SIBELSOUND 400

AUDIOMETRY

USER MANUAL

520-700-MU2 • REV. 1.01

Sibelmed®

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DECLARATION OF CONFORMITY

The **SIBELSOUND 400 Audiometer** has been designed and manufactured in accordance with the **SIBEL S.A.** Quality Manual which complies with quality standard **EN ISO 13485:2004** and **ISO 9001**:**2000**, as well as with European Medical Devices Directive 93/42/EEC. In accordance with the latter directive this is a class IIa device.
It also complies with the following standards:

EN – 60601-1	Safety of Electrical Equipment
EN – 60601-1-1	Safety of Medical Systems
EN – 60601-1-2	Electromagnetic Compatibility
EN – 60601-1-4	Programmable systems
EN – 60645-1	Pure tone audiometry
EN – 60645-2	Speech audiometers
EN – 60645-4	High frequency audiometry

CE 0318

PRODUCT CONFORMS WITH
93/42/EEC Medical Devices Directive
Class II a

Revised
Date: January 2009

José Maria Plana
Technical Director

Approved
Date: January 2009

Carlos Recio
Sales Director

SAFETY

SPECIAL PRECAUTIONS

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.

INTENDED USE

The audiometer generates a series of acoustic and vibrational stimuli and calculates a series of parameters relating to human audiometry.
The audiometer is intended for use by medical staff only, under the supervision and instruction of a doctor.
The audiometer is not intended for use outdoors, nor in conditions or with energy sources other than as set out in this manual.

THE ROLE OF THE PATIENT IN THE USE OF THE AUDIOMETER

The audiometry tests require the cooperation of the patient. The patient must press a button to communicate the detection of a stimulus. The doctor must evaluate the patient's ability to carry out the audiometry tests. Special care must be taken with children, the elderly and the handicapped.

LIMITATIONS OF USE. CONTRAINDICATIONS

Interpretation of test results and any resulting treatment must be carried out by a doctor.
The medical staff must evaluate any symptoms presented by the patient before any audiometric tests are carried out.
The suitability of audiometric testing is the responsibility of the medical staff.
The audiometer should not be used when it is likely that the validity of the results could be compromised by external factors.

ELECTRICAL RISKS

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-60601-1-1. 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.

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

RISK OF EXPLOSION

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

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.

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

This symbol on the product indicates that it must not be disposed of as part of domestic waste.

Rather, if it is to be disposed of, it is the user's responsibility to take it to a designated recycling point for electrical and electronic devices. The separate collection and recycling of different kinds of waste at the point of disposal helps to preserve natural resources and to ensure that recycling will safeguard health and the environment. If you require further information about where to take products of this type for recycling, contact your local authority, the local domestic waste disposal service or the distributor from whom you purchased the product.

1. INSTRUCTIONS FOR INSTALLATION AND USE

1.1 INTRODUCTION

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 audiometric investigation to be carried out quickly, simply and reliably to establish hearing thresholds and to carry out screening tests such as suprathreshold tonal tests.

The **SIBELSOUND 400** audiometer has been developed entirely in Spain, based on current technology and more than 20 years experience in the design and manufacture of this kind of equipment. Its functional design and the elimination of most of the electromechanical components have made possible a device that can provide long service in the field of audiometric testing.

The **SIBELSOUND 400** audiometer has been designed in collaboration with Barcelona University's Surgery Department (Otorhinolaryngology and Audiology) in the Faculty of Medicine and recognised specialists in the area, and meets the standards criteria of both national (U.N.E) and international institutions (I.E.C., I.S.O., etc.).

1.2. INTRODUCTORY INFORMATION

This instruction 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 relevant.

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.

WARNING
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.

1.3. SIBELSOUND 400 AUDIOMETER MODELS

The **SIBELSOUND 400** audiometer comprises six different models:

SIBELSOUND 400 A
SIBELSOUND 400 AM
SIBELSOUND 400 AO
SIBELSOUND 400 AOM
SIBELSOUND 400 AOM+
SIBELSOUND 400 SUPRA

The table below shows each model's built-in features as **standard (Shadedo)** 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. Sales Department or your distributor.

RELACIÓN DE CONTENIDO / PACKING LIST

SIBELSOUND 400 **520-708-010 REV. 4.01 03/02/09**

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	MODELOS / *MODELS* A	AM	AO	AOM	AOM+	SUPRA
520-700-___	1	**SIBELSOUND 400 MODELO / *MODEL* SN: 207-**						
305-350-020	1	CABLE CONEXIÓN DE RED 2m / *MAINS PLUG CABLE 2m*						
305-600-050	1	CABLE USB TIPO A-B 2.0 / *USB CABLE TYPE A-B 2.0*						
520-540-001	1	CONEXIÓN AVISO PACIENTE / *PATIENT SWICHT*						
520-540-002	1	ARICULARES VIA AEREA / *EARPHONE SET*						
291-500-020	1	SUPRESOR DE RUIDO VA / *AUDIOCUPS AC*						
520-700-MU_	1	MANUAL DE USO / *USER MANUAL:*						
520-711-GR_	1	GUIA RAPIDA DE USO / *QUICK REFERENCE*						
520-660-DM0	1	SOFTWARE AUDIOMETRÍA W-50 DEMO/ *AUDIOMETRY DEMO SOFTWARE W-50*						
520-660-LIC 520-66A 520-660-MU_	1 1 1	LICENCIA SOFT. W-50 / *W-50 LICENSE SOFT.* • SOFTWARE W-50 • MANUAL USO /USER MANUAL (Se incluye en el CD)						
520-651-010	1	BOLSA DE TRANSPORTE / *CARRING BAG*						
520-760-000 511-690-001	1 1	MODULO RS232 / *RS232 MODULE* • CABLE RS232 / RS232 CABLE						
520-770-000 520-680-002 520-770-002	1 1 1	MODULO MONITOR-INTERCOMUNICADOR Compuesto por : *MONITOR MODULE Composed by:* • AURICULAR MONITOR / EARPHONE MONITOR • MICROFONO ELECTRET-PINZA /ELECTRET CLIP MICROPHONE						
520-780-000 520-770-002 **520-770-000** 520-680-002 520-770-002	1 1 1 1 1	OPCION FIRMWARE LOGOAUDIOMETRÍA Compuesto por: *SPEECHAUDIOMETRY FIRMWARE OPTION Composed by:* • MICROFONO ELECTRET-PINZA / ELECTRET CLIP MICROPHONE • MODULO MONITOR-INTERCOMUNICADOR Compuesto por : *MONITOR MODULE Composed by:* ○ AURICULAR MONITOR / EARPHONE MONITOR ○ MICROFONO ELECTRET-PINZA /ELECTRET CLIP MICROPHONE						
520-790-000 520-790-001	1 1	OPCIÓN FIRMWARE CAMPO ABIERTO/ *FREE FIELD* • JUEGO ALTAVOCES CAMPO ABIERTO/ FREE FIELD LOUDSPEAKER SET						
520-7A0-000 520-7A0-001	1 1	OPCIÓN FIRWARE ALTA FRECUENCIA • AURICULARES ALTA FRECUENCIA/ EARPHONE HIGH FREQUENCY SET	---	---	---			

RELACIÓN DE CONTENIDO / PACKING LIST

SIBELSOUND 400

520-708-010 REV. 4.01 03/02/09

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	AM	AO	AOM	AOM+	SUPRA
520-7B0-000	1	OPCION FIRMWARE FRECUENCIAS INTERMEDIAS *INTERMEDIATED FREQUENCY SOFTWARE OPTION*					■	■
520-7C0-000	1	OPCION FIRMWARE FRECUENCIAS MUSICALES *MUSICAL FREQUENCIES FIRMWARE OPTION*					■	■
520-7D0-000	1	OPCION FIRMWARE ENMASCARAMIENTO SINCRONIZADO *AUTOMATIC MASKING FIRMWARE OPTION*		■		■	■	■
520-7E0-000	1	OPCION FIRMWARE TONO REFERENCIA *REFERENCE TONE FIRMWARE OPTION*	---	---	---		■	■
520-7F0-000	1	OPCION FIRMWARE SISIGRAMA *SISIGRAM FIRMWARE OPTION*					■	■
520-7G0-000	1	OPCION FIRMWARE BASE DE DATOS INTERNA *INTERNAL DATA BASE FIRMWARE OPTION*				■	■	■
520-7H0-000	1	OPCION FIRMWARE PRUEBAS SUPRALIMINARES *SUPRALIMINARY FIRMWARE OPTION*						■
520-7I0-000 520-550-001	1 1	OPCIÓN FIRMWARE AUD. TONAL VIA OSEA • VIBRADOR VIA OSEA / BONE VIBRATOR SET			■	■	■	■
520-7J0-000	1	TONO PULSANTE/ALTERNADO Y MODULADO/ALTERNADO *ALTERNATED PULSE TONE AND ALTERNATED MODULE*					■	■
520-7L0-000	1	OPCION FIRMWARE RUIDO BANDA ESTRECHA *NARROW BAND NOISE FIRMWARE OPTION*		■		■	■	■
520-7M0-000	1	OPCION FIRMWARE FRECUENCIA Y AMPLITUD MODULADA *FREQUENCY AND AMPLITUDE MODULATION FIRMWARE OPTION*	---	---	---			■
520-7N0-000	1	OPCION FIRMWARE ENMASCARAMIENTO RUIDO BLANCO *MASKING WITH WHITE NOISE FIRMWARE OPTION*		■		■	■	■
520-7O0-000	1	OPCION FIRMWARE ENMASCARAMIENTO RUIDO VOCAL MASKING WITH *SPEECH NOISE FIRMWARE OPTION*					■	■

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

NOTA:
- LOS ARTÍCULOS Y CANTIDADES RELACIONADAS ANTERIORMENTE HAN SIDO CUIDADOSAMENTE COMPROBADAS. EN CASO DE FALTAS O DESPERFECTOS PROCEDAN A COMUNICÁRNOSLO LO MAS PRONTO POSIBLE.
- SI DETECTA ALGÚN DETERIORO EN EL EMBALAJE, CONTACTE INMEDIATAMENTE CON LA AGENCIA DE TRANSPORTE Y CON SU DISTRIBUIDOR ANTES DE PROCEDER A INSTALARLO. NO SE DEBE DESPRENDER DE LOS EMBALAJES, BOLSAS, ETC. HASTA QUE VERIFIQUE TOTALMENTE EL CORRECTO FUNCIONAMIENTO DEL EQUIPO.
- SÍRVANSE DEVOLVERNOS UNA COPIA DEL ALBARAN SELLADA Y FIRMADA.
- EN CASO DE DEVOLUCIÓN DE MATERIAL O EQUIPO EN DEPOSITO, ROGAMOS NOS LO ENVÍEN EN PERFECTO ESTADO, COMPLETO DE ACCESORIOS Y DEBIDAMENTE EMBALADO. CUALQUIER DESPERFECTO OCASIONADO PROVOCARÍA UN CARGO CORRESPONDIENTE A LA REPARACIÓN O REPOSICIÓN.

NOTE:
- THE ITEMS AND QUANTITIES RELATED BEFORE HAVE BEEN CAREFULLY CHECKED. IN CASE OF ANY PART IS MISSING OR IS DAMAGED,NOTIFY US AS QUICKLY AS YOU CAN.
- IF YOU DETECT ANY DAMAGE IN THE PACKAGING, CONTACT WITH YOUR DISTRIBUTOR BEFORE PROCEEDING TO INSTALL IT.
- DO NOT THROW AWAY THE PACKAGING, BAGS, ETC. UNTIL THE CORRECT FUNCTIONING OF THE DEVICE IS VERIFIED
- IN THE CASE OF RETURNING THE GOODS, IT WILL BE APPRECIATED THAT YOU SEND THE DEVICE IN PERFECT ORDER, WITH ALL THE ACCESSORIES AND PROPERLY PACKAGED. ANY DAMAGE SUFFERED WILL MAKE A CHARGE CORRESPONDING TO REPAIR OR NEW PARTS.

PREPARADO/PREPARED FOR..... **REVISADO/ CHECKED FOR**.....

WARNING

In accordance with the various standards, we recommend testing and calibrating the electromedical equipment periodically in order 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 maufacturer or by qualified technical staff authorised by SIBEL S.A., in accordance with the manufacturer's (SIBEL S.A.) Procedures for Verification and Adjustment.

MANUFACTURER'S RESPONSIBILITIES

SIBEL S.A. guarantees the safety, reliability and proper functioning of this equipment provided that:

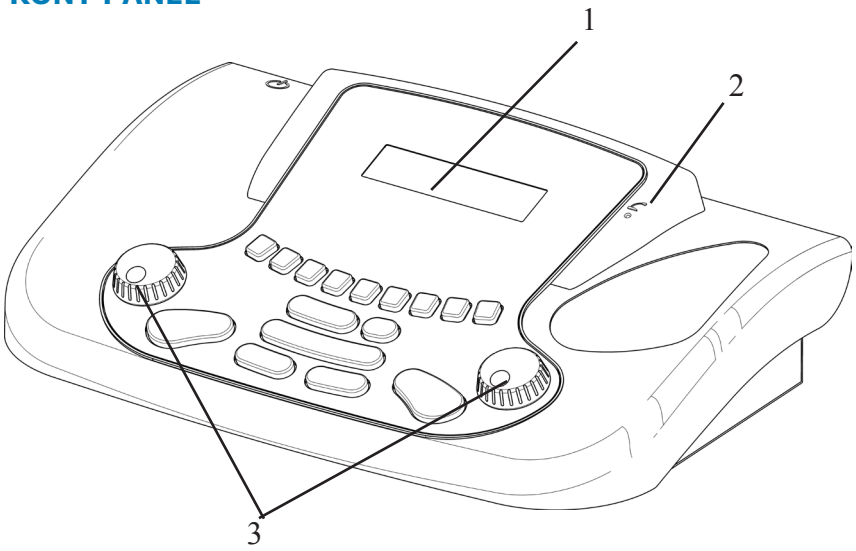
- The location where the equipment is installed complies with the UNE (IEC) requirements for electrical installations, with an earth connection, and such other standards as may apply.

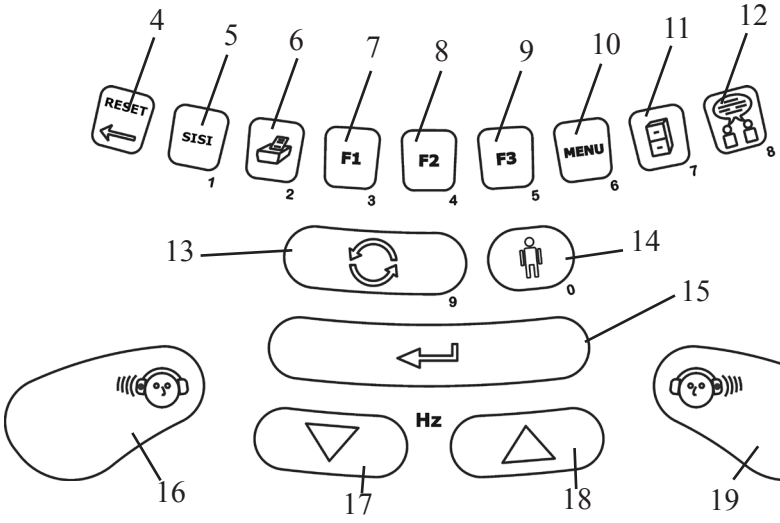
- Repairs, maintenance and modifications, whether within the warranty period or otherwise, are carried out by SIBEL S.A. technical staff.

- The equipment is used by qualified staff and in accordance with the recommendations in this Instruction Manual.

1.4. LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS

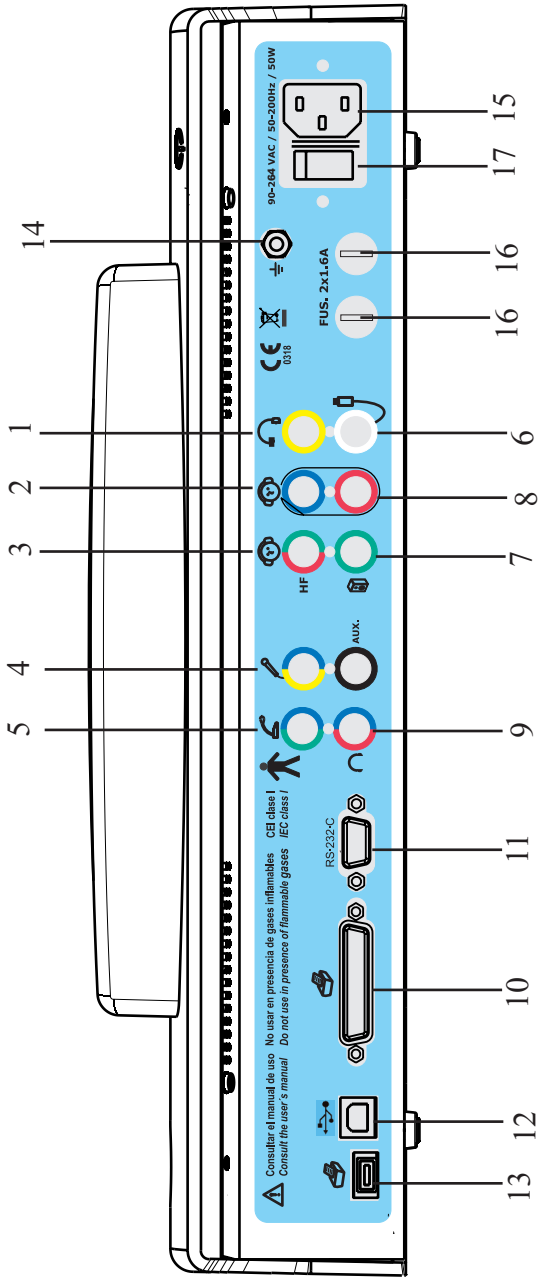
FRONT PANEL





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


90-264 VAC / 50-200Hz / 50W
FUS. 2x1.6A
0318
HF
AUX.
RS-232-C
Consultar el manual de uso
Consult the user's manual
No usar en presencia de gases inflamables
Do not use in presence of flammable gases
CEI clase I
IEC class I
1
2
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11
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13
14
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16
16
17

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- RS·232·C connection

12- USB – PC connection

13- USB connection – Printer

14- Terminal for mains earth connection

15- POWER input 90-264 VAC

16- Fuse holder

17- On/off switch

1.5. INSTALLATION AND START-UP

INSTALLING THE SIBELSOUND 400

In accordance with the type of protection against electrical discharges established in standard **EN – 60601-1**), the **SIBELSOUND 400** audiometer is categorised as CLASS I equipment.

To power up, the **SIBELSOUND 400** audiometer needs a 90V - 264V - 50 /60Hz mains connection with corresponding earth terminal in accordance with current UNE (IEC) standards. The power required is below 50 VA.

The required ambient conditions are:

- Storage temperature 0 to 60 °C
- Ambient temperature between 10 and 40 °C.
- Relative humidity less than 90% (no condensation).

The power cable included with the accessories includes an earth wire (yellow-green), as the EN-60601-1 standard requires the audiometer and all other CLASS I electromedical devices to be connected to earth.

We recommend installing the audiometer together with a soundproof booth for audiometric tests. If this is not possible, the equipment must be installed in an area where the level of ambient noise is low enough not to distort the results of audiometric tests. Failing that, SOUND SUPPRESSORS can be used in the headphones (OPTIONAL).

Remember not to locate the equipment in an area where there may be splashes of water or other liquids, nor to cover it with objects which might impede the circulation of air around it while it is operating.

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 90V - 264V - 50 / 60Hz mains connection.

3 Connect the accessories to the corresponding connection points.

If all the previous instructions have been followed, the equipment is ready for use.

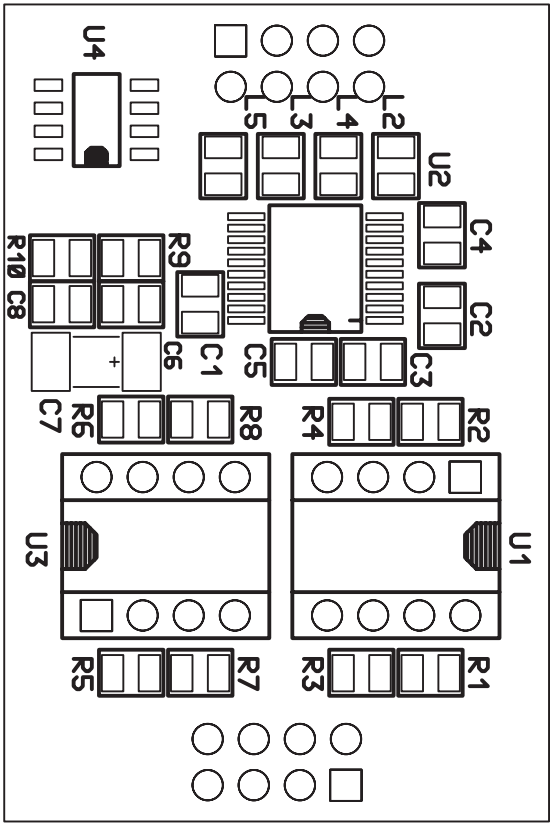
USB MODULE INSTALLATION

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**.

RS MODULE INSTALLATION

The equipment has an optional module which enables communication between the audiometer and a computer over an RS232 connection. The instructions for installation are as follow:

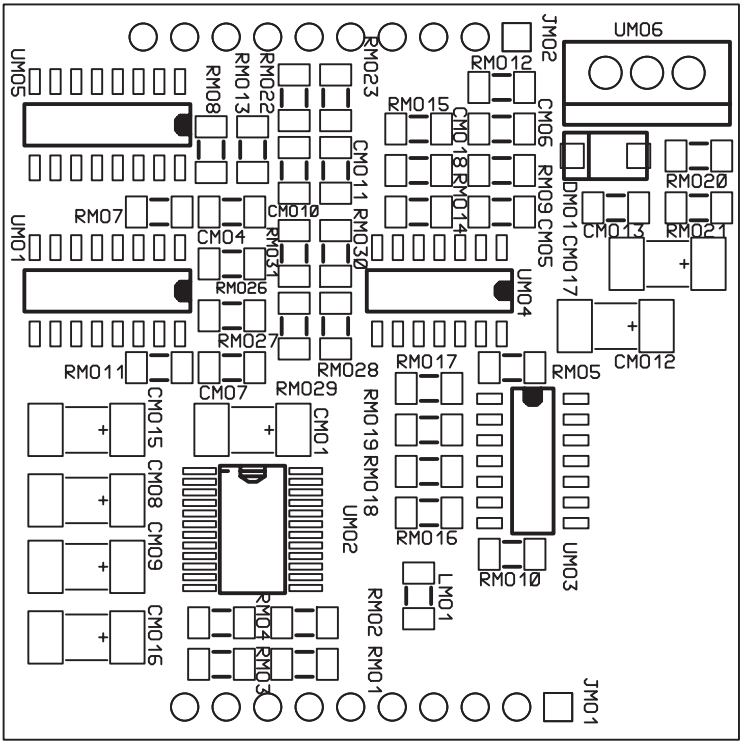
With the audiometer disconnected from the mains, open the audiometer and connect the connectors J_RSP1 and J_RSP3 to the RS232 as shown in the diagram without forcing any of the pins.
The module can only be connected in one position.



INSTALLATION OF THE INTERCOM MODULE

The equipment has an optional module which allows communication to be established with the patient. The instructions for installation are as follow:

With the audiometer disconnected from the mains, open the audiometer and connect the connectors J_A9 and J_A10 to the intercom module as shown in the diagram without forcing any of the pins.
The module can only be connected in one position.



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:

SIBELMED
SIBELSOUND 400

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. This calibration check assumes that the transducers, both for air conduction and bone conduction, are correct and have not suffered any deterioration. To prevent errors in this regard, we recommend performing a MINIMUM ANNUAL PERIODIC CALIBRATION, or when a malfunction is suspected, with an artificial ear and artificial mastoids.

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).

NOTES ON THE HANDLING OF THE DEVICE

Ease of use has been a priority in the development of the audiometer, to make its use as easy and convenient for the user as possible. Given its multiple functions, the device may appear difficult to use. However, its design and actual use quickly reveal how easy and intuitive it is to use for anyone working in the health field.

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:

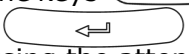
- On starting up the device
- When no key has been pressed for more than 5 minutes
- When the attenuator is pressed again for 1 second or more
- On carrying out a test with masking

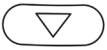
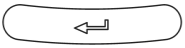
Intercom (Optional) At any time, by holding down the  key, it switches to the SPEECH channel (so that the patient receives the signal from the doctor's microphone) and the patient's microphone is activated so that the doctor can hear the patient.

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.

1.6. 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, to:

THE SIBELSOUND 400 MENU (EXCEPT THE SUPRA MODEL)

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
- 2. CALIBRATION
  - 1. ANSI / ISO
  - 2. CALIBRATION WARNING
  - 3. DEFAULT CALIBRATION
- 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

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).

1.7. PERSONALISING THE DEVICE

Any equipment with complex functionality may be modified voluntarily or otherwise by third parties to change the default configuration of its controls, affecting convenience of use.
To prevent against this anomaly, the **SIBELSOUND 400** audiometer has a configuration program which allows a user to define their initial work configuration and reload it every time they turn the device on.

This information is saved in internal Flash memory so that it does not disappear when the device is turned off.

On turning the device on for the first time, the two configurations are the same. The configuration which is loaded at the start is the user's.
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
- 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. Mexican Social Security Institute
4. ELI Index
5. SAL Index
6. 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

MENU
2. CONFIGURATION

CONFIGURATION
5. FREQUENCY

FREQUENCY
1. FREQ. SEL.

2 Select

CONFIGURATION
5. SEL. FREQ

3 Choose the desired frequencies.

CUSTOMISING MUSICAL FREQUENCIES

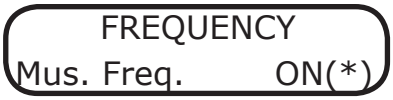
To select the musical frequencies in the Pure Tone and Free tests:

1 From the main menu, access the following option

MENU
2. CONFIGURATION

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:

A HZ C	A HZ C
60	1000* 60

PERSONALISING PRINTING

To select the printer:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

CONFIGURATION
6. PRINTER

3 Choose the printer you wish to use

PERSONALISING LANGUAGE

To personalise language:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

MENU
7. LANGUAGE

3 Choose the required language.

PERSONALISING CALIBRATION

To select the correction table (ISO389 or ANSI S3.6):

1 From the Main Menu access the option

2 Select

3 The following screen appears

Press 

to confirm and select the desired correction table.

To configure the date of the next calibration:

1 From the Main Menu access the option

MENU
3. MAINTENANCE

2 Select

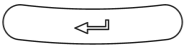
MAINTENANCE
2. CALIBRATION

CALIBRATION
2. CAL. WARNING

3 The following screen appears

Last Calibration
01-05-08

With the date of the last calibration.

Press 

4 The following screen appears

Maint. Interval
Days: 365

Enter the number of days until the next calibration is to take place. On the specified date, a warning message will appear reminding you to calibrate the device.

WARNING
It is not advisable to change the date once it has been programmed with the appropriate interval so that the device will always be correctly calibrated.

RECOVERING THE DEFAULT CALIBRATION

To recover the default calibration:

1 From the Main Menu access the option

2 Select

3 The following screen appears

Press 

to recover the default calibration.

WARNING:PRESSING F1 WILL DELETE THE WORKING CALIBRATION OF THE UNIT, WHICH IS SPECIFIC FOR EACH AUDIOMETER. THE DEFAULT CALIBRATION WILL BE USED INSTEAD, WHICH IS GENERIC FOR ALL THE UNITS.

PERSONALISING CONTRAST

To personalise screen contrast:

1 From the Main Menu access the option

MENU
2. CONFIGURATION

2 Select

CONFIGURATION
8. CONTRAST

3 Choose the required contrast.

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 RESET 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

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 MENU 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:

RESET DEFAULT
F1: YES F3: NO

Press F1 to confirm

RESET DEFAULT
DEFAULT RESET

1.8. 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 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.

These tests include other variants that are not included. The procedures for the latter fall to the specialist to determine. For anyone not familiar with these techniques, we recommend reference to relevant literature.

A brief description of each of the tests displayed on the OPTIONS 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.

1.9. PROCEDURE FOR TONE AUDIOMETRY

GENERAL CONSIDERATIONS

Technician
The technician performing the test must be trained in the theory and practice of audiometric testing, since they will have to take decisions such as:

- Which ear to test first? (Usually the one the patient thinks has the better hearing function)

- Is masking required or not?

- When does the patient's response match the signal? (The **SIBELSOUND 400** gives warning of inconsistencies)

- Is there some external noise or patient response which could invalidate the test?
- In the event of an interruption, should the test be repeated or continued?, etc.

Test duration
Patient exhaustion should be avoided, as it can be difficult to obtain results if the test lasts longer than 20 minutes and the patient is not allowed any rest time.

Ambient Conditions
We recommend installing the audiometer together with a soundproof booth for audiometric tests. If this is not possible, the equipment must be installed in an area where the level of ambient noise is low enough not to distort the results of audiometric tests. Failing that, SOUND SUPPRESSORS can be used in the headphones (OPTIONAL).

PATIENT REPARATION AND INSTRUCTIONS

Patient preparation
Recent exposure on the part of the patient to elevated noise levels could cause a temporary increase in hearing thresholds. Therefore, high noise levels should be avoided before the test or this should be indicated on the report. To avoid errors due to physical effort, we recommend that the patient be at the location of the test at least five minutes before it takes place.
An otoscopic examination is usually carried out by a qualified person, to establish whether there is an obstruction in the external ear canal that needs to be removed.
It is vital that the patient is comfortably seated, calm and rested so they can give maximum attention to the test.

Patient instructions
The technician carrying out the test must explain to the patient what it involves, and also the following:

- The patient response is effected by pressing the patient's response button.
- The patient must respond when they hear the tone, not when they think they hear it.
- Response must begin the moment they hear the tone and cease immediately after they cease to hear it.
- The general sequence of the presentation of tones.

- Which ear will be tested first.
  Putting on the headphones

Glasses and jewellery need to be removed when they prevent correct positioning of headphones for air or bone conduction. Similarly, check that hair does not impede the connection between the transducers and the outer ear or mastoids.
The technician must place the air conduction headphones on the patient, checking that they fit correctly, and following the convention "RIGHT ear" = RED and "LEFT ear" = BLUE.

PREPARING THE AUDIOMETER

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/ **O** Bone Conduction / **-** Disable).

Select with 

+ 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.

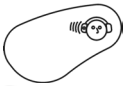
G and P Mode of presentation of the signal
(**C** Continuous signal / **P** Pulsating signal)

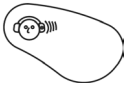
Select with F3 + left or right attenuator according to channel.

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 

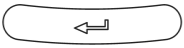
LM left channel. Apply signal with 

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

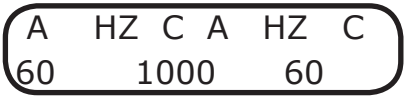
With the audiometer prepared as indicated in section **1.5. INSTALLATION AND START-UP**, proceed as follows:

1 Press the MENU key.

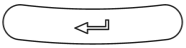
Using the ▽ and △ keys select the option:

and access the test pressing the  key

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



3 Push the 

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:

NEW PATIENT
Age:

NEW PATIENT
Sex: Man

4 Press F1

A HZ C **A** HZ C
AIR AIR

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 F2

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**).

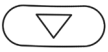
6 Press F3

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

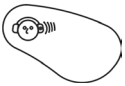
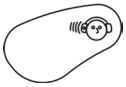
Using the corresponding attenuator, select the **mode** of presentation of the signal for each channel: continuous signal (**C**) or pulsating signal (**P**).

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**

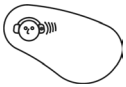
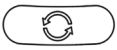
8 Select the **frequency** of the signal (press  or  until the required value is found)

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:
THIS DEVICE IS PROVIDED WITH A PROTECTION SYSTEM THAT PROTECTS THE TDH39 AERIAL HEADPHONES FROM SIGNALS THAT ARE TOO HIGH DURING PROLONGED PERIODS OF TIME. AS A RESULT, AT CERTAIN FREQUENCIES THE SIGNAL DEACTIVATES AUTOMATICALLY AFTER A FEW SECONDS AT MORE THAN 100 DB.
The signal indicator looks like this

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:

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

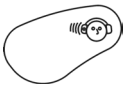
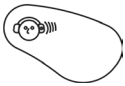
DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING

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.

WARNING
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 1.14 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 and the decibel level of the signal applied is shown blinking.
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
Máx dB HL	50	60	60	70	70	70	70	70
Mín. dB HL	-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.

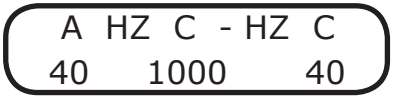
Screening audiometry is a test that determines if a subject has

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.

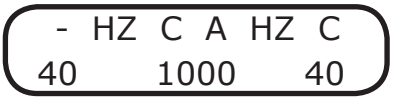
3 First apply a 1000 Hz tone to the subject's right ear at a signal level of 40 dB to check whether the subject has understood the instructions.
If not, the instructions are given again and the tone repeated. If the subject does not respond, increase the level of the tone until there is a response.

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



(The dB level specified is a guideline)

1.10 PROCEDURE FOR SISI 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 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**.

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).

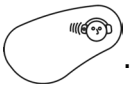
Sxx Counter for the **number of stimulus** (signal increases) applied to the patient (From E00 to E20)

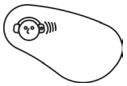
Rxx Counter for the **number of correct responses** from the patient (the patient presses the button after the stimulus has been applied)

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 1.5 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the MENU key.

Using the ▽ and △ keys select the option:

MENU
1. TEST

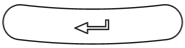
TEST
2. SISI

and access the test by pressing the ↵ key, (the SISI 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:

A R00 S A S00 -
60 1000 60

3 Press the key

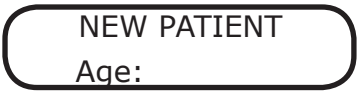
Enter the reference and press 

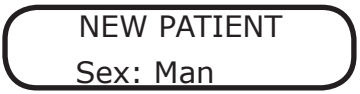
If the thresholds of the previous patient have not been saved to the database, the unit displays a screen for saving them:

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 

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).

7 Press the ↻ key and select:

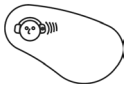
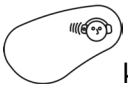
Using the left attenuator, choose the intensity of the increments in signal (between 0,2 and 5 dB).
Using the right attenuator choose the interval between increments in signal (MAN / between 1 and 9 seconds).

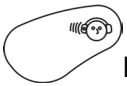
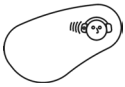
Remember that the stimulus counters only operate when the increment is 1 dB, and the signal is automatically interrupted after 20 stimuli have been generated. The counter must be reset to begin a new test.

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.

1.11. 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 1.9. 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.

ABCDEFGHIJKLMNOP
ABCDEFGHIJKLMNOP

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.

<u>On the second line</u>:

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.

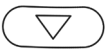
Speech audiometry essentially consists of determining the threshold of intelligibility (the patient hears and understands words pronounced) using a list of words spoken live or via recorded material.

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 1.5 INSTALLATION AND START-UP, the test proceeds as follows:

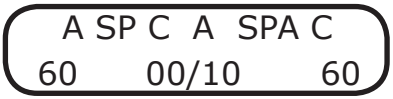
1 Press the 

key. Using the  and  keys

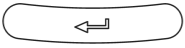
select the option:

and access the test pressing the  key.

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



3 Press the  key

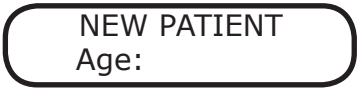
Enter the reference and press  .

If 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 

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

5 Press 

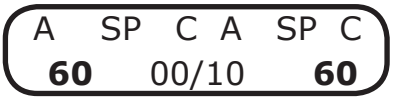
Using the corresponding attenuator, select the signal source: speech audiometry (**SP**), or masking with speech noise (SPN).

6 Press 

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

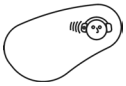
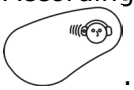
Using the right attenuator, select the **number of words**.
Using the left attenuator, select the **level of signal** to be applied to the patient.

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.

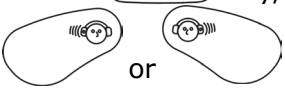
10 If the audiometer is installed in a sound-proof booth, connect the patient's microphone and the headset for the technician carrying out the test to the corresponding connection points.

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.

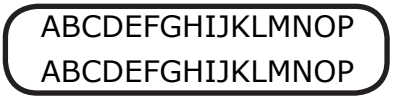
1.12. PROCEDURE FOR PERFORMING THE FOWLER TEST

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 

+ 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.

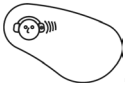
G and P Presentation **mode** of the signal (**C** Continuous / **P** Alternated pulse).

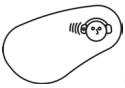
Select with F3 + left or right attenuator according to channel.

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.

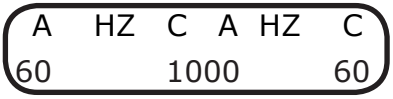
With the audiometer set up as indicated in section 1.5 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

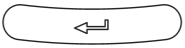
key and select the option:

And access the test by pressing the  .

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



3 Press the  key:

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.

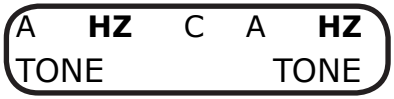
NOTE: When ELI diagnosis is selected, the following screen appears afterwards:

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

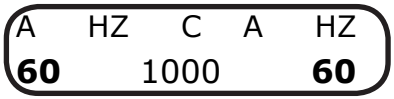


Use the corresponding attenuator to select the source of the signal for each channel: in this case only the frequency in Hz of the pure tone (HZ).

6 Press the F3

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

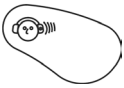
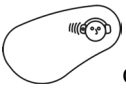
7 Choose the **intensity** of the signal by rotating the attenuators until the required value is found.

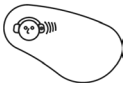


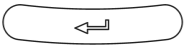
8 Select the **frequency** of the tone between 125 and 8000 Hz by using the ▽ and △.

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

1.13. TONE DECAY TEST PROCECURE

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 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.

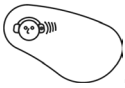
G and P Presentation **mode** of the signal (**C** Continuous)

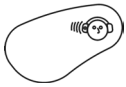
Select with F3 + left or right attenuator according to channel.

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.

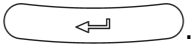
The patient responds through the warning connection while he hears the signal. When he ceases to hear it, he releases the button and at that moment the technician presses the  and the time elapsed during hearing is saved

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.

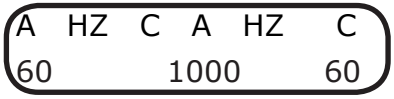
With the audiometer set up as indicated in section 1.5 INSTALLATION AND START-UP, the test proceeds as follows:

1 Press the 

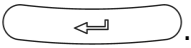
key and select the option:

And access the test by pressing the  .

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



3 Press the  :

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 

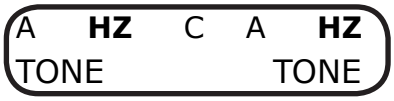
to delete all the thresholds that have been saved of the current test and start it again.

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

4 Press the 

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

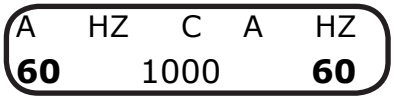


Use the corresponding attenuator to select the **source** of the signal for each channel: in this case only frequency in Hz of Pure Tone (**HZ**).

6 Press the F3

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

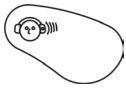
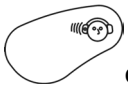
7 Choose the intensity of the signal by rotating the attenuators until the required value is found.

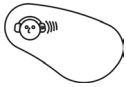
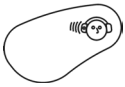


8 Select the frequency of the applied tone between 250, 500 1000, 2000 and 4000 Hz using the ▽ and △.

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

1.14. LUSCHER TEST PROCEDURE

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 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.

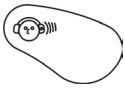
G and P Presentation **mode** of the signal (**M** Modulated)

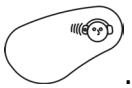
Select with F3 Y + left or right attenuator according to channel.

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.

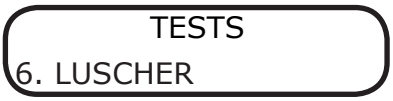
The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING. Special interest shall be taken in explaining the mechanics of the test to the patient to the effect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

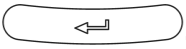
He must press the warning connection when he ceases to hear or starts to hear the ripple in the tone, depending on whether its level is being turned up or down.

With the audiometer set up as indicated in section 1.5 INSTALLATION AND START-UP, the test proceeds as follows:

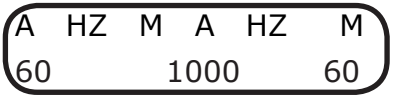
1 Press the 

and select the option:

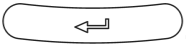


And access the test by pressing the  .

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



3 Press the  :

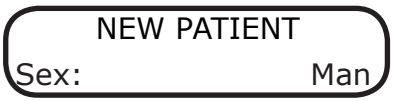
Enter the reference and press  .

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:

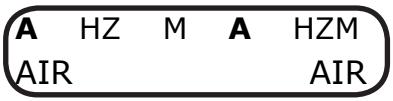
Similarly, the current test can be cancelled by entering the same reference again:

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:

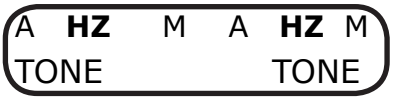


4 Press the F1 key



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

5 Press F2

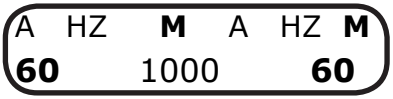


Use the corresponding attenuator to select the source of the signal for each channel: in this case only the frequency in Hz of the pure tone (HZ).

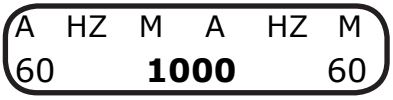
6 Press the F3

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.



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

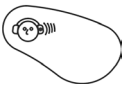
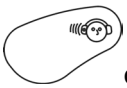


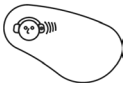
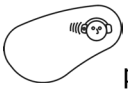
9 Press the ⟲ for 1 second: The following screen will appear:

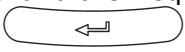
A HZ M	A HZ M
0.2	2.5 0.2

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

1.15. WEBER TEST PROCEDURE

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 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.

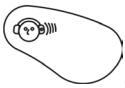
G and P Presentation **mode** of the signal (**C** Continuous)

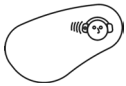
Select with F3 + left or right attenuator according to channel.

On the second line:

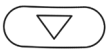
ABC and NOP Signal level applied to the patient in «dB»
ABC right channel. Select with right attenuator.
NOP left channel. Select with left attenuator.

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 1.5 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:

3 Press the  :

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:

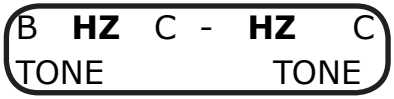
Select F1 to delete all the thresholds of the current test that have been saved and start it again.

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

4 Press the F1

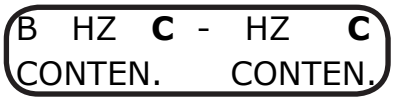
Use the corresponding attenuator to select the application conduction of the signal for each channel: bone (**O**) or disabled (**-**).

5 Press F2



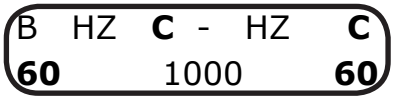
Use the corresponding attenuator to select the source of the signal for each channel: in this case only the frequency in Hz of the pure tone (HZ).

6 Press the F3

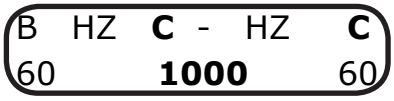


Use the corresponding attenuator to select the signal presentation **mode** for each channel: in this case only the continuous signal (C).

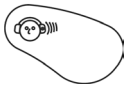
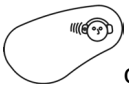
7 Choose the **intensity** of the signal by rotating the attenuators until the required value is found.

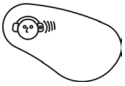
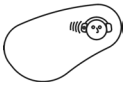


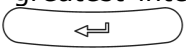
8 Select the **frequency** of the applied tone between 250, 500, 1000, 2000, 3000 and 4000 Hz by using of the ▽ and △.



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

1.16 PURE TONE HF TEST PROCEDURE

The general aspects and the preparation and instructions to the patient are described at the beginning of section 1.9. 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 / **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)

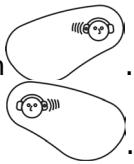
Select with F3 + left or right attenuator according to channel.

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.

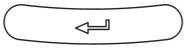
The requirements in terms of general aspects, preparation and patient instructions are similar to those described in the section DETERMINATION OF THE HEARING THRESHOLD VIA AIR CONDUCTION WITHOUT MASKING. Special interest shall be taken in explaining the mechanics of the test to the patient. He will perceive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

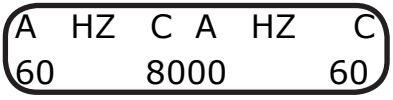
With the audiometer set up as indicated in section 1.5 INSTALLATION AND START-UP, the test proceeds as follows:

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:

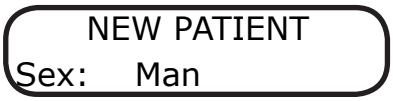
Enter the reference and press  .

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**).

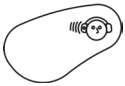
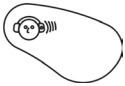
7 Choose the **intensity** of the signal by rotating the attenuators until the desired value is found.

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

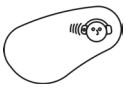
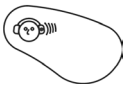
8 Select the **frequency** of the applied tone in the range of 125 to 20.000 Hz by using the ▽ or △ keys.

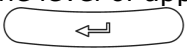
A HZ C	A HZ C
60 **8000**	60

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:

1.17. 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

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

to cancel;

1.18. 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 DIAGNOSIS OF THE MEXICAN INSTITUTE OF SOCIAL

SECURITY

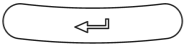
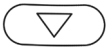
4 ELI (Early Loss Index)

5 SAL INDEX (Speech Average Loss)

6 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.

1.19. 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.

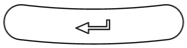
B. Tests which can be printed

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 1.9 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 ⏎.

WARNING
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:

SAVE THRESHOLD
F1: YES F3:NO

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

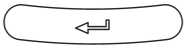
In this test, once the twenty 1 dB signal increases have been applied to the patient and the latter has provided the corresponding responses (assuming they were heard) press the ⏎ key and the device saves the increment and response counters.
The save threshold warning appears when there is a patient

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.

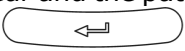
FOWLER

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

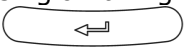
saved, the machine will either allow for these to be deleted or for them to be added to the new frequency.

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.

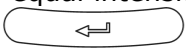
The warning to save the threshold appears when a patient has been registered in the machine, a signal has been applied and someone attempts to change the intensity, the conduction, the source or the signal mode, or if someone attempts to reset the seconds counter.

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.

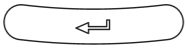
The save threshold warning appears when a patient has been registered on the machine, a signal has been applied and someone attempts to change the frequency, the signal conduction or the source.

WEBER

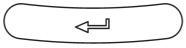
In the Weber test, the patient notifies which ear perceives the tone applied by the vibrator with the greatest intensity or if both ears perceive it with equal intensity. At that time, the technician must press the  and select the ear indicated by the patient.

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.

WARNING

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

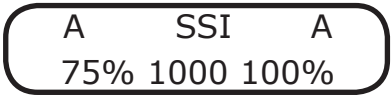
Having performed the tests, if you entered via this option you can neither print nor save the results in the database.

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

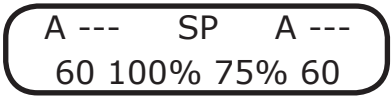
test (TNL, SSI, SP, FWL, DEC, LCH, WBR, THF). The remainder of the information depends on the type of test selected, corresponding to:

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

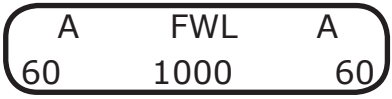
2. Sisi test: Percentage and pathway.



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.



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

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

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 

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 1.15. 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:

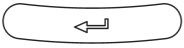
1 Access the Options Menu by pressing the 

key or pressing the  from the test screen.

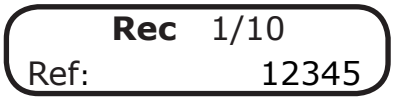
2 Select the option

and press  .

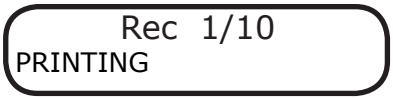
3 Then select

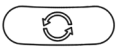
and press  . The user can also access the previous screen directly by pressing the  key for 1 second from the test screen. If there are no thresholds to save, the  key can be pressed as normal.

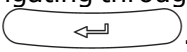
The following screen appears:



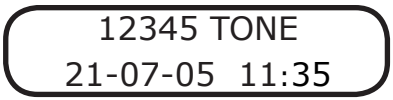
4 From this screen you can print the patient's tests by pressing  :



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  .

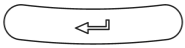
The following screen appears:



7 At this point you may:

- Print the tests for the selected patient by pressing 

- 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:

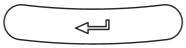
CLEARING THE INTERNAL DATABASE

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

1 Access the Options Menu by pressing the 

key

2 Select the option

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 MENU. 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 F1 to confirm and delete the patient or F3 to return to the previous screen.

1.20. 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.

These communications can be carried out, using the relevant software, via two distinct channels:

- Serial RS232C (Optional)
- USB (standard)

To install the USB module referred to the **Instructions for Use for the W50 Audiometry Software**.

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 **W-50 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 **W-50 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 **W-50 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 W-50 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 W-50 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 **W-50 Audiometry Software**.

To do this, the tests must be transferred from the device to the database selected with the **W-50 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.

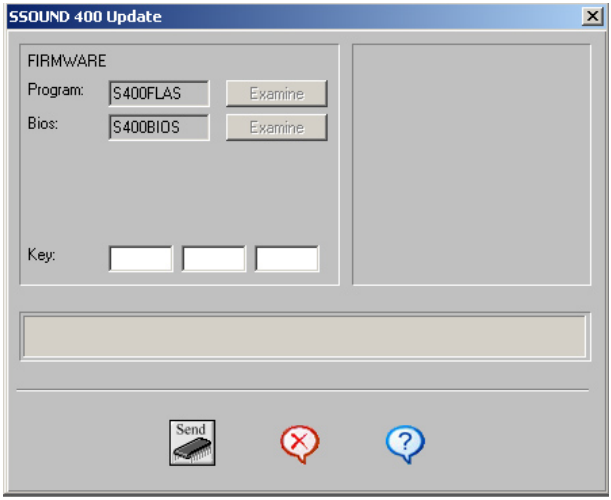
If you have any doubts or questions, please contact **SIBEL S.A.'s Technical Service** or your distributor who will provide you with the information you require.

W-50 AUDIOMETRY SOFTWARE FOR PC

For information relating to the **Audiometry Software W-50**, see the **Instruction Manual**.

1.21. UPDATING THE UNIT FIRMWARE

The SIBELSOUND 400 audiometer from SIBEL S.A. 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.



WARNING:
DO NOT CANCEL THIS 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.

1.22. 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.

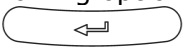
The options can be adjusted from three menus:

- 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:

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

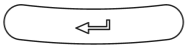
This option allows you to check the device's CPU. Use the attenuators to select the option:

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:

Press  to start each of the LCD tests or 

to exit.

TEST THE KEYBOARD

Select the option:

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:

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

UPDATING PASSWORD

Select the option:

To view the password requested by the Audiometry W-50

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.

Warning:
THIS WILL ALSO RESULT IN THE LOSS OF BOTH USER AND STANDARD CONFIGURATION, WHICH WILL BE REPLACED BY THE DEFAULT FACTORY CONFIGURATION OF THE DEVICE.

MONITOR

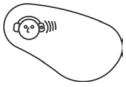
The device has an optional module to monitor the signals

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).

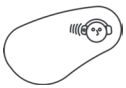
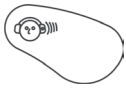
These devices are:

- Technician headphones
- Technician microphone
- Patient microphone

Intercom mode:

To adjust these levels, select the following option:

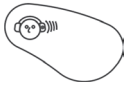
MAINTANCE
4. SPEECH-INTER

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

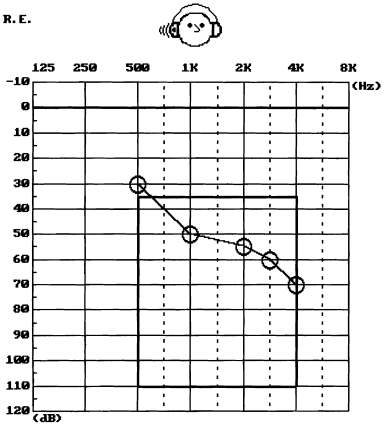
SIBELSOUND 400

Name:
Age(y): 28
Sex: Man
Height(cm):
Weight(Kg):
BMI:
Version: 52072C-2.01

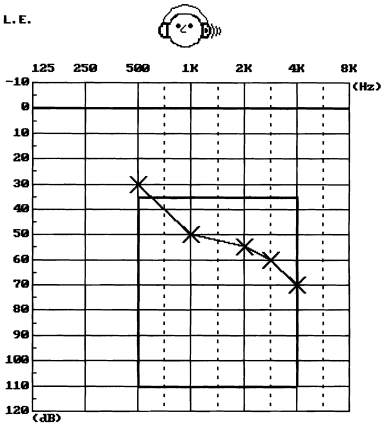
Date of Study: 11/12/2008
Reference: 0123456789
Technician:
Reason:

Origin:
Table: ISO

R.E.



L.E.



COUNCIL OF PHYSICAL THERAPY

	R.E.	L.E.
Hearing Loss (%)	57.5	57.5
Average dBs	51.3	51.3
Bilateral Loss (%)	57.5	

No masking	RE	LE	With Masking	RE	LE
Air Conduction	O	X	Air Conduction	Δ	□
Bone Conduction	<	>	Bone Conduction	<	>
F.Field	⊏	⊐			

Right ear Moderate hypoacusia
Left ear Moderate hypoacusia

OBSERVATIONS:

SISI TEST

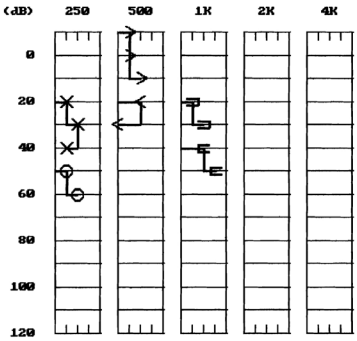
Hz	500	1000	2000	4000
R.E. %	80	90	70	80
L.E. %	70	80	80	70

LUSCHER TEST

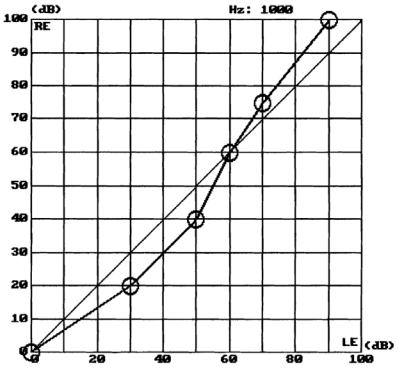
Hz	500	1000	2000	4000	8000
RE dB	0.2	0.6	1.0	2.0	5.0
LE dB	0.2	0.6	1.0	2.0	5.0

Reference: 0123456789 Name: Date of Study: 11/12/2008

TONE DECAY TEST



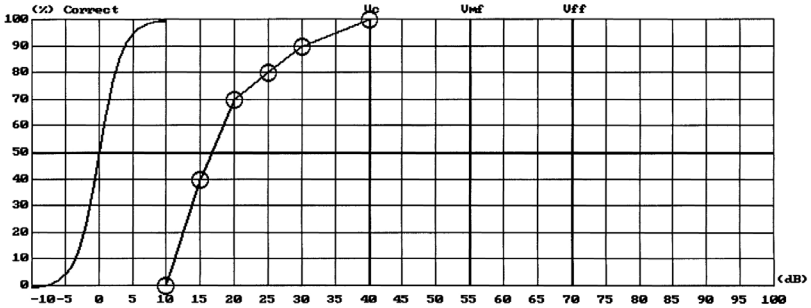
FOWLER TEST



VEBER TEST

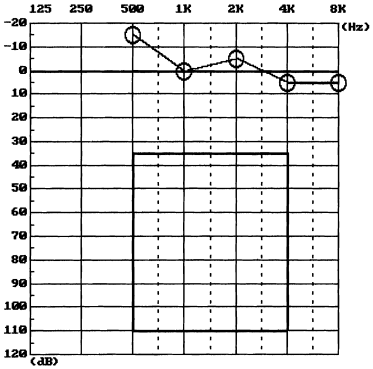
Hz	250	500	1000	2000	3000	4000	
R.E.	>	>	=	=	<	<	L.E.

SPEECH AUDIOMETRY

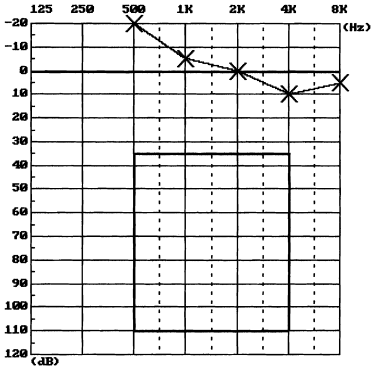


Reference: 0123456789 Name: Date of Study: 11/12/2008

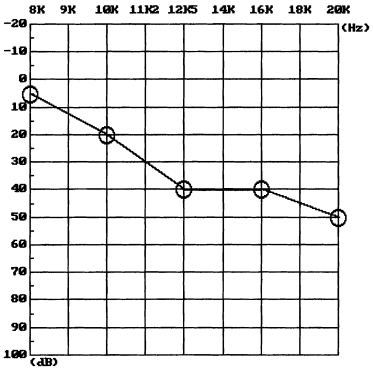
R.E. LF



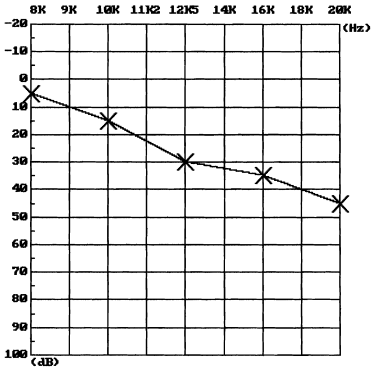
L.E. LF



R.E. HF



L.E. HF



Reference: 0123456789 **Name:** **Date of Study:** 11/12/2008

DIAGNOSIS RESULTS

MINISTRY OF LABOUR AND SOCIAL AFFAIRS BOE 26 January 2000

	R.E.	L.E.
Hearing Loss (%)	35.6	35.6
Average dBs	48.8	48.8
Bilateral Loss (%)	35.6	

Right ear: Moderate hypoacusia
Left ear: Moderate hypoacusia

COUNCIL OF PHYSICAL THERAPY

	R.E.	L.E.
Hearing Loss (%)	57.5	57.5
Average dBs	51.3	51.3
Bilateral Loss (%)	57.5	

Right ear: Moderate hypoacusia
Left ear: Moderate hypoacusia

MEXICAN SOCIAL SECURITY INSTITUTE

	R.E.	L.E.
Hearing Loss (%)	39.0	39.0
Average dBs	48.8	48.8
Bilateral Loss (%)	39.0	

Right ear: Moderate hypoacusia
Left ear: Moderate hypoacusia

DIAGNOSIS BASED ON ELI INDEX

Right ear: Degree E. Clear indication of deafness
Left ear: Degree E. Clear indication of deafness

DIAGNOSIS BASED ON SAL INDEX (Note 1)

	R.E.	L.E.
Hearing Loss (%)	35.6	35.6
Bilateral Loss (%)	35.6	

Degree C. Slight hearing impairment. Has difficulties in normal conversations, but not if people speak up.

DIAGNOSIS BASED ON KLOCKHOFF INDEX

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

Observations:

Note 1: Ministry of Labour and Social Affairs BOE 26 January 2000

2. TECHNICAL SPECIFICATIONS

As described in chapter 1 of the INSTRUCTIONS FOR INSTALLATION AND USE, there are six different models of the SIBELSOUND 400 and they can each be enhanced with options not installed as standard. Therefore, the technical specifications set out below correspond to a device which has all the available options.
In each case, please bear in mind the configuration of your audiometer and the components which are not included.

2.1 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

2.2. 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 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%

- 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%

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

- 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.

2.3. CONTROL OF SIGNAL LEVELS

MAXIMUM SIGNAL LEVELS

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

MAXIMUM HF SIGNAL LEVELS

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Máx dB HL	60	90	110	110	110	110	110	100	100	100	90
Mín. dB HL	-20	-20	-20	-20	-20	-20	-20	-20	-20	-20	-20

Hz	9000	10000	11200	12500	14000	16000	18000	20000
Máx dB HL	90	90	90	50	50	50	50	50
Mín. dB HL	-20	-20	-20	-20	-20	-20	-20	-20

MAXIMUM LEVELS OF MASKING SIGNAL

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

MAXIMUM LEVELS OF HF MASKING SIGNAL

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Máx dB HL	60	80	100	100	100	100	100	100	100	100	80
Mín. dB HL	-20	-20	-20	-20	-20	-20	-20	-20	-20	-20	-20

Hz	9000	10000	11200	12500	14000	16000	18000	20000
Máx dB HL	80	80	80	40	40	40	40	40
Mín. dB HL	-20	-20	-20	-20	-20	-20	-20	-20

MINIMUM SIGNAL LEVELS

- -10 dB HL 125 to 8000 Hz
- -20 dB HL 125 to 20000 Hz by air HF conduction

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

2.4. 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

OUTPUTS

- Parallel printer Centronics/USB
- Serial port RS-232C/USB

2.5. TRANSDUCERS

AIR CONDUCTION LOW FREQUENCY
- Headset TDH39 (pair) Telephonics

AIR CONDUCTION HIGH FREQUENCY
- HDA 200 Sennheiser

BONE CONDUCTION
- Vibrator B71

FREE FIELD
- Loudspeakers with integrated amplifier

SPEECH AUDIOMETRY MICROPHONE
- Electret type

2.6. APPLICABLE STANDARDS

ELECTRICAL SAFETY

- EN60601-1 Seg. medical equipment: Class 1 type B
- EN60601-1-1 Seg. medical equipment
- EN60601-1-4 Programmable systems

EMC

- EN60601-1-2 EMC in medical equipment (Not vital support)
  - -EN 55011 RF Emissions (Group 1 type B)
  - -EN 61000-3-2 Type A harmonic emissions

-EN 61000-3-3 Flicker emissions
-EN 61000-4-2 ESD discharge (+- 6kV contact, +- 8KV air)
-EN 61000-4-3 Radiated RF Immunity at 3V / m
-EN 61000-4-4 BURST (+-2kV power, +-1KV input/output lines)
-EN 61000-4-5 SURGE (+-1kV differential mode, +- 2KV common mode)
-EN 61000-4-6 Conducted RF Immunity at 3 V rms
-EN 61000-4-8 Magnetic field immunity at 3 A/m
-EN 61000-4-11 Immunity to voltage dips

AUDIOMETERS

- EN 60645-1:2001 Pure tone audiometers
- EN 60645.2:1993 Speech audiometers
- High frequency tone audiometry in accordance with EN 60645-4

CALIBRATION

- EN ISO 389-1:2001 Air conduction
- EN ISO 389-3:1999 Bone conduction
- EN ISO 389-4:1999 Narrow band noise
- EN ISO 389-5: 2000 High Frequency
- EN ISO 389-7: 1998 Free Field and Diffuse Field

AUDIOMETRY

- Preliminary audiometry in accordance with EN ISO8253-1
- Audiogram in accordance with recommendations in EN 26189:1991 (ISO6189:1983)
- Speech audiometry in accordance with UNE-EN ISO8253-2

2.7. GENERAL DATA

FUNCTION CONTROL

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

Ambient Conditions

- Storage temperature: 0 to 60 °C
- Working temperature: 10 to 40 °C
- Relative humidity < 90% (no condensation)

POWER SUPPLY

- 90V-264V - 50/60Hz ±3%

POWER

- < 50 VA

DIMENSIONS

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

WEIGHT

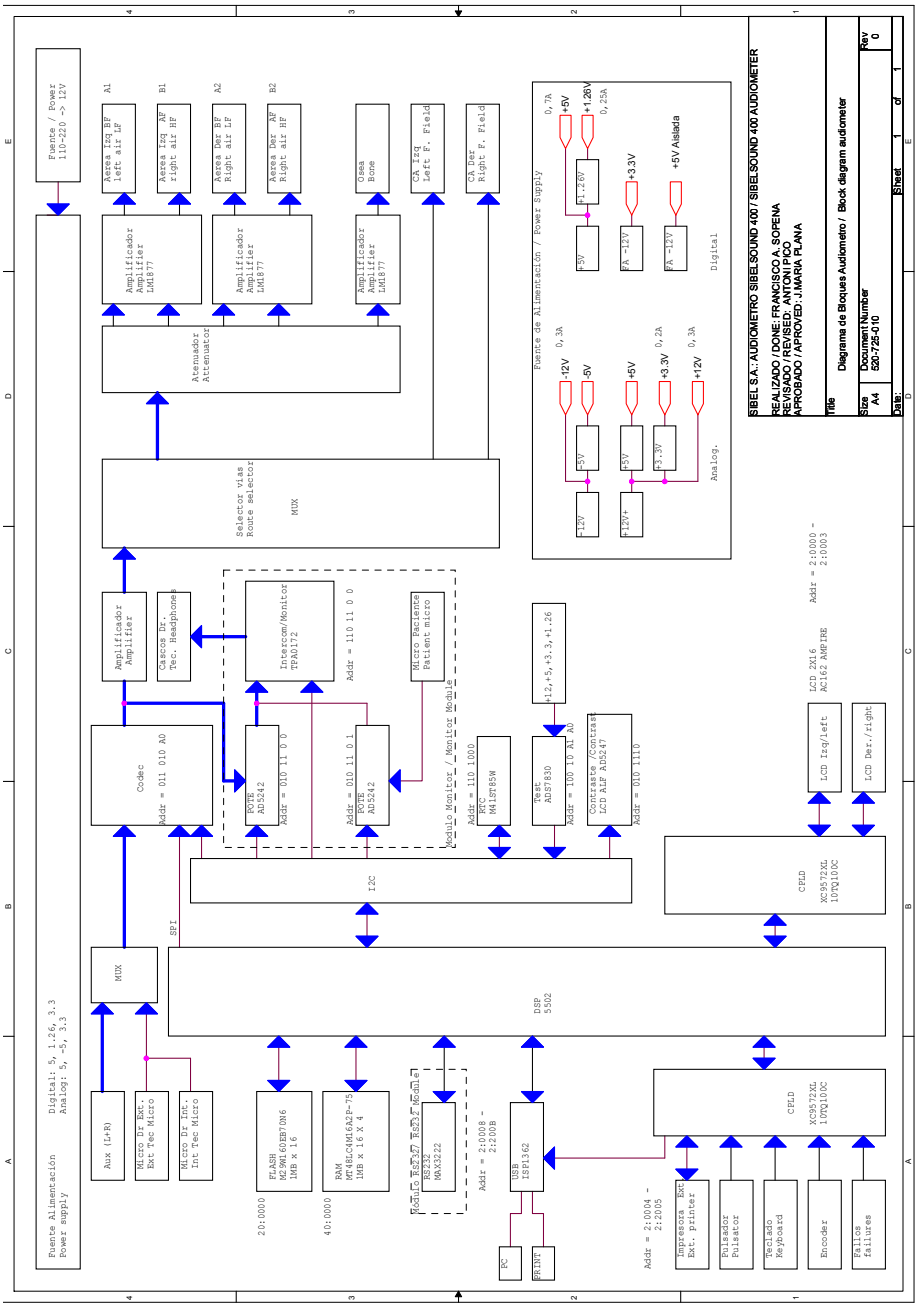
- 2.4 Kg without accessories

3. OPERATING PRINCIPLES

To carry out evaluations of physiological capabilities with electronic devices, we need to reproduce the physical conditions which can stimulate and produce the physiological responses to be evaluated.

In the case of the SIBELSOUND 400 audiometer, this involves reproducing defined sounds which when applied at calibrated and standardised levels obtain responses indicative of the capabilities of the auditor.

The electronic circuits incorporated in the Audiometer for this purpose are described below. As an aid to understanding, the block diagrams are shown in the Figure below:


SIBEL S.A.: AUDIOMETRO SIBELSOUND 400/ SIBELSOUND 400 AUDIOMETER
REALIZADO / DONE: FRANCISCO A. SOPENA
REVISADO / REVISED: ANTONIO PO
APROBADO / APPROVED: MARIA PLANA
Title
Diagrama de Bloques Audiometro / Block diagram audiometer
Size A4
Document Number 620-725-010
Rev 0
Date
Sheet 1 of 1
Fuente / Power 110-220 -> 12V
Fuente Alimentación Power supply
Digital: 5, 1.26, 3.3
Analog: 5, -5, 3.3
Aux (L+R)
Micro Dr Ext. Ext Tec Micro
Micro Dr Int. Int Tec Micro
MUX
SPI
I2C
DSP 5502
Codec
Addr = 011 010 A0
Amplificador Amplifier
Cascos Dr. Tec. Headphone
Intercom/Monitor TPA0172
Addr = 110 11 0 0
Micro Paciente Patient micro
ROTE AD5242
Addr = 010 11 0 0
Addr = 010 11 0 1
Addr = 110 1000
MIC MAX1585W
Addr = 100 10 A1 A0
Test AD57830
Contraste /Contrast LCD AdJ AD5247
Addr = 010 1110
+12,+5,+3.3,+1.26
LCD Izq/Left
LCD Der./right
LCD 2X16 AC162:AMPIRE
Addr = 2:0000 - 2:0003
CPLD XC9572XL 10TQ100C
Addr = 2:0008 - 2:200B
USB ISP1362
PC
PRINT
Addr = 2:0004 - 2:2005
Impresora Ext. Ext. printer
Pulsador Pulsator
Teclado Keyboard
Encoder
Faltas Failures
2:0:0000
FLASH M29W160DB70N6 1MB x 16
4:0:0000
RAM MT48LC4M16A2P-75 1MB x 16 X 4
Modulo RS232 RS232 Module
RS232 MAX3222
Fuente de Alimentación / Power Supply
0, 7A
+5V
+1.26V
0, 25A
+1.26V
+3.3V
+5V Aislada
FA -12V
FA -12V
Digital
0, 3A
-12V
-5V
+5V
+3.3V
0, 2A
+12V
0, 3A
-12V
-5V
+5V
+3.3V
+12V+
Analog.
Astea Izq BF Left air LF
Astea Izq AF Right air HF
Astea Der BF Right air LF
Astea Der AF Right air HF
Amplificador Amplifier LM1877
Atenuador Attenuator
Selector vias Route selector
Osea Bone
CA Izq Left F. Field
CA Der Right F. Field
A1
B1
A2
B2

3.1. RIGHT / LEFT CHANNEL

The left Channel consists of a set of circuits that process the signal received from the Codec and direct it to the headset of the left Air Conduction channel, the Vibrator for Bone Conduction or the Free Field left channel output.

MODULATOR

This equipment produces digital signal modulations using DSP.

ATTENUATOR

The attenuator is divided into three stages. One is in the DSP, another forms part of the Audio Codec (this circuit also incorporates a mute function with attenuation greater than 80 dB) and a final third stage located at the output to the Codec.

SIGNAL INTERRUPTION - SILENCER

Connection and disconnection of the signal is carried out digitally by putting the Codec into Mute mode. This component can effect switches with 50 ms transitions in accordance with Standards.

SOURCE SELECTOR

This selects between the various inputs - doctor's microphone, auxiliary input and the signals generated by the equipment. This consists of an analog selector controlled by the DSP.

ROUTE SELECTOR

Two analog selectors direct the signal either to the amplifier for Right Air Conduction channel, (LF y HF) or the amplifier for Bone conduction or the Free Field output, depending on the code received from the Processor.

AMPLIFIER

The Amplifier consists of several power amplifiers (LF, HF and Bone) which operate directly on the patient's headphones or vibrator

3.2. MICROPROCESSOR

PHYSICAL DESCRIPTION

The DSP set consists of a series of electronic devices which store, process, receive and send information.

Very broadly, it is divided into:

- DSP processor unit
- Governing program residing in 2MB FLASH memory, (1Mb= 1024 Kbytes)
- 4 MB SDRAM Memory for storage of variables and execution of the program.
- Peripheral components.

PROGRAM

The governing program is developed in C language in order to achieve fast execution speeds. It processes all the signals that control the peripherals, read the keyboard, establish a link protocol via the USB and RS channels, process output to an external printer (USB or Centronics Parallel).

DRAM MEMORY

This memory executes the audiometer control program and stores the variables used by the program, as well as other variables which define the status of the audiometer.

FLASH MEMORY

This type of memory allows a program and variables to be stored without the need for any external power.

DSP

This device carries out and processes the instructions contained in the program. It uses a TMS5502 with a clock frequency of 12 Mhz.

CODEC

This component has an internal 24-bit AD converter and generates all of the Audiometer's signals. It also controls the level of the signal and the silencer.

PERIPHERALS

The DSP communicates with the environment via several SPI buses, I2C and parallel.

CPLD

These are programmable logic devices. One of these controls the keyboard signals and the other is responsible for the LCD.

RTC

This component provides us with the current date and time. It is powered by a long life lithium battery to maintain status information even when the device is turned off.

USB CONTROLLER

This component supports communications over the USB channel and also controls a USB printer.

3.3. INTERCOM (Optional)

The Intercom consists of an internally connected module which enables the patient to be listened in on by the Monitor, when they are in an audiometric booth or in a separate room from the Audiometer. The signal coming from the patient's microphone is controlled by means of a digital potentiometer and is power amplified directly to the doctor's headphones.

The intercom mode is used for the patient to be heard by the technician

The monitor mode allows the technician to monitor the signals applied to the patient. 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

3.4. FREE FIELD (Optional)

Free Field audiometry requires equipment to take the place of the patient headphones. The signals coming from the Audiometer are applied, by means of a connection, to the inputs of a set of power amplifiers which cause vibrations in

two loudspeakers, located a certain distance from the patient. Free field calibration is carried out at a distance of 1 m from the loudspeaker at the centre of the axis along which the patient is seated. The ear of the patient and the centre of the loudspeaker must occupy the same horizontal plane. The amplifiers are powered directly from the mains and no controls are provided, with the exception of the ON / OFF switch and the on indicator light.

4. AUDIOMETRY TECHNIQUE

Audiometric techniques are very numerous due to the large number of variants which exist. Describing all of them would be a complex undertaking and beyond the scope of this manual.

However, it is entirely appropriate to follow the recommendations of standard EN 26189 (ISO 6189) regarding the performance of audiometry for the purpose of preserving hearing; the ISO 8253-1 standard regarding audiometry for the purpose of determining hearing thresholds; and ISO 8253-3 standard for carrying out speech audiometry.

Therefore, those specialists who require further information should refer to the many bibliographies which have been published on the subject.

5. UPKEEP, PREVENTIVE AND CORRECTIVE MAINTENANCE

As with any equipment, and in particular for medical applications, the SIBELSOUND 400 requires upkeep and maintenance, primarily in the interest of patient, operator and environmental safety, and secondly to ensure the reliability and accuracy of the functions for which it has been developed. This involves a series of routines which need to be carried out.

5.1. UPKEEP

Upkeep is the set of actions involved in keeping the equipment functioning correctly. The person who carries them out does not require any special technical knowledge other than their own understanding of the functioning and handling of the equipment. It is usually done by the normal user of the equipment. The procedures to be carried out are as follow:

CLEANING THE AUDIOMETER

The audiometer should be cleaned gently with a cloth moistened with water and dishwasher detergent. It can then be wiped dry. Take particular care to ensure that no liquid enters the interior of the device or the connectors and connections.
Do not use abrasive substances or solvents.

CLEANING THE ACCESSORIES

Care of the accessories follows the same method as described above for the device itself.

The earpads for the air conduction headphones can be cleaned more thoroughly if first detached from the headset, washed with water and soap and then dried completely with a cloth before reattaching to the headset.

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.

5.2. PREVENTIVE MAINTENANCE

Preventive maintenance consists of all actions carried out for the purpose of keeping the equipment in perfect working order.

Various guidelines can be established, although there certain standards, such as EN 8253-1 and ISO 26189 that are the most appropriate. The method to follow is at the discretion of the specialist, although as a minimum we recommend the following:

ROUTINE CHECKS AND SUBJECTIVE TESTS

This check is to be carried out weekly and the process is as follows:

1 Check that the connections are all correctly attached, and that there is no sign of cracking or external damage to the cables and/or connectors, or to any other component.

2 Carry out a subjective test to ensure that the audiometer output, via both air conduction and bone conduction, is the same in both channels and for all frequencies. To do this, use a level of 10 or 15 dB, above the hearing threshold. The person carrying out the subjective tests should have normal hearing.

3 Check at a level of 60 dB in air conduction and 40 in bone

conduction that there is no distortion discernible in any of the frequencies, and no noise or interference signals, etc.

4 Check that the signal key works correctly in both direct and inverted modes.

5 Check that the attenuator levels work correctly with no noise or interference between channels.

6 Check the speech audiometry and intercom channel.

7 Check that the attachment bands for the headset and vibrator are in good condition.

OBJECTIVE CHECK

The check consists of a general technical verification of the safety systems, adjustments, functions, calibrations, etc. involved in the configuration of the equipment.

The calibration is carried out with the aid of an artificial ear and mastoids in accordance with applicable standards.

THESE CHECKS MUST BE CARRIED OUT AT LEAST ANNUALLY and in accordance with the Checking and Adjustment Procedure for the **SIBELSOUND 400** audiometer, available from the manufacturer. Procedures of this kind must be carried out by qualified technical personnel from the medical centre's maintenance department, or from the distributor's or manufacturer's technical service department.

In any event, **SIBEL S.A.** as manufacturer, must provide authorisation in writing, at least during the warranty period to the relevant technical service so that they can carry out the above-mentioned maintenance and in no case accepts responsibility for any damage, malfunction, etc. which may arise as a consequence of defective maintenance by persons not employed by **SIBEL S.A.**

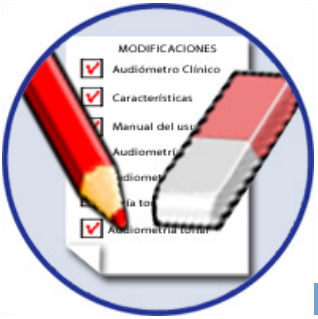
5.3. CORRECTIVE MAINTENANCE

Corrective maintenance involves returning to good working order equipment which no longer functions due to incorrect operation or handling and is in need of repair.

On detecting any fault with equipment which interferes with its normal use, disconnect the equipment from the mains and contact **SIBEL S.A**. Aftersales Service, explaining the problem in as much detail as possible.

If the equipment requires corrective maintenance, it is advisable to also carry out the preventive maintenance described in the section OBJECTIVE CHECK.

This requirement should be communicated to the technical service carrying out the repair, since certain faults may involve misalignments that are not readily detectable without in depth review and calibration.



6. MODIFICATIONS

APPENDIX 1

ELECTROMAGNETIC COMPATIBILITY

Guide and statement from the manufacturer - electromagnetic emissions		
The Sibelsound 400 is designed to be used in the electromagnetic environment specified below. The customer or user must ensure that it is used in such an environment.		
Emissions Test	**Level of compliance**	**Guide – Electromagnetic Environment**
Radiated RF Emissions CISPR 11 (EN 55011)	Group 1	The Sibelsound 400 uses RF energy only for internal use. Therefore, its emissions are very low and it is unlikely to cause interference to surrounding electronic devices.
Conducted RF Emissions CISPR 11 (EN 55011)	Class B	In order to function, the Sibelsound 400 must be connected to the electrical mains.
Harmonic Emissions EN-IEC 61000-3-2	Class B	In order to function, the Sibelsound 400 must be connected to the electrical mains.
Voltage flicker and fluctuations EN-IEC 61000-3-3	Class B	In order to function, the Sibelsound 400 must be connected to the electrical mains.

Manufacturer guide and statement – electromagnetic immunity			
The Sibelsound 400 is designed to be used in the electromagnetic environment specified below. The customer or user of the Sibelsound 400 must ensure that it is used in such an environment.			
Immunity Test	**Test level for EN IEC 60601**	**Level of compliance**	**Guide – Electromagnetic Environment**
Electrostatic Discharge (ESD) EN-IEC 61000-4-2	±6 kV in contact ±8 kV in air	±6 kV in contact ±8 kV in air	The floor must be made of wood, cement or ceramic tiles If the floor is covered in a synthetic material, the relative humidity must be at lest 30 %.
Electrical Fast Transient/Burst EN-IEC 61000-4-4	±2 kV for power lines and earth ±1 kV for input/ output lines	±2 kV for power lines and earth ±1 kV for input/ output lines	The length of I/O lines is less than 3 m.
Shock waves (Surge) EN-IEC 61000-4-5	±1 kV in differential mode ±2 kV in common mode	±1 kV in differential mode ±2 kV in common mode	
Voltage Dips, Short Interruptions and Voltage Variations EN-IEC 61000-4-11	<5 % Ut (>95 % fall in Ut) for 0.5 cycles 40 % Ut (60 % fall in Ut) for 5 cycles 70 % Ut (30 % fall in Ut) for 25 cycles <95 % Ut (>5 % fall in Ut) for 5 seconds	<5 % Ut (>95 % fall in Ut) for 0.5 cycles 40 % Ut (60 % fall in Ut) for 5 cycles 70 % Ut (30 % fall in Ut) for 25 cycles <95 % Ut (>5 % fall in Ut) for 5 seconds	
Magnetic field 50 / 60 Hz EN-IEC 61000-4-8	3 A/m	3 A/m	The magnetic field in the room must be low enough to ensure the test can be carried out.
Note that Ut is the alternating current power supply expected for the purposes of the test.			

Manufacturer guide and statement – electromagnetic immunity

All models of the DEVICE are designed to be used in the electromagnetic environment specified below. The customer or user of the SBELHOME Plus must ensure that it is used in such an environment.

Immunity Test	EN-IEC 60601 test level	Level of compliance	Guide – Electromagnetic Environment
			Portable and mobile RF communication equipment must not be used closer to any part of the SIBEL-HOME Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN-IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	3 Vrms	$d = [\frac{3.5}{3}]\sqrt{P}$
Radiated RF EN-IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	3 V/m	$d = [\frac{3.5}{3}]\sqrt{P}$ from 80 MHz to 800 MHz $d = [\frac{7}{3}]\sqrt{P}$ from 800 MHz to 2.5 GHz Where P is the transmitter's maximum output power in Watts (W) according to the manufacturer and d is the recommended separation distance in metres (m). Field intensities emerging from fixed RF transmitters, determined by electromagnetic measurement at location a, must be less than the compliant level at each frequency margin b. Interference can arise in the proximity of equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, apply the higher frequency margin

Note 2 These recommendations may not apply in all possible situations. Electromagnetic propagation can be affected by absorption and reflection by structures, objects and persons.

[a] The exact field intensities emitted by fixed transmitters, such as radiotelephone base stations (wireless cellular-mobile phones) and mobile radios, radio hams, AM, FM and TV radio broadcasts, cannot be theoretically calculated. To determine the electromagnetic environment due to fixed transmitters, consider carrying out electromagnetic measurements in the area of use.
In the event that the field intensity in the area of use is greater than the compliant level, check whether the behaviour of the DEVICE is normal. If not, it may be necessary to take additional measures such as the reorientation or relocation of the DEVICE.

[b] Above the 150 kHz to 80 MHz frequency range, the field intensity must be less than 3 V/m.

Recommended separation distances between mobile and portable RF communication equipment and the Sibelsound 400

The Sibelsound 400 is designed to be used in an electromagnetic environment in which radiated RF perturbations are controlled. The customer or user of the Sibelsound 400 can help to prevent interference by maintaining a minimum distance between mobile and portable RF communications equipment (transmitters) and the Sibelsound 400 as recommended below, according to the output power of the communications equipment.

Maximum output power of the transmitter W	**Separation distance as a function of the transmitter frequency**	
	From 80 MHz to 800 MHz $d = [\frac{3.5}{3}] \cdot \sqrt{P}$	**From 800 MHz to 2.5 GHz** $d = [\frac{7}{3}] \cdot \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters with a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the relevant equation according to the frequency of the transmitter, where P is the maximum power of the transmitter in Watts (W) according to the manufacturer.

Note 1 At 800 MHz, apply the higher frequency margin

Note 2 These recommendations may not apply in all possible situations. Electromagnetic propagation can be affected by absorption and reflection by structures, objects and persons.

APPENDIX 2

COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC

COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC.

REQUIREMENTS SPECIFICALLY AFFECTING THE USE OF THE DATOSPIR MICRO SPIROMETER

This section seeks to ensure user compliance with the current data protection legislation in relation to the use of this equipment.
A brief description is given as to how the SIBELSOUND 400 Audiometer must be handled to comply with the requirements of this act.

IMPORTANT WARNING

• According to current legislation, the user of this equipment is the only party responsible for saving and processing the details of his patients according to the Law.

• Observance of the recommendations included in this section under no circumstances guarantees the full adaptation of the user's activity to the data protection regulation.

OTHER IMPORTANT ISSUES

• 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 tone audiogram 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

1. The hearing thresholds of each ear are determined at frequencies of 500, 1000, 2000 and 3000 Hz and added.
NOTE: If one of the central frequencies is missing (1000 or 2000) and an adjacent frequency is selected, the audiometer uses this frequency to calculate the diagnosis and includes this modification in the report.

2. The corresponding hearing loss is found in Table 1.

3. If the hearing threshold is 25 dB or lower, this is not considered as loss of hearing.

Example:

Right ear (RE) 500 1000 2000 3000
dB of loss 15 10 5 10
Sum (15+10+5+10 = 40)

% Hearing loss RE 0.0 %
dB Average RE (40/4) 10.0 dB

Left ear (LE) 500 1000 2000 3000
dB of loss 35 30 40 50
Sum (35+30+40+50 = 155)

% Hearing loss RE 20.6 %
dB Average LE (155/4) 38.7 dB

B. Binaural or Bilateral hearing loss

Binaural hearing loss is calculated by multiplying the loss of the best ear by five and adding the loss of the worst ear and then dividing the total by six.

Binaural hearing loss in % = (5x(% loss in best ear) + (% loss in worst ear))/6.

Example:

Binaural hearing loss % = (5x0.0 + 20.6)/6 = 3.4%

C. Categories of Hearing Loss

The MINISTRY diagnosis does not establish categories of hearing loss.
However, professional clinical recommendations have led us to include the following categories depending on the hearing loss in each ear:

HEARING LOSS CATEGORIES
. NORMAL 0 to 10%
. SLIGHT HYPOACUSIA 11 to 30%
. MODERATE HYPOACUSIA 31 to 60%
. SEVERE HYPOACUSIA 61 to 100%

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		

2. "COUNCIL" DIAGNOSIS

The percentage of hearing loss is determined from the pure tone audiogram in accordance with the second formula of the Council of Physical Therapy.
A percentage of the hearing loss in each ear is taken at the 500, 1000, 2000 and 4000 Hz frequencies as a function of their importance, specifically 15% at 500 and 4000 Hz, 30% at 1000 Hz and 40% at 2000 Hz.
A 0% hearing loss corresponds to normal and a 100% hearing loss to cofosis. By reference to a table published by the institution, you can find the percentage hearing loss for each frequency and the level of intensity.

A. Monoaural hearing loss

1. The hearing thresholds of each ear are determined at frequencies of 500, 1000, 2000 and 4000 Hz and added.
2. The corresponding percentage of hearing loss for each frequency and intensity is found in Table 2.
3. The loss values for the four frequencies are added, giving the % of hearing loss of the ear under study.

Example:

Right ear (RE) 500 1000 2000 4000
dB of loss 15 10 5 10
% loss 0.5 0.3 0 0.1
Sum (0.5+0.3+0+0.1 = 0.9)

% Hearing loss RE 0.9%
dB Average RE (40/4) 10.0 dB

Left ear (LE) 500 1000 2000 4000
dB of loss 35 30 40 50
% loss 3.7 5.4 12.9 8.0
Sum (3.7+5.4+12.9+8.0 = 30.0)

% Hearing loss LE 30.0%
dB Average LE (155/4) 38.7 dB

B. Binaural hearing loss

Binaural hearing loss is calculated by multiplying the loss of the best ear by seven and adding the loss of the worst ear and then dividing the total by eight.
Binaural hearing loss in % = (7x(% loss in best ear) + (% loss in worst ear))/8.

Example:

Binaural hearing loss % = (7x0.9 + 30.0)/8 = 4.5%

C. Categories of Hearing Loss

The "COUNCIL" diagnosis does not establish categories of hearing loss. However, the same categories as for the "MINISTRY" diagnosis have been adopted.

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				

3. DIAGNOSIS OF THE MEXICAN INSTITUTE OF SOCIAL SECURITY

The percentage of hearing loss is determined from the pure tone audiogram in accordance with the Mexican Social Security Institute.

A. Monoaural hearing loss

1. The hearing thresholds of each ear are determined at frequencies of 500, 1000, 2000 and 3000 Hz and added.
2. The four values of each ear are added and the average is calculated.
3. The result is then multiplied by 0.8 (Fletcher Index).

Example:

Right ear (RE) 500 1000 2000 3000
dB of loss 15 10 5 10
Average = (15+10+5+10)/4 = 10 dB

% Hearing Loss RE = 10 x 0.8 = 8%
dB Average RE (40/4) 10.0 dB

Left ear (LE) 500 1000 2000 3000
dB of loss 35 30 40 50
Average = (35+30+40+50)/4 = 38.7 dB

% Hearing Loss LE = 38.7 x 0.8 = 31%
dB Average LE (155/4) 38.7 dB

B. Binaural hearing loss

Binaural hearing loss is calculated by multiplying the loss of the best ear by seven and adding the loss of the worst ear and then dividing the total by eight.
Binaural hearing loss in % = (7x(% loss in best ear) + (% loss in worst ear))/8.

Example:

Binaural hearing loss % = (7x8 + 31.0)/8 = 10.9 %

C. Categories of Hearing Loss

The "MEXICAN" diagnosis does not establish categories of hearing loss. However, the same categories as for the "MINISTRY" diagnosis have been adopted.

4. ELI

The ELI (Early Loss Index) is calculated from a frequency of 4000 Hz and following the tables of the Protocol for Specific Health Surveillance (Interterritorial Council of the Spanish National Health System) following the steps below:
1. The ELI is calculated by subtracting the corresponding correction value for presbycusia in Table 3 from the hearing loss at a frequency of 4000 Hz. The frequency of 4000 Hz is evaluated (considering loss due to age and gender).
2. Acoustic trauma is classified on an increasing scale of A-B-C-D-E, from lower to higher hearing capacity according to Table 4.

Example:

Patient: Male, 50 years old
Right ear (RE) 4000
dB of loss 30
Left ear (LE) 4000
dB of loss 40
Applying correction, ELI

Right ear 30 – 20 = 10 dB --- Grade B Normal good
Left ear 40 – 20 = 20 dB --- Grade C Normal

Table for ELI calculation
Correction for presbycusia at 4000 Hz dB

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) evaluates the conversational frequencies (500, 1000 and 2000 Hz) and is defined as the arithmetic mean of hearing loss in decibels of these frequencies. It establishes a classification by degrees A-B-C-D-E-F-G from SAL-A (both ears are within normal limits) to SA-G (complete deafness).

Once this value has been obtained, Table 5 of the SAL Index is used to present the evaluation.

To arrive at the index, both ears need to be tested.

Clinical recommendations have led us to change the text of the SAL Index Table of the Protocol for Specific Health Surveillance (Interterritorial Council of the Spanish National Health System) according to the following:

Grade C changes from "Slightly worse" to "Slight Hearing Impairment"
Grade D changes from "Seriously worse" to "Significant Hearing Impairment"
Grade E changes from "Severely worse" to "Serious Hearing Impairment"
Grade F changes from "Extremely worse" to "Severe Hearing Impairment"

Grade F covers 91 to 99 dB and Grade G applied to 100 dB onwards.

There are some situations not covered by the evaluation table, particularly where impairment is too asymmetric, (one ear within the normal range but the other however displays serious acoustic trauma). This occurs when the best ear presents a drop of <16 dB and the worst ear presents >30 dB. In such cases, the following text is displayed:
"Detected deafness too asymmetric to be evaluated using the SAL table".

As well as the SAL Index, we obtain Monoaural hearing Loss and Binaural or Bilateral Hearing Loss, as described in the MINISTRY diagnosis.

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

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

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

For this test, the 500, 1000, 2000 and 4000 frequencies are investigated, and the criteria set out in Table 6 are applied:
1. If the threshold is not higher than 25 dB at any frequency, the diagnosis is:
"Normal"

2. If the threshold at the 4000 frequency is below 55 dB and below 25 dB in the other frequencies, the diagnosis is:
"Slight Acoustic Trauma"
"No conversational loss"

3. If the threshold at the 4000 frequency is above 55 dB and below 25 dB in the other frequencies, the diagnosis is:
"Advanced Acoustic Trauma"
"No conversational loss"

4. If there are 1 or more frequencies below 25 dB (at least one >25 dB) the diagnosis is:
"Slight hypoacusia by noise"
"Conversational loss"

5. If all the frequencies are affected but none is above 55 dB, the diagnosis is:
"Moderate hypoacusia by noise"
"Conversational loss"

6. If all the frequencies are affected and one or more are above 55 dB, the diagnosis is:
"Advanced hypoacusia by noise"
"Conversational loss"

(Diagram modified by the Lavoro Clinic of Milan)

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.			