W50 SOFTWARE

AUDIOMETRY SOFTWARE

USER MANUAL

520-660-MU2 • REV. 3.02 • 2025-12

Sibelmed®

Revisión: 520-660-MU2 Rev. 3.02

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Please refer to the device's Service Manual for additional information.

This manual can be purchased through the After Sales Service.

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DISCLAIMER
SIBEL S.A.U. is responsible for the safety, reliability and operation of this product only if:
• The computer where the software is installed complies with the IEC electrical installation requirements for medical devices and other applicable regulations.
• Repairs, reviews or modifications, both within and outside the warranty period, are carried out by technical personnel from SIBEL S.A.U.
• The software is used by qualified personnel and in accordance with the recommendations in this User Manual.

PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE REGULATION (EU) 2017/745 (CLASS IIa)

CE 0318

Thank you for choosing **W50 SOFTWARE**!

This product has been developed by the RDI Department of SIBEL S.A.U. in collaboration with the University of Barcelona, Faculty of Medicine, Department of Surgery (Otorhinolaryngology and Audiology) and medical specialists in the area of audiometry.

Revised
Date: 2025-12
Technical Director

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Date: 2025-12
Sales Director

INDEX

1. SAFETY 6
1.1 INTENDED USE 6
1.2 INTENDED USER 6
1.3 INDICATIONS FOR USE 7
1.4 INTENDED PATIENT POPULATION 7
1.5 CONTRAINDICATIONS AND SIDE EFFECTS 7
1.6 LIMITATIONS IN USE 7
1.7 ESSENTIAL OPERATION 8
1.8 RESIDUAL RISK 8
1.9 WARNINGS 8
1.10 DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION 9
2. INSTRUCTIONS FOR USE AND INSTALLATION 11
2.1 INTRODUCTION 11
2.2 PREVIEW 12
2.3 INSTALLATION AND SETUP 12
2.4 AUDIOMETRY SOFTWARE W50 17
3. AUDIOMETRY 52
3.1 INTRODUCTION 52
3.2 TYPES OF AUDIOMETRY 52
3.3 APPLICATIONS OF AUDIOMETRY 54
3.4 DIAGNOSES 55
4. TECHNICAL SPECIFICATIONS 57
4.1 SOFTWARE COMPATIBILITY AND COMPUTER REQUIREMENTS 57
4.2 PARAMETERS 57

4.3 AUDIOMETER COMPATIBILITY 57
4.4 PERSONALISING THE PROGRAM 58
4.5 DATABASE 58
4.6 USEFUL LIFE 58
4.7 STORAGE 58
4.8 DIRECTIVES AND STANDARDS 59
5. MAINTENANCE 61
5.1 CLEANING 61
APPENDIX 1. COMPLIANCE WITH THE GENERAL DATA PROTECTION REGULATION 62
APPENDIX 2. CALCULATION TABLES FOR DIAGNOSES 68

1. SAFETY

The **W50 SOFTWARE** has been designed for use with the safety in mind. All operating instructions must be read before using it. Failure to do so could cause injury to the user or patient and damage to the equipment and/or accessories.

This audiometry software can be used in conjunction with several audiometers manufactured by **SIBEL S.A.U.** It is very important to carefully read the User's Manual of the audiometer before using it with the software, especially the SAFETY section where all the safety considerations related to the audiometer are explained in detail.

Report any serious incident to the manufacturer and competent authority.

1.1 INTENDED USE

The **W50 SOFTWARE** when used stand-alone is intended for:

a) Numerical and graphical representation of stored tests

b) Diagnosis and follow-up of patients with hearing loss (hypoacusis).

Furthermore, when the **W50 SOFTWARE** is connected in real-time to compatible devices it has the following additional intended use:

c) Continuous test data transfer for the diagnosis and follow-up of hearing loss (hypoacusis).

1.2 INTENDED USER

The **W50 SOFTWARE** is designed to be used exclusively by medical personnel, being supervised and instructed by a doctor. Specific training in audiometry technique is recommended. Before using the audiometry software on patients, the user must become familiar with the operation of the product. All the information necessary for its operation is available in this Manual.
For additional training on the technique or on the product, contact

SIBEL S.A.U. or your dealer.

1.3 INDICATIONS FOR USE

The software is intended to be used in combination with compatible devices or as a stand-alone product. The devices compatible with **W50 SOFTWARE** are **SIBELSOUND 400** and **SIBELSOUND DUO,** including all their models.

W50 SOFTWARE is indicated to be used for the diagnosis and follow-up of patients with hearing loss (hypoacusis) of any cause, like noise exposure, illness, trauma or presbycusis. It is also indicated for an early identification of individuals at risk of developing hearing impairment or for medicolegal assessment.

The **W50 SOFTWARE,** together with compatible SIBELSOUND audiometers, allows an easy access to hearing evaluation and is a useful tool for diagnosis, for evaluating the impact of hearing loss on patient communication, and for evaluating patients with sensorineural hearing loss.

1.4 INTENDED PATIENT POPULATION

No contraindications or side effects related to audiometry tests and the **W50 SOFTWARE** have been identified.

1.5 CONTRAINDICATIONS AND SIDE EFFECTS

No contraindication has been identified for audiometry tests. However, special precautions must be considered when performing these tests in children, elderly and disabled subjects.

1.6 LIMITATIONS IN USE

The analysis of the audiometry test results is not enough to give a correct diagnosis of the patient's clinical condition. The patient's records and any tests that the clinician believes necessary must also be considered. A doctor must interpret all data to determine the course of treatment required.
The audiometry tests require patient cooperation. The patient must press a button or provide an indication (e.g. rising the

hand) to communicate the detection of a stimulus. The medical staff administering the audiometry test must assess the patient's capability to perform it. Special care should be taken when testing children, elderly and handicapped persons.

1.7 ESSENTIAL OPERATION

The real-time data transmission, data download and representation of hearing levels are considered essential performance, as well as the storage and integrity of data in the computer.

1.8 RESIDUAL RISK

According to the application of the EN ISO 14971 standard, all risks related to the use of the **W50 SOFTWARE** have beenreduced to maximum, as much as possible. It is important to read carefully all indications of use, contraindications, warnings and recommendations provided in this manual.

1.9 ⚠ WARNINGS

Please read this manual carefully before using the **W50 SOFTWARE**. Use **W50 SOFTWARE** according to the instructions included in the W50 user manual.

Pay special attention to warnings like this one.

To comply with Medical Device Regulation (EU) 2017/745 and for safety and reliability purposes, ensure that the **W50 SOFTWARE** are used by personnel that are adequately trained in the intended use of the system.

The user must have minimal computer skills allowing the safe operation of both the **W50 SOFTWARE** and the Windows environment. It is important that the IT manager trains and informs the user about the computer security measures adopted at workstation and network system levels. These measures may include access control, software installation policy, data sharing, external access, etc.

The computer, monitor and accessories on which the software is used must comply with the Low Voltage Directive (in particular the EN 60950 standard) and the EMC Directive (in particular the EN 55022, EN 61000-3-2, EN 61000- 3-3 and EN 55024).

Contact of liquids with the USB flash memory drive must always be avoided.

Verify that the hardware of your PC works properly.

The **W50 SOFTWARE** must be used in a secure computing environment. It is important that you or your IT manager establish security policies, including access control to the system, restrictions to the installation of new software, management of backup copies, protection of the system against viruses and malware, guarantee of confidentiality and integrity of data transmission, confidentiality of personal data storage, regular system updating and installation of security patches. Using the program outside of its intended environment could result in a loss of data integrity.
Check regularly for updates of the **W50 SOFTWARE**.

This manual is available in PDF format in the flash memory drive provided for installing the **W50 SOFTWARE**. Once installed, the user's manual is also available in the subfolder "Help" of the installation folder (usually C:\SIBEL\W50\Help).

A printed copy may be requested at **SIBEL S.A.U.**

The software W50 runs on PC, make sure you save the test before turning off the PC or disconnect the communication cable with the audiometer.

1.10 DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

The software is delivered on a USB Flash memory drive. The USB Flash memory drive is an electronic product and therefore should not be disposed of in organic waste. Deliver to a designated recycling collection point in accordance with the legal requirements of your country.
You can obtain more information on proper disposal by contacting the **SIBEL S.A.U.** Technical Service. or with your dealer.

2. INSTRUCTIONS FOR USE AND INSTALLATION

2.1 INTRODUCTION

W50 SOFTWARE is a software for the visualization, storage, transfer and analysis of audiometric tests that works in the Microsoft Windows environment.

It is compatible with **SIBELSOUND 400** and **SIBELSOUND DUO** audiometers (including all their models), and its operation can be in real time or delayed.

When used in conjunction with compatible audiometers, the audiometers are connected to the PC via a USB cable, allowing the **W50 SOFTWARE** to acquire the intensity and frequency levels selected on the device in real time, as well as the patient's responses, and display the values for each ear in separate graphs, depending on the type of test and signal applied. With the acquired data, the **W50 SOFTWARE** can calculate a set of test parameters that can be evaluated using various interpretive algorithms selectable by the user and implemented into the software. The **W50 SOFTWARE** allows you to generate a report with the test results and interpretive algorithms that can be printed directly to an external printer or in PDF format. The USB connection also allows previously stored records from compatible audiometers to be downloaded to the **W50 SOFTWARE** database.

W50 SOFTWARE allows, among other functions:

- Performing audiometry tests in real time.
- Importing the tests performed with the audiometers.
- Viewing the different audiometric tests.
- Audiometric graph with test results.
- Comparison of tests from the same patient.
- Consulting diagnostic recommendations.
- Customized reports.
- Report printing.
- Download tests in PDF and XML.
- Management of different databases.
- Firmware upgrades for compatible audiometers

The audiometric tests implemented in the **W50 SOFTWARE** are:

- Air conduction pure tone audiometry
- Bone conduction pure tone audiometry
- Masking
- Speech audiometry
- Suprathreshold tests

With these audiometry tests, a set of parameters is calculated that can be evaluated using various user-selected interpretive algorithms programmed into the software. These algorithms evaluate the measured values to provide a diagnostic classification according to different classification methods.

These tests are the same and have the same functionality as those implemented in the **SIBELSOUND 400** and **SIBELSOUND DUO** audiometers.

When used independently (without connection to the audiometer), the **W50 SOFTWARE** allows you to view and analyze the tests stored in the database, as well as generate a report to an external printer or in PDF format. In addition, the **W50 SOFTWARE** allows you to import and export audiometric data tests in an open CSV format from SIBEL for further viewing and analysis. It also allows you to export tests in XML format.

2.2 PREVIEW

This product is manufactured under strict quality control. However, accidents can occur during the transport or storage of the equipment. It is therefore advisable to carry out an initial check on its condition, and that of the accompanying accessories, before installation.

The **W50 SOFTWARE Audiometry Software** comprises:

REF	Qty.	Description
03024	1	Audiometry Software W50
02303	1	W50 license
520-660-MU2	1	Audiometry software W50 user manual in English.

2.3 INSTALLATION AND SETUP

2.3.1 INSTALLING THE AUDIOMETRY SOFTWARE

⚠ WARNING
The user must have administrator rights in order to install all the program's features. In case of any doubts, contact your System Administrator or check the help of the Operating System.

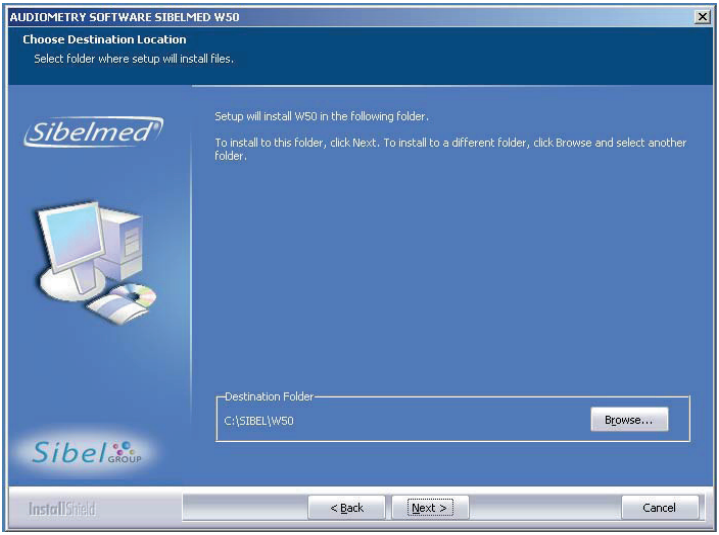
To install the Software on the hard disk of the PC proceed as follows:

1 Plug the USB memory drive into any of the PC's USB ports.
2 Run the program Setup.exe in the USB memory drive.

3 When setup starts, the following window appears offering the choice of install language.



4 Choose the folder where the program is to be installed and the program group name. By default the program is installed in the folder :\SIBEL\W50.



5 Once the installation is done, it will create the SIBEL group of programs' or the one chosen by the user and a shortcut will be created on the desktop.

2.3.2 USB DRIVER INSTALLATION

A driver needs to be installed on the computer in order to USB communications between **SIBELSOUND** audiometers and **W50 SOFTWARE** work properly.

This driver is installed automatically during the installation of the **W50 SOFTWARE**. To perform this process, simply disconnect the USB cable from the computer, install **W50 SOFTWARE** and plug in the USB cable with the audiometer switched on. From this moment, the driver is installed and you can start communications with the device.

2.3.3 START-UP

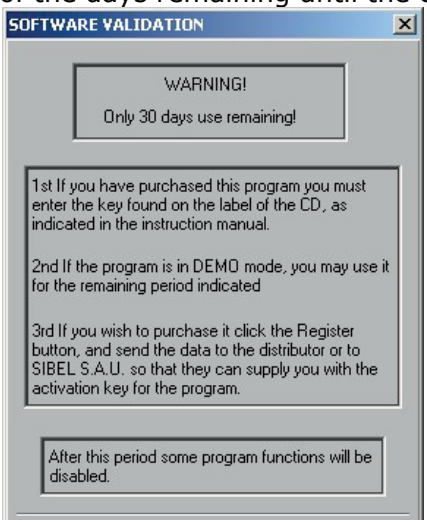
Reboot the PC and launch the program by clicking on the **W50** icon under **All Programs > SIBEL** from the Start menu, or double-clicking on the **W50** short-cut on the desktop.

Press **OK** on the **ABOUT**... screen to access the MAIN WINDOW.

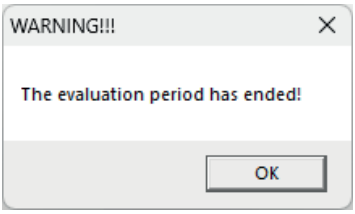


2.3.4 ACTIVATION CODE

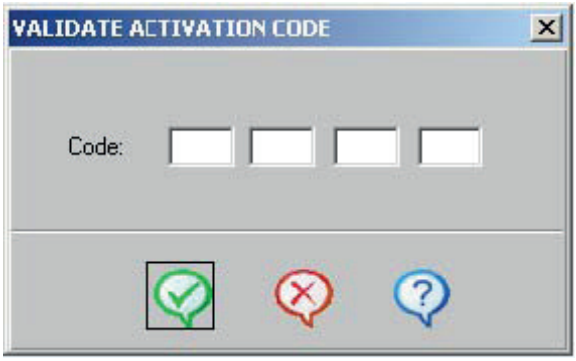
To use the **SIBELSOUND 400** and **SIBELSOUND DUO** audiometers with the **W50 SOFTWARE**, you must enter an activation code in the software. The *W50 SOFTWARE* allows you to work with the audiometers for a period of 30 days before you have to activate the product. During this 30-day period, the program will notify you of the days remaining until the end of the period:



This screen allows ti activate the software by means of the activation code if the "Activar Producto" option is selected. Once the specified period has ended, the communication functions with the audiometers will be deactivated: real-time testing, test downloads, and deletion of the audiometer database. Tests stored into the database may still be reviewed. When the specified evaluation period is finished, some software functions are desactivated. The following warning message is shown:



To activate the program, purchase de licence (item with code 02303), connect the SIBELSOUND 400 or SIBELSOUND DUO audiometer to the PC and select the model of audiometer in Settings/Links. Following, select the options Utilities/Activation Code from the Configuration menu o select the Activar Producto option from the SOFTWARE VALIDATION dialog box the following dialog box is shown.



Enter the activation code provided when the software was purchased. From then onwards you are free to use the W50 SOFTW**ARE** without restriction.

2.3.5 ACQUIRING THE PROGRAM

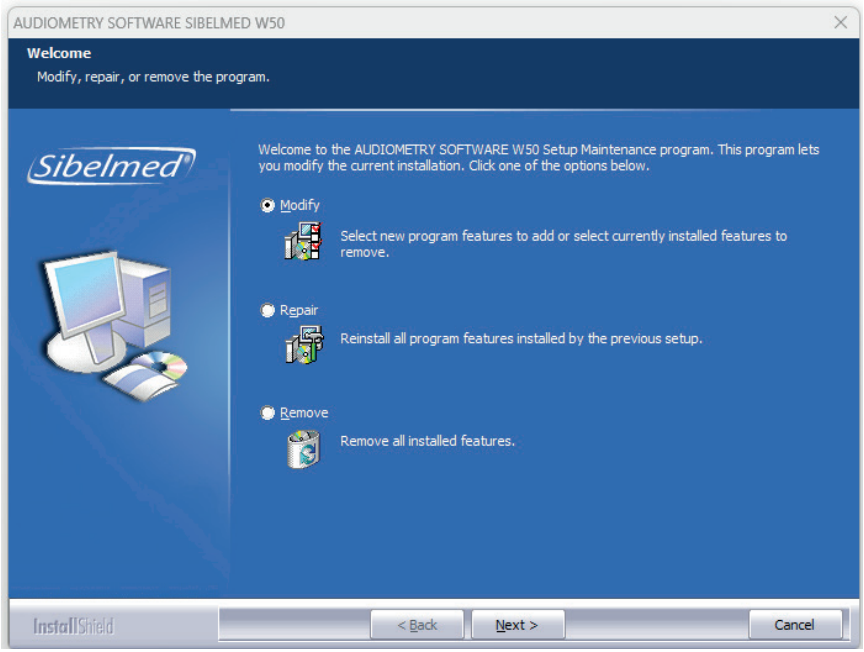
This option allows you to fill in the data required to obtain the activation code and send it by e-mail to **SIBEL S.A.U.** or to your distributor.
The program can be purchased from the Registration option in the SOFTWARE VALIDATION dialog box or from Setup/Utilities/ Purchasing.

2.3.6 UNINSTALLING THE AUDIOMETRY SOFTWARE

1 Plug the USB memory drive into any of the PC's USB ports.

2 Run the program Setup.exe in the spirometry USB memory drive.

3 The following window appears, from which you can choose one of the following options:



- **Modify**: Allows uninstallation by modules. This option is not recommended as you might lose the database if a backup copy has not been made. Use the option **Remove** to carry out the uninstall.
- **Repair**: Reinstalls the program.
- **Remove**: Completely removes the software, but retains the database in the folder in which the program was installed.

2.4 AUDIOMETRY SOFTWARE W50

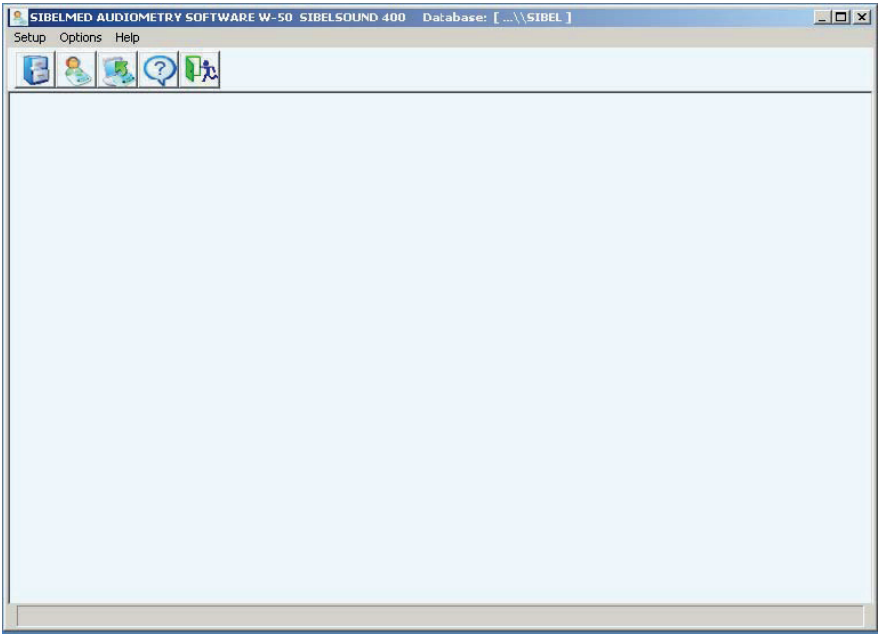
2.4.1 ABOUT THE ON-SCREEN HELP

The **W50 SOFTWARE** provides a link to the user manual to help the user to handle properly the different software options.

Generally, every screen has a Help menu that allows to open the user manual. This help is indicated in every screen with an icon, with text or both.
The user manual is in PDF format and is opened automatically with the software that Windows has registered as viewer of PDF files. If there is none, Windows will ask to select one.

2.4.2 MAIN MENU

This window shows the main options available from the **W50 SOFTWARE** with the corresponding sub-options:



SETUP

- Select Printer
- Links
- Other
- Interoperability
- Utilities (only when the SIBELSOUND 400 or SIBELSOUND DUO audiometer is selected in the setup/Links menu).
- Exit

OPTIONS MENU

- Database
- Audiometry
- Import tests

HELP MENU

- Show the help
- Visit SIBELMED website
- About …

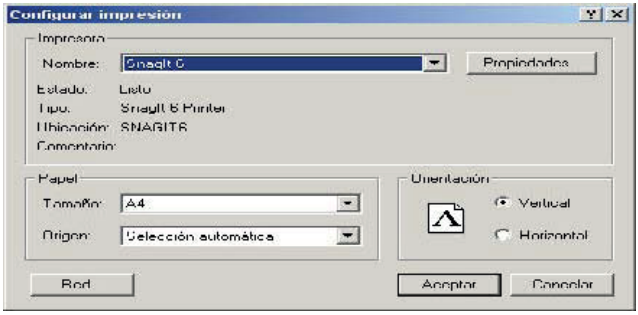
2.4.3 SETUP MENU

The **W50 SOFTWARE** is a versatile program supporting a variety of functional options. Some of these may not be relevant to some users. Therefore, once the process of Installation and Activation has been completed, it needs to be customised to the needs of each user. Accordingly, the system becomes personalised to each user making it simpler to operate and to understand how it works.

The various options that can be personalised from the configuration menu are set out below.

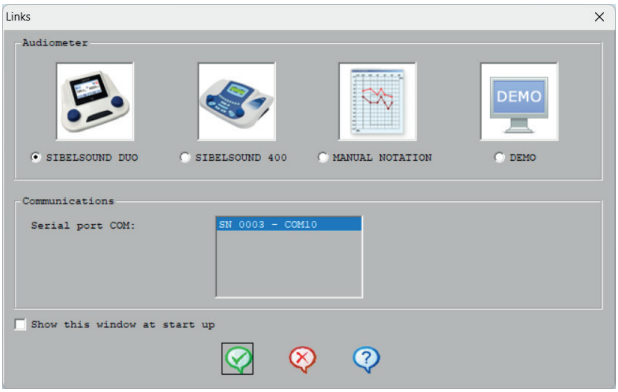
SELECT PRINTER

This option is for configuring a page for printing (size, origin, orientation) and indicates the printer selected by the operating system, as well as the available printers. If the required printer is not listed, it must be added in the normal way for the operating system. Refer to the Manual for the Operating System.

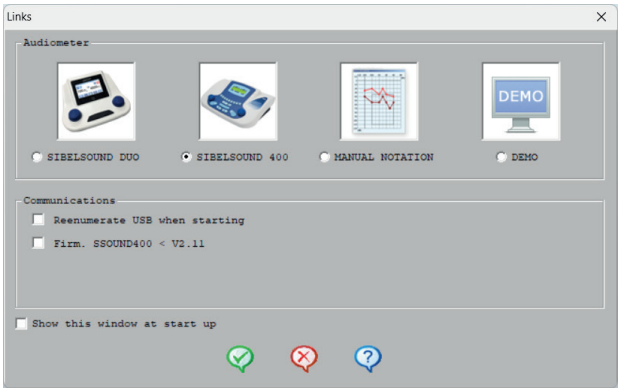


LINKS

On this screen, you can select the audiometer you want to use:
• **SIBELSOUND DUO** audiometer. When you select this audiometer, a list of connected audiometers is displayed, along with their serial numbers and the virtual communications port used. The user must select the audiometer to be used.



• **SIBELSOUND 400** audiometer. Activate the "Firm. SSOUND400 < V2.11" option if your SIBELSOUND 400 audiometer has a firmware version lower than version 2.11. If you encounter communication errors when using your SIBELSOUND 400 audiometer, activate the "Reenumerate USB when starting" option.



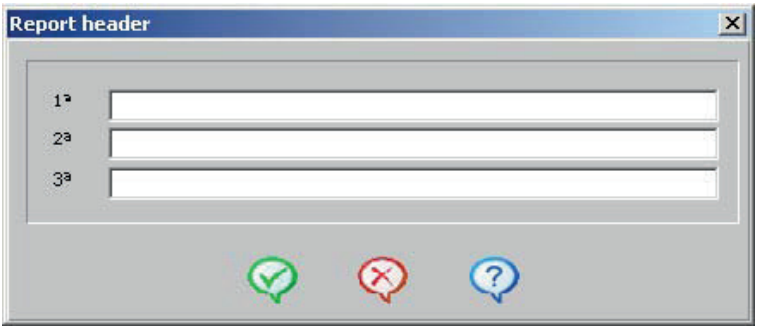
• Manual notation: allows you to perform an audiometric test by manually entering hearing thresholds. In this case, it is not necessary to have the audiometer connected to the PC.
• Demonstration: The "DEMO" option includes recorded sample tests that allow you to try out the software without having to perform any tests with the audiometer.

OTHER

From this menu option you have access to:

REPORT HEADER

A three line header can be inserted in printed reports with data chosen by the user. For example: Name of centre, name of doctor, address, etc.



This header remains in force until modified.

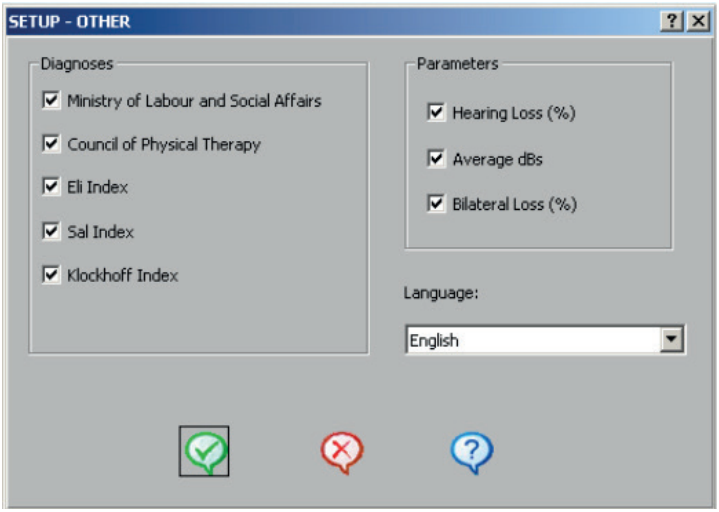
PARAMETERS AND OTHER

This window is for selection of:
• The type of diagnosis for the pure tone audiometry test Ministry of Labour ans Social Affairs(Council of Physical Therapy, Eli Index, Sal Index and Klockhoff Index).

• The parameters which we wish to view in the pure tone audiometry test.

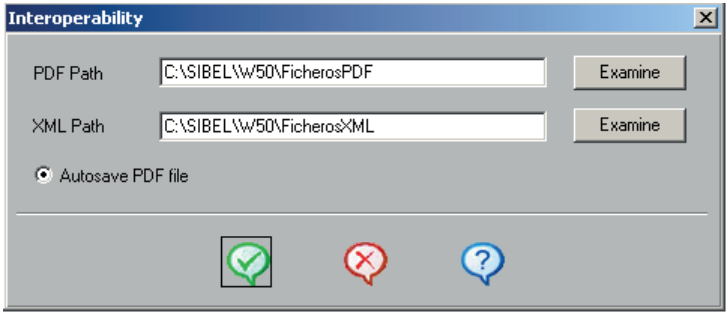
• The language for the application.

• NIF (None, DNI, NIE X, NIE Y, NIE Z). This option calculates the control digit of the selected identification document from the patient reference number automatically. The control digit is added to the reference entered in the audiometer, either during the real-time test or in the download of the equipment database.



INTEROPERABILITY

This menu allows you to configure the export of audiometric tests to XML and PDF format when you save the test in progress in the database.
Select the **INTEROPERABILITY** option within **SETUP** menu."



"This option allows the user to select the following:
• **PDF Path** where the generated PDF file is saved.
• **XML Path** where the generated XML file is saved.
• **Autosave PDF file**, to save it automatically without showing the corresponding dialog box

UTILITIES

This option is only available if the SIBELSOUND 400 or SIBELSOUND DUO audiometer is selected in the Setup / Links menu. The following options are shown:

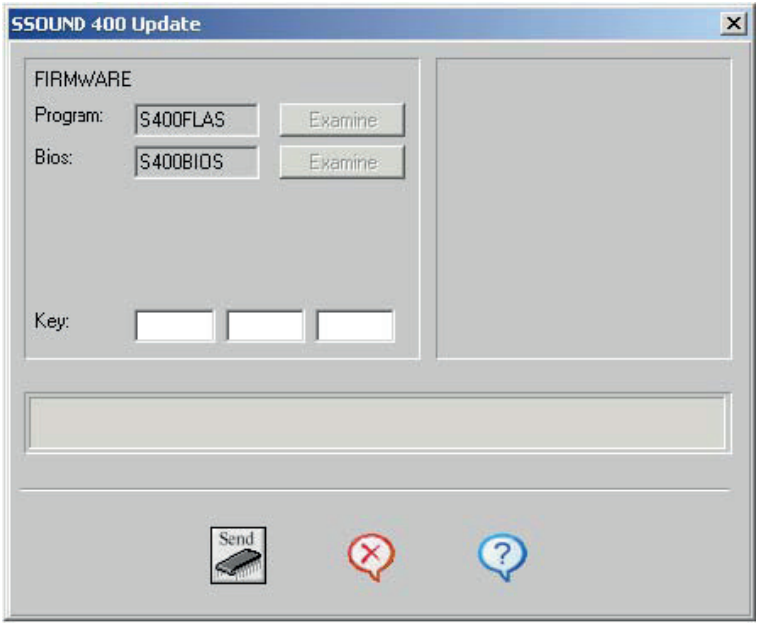
- Update Flash
- Purchasing the program (see the topic ACQUIRING THE PROGRAM)
- Activating the program (see the topic ACTIVATION CODE)
- Download calibration record (only available for SIBELSOUND DUO)

UPDATE FLASH

The **SIBELSOUND 400 and SIBELSOUND DUO** audiometer of **SIBEL S.A.U.** has a firmware updating and maintenance process.

SIBELSOUND 400
Before starting the update process, check that the device is ON and connected to the computer. If you are using serial communications, check if the selected port in Setup / Links menu is correct. To update the version of the firmware, the Setup / Utilities / Update Flash option must be selected. From

the SSOUND 400 Update dialog box, enter the key supplied with the audiometer, click the SEND button and verify the evolution of the loading process in the screen.



⚠ WARNING
Once the update process starts, do not disconnect the USB cable, turn off the PC or cancel the process.

Finally a «transmission correct» message will appear. So the new firmware runs smoothly, you must leave the loading screen, turn off the audiometer and turn it on again. From now on, the device will work perfectly with the new firmware version.

If there was an error during the load process, it's possible to restart the firmware update. You must leave the loading screen, turn off the device and turn it on again. A screen with the following text will be shown in the audiometer: ACT. FIRMWARE / UPDATE FIRMWARE. From this moment, the firmware update process must be repeated.

SIBELSOUND DUO
Before starting the update, check the audiometer is running and connected to the PC. In the audiometer, press the left rotary knob seven times and then the signal generation button once. Select the Update Flash option in the Configuration / Software Utilities menu. Observe the evolution of the update process on the audiometer screen.

⚠ WARNING
Once the update process starts, do not disconnect the USB cable, turn off the PC or cancel the process.

EXIT

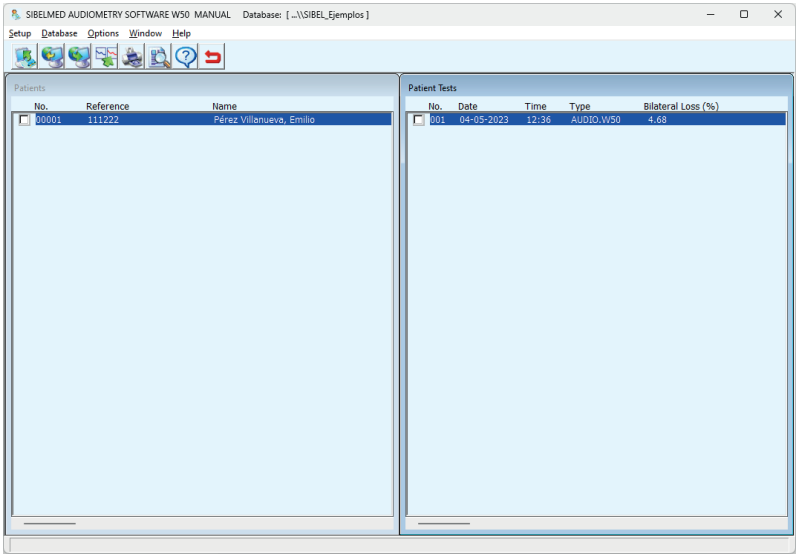
To finisch the program and return to Windows use the exit option.

2.4.4 OPTIONS MENU

DATABASE

The **W50 SOFTWARE** has its own database for storing patients and tests. Users can create multiple W50 databases according to their needs and switch between them (for example, one database for daily patients and another for patients belonging to a specific study).

EXPLORE DATABASE



From this window you can see the relationships between the patients in the database and their respective tests, and in turn have access to the following options from the menu:

- Setup
- Database
- Options
- Window
- Help

There are icons provided for rapid access to: Load Tests (Load), Export tests in CSV format (EXP), Import tests in CSV format (IMP), Test data, Print Report, Print Preview, Help and Exit (RET).

- **SETUP** See the Topic MAIN MENU / SETUP MENU

- **DATABASE**

PATIENT CARD
See the Topic MAIN MENU / OPTIONS MENU / DATABASE / PATIENT CARD

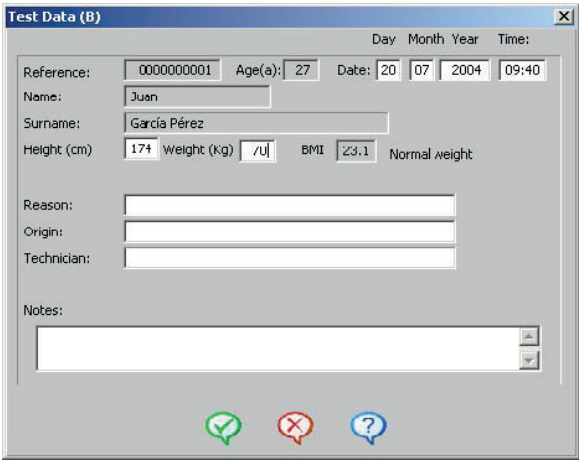
TEST CARD
The test card shows the following data concerning the patient (on a read-only basis):

Reference Age in years Name Surname BMI (Body Mass Index)

And other items may be entered such as:

Date and **time** the test was carried out
Height in **cm** between 100 and 215 cm
Weight in **Kg**. between 15 and 135 Kg.

Reason for carrying out the test **Origin** or centre, department, doctor, etc. from where patient was referred **Technician** who carried out the test **Notes** on the test



DATABASE MAINTENANCE
See the Topic MAIN MENU / OPTIONS MENU / DATABASE / MAINTENANCE

•OPTIONS

IMPORT TESTS

See the Topic MAIN MENU / OPTIONS MENU / IMPORTS TESTS / IMPORT TESTS

EXPORT TESTS IN CSV FORMAT

Allows tests to be exported in CSV format. To do this you must:

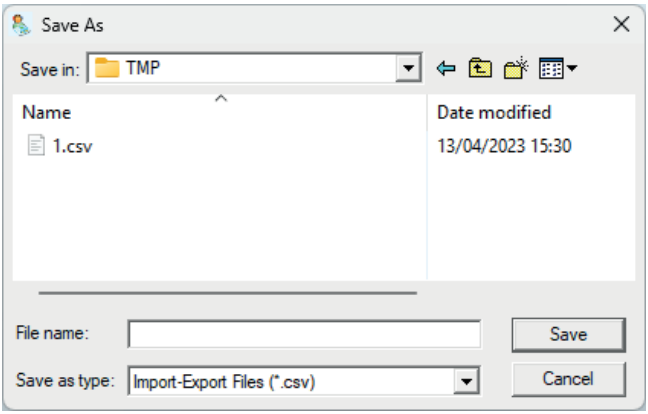
1 Mark the tests you wish to export.

2 Click on the **EXP** icon or select the option **Export tests in**

CSV format from the Options menu. The "Save As" window then appears.

3 Enter the name of the **file** and the **folder** to which you wish the data to be saved.

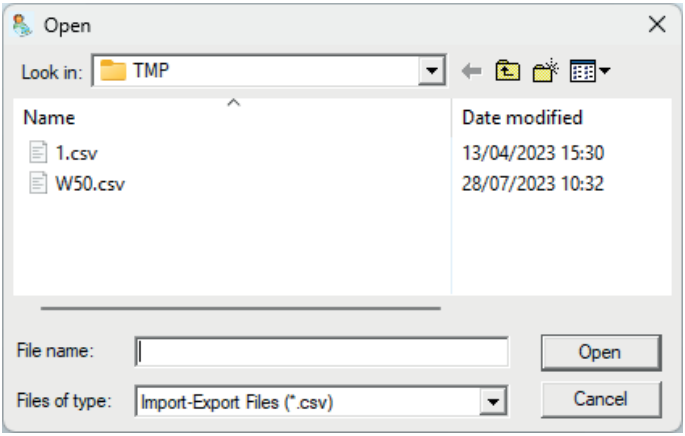
4a Click the **Save** button to save the data. At this point the file is created. or **b** Click the **Cancel** button to return to the previous window without saving the data.



IMPORTING TESTS IN CSV FORMAT

Allows tests saved in CSV format to be imported. To do this you must:

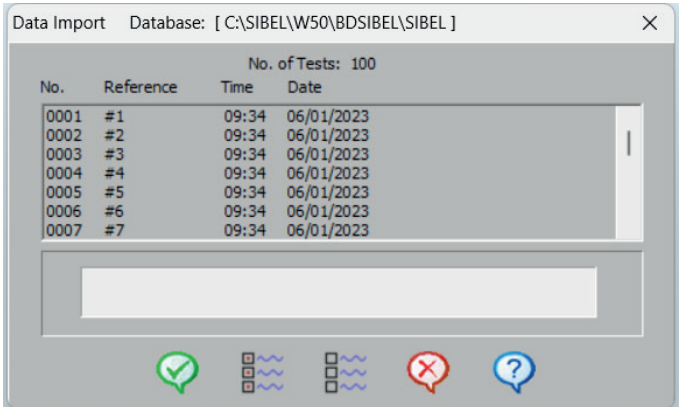
1 Click the **IMP** icon or select the **Import tests in CSV format** from the Options menu. The "Open" window then appears.



2 Find the **folder** containing the file to import and select the **file.**

3a Click the **Cancel** button to return to the previous screen without importing data. or

b Click the **Open** button to proceed with the data import. The "Data Import" window appears showing the tests contained in the selected file.



4 Select the required tests by clicking on the relevant test, or select all of them using the Select All button (to unselect click on the relevant test or click the Unselect All button).

5 Click the **OK** button to import the selected tests. The bar at the foot of the window indicates that the import process is in progress. At the end of the process it indicates that the data import is complete. At this point the tests have been saved in the database.

EXPORT TESTS BY EMAIL
Allows tests to be sent by email. To do this you must:

1 Mark the tests you wish to email.

2 Select the **Export tests by email** option from the Options menu. The email system installed in the PC then opens, displaying a new draft message with an attachment called TESTS containing the data for the selected tests.

3 Enter the destination email address and any message text.

4 Click Send to send the email.

TEST DATA
Opens the tests window to view graphs, parameters, diagnoses, etc. relating to the selected test.

PRINT REPORT
Prints a report of the selected test.

PRINT PREVIEW

Opens a window showing a preview of the report so you can check it is the report you want and is correctly formatted before printing.

The following options are available:
Report: prints the report. **Forward/Back:** moves forwards/backwards within the report so that all pages can be previewed.

Zoom Out/In: allows to decrease/increase the dimensions of preview of the last. Help: displays **Help** in relation to the print preview function. **Return**: returns to the previous window.

- **WINDOW**

SELECT

For selection of a patient or test. Where the Patients window is active, on selecting a patient all that patient's tests are also selected.

UNSELECT

Unselects the selected patient or tests. Where the Patients window is active, on unselecting a patient all that patient's tests are also unselected.

SELECT ALL

Where the Patients window is active, all patients are selected together with all the tests. If the Tests window for a patient is active, all the tests for the selected patient are selected.

UNSELECT ALL

Where the Patients window is active, all patients are unselected together with all the tests. If the Tests window for a patient is active, all the tests for the selected patient are unselected.

CASCADE

Superimposes all the Patients and corresponding Tests subwindows in a cascade arrangement.

TILE HORIZONTAL

Arranges all the Patients and corresponding Tests subwindows above and below each other.

TILE VERTICAL

Arranges all the Patients and corresponding Tests subwindows side by side.

REFRESH
Refreshes the information in the windows.

SORT BY

Sorts the list of patients by criterion selected (record number, Surname or reference).

SHOW DELETED RECORDS
Shows those records marked for deletion.

• **HELP** See the Topic MAIN MENU / HELP MENU
On clicking the right button of the mouse above a patient a menu appears with the following options:

DATA: provides access to the patient file.

DELETE: deletes the patient together with the corresponding tests.
UNDELETE: removes the deletion marker from a patient who has been marked for deletion.

Double-clicking on a **patient** opens their file.

On clicking the **right button** of the mouse above a **test** a menu appears with the following options:

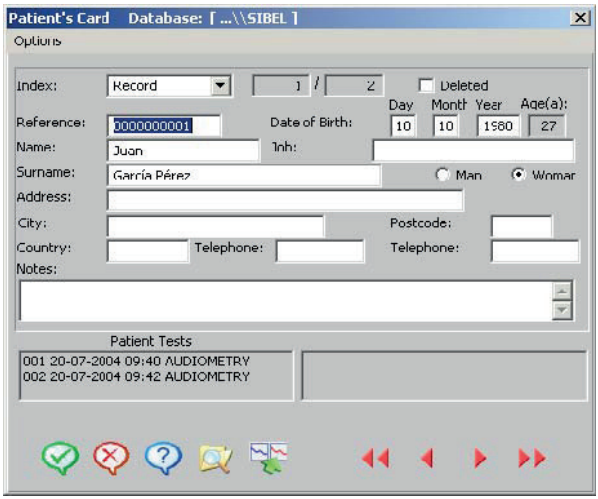
DATA: accesses the test's data card.
DELETE: deletes the test.

UNDELETE: removes the deletion marker from a test which has been marked for deletion. GRAPH: opens the test window.

REPORT: prints the relevant test. Double-clicking on a test opens the test window.

PATIENT CARD

This window provides access to the card for any patient saved in the database and enables their various tests to be viewed along with their key parameters.

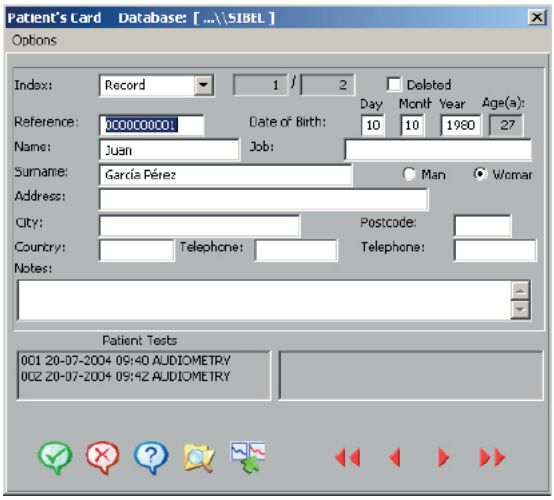


NOTE: The patient data are fictitious.

Field	Type	No. characters
Index	A/N	
Reference	A/N	10 (SIBELSOUND 400) 20 (SIBELSOUND DUO, manual notation)
Date of Birth	N	8 (dd/mm/yyyy)
Name	A/N	20
Surnames	A/N	35
Job Sex	A/N	25
Address		
City	A/N	46
Postcode	A/N	28
Country	A/N	5
Telephone 1	A/N	10
Telephone 2	A/N	10
Notes1	A/N	74
Notes2	A/N	74

A/N = Alphanumeric field
N = Numeric field

⚠ WARNING
Patient data affect the diagnosis, so make sure that data are correct.



On clicking **Options** a drop-down appears with the following options:

REGISTER: Registers a new patient. A dialog box appears for entry of the new reference number. The program warns if the reference has already been used for another patient.

DELETE: Deletes a patient and all that patient's tests

⚠ WARNING
This action cannot be undone. Please make sure you really want to delete the patient and its associated tests.

UNDELETE: Undeletes the deleted records. To use this function you need to access the Options menu from the main window and select Database -Maintenance and then activate the Show deleted records option.

FIND: Finds the file for the required patient. You can search by reference, surname or record number.

EXPORT: Opens the export window.

EXIT: Returns to the previous window.

The find and test data options are also available from the icons in the lower part of the window.

You can also use the slow tab keys (advance one record at a time) or the fast tab keys (move by 10 records at a time) to navigate through the database to find the required card.

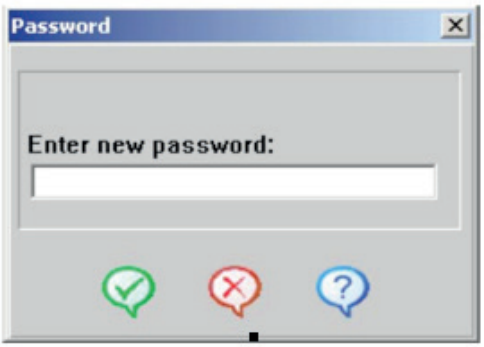
The card shows the number of records in the database and the number of the selected record.

DATABASE MAINTENANCE

This Maintenance option refers only to the database on the computer, not the one in the audiometer. For information on the latter refer to the relevant Instruction Manual for the device. The options provided are:

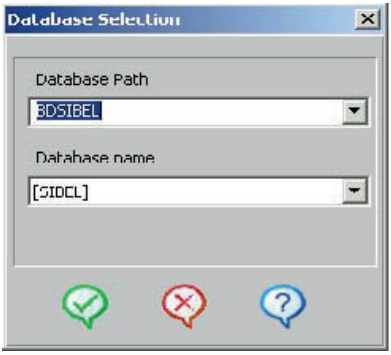
CHANGE PASSWORD

Changes the password for a database. The system requests the new password and confirmation of the latter.



SELECT DATABASE

Allows a database to be selected. To do this enter the **path** where it is located and select the database by **name**.



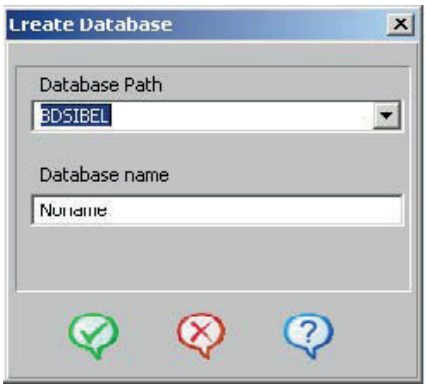
The path could be relative (e.g. BDSIBEL\BASE), or absolute (e.g. C:\BDSIBEL\BASE). Network drives can also be used, provided they are shared and have been given the necessary reading and writing permissions.

NOTE
In case of doubt, consult the system administrator.

The path can be selected using the drop-down menu, or entered using the keyboard. On selecting a path, the available Databases are listed, in the lower drop-down, DATABASE NAME. On selecting a Database the following error message may be displayed: "**Not a Database**". If this happens and the file selected does actually correspond to a Database, the latter must
be recreated with the same name and in the same location. This can be done by selecting the "Create Database" option from Options menu -Database -Database Maintenance. The existing data **WILL NOT BE LOST**. On confirming the selected database, the PASSWORD is requested. Provide the same password as entered when the database was created.

CREATE DATABASE

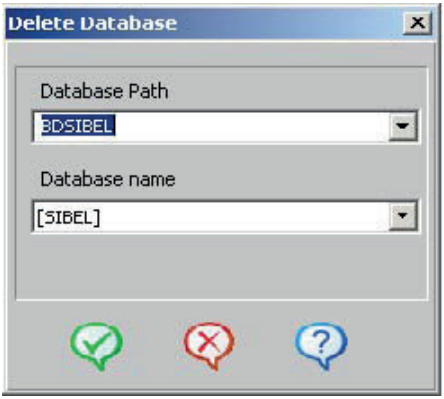
Creates a database. Enter the **path** and the **name of the databas**e. On confirming the name, a **password** is requested. The password must be entered a second time to confirm it.



DELETE DATABASE

On selecting the delete database option, the window lists the database or databases available and the user selects the one they wish to delete. On confirming the database to be deleted, the corresponding PASSWORD is requested. Provide the same password as entered when the database was created. **When a database is deleted** not only are the patient records eliminated but also corresponding graphs, parameters and **any other information recorded**. It is very important to use a password which can be easily remembered.

If the password is forgotten, contact the **SIBEL S.A.U.** Aftersales Service who will explain the process to follow.



⚠ WARNING
Deleting the database will erase all information about patients and its related tests. This action cannot be undone. Please make sure you really want to delete the database before continuing.

COMPACT DATABASE

This option is used to **permanently delete** records marked for deletion by the user and reorganise the remaining records in the database. This option can be used as often as the user wishes but may take some time to carry out, depending on the volume of data stored.

REINDEX RECORDS

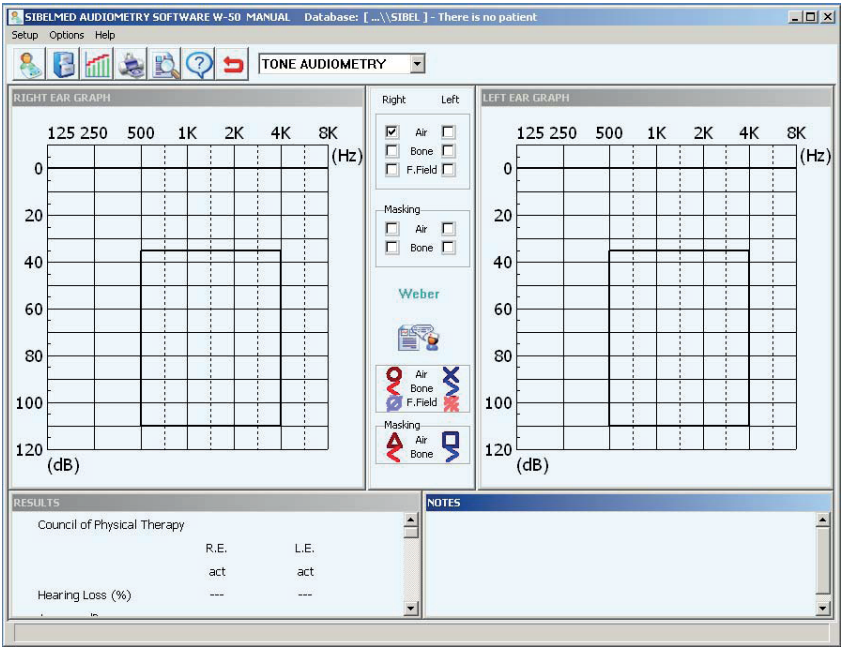
Allows a database to be **reorganised** whenever any problem with it is encountered. This option can be used as often as the user wishes but may take some time to carry out, depending on the volume of data stored.

SHOW DELETED RECORDS

When a Database record is deleted, it remains hidden but is not permanently deleted unless the compact database option is used. You can use this option at any time to see the records marked for deletion.

AUDIOMETRY

In this section we describe the various windows and functions which are specific to audiometry. The various audiometric tests and the procedure to carry them out are described in Chapter 3.



This window enables the user to view the results obtained on carrying out an audiometric test using the **SIBELSOUND 400** audiometer (select **SIBELSOUND 400** in the Setup/Links windows), **SIBELSOUND DUO** audiometer (select **SIBELSOUND DUO** in the Setup/Links windows) or manually enter the data obtained on carrying out an audiometric test using another audiometer (select MANUAL NOTATION in the Setup/Links window).

The following options are available from the **men**u:

SETUP MENU
See the Topic MAIN MENU / SETUP MENU

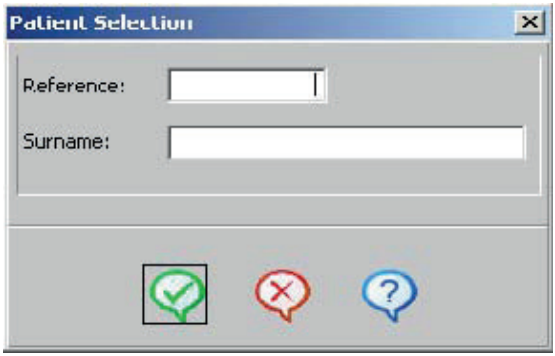
OPTIONS MENU

TESTS

Allows selection of the required audiometric test: Pure Tone Audiometry, Logoaudiometry, Sisi Jerger, Fowler, Tone Decay, Lüscher or Weber. The SIBELSOUND DUO can only perform tone audiometry tests in real time.

NEW PATIENT

Allows selection of a patient in the database or creation of a new one. To do this enter the patient reference.

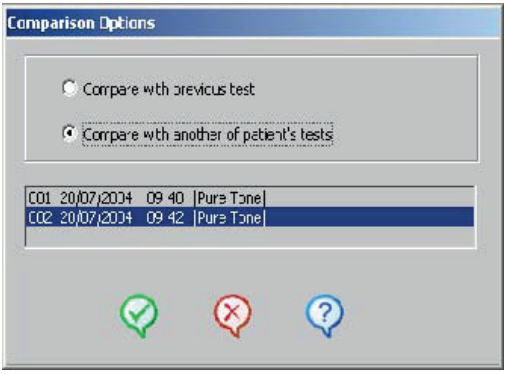


SAVE IN THE DATABASE

Saves the test in the database.

COMPARE

Selects a test against which to make a comparison: Previous test / Other test (in the latter case a window appears for selection of a test from the list of tests for the patient). On selecting a test for comparison, it is displayed superimposed.



PRINT REPORT

Prints a report based on the current test.

PRINT PREVIEW

See the Topic MAIN MENU / OPTIONS MENU / DATABASE / EXPLORE DATABASE

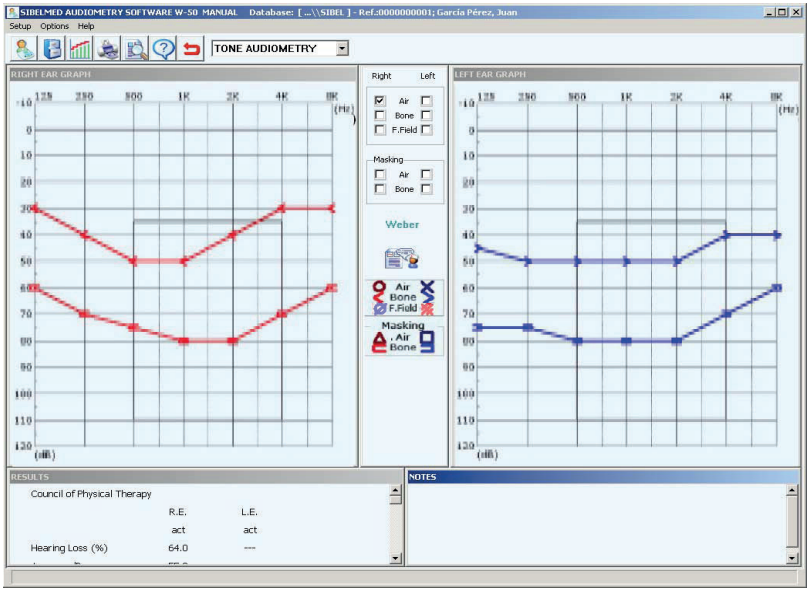
ORGANISE WINDOWS

This option allows the user to make proportionate changes to those windows which have been selected. The user can adjust the window sizes using the mouse and dragging any of the sides or vertices of a window.

HELP MENU

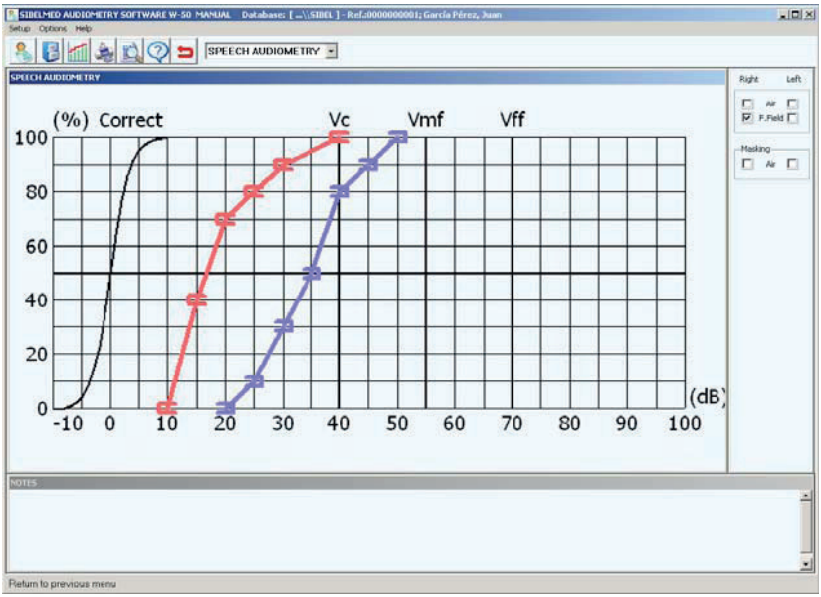
See the Topic MAIN MENU / HELP MENU
The following options are also available from the **icons** at the top of the window: New Patient, Save to database, Compare, Print Report, Print Preview, Help and Exit.
Test selection can also be carried out using the **drop-down menu** at the top of the window.
Depending on the selected test the following windows appear:

PURE TONE THRESHOLD AUDIOMETRY



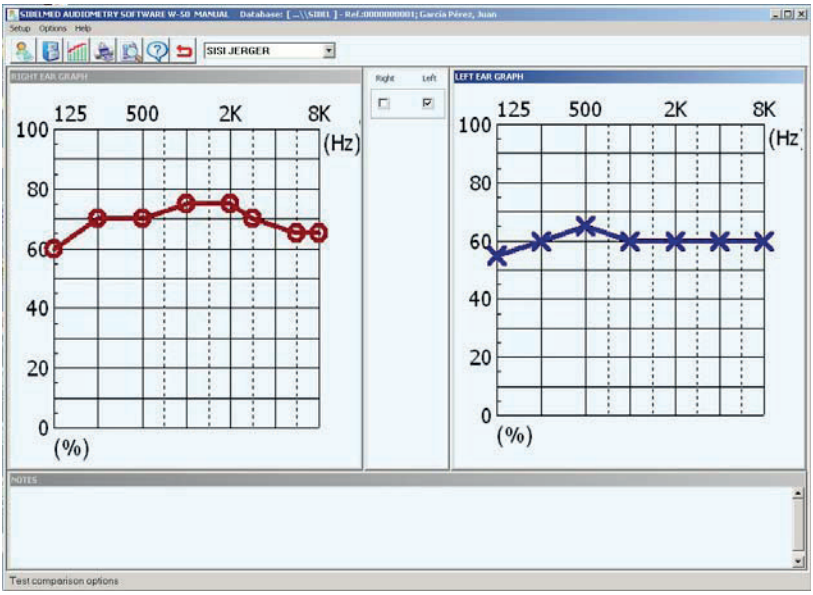
- Window showing graph of Intensity v Frequency for the right ear
- Window showing graph of Intensity v Frequency for the left ear
- Central window for:
  - Selection of route (Air, Bone, Free)
  - Selection of masking
  - Weber Test
  - Access to diagnosis
  - Legend showing symbols for identification of conduction and masking
- Results window (Hearing loss, Average dB, Bilateral loss)
- Notes window

SPEECH AUDIOMETRY



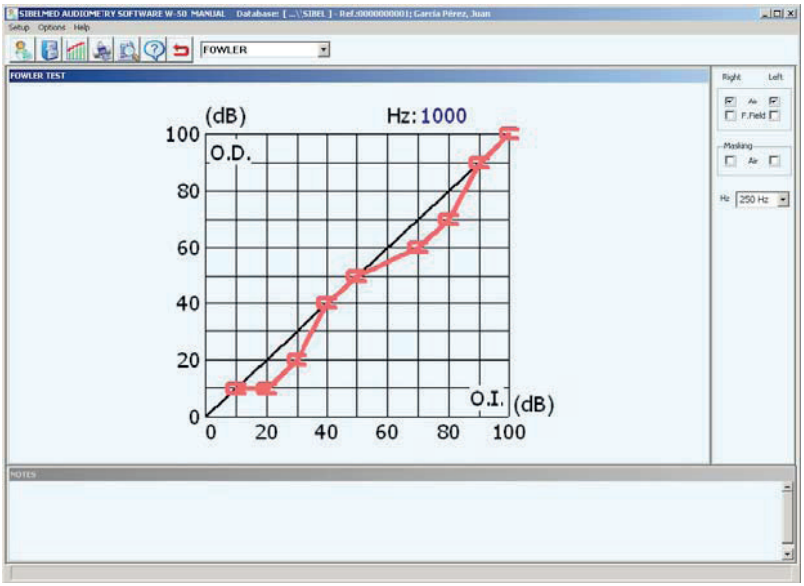
- Window showing graph of Correct detections v Intensity
- Window for:
  - Selection of conduction (Air, Free)
  - Selection of masking
  - Notes window

SISI



- Window showing graph of Correct Detections v Frequency for the right ear
- Window showing graph of Correct Detections v Frequency for the left ear
- Window for ear selection
- Notes window

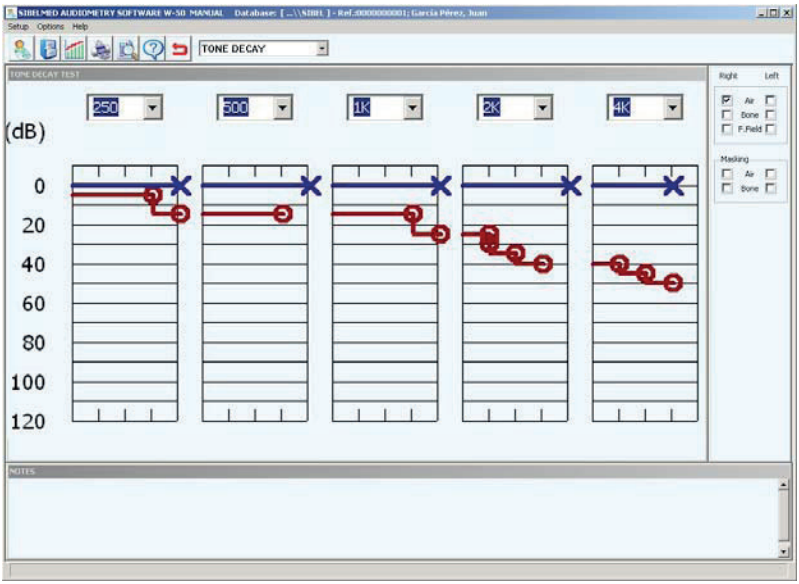
FOWLER TEST



- Window showing graph of intensities

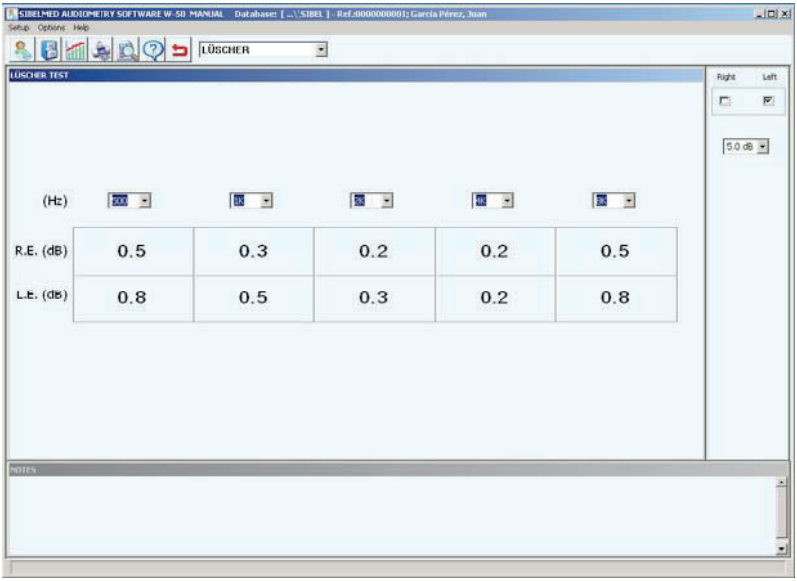
- Window for:
  - Selection of ear
  - Selection of frequency (125 Hz to 8000 Hz)
  - Notes window

TONE DECAY TEST



- Window showing graph of Intensity v Frequency
- Window for:
  - Selection of conduction (Air, Bone, Free)
  - Notes window

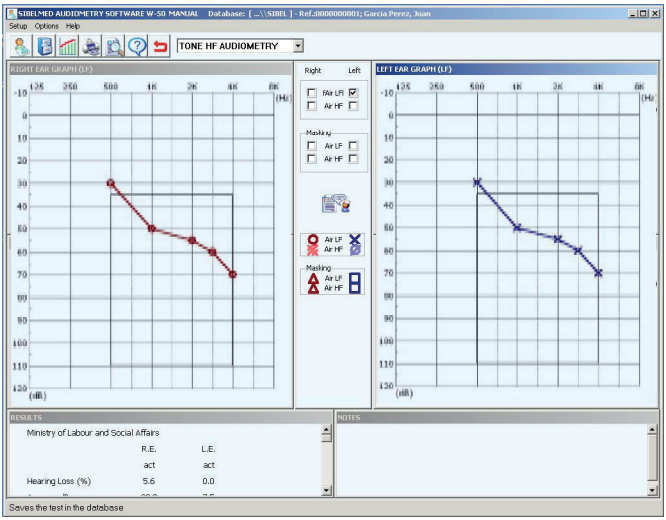
LÜSCHER TEST



- Window showing table of intensities for each frequency

- Window for:
  - Selection of ear
  - Selection of intensities (0.2 dB to 5 dB)
  - Notes window

PURE TONE HF AUDIOMETRY



- Window showing graph of Intensity v Frequency (LF) for the right ear
- Window showing graph of Intensity v Frequency (HF) for the right ear
- Window showing graph of Intensity v Frequency (LF) for the left ear
- Window showing graph of Intensity v Frequency (HF) for the left ear
- Central window with:
  - Selection of conduction (Air LF and Air HF)
  - Selection of masking
  - Access to diagnoses
  - Legend showing symbols for identification of conduction and masking
- Results window (Hearing loss, Average dB, Bilateral loss)
- Notes window

MANUAL ENTRY

Select this option from Setup + Links on the main window. On accessing the tests window (Options + Audiometry) you can enter data manually from an audiometric test carried out with another audiometer. To do this you must:

1 Select new patient (icon or Options menu + New patient)

2 Enter the latter's reference (can be new or an existing reference if the patient has already been registered in the database)

3 Enter the required data in the patient and test cards

4 Select the relevant test from the drop-down menu at the top of the window or from the Options menu + Tests.

5 Depending on the test, various options are available with regard to the application of signal and masking (see description of test windows above). Select the required options.

6 Enter the data obtained, moving the cursor to the graph point corresponding to the result then clicking the left mouse button, and repeating for all data. These points are joined creating a graph of the test.

Once all the data has been entered you may:

- Enter notes by double-clicking on the notes window
- Save the test to the database (icon or Options menu + Save in the database)
- Print a report of the test (icon or Options menu + Print Report)
- Compare with other tests (icon or Options menu + Compare)
- Delete a point (right-click above the point).

IMPORTS TESTS

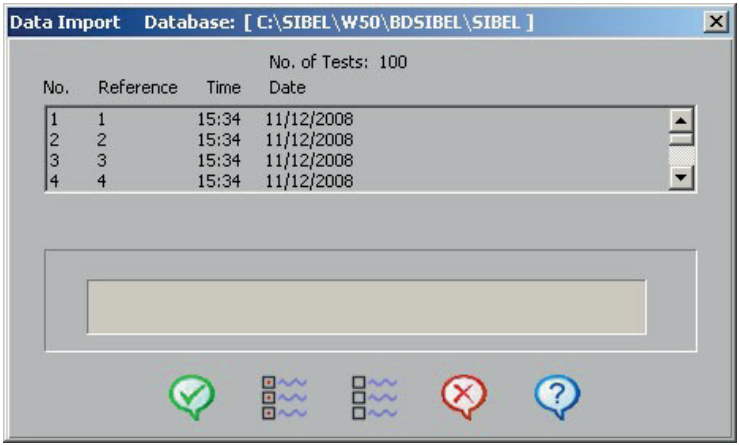
IMPORT TESTS

This option allows downloading each of the tests stored in the audiometer and generating their corresponding PDF and XML files. These files are generated automatically during the download process and are stored in the folders selected in the Interoperability menu.

Select the required tests by clicking on each one individually, or select all of them using the Select All button (to unselect a test click on it or click the Unselect All button).

Click the **OK** button to import the selected tests. The bar at the foot of the window indicates that the import process is in progress. At the end of the process it indicates that the data import is complete. At this point the tests have been saved in the database.

Click **Cancel** to return to the previous window without loading data.



DELETE TESTS ON THE DEVICE
Deletes tests stored in the audiometer.

2.4.5 HELP MENU

SHOW HELP
Opens the W50 user manual in the PDF viewer selected by default.

VISIT SIBELMED WEBSITE
Open the SIBELMED website in the default browser.

ABOUT ...
This screen reports the version of the program, as well as the data of **SIBEL S.A.U.** for any question you wish to make.

3. AUDIOMETRY

3.1 INTRODUCTION

The purpose of audiometry is to chart changes in hearing in response to acoustic stimuli.

The ear comprises two groups of anatomical structures:

- The Transmission System (middle and outer ear) which transmit vibrations to the inner ear.

- The Perception System which constitutes the sensory organ proper (inner ear with cochlea, nervous pathways and higher auditory centres).

3.2 TYPES OF AUDIOMETRY

There are three types of audiometry:

3.2.1 PURE TONE THRESHOLD AUDIOMETRY

This involves determining the minimum hearing thresholds for different frequencies by air conduction and bone conduction.

It is considered that the **hearing threshold** is the sound level at which, under specific conditions, a person achieves a response rate of 50% correct detections over a series of repeated trials.

Air conduction involves transmission of sound via the outer and middle ear to the inner ear. **Bone conductio**n involves transmission of sound to the inner ear principally via mechanical vibration of the cranial bones.

WEBER TEST

For this test all frequencies between 250 and 8000 Hz must be investigated, at 15 dB above the subject's frontal bone threshold. The vibrator is applied frontally, held in place with a headband not by hand, as the latter might allow variation pressure which could lead to error. A note is made of which side the patient perceives

the sound to be coming from. This test is fundamental in clinical audiometry; its physiopathological significance is considered subsequently, for purposes of diagnosing deafness.

PURE TONE HF

It consists of realizing a pure tone audiometry in a range of frequencies extended up to 20.000 Hz. Unlike the classic pure tone audiometry, hearing thresholds are only inspected by air conduction.

3.2.2 PURE TONE SUPRATHRESHOLD AUDIOMETRY

These tests are for evaluation of distortions in the sensation of sound due to disorders in the perception System.

These tests include:

SISI TEST

This involves having the patient hear a continuous, pure sound at 20 dB above the threshold, for two minutes. Every 5 seconds the intensity of the sound increases by 1 dB for 2/10 sec. The patient must signal the occurrence of this brief change in intensity, every time they perceive it.

- If they detect less than 20% of the instances, the test is negative.
- If they detect between 20% and 60% of the instances, the test is inconclusive.
- If they detect more than 60% of the instances, the test is positive.

FOWLER TEST

This tests the balance between the left and right ears. This involves comparing, at the same frequency, the equality of the level of sound intensity between the two ears. This is aimed more

at predominantly unilateral deafness: the two ears must not be identical.

TONE DECAY TEST

This involves exposing the patient to a pure tone at 5 dB above the hearing threshold and observing whether it is perceived clearly for 60 seconds. Normally it would be perceived throughout this period. If not, the level is increased in 5 dB steps until it can again be heard and again successively until the patient confirms they can hear the sound for one minute.

LÜSCHER TEST

This involves distinguishing variations in the modulation of the signal. For the ear to perceive an increase or decrease in physical intensity as a change in subjective intensity (sonority), the physical intensity must change by more than a certain value. This small change in physical intensity which the ear can perceive is called the differential threshold.

3.2.3 SPEECH AUDIOMETRY

Speech audiometry essentially consists of determining the threshold of intelligibility (the patient hears and understands words pronounced) using a list of words spoken live or via recorded material.

3.3 APPLICATIONS OF AUDIOMETRY

The main applications of audiometry are:

1 Obtaining a diagnosis

To provide a diagnosis of hearing loss in a patient in one or both ears. To do this we calculate the percentage hearing loss, the (global) bilateral percentage hearing loss and the average dB hearing loss.

To evaluate distortions in the sensation of sound using

suprathreshold pure tone tests.

To determine the threshold of intelligibility by means of speech audiometry or logoaudiometry.

2 To evaluate incapacity or invalidity

3 Public Health

- Epidemiological prevalence studies
- Environmental effects studies
- Occupational studies

3.4 DIAGNOSES

The **W50 SOFTWARE** calculates and prints the following diagnoses:

1«MINISTRY» DIAGNOSIS ACCORDING TO THE MINISTRY OF LABOUR AND SOCIAL AFFAIRS OSB No. 22 (January 26, 2000)

2 DIAGNOSIS OF THE COUNCIL OF PHYSICAL THERAPY

3 ELI (Early Loss Index)

4 SAL INDEX (Speech Average Loss)

5 KLOCKHOFF DIAGNOSIS (Modified by the Lavoro Clinic of Milan)

The parameters for each diagnosis and the calculation method of each are described in APPENDIX 2 of this manual.

Diagnoses are only calculated for Pure Tone and Pure Tone HF tests. If both tests are performed, only Pure Tone test results are shown.

4. TECHNICAL SPECIFICATIONS

4.1 SOFTWARE COMPATIBILITY AND COMPUTER REQUIREMENTS

The setup of the computer must be carried out in accordance with its Instruction Manual.

The computer used must comply with the following minimum requirements

Hard Disk:	> 20 GB
RAM memory:	> 1GB
Graphic card:	1024 x 768 or higher
Monitor:	15” or higher
Ports:	USB 2.0 / 3.0
Operating system:	Windows 10 (32 / 64 bits) Windows 11

4.2 PARAMETERS

- Hearing Loss (%)
- Average Loss (dB)
- Bilateral Loss (%)
- Diagnosis (Minitry of Labour Social Affairs)
- Diagnosis (Council of Physical Therapy)
- Diagnosis (Eli index)
- Diagnosis (Sal index)
- Diagnosis (Klockhoff index)

4.3 AUDIOMETER COMPATIBILITY

The software can be used with the following audiometers:
- SIBELSOUND 400 models A, AM, AO, AOM, AOM+ and SUPRA
- SIBELSOUND DUO models A and AOM

4.4 PERSONALISING THE PROGRAM

Software Configuration by the user at the level of:

- Type of printer
- Parameters and other
- Language
- Databases
- Communication links with the software

4.5 DATABASE

- Own database. Possibility of creating more than one database and selecting the one to work with.
- Storage of tests
- Registration, deletion and changes to patient cards
- Quick search of the database by: -Record -Reference -Surname
- Printing reports from the database
- Importing / Exporting tests

4.6 USEFUL LIFE

- 7 years

4.7 STORAGE

Store the USB Flash memory drive between -25ºC and 70ºC. Relative humidity must be below 90% (without condensation)

4.8 DIRECTIVES AND STANDARDS

- European Medical Device Regulation (EU) 2017/745.
- General Data Protection Regulation (EU) 2016/679.
- Implementing Regulation (EU) 2021/2226 regarding electronic instructions for use of medical devices.
- Quality (EN ISO 13485:2016+A11:2021, EN ISO 9001:2015)
- Risk management (EN ISO 14971:2019 + A11:2021)
- Medical equipment software (EN 62304:2006 + AC:2008 + A1:2015)
- Usability (EN 62366-1:2015 + A1:2020)
- Documentation and information (EN ISO 20417:2021, EN ISO 15223-1:2021)
- Safety of medical equipment (EN 60601-1:2006+AC:2010+A11:2011+A1:2013)
- Audiometric test methods: EN ISO 8253-1:2010, EN ISO 8253-2:2009, EN ISO 8253-3:2022

4.9 SYMBOLS



MANUFACTURER (Manufacture data, name and address of the manufacturer)



DATA OF ANUFACTURE



TEMPERATURE LIMIT



HUMIDITY LIMITATION



ATMOSPHERIC PRESSURE LIMITATION



WARNING, RISK IDENTIFIED



MEDICAL DEVICE



BATCH NUMBER



REFERENCE



FOLLOW INSTRUCTIONS FOR USE



DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE WEEE DIRECTIVE



KEEP AWAY FROM WATER



FRAGILE

5. MAINTENANCE

The **W50 SOFTWARE** does not require specific maintenance, beyond what any computer program that manages data would require.

- Make a backup copy of the program in case the original becomes damaged.

- Make regular backup copies of the Databases used so they can be restored in the event of loss of information from the computer.

In the event of any problem, doubt, suggestion, etc. you may have before, during or after using the software, we recommend you follow the steps below:

1 Use the help windows available in the program

2 Use this User's Manual properly

3 Keep the program updated. You can check your current version in "HELP - ABOUT". Check the availability of new versions at https://www.sibelmed.com/support

4 Contact with the Technical Service of **SIBEL S.A.U.** at:

SIBEL S.A.U.
Rosellón 500 bajos
08026 BARCELONA (Spain)

TECHNICAL SERVICE
Tel. +34 93 433 54 50
FAX +34 93 436 16 11
e-mail : sat@sibelmed.es

5.1 CLEANING

The USB memory drive should be gently cleaned with a cloth moistened with soapy (neutral) water. Then it can be wiped dry. Particular care must be taken to ensure that no liquid enters the interior of the USB connector. Abrasive substances or solvents must be avoided. Keep the USB memory drive into its package when not in use.

APPENDIX 1. COMPLIANCE WITH THE GENERAL DATA PROTECTION REGULATION

This section is intended to facilitate the user compliance with the legislation in force in relation to the processing of personal data that are regulated and covered by the LOPD (Organic Law 15/1999, of December 13, on Protection of Personal Data) and the new General Data Protection Regulation (REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of individuals with regard to the processing of personal data personal data and to the free movement of such data.

A brief description of the fundamental points of said legislation is given and what needs be done with the **W50 Audiometry Software** and/or operating system in order to comply with the requirements of said law is described.

⚠ ADVERTENCIA
According to current legislation, the software's user is solely responsible for the storage and treatment of their patient data in accordance with the law.

⚠ ADVERTENCIA
Observance of the recommendations included in this section does, in no case, guarantee the full adaptation of user activity to the standards relating to data protection.

Identification and Authentication

The processes for user identification and authentication for use of the SOFTWARE W50 are performed by the PC's operating system. Therefore only Windows Operating Systems which allow the performance of said processes in a secure way are valid, i.e. Windows 10 and Windows 11 with an NTFS file structure. Windows 9x systems or FAT file structures are not valid.

The PC administrator must create a unique and personalized identification for each user and activate authorization verification. The operating system saves the passwords in an unintelligible way.

Access control

The Operating System must be set up to control the access to data, i.e. permit or deny access to data. Likewise, the PC administrator must set up the user account lock in order to impede reiterated attempts for unauthorized access, limiting 3 incorrect attempts. Consult the manual for the operating system in order to set up said system access controls.

Access register

Accesses to the different databases are stored on the one access register file.

Back-up copies (back-up and recovery)

The user must, at least once a week, make back-up copies of all data in order to guarantee full recovery of data in the case of a computer system failure. In the case of the Audiometry Software, full recovery of all database data is guaranteed if the entire BDSIBEL directory of the application directory is saved.

Said back-up copy must be stored at all times in a different place to where the equipment on which the software is used is located.

Operating System Setup

On a Windows operating system level (Windos 10 and 11) and for NTFS partitions, it is possible to restrict the access to the different databases using the security characteristics of said file system. Generally speaking, the control of access to databases is covered by the following points:

Setup of Identification and authentication

Each user that accesses the system must have a unique username and password, whether a local user or a network user connecting to a domain. The passwords must be changed at least once a year and, whilst a series of passwords remain valid, they will be stored in an unintelligible way.

User definition can be carried out from the Users and Passwords icon on the Control Panel. Using the Advanced Administration button on the Advanced Options tab you can access the Local and Group Users setup. From the Users branch, new users can be created or existing properties modified. The access level of users can be set up in user properties on the Users tab of the Users and Passwords icon. We recommend that users are not given Administrator access level. In any event, the Administrator is the person responsible for ensuring that users use their identification in the ways determined both technically and by documentation, as well as making them aware of their obligations in relation to the treatment of personal data.

It is also advisable to activate the security audit in order to register valid and erroneous accesses to the system.

Access setup and control: File access grants

The following step is to set up the access levels to the files which form the databases in relation to the previous users. The database root can be found in the <W50_HOME>\Bdsibel directory. Inside, there is a subdirectory per database, as well as the register file «log» W50.log. One possible setup is to provide full access to the <W50_HOME>\Bdsibel directory to all users (or al least to the application users) and to restrict access to each of the subdirectories according to the user that they belong to. In any event, the owner must always have read and write access for their subdirectory and the files that make up the subdirectory. The rest of the users may have access to said database totally denied, for example. It must be taken into account that in this situation the users may only access their database from the application. On the log file W50.log level, it would be advisable for the users to only have read access so that the application could register the accesses to the different databases.

Permissions can be applied from Windows Explorer itself. Simply access the Properties of the directory of file to which you wish to establish permissions and select the Security tab. From this tab you can select both the users who may access and the permissions (total control, read, modification, write, etc.) of each user.

Encryption of data

It is advisable to proceed with the encryption of the data. For that, the tool Bitlocker, included in the operating system (in Pro versions), can be used or some other tool available from third parties.

File audit.

We recommend the activation of the log file audit in order to register on the security event viewer the actions performed upon it.

To activate this option, you must first enable the audit of said file. At this level, you must specify the users (according to the users which access the <W50_HOME>\Bdsibel directory) and types of access to be audited. The log file audit can be activated from the Security tab of the file Properties. Using the Advanced button you can access the Audit tab. From here, simply add the users and the type of access to be audited. It must be taken into account that if all actions upon the log file are audited, the security events viewer will have many more entries and will complicate the monitoring of unauthorized accesses.

The next step is to activate the audit of access to objects in the local security setup. To do so, access the Administrative Tools icon from the Control Panel. Once there, you must select the Local Security Directive and the Local Directives branch from the directives. You must then access Audit Access to Objects. Both correct and erroneous accesses can be enabled.
Finally, other files must be audited, for example password files <W50_HOME>\Bdsibel\<DB_NAME>\PW.TXT if access to the DB_NAME database by other users has not been completely limited.

Access register description

Access to the different databases are stored on the one log file (W50.log) in the BDSIBEL folder of the directory where the

application is installed (by default C:\SIBEL\W50 and from now on <W50_HOME>\Bdsibel).

This file is created the first time that the application is executed and cannot be deactivated. The system administrator is responsible for the maintenance of said file with regard to size, and the preparation of a monthly report where the periodic reviews carried out are analyzed and any problems detected are reported, should there be any.

The log file is saved by line:

- User
- Time and date of access
- Database accessed
- Action carried out on the database
- Type of access (authorised or denied)
- File path of database accessed
- Reference of the record accessed

The format of each of the lines is the following:

[USER], [YYYYMMDD HH:MM:SS], [BASE], [ACTION], [ACCESS], [PATH], [REFERENCE]

The database comprises a directory and two data files (paciente.dbf and pruebas.dbf) as well as auxiliary files (indexes, etc.). The actions to be recorded are divided into:

- Action on the actual database itself (open, close, delete, etc.)
- Action on the records stored in the paciente.dbf and pruebas.dbf data files (insert, find, delete, etc.)

In any event, the register or access control «log» file, must be kept for a minimum period of two years.

Below, all actions registered on the log file are listed:

- Opening a db file
- Closing a db file
- Selecting a db
- Creating a db

- Creating a db file
- Deleting a db
- Deleting a db file
- Re-indexing a db file
- Compacting a db file
- Changing password
- Finding a record
- Adding a record
- Marking a record
- Recovering a record
- Changing a record
- Deleting a record
- Exporting a record
- Importing a record

Other important subjects

· Printing documents:

In the case of storage for paper prints containing patient details, it is required that said documents remain duly safeguarded in such a way that only duly authorized personnel have access to them. Likewise, in the case of a user deciding to dispose of the printed documents, it will be necessary to ensure their effective physical destruction in order to avoid unauthorized access to data.

· Exporting tests

The software allows for tests to be exported only if the user is identified and authorized to read the database. Once the test has been exported to a file, the software user is responsible for the security of said file, and its later deletion.

· Data transmission:

The software permits the transmission of files with patient data via the internet. If this functionality is used, the user must configure their e-mail server so that the data is encrypted before transmission and is therefore converted into unintelligible data for any unauthorized access.

APPENDIX 2. CALCULATION TABLES FOR DIAGNOSES

1. "MINISTRY" DIAGNOSIS

The percentage of hearing loss is determined by the pure from the tonal audiogram for the 500, 1000, 2000 and 3000 Hz frequencies, and according to the evaluation criteria for discapacity due to hearing deficiency as established by the Spanish Ministry of Labour and Social Affairs in OSB No. 22 of January 26, 2000.

A. Monoaural hearing loss

• Add up the hearing thresholds from the 4 frequencies for each ear.
• Hearing Loss (%) = Value from Table 1 corresponding to the sum of the thresholds. If the sum result is below 100 dB, it will not be classed as hearing loss.
• Average dB = (total thresholds) / 4.

B. Bilateral hearing loss

• Bilateral Loss (%) = (5 * (loss % in the best ear) + (loss % in the worst ear)) / 6.

Table 1. CONVERSION OF THE ESTIMATED HEARING LEVEL IN PERCENTAGE OF MONOAURAL HEARING LOSS.

dshl, dB	% loss	dshl, dB	% loss	dshl, dB	% loss	dshl, dB	% loss
100	0.0	170	26.2	240	52.5	310	78.8
105	1.9	175	28.1	245	54.4	315	80.6
110	3.8	180	30.0	250	56.2	320	82.5
115	5.6	185	31.9	255	58.1	325	84.4
120	7.5	190	33.8	260	60.0	330	86.2
125	9.4	195	35.6	265	61.9	335	88.1
130	11.2	200	37.5	270	63.8	340	90.0
135	13.1	205	39.4	275	65.6	345	90.9
140	15.0	210	41.2	280	67.5	350	93.8
145	16.9	215	43.1	285	69.3	355	95.6
150	18.8	220	45.0	290	71.2	360	97.5
155	20.6	225	46.9	295	73.1	365	99.4
160	22.5	230	48.9	300	75.0	370	100.0
165	24.4	235	50.5	305	76.9		

C. Categories of Hearing Loss

The 'MINISTRY diagnosis do not establish a hearing loss diagnostic classification. The WHO 2021 system indicated in section 7 is used.

2. "COUNCIL" DIAGNOSIS

The percentage of hearing loss is determined from the tonal audiogram, and according to the 2nd formula of the Council of Physical Therapy. A percentage of hearing loss is applied to each ear at the 500, 1000, 2000 y 4000 Hz frequencies, according to the corresponding threshold.

A. Monoaural Hearing Loss

• In Table 2, look for the correspondence between the hearing thresholds for each frequency and their % of hearing loss.
• Hearing Loss (%) = Sum of the hearing losses for all four frequencies.
• Average dB = (total thresholds) / 4.

B. Bilateral Hearing Loss

• Bilateral Loss (%) = (7 * (loss % in the best ear) + (loss % in the worst ear)) / 8.

C. Diagnostic Classification of the Hearing Impairment

The 'COUNCIL' diagnosis do not establish a hearing loss diagnostic classification. The WHO 2021 system indicated in section 7 is used.

Table 2. COUNCIL OF PHYSICAL THERAPY

Loss in dB	500	1000	2000	4000
5				
10	0.2	0.3	0.4	0.1
15	0.5	0.9	1.3	0.3
20	1.1	2.1	2.9	0.9
25	1.8	3.6	4.9	1.7
30	2.6	5.4	7.3	2.7
35	3.7	7.7	9.8	3.8
40	4.9	10.2	12.9	5.0
45	6.3	13.0	17.3	6.4
50	7.9	15.7	22.4	8.0
55	9.6	19.0	25.7	9.7
60	11.3	21.5	28.0	11.2
65	12.8	23.5	30.2	12.5
70	13.8	25.5	32.2	13.5
75	14.6	27.2	34.4	14.2
80	14.8	28.8	35.8	14.6
85	14.9	29.8	37.5	14.8
90	15.0	29.9	39.2	14.9
95	15.0	30.0	40.0	15.0
100				

3. ELI

The ELI Index (Early Loss Index) is calculated from the 4000 Hz frequency, following the Specific Health Surveillance Protocol (Spanish Interterritorial Council of the National Health Service). The percentages of hearing loss are not indicated.

A. ELI Index

ELI Index = Threshold at 4000 Hz – Table 3 value according to age and gender

B. Diagnostic Classification of the Hearing Impairment

In Table 4, acoustic traumas are classified with an increasing A-B-C-D-E scale, from greater to lesser hearing capacity.

Table 3. CORRECTION FOR PRESBYACUSIA AT 4,000 Hz (Db) FOR CALCULATION OF THE ELI INDEX.

Age	Women	Men
25	0	0
30	2	3
35	3	7
40	5	11
45	8	15
50	12	20
55	15	26
60	17	32
65	18	38

Table 4. CLASSIFICATION OF ACOUSTIC TRAUMAS

Céorrected Audiometric Loss, dB	Degree of ELI	Classification
<8	A	Normal excellent
8-14	B	Normal good
15-22	C	Normal
23-29	D	Suspicion of deafness
>30	E	Clear indication of deafness

4. SAL INDEX

The SAL Index (Speech Average Loss) assesses conversational frequencies (500, 1000 and 2000 Hz), and is defined as the arithmetic mean of hearing loss, in decibels, at those frequencies.

A. Monoaural and Bilateral Hearing Loss

They are calculated in the same way as the MINISTRY diagnosis.

B. Diagnostic Classification of the Hearing Impairment

As per table 5.

When the best ear presents a decline of <16 dB and the worst ear >30 dB, it is considered that there are alterations which are excessively asymmetric, not considered in table 5. In this case, the following text appears:

'The deafness detected is excessively asymmetric to be evaluated using the SAL table'.

Table 5. TABLE FOR EVALUATION AND INTERPRETATION OF SAL INDEX.

Degree of Sal	dB	Class name	Characteristics
A	16 worse ear	Normal	Both ears are within normal limits, with no difficulty in quiet conversations.
B	16-30 one of the ears	Close to normal	Has difficulty with quiet conversations but nothing more.
C	31-45 better ear	Slight Auditory Loss	Has difficulties in normal conversations, but not if people speak up.
D	46-60 better ear	Serious Auditory Loss	Has difficulties even when people speak up.
E	61-90 better ear	Serious Auditory Loss	Can only hear a conversation using a hearing aid.
F	91-99 better ear	Profound Auditory Loss	Cannot hear a conversation even with a hearing aid.
G	> 100 better ear	Totally deaf in bothears	Can hear no sound at all.

5. KLOCKHOOF DIAGNOSIS (MODIFIED BY THE LAVORO CLINIC OF MILAN)

This diagnosis evaluates the 500, 1000, 2000 and 4000 Hz frequencies. The following criteria apply in accordance with Table 6.

Table 6. KLOCKHOFF CLASSIFICATION.

NORMAL	**The threshold does not exceed 25 dB at any frequency.**		
ISOLATED ACOUSTIC TRAUMA	**No conversational loss**	**LIGHT**	**The threshold at the 4000 frequency is below 55 dB and below 25 dB in the other frequencies.**
		ADVANCED	**The threshold at the 4000 frequency is above 55 dB and below 25 dB at the other frequencies.**
GLOBAL ACOUSTIC TRAUMA	**Conversational loss**	**LIGHT**	**One or more frequencies are not affected (are below 25 dB).**
		MODERATE	**All frequencies are affected (above 25 dB) but none is above 55 dB.**
		ADVANCED	**All frequencies are affected (above 25 dB) and one above 55 dB**
OTHER LOSS not due to exposure to sound.			

6. DIAGNOSTIC CLASSIFICATION OF HEARING LOSS

The **SIBELSOUND 400** audiometer provides a hearing loss classification system based on the 2021 World Health Organization (WHO) recommendations, as shown in the following table:

Grade	Hearing threshold‡ in better hearing ear in decibels (dB)	Hearing experience in a quiet environment for most adults	Hearing experience in a noisy environment for most adults
Normal hearing	Less than 20 dB	No problem hearing sounds	No or minimal problem hearing soundszzzz
Mild hearing loss	20 to < 35 dB	Does not have problems hearing conversational speech	May have difficulty hearing conversational speech
Moderate hearing loss	35 to < 50 dB	May have difficulty hearing conversational	Difficulty hearing and taking part in conversation
Moderately severe hearing loss	50 to < 65 dB	Difficulty hearing conversational speech; can hear raised voices without difficulty	Difficulty hearing most speech and taking part in conversation
Severe hearing loss	65 to < 80 dB	Does not hear most conversational speech; may have difficulty hearing and understanding raised voices	Extreme difficulty hearing speech and taking part in conversation
Profound hearing loss	80 to < 95 dB	Extreme difficulty hearing raised voices	Conversational speech cannot be heard
Complete or total hearing loss/ deafness	95 dB or greater	Cannot hear speech and most environmental sounds	Cannot hear speech and most environmental sounds
Unilateral	< 20 dB in the better ear, 35 dB or greater in the worse ear	May not have problem unless sound is near the poorer hearing ear. May have difficulty in locating sounds	May have difficulty hearing speech and taking part in conversation, and in locating sounds

‡ "Hearing threshold" refers to the minimum sound intensity that an ear can detect as an average of values at 500, 1000, 2000, 4000 Hz in the better ear.