create it with a password.

The screenshot shows a 'Management Operators' dialog box with the following sections:

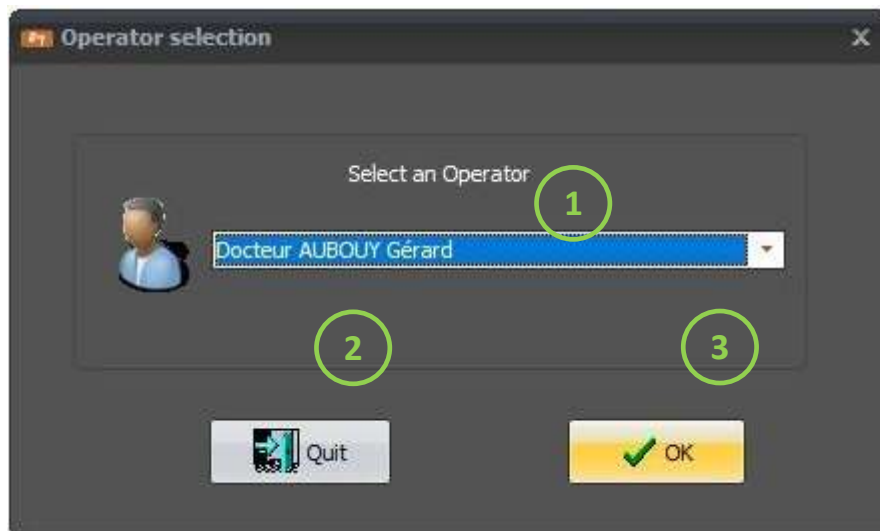
- Identity:** Fields for Title, Surname, and First name, each marked with an asterisk (*). To the right are 'OK' (green checkmark) and 'Annuler' (red X) buttons.
- Password enabled:** A checkbox that is currently checked.
- Contact:** Fields for Company, Address, Postcode, City, Country, Phone number, Mobile phone, and E-mail.
- Notes:** A large text area at the bottom for additional information.

Fields marked with an asterisk (*) are mandatory.

If you press cancel, it is impossible to connect. You will only be able to quit the software, and restart the operation at the next launch.

3.2.Login

After displaying a stealth presentation page, the next page of "Login" asks you which operator should connect. By default, during the first execution, the new operator creation page is automatically displayed (see [First launch](#)).



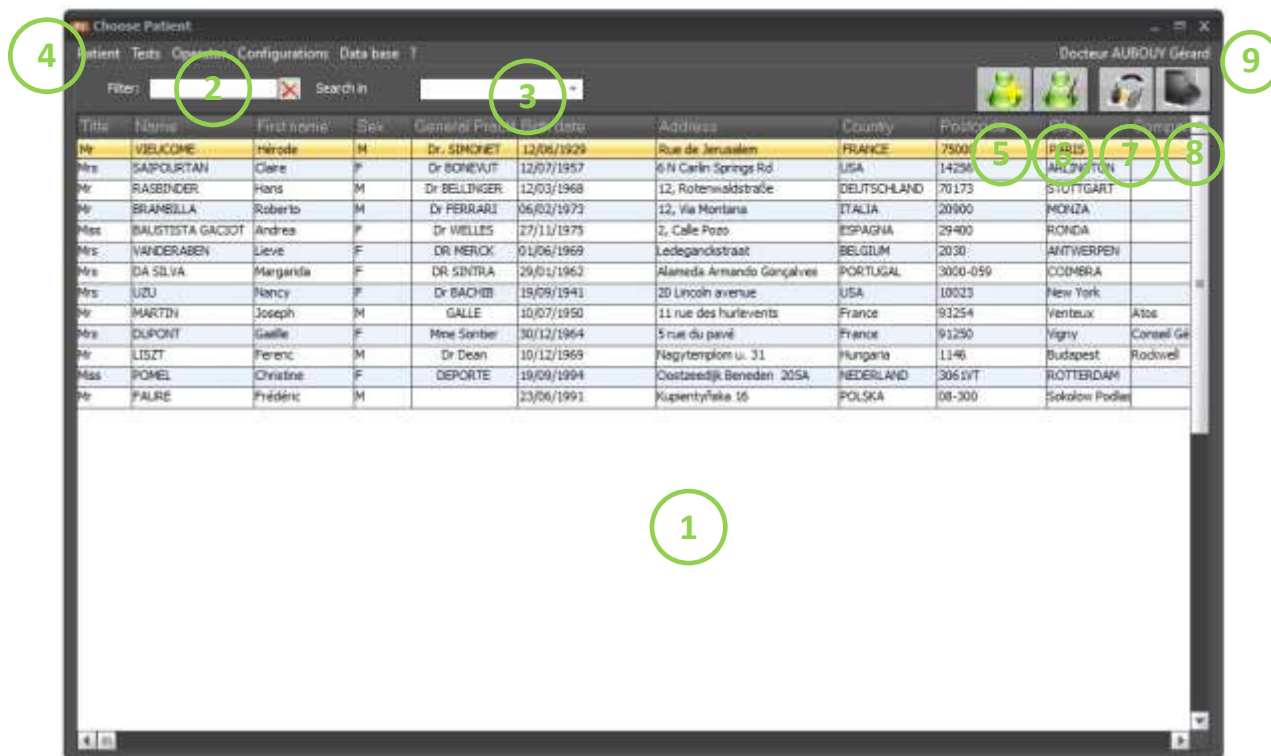
- ① Drop-down menu to choose the operator
- ② Button to close the software without connecting
- ③ Button to confirm the operator's choice

After the choice of the operator, a password may be requested if the operator has been created with a password.



3.3. Patient display / main page

This page provides access to all the features of the 820M software.



The order of the information columns can be repositioned by dragging with the mouse. Ascending/descending sorting is also possible by clicking on the desired column.

② **Filter for search:** Search in field no. 3 - only displays the data containing the entered text.

③ **Selecting the search column.**

④ **Menu bar** to access all features and configuration.

- **Patients:** Creating, editing and deleting patients. See [\(Patient creation/modification\)](#).
- **Tests:** Access to new audiometric or historical test.
- **Operators:** Creating, changing or deleting an operator identifier.
- **Configuration** Test configuration ([Test configuration](#)) or general or advanced software configuration ([General configuration](#)), printing or interfacing pages.
- **Database management:** Merging, synchronization, replacement or import of database.

⑤ **Creating a new patient:** menu short cut.

⑥ **Changing patient data:** menu short cut.

⑦ **Start audiometric test:** to perform an audiometric test for the highlighted patient, Tests menu short cut.

⑧ **History of audiometric tests:** View old audiometric tests for the highlighted patient, Tests menu short cut.

⑨ **Name of operator currently connected** (disconnection possible via this method)

3.4.Creating/changing patient record

Accessible via the "Patient | Create" menu, "Patient | Modify " menu, or on click on icons below.



Pressing one of these buttons above displays the next window.

When creating a new record, **only** fields marked with an asterisk are mandatory. The Identifying number (in green) is generated automatically, and cannot be modified by the operator.

The "Personal ID Number" field is a free user field, usually a patient record identifier from another source.

The icon next to the date of birth gives you a calendar in which you can select the date of birth.

The window is identical when creating or modifying the patient record.

The check box at the top right allows you to differentiate patients according to the connected operators:

- ☐ If ticked, the patient is only visible to the currently connected operator.
- ☐ If not ticked, the patient is visible to all operators

3.5. Display configuration of patient sheet

Accessible via the "Configurations | Display of the Columns" menu

This patient allows you to display or hide columns on the [patient display page](#)

On the page that appears, simply tick or untick the boxes corresponding to the columns concerned.

Visual display configuration of the Patient sheet

Select the fields to be displayed

Identification

Identity

- ☒ Title
- ☒ Name
- ☒ First name
- ☐ Maiden surname
- ☒ Birth date
- ☒ Last audiogram
- ☒ Sex
- ☒ Personal ID Number

Professional

- ☒ Company name
- ☒ Function
- ☒ Service

Medical

- ☒ General Practitioner
- ☐ Social Security number

Contact

- ☒ Address
- ☐ Continued
- ☒ Postcode
- ☒ City
- ☒ Country
- ☒ Phone number
- ☒ Mobile phone
- ☒ E-mail
- ☒ Notes

Sorting column at starting: **Name** 1

OK **Cancel**

The "Name" and "First name" fields cannot be hidden.

Field ① allows you to select the column sorted in alphabetical order automatically when the 820M software starts.

3.6.Operator management

Accessible via the "Operators | Management" menu

This menu allows you to create/modify/delete operators, the following window appears.

- ① List of operators registered on software database .
- ② All data concerning the operator selected in field ①, read-only
- ③ Pressing the "New Operator" button displays a new page to record the information for a new operator.
Fields marked with an asterisk (*) are mandatory.
- ④ Pressing the "Modify" button brings you to a new form where you can change the information for the selected operator. Fields marked with an asterisk (*) are mandatory.
- ⑤ The "Delete" button is only visible if the selected operator is not the current one (no auto-delete).
If an operator is deleted, all patients visible only to this operator will be visible to all (box "[visible only to connected operator](#)" not ticked).
If the operator is protected by a password, he/she is requested to enter it before deletion is performed.

3.7.Add operator

Pressing the "New Operator" or "Edit" button takes you to the next page.

Fields marked with an asterisk (*) are mandatory.

If you wish to change the information, simply fill in the desired fields and press the "OK" button.

3.8.Operator password

On the add/edit operator page, the check box ① allows the user's account to be protected.

Figure 1

When editing, if a password has already been registered, enter the old password (Figure 2) and then enter the new password and its confirmation (Figure 3). Pressing the "OK" button in Figure 1 saves the changes after the new password is re-entered.

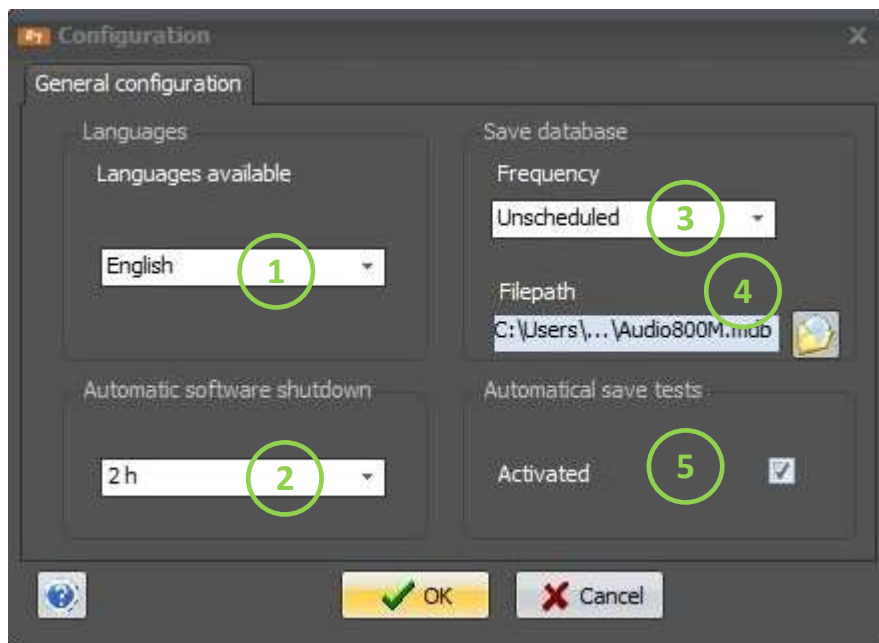
Figure 2

Figure 3

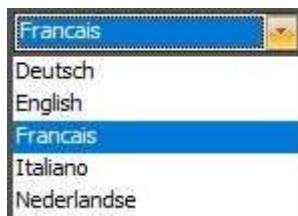
3.9.General configuration

This menu is accessible via "Configuration | General".

The following page appears:



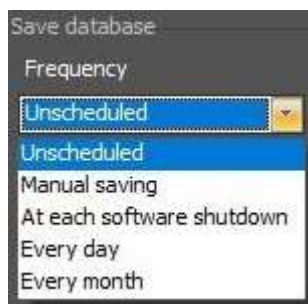
- ① Selecting the current software language



- ② This list allows you to program automatic shut-down of the software at the end of the programmed time, this function is disabled when performing an audiometric test. The programmable times are: off (---), 15 min, 30 min, 1 hour or 2 hours.



③ Database backup



Several choices are possible:

- Either manual backup
- Automatic backup.

The different possibilities for automatic backup are:

- Each time the software stops
- Every day (at the 1st launch of the day)
- Every month (at the 1st launch of the current month)

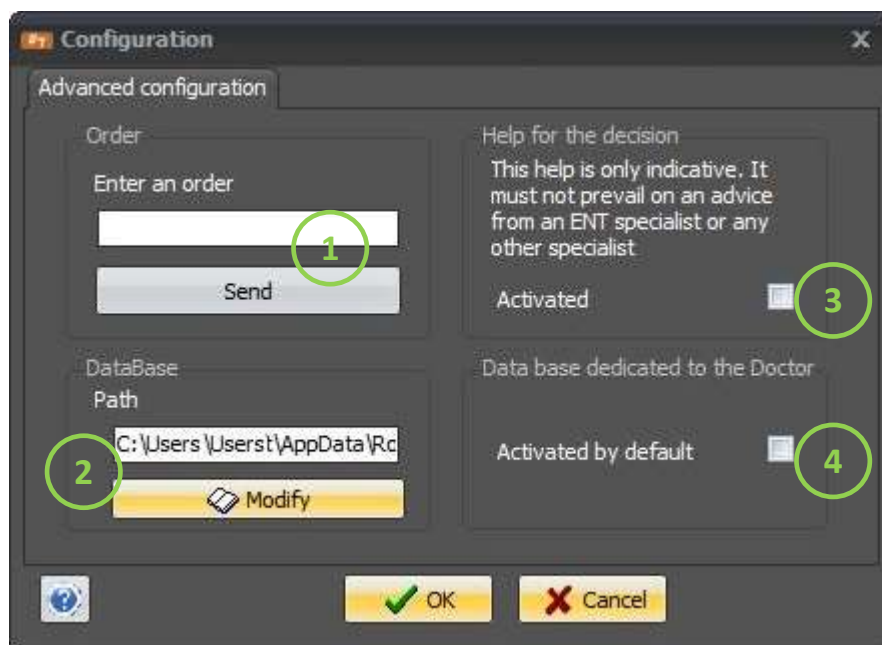
④ The backup location is configured by clicking on field ④ or the icon next to it.

In cases of manual backup, the input is recorded at the time the backup location is configured, or at the time of selection in field ③.

⑤ Activating the automatic test recording avoids manual saving of the test that has just ended (this activation has no effect in the manual test procedure).

3.10. Advanced Configuration

This menu is accessible via "Configuration | Advanced".

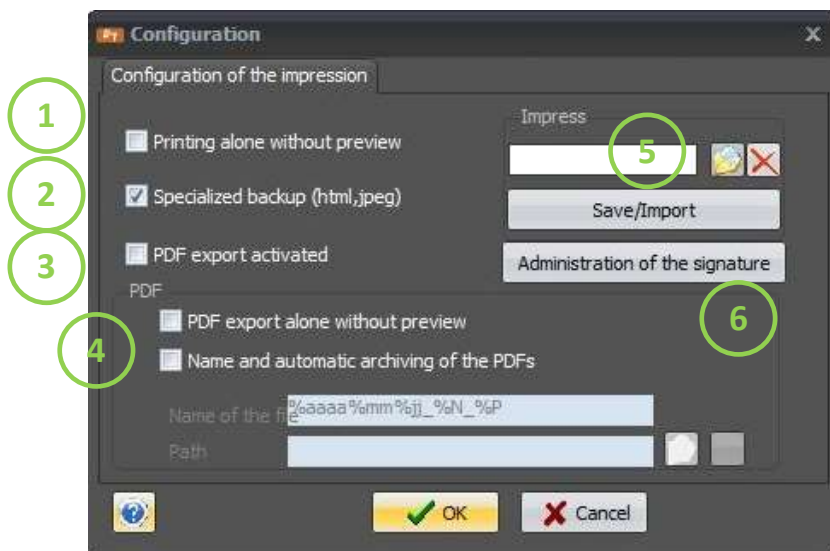


- ① Diagnostic command (manufacturer only)
- ② Change of database route. To be used if it is on a network.
- ③ Activation of decision support (see chapter on "[decision support](#)")
- ④ Dedicated database, each operator has his/her own customers. The box "visible only by connected operator" on the "[Create/edit patient record](#)" page is automatically checked if box ④ is ticked.

3.11. Printing Configuration

This menu is accessible via "Configuration | Printing".

This menu allows customisation of all audiometric test impressions.



- ① Print only without preview: if ticked, pressing the print button will send the document directly to the printer via the Windows print menu. No print preview will be presented.
- ② Specialized backup: allows export to other formats: pdf, html, and jpeg
- ③ PDF export enabled: allows the generation of the document in pdf format. If checked, unlock the ④ menus
- ④ PDF Option:
 - Export pdf only without preview: generates the document directly in PDF format, without preview, and then opens the document.
 - Automatic naming of pdf: when ticked, saves the pdf created in the directory entered in the "Path" field. If the path is not filled in, the document will be created in the working directory of the application (Windows "Roaming" directory).

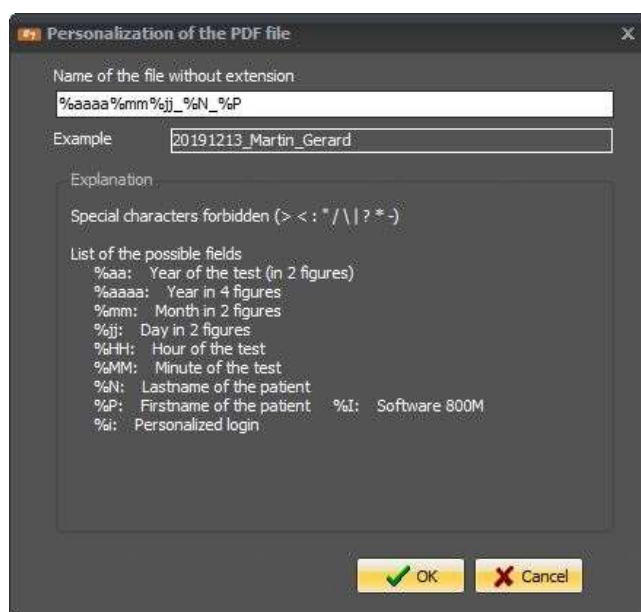
The file will be named according to the "File name" field according to the following rules:

Prohibited characters: ">", "<", ":", " ", "/", "\", "|", "?", "*" and "-".

List and coding of possible fields:


%aa	Year, 2 test digits
%aaaa	Year, 4 digits
%mm	Month, 2 digits
DD	Day, 2 digits
%HH	Test time, hour
%MM	Test time, minutes
%N	Patient's last name
%P	Patient's first name
%	Software ID 820M
%i	Personalized identifier

Clicking on the "File name" field opens another configuration page with an example.



The field below the entry gives a real-time example that follows the current entry.


By default, the value is: %yyyyyy%mm%DD_%N_%P, which gives:
year, month, day, followed by last name and first name.

Clicking on the path field or the open  icon triggers a folder selection window. The red cross is used to delete the folder.

If the field is not renamed, the destination directory is the Windows Roaming directory.

Warning:

The backup overwrites the previous file if it has the same name without any confirmation.

- ⑤ Insertion of a personalized logo on print form. After selecting the file via the button , click on "Save / Import" to validate the new logo that will appear at the top left of the print page. If not indicated, the "ELECTRONICA Technologies" logo will be displayed.

- ⑥ The "Administration of the Signature" button allows you to insert a signature automatically at the end of the audiogram. It is associated with an operator. It is associated with an operator. The signature information is provided on the following page:

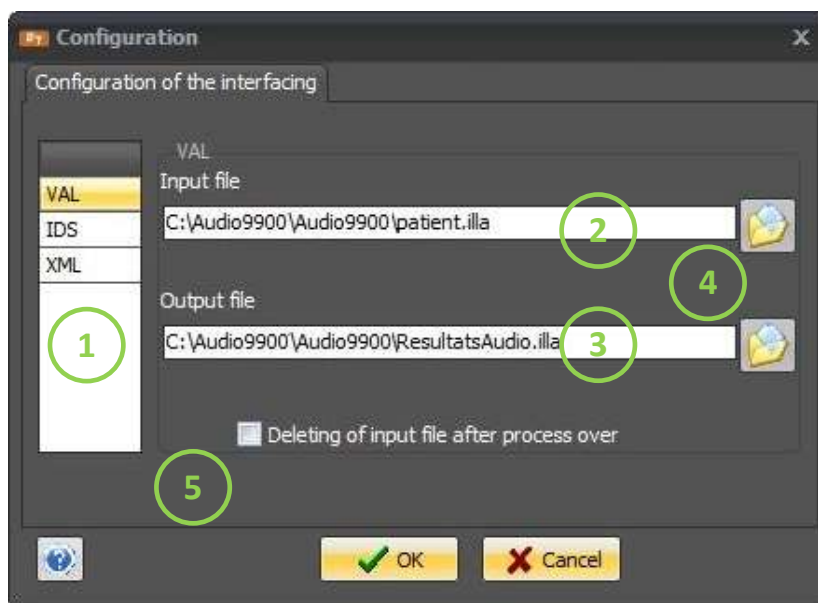


JPEG file only, to avoid distortion caused by scaling when inserting the image, prefer an image in the order of 140 by 90 pixels.

It is possible to disable the function without losing the signature path. No local copies are made. If the file disappears, the function is automatically disabled.

3.12. Interfacing Configuration

This menu is accessible via "Configuration | Interfacing".



This tab allows you to configure the interface of the 820M software with other clinical database management software.

The interface mode allows only one audiometric test to be performed; no trace of the test or patient remains in the 820M software after the test.

Before performing an audiometric interface test, it is necessary to configure the test in the "[Test Configuration](#)" menu.

- ① List of supported interfaces
- ② Interface input file (including patient information)
- ③ Interface output file (test result)
- ④ Buttons allowing the path to be input by file explorer
- ⑤ Check this box if you want the input file to be deleted after processing by the 820M software

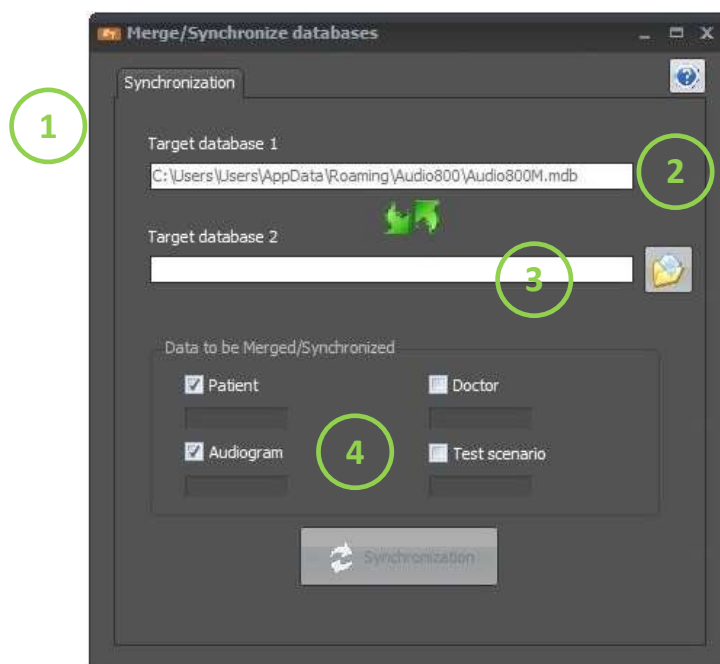
3.13. Database synchronization/merge

The 820M software uses a database file (with the ".mdb" extension).

This menu is accessible under:

"Database | Merge"

"Database | Synchronization"



① 3 different options are available depending on the choice in the menu:

- Merger: The additional entries in the database referenced by field no. ③ are added to the database currently in use (no. ②), no entries are deleted. It is a unidirectional mode. Only the "Target Database 1" is affected by the operation.
- Synchronization: all additional data from each database are added to the other database. The "Target Database 1" and "Target Database 2" are affected by the operation.
- Replacement: The current database is deleted and replaced by the one mentioned in field ③.

② Route of database currently used

③ Database with which we will proceed with the operation.

④ Database fields that will be subject to operations:

- Patient: concerns patient records
- Audiogram: concerns patient tests
- Doctor: concerns operators
- Test scenario: concerns the scenarios that have been constructed

3.14. Database replacement

This particular mode allows you to replace the current database with a new one. All current data will be lost.

This menu is accessible under:
"Database | Replacement"

In the event of a handling error, it is possible to go back through the following procedure.

Close the software.

Open a file explorer.

On XP, Start Menu, Workstation.

On Windows 7 and Vista, Windows Flag, Computer.

On Windows 10 right click on Windows Flag then file explorer

Go to the data directory.

C:\User\xxxxxx\AppData\Roaming\Audio800\

Delete the file named "Audio800.mdb".

Go to the "Old" directory. This directory was created automatically during the replacement operation.

Make "Copy" with the mouse on the file named "Bddj-mm-aaaa_hhh_mnmn_ss.old" (where dd is the day of the replacement operation, mm the month, aaaa the year, hh the hour, mnmn the minutes and ss the seconds).

Go back to the application directory.

Make "Paste" with the mouse.

Rename the file "Bddj-mm-aaaa_hh_mnmn_ss.old" in Audio800M.mdb. Validate the warning message.

The old file has been restored.

Restart the software.

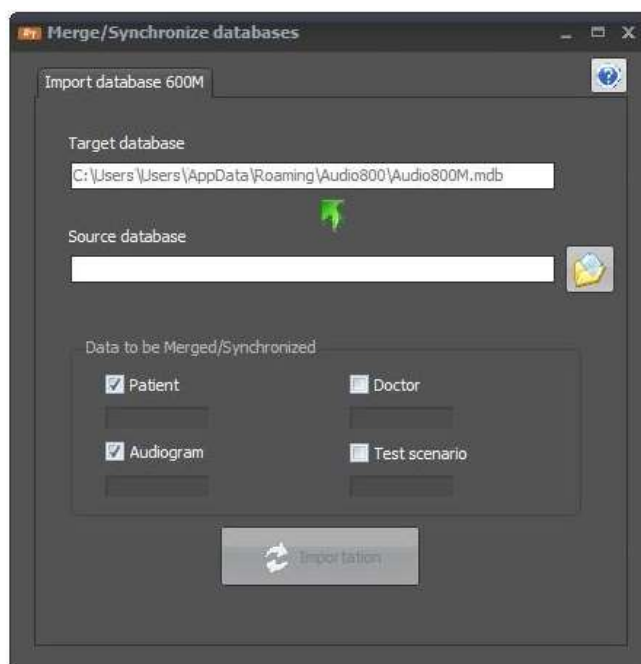
3.15. Database importation from 600M

From the database sub-menus, it is possible to import an old 600M database containing operators, patient records, audiograms, and scenarios.

This menu is accessible under:

"Database | Import database 600M"

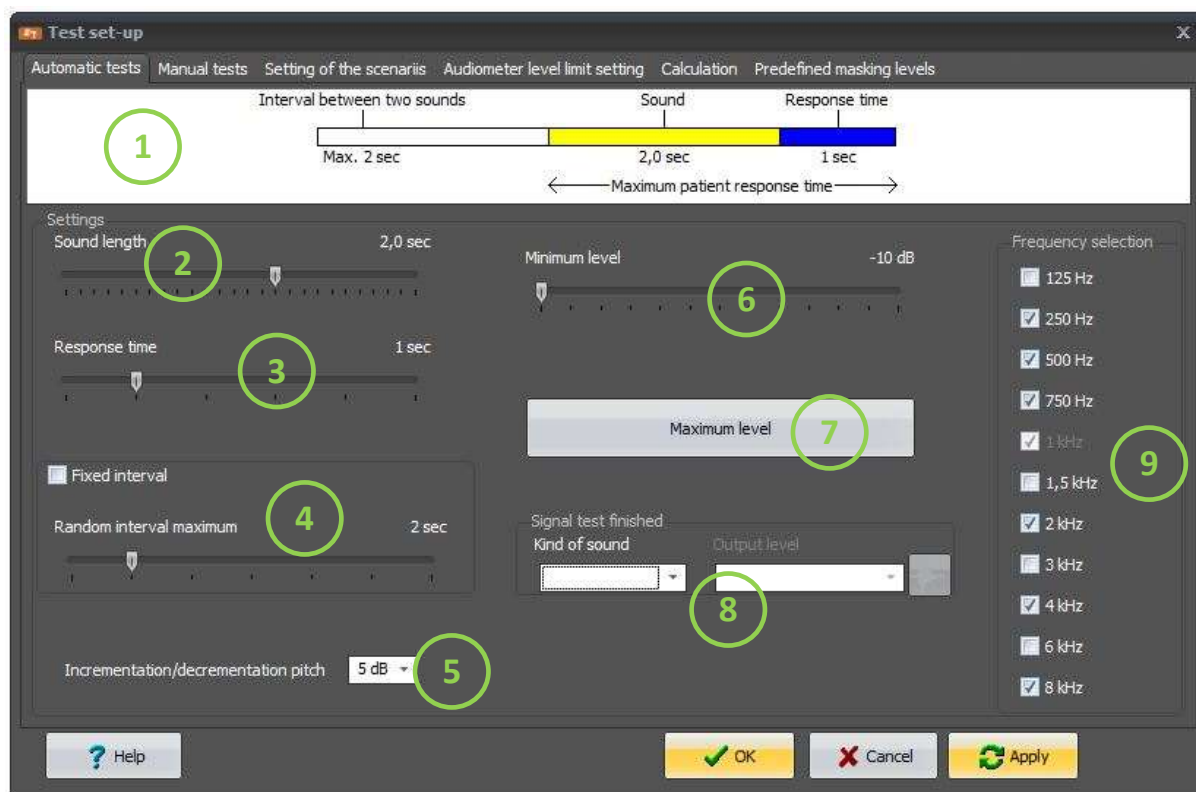
As with the database mergers, it is sufficient to fill in the 600M database file ("Audio600M.mdb"), select the tables to be imported, and start the import.



3.16. Configuration of automatic tests

This menu is accessible under: "Configurations | Tests", tab "Automatic tests"

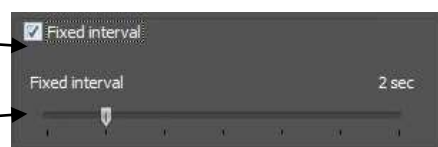
This menu allows you to set up pre-programmed automatic tests (standard and random automatic tests).



- ① Graphical representation of the data entered: in ②, ③, and ④.
- ② Sound duration (continuous or pulsed) during an automatic test, adjustable from 0.5 to 3 seconds.
- ③ Additional time available for the patient to respond after the end of the sound ②, adjustable from 0 to 5 seconds.
- ④ Interval between 2 sound emissions:

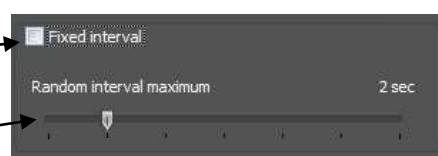
If ticked, the interval between 2 tests is fixed

Duration of the fixed interval (from 1 to 7 seconds)



If not ticked, the interval between 2 tests is random (min 1 sec, max according to the parameter below)

Duration of random interval (from 1 to 7 seconds)

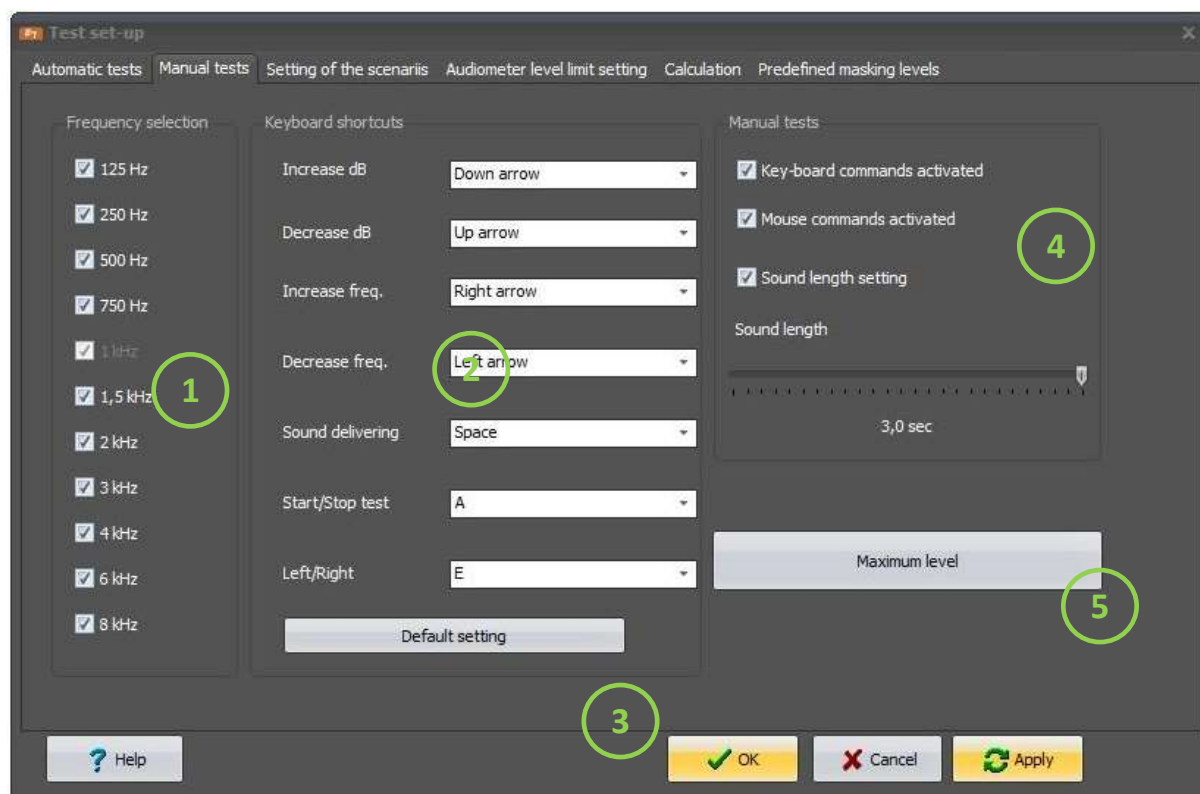


- ⑤ Increment value or decrement value during an automatic test. After a sound is sent, if the patient does not press the response, the sound level increases by this value. If the patient responds, the sound level is decreased by this value (possible values: 5, 10 and 15 dB).
- ⑥ Minimum sound levels: the frequency test is considered complete if the patient still responds to this level, the test then moves to the next frequency (value between -10 and 50 dB).
- ⑦ Maximum sound levels: the frequency test is considered complete if the patient still does not respond to this level, then the test is moved to the next frequency (value between 50dB and the audiometer maximum). Return to the "Audiometer Limit Setting" tab. See [Max. adjustment](#).
- ⑧ You can add a beep to signal the end of the test
- ⑨ Frequencies subject to testing. The 1kHz frequency is mandatory.

3.17. Configuration of manual tests

This menu is accessible under: "Configurations | Tests", tab "Manual tests"

This menu allows you to set up manual tests.



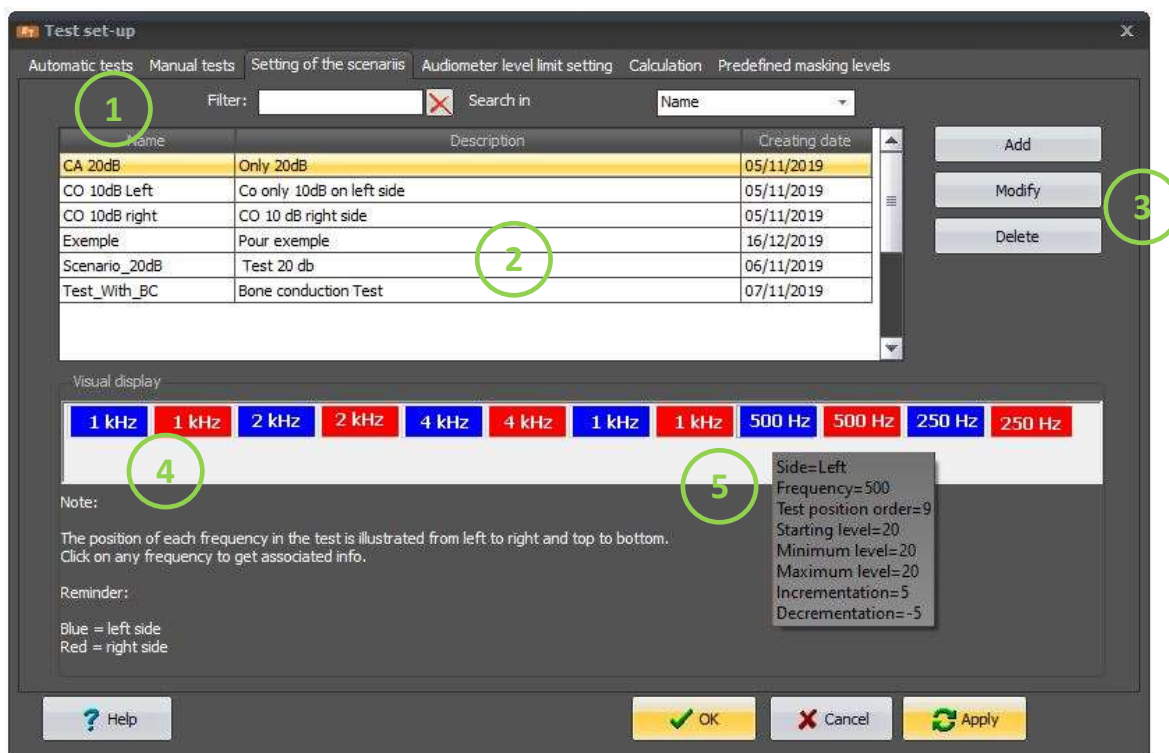
- ① Possible test frequencies. The 1kHz frequency is mandatory.
- ② Configuration of keyboard short cuts (without upper case differentiation) if enabled (point ④).
- ③ Factory default settings for keyboard short cuts
- ④ Configuration of test control:
 - Active control of manual test possible (both tests simultaneously are allowed):
 - Mouse control
 - Keyboard control
 - Automatic or manual adjustment of sound duration
 - If the box is checked, the duration can be adjusted from 0.5 to 3 seconds
 - If the box is not ticked, the sound duration is 2 seconds
- ⑤ Setting the alert level (see Max. setting)

3.18. Configuration of customised automatic tests / scenarios

This menu is accessible under: "Configurations | Tests", tab "Settings of the scenarios"

This menu allows you to set up the test scenarios.

The 820M software allows you to create your own automatic tests called test cases.



- ① Quick scenario search: only displays scenarios whose name or description contains the text input
- ② List of scenarios already created (display according to filter). The columns can be repositioned, and clicking on the title of a column allows you to choose whether to display the column content in ascending or descending order.
- ③ Three possibilities: Add a new scenario, modify a scenario (see [scenario creation](#)), or delete a scenario. The deletion requires only confirmation.
- ④ Representation of order of passage of frequencies.
- ⑤ Tooltip to view the test frequency settings (displayed when the mouse pointer stops at the desired frequency):
 - Right or left ear
 - Test frequency (in Hz)
 - Order of passage in the test
 - Test start level for the frequency specified above
 - Minimum test level for the specified frequency
 - Maximum test level for the specified frequency
 - Increase in noise level in case of non-response
 - Decrease in noise level in case of response

Delete a scenario

From the menu accessible under "Configurations | Tests", tab "Settings of the scenariis", click on "Delete" button to remove scenario from the database.

Warning:

There is no possibility of recovering a destroyed scenario.

Creating and modifying scenarios

From the menu accessible under "Configurations | Tests", tab "Settings of the scenariis", click on "Add" button to create a new scenario or "Modify" to change the content of a scenario.

The scenarios allow the operator to build the audiometric test as desired and in an automated way.

The screenshot shows the 'Add a scenario' dialog box with the following elements and callouts:

- 1**: Name field (Example Name)
- 2**: Description field (just for exemple)
- 3**: Bone Conduction section header
- 4**: Setting of the lengths section header
- 5**: Sound length dropdown (2,5 s)
- 6**: Response time after sound end dropdown (0 s)
- 7**: Fixed interval checkbox (checked)
- 8**: Fixed interval dropdown (3 s)
- 9**: Random interval maximum dropdown (0 s)
- 10**: Default setting section header
- 11**: Start level dropdown (20 dB)
- 12**: Min threshold dropdown (0 dB)
- 13**: Max threshold dropdown (70 dB)
- 14**: Increment dropdown (+ 5 dB)
- 15**: Decrement dropdown (- 5 dB)
- 16**: Signal test finished section header
- 17**: Kind of sound dropdown (DingDong)
- 18**: Output level dropdown (Hearing level 1kHz + 4)
- 19**: Green arrow button (Next)
- 20**: Grey arrow button (Previous)
- 21**: OK button
- 22**: Cancel button
- 23**: Help button

Each frequency and sound level can be customized. The creation or modification of scenarios takes place in 3 steps

The first is to configure the general elements of the test:

- ① Name and description of test/scenario
- ② Information on bone or air conduction
- ③ Sound duration and time intervals
- ④ Default setting for all frequencies added
- ⑤ Add a test-end sound directly to the headset
- ⑥ The "Apply" button only appears in scenario modification
- ⑦ In bone conduction only, positioning of the transducer

The ⑧ buttons allow you to go to the next or previous phase (common to all 3 phases).

The ⑨ buttons from top to bottom allow you to save the scenario, close the window without saving, or access on-line help (common to all 3 phases).

To create a scenario:

- Enter a name (mandatory), and a description (optional) ①
- Define the sound parameters (valid for the whole test) ③

Setting of the lengths

Sound length: 2,5 s

Response time after sound end: 0 s

Fixed interval: ☒ Fixed interval: 3 s

Random interval maximum: 5 s

Active duration of sound

Additional allocated response time

Waiting time for next sound (fixed when ticked, random with maximum if not ticked)

- to set ④ the default values of all frequencies to be added (it is advisable to configure the values that will be most used)

Default setting

Start level: 20 dB

Min threshold: 0 dB

Max threshold: 70 dB

Increment: + 5 dB

Decrement: - 5 dB

Apply

Starting noise level (from 0 to 70 dB)

Minimum noise level (from -10 to 60 dB)

Noise level not to be exceeded (from 10 to 100 dB within audiometer limit)

Increase in noise level in case of non-response

Decrease in noise level if the patient has still responded

Application of the above parameters to all frequencies. This button ⑥ is only accessible if it is modified or after moving on to phase 2.

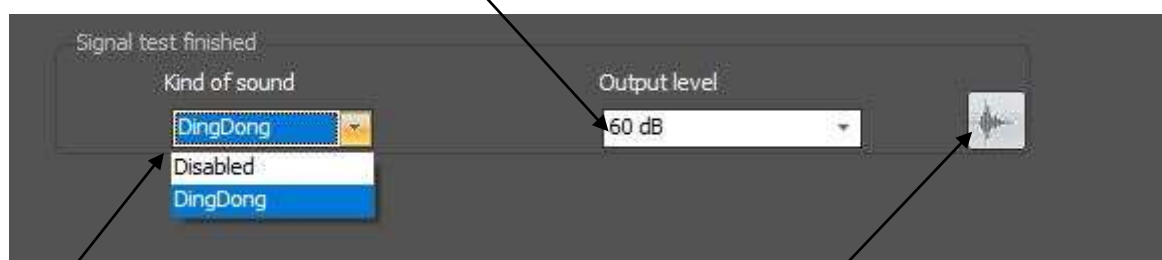
Warning: pressing this button replaces all of the old configuration, so we strongly recommended doing this filling up initially.

➤ If necessary, adjust the end of test sound ⑤.

This sound occurs when the test is completed. It takes the form of a "Ding Dong" or a voice indicating "Test completed".

Noise level

- 60db
- 80dB
- Hearing level 1kHz + 20dB
- Hearing level 1kHz + 30dB
- Hearing level 1kHz + 40dB



Type of sound

Choice between

- Deactivated
- Voice (available only in French)
- Ding Dong

Level test, pressing this button

simulates the sound in the headset. The 1kHz hearing level is then set to 40 dB

When the box ② "Bone conduction" is ticked, a selection box is displayed next to it to define the location of the bone transducer.

Proceed to step 2 by clicking on the button



Case of Air Conduction

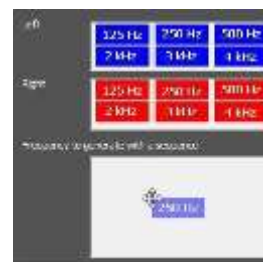
(Box ⑧ unticked)

This phase allows you to select the frequencies and the order of passage of each frequency.



Frequencies are selected using the drag and drop method.

To do this, right-click on the desired frequency in the ① or ② area and move the cursor to the ③ area. Release the button. Do the same for all desired frequencies.




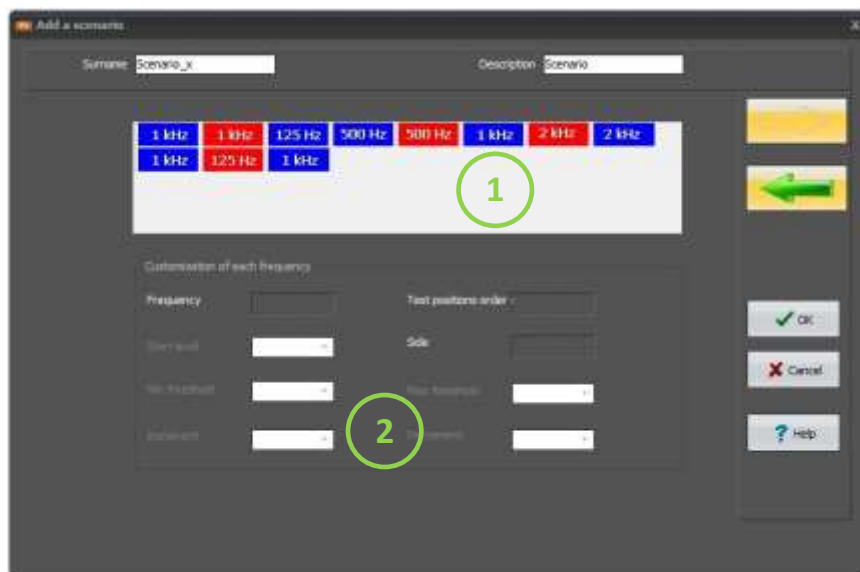
To insert a frequency between two others, also drag and drop by positioning the mouse at the desired location. A frequency already positioned can also be moved using the same method.



To delete a frequency, drag and drop it to the recycle bin ④.

The number of frequency tests shall be limited to 24. A frequency can be repeated several times.

- Once all the desired frequencies are positioned, we can move on to the last step, customizing each of the sounds via the button .



It is still possible at this point to move the frequencies (by dragging and dropping). To add new ones, go back to step 2.

All frequencies have the values defined in the first stage in field no. ③.

These values can be known thanks to the tooltip that appears when the mouse pointer stops on one of them.



To configure a frequency test, simply press one of the buttons in field no. ①. All the values relating to it are displayed in field no. ②.

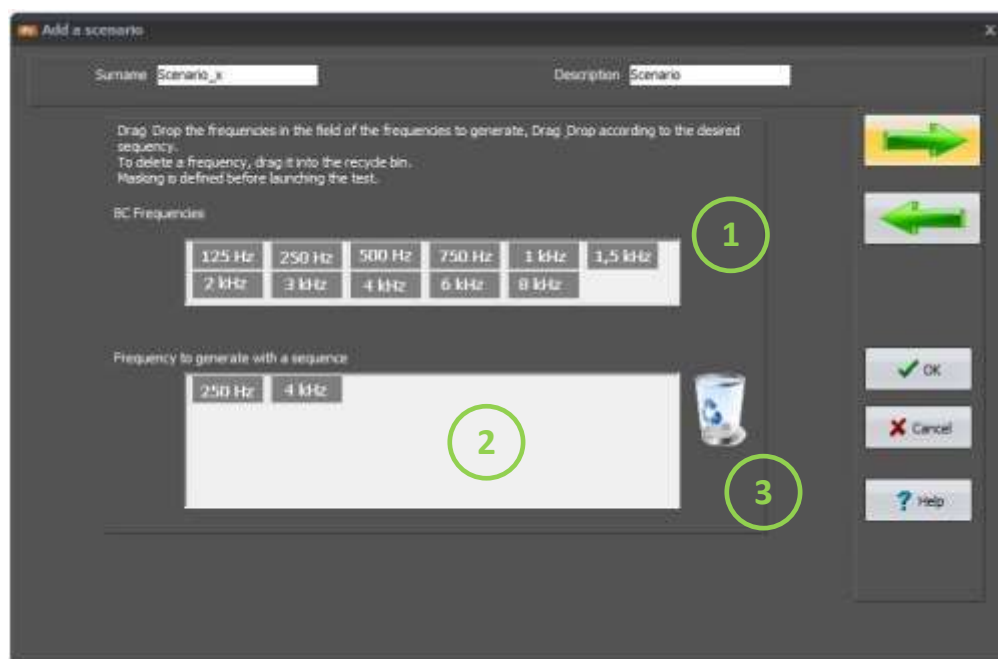


The upper value of the maximum threshold is defined by the audiometer limits.

Case of bone conduction

(Box ⑧ ticked)

This phase allows you to select the frequencies and the order of passage of each frequency.



Frequencies are selected using the drag and drop method.

To do this, right-click on the desired frequency in area ① and move the cursor to area ②. Release the button. Do the same for all desired frequencies.



To insert a frequency between 2 others, also drag and drop by positioning the mouse at the desired location. A frequency already positioned can also be moved using the same method.

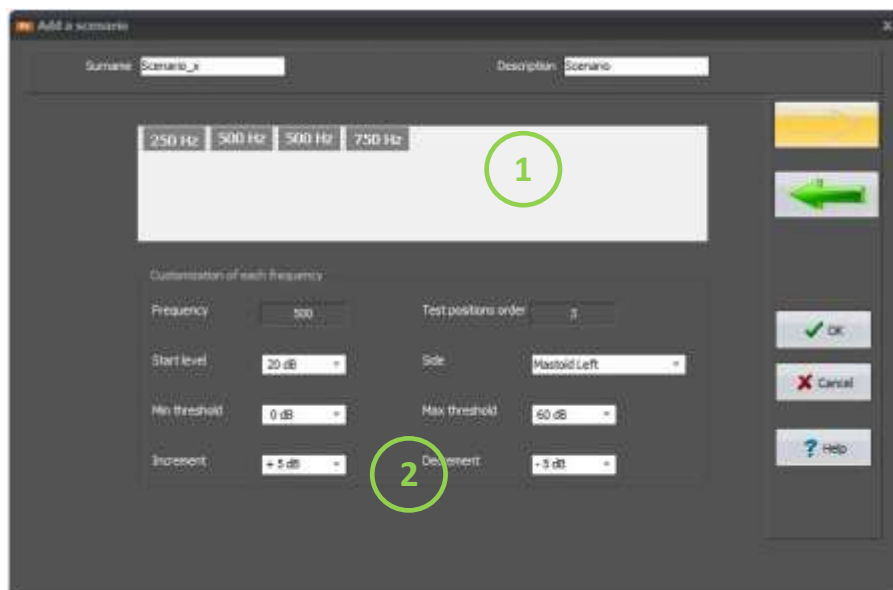


To delete a frequency, drag and drop it to the recycle bin. ③



The number of frequency tests shall be limited to 24. A frequency can be repeated several times.

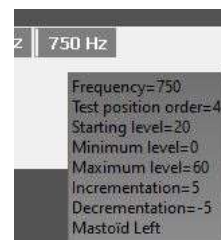
- Once all the desired frequencies are positioned, we can move on to the last step, customizing each of the sounds via the button .



It is still possible at this point to move the frequencies (by dragging and dropping). To add new ones, go back to step 2.

All frequencies have the values defined in the first stage in field no. ③.

These values can be known thanks to the tooltip that appears when the mouse pointer stops on one of them.



To configure a frequency test, simply press one of the buttons in field no. ①. All the values relating to it are displayed in field no. ②.



The upper value of the maximum threshold is defined by the audiometer limits. This value is automatically adjusted if the default level configured exceeds the physical limits of the audiometer.

The "Side" box can be different depending on whether a mastoid or binaural position is adopted:

- Mastoid case: choice between "Left Mastoid" and "Right Mastoid"
- Binaural case: "Binaural without masking", "Binaural mask on right", and "Binaural mask on left"

If, for example, right mastoid is configured, it is advisable to have a "masking" present on the left ear. And vice versa.

In binaural, if "Binaural mask on xxx", is selected, a mask must be configured at the time of the test, otherwise it automatically switches to "Binaural without mask".

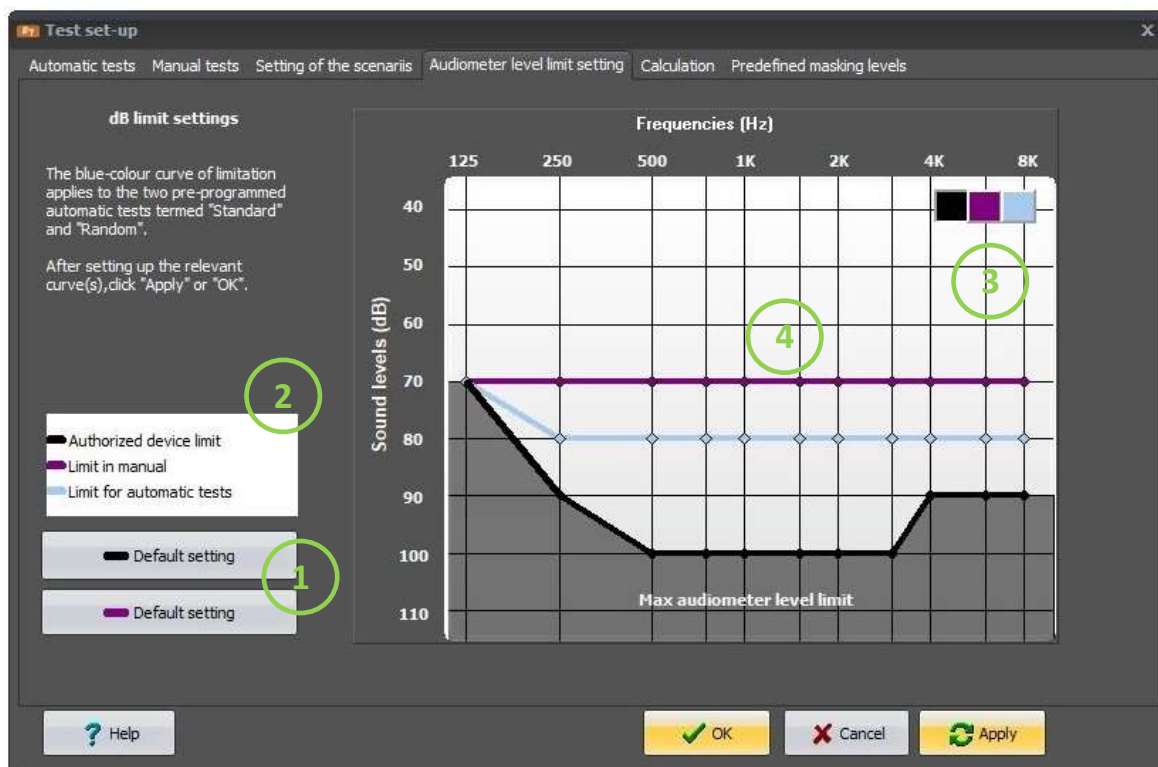
All masking levels are to be configured during the test; a "predefined mask" recall function is possible.

3.19. Setting audiometer limitations

This menu is accessible under "Configurations | Tests", tab "Audiometer level limit setting"

Three maximum sound level settings are available:

- Maximum automatic test sound levels (excluding scenario), sky blue curve
- Maximum sound levels before confirmation request - excess alert (manual test only), purple curve
- Absolute maximum sound levels (all tests combined), black curve



- ① Factory default setting of black and violet curves (absolute maximum sound levels and alert level in manual test).

Default value:

Frequencies	Absolute maximum levels (black)	Max levels in manual mode before confirmation (purple)
125	70 dB	70 dB
250	90 dB	80 dB
500	100 dB	80 dB
750	100 dB	80 dB
1000	100 dB	80 dB
1500	100 dB	80 dB
2000	100 dB	80 dB
3000	100 dB	80 dB
4000	90 dB	80 dB
6000	90 dB	80 dB
8000	90 dB	80 dB

- ② Curve Captions
- ③ Choice among the 3 setting curves
- ④ Graphical display of maximum sound levels:
 - Maximum sound levels in automatic tests (blue curve)

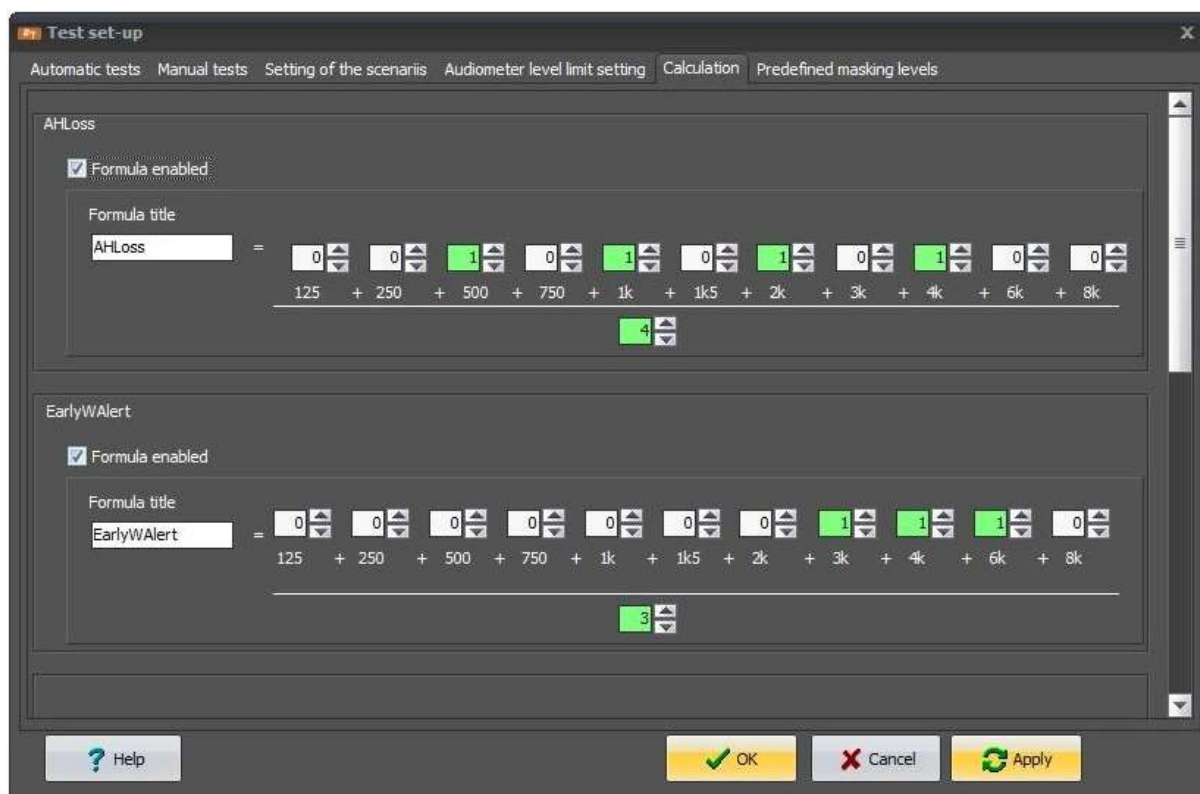
This curve is only valid for pre-programmed automatic tests (excluding scenarios), and allows you to choose the maximum level for each frequency in an automatic test (the test stops at this level if there is still no response from the patient).
 - Maximum sound level before confirmation request (purple curve)

This curve helps avoid handling errors during a manual test that could put the patient off. However, if this curve is configured to the maximum of the device's capabilities, a warning message is still displayed if a level greater than or equal to 100 dB is requested (as recommended in EN60645-1).
 - Absolute maximum levels (black curve): This curve represents the absolute maximum level for all types of tests combined. The default setting corresponds to the maximum capacities of the device.

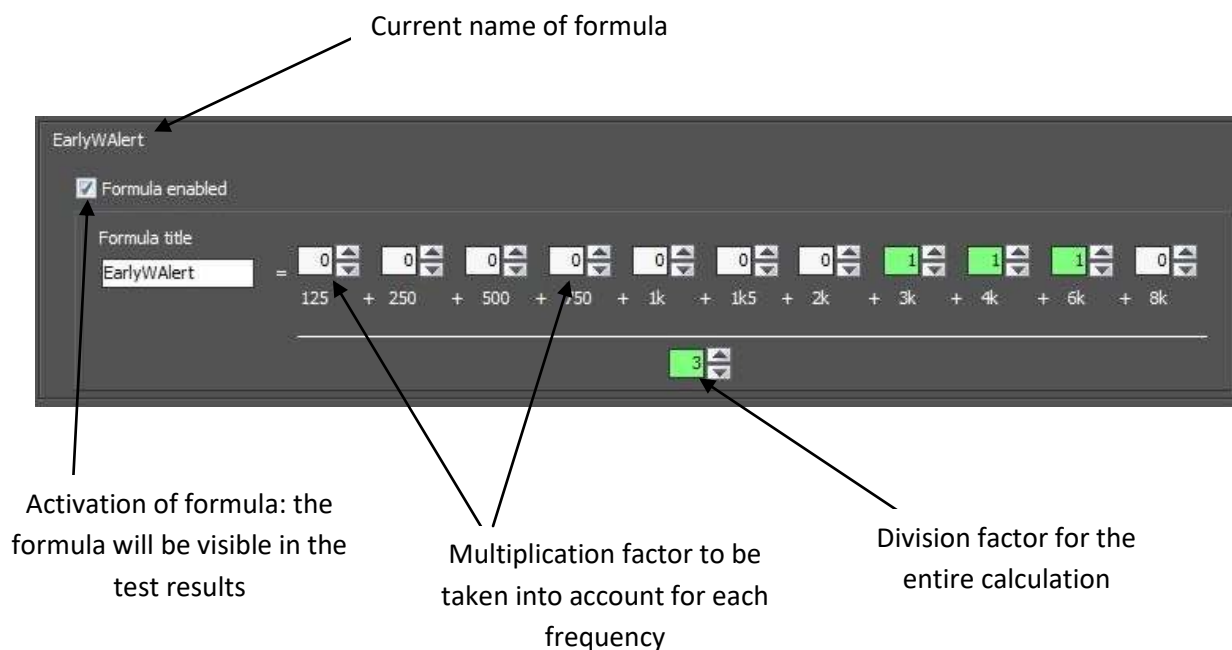
To change levels, select the curve in field ③ (the cursor becomes the same colour as the curve), then simply click on the level and the desired frequency.

3.20. Calculation Configuration:

Menu accessible via "Configuration | Tests", tab "Calculation"



5 types of search can be configured: They can be configured in the same way.



Multiplication factors are limited to 100.

The results of the formulae are visible in the audiometric, historical, and printing test pages.

	AHLoss	EarlyWAlert
Left AC	---	---
Right AC	---	---

It should be noted that if a frequency does not give rise to any patient signal feedback, then the calculation is not established.

3.21. Pre-definition of masks

Menu accessible via "Configuration | Tests", tab "Predefined masking levels"

To facilitate the configuration of mask levels, this function allows rapid recollection, in the test page, of the masking levels for each of the frequencies used during the tests.

This is particularly useful for scenarios where not all frequencies are tested.

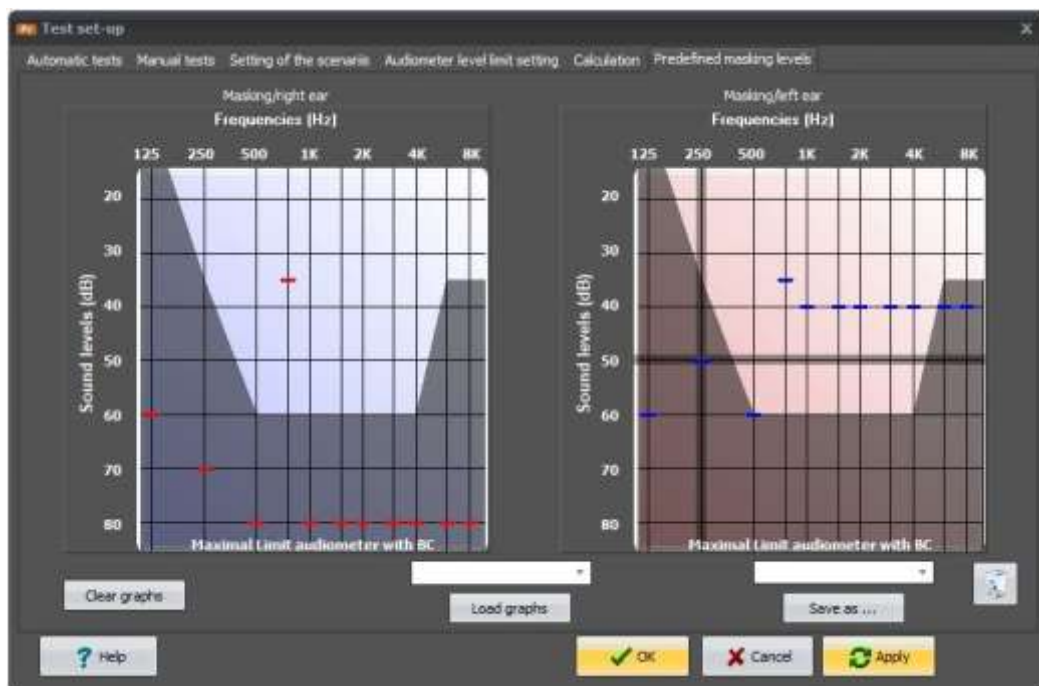


- ① Graphical input area for masking on the right ear, to test the left side
- ② Graphical input area for masking on the left ear, to test the right side
- ③ Button to delete everything in the graphs
- ④ Reminder of saved pre-set, model selection, followed by "graphic load" button to display it
- ⑤ Saving the currently defined model. An existing one may be rewritten (selection by the down arrow), or a new one created (by typing the name directly in the box)
- ⑥ Deletion of the template mentioned in the box left of the button (deletion after confirmation)

To add a level, simply click on the graph, a coloured bar appears. Clicking a second time (on the bar) deletes it.

Blue bar for masking on the left ear to allow the test on the right side.

Red bar for masking on the right ear to allow the test on the left side.



The audiometer limits for masking are as follows:

Frequencies (Hz)	Sound limits (dB)
125	60
250	70
500	80
750	80
1000	80
1500	80
2000	80
3000	80
4000	80
6000	80
8000	80

3.22. Test history

Menu accessible via "Tests | History of the tests"

Or press the History button on upper right corner.

Or double-click on the patient's line



A screen similar to this one appears.



① Summary of patient data including last name, first name and age.

Patient data	
Age	46
First name	Roberto
Surname	BRAMBILLA

- ② List of tests already performed, classified from most recent to oldest, with type of test (manual or automatic) and time stamp.

Sorting is possible by clicking on the column titles

Test history	
	Date
Auto	05/11/2019 15:58:17
Auto	05/11/2019 15:57:00
Manuel	22/06/2013 20:50:51
Auto	20/12/2010 16:52:11

- ③ This table gives some information about the test

Test data	
Operator	Docteur Martin Pascal
Type of test	Auto Normal Continuous CA 20dB 0 mn 55 s
Audiometer	Audio 820M V2,200 1910EAT67PR01

← The operator who performed the test →

← Test characteristics: →

← The audiometer used for the test →

Test data	
Operator	Nurse Monroe Carla
Type of test	Manuel Continu 1 mn 22 s
Audiometer	Audio 820 V1,000 1005EAT50PRO1

Test characteristics:

- 1st line: Mode
Auto
Manual
- 2nd line: Type of diagnosis:
Normal
According to Hughson Westlake's modified algorithm
- 3rd line: Type of sound sent:
"Continuous"
"Pulse"
- 4th line: Name of scenario used (for automatic testing only)
- 5th line: Test duration in minutes and seconds.

Audiometer characteristics:

- 1st line: type of audiometer with its version
- 2nd line: audiometer serial number

- ④ Graphical representation of results (audiogram)
- ⑤ Tabular representation of results
- ⑥ Button to switch to test results in calculation form (hearing loss)

	AHLoss	EarlyWAlert
Left AC	---	---
Right AC	---	---

For formulas, refer to the [Calculation Configuration](#).

- ⑦ Display of comments related to day of test, they can be completed on this history page.
- ⑧ Control buttons



The following operations can be performed (from left to right):

- Save: saves only the comments added
- Audiometric test: perform a new audiometric test
- Delete: delete this test
- Print the results of this test
- Exit history and return to patient display

3.23. Printing

Depending on the print configuration, it can pass through a print preview that allows the desired format to be chosen: paper via printer, html, jpeg, or PDF.

See " [Print Configuration](#) "

If the format is in PDF, the associated reader opens automatically when the document is generated

Print sample:

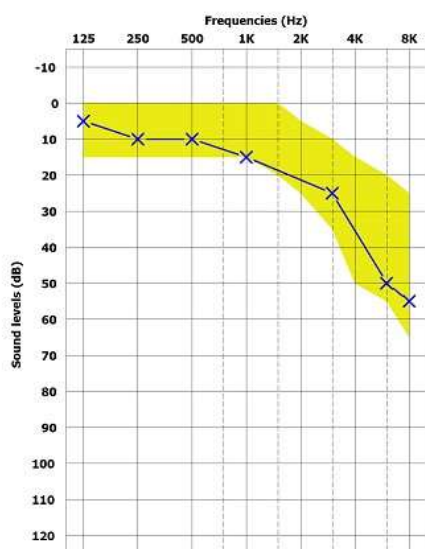


Nurse Carla Monroe

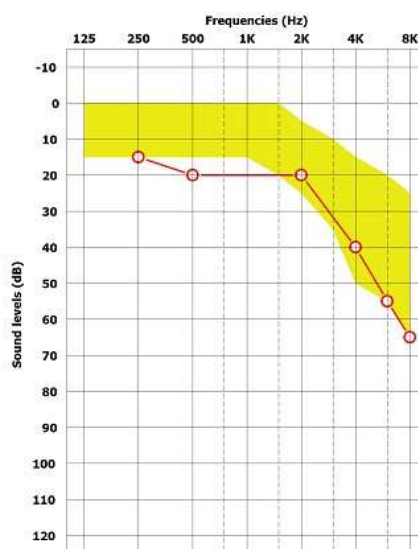
Date of the test: 22/06/2013 20:50:51
Duration: 1mn 22s
Type of test: Manuel
Continu

Patient data	
Patient data	Martin Joseph
Birth date	10/07/1950
Age	62
Company name	Atos
ID	10051010491257867

Audiometer	
Type:	Audio 820 V1.000
Serial number:	1005EAT50PRO1
Calibrated on:	03/03/2011



Left ear



Right ear

	125	250	500	750	1k	1k5	2k	3k	4k	6k	8k
Left AC	5	10	10		15			25		50	55
Right AC		15	20				20		40	55	65

Calculation	AHLoss	EarlyWAlert
Left AC	---	---
Right AC	---	---

Notes

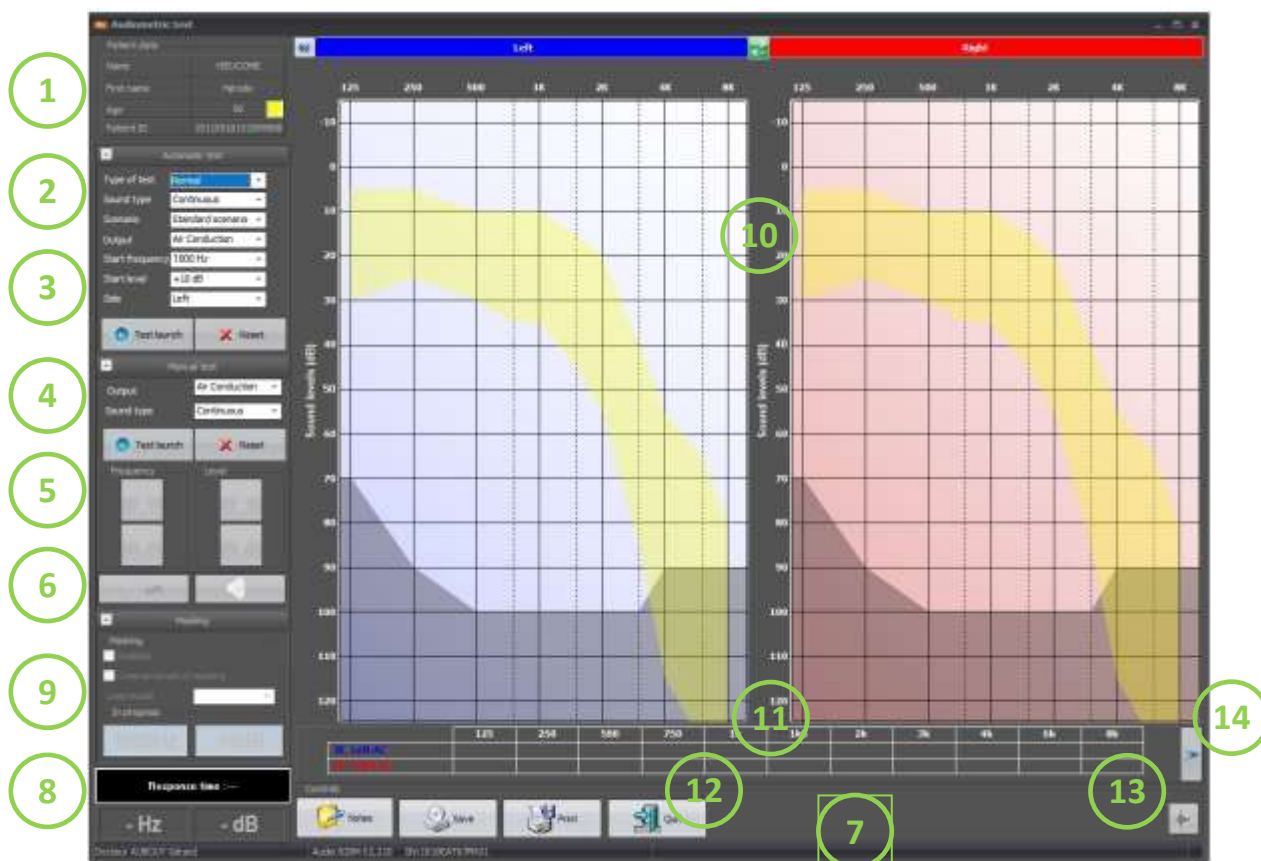
Signature

3.24. Audiometric tests

This menu can be accessed on the patient display page, as well as on the test history page, by pressing the following button.



The following page appears:



- ① Summary of patient information
- ② Configuration of automatic audiometric test
- ③ Automatic test launch button
- ④ Manual test launch button
- ⑤ Control panel for manual testing
- ⑥ Masking management
- ⑦ Audiometer status
- ⑧ Frequency and sound level during test
- ⑨ State of patient button
- ⑩ Audiogram updated in real time
- ⑪ Ongoing test results updated in real time
- ⑫ Panel control buttons
- ⑬ "End of test" sound test button
- ⑭ Button for accessing calculation results (if one or more formulae have been configured)

3.25. Automatic test

Before starting an automatic test, it must be configured via area ② in the test page.

When the page is displayed, we find the same parameters as those used during the last test.

Type of test:	choice between Normal and Hughson Westlake
Sound type:	choice between Continuous and Pulse
Scenario:	choice between Standard Scenario, Random Scenario and all created scenarios
Output:	Choice between air conduction (AC) or bone conduction (BC)
Start Frequency:	The test sequence may only be started by this frequency for pre-programmed scenarios (standard and random)
Start level:	Starting noise level for each frequency (valid for standard and random pre-programmed scenarios only)
Side:	choice of start between both 2 ears (valid for pre-programmed tests).

After these parameters are configured, the test can be started by pressing the "Launch Test" button.

At the bottom right is the chronology of the tests to be applied, with a small cursor indicating level of progress in the test. ③



This chronogram shows the sequence of a test. Above, it corresponds to a pre-programmed "standard" test.

Typical sequence of a standard automatic test:

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

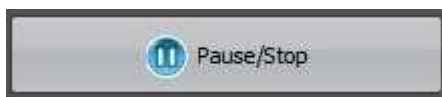
Depending on the starting frequency, the beginning of the sequence moves to the mentioned frequency. For each frequency, the two ears are tested one after the other.

In cases of random scenario, all the above frequencies are mixed; only the starting frequency with the side is identical.

The frequencies tested are those configured in the "[Configuration of automatic tests](#)" menu.

When the test is completed, a message appears on the screen asking you to save the test, if the general configuration is on manual save; otherwise a message will advise that the test is finished.

During the test, it is possible to take a break by pressing the Pause button.



The test can also be stopped completely at this precise moment. The record must be input manually by pressing the "Save" button.

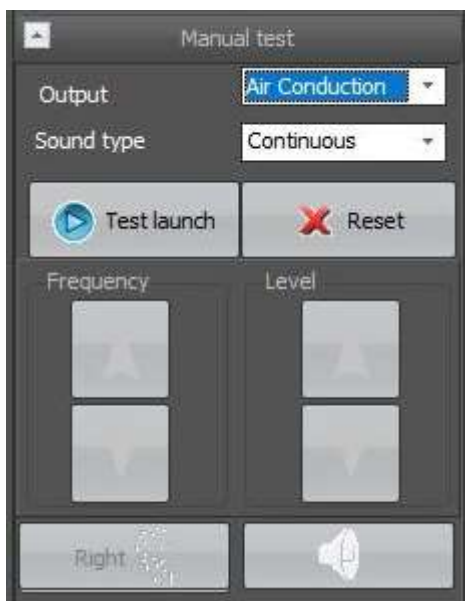
The test can also be restarted from the beginning by pressing the reset button.

Warning: In this case, the current test is lost, and there is no warning message.

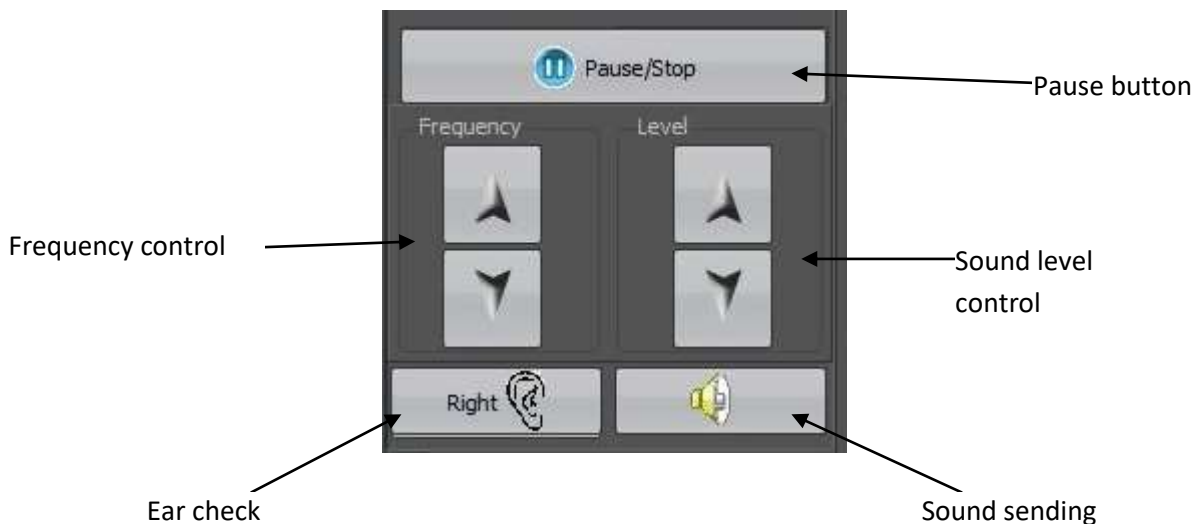
To resume the test, simply press the "resume" button. The level in progress during the pause reappears.

3.26. Manual test

No configuration is necessary to start a manual test, however, it is essential to select air or bone conduction, as well as continuous or pulsed sound application.



After the manual test is started, the control panel becomes active.



There are 3 ways to control a manual test:

- Via the control panel (above)
- Via the keyboard (via the short cuts mentioned in the [configuration manual tests tab](#))
- With the mouse by clicking directly on the audiogram

Mouse and keyboard commands can be disabled when configuring manual tests.

3.27. During the tests

During the tests, several indicators are available on panel ⑨: status of patient switch

When no sound is generated and there is no action on the audiometer, the panel is as follows



If the patient drop is pushed in (during or outside the test), the panel turns into this one.



Green colour indicating that patient drop is activated

If the patient drop is pressed before the sound is emitted, a "caution" symbol is displayed.



Caution
symbol

Example of a normal response that can be taken into account.

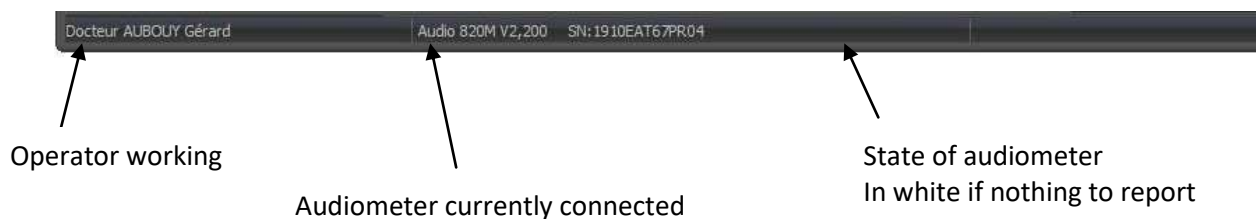


Patient response time

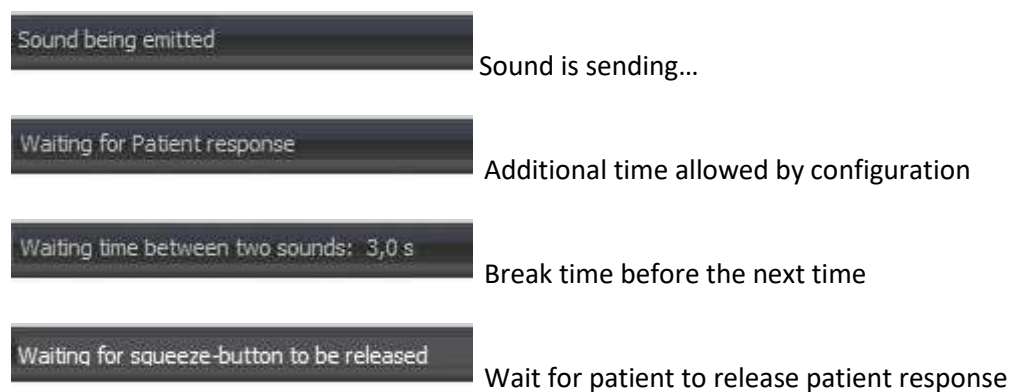
In manual mode, wait until the button is released (the panel turns grey) to proceed to the next test.

In automatic mode, the software waits for the patient response to be released.

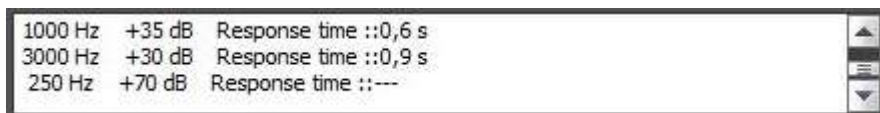
Status bar ⑦ (at bottom of page):



Audiometer status changes according to current sequence



In manual mode, a history of test results is displayed in the lower right-hand corner, recalling the frequency and sound level pairs and the patient's response time.



3.28. Diagnosis

3.28.1. "Normal" diagnosis

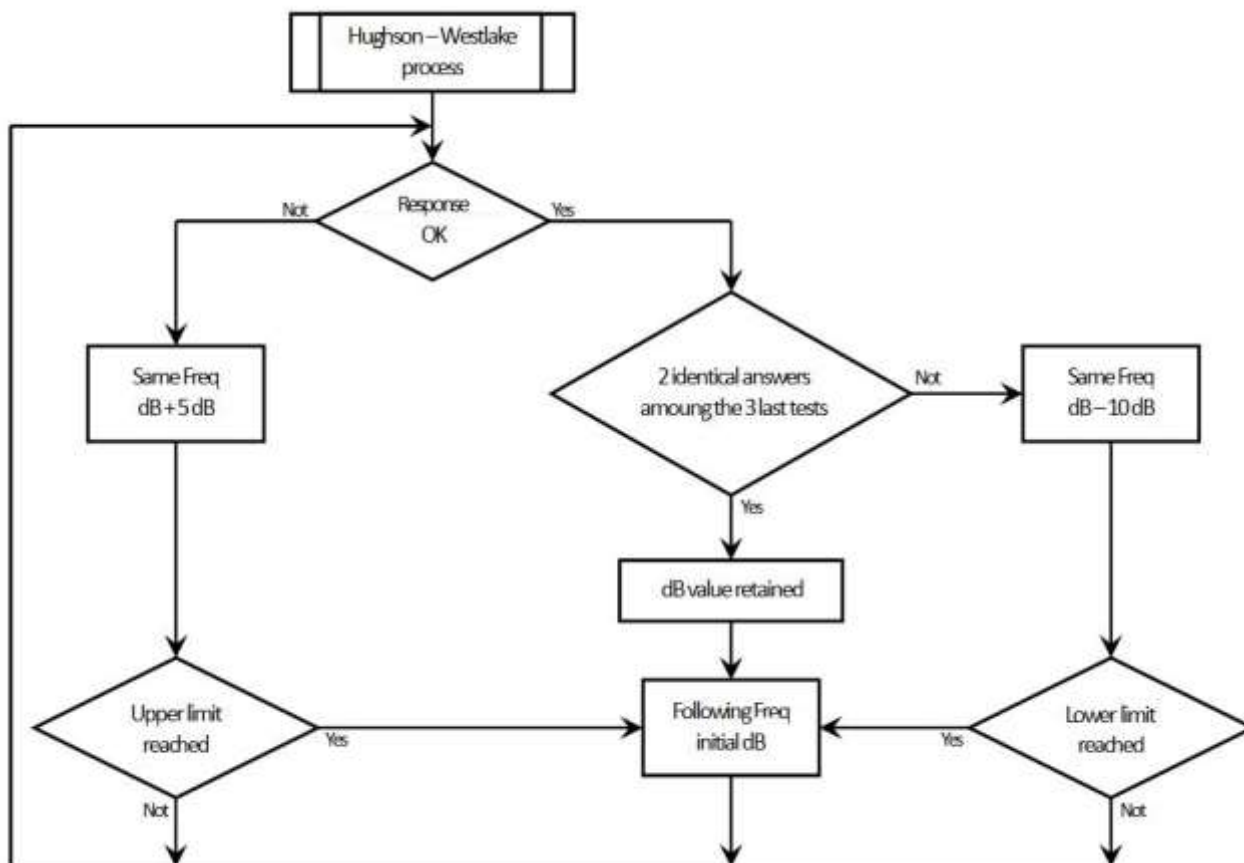
The 1st sound for the specified frequency is sent.

If there is no response, the sound level is increased until the patient hears the sound. This hearing noise level is selected, and the next test is performed.

If there is a response to the 1st sound, the level is decreased until the sound is not heard. The level of the last sound heard is the one used.

3.28.2. Diagnosis according to "Hughson Westlake".

The screening method uses the algorithm below. It involves retaining as the hearing threshold the sound level that gave rise to a patient response twice among the last three responses.



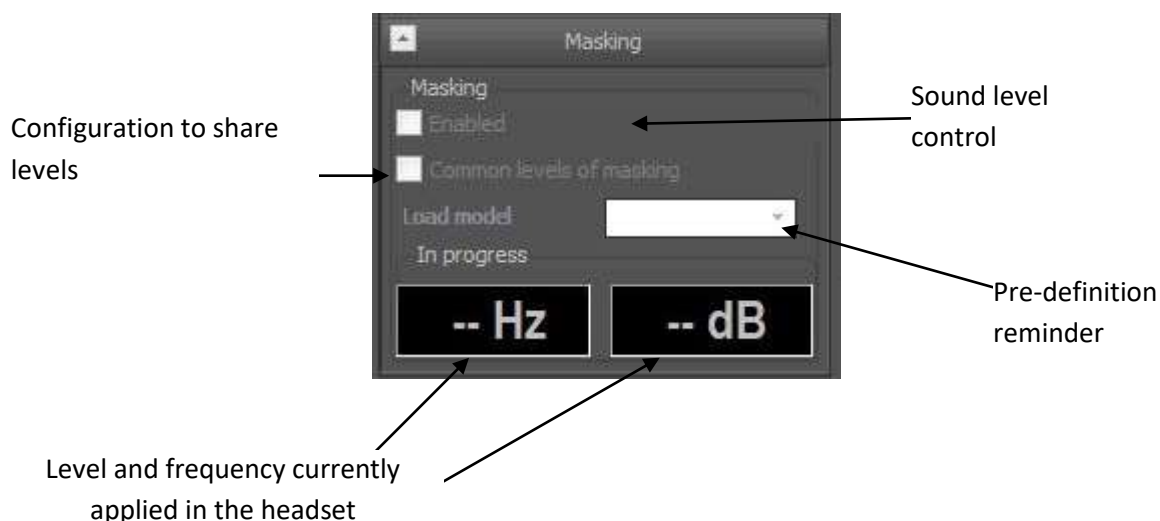
By default, the decrement and increment are -10dB and +5dB respectively.

3.29. Masking

An additional menu below the manual test allows you to configure the masks⑥.

Masking is only possible with bone conduction. The operator's choice of the level of masking depends on his experience and the objective sought. The maximum sound levels for masking signals are defined on the technical characteristics page.

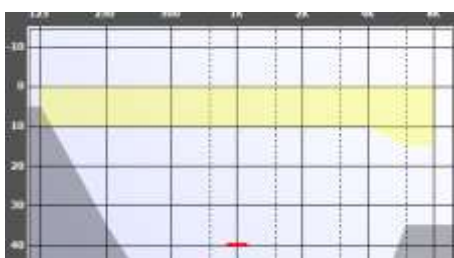
In air conduction, it is impossible to validate this function; the "function validated" box is disabled.



To activate masking, the "function enabled" box must be ticked.

When the function is validated, a cursor is displayed on the audiogram graphs, and mask levels can be added directly on the graphs by right-clicking the mouse. Note that the only way of controlling masking levels is with the mouse.

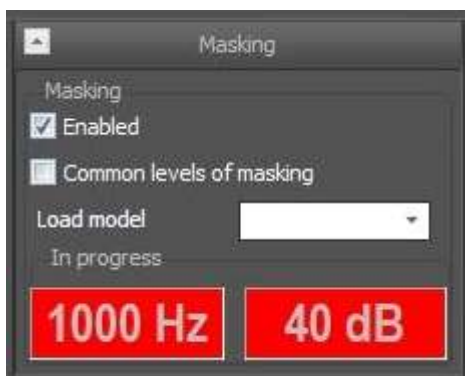
If a mask is validated, it is marked with a coloured line in the graph.



Red line if applied to the right ear, blue for the left ear.

The mask is always applied on the opposite side from that to be tested.

When a masking sound is applied, its characteristics are mentioned in the "masking" tab ⑥.
Red for emission to right ear, blue for emission to left ear.



All masks are configured using the right mouse button.

- A first right click activates the mask sound at the cursor location (with emission in the headset).
- Right-clicking on another frequency activates the mask at the frequency chosen, and the audiometric box emits the masking sound on this new value.
- Right-clicking on a mask level other than the current level on the same frequency changes the sound level.
- Right-clicking on the same frequency and level cancels the masking on that frequency.

If no mask is present, a right click validates it on the right and left, and it is deactivated on both sides; it is not possible, for the same frequency, to have a mask on one ear only.



















If a mask is configured for a frequency, a left click to emit a sound on the ossivibrator activates the emission of the masking sound on the frequency tested.

The "Common Levels" box allows all frequencies to be set to the same levels at the same time within the physical limit of the audiometer.

The drop-down list allows you to recall a previously predefined configuration via the:
" [Configuration | Tests](#) " menu.

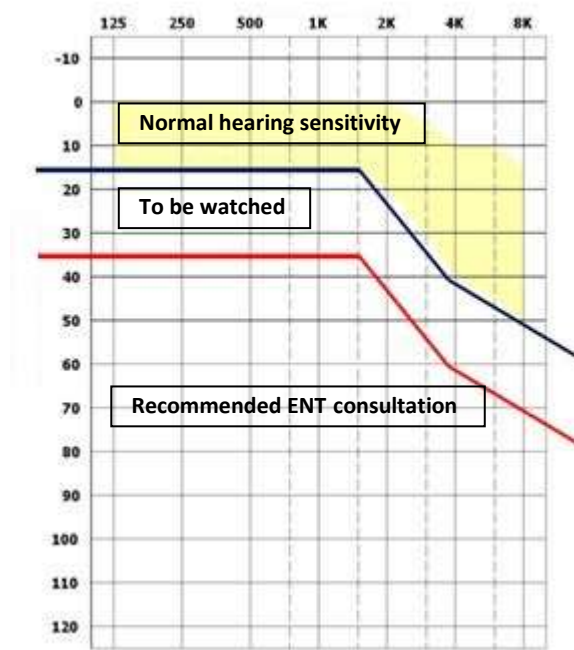
3.30. Audiogram symbols

The symbols used in the graphs are as follows:

Test type:	With answer		Without answer	
	Right	Left	Right	Left
Unmasked air conduction				
Unmasked mastoid bone conduction				
Masked mastoid bone conduction				
Unmasked frontal bone conduction				
Masked frontal bone conduction				

3.31. Help with decision making

If validated, this function allows a quick approach to the results (does not take the place of a specialist's opinion).



In screening, a first approach interpretation can be performed on the basis of graphic fringes, as follows:

- **"Normal hearing sensitivity"**: corresponds to the yellow fringe specific to each age (EN ISO 7029).
- **"To be watched"**: corresponds to a fringe 20 dB higher than the yellow fringe.
- **"Recommended ENT consultation"**: corresponds to the fringe delimited by the previous one and the maximum levels.

Conditions necessary for interpretation to be valid:

- At least 50% of the points must be located in the corresponding fringe
- The least favourable audiogram of the right or left ear should prevail
- The number of points explored must not be 3 or less (this will not be considered significant)
- If a point has a deviation of 20 dB or more from the highest sound level framing point, it must be considered as "inconsistent"

Warning: This aid is for information only, is subject to assessment by the Patient's Clinic, and must not in any circumstances prevail over the advice of an ENT doctor or other specialist.

3.32. Uninstalling the software

Close the software

Open the control panel (Start Menu)

Use the program uninstall menu and select the program to uninstall: 820M Software

Confirm the messages.

The software is now uninstalled.

Some files are not deleted, but must be deleted manually using a Windows explorer from the "Roaming" directory. These include log files (*.log), the "old" database directory, and the latest PDF files (reportxx.pdf) referring to the latest prints/backups.

4. Technical specifications

General definitions:

Type 4 tonal audiometer according to EN 60645-1

Classification:

Group 1, class B (EN 60601-1)

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 levels are expressed in the HLdB (hear level) sound scale. This is a so-called compensated curve where the "0 dB" of each frequency corresponds to the minimum hearing threshold of an otologically normal subject (definition according to EN 60645-1). The levels are adjustable in 5-dB steps.

Maximum bone conduction levels (HLdB):

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
dB	5	35	60	60	60	60	60	60	60	35	35

Maximum sound levels for masking (HLdB):

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
dB	60	80	90	90	90	90	90	90	80	80	80

Power supply:	Directly via USB line (cable provided, length 1 m) 5V +/- 0.2V
Computer connection:	Mini-USB connector
Audio Outputs:	On two 6.35 mm mono jack. (1 jack per audio channel)
Bone transducer output:	On 3.5 mm mono jack
Frequency tolerance:	+/-2%
Sound presentation:	Pure sinusoidal sound with digital management. Channel selection (left/right) via PC software interface.
Calibration:	Individual on calibration bench in air conduction
Environment:	Storage temperatures: -10° to 60° C Operating temperature: 15° to 35° C Humidity: between 30% and 90% relative Atmospheric pressure: between 98 kPa and 104 kPa
Weight (box only):	230 grams (820M)
Dimensions and weights:	150 x 92 x 36 mm (audiometer only) L = 320, W = 290, H = 105 mm - 1.7 kg. (Complete case)
Patient response:	Removable connection with jack plug, diameter 6.35
Length of cable:	1.20 m
Electrical Isolation:	4000V as per Standard NF EN 60601-1 (USB / Headset)
Setting up temperature:	Less than 5 seconds
Operation indicator:	Blue LED

5. Regulatory specifications

5.1. Instructions for use

Use in professional health care facilities (medical practice) or in home care settings (schools, offices etc)

5.2. CE marking

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



5.3. Origin of product

Device designed and manufactured in France by:

“Electronica-Technologies, ZA de la Tour, 03200 Abrest”

First CE 0459 marking obtained in 2020.

5.4. Electromagnetic compatibility

In exceptional cases, if the audiometer is exposed to strong static electricity discharges, or is exposed to an excessively intense electromagnetic environment, it may stop working and no longer be able to generate the sounds for which it was designed. This problem does not affect the basic security in any way. The result will be a total absence of reaction (no more communication with the PC, no sound generation). If this happens, simply disconnect the USB cable for a few moments and then reconnect the audiometer.

If the problem persists, contact your distributor/retailer.

Warning

It is advisable not to use this device in conjunction with or stacked on other devices because this may cause malfunction. If such use is necessary, this or other devices should be observed to check that they are functioning normally.

Warning

The use of accessories, transducers and cables other than those provided by the manufacturer of this equipment may cause an increase in electromagnetic emissions or reduce the immunity of this equipment and result in improper operation.

Warning

Portable RF communications devices (including peripherals such as antenna cables and external antennae) should not be used within 30 cm of any part of the audiometer, including cables specified or provided by the manufacturer. Otherwise, the performance of these devices could be affected

Guidelines and manufacturer's declaration - electromagnetic emissions		
The audiometer is intended for use in the electromagnetic environment specified in the chapter on "Environment in which Device is Used". The customer or audiometer user should ensure that it is used in such an environment.		
Emissions test	Conformity	Electromagnetic environment - guidelines
RF emissions CISPR 11	Group 1	The audiometer uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The audiometer is suitable for use in all establishments, including domestic premises. The audiometer is subject to a conditional connection
Harmonic emissions CEI 61000-3-2	Not applicable	
Voltage fluctuation / flicker emission CEI 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration - electromagnetic immunity


The audiometer is intended for use in the electromagnetic environment specified in the chapter on "Environment in which Device is Used". The customer or audiometer user should ensure that it is used in such an environment.

Immunity test	Test level IEC 60601	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) CEI 61000-4-2	±8 kV on contact ±15 kV in air	±8 kV on contact ±15 kV in air	Flooring should be composed of wood, concrete or ceramic tiles. If floors are covered with synthetic material, it is necessary for the relative humidity to be at least 30%.
Fast electrical transients in bursts. CEI 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The quality of the power supply grid should be that of a typical commercial or hospital environment.
Shock wave CEI 61000-4-5	±1 kV in differential mode ±2 kV in common mode	±1 kV in differential mode ±2 kV in common mode	The quality of the power supply grid should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines CEI 61000-4-11	< 5% U_T (low >95% of U_T) for 0.5 cycles 40% U_T (low = 60% U_T) for 5 cycles 70% U_T (trough = 30% U_T) for 25 cycles <5% U_T (trough >95% U_T) for 5 seconds	< 5% U_T (low >95% of U_T) for 0.5 cycles 40% U_T (low = 60% U_T) for 5 cycles 70% U_T (trough = 30% U_T) for 25 cycles <5% U_T (trough >95% U_T) for 5 seconds	The quality of the power supply grid should be that of a typical commercial or hospital environment. If the audiometer user requires continued operation during breaks in the power network, it is advisable to power the audiometer from a UPS power supply or battery.
Magnetic field at the electrical grid frequency (50/60Hz) CEI 61000-4-8	30A/m	30A/m at 50 and 60 Hz	The magnetic fields in the frequency of the power grid should have levels characteristic of a location in a typical commercial or hospital environment.

NOTE: NOTE U_T is the alternative grid voltage prior to application of the test level

Guidelines and manufacturer's declaration - electromagnetic immunity

The audiometer is intended for use in the electromagnetic environment specified in the chapter on "Environment in which Device is Used". The customer or audiometer user should ensure that it is used in such an environment.

Immunity test	Test level IEC 60601	Compliance level	Electromagnetic environment - guidelines
RF conduct CEI 61000-4-6	3 Veff From 150kHz to 80 MHz	3 Veff From 150kHz to 80 MHz	Portable and mobile RF communication apparatus should not be used too close to any part of the audiometer, including the cables; the recommended separation distance, calculated using the equation applicable to the transmitter frequency, should be respected. Recommended separation distance $d = 0,35\sqrt{P}$ above 80 MHz $d = 0,35\sqrt{P}$ from 80 MHz to 800 MHz $d = 0,7\sqrt{P}$ from 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
RF conduct CEI 61000-4-3	3 V/m From 80 MHz to 2.5 GHz	3 V/m From 80 MHz to 2.5 GHz	The field strengths from fixed RF transmitters, as determined by an electromagnetic site ^a , should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol: 
NOTE 1: At 80MHz and at 800MHz, the range of the highest frequency applies. NOTE 2: NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a	The field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment produced by fixed RF transmitters, an electromagnetic investigation of the site should be considered. If the field strength measured at the location where the audiometer is used exceeds the applicable RF compliance level shown above, the audiometer should be observed to check that operation is normal. If abnormal performance is observed, additional measures may be necessary in order to reorientate or reposition the audiometer.		
^b	Over the frequency range of 150 kHz to 80 MHz, the field strengths should be lower than 10V/m.		

6. Precautions for Use

The audiometer should be placed on a table so that it is stable and does not fall. In case of prolonged non-use, it must be stored in its case.

The device is intended to operate only with the accessories supplied (headset, bone transducer, patient response button, USB cable). The use of accessories other than those supplied with the device or distributed by the manufacturer may lead to deterioration of electromagnetic immunity and malfunction of the device.

However, a standard USB cable may be used, but under no circumstances should it exceed 2 metres.

The audiometer is calibrated with the headset and the bone transducer, contained in the case, and using another headset or bone transducer, (even of identical reference) could distort the measurements (the last 4 digits of the headset/ bone transducer, and audiometer serial numbers are identical).

Be sure to use only stimulation intensities that will be acceptable to the patient.

Similarly, the use of wireless communication equipment can interfere with the proper function of the audiometer. For minimum distances, refer to the chapter on "Technical Data".

Between each patient, it is advisable to check the condition of the headset/patient support area surface so that it does not have any rough areas likely to hurt the patient. It is also advisable to clean this area to avoid contamination (recommended products: Linet'Anios, Biohit Proline Biocontrol or any equivalent product) while taking care to prevent any liquid from entering the headset or bone transducer.

The other parts of the device can be cleaned with a soft damp cloth, possibly soaked in soapy water, taking care to prevent any liquid entering the device.

The audiometer should only be used in a dry and temperate room, and no liquid should enter the accessories (case, headset, bone transducer, patient response cord).



At the end of its life, the audiometer should not be disposed of in a bin. It must be returned to the seller for disposal.

This audiometer is intended for screening by a doctor, nurse or other health professional. It cannot in any circumstances replace a diagnosis that could be made by a specialized doctor. The operator must have the necessary knowledge to implement and interpret the results. Otherwise, it is advisable to contact the audiometer distributor or a training organization in order to further develop audiometric skills.

The operator must ensure that the patient is able to assimilate the instructions given to him, before carrying out the audiometric test and implementing them, taking into account his level of understanding (age, intellectual capacity, ...).

It should be checked that the device or its accessories do not show any signs of impact or damage that could lead to malfunction or pose a danger to the operator or patient.

To achieve good results, the patient must be placed in a room with very low ambient noise (less than 35 dB).

The headset must be adjusted according to the patient's shape so that it fits perfectly on his/her head. The left and right sides of the headset must be respected. Patients wearing glasses should remove them.

The bone transducer must be applied:

- Either on the mastoid of the ear tested and without contact with the pinna.
- Either on the forehead.

The patient should be told how to respond if he/she hears the sound by pressing the patient response push button (or by any other visual means if the push button cannot be used).

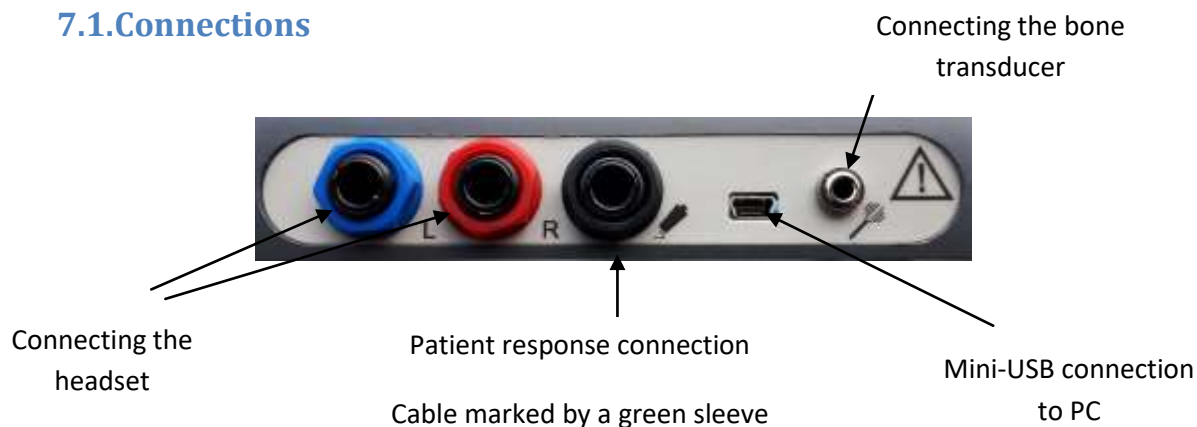
Before each installation of the PC-audiometer assembly, the operator must check the operation of the audiometer (in particular to check that the connectors are properly connected).

To avoid noise interference during a test, it is advisable to use a PC with a silent mouse or with TouchPAD.

As with any software, it is advisable to take the necessary measures to back up the files and database (see paragraph on " [GeneralConfiguration](#) ").

7. Audiometric housing

7.1.Connections



Patients are strongly advised not to be wearing the headset or ossivibrator when it is being connected to the casing.

7.2.Indicator light

On the front panel, an indicator light indicates the connection status with the PC.

It indicates 3 different states:

- **Sleep Mode:** the software has not been launched.
- **Active mode:** the software is running, but not in test mode.
- **Test mode:** a test is in progress.

Standby Mode: Light off for 7.5 seconds, on for 0.25 seconds

Active mode: Light off for 3.5 seconds, on for 2 seconds

Test Mode: Light off for 0.1 second, on for 7.5 seconds

7.3.Symbols

The meaning of the symbols on the label on the casing is as follows:



See instructions for use



Electronic equipment, must be properly sorted



Type B device (EN60601-1)



Name and address of manufacturer

8. Operational incidents

Defect found	What should I do?
The blue LED does not come on	<ul style="list-style-type: none"> ➤ It comes on for a short time in standby mode; check that after 10 seconds it has still not come on ➤ Check the correct connection of the USB cable between the PC and the audiometer ➤ Check that the PC is working properly
Test cannot be performed; buttons remain greyed out	<ul style="list-style-type: none"> ➤ Check that the PC is properly connected to the audiometer
Test launch buttons remain greyed out	<ul style="list-style-type: none"> ➤ No audiometer is connected ➤ The USB cable is defective, replace it ➤ A different audiometer is connected ➤ Disconnect, then reconnect the audiometer
The software shows "Checksum Error" before a test is launched	<ul style="list-style-type: none"> ➤ Disconnect, then reconnect the audiometer
No sound in the headset No sound in the bone transducer	<ul style="list-style-type: none"> ➤ Check that it is properly connected ➤ Check that the level is high enough to be heard.
The patient response button does not work	<ul style="list-style-type: none"> ➤ Check that the connection is in the right place (centre connector)
Inconsistent vibration or sound in the headset (too loud, random, etc.)	<ul style="list-style-type: none"> ➤ Contact the after-sales service
The headset/patient support surface is damaged:	<ul style="list-style-type: none"> ➤ Consider changing the bearings
Headset or bone transducer damaged	<ul style="list-style-type: none"> ➤ Change the pads if the support surface of the headset in contact with the patient is degraded ➤ Return to supplier in the event of physical damage to: the bone transducer the headset for any other type of degradation.
Printer does not operate	<ul style="list-style-type: none"> ➤ Install Acrobat Reader or equivalent

If the problem persists, remember to contact the supplier's after-sales service

9. Maintenance

For optimal use of the audiometer, the customer is advised to read the manual carefully.

It is advisable to carry out functional tests (see ISO 8253-1 for full test procedures):

- Routine control and subjective tests with headset, bone transducer and patient response switch every week and/or before use
- Basic calibration every 3 years

The audiometer should only be used in a dry and temperate room, and no liquid should enter the accessories (case, headset, bone transducer, patient response cord).

10. Guarantee

The device must not be open. No parts may be replaced without the manufacturer's intervention. The product may not be modified or used for any purpose other than those provided for in this manual. Any other intervention or use will totally release the manufacturer from liability.

The following are not guaranteed:

- Calibration checks.
- Replacement of parts due to normal wear and tear.
- Defects caused by alterations made by the user.

The warranty service is excluded if the damage or defects are caused by:

- Any inappropriate or excessive use, or manipulation or use of the audiometer in breach of the user manual instructions.
- Any repair by a person not approved by the establishment producing the audiometer.
- Any use of parts incompatible with the audiometer (headset, bone transducer, etc.)

For the contractual guarantee period, refer to your distributor's general terms and conditions of sale.

