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Instructions for Use - US

Luna

D-0128842-A– 2020/12

Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for the Luna screening audiometer, Luna Suite PC software included.

The product is manufactured by:

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Denmark
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1.2 Intended use

Luna is a PC-based screening audiometer intended to be used for assessing the hearing level of the patient by means of either manual or automatic tests. Luna should be used by hearing care professionals such as special trained nurses, peditricians or any other special trained personnel. Even a normal hearing assessement may not refrain the professional from referring the patient to a specialist, if any doubt is related to the result. Any detected hearing loss must always lead to consulting a hearing specialist.

1.3 Contraindications

Patient is too young to undergo a hearing test. If the headset can not be fitted.
Patient is uncooperative. The professional operator's evaluation.
The hearing test has to be performed in a separate room, no silent booth required.

1.4 Product description

Luna is delivered with the following:
Headset mounted with DD65 transducers and USB cable, patient response, carrying bag, PC software (through online download), quick guide and calibration certificate.
The Luna headset delivers a tone to the patient's ear. When the patient hears the presented tone, he presses the response button, and the result is noted automatically in the audiogram.

1.5 Warnings and precautions

The following safety warnings are used throughout the manual to alert you to important information regarding safe and appropriate use of the product.

WARNING — The WARNING label identifies conditions or practices that may present danger to the patient and/or user.

CAUTION — The CAUTION label identifies conditions or practices that could result in damage to the equipment.

NOTICE — **NOTICE** is used to address practices not related to personal injury.

1.5.1 Electrical system safety

When connecting the instrument to the computer, the following warnings must be observed:
This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 62368-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. If the instrument is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.
A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16

1.5.2 Electrical safety

Do not modify this equipment without authorization of Interacoustics Do not disassemble or modify the product as this may impact on the safety and/or performance of the device. Refer servicing to qualified personnel.
For maximum electrical safety, turn off the power when it is left unused
The power plug shall be placed so it is easy to pull out the plug
Do not use any additional multiple socket-outlet or extension cord. For safe setup please refer to section 2.

Do not use the equipment if it is showing visible signs of damage.

The instrument is not protected against ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return for service No part of the equipment can be serviced or maintained while in use with the patient.

1.5.3 Explosion hazards

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.

Do NOT use the instrument in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.
Before cleaning make sure to disconnect power source

1.5.4 Electromagnetic compatibility (EMC)

Although the instrument fulfils the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to the appendix regarding EMC.
Use of accessories, transducers, and cables other than specified, with the exception of transducers and cables sold by Interacoustics or representatives, may result in increased emission or decreased immunity of the equipment. For a list of accessories, transducers and cables that fulfil the requirements please also refer to the appendix regarding EMC..

1.5.5 Cautions – General

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Interacoustics' specifications.
Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.
This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used.
Make sure all connections to external accessories are secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Interacoustics.

The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist authorized service personnel to repair those parts of this instrument that are designated by Interacoustics as repairable by service personnel.
No parts of the equipment can be serviced or maintained while in use with the patient.
Connect only accessories purchased from the manufacturer to the instrument. Only accessories which have been stated by the manufacturer to be compatible are allowed to be connected to the device.

Check calibration if any parts of the equipment are exposed to shock or rough handling.

Components marked for ‘single use’ are intended for a single patient during a single procedure, and there is a risk of contamination if the component is re-used.
Components marked for ‘single use’ are not intended to be reprocessed.

1.5.6 Environmental factors

Storage outside temperature range as specified in Section 5 may cause permanent damage to the instrument and its accessories.
Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorized service technician.
Do not place the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.

1.5.7 NOTICE

To prevent system faults take appropriate precautions to avoid PC viruses and similar.
Please note that connecting the device to a PC implies connecting the device to an IT-network. The connectinon to an IT-network may result in previously un-identified risks which must be identified, analysed, evaluated and mitigated by the responsible organisation.
Any change to the IT-network (network configuration, (dis)connection of items, update or upgrade of equipment) may introduce new risks that require additional analysis.

Within the European Union, it is illegal to dispose of electric and electronic items in unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin symbol, shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.
Outside the European Union, local regulations should be followed when disposing of the product after end of life.

If this apparatus is connected to one or more other devices with medical CE marking, to make up a system or pack, the CE marking is only valid also for the combination if the supplier has issued a declaration stating that the requirements in the Medical Device Directive article 12 are fulfilled for the combination.

There is no warm-up time for the instrument, but allow it to become acclimatised before use.

The specification for the instrument is valid if the instrument is operated within the environmental limits specified in technical specifications.

1.6 Complaints/safety reporting:

Please contact your local distributor in case of any incident related to product defects (hardware defects or software bugs) or adverse events (which does not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with serious health impact for the patient or user (serious adverse events), local distributor shall report to Interacoustics through its appropriate vigilance system. Interacoustics shall ensure that the regulatory authority in patient's home country is informed according to the vigilance requirements. Interacoustics shall handle all the product complaints and adverse events as per the internal procedure.

2 Unpacking and installation

2.1 Inspection and system requirements

Check for damage

When the instrument is received, ensure that you have received all the components on the shipping checklist. All the components should be checked visually for scratches and missing parts before use. All the contents of the shipment have to be checked for their mechanical and electrical functioning. If the equipment is found faulty, please contact your local distributor immediately. Keep the shipping materials for the carrier's inspection and insurance claim.

Keep carton for future shipment

The instrument comes with shipping cartons, which are specifically designed for the components. It is recommended to keep the cartons for future shipments in case of any need for return or service.

Reporting and returning procedure

Any missing part or malfunction or any damaged components (due to shipment) should be reported immediately to the supplier/local distributor along with the invoice, serial number and a detailed report of the issue. For any on-site service-related information, please contact your local distributor. If the system / components are to be returned for service, please fill all the details related to product issues in the **'Return Report'**, which is attached to this manual. It is very important that you describe all the known facts about the issue in the return report, as this will help the engineer to understand and solve the problem to your satisfaction. Your local distributor holds the responsibility for coordinating any service/return procedure and related formalities.

Storage

If you need to store the Luna for a period, please ensure it is stored under the appropriate conditions.

2.2 Definition of symbol

The following symbols can be found on the instrument:

Symbol	Explanation
	Type B applied parts.
	Follow Instructions for Use
CE 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex IX of the Regulation (EU) 2017/745 (MDR)" Product Service, Identification No. 0123, has approved the quality system
	WEEE 2002/96/EC Please refer to warning and pre-cautions
MD	Medical Device
	Manufacturer
	Date of manufacture.
SN	Serial number
REF	Reference number
ETL CLASSIFIED Intertek 4005727 Conforms to ANSI/AAMI ES60601-1:2005/A1:2 Certified to CAN/CSA-C22.2 No. 60601-1:2(	ETL listing mark
Interacoustics	Company Logo

2.3 Software installation

Minimum system requirements:
Luna Suite is built to run Windows OS Framework 4.7.

NOTICE: As a part of data protection, ensure to be compliant with the following points
1. Use Microsoft supported operating systems
2. Ensure operating systems are security patched
3. Enable database encryption
4. Use individual user accounts and passwords
5. Secure physical and network access to computers with local data storage
6. Use updated antivirus and firewall and anti-malware software
7. Implement appropriate backup policy
8. Implement appropriate log retention policy

System requirements:

Processor:	2 GHz
RAM:	2 GB
Display:	1366x768px (standard)

Supported operating systems:
Microsoft Windows® 10 Pro
Maximum scaling: 125%

Windows® is a registered trademark of Microsoft Corporation in the United States and other countries.

Citrix: If your computer runs on a citrix sever the Luna Suite will work as long as the Luna Suite is installed locally on your computer.

NOTICE: Using operating systems where Microsoft have discontinued software and security support will increase the risk for viruses and malware, which may result in breakdowns, data loss and data theft and misuse.
Interacoustics A/S cannot be held liable for your data. Some Interacoustics A/S products support or may work with operating systems unsupported by Microsoft.

Installation
Included with your Luna audiometer you will find a link to download of the software as well as a license key to open and activate the Luna software.

NB: Keep the link for the Luna software in a safe place, in case you want to install it on a different computer. In this case you will need to require a new license key.

Interfaces:
Luna Suite is equipped with a general XML interface for easy interfacing to any other patient file system you may wish.

When clicking on the link an automatic installation will start, showing the below window:

Allow your computer to continue the installation of the Luna Suite by clicking

After installation the software will leave this icon on your desktop for easy access to your Luna software:

By double clicking the key icon, the Luna software will open, and you are ready to enter the software key:

Click here

This screen will open allowing you to enter the unique product key.

This is only required once.

You will receive the license key together with your Luna audiometer.
Insert it here

Finish the key activation by pressing "activate"

3 Operating instructions

After succesfully installing the Luna PC software, you are ready to use yor device.

3.1 Language editor

When installing the Luna Suite software, the system automatically chooses the language in accordance with the language setting of your PC.
If you want to change the language, do the follwoing:

Click here:

Then choose your language by means of the drop down menu:

The language change will take effect once you re-boot the Luna Suite.

3.2 How to create an operator (the opening screen)

1. Entering the software key.
2. System status for correct connection.
3. Minimize/maximize.
4. Exit your Luna. Remember to save before exit.
5. Add a new operator.
6. Search for an operator.
7. Delete an operator.
8. Edit operator information.

Enter a new operator:
Each test setting will be connected to the operator you have chosen.

1. Mandatory information.
2. Optional Information.
3. Other information if relevant.
4. Press"create" to save settings.

3.3 How to create a new patient

1. Back to previous screen.
2. Search for a patient.
3. Enter a new patient.
4. Edit information bar.
5. Delete a patient (irreversible).
6. Edit patient information.
7. If you only want to see your patients, click here.

Entering a patient:

1. Mandatory patient information. You may use social security number or a randomly generated ID.
2. If further information about the patient is relevant you may enter it here.
3. Anamnesis information or other relevant information with potential impact on test result.
4. Remember to press ”create” in order to save the settings.

3.4 PDF editor

If needed you may create your own PDF document for saving or printing.
The setting of the PDF is attached to the operator. Thus, each operator can have their own special PDF layout if needed.

If you want to create a new PDF setting, click here:

What you set up is the labeling of information on the print out – not the content of each area.

3.5 How to enter set-up mode of hearing tests

By clicking these icons you will enter the settings of the various hearing tests.

3.6 Operating panel – automatic testing

1. Test frequencies. All frequencies will be tested. 2. Start/stop test. 3. Right ear color indication.

If some frequencies have been left out:

1. Some frequencies have been left out.
2. Color indication (green bar) of how much of the allowed time the patient uses before answering.
3. Tested – but not heard.
4. Left ear color indication.

3.7 Description of automatic random test and settings

The test:
The Automatic Random test runs fully automatic, and will allow you to include/exclude any frequency you may wish. With the default setting on 20 dB, the test will reset to 20 dB by each change of frequency. If ”no response”, the test will increase with 5 dB until answer, and reset to 20 dB by change of frequency. The test will, randomly, switch between frequency and ear, until test is completed.
Default settings for this test:

Off time:	2 sec.
Random off time:	3 sec.
Tone length:	1,5 sec.
Response window:	3 sec.
20 dB start level:	20dB
105 dB max level:	40 dB
Test frequency:	250, 500, 1000, 2000, 4000, 6000, 8000 Hz
Start frequency:	1000 Hz
Start test ear side:	Right
Step size:	5 dB
Signal:	Tone

3.7.1 Description of settings:

Off time:	2 – 7 sec.	A fixed set time, in which there is no tone.
Random off time:	0 – 7 sec.	An extra time off, added to the ”Off time”, making it more difficult for the patient to figure out when the tone is present. The extra random time will vary throughout the test randomly. Example: If the Off time is set to 7 sec. and the random time off is also set to 7 sec, the time off will vary between 7 and 14 sec.
Tone length:	0.3 – 2 sec.	The duration of the tone given from the earphone.
Response window:	2 – 9 sec.	The duration of time the patient has to answer. If a patient is young, very old or unconcentrated, you may wish to set this time a little longer to be sure you gather the correct information about the hearing ability.

20 dB start level:	-10 to 105 dB	With this setting you may decide which dB level you want by change of fequency. Example: If you only want to test at 20 dB, and never below, you set this value at 20 dB.
Test frequencies:		125, 250, 500 ,750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Start frequencies:		The frequency you want your test to begin with.
Start test ear side:		In which side the test should commence.
Step size:		When a tone is ”not heard” the dB automatically increases with either 5 or 10 dB.
Signal:		You may choose between Tone, Warble, Pulse.

3.8 Description of automatic test and settings

The test:
The Automatic test runs fully automatic, and will allow you to include/exclude any frequency you may wish. With the default setting on 20 dB, the test will reset to 20 dB by each change of frequency. If ”no response”, the test will increase with 5 dB until answer, and reset to 20 dB by change of frequency.

3.8.1 Description of the settings:

Off time:	2 – 7 sec.	A fixed set time, in which there is no tone.
Random off time:	0 – 7 sec.	An extra time off, added to the ”Off time”, making it more difficult for the patient to figure out when the tone is present. The extra random time will vary throughout the test randomly. Example: If the Off time is set to 7 sec. and the random time off is also set to 7 sec, the time off will vary between 7 and 14 sec.
Tone length:	0,3 – 2 sec.:	The duration of the tone given from the earphone.
Response window:	2 – 9 sec.:	The duration of time the patient has to answer. If a patient is young, very old or unconcentrated, you may wish to set this time a little longer to be sure you gather the correct information about the hearing ability.
20 dB start level:	-10 to 105 dB	With this setting you may decide which dB level you want by change of fequency. Example: If you only want to test at 20 dB, and never below, you set this value at 20 dB.
Test frequencies:		125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Start frequencies:		The frequency you want your test to begin with.
Start test earside:		When a tone is ”not heard” the dB automatically increases with either 5 or 10 dB.
Signal:		You may choose between Tone, Warble, Pulse.

3.9 Description of manual test and settings

The test:
The manual test may be oprated by means of the mouse or by means of shortcuts to the computer keyboard.

The short cuts:
If you want to change the pre-set shortcuts,
click here

The preset shortcuts:

Action	Shortcut key
Frequency up	Right arrow
Frequency down	Left arrow
dB level down	Up arrow
dB level up	Down arrow
Signal type	S
Step size	T
Ear side	E
Tone	Space
Delete	Delete
Heard	W
Not heard	Q
Left ear	L
Right ear	R

The screen:

1. Erase a test result. 2. Present tone. 3. Tone indication.
4. Frequency down/up. 5. dB down/up. 6. Toggle dB steps
7. Toggle ears.(1,2 and 5 dB).

3.9.1 Description of settings

Tone length::	0,3 – 2 sec.	The duration of the tone given from the earphone.
Response window:	2 – 9 sec.:	The duration of time the patient has to answer. If a patient is young, very old or unconcentrated, you may wish to set this time a little longer to be sure you gather the correct information about the hearing ability.
20 dB start level:	-10 to 105 dB	With this setting you may decide which dB level you want by change of fequency. Example: If you only want to test at 20dB, and never below, you set this value at 20 dB.

Test frequencies:	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Start frequencies:	The frequency you want your test to begin with.
Start test ear side:	When a tone is ”not heard” the dB automatically increases with either 5 or 10 dB.
Signal:	You may choose between Tone, Warble, Pulse.

3.10 Special features

3.10.1 Overlays

For communication purposes you may use overlays, making it possible to compare actual test results with standards or previous data.
Also you may toogle the placing of left/right audiogram.

Example: if you want your patient to turn the back to you, when testing, you may align the laft/right audiogram to correspond to the ears of the test person.

You may also choose to have test results from both ears on the same audiogram.

1. Relating the hearing loss to the values in the audiogram.

2. Speech banana – speech sounds distributed in the audiogram.
3. Toggle between placing the left/right audiogram on the screen.
4. Show data in one or two audiograms.
5. Old tests on each patient. May be used as overlay in current test. Only values different from the first test are shown.

3.10.2 Re-testing manually in automatic mode

If you want to re-test a frequency, you need to do this BEFORE saving the test results.
You may experience odd results on a particular frequency, and if you want to be sure, you may re-test this frequency manually.

Click here: the one test result will disappear.

To make the manual test panel available click here:

You can re-test the chosen frequency using the manual panel :

You may set the tone anywhere, and from there you may test again until you are certain of the correct reault.

Click save, and ths test will be saved as the original automatic test.

4 Care and maintenance

4.1 General maintenance procedures

Your Luna may be gently cleaned by means of a soft cloth dampened with luke warm water. The black mesh in each ear cup may also be rinsed gently. For further protection by means of ear cushion covers and disinfection fluids, please consult your supplier.

4.2 General cleaning procedures

CAUTION

- Before cleaning always switch off and disconnect from the power supply
- Follow local best practice and safety guidelines if available
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones / headphones
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Ensure that isopropyl alcohol does not come into contact with any silicone tubes or rubber parts

Recommended cleaning and disinfection solutions

- Warm water with mild, nonabrasive cleaning solution (soap)
- Normal hospital bactericides

Procedure

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution
- Clean cushions and patient hand switch and other parts with a lint free cloth lightly dampened in cleaning solution
- Make sure to not get moisture in the speaker portion of the earphones and similar parts

To maintain electrical safety during the lifetime of the instrument, a safety check must be made regularly according to IEC 60601-1, Class 1, Type B. E.g when yearly calibration is done.

4.3 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

1. assembly operations, extensions, readjustments, modifications or repairs are carried out by authorized persons,
2. a 1 year service interval is maintained
3. the electrical installation of the relevant room complies with the appropriate requirements, and
4. the equipment is used by authorized personnel in accordance with the documentation supplied by Interacoustics.

It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises. This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unlikely worst case scenario of death or serious injury to a patient or user).

4.4 Warranty

Interacoustics warrants that:

- The Luna is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service center to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics is at the purchaser's risk.

Under no circumstances shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative
- altered in any way so as, in Interacoustics' judgement, to affect its stability or reliability
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics

This warranty is in lieu of all other warranties, expressed or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

Interacoustics disclaims all other warranties, expressed or implied, including any warranty of merchantability or for function of fitess for a particular purpose or application.

5 General technical specifications

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of the EU Regulation 2017/745 (MDR). Approval of the quality system is made by TÜV – identification no. 0123	
Standards:	**Safety:**	IEC 60601-1 2005/EN 60601-1 2006 and A1 2012 ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 No. 60601-1:14 Type B applied parts
	EMC:	IEC 60601-1-2 (2014)
	Audiometer Tone:	Tone Audiometer: IEC 60645 -1 (2017), ANSI S3.6 (2018), Type 4
Construction:		Plastic cabinet.
Power:		USB-powered Average: 300mA (Max: 500mA)
Operation environment:		
Ambient noise:		The Luna audiometer should be used in a quiet place such as a separate room
Rel. Humidity: **Temperature:** **Ambient Pressure:**		15 – 90% 10-35° 98 kPa – 104 kPa
Transport temperature:		-20-50 °C
Storage temperature:		0-50 °C
Humidity transportation & storage:		10% to 95% RH. Non condensing

5.1 Technical specifications

	Transducers
[A]	– two earphones
[A]	Hearing levels from -10 to 100 dB HL for air conductors
[A]	Frequency from 250 Hz to 8 kHz for air conductors (250 Hz, 500 Hz, 750 Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz, 8 kHz)
[A]	Output level control in 5 dB HL steps
	Test signal switching
[A]	– presentation/interruption
[A]	– continuous pure-tone
[A]	– pulsed pure-tone
[A]	– warble-tone freq. 10 Hz Sinus
[A]	– warble-tone modulation depth 10%
[A]	Subject response system
[A]	Fixed USB cable from headset to type A male connector. Optional: 4-pin to USB Micro cable. Optional: 4-pin to USB C cable. Replaceable by technician.

5.2 Reference equivalent threshold values for transducers

Hz	Max dB level HL
125	70
250	90
500	100
750	100
1000	100
1500	105
2000	105
3000	105
4000	100
6000	90
8000	85

Appendix A: Electromagnetic Compatibility (EMC)

- This instrument is suitable in hospital environments 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
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in this appendix.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTICE ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:

- This instrument does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge There are no deviations from the collateral standard and allowances uses
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1

NOTICE: There are no deviations from the collateral standard and allowances uses NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

Portable and mobile RF communications equipment can affect the LUNA. Install and operate the LUNA according to the EMC information presented in this chapter.
The LUNA has been tested for EMC emissions and immunity as a standalone instrument. Do not use the LUNA adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The LUNA is intended for use in the electromagnetic environment specified below. The customer or the user of the LUNA should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The LUNA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LUNA is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the LUNA.			
The LUNA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LUNA can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LUNA as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The LUNA is intended for use in the electromagnetic environment specified below. The customer or the user of the LUNA should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the LUNA requires continued operation during power mains interruptions, it is recommended that the LUNA be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The LUNA is intended for use in the electromagnetic environment specified below. The customer or the user of the LUNA should assure that it is used in such an environment,			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,7 MHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the LUNA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LUNA is used exceeds the applicable RF compliance level above, the LUNA should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LUNA. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

Item	Manufacturer	Model
Patient response switch	Radioear	APS3
USB cable	Interacoustics	8011241

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length (m)	Screened (Yes/No)
Patient response switch	2.0	Yes
USB cable	1.9	Yes

Return Report – Form 001

Interacoustics

Opr. dato:	af:	Rev. dato:	af:	Rev. nr.:
2014-03-07	EC		MSt	4

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods: _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

[1] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.