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AUDIOMETER

TRIANGLE

FR

MULTILANGUAGE USER MANUAL

DE

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AUDIOMETER

TRIANGLE

USER MANUAL

Read this manual thoroughly before using the device. Pay particular attention to Chapter 1 ("Safety: warnings and information") and Chapter 2 ("Installation, power up and power down").

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

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Summary

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Foreword

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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
Safety: warnings and information

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Be sure to read this manual through completely, so that all of the features offered by the instrument can be used to their full potential. In particular, be sure to read this chapter in its entirety, as it contains information and warnings that are of fundamental importance in ensuring safe and correct use of the device.
The safety warning symbol illustrated below is used in this manual to draw the attention of the reader to information of particular importance in matters of safety, and to guard against incorrect 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 PURPOSE

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.

1.4 MEDICAL CONDITIONS

Conditions of impaired sensitivity of the auditory system or any conditions in which the auditory system is thought to play a role in diagnosis.

1.5 PRECAUTIONS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 environmental conditions are met (during transport, storage and operation):

Operation	*Temperature: 15°C (59°F) and 35°C (95°F)* *Relative humidity: 30% to 90% (no condensation)* *Pressure: 700 hPa to 1060 hPa*

Transport and storage	*Temperature: between -10°C (14°F) and 50°C (122°F)* *Relative humidity: 0% to 90% (no condensation)* *Pressure: 500 hPa to 1060 hPa*
Warm-up time	*1 minute*

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

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

Use only original accessories supplied by INVENTIS S.r.l., unless specifically indicated otherwise.

Use only the medical-grade power supply unit supplied with the device, which complies with the IEC 60601-1 standard, with the following specifications:

Internal battery	*Rechargeable Li-Ion, 18650 standard, 3.7V 2.6Ah*
	Endurance: 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
External power adapter	*Input 100-240Vac 50/60Hz, 0.3-0.15A* *Output 5Vdc 1.4A* *Compliant with the IEC 60601-1 standard.*

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 in accordance with the information on electromagnetic compatibility (EMC) provided at the end of this manual.

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 at the end of this manual.

1.5.2 Calibration

The calibration should be performed at least once every 12 months, and whenever a transducer is replaced.

The calibration of the instrument is valid only for the transducers supplied. If a transducer is replaced, the instrument must be recalibrated.

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. 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 pads between one patient and the next, following the procedure described in Chapter 4: Maintenance.

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.

When conducting audiometry using insert earphones, do not insert or in any way try to conduct measurements without proper foam tip in place.

Maintaining the previous intensity of the stimulus when changing frequency, transducer or stimulation side can result in potentially harmful signals being presented to the patient.

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 COMPLIANCE

The Triangle audiometer is a class IIa device, according to Annex VIII of Medical Device Regulation (MDR) 2017/745/EU.
The Inventis Quality Management System has been certified by leading assessment body TÜV as compliant with ISO 13485 standard.

1.8 SYMBOLS

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

Refer to instruction manual for use.

MD *Medical device*

SN *Serial number of the device. The number is made up of 13 alphanumeric characters indicating the model, series, year of*

manufacture and serial number. In particular, the number comprises these segments:

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

Catalog code

Name and address of manufacturer

Type B applied parts (IEC 60601-1)

Product conforms to European Community Medical Device Regulation (MDR) 2017/745/EU. Class IIa device; number of 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.

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UDI code

Chapter 2
Installation, power-up and power down

2.1 PACKAGE OPENING AND CONTENTS INSPECTION

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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 detachable parts 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 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 position of the affected device.
- 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.

2.3 CONNECTIONS

All connectors for detachable parts are located on the rear panel.

Plug all transducers and detachable parts 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.

Make certain that the electrical power supply and ground connections comply with the applicable standards for electro-medical devices. Risk of electric shock

2.4 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
dB MASKING dB Fn + – +	Change the masking level
Hz – +	Change the testing frequency

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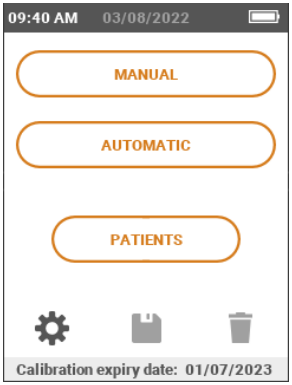
2.5 POWER-UP, POWER-DOWN AND MAIN SCREEN

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:



2.6 CONNECTION TO PC

The Triangle audiometer can be interfaced with a personal computer equipped with the Inventis Maestro software. Connect the Triangle audiometer to a USB port of the computer using the cable provided.

The Triangle can be connected either to a PC for recharging and transferring test data, or to the power adapter supplied.

Use the supplied cable to connect the Triangle to one of the USB ports of the computer

After a few seconds, the connected device will be recognized by the operating system.

Refer to Maestro user manual for more details about the software.

Chapter 3
Controls and exams

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3.1 CONTROLS FOR DIRECT ACCESS TO EXAMS

Button	Function
MANUAL	Access the manual Pure Tone Audiometry (PTA)
AUTOMATIC	Access the Automatic PTA
PATIENTS	Access Patient Management
	Save the current test to patient record
	Delete the current exam
	Access the Settings screen

3.1.1 Function buttons

Button	Function
	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

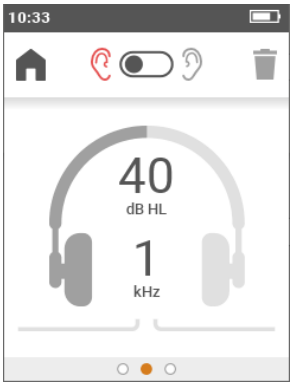
3.2 AUDIOMETRY

3.2.1 Common indicators

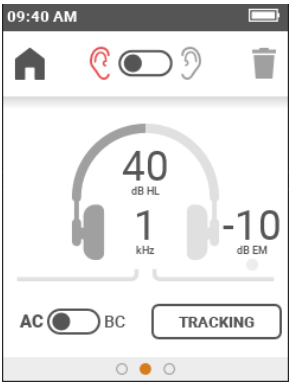
The following indicators are common to both manual and automatic tone audiometry tests.

Indication	Information
	Patient response button not pressed
	Patient response button pressed
	Headphones
	Headphones with active stimulus
	Bone (only in Manual testing mode)
	Insert earphones

3.2.2 Manual audiometry



Without “Bone conductor” license



With “Bone conductor” license

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

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

Indication	Information
	Masking level
	Masking enabled
	Masking disabled

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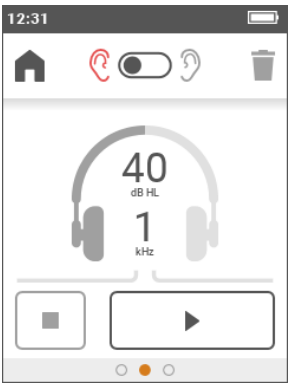
Swipe the screen to the left to view the stored thresholds. Swipe the screen to the right to access the parameters:

- 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.

3.2.3 Automatic audiometry

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



Button	Function
▶	Start the test
⏸	Pause the test
■	Stop the test

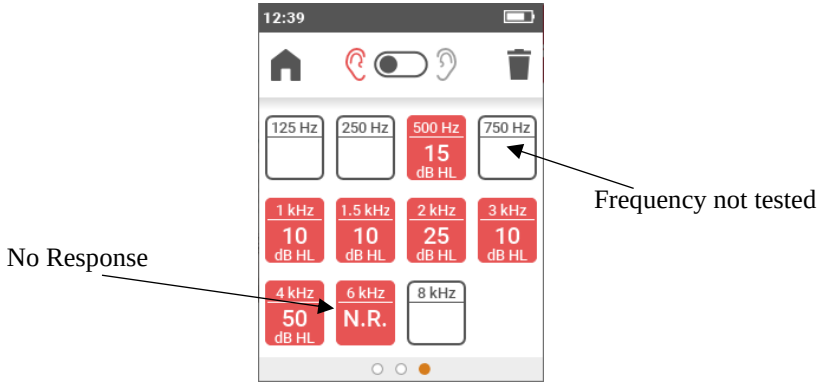
Swipe the screen to the left to view the stored thresholds. Swipe the screen to the right to access the parameters:

- 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: Houghson-Westlake
- Minimum Level / Maximum Level: Set the range of test levels. Default: -10 – 100 dB

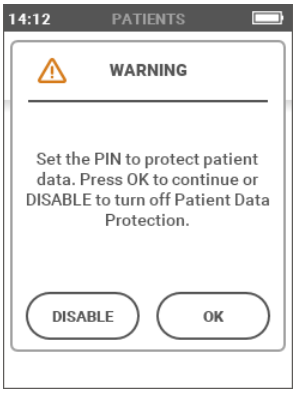
- Familiarization: Enables/disables the additional phase used to train the patient on the threshold determination procedure.

3.2.4 Results



3.3 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

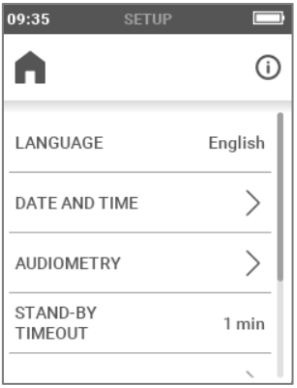
Patient Management screen

It is recommended to enable the PIN for patient data protection

Button	Function
	Go back to the main screen
	Create a new patient
	Delete all the stored patients
	Go back to the patient list
	Side of thresholds stored
	Delete current patient

3.4 SETTINGS

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



Button	Function
	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

3.4.1 User-settable parameters

General configuration parameters for the device are listed below.

- **Language**: Interface language. Default value: English (may vary based on destination)
- **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 4
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.

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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 S.r.l..

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

4.1 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 detachable parts 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 60 dB in AC and 30 dB 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.

If any part or transducer has any malfunction, consult Appendix A "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 S.r.l.. The operation should be performed at least once every 12 months and whenever a transducer is replaced.

4.2 MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the audiometer.

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

- the cushions of the headphones are made of biocompatible material but are not sterile. To prevent the spread of infections and to ensure their biocompatibility, they must be sanitized before being used on a new patient using wipes or a microfiber cloth dampened with denatured alcohol.
- The earpieces of the insert earphones are intended to be inserted in the patient's ear canal. They 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.

The headphone cushions can be repeatedly cleaned as described in the "Maintenance of Transducers" paragraph. In the event of any malfunctioning after any cleaning operation, contact an Inventis service technician.

Though the headphone cushions can be repeatedly cleaned, always check that their characteristics and integrity are maintained. To do so, it is sufficient to perform the tests described in the "Periodic checks" paragraph. As soon as any failure is encountered, contact an Inventis service technician to verify whether your transducer needs to be replaced.

To avoid damaging the headphones, do not crush them against a flat surface: this can create a vacuum and cause damage to the transducer (suction cup effect).

4.3 CLEANING THE INSTRUMENT

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.

4.4 REPLACING THE BATTERY

If the device fails to operate as long as expected despite a full charge, the battery may be damaged or dead.

The incorrect battery replacement can potentially be dangerous. Take particular care to replace it.

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

4.5 REPAIRS AND TECHNICAL ASSISTANCE

Before contacting the service department, make certain that all the possible solutions in appendix *Troubleshooting* 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 detachable parts and transducers.

Chapter 5
Troubleshooting

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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