SIBELSOUND 400

AUDIOMETRY

USER MANUAL

CE 0318

520-700-MU2 • REV. 3.02 • 2025-10

Sibelmed®

Revision: 520-700-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 security, reliability and performance of this equipment only if:
• The place where the systrem is installed or used meets the requirements for electrical installations IEC and other applicable regulations.
• All repairs, revisions or modifications, both in and out of the warranty period, are made by technical staff of SIBEL S.A.U.
• The system is used by qualified staff in accordance with the recommendations stated in this User's Manual.

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

CE 0318

Thank you for choosing **SIBELSOUND 400**!
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. **SIBELSOUND 400** is manufactured according to the European Medical Device Regulation and with the best quality standards.

Revised
Date: 2025-10
Technical Director

Approved
Date: 2025-10
Sales Director

1. SAFETY

The **SIBELSOUND 400** audiometer has been designed to the highest safety standards.
You should read all operating instructions carefully before operating the device. Failure to do so could cause injury to the user or patient and damage to the equipment and/or accessories.

Report any serious incident to the manufacturer and competent authority.

1.1 INTENDED USE

SIBELSOUND 400 is desktop audiometer designed for the diagnosis and follow-up of patients with hearing loss (hypoacusis) by means of generating acoustic and vibration stimuli.

The following conditions must be considered:

- Use exclusively by medical staff supervised and/or instructed by a medical doctor.
- Use in a health center or similar (not intended for outdoor use).
- Not intended for use in moving transport vehicles

1.2 USER PROFILE

The audiometer is designed to be used exclusively by health personnel, being supervised and instructed by a doctor. Specific training in the audiometry technique is recommended. Before using the audiometer on patients, the user should be familiar with the operation of the equipment. All information necessary for its operation is available in the Manual.

For additional training on the technique or on the product, contact **SIBEL, S.A.U.** or your dealer.

1.3 INDICATIONS FOR USE

SIBELSOUND 400 is a desktop audiometer indicated for applying acoustic and vibration stimuli to the patient's ears and recording the patient response. The graphical representation of hearing levels at different frequencies via air and/or bone conduction and the calculated parameters are helpful in assessing the hearing function of subjects.

SIBELSOUND 400 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. The audiometer is also indicated for an early identification of individuals at risk of developing hearing impairment or for medicolegal assessment.

SIBELSOUND 400 allows 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

- Age: more than 4 years until elderly
- Weight: without limitations
- Height: without limitations
- Health status: physical and mental condition that allows understanding instructions from health personnel, wearing the headphones or vibrator, and indicating auditory perceptions by means of a patient's response button or by gestures.

1.5 CONTRAINDICATIONS AND SIDE EFFECTS

No contraindications or side effects related to Sibelsound 400 have been identified.

1.6 LIMITATIONS FOR 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 health personnel administering the audiometry test must assess the patient's capability to perform it.

Special care should be taken when performing these tests on children, elderly and disabled persons.

1.7 ESSENTIAL OPERATION

The generation of acoustic and vibration signals is considered essential performance (in order to comply with the specified accuracy and/or not affect the patient's diagnosis), the presentation of results and the storage and integrity of the data in memory.
The communication with the computer, the printing of the results or the intercommunication signals are not considered essential operation, provided that the integrity of the data is guaranteed and that no data is transmitted incorrectly.

1.8 RESIDUAL RISKS

According to the application of the EN ISO 14971 standard, all risks related to the use of the **SIBELSOUND 400** have been reduced 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

The audiometer is not intended for use outdoors, nor in conditions or with energy sources other than as set out in this manual.

If you find any damage to the packaging, you should immediately contact the transport agency and the distributor before proceeding to install. You must not discard the packaging, bags, etc. Before thoroughly verifying that the equipment functions correctly.

The device should be placed in a safe position to prevent falls that may cause a damage to the equipment or harm to the patient and/or user.

The device should NOT be used stacked or adjacent to other equipment.

DO NOT use the **SIBELSOUND 400** in moving transport vehicles.

DO NOT cover the audiometer with objects that prevent proper air circulation while it is running.
DO NOT use transducers (headphones for air/bone conduction, loudspeakers, ...) that have not been calibrated with the audiometer. THAT COULD INVALIDATE THE AUDIOMETRIC TEST PERFORMED.

Handle accessories by their strongest parts (e.g. the connectors when manipulating the USB cable). DO NOT get them wet or expose them to very abrupt changes of temperature. DO NOT apply excessive stress to the accessories and the audiometer. In particular, avoid pulling or bending any part of the cables. DO NOT disconnect the cable from the device by pulling the cable. You can damage the device or accessories reducing the product's safety. Always hold the cable by the connector.

Use only the **SIBELSOUND 400** with accessories provided by the manufacturer or dealer, or those that meet the specifications of this manual. The use of other accessories with the **SIBELSOUND 400** can cause damage to the device, increase electromagnetic emissions or decrease immunity.

Contact of liquids with the internal parts of the device and the connectors must always be avoided.

In case of device over-heating during use, immediately turn off the device and please contact **SIBEL's After Sales Service** or your dealer.

The equipment must be stored and used within the temperature, pressure and humidity ranges specified in this manual.

In accordance with the various standards, we recommend testing and calibrating the electromedical equipment periodically to guarantee reliable operation of the functions and patient, user and environmental safety.

In addition to the necessary routine maintenance of the **SIBELSOUND 400** audiometer, we recommend calibrating the transducers and performing a general check of the safety systems, adjustments, functions, etc. at least once every twelve months (ISO 8253-1). This should also be done whenever there is reason to suspect that the equipment is malfunctioning.
These checks should be carried out by the manufacturer or by qualified technical staff authorized by **SIBEL S.A.U.**, in accordance with the manufacturer's (**SIBEL S.A.U.**) Procedures for Verification and Adjustment.

ELECTRICAL RISK

To ensure safety in accordance with standard EN 60601-1, only connect equipment which meets current electrical safety standards to this instrument.

DO NOT tamper with the integrity of the system's electric earth connection. Protection against electrical discharge is provided by the connection of the chassis to an electrical earth connection. The earth connection is only effective when the three-wire power cable supplied with the equipment is connected to a suitably earthed electrical socket.

DO NOT use multiple mains sockets, unless they comply with EN 60601-1. They can degrade electrical safety.

DO NOT remove the device cover. Servicing and repair of the apparatus must only be carried out by trained personnel.

Contact with the voltage inside the system can cause serious injury.

DO NOT use the equipment if the power cable is in poor condition or cracked.

DO NOT use the transducers if they are in poor condition.

NEVER immerse any part of the equipment in liquid. THIS COULD CAUSE AN ELECTRICAL DISCHARGE.

SIBELSOUND 400 can be used in conjunction with the software application W50 Audiometry Software, which runs on an external device. This device must comply with the current standards of electrical safety and electromagnetic compatibility.

RISK OF EXPLOSION

DO NOT use this equipment in the presence of anaesthetics or inflammable gases. THIS COULD CAUSE AN EXPLOSION.

RISK OF CONTAMINATION

Perform cleaning and maintenance of device and accessories with the specified frequency and following the instructions in this manual in order to keep product's safety.

INTERFERENCE RISK

This is an electronic product, so high frequency emissions can interfere with its correct use. For this reason, products which can cause interference (radios, mobile telephones, etc.) must be kept away from the audiometer.
SIBELSOUND 400 as an electronic device, and special precautions regarding Electromagnetic Compatibility must be taken. The device must be installed following the electromagnetic guide in Annex 1.

Do not use the system in and MRI environment.



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

ADVERTENCIA

DO NOT dispose SIBELSOUND 400 audiometer and/ or accessories with household waste. Deliver it in a designated collection point for recycling in accordance with the legal requirements of your country.

The unit uses a lithium button cell battery.

To obtain further information on the correct disposal of the product and its accessories, please contact **SIBEL S.A.U.** Customer Service or your distributor.

2. INSTRUCTIONS FOR INSTALLATION AND USE

2.1 INTRODUCTION

SIBELSOUND 400 is a desktop audiometer intended for the diagnosis and follow-up of patients with hearing loss (hypoacusis), by means of generating acoustic and vibration stimuli. Pure tone audiometry, both by air and bone conduction (with and without masking with noise), is the most common test for assessing hypoacusis caused by continuous exposure to high noise levels, exposure to peak intensity sounds, traumatic injuries, some illnesses or presbycusis caused by age. Speech audiometry test also allow the assessment of a subject's perception of speech. The inclusion of suprathreshold tests like Short Increment Sensitivity Index (SISI), Lüscher, Fowler, Tone Decay or Weber tests allows the evaluation of patients with sensorineural hearing loss. The audiometer generates sound signals of different frequencies and intensities, that could optionally include white or narrow band noise and amplitude or frequency modulation. The hearing threshold at each frequency and other parameters can be identified according to the responses of the patient when he/she is able to hear each signal. These parameters can be evaluated using several user-selectable interpretative algorithms programmed in the audiometer. Considering all this information, together with the clinical history of the studied subject, the health personnel is able to determine a diagnosis, to follow-up the progression of the disease or to evaluate the effectiveness of treatments.

The **SIBELSOUND 400** clinical audiometer is a compact two-channel device, the main components of which are a tone generator, a noise generator, a set of headphones for air conduction, a vibrator for bone conduction and an alphanumeric liquid crystal screen. The whole system is controlled by a Digital Signal Processor (DSP) that allows performing an audiometric exploration in a quick, simple and reliable way to establish hearing thresholds, to carry out screening tests and suprathreshold tests.

This user's manual applies to all models and all options which may be included in the **SIBELSOUND 400** audiometer. Accordingly, only those functions or options which are found in your particular model will be applicable.

2.2. SIBELSOUND 400 AUDIOMETER MODELS

The audiometer has six different models depending on the type of tests allowed (Air conduction, Bone conduction, Masking, Speech audiometry or Suprathreshold tests). Each model is classified in one of the 4 types and in the classes (speech audiometry) defined in EN 60645-1:2017 according to the following:

SIBELSOUND 400 A (Type 4)
SIBELSOUND 400 AM (Type 4)
SIBELSOUND 400 AO (Type 4)
SIBELSOUND 400 AOM (Type 3)
SIBELSOUND 400 AOM+ (Type 2, Class B)
SIBELSOUND 400 SUPRA (Type 2, Class B)

The table below shows each model's built-in features as **standard (Shaded)** and other items which can be included as **optional (White)**. You can upgrade to a higher model by adding the relevant features at any time. All you need to do is contact the **SIBEL S.A.U.** Sales Department or your distributor.

RELACIÓN DE CONTENIDO / PACKING LIST

SIBELSOUND 400 CE0318

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MODELOS / *MODELS*

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	AM	AO	AOM	AOM+	SUPRA
_____(*)	1	**SIBELSOUND 400** **SN: 207-_____(*)**						
_____	1	SIBELSOUND 400 MANUAL DE USO / *USER'S MANUAL* (Doc. 520-700-MU_(*)) Rev:_____						
_____	1	SIBELSOUND 400 GUIA RAPIDA / *QUICK GUIDE* (Doc. 520-711-GR_(*)) Rev:_____						
_____	1	CABLE CONEXIÓN DE RED 2m / *MAINS PLUG CABLE 2m*						
03658	1	CABLE USB TIPO A-B 2.0 / *USB CABLE TYPE A-B 2.0*						
01807	1	PULSADOR AVISO PACIENTE / *PATIENT RESPONSE BUTTON*						
09460	1	CONJUNTO AURICULARES DD45 / *EARPHONE SET DD45*						
02258	1	CONJUNTO VIBRADOR VIA OSEA / BONE VIBRATOR SET						
03024	1	SOFTWARE W50 / *W50 SOFTWARE* Clase IIa CE0318 MANUAL USO (en el pen USB)/ *USER MANUAL (Included in USB pen)*						
(02303)	1	LICENCIA W50 / *W50 LICENSE*						
00807	1	OPCION LOGOAUDIOMETRÍA Compuesto por: *SPEECH AUDIOMETRY OPTION Composed by:*						
03623	1	• MICROFONO DOCTOR ELECTRET-PINZA / *ELECTRET CLIP MICROPHONE*						
03573	1	• ADAPTADOR JACK 3.5H/6.3M / *JACK ADAPTER*						
07029	1	• MODULO MONITOR-INTERCOMUNICADOR Compuesto por: *MONITOR MODULE Composed by:*						
01383	1	○ AURICULAR MONITOR / *MONITOR EARPHONE*						
03623	1	○ MICROFONO PACIENTE ELECTRET-PINZA / *ELECTRET CLIP MICROPHONE*						
03573	1	○ ADAPTADOR JACK 3.5H/6.3M / *JACK ADAPTER*						
OTRAS OPCIONES Y COMPONENTES / *OTHER OPTIONS AND COMPONENTS*								
03078	1	SUPRESOR DE RUIDO VA / *AUDIOCUPS AC*						
01507	1	BOLSA DE TRANSPORTE / *CARRING BAG*						
07029	1	MODULO MONITOR-INTERCOMUNICADOR Compuesto por: *MONITOR MODULE Composed by:*						
01383	1	• AURICULAR MONITOR / *EARPHONE MONITOR*						
03623	1	• MICROFONO PACIENTE ELECTRET-PINZA /*ELECTRET CLIP MICROPHONE*						
03573	1	• ADAPTADOR JACK 3.5H/6.3M / *JACK ADAPTER*						
02559	1	OPCIÓN CAMPO LIBRE / *FREE FIELD OPTION*						
07431	1	• JUEGO ALTAVOCES CAMPO LIBRE / *FREE FIELD LOUDSPEAKER SET*						
10195 **ó** 03573	1	• CABLE RCA M a JACK 6.3M / *RCA M to JACK 6.3 M CABLE* **o** ADAPTADOR JACK 3.5H/6.3M / *JACK ADAPTER*						
02557	1	OPCIÓN ALTA FRECUENCIA / *HIGH FREQUENCY OPTION*	---	---	---			
07429	1	• AURICULARES ALTA FRECUENCIA/ *HIGH FREQUENCY EARPHONE SET*						
03573	1	• ADAPTADOR JACK 3.5H/6.3M / *JACK ADAPTER*						
02558	1	OPCIÓN AUD. TONAL VIA OSEA / *BONE CONDUCTION PURE TONE AUDIOMETRY OPTION*						
02258	1	• VIBRADOR VIA OSEA / *BONE VIBRATOR SET*						

RELACIÓN DE CONTENIDO / PACKING LIST

SIBELSOUND 400 CE0318

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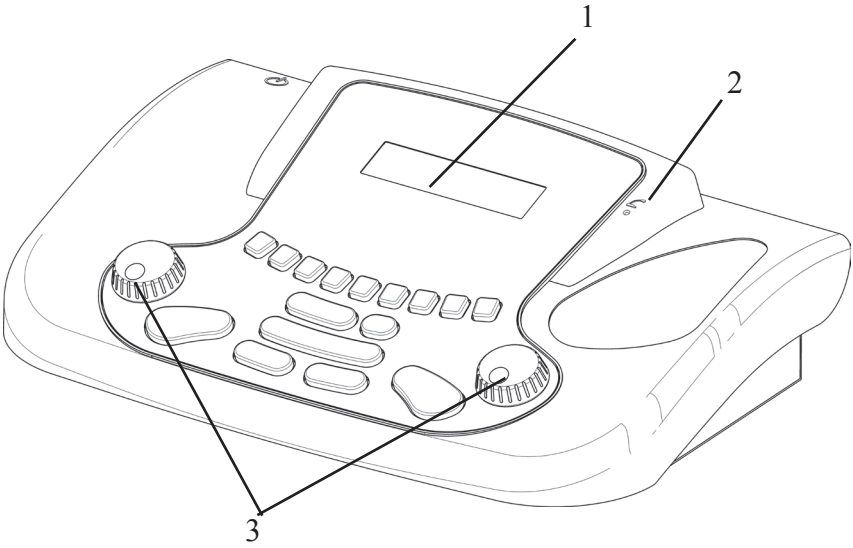
2025-10

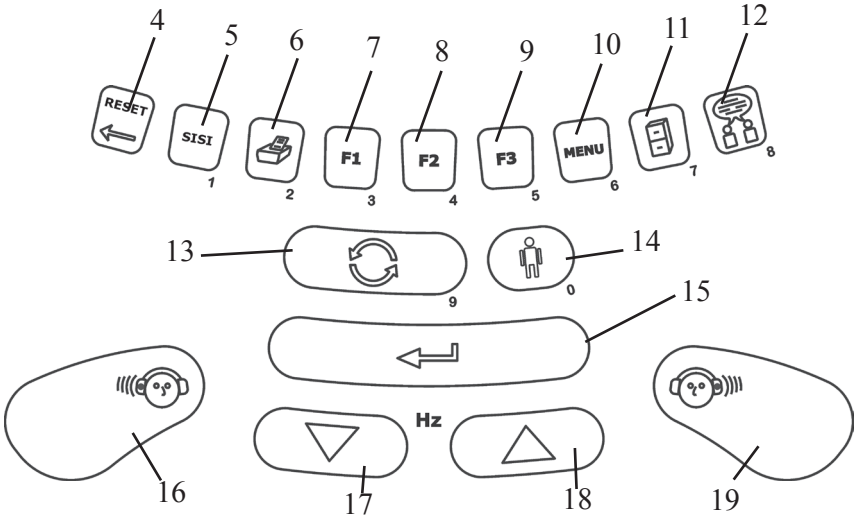
CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	AM	AO	AOM	AOM+	SUPRA
OPCIONES DE FIRMWARE / *FIRMWARE OPTIONS*								
06408	1	OPCION FIRMWARE FRECUENCIAS INTERMEDIAS *INTERMEDIATE FREQUENCY SOFTWARE OPTION*	■	■	■	■	■	■
06402	1	OPCION FIRMWARE FRECUENCIAS MUSICALES *MUSICAL FREQUENCIES FIRMWARE OPTION*					■	■
06403	1	OPCION FIRMWARE ENMASCARAMIENTO SINCRONIZADO *AUTOMATIC MASKING FIRMWARE OPTION*		■		■	■	■
06404	1	OPCION FIRMWARE TONO REFERENCIA *REFERENCE TONE FIRMWARE OPTION*	---	---	---		■	■
02564	1	OPCION FIRMWARE TEST SISI *SISI FIRMWARE OPTION*					■	■
00753	1	OPCION FIRMWARE BASE DE DATOS INTERNA *INTERNAL DATA BASE FIRMWARE OPTION*				■	■	■
00755	1	OPCION FIRMWARE PRUEBAS SUPRALIMINARES *SUPRATHRESHOLD FIRMWARE OPTION*						■
00764	1	OPCION FIRMWARE TONO PULSANTE/ALTERNADO Y MODULADO/ALTERNADO *PULSED/ALTERNATED TONE AND MODULATED/ALTERNATED TONE FIRMWARE OPTION*					■	■
06405	1	OPCION FIRMWARE RUIDO BANDA ESTRECHA *NARROW BAND NOISE FIRMWARE OPTION*		■		■	■	■
00763	1	OPCION FIRMWARE FRECUENCIA Y AMPLITUD MODULADA *FREQUENCY AND AMPLITUDE MODULATION FIRMWARE OPTION*	---	---	---		■	■
06406	1	OPCION FIRMWARE ENMASCARAMIENTO RUIDO BLANCO *MASKING WITH WHITE NOISE FIRMWARE OPTION*		■		■	■	■
06407	1	OPCION FIRMWARE ENMASCARAMIENTO RUIDO VOCAL *MASKING WITH SPEECH NOISE FIRMWARE OPTION*					■	■

■ STANDARD ☐ OPCIONAL / *OPTIONAL* --- NO DISPONIBLE / *NOT AVAILABLE*

2.3. LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS

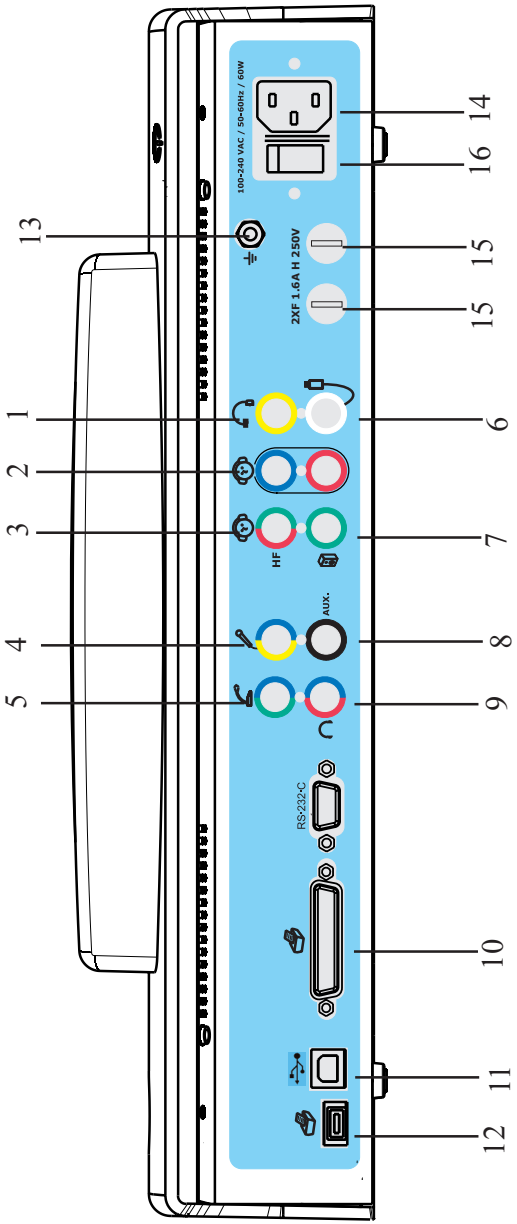
FRONT PANEL





1- Display.
2- Doctor's microphone.
3- Attenuators: to increase or decrease the signal level applied to the patient (dBs) and select the menu options.
4- Reset: deletes certain information.
5- Sisi: generates the manual increments for the SISI test.
6- Print: prints the audiometric file which has been created, if thresholds have previously been saved.
7- F1: selects the conduction route for the application of the signal.
8- F2: selects the signal source.
9- F3: selects the signal presentation mode.
10- Menu: provides access to the various options.
11- Database: saves a test in the database.
12- Intercom: activates the intercom.
13- Invert: inverts the "direct/inverted" operation of the SIGNAL keys (no. 16 and 19).
14- Patient: enables entry of a patient reference for a test to be printed, saved in the internal database or transferred to a database on a PC.
15- Enter: used to save the thresholds recorded in a test or to confirm information entered or selected.
16- Right hand channel signal: silencer or key - transmits or blocks the signal to the patient when pressed, depending on whether "direct" or "inverted" mode has been selected.
17- Decreases the frequency of the pure-tone signal applied to the patient.
18- Increases the frequency of the pure-tone signal applied to the patient.
19- Left hand channel signal (idem right channel).

REAR PANEL



1- Bone Conduction
2- Air Conduction
3- High Frequency Air Conduction
4- Patient Microphone
5- Doctor's Microphone
6- Patient response button
7- Free field
8- Auxiliary input
9- Intercom headset
10- Parallel printer
11- USB – PC connection
12- USB connection – Printer
13- Terminal for mains earth connection
14- POWER input 100V - 240V
15- Fuse holder

NOTE: The 2 fuses used are 1.6A, fast (F), and high cutting capacity (H).

16- On/off switch

NOTE: According to the EN60601-1 standard, the switch isolates both phases at the same time isolating the electric current when the equipment is off.

2.4. INSTALLATION AND START-UP

INSTALLING THE SIBELSOUND 400

This audiometer is made from professional quality solid state components, 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 sequence of operations to prepare the **SIBELSOUND 400** to carry out audiometric tests is as follows:

1 Main power switch in position "0" OFF.

2 Connect the mains power cable to the device and to a 100-240 VAC / 50-60 Hz mains connection.

3 Connect the necessary accessories to the rear side of the device as indicated in section 2.4 and ensuring that the cables do not interfere the working area.

WARNING

It is recommended to install the audiometer together with a soundproof booth for audiometric tests. If this is not possible, the equipment must be installed in a room whose ambient noise level is low enough so that it does not distort the results of the audiometric tests. If not possible, NOISE SUPPRESSORS can be adapted to the headphones (OPTIONAL).

USB MODULE INSTALLATION

The equipment has an integrated Microcontroller for exclusive USB control, which is ready for use.
To use with a computer, simply install the **USB driver** and the **W50 Audiometry Software** in the PC.
To carry out these two installations, refer to the **Instructions for Use for the W50 Audiometry Software**.

START-UP

To start up the **SIBELSOUND 400** audiometer, move the main power switch to position "I" ON. The following screen will appear for several seconds:



The equipment then performs a self-check in which it tests whether all the accessories are connected and whether the original calibration is correct. If the result is negative, it displays an alert showing which accessories are missing and/or the date of the most recent calibration.

Once the self-check has been completed, the audiometer automatically sets all the controls and indicators in accordance with the saved configuration (See section 1.7 PERSONALISING THE DEVICE).

CALIBRATION

It is recommended to calibrate the transducers and to perform a general check of their safety systems, settings, functions, etc. with a frequency not exceeding twelve months (EN ISO 8253-1), or when malfunction of the unit is suspected.
The unit must be calibrated following the manufacturer's indications, available for the Technical Departments or personnel authorized by **SIBEL S.A.U.**

NOTES ON THE HANDLING OF THE DEVICE

All the functions are accessible by means of the keyboard following the instructions which appear on the screen (LCD).

Both the keyboard and screen are located on the front panel of the device.

The screen consists of two lines of 16 alphanumeric characters each.

Printer
All models can be connected, whether as a standard feature or an option, to an external printer, if this option has been selected previously in the Configuration. In this event, follow the instructions for the relevant printer.

Attenuators
You can change the channel which controls an attenuator. This allows you to control both channels with the same attenuator. To do so, press the relevant attenuator (the one you wish to take control) for 1 second. On effecting the change an indication appears (RIGHT <- / -> LEFT) for a few seconds, showing the new channel controlled by the particular attenuator.

This change is disabled in the following cases:

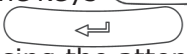
- On starting up the device
- When no key has been pressed for more than 5 minutes
- When the attenuator is pressed again for 1 second or more
- On carrying out a test with masking

Intercom (Optional) At any time, by holding down the  key, it switches to the SPEECH channel (so that the patient receives the signal from the doctor's microphone) and the patient's microphone is activated so that the doctor can hear the patient.

The volume of the signal from the doctor and the sensitivity of the patient's microphone can be adjusted by operating the attenuators while holding down this key.

2.5. FUNCTION TREE

For a better understanding of the structure of the **SIBELSOUND 400** audiometer we have included its function tree.

In general, it is possible to navigate through the various menu options by means of the keys  / or by rotating the attenuators The  key selects the chosen option (similarly pressing the attenuators).

In the case of menus which allow several options to be selected (for example the Diagnosis menu), navigate through the options using the attenuators and select by using the  and  keys, pressing  to confirm. For menus which only allow selection of a single option which cancels all the others (for example, the Printer or Language menu), navigation is carried out with the attenuators and selection is made by pressing the  key directly.

The  key returns to the previous menu (if this key is held down for more than 1 seconds it returns to the Main Menu).

Not pressing any key for 60 seconds returns to the main screen.

When the device is turned on, the screen for the test which has been configured appears (default test is the Free test).

To access the menu with all functions press .

The Main Menu appears and, depending on the options, access,

MENU SIBELSOUND 400

1. TESTS
- 1. PURE TONE
- 2. SISI
- 3. SPEECH
- 4. FOWLER
- 5. TONE DECAY
- 6. LÜSCHER
- 7. WEBER
- 8. PURE TONE HF
- 9. FREE

2. CONFIGURATION
- 1. SAVE CONFIGURATION
- 2. MODIFY DEFAULT
- 3. RESET DEFAULT
- 4. DIAGNOSIS
- 5. FREQUENCY
  - 1 FREQ. SEL.
  - 2 MUSICAL FREQ.
- 6. PRINTER
- 7. LANGUAGE
- 8. CONTRAST
- 9. DATE - TIME

3. MAINTENANCE
- 1. TEST DEVICE
  - 1. CPU
  - 2. LCD
  - 3. KEYBOARD
  - 4. PRINTER
  - 5. UPDATE KEY
  - 6. VERSION
  - 7. RESET DEVICE
  - 8. SERIAL NO.
- 2. CALIBRATION
  - 1. CALIBRATION WARNING
- 3. MONITOR
- 4. SPEECH-INTER
- 5. AUXILIARY

4. DATABASE
- 1. VIEW
- 2. CLEAR DB
- 3. PATIENT SEARCH
- 4. PATIENT DELETE

5. REFERENCE TONE
6. AUTO MASK
7. AUTO SAVE

The various options can also be accessed directly. To do this just press the MENU key and enter the numerical sequence of the various menus you would navigate through to access the required option. For example, to carry out the keyboard test you would need to press: (Menu), 3 (Maintenance), 1 (Test Device) and 3 (Keyboard).

2.6. AUDIOMETRIC TESTS

The **SIBELSOUND 400** audiometer supports many types of audiometric investigations.

For ease of use, the Main Menu allows you to access the various tests and, if you wish, prepare the printed report automatically. This does not prevent the user from setting up the report manually or carrying out many other tests using the FREE AUDIOMETRY option.

To carry out a test, push the MENU key:



press the ↵ key, and choose the TEST you require:

1. PURE TONE (Tone Audiometry)
2. SISI (SISI test)
3. SPEECH (Speech audiometry)
4. FOWLER
5. TONE DECAY
6. LUSCHER
7. WEBER
8. PURE TONE HF (Pure tone high frequency audiometry)
9. FREE (Free audiometry)

This manual explains the usual procedure for carrying out various audiometric tests. There are different procedures for conducting the test; the health professional must determine which procedure is most appropriate for each patient.
A brief description of the tests displayed on the TESTS MENU is shown below.

TONE AUDIOMETRY

Tone audiometry is the basic test which involves the determination of threshold hearing levels via air and bone conduction, with or without NBN masking.
Free-field audiometry is carried out in a similar way to tone audiometry via air conduction.
This test can be carried out using air conduction with any **SIBELSOUND 400** model. Free-field tests, via bone conduction and masking are only integrated in some models and are optional in others.

SISI TEST

SISI (Short Increment Sensitivity Index following Jerger). This consists of increments in a continuous pure tone of 1dB with rise time of 50 ms, duration of 200 ms and fall of 50 ms. The stimulus may be applied manually or automatically.
It is provided as standard with the **SIBELSOUND 400 AOM+, SUPRA** model, and in other models if incorporated as an option.

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.

Speech audiometry has many variants not addressed in this manual, which are left to specialist criteria.

It can be carried out with the **SIBELSOUND 400 AOM+, SUPRA** and SUPRA models, and other models if incorporated as an option.

FOWLER

The Fowler test is used to verify the balance between the two ears. This involves comparing equal sound intensity between the two ears at the same frequency. This is aimed more at predominantly unilateral deafness: the two ears must not be identical. This test is performed to ascertain whether recruitment occurs when the hearing threshold is normal or less than 30 dB and the other ear shows a hearing loss of 25 to 60 dB. It is also called ABLB (Alternate Binaural Loudness Balance).

It is performed with the **SIBELSOUND 400 SUPRA** model and also with the other models if this option is included.

TONE DECAY

The Tone Decay test 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 he can hear the sound for one minute.
It is performed with the **SIBELSOUND 400 SUPRA** model and also with the other models if this option is included.

LUSCHER

The Luscher test consists in distinguishing between signal modulation variations. For the ear to perceive an increase or decrease in physical intensity due to a change in subjective intensity (sonority), the physical intensity must change by more than a certain value. This small change in physical intensity perceived by the ear is called the differential threshold. This is done by applying a modulated tone with a band width of 40 dB above the threshold and ascertaining the modulation threshold at which the subject ceases to hear or begins to hear the tone modulation, depending on whether the level rises or falls.

It is performed with the **SIBELSOUND 400 SUPRA** model and also with the other models if this option is included.

WEBER

The Weber test consists in investigating all frequencies between 250 and 4000 Hz, at 15 dB above the subject's forehead bone threshold. The vibrator is applied to the forehead and it is held in place with a headband and not by hand, as this could influence the pressure and 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.

It is performed with the **SIBELSOUND 400 SUPRA** model and also with the other models if this option is included.

PURE TONE HF

Pure Tone HF audiometry is basically a pure tone audiometry in which the frequency range wide up to 20.000 Hz and is applied by the air HF conduction. It also allows to realize masking with narrow band noise and white noise sources.

It’s an option in the **SIBELSOUND 400 AOM, AOM+** and **SUPRA** models.

FREE AUDIOMETRY

This audiometer option MUST NOT BE CONFUSED WITH FREE FIELD.
By selecting "Free Audiometry" the user can carry out any other test with the audiometer, including those described above, as the audiometer permits access to and selection of all of its functions, even though some may appear absurd.

In the tests described earlier, the device software blocks certain functions which are not normally relevant to the test being carried out and therefore variants are not possible. With the "FREE AUDIOMETRY" option, there is access to the full range of capabilities of the equipment.

It is available with all models.
With this option it is not possible to produce reports or save tests in the database.

2.7. PROCEDURE FOR TONE AUDIOMETRY

GENERAL CONSIDERATIONS

Tonal audiometry is the basic test for the diagnosis of hearing loss; it consists of determining hearing threshold levels via air and/or bone conduction, with or without masking.

Tests should be carried out by a technician trained on how to perform audiometric tests, since they need to decide which ear is
to be tested first (usually, the one with better hearing), whether or not masking is required, if the patient is producing coherent responses (**SIBELSOUND 400** warns in case of discrepancies) and whether or not it is necessary to interrupt the test.

It is recommended to explore, at least, 4 frequencies through air conduction (500, 1000, 2000 and 3000 or 4000 Hz) for both ears. Preferably, tests should last less than 20 min, to prevent patient fatigue.

PATIENT REPARATION AND INSTRUCTIONS

Before performing the test, perform an otoscopic examination of the patient in order to identify possible obstructions in the external auditory canal which would need extracting.

It is recommended that the patient arrives at the test site at least 5 minutes in advance, to avoid possible exposure to high-noise levels, or previous physical activities which might alter the test results.

Before starting, the technician should give the patient instructions about the test procedure, indicating, amongst others, the following:

- Which ear will be examined first.
- The general tone presentation sequence.
- How to indicate a response using the patient's response button (or gestures).

• When the patient is expected to provide a response (when they hear the tone, not when they think they hear it).

Patients need to take off their glasses and/or accessories, and tie their hair back, whenever these may prevent the correct placement of the headphones or the bone vibrator. When placing the air conduction headphones, make sure that the **RED** headphone is on the patient's right ear, and the **BLUE** one on the left ear.

WARNING

DO NOT use transducers (headphones for air/ bone conduction, loudspeakers, ...) that have not been calibrated with the audiometer. THAT COULD INVALIDATE THE AUDIOMETRIC TEST PERFORMED.

Each transducer is labeled with the serial number of the audiometer with which it was calibrated. Check that they match before using the transducer (headset, vibrator,...).

AUDIOMETER PREPARATION

Before explaining the procedure for performing the test, it is convenient to present the characters which may appear on the screen. These show the operational status of the device at all times.

As mentioned previously, the screen consists of two lines of **16 alphanumeric characters** each.

On the first line, the characters located in positions **0 to 7** refer to the **right channel** and those located at positions **8 to 15** to the **left channel**.

The characters which can appear in each of the positions on the screen when a test is being carried out are described below.

ABCDEFGHIJKLMNOP
ABCDEFGHIJKLMNOP

On the first line:

A and J Route of application (**A** Air Conduction/ **O** Bone Conduction / **-** Disable).

Select with F1 + left or right attenuator according to channel.

CDE and LMN Signal source
(**HZ** Frequency of Pure Tone in Hz / **NBN** Masking with Narrow Band Noise / **WN** White Noise)

Select with F2 + left or right attenuator according to channel.

G and P Mode of presentation of the signal
(**C** Continuous signal / **P** Pulsating signal)

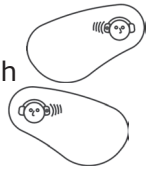
Select with F3 + left or right attenuator according to channel.

On the second line:

ABC and **NOP Signal level** applied to the patient in "dB"
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and **LM** Two cursors that indicate that a **signal** is being applied to the patient.

DE right channel. Apply signal with



LM left channel. Apply signal with

FGHIJ Frequency in Hz of the tone applied

Select with ▽ / △

With the audiometer prepared as indicated in section **2.4. INSTALLATION AND START-UP**, proceed as follows:

1 Press the MENU key.

Using the ▽ and △ keys select the option:

MENU
1. TESTS

TESTS
1. PURE TONE

and access the test pressing the ⏎ key

2 A screen appears showing the configured options. By default these are the following:

A	HZ	C	A	HZ	C
60		1000		60	

3 Push the

NEW PATIENT
Ref:

Enter the reference and press ⏎

If the thresholds of the previous patient have not been saved to the database, the unit displays a screen for saving them:



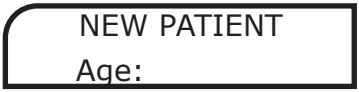
Likewise, a test being performed can be restarted by entering the same reference again:



Select 

to delete all the thresholds saved for the current test and start the test again.

NOTE: When ELI diagnosis is selected, after the previous screen the following appear:





4 Press 



Using the corresponding attenuator, select the **route** of application of the signal for each channel: air (**A**), bone (**O**), free field (**F**) or disabled (**-**).

5 Press 

A **HZ** C	A **HZ** C
TONE	**TONE**

Using the corresponding attenuator, select the **source** of the signal for each channel: frequency of pure tone in Hz (**HZ**) , masking with narrow band noise(**NBN**) or masking with white noise(**WN**).

6 Press F3

A HZ **C**	A HZ **C**
CONTIN.	**CONTIN.**

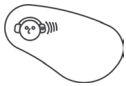
Using the corresponding attenuator, select the **mode** of presentation of the signal for each channel: continuous signal (**C**) or pulsating signal (**P**).

7 Choose the **intensity** of the signal by rotating the attenuators until the required value is found.

A HZ C	A HZ C
60 1000	**60**

8 Select the **frequency** of the signal (press ▽ or △ until the required value is found)

A HZ C	A HZ C
60 **1000**	60

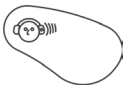
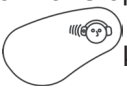
●To apply the signal to the patient press the  or  keys, depending on the channel on which you wish to apply it.

WARNING

The equipment has a protection system to avoid exposing the patient to high intensity signals for long periods of time. To do this, at some frequencies the signal is automatically deactivated above 100 dB after a few seconds.

A	HZ	C	A	HZ	C
60	II	**1000**			60

These keys have two positions: "direct and inverted". The "direct" position applies the signal to the patient when the key is pressed, otherwise no signal is applied.
The "inverted" position blocks the signal to the patient when the key is pressed, otherwise a signal is applied.

You can switch from one option to the other by holding down the  or  key for the relevant channel and pressing  for a moment.

- If two cursors appear in the relevant part of the screen, this indicates that the signal is being applied to the patient; otherwise it is not being applied.
- When the patient detects a signal, they should press the button.

  If you wish to save the threshold at this point, press the  key.

  The following screen appears:

PURE TONE TEST
THRESHOLD SAVED

The following variants of tone audiometry can be distinguished:

- DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING
- DETERMINATION OF THE HEARING THRESHOLD VIA BONE CONDUCTION WITHOUT MASKING
- DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITH MASKING
- DETERMINATION OF THE HEARING THRESHOLD VIA BONE CONDUCTION WITH MASKING
- SCREENING AUDIOMETRY
  As explained earlier, this manual explains the mechanism for carrying out various audiometric investigations. This is not the only possible mechanism and must therefore be adapted to the criteria which the specialist regards as most appropriate in each case.
  A description of each type of tone audiometry in accordance with standard ISO 8253-1, is shown below

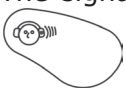
DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING

The **SIBELSOUND 400** audiometer provides the following frequencies and pure tone levels for application by air conduction:

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Max dB HL	80	100	120	120	120	120	120	120	120	110	110
Min. dB HL	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10

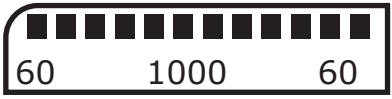
Once the steps described above have been carried out, you can proceed to determine the hearing thresholds in each ear.

NOTE:
If you wish to save the thresholds to print them as a graph, save them in the internal database and/or transfer them to a database in a PC, see section 2.17 PRINTING AND SAVING AUDIOMETRIC TESTS.

The test tone is continuous and has a duration between 1 and 2 seconds. The signal is applied in "direct" mode using the  or  keys. When there is a patient response, the interval between the sounding of the tone varies but is never shorter than the duration of the tone.

NOTE:

When the patient presses the response button, the response is displayed on the screen as follows:



If the patient presses the button in the absence of a signal, the message "NO SIGNAL" appears on the screen. It is advisable to carry out a training test first to familiarise the patient with the procedure. This is done as follows:

- Apply a 1000 Hz (frequency) tone using  or .
- Use a level which is clearly audible (for example an intensity of 40 dB, for a normal subject), rotating the attenuators until this value is found.
- Reduce the level in 20 dB steps until the subject can no longer hear it.
- Increase the level until they can again hear it.
- Sound the tone again at the same level.

If the patient responds consistently, they are appropriately familiarised. If not, repeat the process.

The steps to take to determine the hearing thresholds are as follow:

1 The order of sounding of pure tones is: 1000, 1500, 2000, 3000, 4000, 6000, 8000, 750, 500, 250 and 125 Hz.
Some of these frequencies can be omitted, depending on the specialist's criteria.

2 Sound the test tone at a level 10 dB below the threshold detected during training. Carry on increasing the level in 5 dB steps until there is a response from the patient.

3 Following the response, reduce the level in 10 dB steps until there ceases to be a response and then start to increase it again (new "ascent"). Continue the process until there have been three responses at the same level within a maximum of five ascents (auditory responses within three ascents, abbreviated method). If less than three responses are detected in five ascents (or less than two responses in three ascents), switch to a tone with a level 10 dB higher than the level of the previous response and repeat the process.

4 On the graph of the ear being tested, write down the hearing threshold level which corresponds to the lowest level at which the number of patient responses exceeds half the number of ascents.

Note:
If the lowest response levels for a particular frequency differ by more than 10 dB, the threshold hearing level should be regarded as dubious and it is advisable to repeat the process. If there is a difference greater than or equal to 15 dB between two correlative frequencies, the audiometry can be considered doubtful, unless this represents a sustained gradient along the curve. In the event of neurosensory hypoacusia with a serious loss of high frequencies, there tends to be more than 15 dB between two correlative frequencies, but the whole curve exhibits that gradient.

5 Repeat steps 2, 3 and 4 for the next frequency.

An audiometric file output via a printer is shown at the end of this chapter.

DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITH MASKING

To avoid the test tone being heard by the ear other than the one being tested, it is necessary to apply a masking noise to that ear.

The **SIBELSOUND 400** audiometer provides Narrow Band Noise NBN with the following levels of masking in each of the frequencies for application via air conduction:

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Max dB HL	60	80	100	100	100	100	100	100	100	100	90
Min. dB HL	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10

Although experience largely dictates the process and level of noise to apply, a recommended method for determining hearing thresholds with masking is presented below.

1 Apply a test tone to the ear being tested with a level equal to the hearing threshold without masking. Select narrow band noise NBN in the other audiometer channel and apply a level of effective masking to the other ear that is equal to the hearing threshold level of the latter.
Increase the level of masking until the test zone is inaudible or until it exceeds the level of the test tone.

2 If the test tone is still audible when the level of noise is equal to the level of the tone, this is taken as the hearing threshold. If the test tone remains masked, the level of the latter is increased until it is audible once again.

3 Increment the noise level in 5 dB steps. If the test tone is inaudible, increase the level until it is audible once again. Repeat this process until the test tone remains audible even though the level of masking noise has been increased by more than 10 dB. This level of masking (which is the level from which no subsequent increase in the level of tone was required to make it audible) is the correct level and this process should

have resulted in the correct hearing threshold for the test frequency. Make a note of the correct level of masking.

DETERMINATION OF THE HEARING THRESHOLD VIA BONE CONDUCTION WITHOUT MASKING

The **SIBELSOUND 400** audiometer provides the following frequencies and pure tone levels for application by bone conduction:

Hz	250	500	750	1000	1500	2000	3000	4000	6000
Máx dB HL	50	60	60	70	70	70	70	70	55
Mín. dB HL	-10	-10	-10	-10	-10	-10	-10	-10	-10

Application of the test tone to the patient is carried out by means of the bone conduction vibrator.

WARNING

The bone conduction vibrator is a very fragile component, and even small impacts can lead to a deterioration in its characteristics. Therefore, you are advised to handle it with great care.

The investigation involves determining the level of hearing when pure tones are transmitted without masking by bone conduction.

The determination of thresholds using bone conduction is a much more delicate procedure to carry out and interpret. Very special care is required at the time of the investigation.

Correct positioning of the vibrator is very important when carrying out investigations by bone conduction. It is placed on the mastoids and a tone is applied, a few decibels above the hearing threshold, and the patient is asked to move it around the mastoids until they find the area that maximises the volume of the tone. Make sure that the vibrator is perfectly attached to the mastoids and is not in contact with the external part

of the year so as to avoid conduction through the cartilage. When determining thresholds using bone conduction without masking, the opposite ear must be completely unobstructed, that is, must not be covered by a headset for air conduction or by any other object which might alter the results of the test. When this is not the case, it must be indicated.

With the exception of the indications mentioned above, the determination of thresholds using bone conduction must be carried out as described in the previous section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING.

DETERMINATION OF THE HEARING THRESHOLD VIA BONE CONDUCTION WITH MASKING

The **SIBELSOUND 400** audiometer provides Narrow Band Noise NBN masking with the following levels of masking in each of the frequencies for application via bone conduction:

Hz	250	500	750	1000	1500	2000	3000	4000
Máx dB HL	50	60	60	70	70	70	70	70
Mín. dB HL	-10	-10	-10	-10	-10	-10	-10	-10

The **SIBELSOUND 400** audiometer enables masking when determining hearing thresholds via bone conduction without the need to invert the air conduction headset over which the masking noise is applied. Choose the masking channel depending on the channel being used for investigation by bone conduction.
Place the vibrator on the mastoids corresponding to the ear which is being investigated and position the air conduction headset correctly. Make sure that the transducer cables do not interfere with each other.

For the purposes of this explanation, assume that the investigation of thresholds will begin with the right ear.
Although experience largely dictates the process and level of noise to apply, a recommended method for determining hearing

thresholds via bone conduction with masking is described below.

1 Apply a test tone to the ear being investigated at a level equal to the hearing threshold via bone conduction without masking. Select narrow band noise NBN with the other audiometer channel and apply a level of effective masking to the other ear equal to the threshold hearing level via air conduction for the latter. Increase the level of masking until the test tone is inaudible or until it exceeds the level of the test tone by 40 dB.

2 If the test tone is still audible when the noise level is 40 dB higher than the test tone, this is taken as the hearing threshold. If the test tone remains masked, the level of the latter is increased until it is audible once again.

3 Increment the noise level in 5 dB steps. If the test tone is inaudible, increase the level until it is audible once again. Repeat this process until the test tone remains audible even though the level of masking noise has been increased by more than 10 dB. This level of masking (which is the level from which no subsequent increase in the level of tone was required to make it audible) is the correct level and this process should have resulted in the correct hearing threshold for the test frequency. Make a note of the correct level of masking.

SCREENING AUDIOMETRY

This type of test is used in cases where the objective is to establish whether or not the subject can hear certain levels, rather than to determine hearing thresholds. It is a simple and quick method.

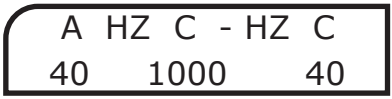
Screening audiometry is a test that determines if a subject has a hearing threshold better, equal to or worse than a determined screening level. The screening level is left to the discretion of a specialist.
Screening audiometry can then be completed by determining the hearing threshold for those frequencies where the subject failed the screening test. In this case, the procedure

for determining thresholds is as described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING .

The general aspects and the preparation for and instructions to the patient are as described at the beginning of that section.

To carry out the test follow the procedure described below:

1 Select each channel with the following screen display:



For the purposes of this explanation, assume that the investigation will begin with the right ear.

2 Select the frequency and the screening level. The order of application of pure tone frequencies is: 1000, 2000, 4000, 6000, 8000, 500 and 250 Hz. Some of these frequencies may be omitted or others added from the range the audiometer has available, at the discretion of the specialist.

3 First apply a 1000 Hz tone to the subject's right ear at a signal level of 40 dB to check whether the subject has understood the instructions.
If not, the instructions are given again and the tone repeated. If the subject does not respond, increase the level of the tone until there is a response.

4 Adjust the signal level to be applied to match the screening level and present two tones with duration of 1 and 2 seconds and an interval between each tone of 3 to 5 seconds. If the subject detects both tones, they have passed the test at this frequency. If only one tone was heard, present another tone. If the third tone has been detected, the subject has passed the test at this frequency. If the third tone or the first two tones were not heard by the subject, they have not passed the screening test at this frequency.

5 Select another frequency and repeat point **4**.

6 Once the right ear has been tested, repeat the process described in points **4** and **5**, blocking the right channel signal and activating the left, according to

- HZ C A HZ C
40 1000 40

(The dB level specified is a guideline)

2.8 PROCEDURE FOR SISI TEST

The general aspects and the preparation for and instructions to the patient are as described at the beginning of section 2.7. PROCEDURE FOR TONE AUDIOMETRY.

Before explaining the procedure for performing the test, it is convenient to present the characters which may appear on the screen. These show the operational status of the device at all times.

A Rxx S A Sxx S
ABCDEFGHIJKLMNOP

As mentioned previously, the screen consists of two lines of **16 alphanumeric characters** each.

On the first line, the characters located in positions **0 to 7** refer to the **right channel** and those located at positions **8 to 15** to the **left channel**.

In this test the **signal source** to be used is a Pure Tone in Hz.

The characters which can appear in each of the positions on the screen when a test is being carried out are described below.

On the first line:

A Route of application (**A** Air Conduction / **-** Disabled)

Select with F1 + left or right attenuator according to channel.

S Mode of presentation of the signal (**S** Sisi-test / **-** Disabled)

Select with F3 + left or right attenuator according to channel (only one channel can be activated).

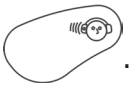
Sxx Counter for the **number of stimulus** (signal increases) applied to the patient (From E00 to E20)

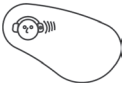
Rxx Counter for the **number of correct responses** from the patient (the patient presses the button after the stimulus has been applied)

On the second line:

ABC and **NOP Signal level** applied to the patient in "dB"
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and **LM** Arrow which indicates that a **signal** is being applied to the patient.

DE right channel. Apply signal with .

LE left channel. Apply signal with .

FGHIJ Frequency in Hz of the tone applied
Select with ▽ / △.

On pressing the ⟳ key :

EFG Intensity of the increases in signal (From 0,2 to 5 dB).

Select with right attenuator.

NOP Spacing between applications of the signal (**MAN**: Manual / **1- 9 seconds**: automatic).

Select with left attenuator.

The SISI (Short Increment Sensitivity Index) test measures the ear's ability to detect small increases in intensity.

The test involves the application of 1 dB increments to a continuous tone with a rise time of 50 ms, duration of 200 ms and fall of 50 ms. The level of increments can be from 0,2 to 5 dB for training the patient. Application of the increments can be automatic or manual and the interval in automatic mode can vary between 1 and 9 seconds, the usual value being 5 seconds.

The device has a counter for the number of increments applied (which only counts in increments of 1 dB), and another counter for patient responses. The maximum count is 20 increments.
The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING (A and B). It is particularly important to explain the test method to the patient and that they will hear a pure continuous tone and from time to time detect a jump in the volume of the tone.
On each such occasion they must respond by pressing the button.

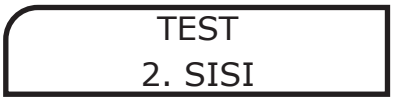
With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

key.

Using the  and  keys select the option:





and access the test by pressing the  key, (the 

test can also be accessed from any other test by pressing the corresponding key).

2 A screen appears showing the configured options. By default these are the following:



3 Press the  key



Enter the reference and press 

If the thresholds of the previous patient have not been saved to the database, the unit displays a screen for saving them:

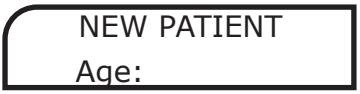


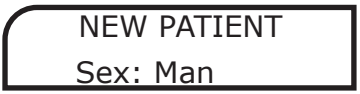
Likewise, a test being performed can be restarted by entering the same reference again:



Select F1 to delete all the thresholds saved for the current test and start the test again.

NOTE: When ELI diagnosis is selected, after the previous screen the following appear:





4 Press F1



Using the corresponding attenuator, select the **route** of application of the signal for each channel: air (**A**), or disabled (-).

5 Press F3



Using the corresponding attenuator select the signal presentation mode for each channel: **SISI** (S) o **DISABLE** (-).

6 Select the frequency of tone to apply from 500, 1000, 2000 or 4000 Hz (Press ▽ or △ until the required value is found).

A R00	**S** A	S00 -
60	**1000**	60

7 Press the ⟲ key and select:

A R00	**S** A	S00 -
INC 1.0		FREQ 1

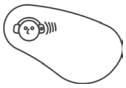
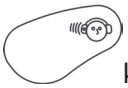
Using the left attenuator, choose the intensity of the increments in signal (between 0,2 and 5 dB).
Using the right attenuator choose the interval between increments in signal (MAN / between 1 and 9 seconds).

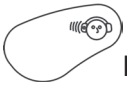
Remember that the stimulus counters only operate when the increment is 1 dB, and the signal is automatically interrupted after 20 stimuli have been generated. The counter must be reset to begin a new test.

8 Apply 20 dB more than the patient's hearing threshold in the right channel by rotating the right attenuator.

9 The increments are applied manually using the SISI key or automatically, depending on the option selected in point **7**. Under the automatic option additional stimuli can be applied using the SISI key.

10 The test can be carried out in two different ways:

• **Normal**: press the  or  key for the channel corresponding to the ear being tested and keep it pressed for the duration of the test.

• **Inverted**: keep the  key pressed, press the  key and release them both. The signal is then applied when you are **NOT** pressing the  key. (Similarly for the left channel)

We recommend working with the signal levels in inverted mode for greater convenience while performing this test.

11 The stimulus counter (Sxx) will accumulate 1 dB applied and the response counter (Rxx) will indicate the responses registered. These counters can be zeroed at any time with the 

key.

12 Depending on how the test is being carried out, the increments and responses registered are noted down or saved to the audiometer, and the test continues with the next frequency.

The results recorded are usually expressed as a percentage representing % = No. of responses x 100 / No. of increments

13 Once all frequencies have been tested for the right ear, the test proceeds with the left ear.
An audiometric file output via a printer is shown at the end of this chapter.

2.9. PROCEDURE FOR SPEECH AUDIOMETRY TEST

The general aspects and the preparation for and instructions to the patient are as described at the beginning of section 2.7. PROCEDURE FOR TONE AUDIOMETRY.

Before explaining the procedure for performing the test, it is convenient to present the characters which may appear on the screen. These show the operational status of the device at all times.

As mentioned previously, the screen consists of two lines of **16 alphanumeric characters** each.
On the first line, the characters located in positions **0 to 7** refer to the **right channel** and those located at positions **8 to 15** to the **left channel**.

The characters which can appear in each of the positions on the screen when a test is being carried out are described below.



On the first line:

A and J Route of application (**A** Air Conduction / **C** Free (Optional) Field / **-** Disabled)

Select with F1 + left or right attenuator, depending on the channel.

CDE and LMN Signal source (**SP**: Speech audiometry / **SPN**: Masking with Speech Noise)

Select with F2 + left or right attenuator, depending on the channel.

G and P Mode of presentation of the signal (**C** Continuous / "**P**"Pulsating).

Select with F3 + left or right attenuator, depending on the channel.

On pressing the ⟲ key, for 1 second:



The input device (MICROPHONE (microphone for the technician) / AUXILIARY) appears in positions 4 to 13. The selected device starts blinking.

Select with F1.

On the second line:

ABC and **NOP Signal level** applied to the patient in "dB"
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

FGHIJ Number of correct responses/Number of words

Increment the number of correct responses with the △ key
In positions 4 to 13, on pressing the signal keys  or  a vumeter appears indicating the intensity of the signal the patient hears.

This disappears on pressing ↵ to save the threshold or when the signal is stopped.

On pressing the ⟳ key, for 1 second

AB Number of words
Select with right attenuator, (NUMBER OF QUESTIONS NQ) to ask the patient during the test.

OP Device Volumen (DV) applied to the patient
Using the left attenuator, select the level of signal to be applied to the patient.
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.

There is little standardisation of this test either in terms of the procedure to be followed or the material to use, so these are left to the discretion of the specialist.

In this section we only provide a basic description of how to use the equipment in this mode.

The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING . It is important to explain the test method to the patient and that they will hear a series of words which they are required to repeat.
With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the MENU key. Using the ▽ and △ keys select the option:

MENU
1. TEST

TEST
3.SPEECH

and access the test pressing the ↵ key.

2 A screen appears showing the configured options. By default these are the following:

A SP C A SPA C		
60	00/10	60

3 Press the key

NEW PATIENT
Ref:

Enter the reference and press ↵.

If the thresholds of the previous patient have not been saved to the database, the unit displays a screen for saving them:

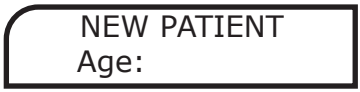


Likewise, a test being performed can be restarted by entering the same reference again:



Select F1 to delete all the thresholds saved for the current test and start the test again.

NOTE: When ELI diagnosis is selected, after the previous screen the following appear:





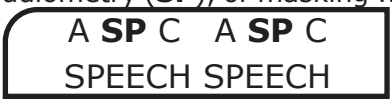
4 Press F1



Using the corresponding attenuator, select the **route** of application of the signal for each channel: air (**A**), free field (**F**).

5 Press F2

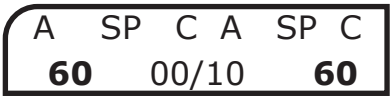
Using the corresponding attenuator, select the signal source: speech audiometry (**SP**), or masking with speech noise (SPN).



6 Press F3
Using the corresponding attenuator, select the mode of presentation of the signal: continuous (**C**), pulsating (**P**).



7 Choose the **intensity** of the signal applied to the patient in dB by rotating the attenuators until the required value is found.



8 Press , for 1 second:



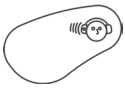
Using F1 select the **input device**: MICROPHONE (microphone for the technician) or AUXILIARY.

Using the right attenuator, select the **number of words**.
Using the left attenuator, select the **level of signal** to be applied to the patient.

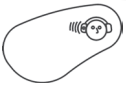
9 Connect the microphone for the technician carrying out the test if it is a live voice test or the tape recorder if recorded material is being used.

10 If the audiometer is installed in a sound-proof booth, connect the patient's microphone and the headset for the technician carrying out the test to the corresponding connection points.

11 For this test, it is most convenient to work with signal levels in "inverted" mode (a signal is applied without the signal key being pushed) in the relevant channel.

To activate the inverted mode, keep the  key pressed, press the  key and release them both.
Accordingly, there will be a signal when **NOT** pressing the .

Do the same for the left channel.

12 Carry out a training test adjusting the level of input signal applied to the microphone. To do this, push the  key, for 1 second, and apply a pulsating signal  or  so that the vumeter indication is displayed. Adjust the volume using the right attenuator, so that only the first seven positions of the vumeter are illuminated when talking normally. In this situation, the signal level applied to the patient is as indicated by the position of the attenuator.

The vumeter range is between -20 dB (first position) and 3 dB. (last 3 positions).This comprises the 10 central characters of the LCD. When the first seven characters are activated there is neither increment nor loss in the level of signal applied to the patient (0 dB).
Bear in mind that the level of signal applied to the patient depends on the dB level selected for each channel. If the indicator for the level of signal in speech audiometry is fully lit up, this represents an increase in the applied signal of 3 dB. On the other hand, if only the first character is illuminated, this represents a 20 dB reduction in the signal applied.

13 If the device has an intercom, the volume control can be used to adjust the level of the patient's voice in the technician's headset. The intercom can be activated at any time during the SPEECH function.

14 From that moment on, the device is ready to commence the Speech audiometry test.

An audiometric file output via a printer is shown at the end of this chapter.

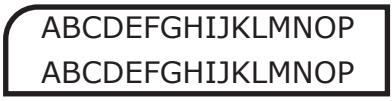
2.10. PROCEDURE FOR PERFORMING THE FOWLER TEST

The general aspects and the preparation for and instructions to the patient are as described at the beginning of section 1.9. PROCEDURE FOR TONE AUDIOMETRY.

Before explaining the test procedure, it is advisable to describe the characters which may appear on the screen. These show the operational status of the device at all times.
As mentioned previously, the screen consists of two lines of 16 alphanumeric characters each.

On the first line, the characters located in positions 0 to 7 refer to the right channel and those located at positions 8 to 15 to the left channel.

The characters which can appear in each of the positions on the screen when a test is being carried out are described below.



On the first line:

A and J Application conduction (**A** Air Conducted / - Disabled)

Select with F1 + left or right attenuator according to channel.

CDE and LMN Signal source (**HZ** Frequency in Hz of Pure Tone)

Select with F2 + left or right attenuator according to channel.

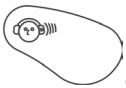
G and P Presentation **mode** of the signal (**C** Continuous / **P** Alternated pulse).

Select with F3 + left or right attenuator according to channel.

On the second line:

ABC and NOP Signal level applied to the patient in «dB»
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and LM Two cursors that indicate that the **signal** is being applied to the patient.

DE right channel. Apply signal with .

LM left channel. Apply signal with .

FGHIJ Frequency in Hz of the applied tone

Select with ▽ and △.

The Fowler test is also referred to as the Alternate Binaural Loudness Balance test or ABLB. This test is performed to ascertain whether there is recruitment when the hearing threshold is normal or less than 30 dB and the other ear shows a hearing loss of between 25 and 60 dB.

This test procedure consists in sending a tone with the same frequency to both ears, alternating it in both of them once a second. The intensity level for the best ear is progressively increased from the threshold in 10 to 30 dB steps, while the subjective sound levels are equalled in the worst ear, and its relationship with the best ear is plotted on a graph.

The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING . Special interest shall be taken in explaining the mechanics of the test to the patient to the effect that he will perceive a constant tone of the same frequency in both ears. The patient must press the button when he perceives the same intensity in both ears.

With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the MENU key and select the option:

MENU
1. TESTS

TESTS
4. FOWLER

And access the test by pressing the ↵.

2 A screen appears showing the configured options. By default these are the following:

A	HZ	C	A	HZ	C
60			1000		60

3 Press the key:

NEW PATIENT
Ref:

Enter the reference and press .

If there are thresholds that have not been saved (recorded) in the database from the previous patient, the equipment will display the following screen which allows them to be saved:



Similarly, the current test can be cancelled by entering the same reference again:



Select 

to delete all the thresholds of the current test that have been saved and start it again.

NOTE: When ELI diagnosis is selected, the following screen appears afterwards:





4 Press the 

key



Use the corresponding attenuator to select the application

conduction of the signal for each channel: aerial (**A**), or disabled (-).

5 Press F2

A	**HZ**	C	A	**HZ**
TONE				TONE

Use the corresponding attenuator to select the source of the signal for each channel: in this case only the frequency in Hz of the pure tone (HZ).

6 Press the F3

A	HZ	**C**	A	HZ
CONTIN.				CONTIN.

Use the corresponding attenuator to select the signal presentation **mode** for each channel: continuous signal (**C**) or alternated pulse signal (**P**).

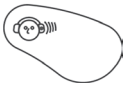
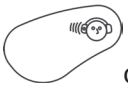
7 Choose the **intensity** of the signal by rotating the attenuators until the required value is found.

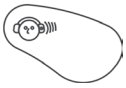
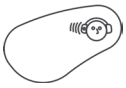
A	HZ	C	A	HZ
60		1000		**60**

8 Select the **frequency** of the tone between 125 and 8000 Hz by using the ▽ and △.

A	HZ	C	A	HZ
60		**1000**		60

9 The test can be carried out in two different ways:

• **Normal**: by pressing the  or  of the corresponding channel.

• **Inverted**: by keeping the  or  key pressed, pressing the INVER key and releasing both of them. This way, the signal appears when the silencers are **NOT** pressed.

In this test, the frequency and intensity levels (for both channels) that the patient states he has heard at the same level in both ears are saved. To save this threshold the  must be pressed. The following screen will appear:

FOWLER TEST
THRESHOLD SAVED

10 If we want to modify the frequency for exploration while the test is being performed, the previous threshold values can be deleted or retained on the audiometer. To do so, simply select the desired option on the following screen:

DEL. THRESHOLDS	
F1:YES	F3: NO

2.11. TONE DECAY TEST PROCECURE

The general aspects and the preparation for and instructions to the patient are as described at the beginning of section 2.7. PROCEDURE FOR TONE AUDIOMETRY.

Before explaining this test procedure, it is advisable to describe the characters which may appear on the screen. These will display the operating status of the equipment at all times. As mentioned previously, the screen consists of two lines with 16 alphanumeric characters each.

On the first line, the characters located in positions 0 to 7 refer to the right channel and those located at positions 8 to 15 to the left channel.
The characters which can appear in each of the positions on the screen when this test is being carried out are described below.

ABCDEFGHIJKLMNOP
ABCDEFGHIJKLMNOP

On the first line:

A and J **Application conduction** (**A** Air Conduction / **O** Bone Conduction / **C** Free Field (optional) / - Disabled)

Select with F1 + left or right attenuator according to channel.

CDE and LMN **Signal source** (**HZ** Frequency in Hz of Pure Tone)

Select with F2 + left or right attenuator according to channel.

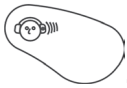
G and P Presentation **mode** of the signal (**C** Continuous)

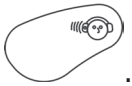
Select with F3 + left or right attenuator according to channel.

On the second line:

ABC and NOP **Signal level** applied to the patient in «dB»
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and LM Two cursors that indicate that the **signal** is being applied to the patient.

DE right channel. Apply signal with .

LM left channel. Apply signal with .

FGHIJ **Frequency** in Hz of the applied tone

Select with  and .

HI Duration in seconds of the applied signal (displayed when a signal is applied to one of the two channels and hidden when the threshold is saved).

The Carhart Tone Decay test consists in applying a tone that is 5 dB above the threshold to the patient and observing whether he perceives it clearly for 60 seconds.

In normal circumstances, it is perceived during this time. If not, the level is increased in 5 dB steps until it can again be heard and again successively until the patient confirms he can hear the sound for the entire minute.

As mentioned previously, the two central characters on the lower line on the screen become seconds counters, and can count up to 90 seconds. These are activated once the signal is applied.

This test procedure consists in applying a signal level 5 dB above the hearing threshold and a frequency of 250, 500, 1000, 2000 or 4000 Hz.

The test starts by applying the tone using the SIGNAL key in "direct" or "inverted" mode for 60 seconds if the response persists. Otherwise, the tone level is increased.

The patient responds through the warning connection while he hears the signal. When he ceases to hear it, he releases the button and at that moment the technician presses the  and the time elapsed during hearing is saved

The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING. Special interest shall be taken in explaining the mechanics of the test to the patient to the effect that he will perceive a constant tone of the same frequency in the ear being studied. He must keep the warning connection pressed while he perceives a signal.

With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

key and select the option:

MENU
1. TESTS

TESTS
5. TONE DECAY

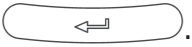
And access the test by pressing the .

2 A screen appears showing the configured options. By default these are the following:

A HZ C	A HZ C
60	1000 60

3 Press the :

NEW PATIENT
Ref:

Enter the reference and press .

If there are thresholds that have not been saved (recorded) in the database from the previous patient, the equipment will display the following screen which allows them to be saved:

SAVE PREVIOUS	
F1: YES	F3: NO

Similarly, the current test can be cancelled by entering the

same reference again:

NEW TEST	
F1: YES	F3: NO

Select F1 to delete all the thresholds that have been saved of the current test and start it again.

NOTE: When ELI diagnosis is selected, the following will appear afterwards:

NEW PATIENT	
Age:	

NEW PATIENT	
Sex:	Man

4 Press the F1

A HZ C **A** HZ	
AIR	AIR

Use the corresponding attenuator to select the application conduction of the signal for each channel: air (**A**), bone (**O**), free field (C - optional), disabled (-) or (**F** - optional).

5 Press F2

A **HZ** C A **HZ**	
TONE	TONE

Use the corresponding attenuator to select the **source** of the signal for each channel: in this case only frequency in Hz of Pure Tone (**HZ**).

6 Press the 

A	HZ	**C**	A	HZ
CONTIN.			CONTIN.	

Use the corresponding attenuator to select the signal presentation **mode** for each channel: in this case only the continuous signal (**C**).

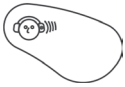
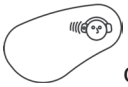
7 Choose the intensity of the signal by rotating the attenuators until the required value is found.

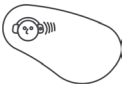
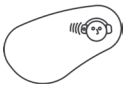
A	HZ	C	A	HZ
60		1000		**60**

8 Select the frequency of the applied tone between 250, 500 1000, 2000 and 4000 Hz using the  and .

A	HZ	C	A	HZ
60		**1000**		60

9 The test can be carried out in two different ways:

• Normal: by pressing the  or  of the corresponding channel.

• Inverted: by keeping the  or  pressed, pressing the INVER key and releasing both of them. This way the signal appears when the silencers are NOT pressed.

In this test the intensity level and its duration are recorded. To save the threshold the  must be pressed. The following screen will appear:

TONE DECAY TEST
THRESHOLD SAVED

2.12. LUSCHER TEST PROCEDURE

The general aspects and the preparation for and instructions to the patient are as described at the beginning of section 2.7. PROCEDURE FOR TONE AUDIOMETRY.

Before explaining this test procedure, it is advisable to describe the characters which may appear on the screen. These show the operational status of the device at all times. As mentioned previously, the screen consists of two lines of 16 alphanumeric characters each.

On the first line, the characters located in positions 0 to 7 refer to the right channel and those located at positions 8 to 15 to the left channel.

The characters which can appear in each of the positions on the screen when this test is being carried out are described below.

ABCDEFGHIJKLMNOP
ABCDEFGHIJKLMNOP

On the first line:

A and J Application conduction (A Air Conducted / - Disabled)

Select with F1 + left or right attenuator according to channel.

CDE and LMN Signal source (**HZ** Frequency in Hz of Pure Tone)

Select with F2 + left or right attenuator according to channel.

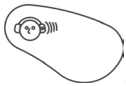
G and P Presentation **mode** of the signal (**M** Modulated)

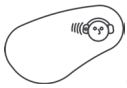
Select with F3 Y + left or right attenuator according to channel.

On the second line:

ABC and NOP Signal level applied to the patient in «dB»
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and LM Two cursors that indicate that the **signal** is being applied to the patient.

DE right channel. Apply signal with .

LM left channel. Apply signal with .

FGHIJ Frequency in Hz of the applied tone

Select with ▽ and △.

On pressing the ⟳ for 1 second:

ABC and NOP Modulation **bandwidth**: 0.2, 0.3, 0.4, 0.5, 0.6, 0.8, 1, 2, 3, 4 or 5 dB

The Luscher test consists in applying a tone level of 40 dB above the hearing threshold and determining the modulation threshold. This will be at the threshold where the subject ceases to hear or starts to hear the "ripple" of the tone, depending on whether the level rises or falls.

The advantage of this test is that it is carried out on one ear only, so recruitment can be ascertained when the Fowler test is not of any use, due to the symmetry in the hearing loss.

In this test only the **modulated** mode is activated, as well as the **pure tone** source and the aerial conduction. The active frequencies are 500, 1000, 2000, 4000 and 8000 Hz. The modulation bandwidth level can be selected at 0.2, 0.3, 0.4, 0.5, 0.6, 0.8, 1, 2, 3, 4 or 5 dB and the frequency setting of the modulation signal is fixed
at 2.5 Hz.

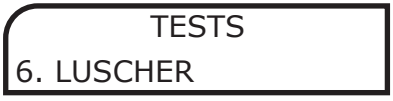
The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING. Special interest shall be taken in explaining the mechanics of the test to the patient to the effect that he will perceive a constant tone of the same frequency with bandwidth modulation in the ear being studied. He must press the warning connection when he ceases to hear or starts to hear the ripple in the tone, depending on whether its level is being turned up or down.

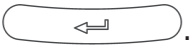
With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

and select the option:





And access the test by pressing the .

2 A screen appears showing the configured options. By default

these are the following:

A	HZ	M	A	HZ	M
60			1000		60

3 Press the  :

NEW PATIENT
Ref:

Enter the reference and press .

If there are thresholds that have not been saved in the database from the previous patient, the equipment will display the following screen which allows them to be saved:

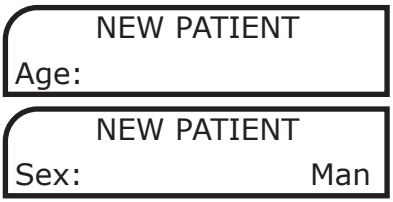
SAVE PREVIOUS
F1: YES F3: NO

Similarly, the current test can be cancelled by entering the same reference again:

NEW TEST
F1: YES F3: NO

Select  to delete all the thresholds of the current test that have been saved and start it again.

NOTE: When ELI diagnosis is selected, the following screen will appear afterwards:



4 Press the F1 key



Use the corresponding attenuator to select the application conduction of the signal for each channel: air (A), or disabled (-).

5 Press F2



Use the corresponding attenuator to select the source of the signal for each channel: in this case only the frequency in Hz of the pure tone (HZ).

6 Press the F3



Use the corresponding attenuator to select the signal presentation mode for each channel: in this case only a modulated (M) signal.

7 Choose the intensity of the signal by rotating the attenuators until the required value is found.

A HZ	M	A HZ	M
60	1000		**60**

8 Select the frequency of the applied tone between 500, 1000, 2000, 4000 and 8000 Hz using the ▽ and △.

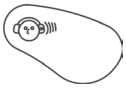
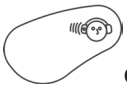
A HZ	M	A HZ	M
60	**1000**		60

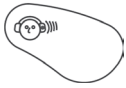
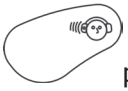
9 Press the ⟲ for 1 second: The following screen will appear:

A HZ	M	A HZ	M
0.2	2.5		0.2

Select the modulation bandwidth level from 0.2, 0.3, 0.4, 0.5, 0.6, 0.8, 1, 2, 3, 4 or 5 dB by rotating the attenuator of the corresponding channel. The frequency setting of the modulation signal is fixed at 2.5 Hz. Press ENTER to accept the changes and return to the test screen.

10 The test can be carried out in two different ways:

• Normal: by pressing the  or  of the corresponding channel.

• Inverted: by keeping the  or  pressed, pressing the INVER key and releasing both of them. This way the signal appears when the silencers are NOT pressed.

In this test the modulation bandwidth level and the frequency are recorded. To save the threshold the ↵ must be pressed. The following screen will appear:

LUSCHER TEST
THRESHOLD SAVED

2.13. WEBER TEST PROCEDURE

The general aspects and the preparation for and instructions to the patient are as described at the beginning of section 2.7. PROCEDURE FOR TONE AUDIOMETRY.

Before explaining this test procedure, it is advisable to describe the characters which may appear on the screen. These show the operational status of the device at all times. As mentioned previously, the screen consists of two lines of 16 alphanumeric characters each.

On the first line, the characters located in positions 0 to 7 refer to the right channel and those located at positions 8 to 15 to the left channel.

The characters which can appear in each of the positions on the screen when this test is being carried out are described below.

ABCDEFGHIJKLMNOP
ABCDEFGHIJKLMNOP

On the first line:

A and J Application conduction (**O** Bone Conducted / - Disabled)

Select with F1 + left or right attenuator according to channel.

CDE and LMN Signal source (**HZ** Frequency in Hz of Pure Tone)

Select with F2 + left or right attenuator according to channel.

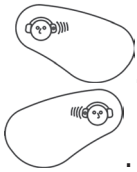
G and P Presentation **mode** of the signal (**C** Continuous)

Select with F3 + left or right attenuator according to channel.

On the second line:

ABC and NOP Signal level applied to the patient in «dB»
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and LM Two cursors that indicate that the **signal** is being applied to the patient.

DE right channel. Apply signal with .

LM left channel. Apply signal with .

FGHIJ Frequency in Hz of the applied tone

Select with ▽ and △.

The Weber test consists in applying a tone level 15 dB above the frontal bone threshold of the subject at frequencies between 250 and 4000 Hz. The vibrator is applied to the forehead and held in place with a headband and not by hand, as this could affect the pressure and lead to error. The technician takes note of the side on which the patient perceives the sound with the greatest intensity. This test is fundamental in clinical audiometry; its physiopathological significance is considered subsequently, for purposes of diagnosing deafness.

In this test only the **continuous** mode is activated, as well as the **pure tone** source and the **bone** conduction. The active frequencies are 250, 500, 1000, 2000, 3000 and 4000 Hz.

The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING. Special interest shall

be taken in explaining the mechanics of the test to the patient to the effect that he will perceive a constant tone of the same frequency by means of a vibrator applied to the forehead. He must indicate on which side he hears the sound with the most intensity.

With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

and select the option:

MENU
1. TESTS

TESTS
7. WEBER

And access the test by pressing the .

2 A screen appears showing the configured options. By default these are the following:

B HZ C - HZ C
60 1000 60

3 Press the :

NEW PATIENT
Ref:

Enter the reference and press .

If there are thresholds that have not been saved in the database from the previous patient, the equipment will display the following screen, which allows them to be saved:

SAVE PREVIOUS	
F1: YES	F3: NO

Similarly, the current test can be cancelled by entering the same reference again:

NEW TEST	
F1: YES	F3: NO

Select  to delete all the thresholds of the current test that have been saved and start it again.

NOTE: When ELI diagnosis is selected, the following screen will appear afterwards:

NEW PATIENT
Age:

NEW PATIENT	
Sex:	Man

4 Press the 

B HZ C - HZ C
BONE DISABLED.

Use the corresponding attenuator to select the application conduction of the signal for each channel: bone (**O**) or disabled (**-**).

5 Press F2



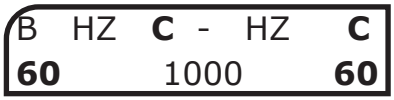
Use the corresponding attenuator to select the source of the signal for each channel: in this case only the frequency in Hz of the pure tone (HZ).

6 Press the F3



Use the corresponding attenuator to select the signal presentation **mode** for each channel: in this case only the continuous signal (C).

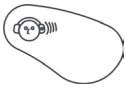
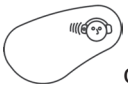
7 Choose the **intensity** of the signal by rotating the attenuators until the required value is found.

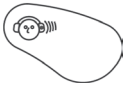
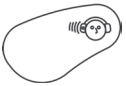


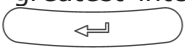
8 Select the **frequency** of the applied tone between 250, 500, 1000, 2000, 3000 and 4000 Hz by using of the ▽ and △.

B HZ	C - HZ	C
60	**1000**	60

9 The test can be carried out in two different ways:

• Normal: by pressing the  or  of the corresponding channel.

• Inverted: by keeping the  or  pressed, pressing the INVER key and releasing both of them. This way the signal will appear when the silencers are NOT pressed.

In this test, the side and the frequency at which the patient states hearing with the greatest intensity are recorded. To save the threshold the  key must be pressed. The following screen will appear:

R.E.	LEVEL	L.E.
F1:>	F2:=	F3:<

Press the  if the patient perceived the tone with more intensity with the right ear,  if he perceived it with the greatest intensity with the left ear and  if no difference was noticed between both ears. Then save the threshold:

WEBER TEST
THRESHOLD SAVED

2.14 PURE TONE HF TEST PROCEDURE

The general aspects and the preparation and instructions to the patient are described at the beginning of section 2.7. PROCEDURE FOR TONE AUDIOMETRY

Before explaining this test procedure, it is advisable to describe the characters which may appear on the screen. These show the operational status of the device at all times. As mentioned previously, the screen consists of two lines of **16 alphanumeric characters** each.

On the first line, the characters located in positions **0 to 7** refer to the **right channel** and those located at positions **8 to 15 to the left channel**.

The characters which can appear in each of the positions on the screen when this test is being carried out are described below.



On the first line:

A and J Application conduction (**A** Air Conducted / **-** Disabled)

Select with F1 + left or right attenuator according to channel.

CDE and LMN Signal Source (**HZ** Frequency in Hz of Pure Tone / **NBN** Narrow Band Noise / **WN** White Noise)

Select with F2 + left or right attenuator according to channel.

G and P Presentation Mode of the signal (**C** Continuous / **P** Pulsating)

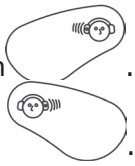
Select with F3 + left or right attenuator according to channel.

On the second line:

ABC and NOP Signal level applied to the patient in «dB»

ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

DE and LM Two cursors that indicate that the signal is being applied to the patient.

DE right channel. Apply signal with  .

LM left channel. Apply signal with .

FGHIJ Frequency in Hz of the applied tone

Select with  or  .

The Pure Tone HF test consists of a pure tone test, in which the hearing thresholds can be determined for frequencies higher than 8.000 Hz. The **SIBELSOUND 400** audiometer allows the 9.000, 10.000, 11.200, 12.500, 14.000, 16.000, 18.000 y 20.000 Hz frequencies, besides the frequencies of 125 to 8.000 Hz. In this test, only the air conduction is active, the pure tone, narrow band noise and white noise as sources and continuous and pulsating modes.

The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING. Special interest shall be taken in explaining the mechanics of the test to the patient. He will perceive tones of several frequencies to different intensities. Pressing the response button, the patient must indicate the level he starts perceiving the tone that will determine the hearing threshold.

To realize pure tone high frequency audiometries with masking, general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION

OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITH MASKING.

With the audiometer set up as indicated in section 2.4 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

key and select the option:





And access the test by pressing the  key.

2 A screen appears showing the configured options. By default these are the following:



3 Press the  key:



Enter the reference and press .

If there are thresholds that have not been saved in the database from the previous patient, the equipment will display the following screen, which allows them to be saved:



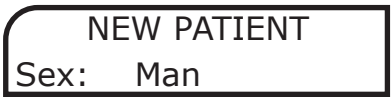
Similarly, the current test can be cancelled by entering the same reference again:



Select F1 to delete all the thresholds of the current test that have been saved and start it again.

NOTE: When ELI diagnosis is selected, the following screen will appear afterwards:





4 Press the F1 key



Use the corresponding attenuator to select the **application conduction** of the signal for each channel: air (**A**) or disabled (**-**).

5 Press the F2 key

A **HZ** C	A **HZ** C
TONE	TONE

Use the corresponding attenuator to select the **source of the signal** for each channel: Hz of pure tone (**HZ**), narrow band noise (**NBN**) or white noise (**WN**)

6 Press the F3 key

A HZ **C**	A HZ **C**
CONTIN.	CONTIN.

Use the corresponding attenuator to select the **signal presentation** mode for each channel: continuous (**C**) or pulsating (**P**).

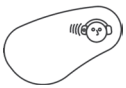
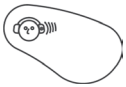
7 Choose the **intensity** of the signal by rotating the attenuators until the desired value is found.

A HZ C	A HZ C
60 8000	**60**

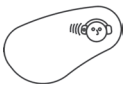
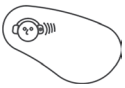
8 Select the **frequency** of the applied tone in the range of 125 to 20.000 Hz by using the ▽ or △ keys.

A HZ C	A HZ C
60 **8000**	60

9 The test can be carried out in two different ways:

• **Normal**: by pressing the  or  keys of the

corresponding channel.

• **Inverted**: keep the  or  key pressed, press the  key and release both of them. This way the signal will appear when the silencers are NOT pressed.

Like in the pure tone test, frequency and threshold level of intensity for every channel are saved, in which the patient had pressed the response button. If the test has been realized with masking, the level of applied noise is also stored. To save the threshold,  key must be pressed. The following screen will appear:



2.15. PROCEDURE FOR FREE AUDIOMETRY

As explained above, many of the audiometric tests have several variants in terms of the procedure to be followed, so that to describe them all would be very lengthy, and moreover likely to involve omissions or errors. Therefore options have been provided for the **SIBELSOUND 400** audiometer to simplify the execution of each kind of test.

However, specialists for whom the options described are too limited can use the free audiometry option to carry out such tests as they wish without being limited by the software, subject only to the capabilities of the audiometer.

This audiometer option MUST NOT BE CONFUSED WITH FREE FIELD. By selecting "Free Audiometry" the user can carry out any other test with the audiometer, including those described above, as the audiometer permits access to and selection of all of its functions, even though some may appear absurd.

With this option it is not possible to produce reports or save tests in the database.

REFERENCE TONE (OPTIONAL)

This option allows increase/decrease in the level of signal applied the patient in steps of 1 dB and is only active in Free tests (where this option is selected), so the test cannot be printed or saved in the database. This option is deactivated automatically after 15 minutes during which no key on the device has been pressed.
To select the reference tone:

1 From the Main Menu access the option

MENU
5. REF. TONE

2 Using the attenuators, select the reference tone (ON-1dB) and press ⏎ to accept or RESET to cancel;

REF. TONE
ON 1dB

2.16. DIAGNOSTIC CALCULATIONS

The **SIBELSOUND 400** audiometer can determine the following diagnoses based on their respective parameters:

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 KLOCKHOOF DIAGNOSIS (Modified by the Lavoro Clinic of Milan)

The parameters for each diagnosis and the calculation method of each are described in APPENDIX 3 of this manual.

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

2.17. PRINTING AND SAVING AUDIOMETRIC TESTS

The **SIBELSOUND 400** audiometer can print and/or save certain audiometric tests to the device itself or to an external database.
The audiometer can save the hearing thresholds detected to a temporary memory. As mentioned above, this operation can be carried out by pressing  after evaluating a threshold.
To review these thresholds press the  key. Once in review mode, use the attenuators to select the route and the  /  keys to explore the thresholds saved during the various tests.

Once the thresholds are saved you can do any of the following:

- Print the audiometric data using an external printer.
- Save the audiometric data to an INTERNAL DATABASE.
- Transfer the audiometric data to an EXTERNAL DATABASE ON A PC.

PRINTING AUDIOMETRIC DATA

A. Type of printer

The device is capable of controlling any printer that works with IBM GRAPHICS or HP PCL.
We recommend using an inkjet printer with a low noise level.

B. Tests which can be printed

The information which can be printed is everything defined in section 1.8. AUDIOMETRIC TESTS, with the exception of the

FREE AUDIOMETRY option.

- TONE AUDIOMETRY
- SISI TEST
- SPEECH AUDIOMETRY
- FOWLER
- TONE DECAY
- LUSCHER
- WEBER
- PURE TONE HF.

C. Printing the Report

The process to follow when carrying out the tests you wish to print is as follows:

1 Press the  key and assign a reference number of up to 10 characters to the patient being tested. This reference is entered with the keys which are associated with the digits from 0 to 9 and confirmed with the  key.

2 Carry out the audiometric test on the patient as described in section 2.7 PROCEDURE FOR TONE AUDIOMETRY and subsequent sections.

The following considerations apply depending on the type of test:

TONE AUDIOMETRY

The only proviso is that, once each hearing threshold has been determined, along with the level for the channel corresponding to that threshold, the  key must be pressed for a few seconds until the message "THRESHOLD SAVED" appears on the screen. If masking is being applied to the other ear, it must be at the right level before pressing .

NOTE
Saving of data is carried out independently for each threshold and each level of masking, if applicable.

The device only saves the latest threshold detected before pressing the ⏎ key.

To remind the technician to save the thresholds, the audiometer generates a warning before the next one begins, via the following screen:



If the audiometry is pure tone, this warning appears when there is a patient registered in the device, the signal has been applied and the user attempts to change the frequency, the path or the source

SISI TEST

In this test, once the twenty 1 dB signal increases have been applied to the patient and the latter has provided the corresponding responses (assuming they were heard) press the ⏎ key and the device saves the increment and response counters.
The save threshold warning appears when there is a patient registered in the device, stimuli have been applied and the user attempts to modify the intensity, the pathway or mode of the signal, or there is an attempt to reset the stimuli and responses.

If the frequency is modified when a patient is registered in the device and stimuli have been applied, the threshold is saved automatically.

SPEECH AUDIOMETRY

In speech audiometry, we enter the number of words sent to the patient and received from the latter at a determined level.

With the level selector in the correct position, press

 and the audiometer saves the number of words applied and the correct responses received.

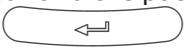
The save threshold warning appears when there is a patient registered in the device, the signal has been applied and an attempt is made to modify the intensity, the pathway or the signal source, or if an attempt is made to reset the number of correct responses.

FOWLER

In the Fowler test, once the signal has been applied to the patient in both ears and the patient presses the button to notify equal perception of level in both ears, press the ENTER key to record the frequency and the intensity levels on the machine.

The warning to record the threshold appears when a patient has been registered on the machine, a signal has been applied and someone attempts to change the signal conduction or source. If the frequency is changed and thresholds have been saved, the machine will either allow for these to be deleted or for them to be added to the new frequency.

TONE DECAY

In the Tone Decay test, once the signal is applied to the patient's ear and the patient stops pressing the warning button, press the  key to record the time elapsed during the audition on the machine.

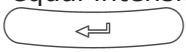
The warning to save the threshold appears when a patient has been registered in the machine, a signal has been applied and someone attempts to change the intensity, the conduction, the source or the signal mode, or if someone attempts to reset the seconds counter.

LUSCHER

In the Luscher test, the patient uses the connection to notify when he ceases to hear or begins to hear the ripple of the applied tone, depending on whether its level is rising or falling.

At that time, the technician must press the  key and the machine will save the modulation level and the frequency.
The save threshold warning appears when a patient has been registered on the machine, a signal has been applied and someone attempts to change the frequency, the signal conduction or the source.

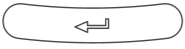
WEBER

In the Weber test, the patient notifies which ear perceives the tone applied by the vibrator with the greatest intensity or if both ears perceive it with equal intensity. At that time, the technician must press the  and select the ear indicated by the patient.

The save threshold warning appears when a patient has been registered on the machine, a signal has been applied and someone attempts to change the frequency, the signal conduction or the source.

PURE TONE HF

Like in the pure tone audiometry, once each hearing threshold has been determined, along with the level for the channel corresponding to that threshold, the  key must be pressed and for a few seconds the message "THRESHOLD SAVED" appears on the screen. If masking is being applied to the other ear, it must be at the right level before pressing INTRO.

NOTE
Saving of data is carried out independently for each threshold and each level of masking, if applicable. The device only saves the latest threshold detected before pressing the  key.

The warning to record the threshold appears when a patient has been registered on the machine, signal has been applied and someone attempts to change the frequency, signal conduction or source.

FREE AUDIOMETRY

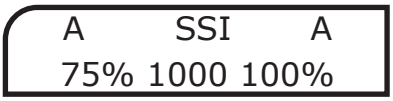
Having performed the tests, if you entered via this option you can neither print nor save the results in the database.

3 With the hearing thresholds in the temporary memory, these can be reviewed for queries or errors. Pressing the  key, each of the hearing thresholds held in the memory is shown. In the central part of Line 1 you can see the type of test (TNL, SSI, SP, FWL, DEC, LCH, WBR, THF). The remainder of the information depends on the type of test selected, corresponding to:

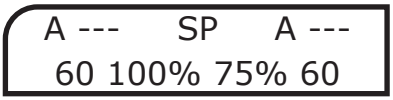
1. Tone Audiometry: Threshold, pathway and mask. If masking has been applied, the level is indicated above the threshold.



2. Sisi test: Percentage and pathway.



3. Speech audiometry: Threshold and percentage of correct answers displayed, pathway and mask. If masking has been applied, the level is indicated above the threshold.



4. Fowler: threshold, frequency and conduction.

A	FWL	A
60	1000	60

5. Tone Decay: seconds (on the first line) and threshold, frequency and conduction (on the second line).

A	15	DEC	A
60		1000	60

6. Luscher: threshold (modulation level), frequency and conduction.

A	LCH	A
0.3	1000	0.2

7. Weber: frequency, side (>, = or <) and conduction:

B	WBR	B
R.E.<L.E	1000	0.2

8. Pure Tone HF: Threshold, frequency, conduction and mask. If masking has been applied, the level is indicated above the threshold.

A ---	THF A	---
60	8000	60

4 If a threshold has been entered incorrectly it is repeated for the corresponding frequency and channel.

5 When carrying out more than one kind of test for the same patient, it is not necessary to print a report after each test separately. All the results can be printed together at the end.

6 On completing the test, press the  key and the report

will be printed automatically.

Press the RESET key to cancel printing.

The information on the Tone, SISI and Luscher tests is printed on the first page.

The information on the Tone Decay, Fowler, Weber and SPEECH tests is printed on the second page.

On the third page Pure Tone HF results are printed.

On the fourth page diagnosis results are printed.

Each of these last three pages are only printed out if a Tone Decay, Fowler, Weber, Speech or Pure Tone HF tests are carried out or if more tan one diagnosis has been selected in the configuration.

An audiometric file output via a printer is shown at the end of this chapter.

SAVING AUDIOMETRIC DATA IN THE INTERNAL DATABASE

The **SIBELSOUND 400** audiometer has a FLASH memory with capacity for more than 1000 tone tests via air conduction and bone conduction in both channels at the frequencies 500, 1000, 2000, 3000 and 4000 Hz.

This stored information can be used for:

- Subsequent transfer to a database on a PC
(See section 2.19. COMMUNICATIONS SYSTEMS)
- Printing using an external printer.

SAVING A TEST

To save a test in the database press the key. The test is saved in its existing state.

A screen then appears similar to the following (the first line depends on the test carried out):



VIEWING, PRINTING AND DELETION OF SAVED TESTS

To view the tests saved in the database proceed as follows:

1 Access the Options Menu by pressing the MENU key or pressing the from the test screen.

2 Select the option



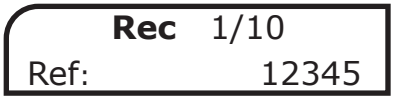
and press .

3 Then select

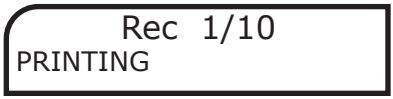


and press . The user can also access the previous screen directly by pressing the key for 1 second from the test screen. If there are no thresholds to save, the key can be pressed as normal.

The following screen appears:

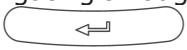


4 From this screen you can print the patient's tests by pressing :

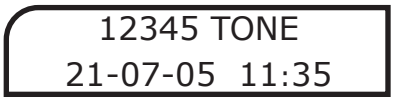


5 From this screen, the patient's tests can be deleted by pressing  +  .



6 Select the required patient, navigating through the database using the attenuators and press .

The following screen appears:



7 At this point you may:

- Print the tests for the selected patient by pressing 

12345 TONE PRINTING

● Select other tests for the same patient (if any), using the attenuators.

● View the test values by pressing 
In this case a screen similar to the following appears:

A --- TNL A --- 60 1000 ---

CLEARING THE INTERNAL DATABASE

To clear the internal database of data, follow these steps:

1 Access the Options Menu by pressing the 

key

2 Select the option

MENU 4. DATABASE

and press .

The user can also access the previous screen directly by pressing the  key for 1 second from the test screen. If there are no thresholds to save, the  key can be pressed as normal.

3 Then select



and press ⏎. The following screen appears



4 Press F1 key to clear the database and the following message appears:



WARNING:
This process destroys all information held in the Internal Database and it can NOT be recovered.

FINDING A PATIENT IN THE INTERNAL DATABASE

To find a patient in the internal database proceed as follows:

1 Access the Options Menu by pressing the MENU key.
2 Select the option



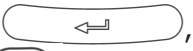
and press ⏎.

The user can also access the previous screen directly by

pressing the  key for 1 second from the test screen. If there are no thresholds to save, the  key can be pressed as normal.

3 Then select

```
DATABASE
3. PAT. SEARCH
```

and press , (access is also possible by pressing the key  from within the Database menu).
The following screen appears

```
PATIENT SEARCH
Ref:
```

Enter the reference for the patient you wish to find using the numeric keypad. If the patient is stored in the Database, the following screen appears:

```
Rec  1/10
Ref:          12345
```

DELETE A PATIENT FROM THE DATABASE

To delete a patient from the internal database proceed as follows:

1 Access the Options Menu by pressing the 

. key.

2 Select the option

MENU
4. DATABASE

and press . The user can also access the previous screen directly by pressing the  key for 1 second from the test screen. If there are no thresholds to save, the  key can be pressed as normal.

3 Then select

DATABASE
4. CLEAR PATIENT

and press . The following screen appears:

Rec 1/10	
Ref:	12345

Use the attenuators to select the patient to be deleted and press .

DELETE PATIENT	
F1:YES	F3:NO

Press  to confirm and delete the patient or  to return to the previous screen.

2.18. PERSONALISING THE DEVICE

The **SIBELSOUND 400** audiometer includes a configuration program which allows the user to define their initial work configuration and reload it every time the Device is turned on.

The sub-section INITIAL CONFIGURATION explains the procedure for selecting a particular initial configuration.

The options which can be configured are:

- Diagnosis
- Frequencies
- Printer
- Contrast
- Language
- Calibration
- Inicial test
- Parameters for each of the various test
- Date-Time
- Auto-mask
- Auto-Saved of hearing thresholds (Pure Tone audiometry)
- High Frequency in the Free test.

PERSONALISING DIAGNOSIS

Take the following steps to select the type of diagnosis that will appear in the report:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

CONFIGURATION
4. DIAGNOSIS

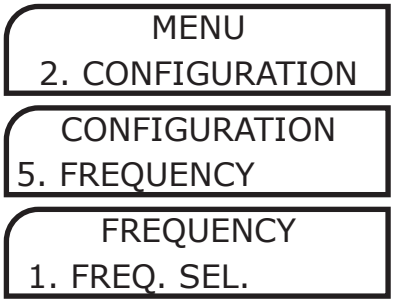
3 Choose the diagnosis you require from the following:

1. Ministry of Labour and Social Affairs
2. Council of Physical Therapy
3. ELI Index
4. SAL Index
5. Klockhoff Index

PERSONALISING FREQUENCIES

To select the frequencies for inspection in the Pure Tone and Free tests:

1 From the Main Menu access the option



2 Select



3 Choose the desired frequencies.

CUSTOMISING MUSICAL FREQUENCIES

To select the musical frequencies in the Pure Tone and Free tests:

1 From the main menu, access the following option

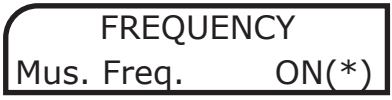


2 Select





3 Use the attenuators to choose whether or not you want to use musical frequencies and press "ENTER".



The musical frequencies appear on the chart below and correspond to traditional frequencies when shown on the screen or on reports:

MUSICAL FREQUENCY (Hz)	CONVENTIONAL FREQUENCY (Hz)
130.8	125
261.6	250
523.3	500
1046.5	1000
2093.0	2000
4186.0	4000
8372.0	8000

If the musical frequencies have been selected, they are shown on the Pure Tone and Free test screen of the threshold review

and the database with an asterisk next to the value of the frequency. They are indicated in the reports with the warning: "Attention: Musical frequencies", underneath the Pure Tone test graphs.

Example of a Pure Tone test screen with the Musical Frequencies option selected:



PERSONALISING CALIBRATION

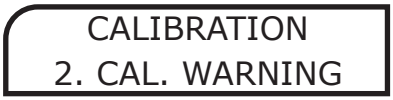
To configure the date of the next calibration:

1 From the Main Menu access the option



2 Select





3 The following screen appears



With the date of the last calibration and the model of headset calibrated with the equipment.

Press 

4 The following screen appears

INTERVAL 455 d
Cal Warn ON (*)

With the interval of days that the calibration warning is programmed and the option to deactivate it.
Select whether or not to display the calibration warning by means of the dimmers.

WARNING
It is recommended NOT to deactivate the warning to ensure that the equipment is always well calibrated.

PERSONALISATION OF DATE AND TIME

To configure the device date and time:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

CONFIGURATION
9. DATE - TIME

3 Use the attenuators to navigate through the various fields.

You can delete the value of a field by pressing 

and enter

a new value using the numeric keypad. Press ⏎ to accept the changes RESET for a second to cancel them and exit.

AUTOMATIC MASKING

To select automatic masking:

1 From the Main Menu access the option

```
MENU
6. AUTO MASK
```

2 Use the attenuators to select whether or not to use automatic masking and press ⏎.

```
AUTO MASK
Auto Mark ON (*)
```

Before performing a masked test, adjust the intensity difference between the mask channel and the signal channel by moving the masking channel attenuators. After doing so, if the intensity of the signal channel is changed, you will notice that the difference between the two channels remains constant (except at the top and bottom limits of the attenuation range). This difference can be modified at any time by using the masking channel attenuator. If you press the silencer of the signal channel, the masking signal will also be applied to the other channel, regardless of whether direct or inverted mode is selected.

AUTO-SAVED OF HEARING THRESHOLD

This option allows the audiometer to save automatically the hearing thresholds detected to a temporary memory. (Only valid for **Pure Tone Audiometry Test).**

Take the following steps to select the option:

1 From the main menu, access the AUTO-SAVE option:

MENU
7. AUTO SAVE

2 Use the attenuators to choose whether or not you want to saved automatically the thresholds and press ⏎.

AUTO SAVE
Auto Save. ON (*)

When performing a Pure Tone test, after the entry of a patient reference and the appliance of signal; the threshold will be saved automatically, each time that the patient presses the response button.

PURE TONE TEST
THRESHOLD SAVED

WARNING

Thresholds are saved in the temporary memory, NOT into the database, so this information will be deleted when the device is turned off or if you change the patient.

If you want to record the results permanently in the database, press the  button.

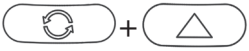
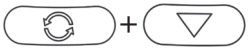
HIGH FREQUENCY

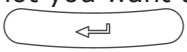
This option allows to realize a Free test by Air HF conduction in the range from 125 to 20.000 Hz. To select the high frequency option:

1 From the Main Menu, select the Free test





2 Press simultaneously  o  keys.

3 Use the attenuators to choose whether or not you want to enable the High Frequency option and press .



INITIAL CONFIGURATION

The process to specify the initial working configuration is as follows:

1 Set the controls to the positions which you would like them to be in when the audiometer is turned on.

2 Access each of the tests and select: the values for the attenuators, the conduction route, the mode, the source and the frequency.
For the SPEECH test select: the number of questions, the volume of the signal to the patient and the input device.
For SISI test: choose the increments in dB and the time between stimuli.

3 Set up each of the above-mentioned configurations.

4 Press the  key

5 Using the △ or ▽ keys select the option:

MENU
2. CONFIGURATION

and press the ↵ key

6 Using the ▽ or △ keys select the option:

CONFIGURATION
1. SAVE CONF.

and press the ↵ key.

7 The following message appears:

SAVE CONF.	
F1: YES	F3: NO

Press F1 to confirm

SAVE CONF.
CONF. SAVED

Once this has been done, the audiometer will set itself in the selected position each time it is turned on.

The only function it cannot memorise is the "silencer" function for each channel.
These always remain in the "direct" position (no signal is applied unless the relevant keys are pressed).

DEFAULT CONFIGURATION

To modify the default configuration:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

CONFIGURATION
2. MODIF DEFAULT

3 The following message appears:

MODIF. DEFAULT	
F1: YES	F3: NO

Press F1 to confirm

MODIF. DEFAULT
DEFAULT CHANGED

To copy the default configuration to the user's configuration:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

CONFIGURATION
3. RESET DEFAULT

3 The following message appears:



Press  to confirm

2.19. COMMUNICATIONS SYSTEMS

One of the features of the **SIBELSOUND 400** is the Communications System with other media which allows it to:

- Transfer information from the device's internal database to a PC.
- Communicate in real time with a PC.
- Export patient tests to other Management Systems.
- Update the device's internal Firmware.

The communications are performed via USB, using the W50 software. Read the Instructions for Use for the W50 Audiometry Software for installing the USB module.

TRANSFER OF TESTS TO THE PC

If you wish to view, print, or manage the tests saved in the internal database of the audiometer and/or store them using a PC, you need to use the **W50 Audiometry Software**.

The process to carry out the transfer is as follows:

1 Save the tests you require in the device's Internal Database.

2 Install the **W50 Audiometry Software**, as described in the **Instructions for Use**.

3 From the PC load the data in the database using the option **Import tests** from the menu Options – Importing tests in the **W50 Software**.

4 The screen displays a list of the tests stored in the device. Select the ones you wish to import into the **PC Database**(the one chosen using the W50 Software).

5 From this point you can select, view or print any of the tests imported or transferred to the PC.

COMMUNICATION IN REAL TIME WITH THE PC

The **SIBELSOUND 400** audiometer can communicate in real time with a PC. This allows the data of the tests being carried out to be viewed directly on the computer screen.
The above-mentioned software provides total control of the device and real time viewing on the computer screen of graphic displays of the audiometric tests being carried out.
See the Instructions for Use for the W50 Audiometry Software.

Any changes you make directly using the audiometer are also updated on the computer screen.

EXPORTING TESTS TO OTHER SYSTEMS

The **SIBELSOUND 400** audiometer provides the option of exporting tests previously saved in the internal database to the medical centre's other management systems using the **W50 Audiometry Software**.

To do this, the tests must be transferred from the device to the database selected with the **W50 Software.** From there, the tests can be exported in **comma separated variables mode**, a format compatible with many different systems.

The information is available in the **PRUEBAS.TXT** file, which contains the tests in the database.

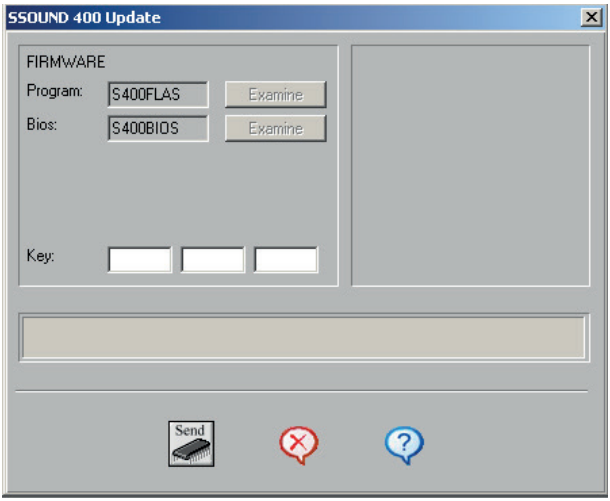
If you have any doubts or questions, please contact **SIBEL S.A.U.'s Technical Service** or your distributor who will provide you with the information you require.

W50 AUDIOMETRY SOFTWARE FOR PC

For information relating to the **Audiometry Software W50**, see the **Instruction Manual**.

2.20. UPDATING THE UNIT FIRMWARE

The **SIBELSOUND 400** audiometer from **SIBEL S.A.U.** is provided with a firmware updating and maintenance process. Before updating, make sure that the audiometer is operating and connected to the PC. If serial communications are being used, check the port selected in Configuration / Links. Once these checks are completed, select the Udpate Flash option in the Configuration / Utilities menu. In the Update SSOUND 400 dialogue box, enter the update password provided with the audiometer, press the SEND button and watch the loading process.



NOTE:
Do not cancel the loading process once it has been started.

On completion, a "transmission correct" message appears. For

the new firmware to work correctly, the user must exit the loading screen, switch the audiometer off and switch it back on. From then on, the unit will operate with the new firmware version.
If an error occurs during the loading process and the process is not completed correctly, the updating procedure can be repeated. To do so, exit the loading screen, switch off the audiometer and switch it back on. A screen should appear with the folowing text: ACT. FIRMWARE / UPDATE FIRMWARE. The procedure to update the audiometer firmware can now be repeated.

2.21. MAINTENANCE PROGRAM

The device has a maintenance program which allows it to adjust and/or check the functioning of certain options.
A series of options grouped in the Equipment Test menu can be used to verify unit operation. From this menu it is possible to:

- Check the device hardware (CPU and LCD).
- View the updating password and version of the equipment.
- Test that the keyboard and the printer work properly.
- Reset the device.

The options can be adjusted from three menus:

- Monitor: to adjust the volume of the monitor.
- Speech-Inter: to adjust the volume of the technician microphone and headphones and the patient microphone.
- Auxiliary: to adjust the volume of the auxiliary input.

To access it, turn the device on and press the 

key.
Use the attenuators to select:

MENU
3. MAINTENACE

TEST DEVICE

From the maintenance menu, use the attenuators to select the following options:
Press ↵ to access the various options:



Press ↵ to access the various options:

CPU TEST

This option allows you to check the device's CPU. Use the attenuators to select the option:



Press ↵ to start the various CPU tests. When the tests are completed, the following screen appears:



Press F3 to exit. In the event of errors, a message is displayed for each error, scroll forward using the ↵ key. The previous screen is displayed again. If no errors have occurred, the device exits the CPU test.

LCD TEST

This option allows you to check the device's LCD. Use the

attenuators to select the option:

```
    TEST DEVICE
2. LCD
```

Press  to start each of the LCD tests or 

to exit.

TEST THE KEYBOARD

Select the option:

```
    TEST DEVICE
3. KEYBOARD
```

The test will request the user to press each of the keys on the keyboard.

To exit press the  key for 1 second.

PRINTER TEST

Select the option:

```
    TEST DEVICE
4. PRINTER
```

This verifies that the printer is functioning correctly by printing out a test report.

UPDATING PASSWORD

Select the option:

```
    TEST DEVICE
5. UPDATE KEY
```

To view the password requested by the Audiometry W50 software, it is necessary to load the device firmware again.

VERSION

Select the option:



To view the Bios and Program version of the unit firmware.

RESET DEVICE

Select the option:



The following screen appears:



Press 

to reset the device.

NOTE:
If you perform a device reset, you will lose the user configuration and the standard configuration that will be replaced by the factory configuration of the equipment.

SERIAL NUMBER

Select option 8 from the menu to display the serial number of the equipment.

MONITOR

The device has an optional module to monitor the signals applied to the patient, that also functions as an intercom.

If the level of the monitor is set to 0, the monitor mode is deactivated and the module only operates as an intercom. The level of the monitor signal can be set between 1 and 10 (each unit corresponds to approximately 5.5 dB).

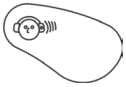
For more convenient hearing, the monitor module adjusts the signal applied to the technician headphones at two levels, if the signal is too high the monitor automatically fades it and if it is too low the monitor amplifies it, so the signal is always within a comfortable hearing range.

Monitor mode:



To adjust the level of the monitor, select the following option:

MAINTANCE
3. MONITOR

Place the technician headphones, apply the signal with the  o  keys or use the attenuators to adjust the level of the monitor to the desired setting. To deactivate the monitor function, adjust the setting to 0.

SPEECH-INTER

This menu is used to adjust the level of the devices used in the Speech test and the intercom function (both optional).

These devices are:

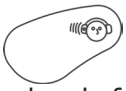
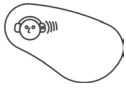
- Technician headphones
- Technician microphone
- Patient microphone

Intercom mode:



To adjust these levels, select the following option:

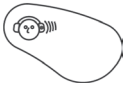
MAINTANCE
4. SPEECH-INTER

Apply the signal using the  o  keys and use the attenuators to adjust the level of the devices to the desired setting. To change the device, press the  o .

AUXILIARY

This menu is used to adjust the level of the auxiliary signal that can be used in the Speech test (optional). To adjust the level, select the following option:

MAINTANCE
5. AUXILIAR

Apply the signal using the keys  o  and use the attenuators to adjust the level of the auxiliary signal.

The following table shows the signal flow and the adjustment options of the previous menus:

Option to adjust	Signal flow Patient headphones	Technician headphones
Monitor volume	1Khz dB tone selected	1Khz dB tone selected
Auxiliary volume	Auxiliary signal	Silence
Technician headphones	Silence	Patient microphone
Technician microphone	Technician microphone	Silence
Patient Microphone	Silence	Patient microphone

AUDIOMETRY REPORT

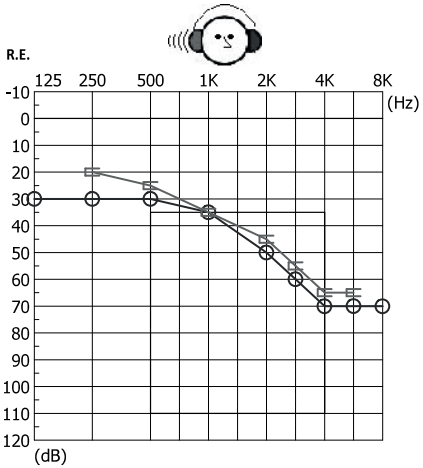
Name:
Age(y): 43
Sex: Man
Height (cm):
Weight(Kg):
BMI:
Version: 52072C-3.00

SIBELSOUND 400

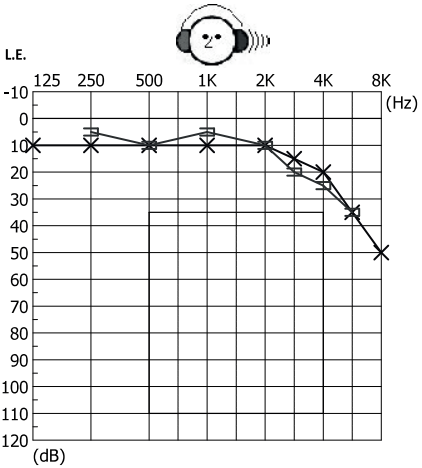
Test date: 04/05/2023
Reference: 111222
Technician:
Reason:

Origin:
Serial number: 207-B118

R.E.



L.E.



No Masking	R.E.	L.E.	With Masking	R.E.	L.E.
Air	O	X	Air	△	□
Bone	<	>	Bone	⊏	⊐
F.Field	Ø			[	]
No response					

COUNCIL OF PHYSICAL THERAPY

	R.E.	L.E.
Hearing Loss (%)	46.2	1.8
Average dBs	46.2	12.5
Bilateral Loss (%)	7.3	

Right ear Moderate hypoacusia
Left ear Normal

COMMENTS:

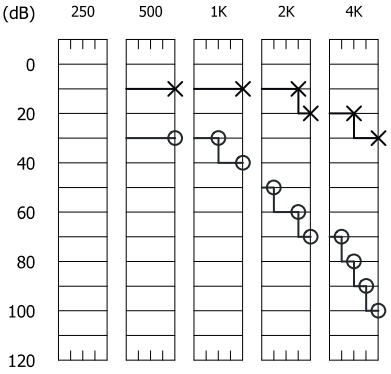
SISI TEST

Hz	500	1000	2000	4000
R.E. %	10	30	100	100
L.E. %	5	10	10	20

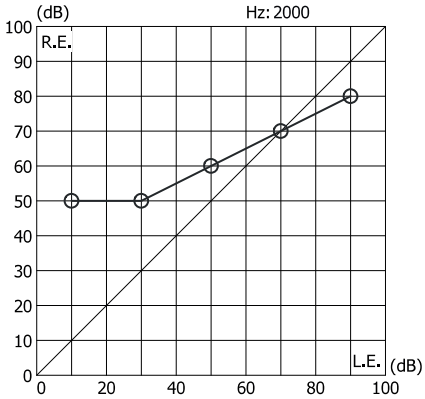
LÜSCHER TEST

Hz	500	1000	2000	4000	8000
R.E. dB	1.0	0.8	0.6	0.4	---
L.E. dB	2.0	2.0	1.0	0.8	---

TONE DECAY TEST



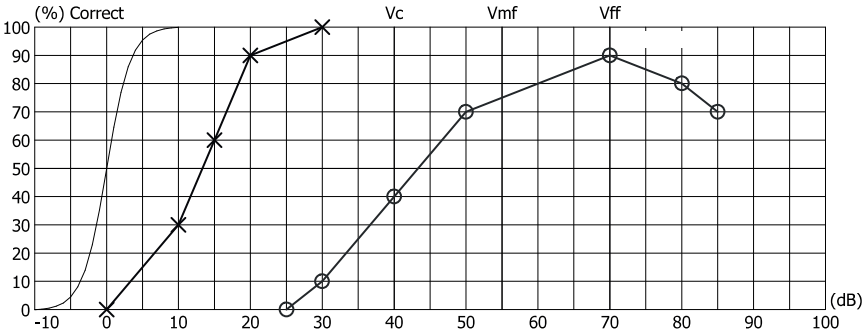
FOWLER TEST

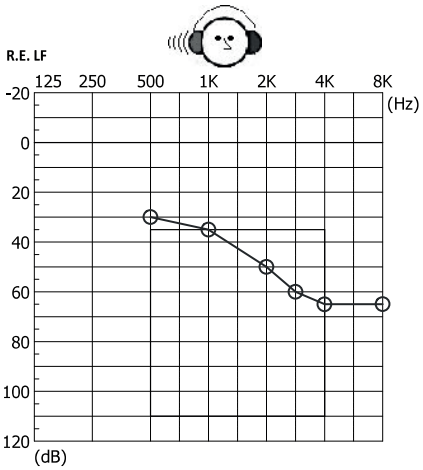


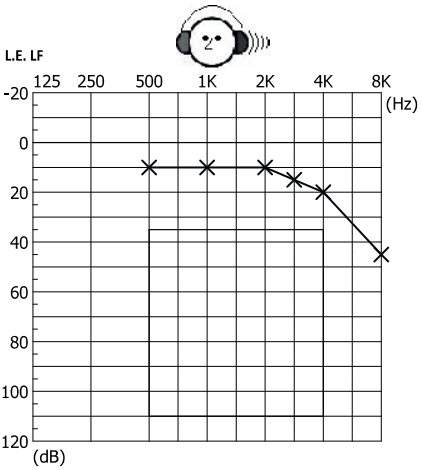
WEBER TEST

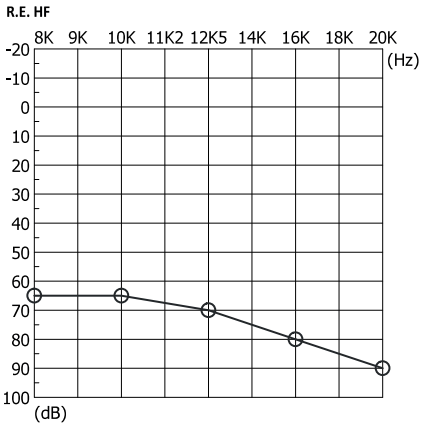
Hz	250	500	1000	2000	3000	4000	
R.E.	>	>	>	>	>	>	L.E.

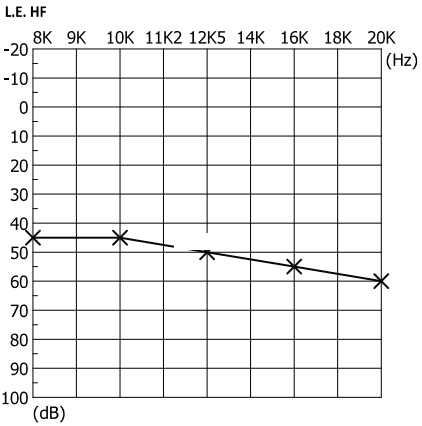
SPEECH AUDIOMETRY




R.E. LF
125 250 500 1K 2K 4K 8K
(Hz)
-20 0 20 40 60 80 100 120
(dB)


L.E. LF
125 250 500 1K 2K 4K 8K
(Hz)
-20 0 20 40 60 80 100 120
(dB)


R.E. HF
8K 9K 10K 11K2 12K5 14K 16K 18K 20K
(Hz)
-20 -10 0 10 20 30 40 50 60 70 80 90 100
(dB)


L.E. HF
8K 9K 10K 11K2 12K5 14K 16K 18K 20K
(Hz)
-20 -10 0 10 20 30 40 50 60 70 80 90 100
(dB)

DIAGNOSTIC RESULTS

MINISTRY OF LABOUR AND SOCIAL AFFAIRS Official Gazette 26 January 2000

	R.E.	L.E.
Hearing Loss (%)	28.1	0.0
Average dBs	43.8	11.2
Bilateral Loss (%)	4.7	

Right ear	Slight hypoacusia
Left ear	Normal

COUNCIL OF PHYSICAL THERAPY

	R.E.	L.E.
Hearing Loss (%)	46.2	1.8
Average dBs	46.2	12.5
Bilateral Loss (%)	7.3	

Right ear	Moderate hypoacusia
Left ear	Normal

DIAGNOSIS ACCORDING TO ELI INDEX

Right ear	Degree E. Clear evidence of deafness
Left ear	Degree A. Normal excellent

DIAGNOSIS ACCORDING TO SAL INDEX (Note 1)

	R.E.	L.E.
Hearing Loss (%)	28.1	0.0
Bilateral Loss (%)	4.7	

Detected deafness too asymmetric to be evaluated using the SAL table

DIAGNOSIS ACCORDING TO KLOCKHOFF INDEX

Right ear	Conversational loss. Advanced hypoacusia by noise
Left ear	Normal

COMMENTS:

Note 1: According to the Ministry of Labour and Social Affairs Official Gazette 26 January 2000

3. TECHNICAL SPECIFICATIONS

3.1 TYPES OF TESTS

TONE AUDIOMETRY
- Air conduction without masking
- Bone conduction without masking
- Air conduction with masking
- Bone conduction with masking
- Screening audiometry
- Free field

SISI TEST
SPEECH AUDIOMETRY
FOWLER
TONE DECAY
LUSCHER
WEBER
PURE TONE HF
FREE AUDIOMETRY

- Multiple tests or variants, depending on the specifications of the device (WARBLE, STENGER, etc.)
- Free field audiometry

3.2. SIGNAL GENERATORS

TWO INDEPENDENT CHANNELS

- Right ear
- Left ear

ROUTES OF APPLICATION OF THE SIGNAL

- Air conduction (LF and HF)
- Bone conduction
- Free field
- Monitor/Intercom

SIGNAL SOURCES

- Pure tones

LF Frequency: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 , 8000 Hz
Accuracy: 1%

HF Frequency: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 9000, 10000, 11200, 12500, 14000, 16000, 18000, 20000 Hz
Accuracy: 1%

- Narrow band noise (NBN) for masking
  Band: In accordance with EN 60645-1
  Out of band attenuation: Equal to or greater than 12 dB/octave

- Speech noise (SN) for masking
  Band: 125 Hz to 8000 Hz +- 3dB
  Out of band attenuation: 12 dB/octave

- White Noise (WN) for masking
  Band: 125 - 20000 Hz +- 3 dB

- Frequency modulation (FM)
  Carrier frequency: Pure tones
  Modulation waveform: triangular
  Modulation frequency: 5 Hz ±1%
  Percentage modulation: +5%

- Speech audiometry
  Range: Variable
  Inputs:
  . Electret microphone
  . Auxiliary input 200 mV, 50KOhms (Stereo 2 channels) for CD, etc.
  Level meter: Indicator on LCD Display.

MODES OF PRESENTATION OF THE SIGNALS

- Continuous
- Pulsating in all sources

In accordance with EN-60645-1 Frequency: 2 Hz (50 ms signal rise, 200 ms signal, 50 ms signal fall and 200 ms silence)
Accuracy: 3%

- Alternated pulse

  As per EN-60645-1 the same characteristics as the above but alternating between the right and the left channels.

- SISI test

  Presentation of increases: Manual or automatic
  Level of increases: 1, 2, 3, 4 or 5 dB
  Presentation in automatic mode: Every 1, 2, 3, 4, 5, 6, 7, 8 or 9 seconds
  Duration of increase: 50 ms signal rise, 200 ms signal and 50 ms signal fall
  Accuracy: 3%

- Range modulation

  Frequency: 2.5 Hz ±1%
  Range modulation: 0.2, 0.3, 0.4, 0.5, 0.6, 0.8, 1, 2, 3, 4 or 5 dB.
  Rise and fall time: 50 ms
  Level meter: Indicator on LCD Display.
  Accuracy: 3%

- Alternated modulation

  The same characteristics as the above but alternating between the right and the left channels.

3.3. CONTROL OF SIGNAL LEVELS

MAXIMUM AND MINIMUM SIGNAL LEVELS:

FREQUENCIES AND LEVELS												
STANDARD FREQUENCY	125	250	500	750	1.000	1.500	2.000	3.000	4.000	6.000	8.000	Hz
MUSICAL FREQUENCY	131	262	523	__	1.047	__	2.093	__	4.186	__	8.372	Hz
Air conduction	80	100	120	120	120	120	120	120	120	110	110	dB HL
Bone conduction	__	50	60	60	70	70	70	70	70	55	__	dB HL
Free field	__	70	80	80	80	80	80	80	80	80	__	dB HL
Minimum levels	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	dB HL
MASKING NOISE												
Narrow bandwidth AC	60	80	100	100	100	100	100	100	100	100	90	dB HL
Narrow bandwidth BC	__	50	60	60	70	70	70	70	70	__	__	dB HL
White AC						100						dB SPL
Speech						100						dB SPL
Minimum levels	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	dB HL
HIGH FREQUENCY	≤8.000	9.000	10.000	11.200	12.500	14.000	16.000	18.000	20.000			Hz
Air conduction	≤110	90	90	90	50	50	50	50	50			dB HL
Masking noise	≤100	80	80	80	40	40	40	40	40			dB HL
Minimum levels	-20	-20	-20	-20	-20	-20	-20	-20	-20	-20	-20	dB HL
LOGO-AUDIOMETRY												
Air conduction						max 100						dB HL
Free field						max 80 dB at 1 m. from the patient						dB SPL

INCREASES IN SIGNAL LEVEL

- Jumps of 5 dB ±1 dB
- Jumps of 1 dB (Reference tone)

ACCURACY OF THE SIGNAL LEVELS

- Accuracy: ±2 dB

INTERRUPTION OF THE TONE

- Independent for each channel
- Modes
  "direct" (there is signal on pressing)
  "inverted" (there is signal without pressing)
- Attenuation: > 80 dB
- Rise and fall time: 50 ms

3.4. OTHER FUNCTIONS

PERSONALISED FUNCTION CONFIGURATION
PRESENTATION OF FUNCTION STATUS

- Independent for each channel
- Alphanumerical LCD display with 2x16 characters

INTERCOM

- Between operator and patient
- Adjusts the level of signal

MEMORY

- Type: SDRAM
- Capacity: more than 1000 aerial and bone tone tests in both channels at frequencies of 500,1000,2000,3000 y 4000 Hz

CONNECTIVITY

- USB for external printer
- USB for PC connection

3.5. TRANSDUCERS

AIR CONDUCTION LOW FREQUENCY
- Radioear DD45
- Telephonics TDH39

AIR CONDUCTION HIGH FREQUENCY
- DD450 Radioear

BONE CONDUCTION
- Vibrator B71W

FREE FIELD
- Loudspeakers with integrated amplifier

SPEECH AUDIOMETRY MICROPHONE
- Electret type

3.6. APPLICABLE STANDARDS

- European Medical Device Regulation (EU) 2017/745.
- Rohs Directive 2011/65/EU.
- Waste disposal according to WEEE Directive 2012/19/EU.
- EU Regulation 2023/1542 on waste batteries and accumulators.
- Regulation (EC) 1272/2008 and EC 1907/2006 on classification, labeling and packaging of substances and mixtures (REACH).
- Packaging and packaging waste directive 94/62/EC
- Quality (EN ISO 13485:2016+A11:2021, EN ISO 9001:2015)
- Risk management (EN ISO 14971:2019 + A11: 2021)
- Safety Medical devices (EN 60601-1:2006 + AC:2010 + A11:2012 + A1:2013 + A12:2014 + A2:2021 + A13:2024) Class I device.
- Electro-magnetic Compatibility (EN 60601-1-2:2015 + A1:2021)
- Audiometry (EN 60645-1:2017)
- Software of medical devices(EN62304:2006+AC:2008 +A1:2015)
- Usability (EN 60601-1-6:2010+A1:2015+A2:2021 and EN 62366-1:2015 + A1:2020)
- Biocompatibility (EN ISO 10993-1:2020)
- Documentation and information (EN ISO 20417:2021 and EN ISO 15223-1:2021)

OTHER STANDARDS

- ANSI/ASA S3.6-2018 Specifications for audiometers
- EN ISO 389-1:2018 Air-Conduction Calibration (supra-aural headphones)
- EN ISO 389-3:2016 Bone-Conduction Calibration
- EN ISO 389-4:1998 Narrow-band Masking Noise Calibration
- EN ISO 389-5:2006 high frequency pure tones calibration
- EN ISO 389-7:2019 free field and diffuse field
- EN ISO 8253-1:2010 Fundamental pure-tone air and bone conduction threshold audiometry
- EN ISO 8253-2:2009 Free field audiometry with test signals of pure tones and narrow bands noise
- EN ISO 8253-3:2022 Speech audiometry
- EN 60068-2-1:2007, EN 60068-2-2:2007, EN 60068-2-14:2009 Environmental testing: temperature

3.7. GENERAL DATA

FUNCTION CONTROL
- Microprocessor type DSP
- Access: Silicon keyboard
- Display: LCD screen

Ambient Conditions
- Storage temperature: -5 to 70 °C
- Working temperature: 5 to 40 °C
- Relative humidity < 90% (no condensation)
- Atmospheric pressure: 700hPa - 1060hPa

POWER SUPPLY
- 100-240 VAC / 50-60 Hz ±5%

POWER
- 60 VA

DIMENSIONS
- Width: 390 mm
- Depth: 260 mm
- Height: 105 mm

WEIGHT
- 2.4 Kg without accessories

USEFUL LIFE
- 7 years

3.8. SYMBOLS

	MANUFACTURER (The date of manufacture, name and address of manufacturer)
	MANUFACTURING DATE
	SERIAL NUMBER
	REFERENCE
	LOT NUMBER
	PRODUCTO SANITARIO
	CE MARKING
	TEMPERATURE LIMITATION
	PREASURE LIMITATION
	HUMIDITY LIMITATION
	WARNING, RISK IDENTIFIED
	WARNING, IDENTIFIED RISK
	DIRECTIONS FOR USE



APPLICABLE PART B



GROUND



DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC AGREEMENT TO THE WEEE DIRECTIVE



KEEP AWAY FROM WATER



FRAGILE



STACKING LIMITATION



THIS WAY UP

4. UPKEEP, PREVENTIVE AND CORRECTIVE MAINTENANCE

4.1 CLEANING

WARNING

Do not use abrasive substances or solvents. The device and accessories can be damaged.

Clean the unit and its accessories with a wet, soft cloth, with water and a mild soap, or with isopropyl alcohol. Then, dry all the parts thoroughly. Ensure that no liquid or foreign body enters the unit, connectors or connections.

The air-conduction headphone pads can be removed for thorough cleaning. Dry them with a cloth before replacing.

WARNING

The bone conduction vibrator is a very fragile component, and even small impacts can lead to a deterioration in its characteristics. Therefore, you are advised to handle it with great care.

4.2 PREVENTIVE MAINTENANCE

Preventative maintenance consists of all those actions that keep the equipment in good working order. It is recommended to do the following every week:

- Verify that all connections, accessories and other external elements are in perfect condition, without cracks or external damage.
- Check that all accessories are properly connected to the unit's back panel.
- Check the correct calibration of the unit. If a calibration warning appears when starting the unit, contact your supplier or **SIBEL S.A.U. Technical Department.**

Some basic checks can be performed accessing the 3. MAINTENANCE -> 1. TEST DEVICE menu and following the on-screen instructions.

If some anomaly or unusual device behavior is detected, contact your supplier or **SIBEL S.A.U.** Technical Department.

4.3 CORRECTIVE MAINTENANCE

The corrective maintenance consists of repairing and restoring the use of the equipment, when poor operation or improper use may have affected its functionality.
If some fault is detected, which prevents the correct operation of the unit, contact your technical support service or **SIBEL, S.A.U. Technical Department**, indicating the type of anomaly encountered. The technical documentation necessary to perform the unit's corrective maintenance is available for the technical support services or for technical staff authorized by **SIBEL S.A.U.**

APPENDIX 1. ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
SIBELSOUND 400 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	**Compliance**	
RF (Radiated) emissions CISPR 11 (EN 55011)	Grupo 1 Clase B	
RF (Conducted) emissions CISPR 11 (EN 55011)	Grupo 1 Clase B	
Harmonic emissions EN-IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Cumple	

Guidance and manufacturer's declaration – electromagnetic emissions			
SIBELSOUND 400 is intended for use in the electromagnetic environment specified below. The costumer or the user of **SIBELSOUND 400** should assure that it is used in such an environment. Tests EN-IEC 61000-4-4 y -4-5 are applicable to AC/DC power inputs, and input/output signal. Test EN-IEC 61000-4-6 additionally applies to patient connections. Test EN-IEC 61000-4-11 only applies to AC power inputs.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –Guidance**
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines and earth ±1 kV for input/ output lines Frecuency 100 kHz	±2 kV for power supply lines and earth Not applicable	Mains power quality should be that of a typical commercial or hospital environment. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±0.5, ±1 kV differential mode (Line to line). ±0.5, ±1, ±2 kV common mode (Line to ground).	±0.5, ±1 kV differential mode (Line to line). ±0.5, ±1, ±2 kV common mode (Line to ground).	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF EN-IEC 61000-4-6	3 Vrms de 150KHz a 80 MHz 6 Vrms in ISM bands 80% AM a 1kHz	3 Vrms 6 Vrms	
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	0% Ut ; 0.5 cycles: 0º, 45º, 90º, 135º, 180º, 225º, 270º y 315º. 0% Ut; 1 cycle 70% Ut; 25/30 cycles: 0º 0% Ut ; 250/300 cycles (5 segundos)	0 % Ut ; 0.5 ciclos a: 0º, 45º, 90º, 135º, 180º, 225º, 270º y 315º. 0 % Ut; 1 ciclo 70 % Ut ; 25/30 ciclos a 0º 0 % Ut ; 250/300 ciclos (5 segundos)	Mains power quality should be that of a typical commercial or hospital environment.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
SIBELSOUND 400 is intended for use in the electromagnetic environment specified below. The costumer or the user of **SIBELSOUND 400** should assure that it is used in such an environment. Below mentioned tests are applicable to enclosure. Additionally, test EN-IEC 61000-4-2 is applicable to input/output signal and patient connections.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV, air	±8 kV contact ±2, ±4, ±8, ±15 kV, air	
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m	
Proximity fields from RF communications EN-IEC 61000-4-3	(View following table).		Portable and mobile RF communications equipment should be used no closer than 30cm to any part of **SIBELSOUND 400**, including cables. The distance is calculated according to: $d = \left[\frac{6}{E}\right]\sqrt{P}$ where P is the output power rating of the transmitter in watts (W), d is the recommended separation in meters (m) and E is the immunity level in V/m.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	30 A/m	30 A/m	Only applicable to devices sensitive to magnetic fields.

Proximity fields EN-IEC 61000-4-3					
Frecuency (MHz)	Band (MHz)	Modulation	Power (W)	Distance (m)	E (V/m)
385	380-390	Pulso 18Hz	1.8	0.3	27
450	430-470	FM D:+/-5kHz 1kHz sinus	2	0.3	28
710 745 780	704-787	Pulso 217Hz	0.2	0.3	9
810 870 930	800-960	Pulso 18Hz	2	0.3	28
1720 1845 1970	1700-1990	Pulso 217Hz	2	0.3	28
2450	2400-2570	Pulso 217Hz	2	0.3	28
5240 5500 5785	5100-5800	Pulso 217Hz	0.2	0.3	9

APPENDIX 2. COMPLIANCE WITH THE DATA PROTECTION REGULATIONS

This section is aimed at facilitating the user to comply with the regulation in force related to the treatment of personal data that are regulated and covered by REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

A brief description of the basic points of this regulation is provided and the issues to be considered for fulfilling the requirements of such regulation are detailed.

IMPORTANT WARNING
According to the regulation in force, the user is the only party responsible for saving and processing the data of his patients according to the Law.

The observance of the recommendations included in this section does not guarantee, in any case, the complete adequacy of the user's activity to the regulation on data protection.

Requirements specifically affecting the use of the DATOSPIR MICRO Spirometer

To comply with the LOPD it is necessary to avoid using references that allow the identification of the patient, type ID number, ...

- Printing documents:

  In the event of saving paper printouts containing patient details, these documents must be properly stored so that only duly authorised personnel have access to them. Furthermore, in the event of users deciding to dispose of the printed documents, their effective physical destruction must be ensured to avoid unauthorised access thereto.

- Data transmission:

The **SIBELSOUND 400** audiometer can transmit files containing patient details via PC connection so that work can be subsequently carried out on them using the W50 Audioometry Software. This software is also compliant with the Data Protection Act, as explained in the W50 Audiometry Software User's Manual.

APPENDIX 3. 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 2ª FÓRMULA

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				

4. 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

5. 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 both**ears	**Can hear no sound at all.**

6. 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.			

7. 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.