inventis

EN

AUDIOMETER

TRIANGLE

USER MANUAL

Read this manual carefully before using the device. Pay particular attention to the instructions given in Chapter 1 and in Chapter 2.

Internal inspections and repairs must only be performed by authorized personnel.

CE
0123

Summary

Foreword

EN

Thank you for purchasing an Inventis audiology device.

Advantageously compact and lightweight, the Triangle audiometer is a powerful and versatile portable device, ideal for fast and accurate hearing level screening.

The Inventis company has always considered the use of its devices in conjunction with computers to be a factor of key importance. Installing the Maestro software suite, available with or without proprietary database or as a Noah module, any Inventis audiology device can be connected to a computer, and all examinations conducted then archived in the user's own database.

Bear in mind also that Inventis has developed a complete line of audiology devices: in addition to audiometers, the company's product line includes a range of middle ear analyzers, REM and HIT hearing aid fitting devices, a wireless video otoscope and much more.

For further information, and to report any problems of any kind, contact the company at:

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Chapter 1
Introduction

Be sure to read this manual through completely, so that all the features offered by the device can be used to their full potential.
In this manual, the safety symbol shown below draws the reader's attention to information that is particularly important for safe and correct use.

1.1 OPERATOR RESPONSIBILITIES

The Triangle audiometer is guaranteed to work efficiently and reliably only when used according to the instructions and procedures outlined in this manual.

Should the device need to undergo repair or maintenance, it must be disconnected from the electrical power supply and not used again until after the servicing has been completed. Defective or faulty parts must only be replaced with original spare parts supplied by Inventis, and all repairs must be carried out exclusively by Inventis or by personnel it has authorized. No parts of the device must be modified or replaced without authorization from Inventis.

The user assumes full responsibility for any malfunction resulting from improper use or operation, likewise from maintenance or repair work performed by third parties other than Inventis or its approved Service Centers. Inventis and approved Service Centers will answer to the performance and reliability of the equipment only if:

1. Adjustments, modifications or repairs are performed exclusively by personnel authorized by Inventis.
2. The electrical system and earthing of the installation comply with the standards for electro-medical devices.

1.2 INTENDED USE

The Triangle medical device is an audiometer. An audiometer is a device that helps the operator define the patient's auditory sensitivity by generating and

delivering to the patient sound stimuli of different types and intensities for diagnostic purposes.

1.3 INDICATION FOR USE AND END USERS OF THE DEVICE

Triangle is intended for use by healthcare ENT professionals in hospitals, ENT clinics and audiology offices in conducting hearing evaluations and assisting in diagnosis of possible otologic disorders. There is no patient population restriction in the use of the device. Always be sure to perform an otoscopy before using the device.

These tests must be conducted in a quiet environment to avoid artifacts and to ensure that errors are not committed when determining the hearing threshold.

1.4 MAIN FEATURES

The Triangle is a portable device that can be used to conduct audiometric screening tests simply, swiftly and accurately. The device is able to meet the needs of private medical practices, clinics and hospitals alike.

The main strengths of the device are:

- Backlit color display with touchscreen interface.
- Compact and ergonomic design, lightweight construction.
- Long durability with built-in rechargeable lithium battery.

1.5 WARNINGS AND PRECAUTIONS

To ensure correct and safe use of the device, the following precautions must be observed.

1.5.1 General precautions

Make certain that the required ambient conditions are met (during transport, storage and operation) as indicated in Appendix A.

The device will not be protected if exposed during use to flammable anesthetic gases or similar products. Risk of explosion.

Use only original accessories supplied by Inventis srl, unless specifically indicated otherwise.

Triangle can be used in conjunction with a soundproof booth to conduct tests under optimum acoustic conditions. Before connecting the device to a soundproof booth, check that the sockets are compatible with the specifications prescribed for each connector.

Use only the medical grade power adapter supplied with the device, IEC 60601-1 certified. For further information see Appendix A.

Triangle is a medical device: if connected to a computer (or any external device) located within the "patient area" (as defined in IEC 60601-1), this likewise must be a medical device, or protected by an isolating transformer, in order to ensure that the combination of computer (external device) + audiometer is in compliance with IEC 60601-1.

Triangle must be installed and operated taking into account the information regarding electromagnetic compatibility (EMC) provided in Appendix C.

Avoid installing and using the device near sources of strong electromagnetic fields, which could interfere with the equipment's operation.

The proximity of portable and mobile appliances used for RF communications can affect the operational efficiency of the instrument box. Refer to the information regarding electromagnetic compatibility (EMC) provided in Appendix C.

1.5.2 Calibration

The calibration is valid for transducers supplied with the equipment, if connected directly to the device without any interposition of extension leads or other connectors (e.g. when connected to a soundproof booth). If a transducer is replaced or not connected directly to the device, a new calibration is required before using the device.

If the transducer selected is not calibrated, an alert will appear in the test screens. It will not be possible to present any stimulus to the patient using non-calibrated transducers.

Take note of the calibration interval indicated. Use of the device after the calibration expiration can lead to unreliable diagnoses.

1.5.3 Hygiene

Disinfect the headphone cushions between one patient and the next, following the procedure described in Chapter 7.

Earpieces of the insert earphones are disposable. Do not use the same earpiece for different patients. Dispose of them after use.

1.5.4 Use

The device can generate tones at an intensity potentially damaging to the patient. Take particular care to set the intensity of the tone correctly before it is presented.

Do not perform any service or maintenance while the device is being used on a patient.

1.6 DISPOSAL

Like any other electronic device, your audiometer contains extremely small quantities of certain hazardous substances. If such substances enter the normal waste disposal cycle without suitable preliminary treatment, they can cause damage to the environment and to health. Accordingly, at the end of its service life, each component of the device must go through a sorted collection process. This means that the user should deliver (or dispatch) waste items to the sorted collection centers set up by local authorities, or alternatively return them to the reseller when purchasing a new device of the same or similar type.

Thanks to the sorted collection of waste items and the subsequent processing, recovery and disposal operations they undergo, appliances can be made from recycled materials, and any negative impact of improper waste management on the environment and on health can be suitably limited.

1.7 CONFORMITY

The Triangle audiometer is a class IIa device, in accordance with Annex IX of the medical devices directive 93/42/EEC as amended and supplemented by directive 2007/47/EC. Inventis srl is a company ISO 13485 certified.

1.8 SYMBOLS

Warning: the use of this device requires certain precautions. To ensure safe use, consult the accompanying documentation.

Refer to the instructions for use.

Follow instructions for use.

SN

Device serial number:
- *Characters 1-5: Inventis product code*
- *Characters 6-7: year of manufacture ("20" denotes 2020)*
- *Characters 8-13: progressive serial number*

REF

Catalog code

Name and address of manufacturer

Type B applied parts (IEC 60601-1)

CE 0123

Conformity with Council Directive 93/42/EEC concerning medical devices (as amended and expanded by Directive 2007/47/EC) – Class IIa device, notified body 0123 (TÜV SÜD Product Service GmbH).

Rx only

Caution: US Federal law restricts the sale of this device to or on behalf of sale by or on the order of a licensed healthcare practitioner

The product is subject to the requirements of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). In the event of this product being sold and/or scrapped, it must not be disposed of as ordinary household or industrial waste but collected separately.

Do not reuse.
Components bearing this mark can be used only once and must not be reused thereafter.

(01)08054187380778
(21)AU1SA19221923

UDI code

Chapter 2
Installation and use

2.1 PACKAGE OPENING AND CONTENTS INSPECTION

Upon receiving the package, check that the box is not damaged and that the parts contained are neither damaged nor defective.

Having made the various connections, carry out a further visual inspection before switching on, to check for possible damage.

Should the device or any of its parts or accessories appear to be damaged or defective, contact the dealer or Inventis service.

Keep the packaging materials in case you need to send the device to the dealer or to Inventis for any reason.

2.2 PARTS, ACCESSORIES AND LICENSES

Parts and accessories supplied with the product are:

- Audiometer (lithium-ion battery included)
- RadioEar DD45 supra-aural headphones[1] or RadioEar DD65 circum-aural headphones[1]
- Patient response button[1]
- USB cable
- Medical grade USB multi socket power adapter
- Carrying case
- Audiometer user manual
- Audiogram cards
- Conformity and calibration certificates

Optional accessories are:

- Etymotic Research Inc. ER-3C[2] insert earphones
- RadioEar B-71 bone conductor[2]

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[1] Applied part according to IEC 60601-1
[2] Applied part according to IEC 60601-1

Additional licenses available are:

- "Computer connectivity" for the connection of the Triangle with the computer.
- "Bone conduction" to enable the bone conduction stimulation and noises on the AC contralateral headphone.

2.3 PRECAUTIONS

Installation of the Triangle audiometer is easy but needs to be done carefully. Incorrect installation could lead to safety issues while using the system.

Like any other electrical or electronic device, the audiometer will emit electromagnetic waves. While the level of emissions is guaranteed to remain within statutory limits, other electronic devices operating in the immediate vicinity could be affected if particularly sensitive to electromagnetic interference. If this should occur (interference is verifiable by turning the device off and then turning it on again), it may be possible to solve the problem by adopting one or more of the following solutions:

- Change the orientation and/or the position of the device affected by interference.
- Change the device's distance from the audiometer.
- Plug the affected device into a power socket on a circuit that is different from that of the audiometer.
- Consult the manufacturer or a service center for assistance.

2.4 CONNECTIONS

All connectors for accessories are located on the rear panel.

Plug all transducers and accessories into the respective sockets as indicated in the following table:

Connector	Attachment
BONE	Bone vibrator
ACL	AC headphones: Left
ACR	AC headphones: Right
P.RESP	Patient response switch

	USB cable for power adapter or PC

Connect transducers and patient response switch only with the device turned off.

The Triangle can be connected either to a PC for recharging and transferring test data, or to the power adapter supplied. Use only the USB cable supplied with the product.

2.5 KEYBOARD CONTROLS

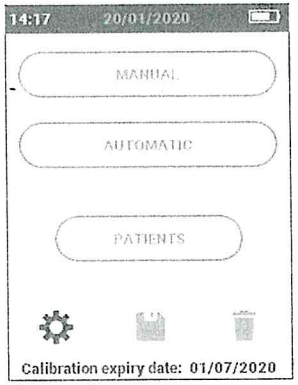
Control	Operation
⏻	When the device is OFF, press to power ON. If the device is ON, press to safely power it OFF, or hold down for 10 seconds to turn off the device without saving session data.
Fn	When pressed with other buttons, enables the second functions
MASKING / STIMULUS	Send stimulus
Fn + MASKING / STIMULUS	Send masking
NO RESP. / STORE	Store the hearing level
Fn + NO RESP. / STORE	Store a "no response"
TALK OVER	Talk to the patient through the mic (located above the Talk over button)
dB MASKING / dB / − +	Change the stimulus level
Fn + dB MASKING / dB / − +	Change the masking level

Hz – +	Change the testing frequency

2.6 POWER-UP AND MAIN SCREEN

Once all the cables are connected, Triangle can be turned on by pressing and holding the power button for few seconds. The device can be turned off at any time by pressing and holding the same button.

A few seconds after power-up, the display will show the following screen:



Icon	Operation
MANUAL	Access the manual Pure Tone Audiometry (PTA)
AUTOMATIC	Access the Automatic PTA
PATIENTS	Access the Patient Management (see Chapter 4)
	Store the current exam in the patient memory (see Chapter 4)
	Delete the current exam
	Access the Settings screen (see Chapter 5)

Chapter 3
Audiometry

The audiometry test can be conducted either in manual mode or in automatic mode. Before proceeding with the test, have the patient wear the chosen transducers and check the info screen accessible from the settings screen to make sure that the transducers are the ones calibrated

3.1 TOUCHSCREEN CONTROLS

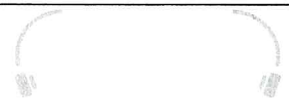
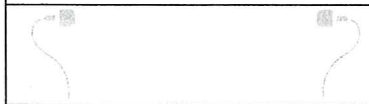
The following touchscreen controls are common for both Automatic and Manual pure tone audiometry.

Icon	Operation
	Go back to the main screen
	Select the ear to be tested (Right selected in this example)
	Delete the threshold saved for the selected ear

3.2 COMMON INDICATORS

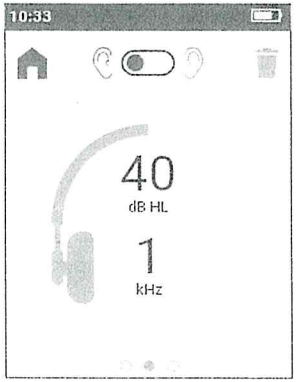
The following indicators are common for both Automatic and Manual pure tone audiometry.

Icon	Information
	Patient response button not pressed
	Patient response button pressed
right left	Headphones

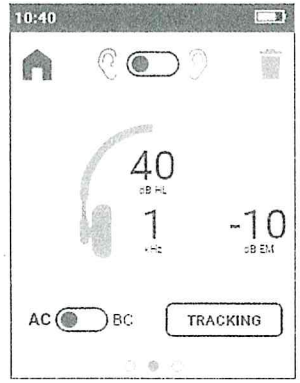
	Headphones with active stimulus
	Bone (only in Manual testing mode)
	Insert earphones

3.3 MANUAL AUDIOMETRY

Use keyboard controls (see paragraph 2.5) and touch controls (see paragraph 3.1) to modify the exam parameters and send stimulus to the patient.

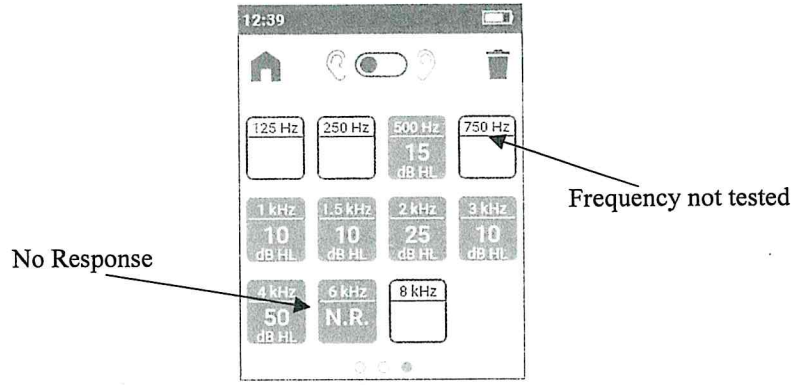


Without "Bone conductor" license



With "Bone conductor" license

If either a threshold or a No Response has already been stored with the current settings for transducer, side and frequency, the frequency label will be highlighted with the color of the current side. Swipe the screen to the left to view the stored thresholds.

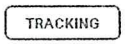


Swipe the screen to the right to access the parameters:

- Stimulus type: Tone or Warble. Default: Warble.
- Stimulus mode: Continuous or Pulsed 1 Hz. Default: Continuous.
- Default intensity: Sets the default intensity of the stimulus. Default: 40 dB HL.
- Maintain intensity: Maintain the level after changing the frequency. Default: disabled.
- Interrupter mode: Allows the interrupter key to be used as a button (stimulation is active when the key is pressed) or switch (the first key pressure activates the stimulus, the second one deactivates it). Default: button.
- Automatic frequency jump: Enables/disables automatic frequency jump after a value is stored. Default: disabled.
- Frequency selection: Access the frequency selection screen to individually enable/disable the frequencies to be tested. Default value: all frequencies enabled.

3.3.1 "Bone conduction" license

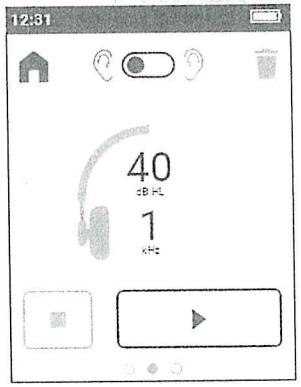
The following controls and information are available only when the "Bone conduction" license is enabled:

Icon	Operation
	Select the transducer
	Enable tracking (keep the same difference in dB between stimulus and masking)

Icon	Information
40 dB EM	Masking level
	Masking enabled
	Masking disabled

3.4 AUTOMATIC AUDIOMETRY

Automatic audiometry is performed only with the AC transducer, without masking.



Icon	Operation
▶	Start the test
⏸	Pause the test
■	Stop the test

Swipe the screen to the left to view the stored thresholds. Swipe the screen to the right to access the parameters:

- Frequency selection: Access the frequency selection screen to individually enable/disable the frequencies to be tested. Default value: all frequencies enabled.
- Test mode: Select the desired automatic algorithm:

  - Hughson-Westlake auto-threshold, modified by Martin (the threshold is taken in case of 2 correct answers out of 3)
  - Quick search (a single correct answer stores the threshold)
  - Fixed intensity (every frequency is tested once)

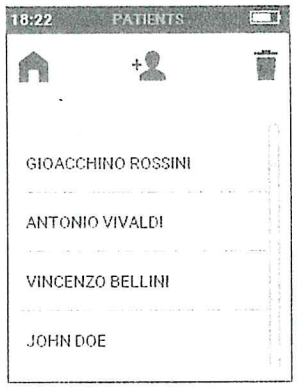
  Default: Hughson-Westlake

- Minimum Level / Maximum Level: Set the range of test levels. Default: -10 – 100 dB
- Familiarization: Enables/disables the additional phase used to train the patient on the threshold determination procedure.

Chapter 4
Patient management

The Patient management screen allows adding (or modifying) patients and reviewing stored exams. The first time the Patient Management screen is accessed, Triangle asks for a PIN to prevent data access from unwanted accesses. You can choose either to enter the PIN or disable data protection.

Message prompt at the first Patient Management screen access



Patient Management screen

4.1 TOUCHSCREEN CONTROLS

The following touchscreen controls are available on the interface:

Icon	Operation
	Go back to the main screen
	Create a new patient
	Delete all the stored patients

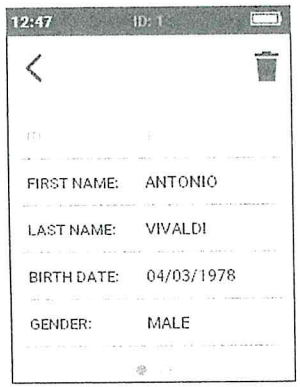
4.2 CREATE NEW PATIENT

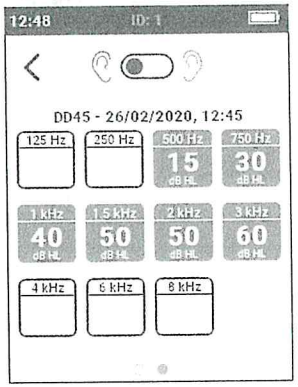
Enter the patient's personal details by pressing the relevant item and fill in the fields using the keypad. The *ID* field contains a unique code that is assigned automatically by the system at the time of creation and cannot be changed.

4.3 VIEW PATIENT DATA

By tapping on the desired patient name or code, the user can access the details stored. By swiping to the left and right, the following information will appear:

- Personal details associated with the patient
- Audiometry test associated with the patient (if stored)





Icon	Operation
	Go back to the patient list
	Side of thresholds stored
	Delete current patient

4.4 STORE TESTS

To associate the test data acquired during the current session with a patient, press the  icon on the main screen and select the desired patient from the list, or alternatively create a new patient.

Chapter 5
Settings

The Settings screen allows the user to modify the Triangle's parameters.

Icon	Operation
	Go back to the main screen
	Access the info screen, with serial number of the device, calibrated transducers, firmware version and other information for service

5.1 USER-SETTABLE PARAMETERS

- Language: Interface language. Default value: English
- Date and time: Access the menu to adjust date and time and its format.
- Audiometry: Access the menu to select
  - AC output type: Select the AC transducer type, headphones (AC) or insert earphones (AC-INS). Default: AC.
  - PTA at start-up: Automatically start the device in Manual pure tone screen. Default: disabled.

- Stand-by timeout: Sets the time before going to low-power mode. Default: 1 minute.
- Data security: Access the menu to modify the PIN and enable/disable it.
- Display brightness: Set the display brightness between 20% and 100%. Default: 80%.
- Licenses: Access the menu to enable additional licenses.

Chapter 6
Interface with PC

The Triangle audiometer can be interfaced with a personal computer equipped with the Inventis Maestro software. Refer to the User Manual *Maestro – General Functionalities* for a detailed description of the procedures involved when installing Maestro on the computer, and to the User Manual *Maestro – Impedance Audiometry functionalities* for more information on using the Triangle audiometer with a computer.

6.1 CONNECTION TO PC

Connect the Triangle audiometer to a USB port of the computer using the cable provided.

After a few seconds, the connected device will be recognized by the operating system. Installation is complete when the following message appears:

Chapter 7
Maintenance

The Triangle audiometer does not require any special periodic maintenance other than calibration and normal cleaning, both of which are described in this chapter. The device must be turned off before starting any kind of cleaning operation.

The performance and safety of the device will be assured as long as the recommendations for care and maintenance indicated here are correctly followed.

Apart from replacing the battery, the inspection and servicing of internal components must be left entirely to technicians approved by Inventis srl.

Transducers are manufactured utilizing ultra-fragile diaphragms that could be damaged in the event of impact. Handle with care during maintenance.

7.1 PERIODIC CHECKS

The procedure described under this heading must be carried out when the device is used for the first time each day.

The tests must be conducted with the device positioned for normal use.

Before switching on the device, be sure that there is no sign of damage visible on the equipment, including the accessories and the external power adapter. Visually inspect the power cable and connectors to verify the insulation's integrity, and make sure that they are not subject to any kind of mechanical loading or stress that could cause damage. Make sure that all parts and cables are properly connected.

Check subjectively that the air conduction and bone conduction output is equal on both channels and all frequencies, e.g. by generating a stimulus @ 10 or 15 dB, just enough to hear. The person who carries out this check should have good hearing.

Check at a level of 60dB in AC and 30dB in BC that there is no distortion, noise or parasitic signals in any of the frequencies.

Check that the interrupter key, the patient response switch and the keyboard indicators function correctly.

Check that the attenuator knobs function correctly without noise or interference between channels.

Check the headband strain of headset and of the bone vibrator.

Check the communication with the patient.

Should any accessory not function correctly, consult Appendix - "Troubleshooting".

Check whether that the calibration interval has not expired: the date is shown on the info screen accessible from the setup menu.

Calibration must be entrusted to technicians approved by Inventis srl. The operation should be performed at least once every 12 months and whenever a transducer is replaced.

7.2 TRANSDUCERS MAINTENANCE

Do not use liquids or sprays to clean the audiometer.

Do not allow dust to collect on the transducers. Also:

- The cushions of headphones are made of biocompatible material but are not sterile. Before being used on a new patient, these items must be sanitized by wiping the surfaces with a proprietary hypoallergenic disinfectant, following the manufacturer's instructions. This will prevent the spread of infection.
- The earpieces of the insert earphones are made of biocompatible material and must be used only once, then discarded in compliance with current waste disposal regulations.

The eartips of insert earphones are not sterile. The use of unsterilized earpieces can cause ear infections.

7.3 CLEANING THE DEVICE

Clean the device using a lint-free soft cloth moistened with water and mild detergent. If it needs to be sanitized, moisten the cloth with a 3% solution of hydrogen peroxide.

7.4 REPLACING THE BATTERY

Should the device appear to last shorter than expected (see *Appendix A*) even when fully recharged, it may be that the battery is damaged or spent.

Purchase a new battery from an Inventis-approved dealer, then replace the existing battery as described below:

- Turn off the device and disconnect it from the USB cable.
- Position it face down (display directed downwards) on a soft surface.
- Undo the screw retaining the flap of the battery compartment.
- Remove the battery. Separate the connectors without tugging. Ease apart using tweezers.
- Connect the new battery.
- Position the lead inside the compartment below the screw and position the new battery in its housing, then close the flap and secure with the retaining screw.

Recharge the device completely before use.

All accessories mentioned in the manual are designed specifically for use with this device. Only accessories supplied by Inventis should be connected to the audiometer.

7.5 REPAIRS AND TECHNICAL ASSISTANCE

Before contacting the service department, make certain that all the possible solutions in *Appendix B* have been tried.

Parts that are to be returned to the manufacturer must be cleaned and sanitized, following the directions in this manual. Transducers must be shipped in a closed, sealed transparent bag.

Should the instrument need to be sent to the service department or returned to the dealer, it is important that the original packing be used, enclosing all accessories and transducers.

Appendix A
Technical Specifications

APPLICABLE STANDARDS	
Performance	IEC 60645-1 type 4, ANSI S3.6 type 4
Electrical safety	IEC 60601-1, Class II, Type B
EMC	IEC 60601-1-2

CALIBRATION	
Duration of calibration	12 months

POWER SUPPLY	
Battery	Rechargeable Li-Ion, standard 18650, 3.7V 2.6Ah
Duration	Minimum 12h (continuous use)
Auto-off time	5 minutes
Stand-by time	1 minute
Recharge time	From PC, standard USB port: 10h max From dedicated power adapter: 3h max
Max power consumption	7W
External power adapter	Mod. FOX6-XM-USB, USB type, IEC 60601-1 compliant. Input 100-240Vac 50/60Hz, 0.3-0.15A, Output 5Vdc 1.4A

AMBIENT CONDITIONS	
Operation	Temperature: 15°C to 35°C Relative humidity: 30% to 90% (no condensation) Pressure: 700 mbar to 1060 mbar
Transport and storage	Temperature: -10°C to 50°C Relative humidity: 0% to 90% (no condensation) Pressure: 500 mbar to 1060 mbar
Warm-up time	1 minute

CE CERTIFICATE	
93/42 classification	Class IIa, Rule 10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65, D-80339 Műnchen
Notified body number	0123

AVAILABLE TESTS
Manual pure tone audiometry, Automatic pure tone audiometry (Fixed intensity, Screening, Houghson Westlake)

AVAILABLE SIGNALS	
Stimulus	Pure tone, Warble
Masking	Narrow-band noise (NBN), White noise (WN)

SIGNAL SPECIFICATIONS	
Attenuators step	5 dB
Presentation mode	Continuous, Pulsed (rate: 0.5Hz 1Hz, 2Hz)
Frequency accuracy	0.1%
Intensity accuracy	±3 dB between 125Hz and 4kHz ±5 dB above 4kHz
Total Harmonic Distortion (THD)	AC: less than 2.5% BC: less than 5.5%
Warble tone	Frequency of the modulating signal: 5Hz Modulation waveform: sine wave Modulation range: ±12%
NBN	Band: ½ octave, i.e.: - lower cut-off frequency $f_l = f/1.1892$ - upper cut-off frequency $f_u = f * 1.1892$ where f is the center frequency
WN	Lower cut-off frequency: 100Hz Upper cut-off frequency: 24kHz

COMPATIBLE TRANSDUCERS		
Type	*Manufacturer*	*Model*
Supra-aural headphones	Radioear Corp.	DD45
Circum-aural headphones	Radioear Corp.	DD65
Insert earphones	Etymotic Research Inc.	ER-3C
Bone vibrator	Radioear Corp.	B71[1]

PURE TONE AND WARBLE TONE AVAILABLE FREQUENCIES AND MAXIMUM INTENSITIES				
Freq. [Hz]	**AC DD45 [dB HL]**	**AC DD65 [dB HL]**	**AC ER-3C [dB HL]**	**BC B71 [dB HL]**
125	65	65	80	-
250	85	80	90	35
500	100	95	100	50
750	100	95	100	55
1.000	100	95	100	60
1.500	100	95	100	60
2.000	100	95	100	60
3.000	100	95	100	60
4.000	100	95	100	60
6.000	95	80	90	40
8.000	85	80	75	35

NARROW BAND NOISE (NBN) AVAILABLE FREQUENCIES AND MAXIMUM INTENSITIES			
Freq. [Hz]	**AC DD45 [dB EM]**	**AC DD65 [dB EM]**	**AC ER-3C [dB EM]**
125	40	40	60
250	65	60	75
500	80	75	85
750	85	75	90
1.000	85	80	90
1.500	85	80	90
2.000	85	80	90
3.000	85	80	90
4.000	85	80	90
6.000	85	70	85
8.000	85	70	80

[1] Available if the optional "Bone conduction" license is activated

WHITE NOISE (WN) MAXIMUM INTENSITIES		
AC DD45 [dB SPL]	**AC DD65 [dB SPL]**	**AC ER-3C [dB SPL]**
100	85	95

REFERENCE EQUIVALENT THRESHOLD LEVEL FOR PURE TONE				
	DD45	**DD65**	**ER-3C**	**B71(*)**
Ref. std.	**ISO 389-1 (ANSI S3.6)**	**Vendor Tech. Specificat.**	**ISO 389-2 (ANSI S3.6)**	**ISO 389-3 (ANSI S3.6)**
	Coupler: IEC 60318-3	Coupler: IEC 60318-1	Coupler: IEC 60318-5	Mastoid: IEC 60318-6
Freq. [Hz]	**dB [re 20 µPa]**	**dB [re 20 µPa]**	**dB [re 20 µPa]**	**dB [re 1 µN]**
125	47.0	30.5	26.0	-
250	27.0	17.0	14.0	67.0
500	13.0	8.0	5.5	58.0
750	6.5	5.5	2.0	48.5
1000	6.0	4.5	0.0	42.5
1500	8.0	2.5	2.0	36.5
2000	8.0	2.5	3.0	31.0
3000	8.0	2.0	3.5	30.0
4000	9.0	9.5	5.5	35.5
6000	20.5	21.0	2.0	40.0
8000	12.0	21.	0.0	40.0

(*) Calibration of bone vibrator (B71) refers to mastoid placement.
(**) Value to apply for ANSI S3.6-2010

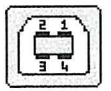
SOUND ATTENUATION VALUES			
Freq	**DD45(*)**	**DD65**	**ER-3C**
[Hz]	[dB]	[dB]	[dB]
125	3.0	8.3	33.5
250	5.0	15.5	34.5
500	7.0	26.1	34.5
750	-	-	-
1000	15.0	32.4	35.0
1500	-	-	-
2000	26.0	43.6	33.0
3000	-	-	-
4000	32.0	43.8	39.5
6000	-	-	-
8000	24.0	45.6	43.5

(*) *With MX41\AR or PN 51 cushions*

PHYSICAL SPECIFICATIONS	
Dimensions	(WxDxH) 160 x 217 x 48 mm / 6.3 x 8.5 x 1.9"
Weight	420g / 14.8oz
Display	LCD TFT 2.8" RGB, 240 x 320 pixels Viewing area 43.2 mm x 57.6 mm
Touchscreen	Capacitive

PATIENT – OPERATOR COMMUNICATION
Talk-over through embedded microphone
Patient response trigger

PATIENT MANAGEMENT	
Max number of patients	100
Details stored	Patient details (first name, last name, date of birth, gender), date and time of test, left and right audiogram (AC and BC)

SOCKETS ON THE REAR PANEL			
Description	*Connector*	*Pins*	*Specifications*
Power supply / Computer communication	USB type B		1 5V DC 2 Data – 3 Data + 4 GND
L and R headphones	Audio jack, 1/4" mono		1 GND 2 Signal (8V on 10Ω load)
Bone vibrator			
Patient response trigger			1 GND 2 Input Switch

INTERFACE WITH COMPUTER[2]

[2] Available if the optional "Computer connectivity" license is activated

Connection	USB (no driver needed)
Compatible software products	Inventis Maestro suite

On request Inventis will make available circuit diagrams, component part lists, descriptions, calibration instructions or other information that will help service personnel to repair those parts of the device that are designated by Inventis as repairable by service personnel.

Appendix B
Troubleshooting

Problem	Possible cause	Solution
No signal from a transducer	Transducer not connected properly	Make sure that the transducer is connected properly
	Transducer damaged	Contact the Inventis service department or dealer
Unable to establish a direct connection between the PC and the Triangle	Problems with USB connection	Check the USB connection between the device and the computer
	USB cable damaged	Change the USB cable (USB A –B standard)
The instrument does not switch on	Low battery	Connect the device to a power source
The display remains blank (LED on)	Device in stand-by	Touch the screen or press the power button
	Display damaged	Contact the Inventis service department or dealer
Battery does not recharge	USB cable damaged	Change the USB cable (USB A –B standard)
	Adapter damaged	Contact the Inventis service department or dealer
	Battery damaged	Replace the battery - Contact the Inventis service department or dealer

Problem	Possible cause	Solution
message: "Hardware error"	Non-fatal internal error	Press OK to continue. If the problem persists, contact the Inventis service department
message: "Serious error"	Fatal internal error	Restart the device. If the problem persists, contact the Inventis service department

Appendix C
Electromagnetic compatibility

The Triangle has been thoroughly tested and respects the limits for electro-medical devices specified by IEC 60601-1-2 standards. These limits ensure reasonable protection against hazardous interference in typical medical installations.

The device generates, uses and radiates radio frequency energy. If not installed and used according to the instructions in this manual, it may interfere with other nearby devices. No guarantee is given that interference will not occur under certain conditions.

This device is suitable for use in professional healthcare facility environments, i.e. in hospitals, except for near active HF surgical equipment and RF-shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Triangle should not be used adjacent to or stacked on other equipment. If adjacent or stacked use is necessary, Triangle should be observed to verify its normal operation in the configuration in which it will be used.

The existence of electromagnetic interference can be verified easily by turning the device off and back on again. If it is found that the device is indeed interfering with other equipment, try to solve the problem by adopting one of the following solutions:

- Change the orientation and/or position of the affected device.
- Move the two devices further away from each other.
- Contact the manufacturer or authorised service center for further assistance.

List of cables, transducers and accessories

Cables, transducers and accessories for which Inventis claims compliance with the IEC 60601-1-2 standard are those supplied with the device itself, as specified in section 2.2.