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Instructions for Use - EN

Luna

Interacoustics

D-0127685-G – 2023/10

Table of contents

1 Introduction

1.1 About this manual

This manual is valid for the Luna screening audiometer, Luna Suite 1.3 PC software included.

The product is manufactured by:

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Audiometer Allé 1
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Denmark
Tel.: +45 6371 3555
E-mail: info@interacoustics.com
Web: www.interacoustics.com

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, pediatricians, or any other special trained personnel. Even a normal hearing assessment 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

The patient is too young to undergo a hearing test.
The headset cannot be fitted.
Patient is uncooperative.

1.4 Product description

Luna is delivered with the following:
Headset mounted with DD65 transducers and USB cable, patient response button, 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/she 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.

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. 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

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.

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 near 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

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 adjadent 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, except for 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.

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.

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 meet 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.

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 connection 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.

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 acclimatized before use.

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

1.6 Malfunction

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.
Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.

1.7 Disposal of the product

Interacoustics is committed to ensuring that our products are safely disposed of when they are no longer usable. The cooperation of the user is important to ensure this. Interacoustics therefore expects that local sorting and waste regulations for disposal of electric and electronic equipment are followed, and that the device is not discarded together with unsorted waste.
In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.

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 must 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, ensure it is stored under the appropriate conditions (see section 5.1 Technical Specifications).

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 in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745. Approval of the quality system is made by TÜV – identification no. 0123.
	WEEE (EU Directive) This symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection for facilities for recovery and recycling.
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.

System requirements (for laptops, PC, and tablets):

Processor:	2 GHz
RAM:	2 GB
Display:	1366x768px (standard)
Windows® tablet:	It is recommended to activate rotation lock.

Supported operating systems:
Microsoft Windows® 10
Microsoft Windows® 11
Maximum scaling: 125%

Citrix: If your computer runs on a Citrix server, the Luna Suite will work if the Luna Suite is installed locally on your computer.

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

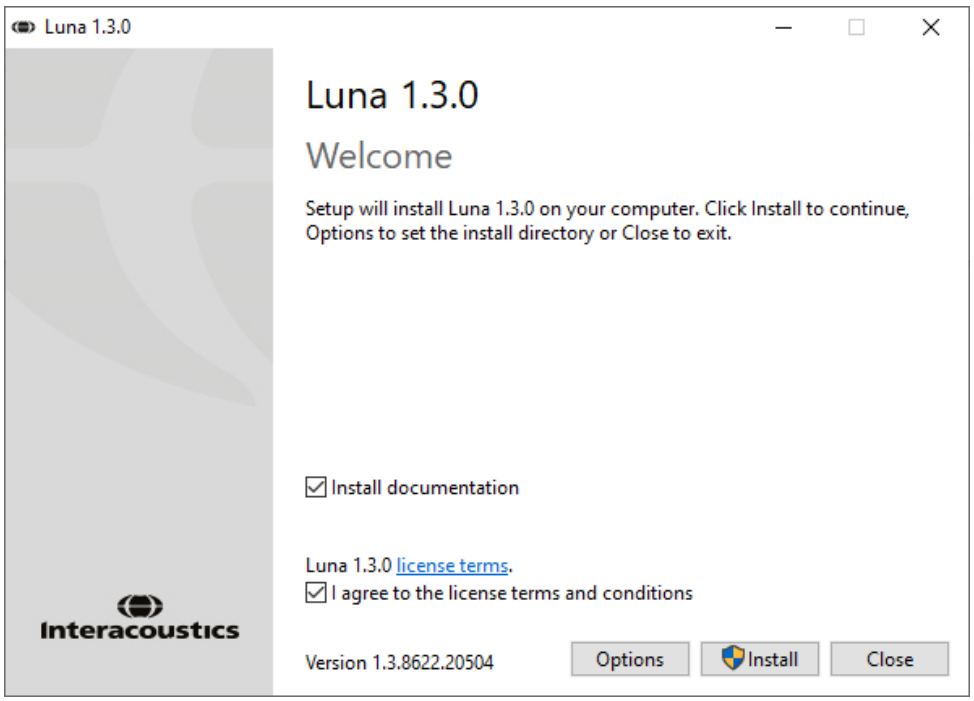
NOTICE: As a part of data protection, ensure to be compliant with the following points
1. Use Microsoft supported operating systems
2. Ensure operating systems are security patched
3. Enable database encryption
4. Use individual user accounts and passwords
5. Secure physical and network access to computers 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

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.

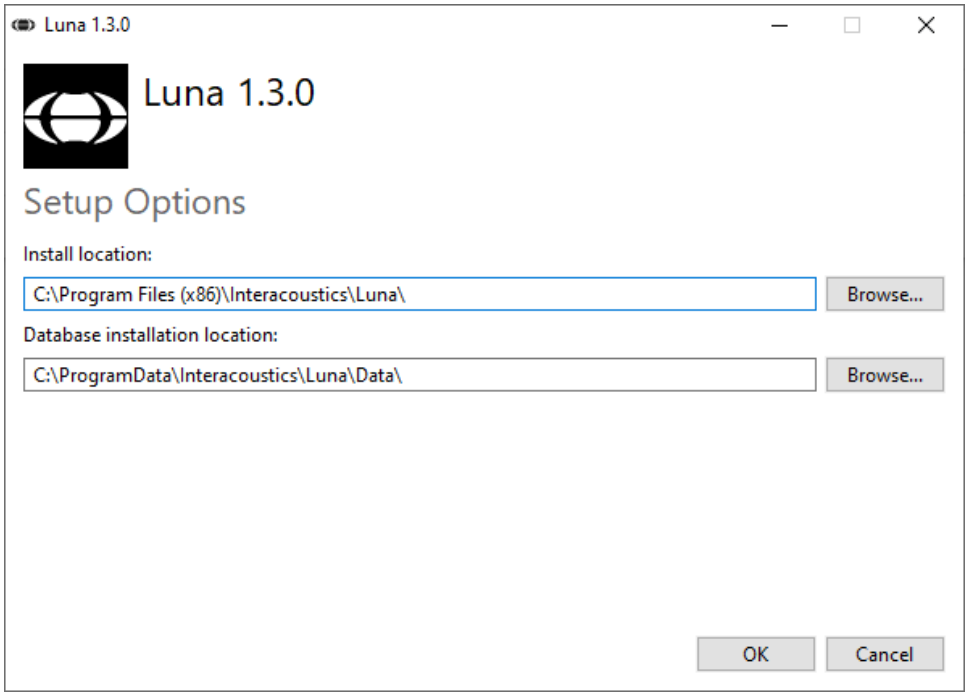
Interfaces:
Luna Suite is equipped with a general XML interface for easy interfacing to any other patient file system you may wish.

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.

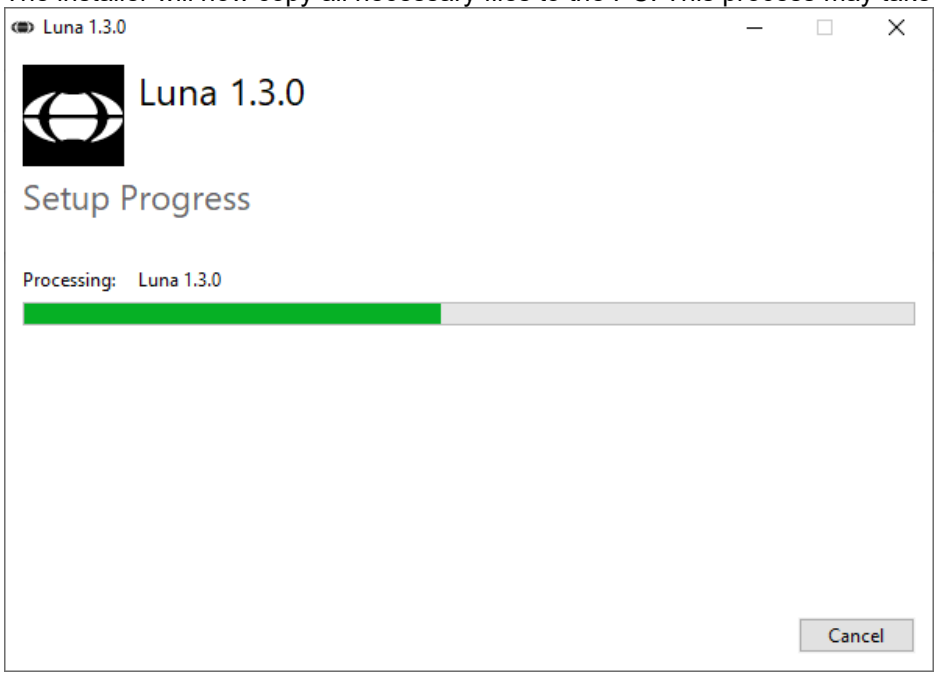


Should you wish to install the software to a different location than the default, please click on 'Options' ahead of "Install".

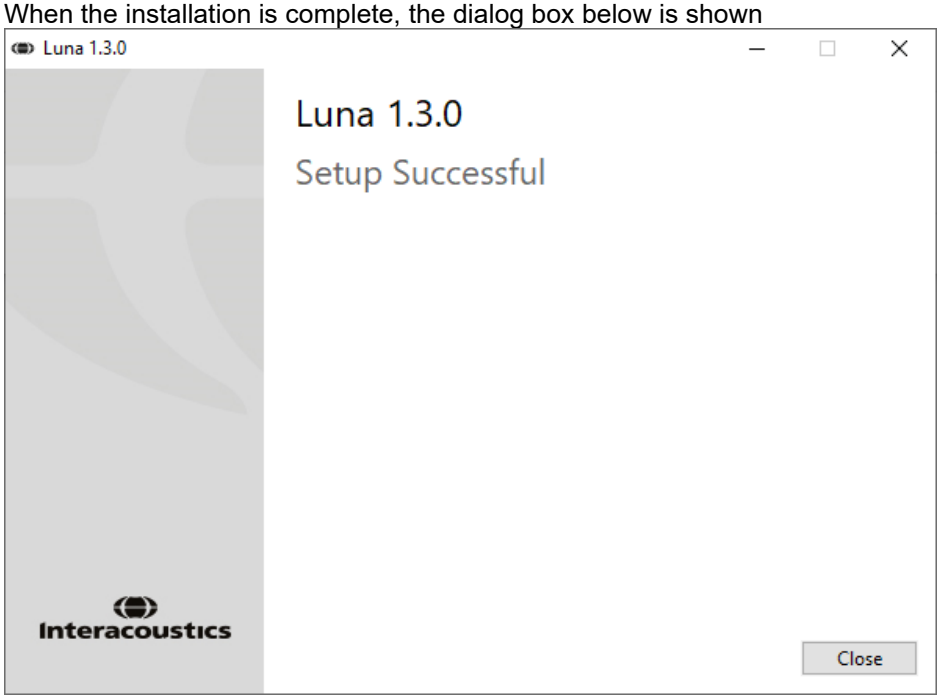


User Accounts Control may ask if you want to allow the program to make changes to your computer. Click Yes, if this happens

The installer will now copy all necessary files to the PC. This process may take several minutes.



When the installation is complete, the dialog box below is shown

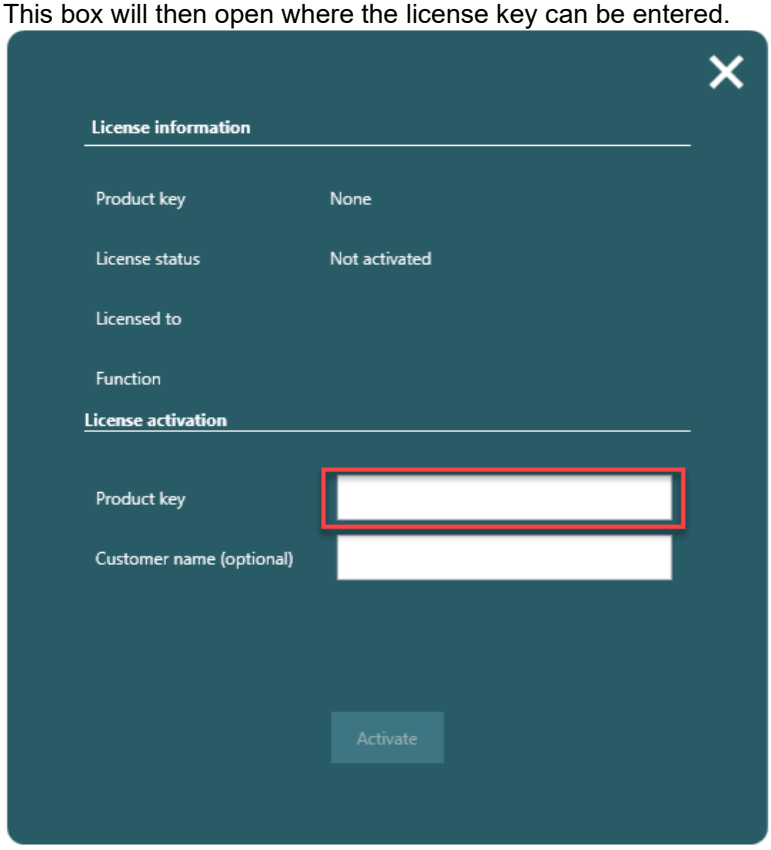


Click “Close” to finish the installation. The Luna Suite is now installed.

License key

When opening the Luna Suite for the first time, the system will ask for the product key to activate the Luna headset. To access the License key, click on the key icon at the top bar.

This box will then open where the license key can be entered.

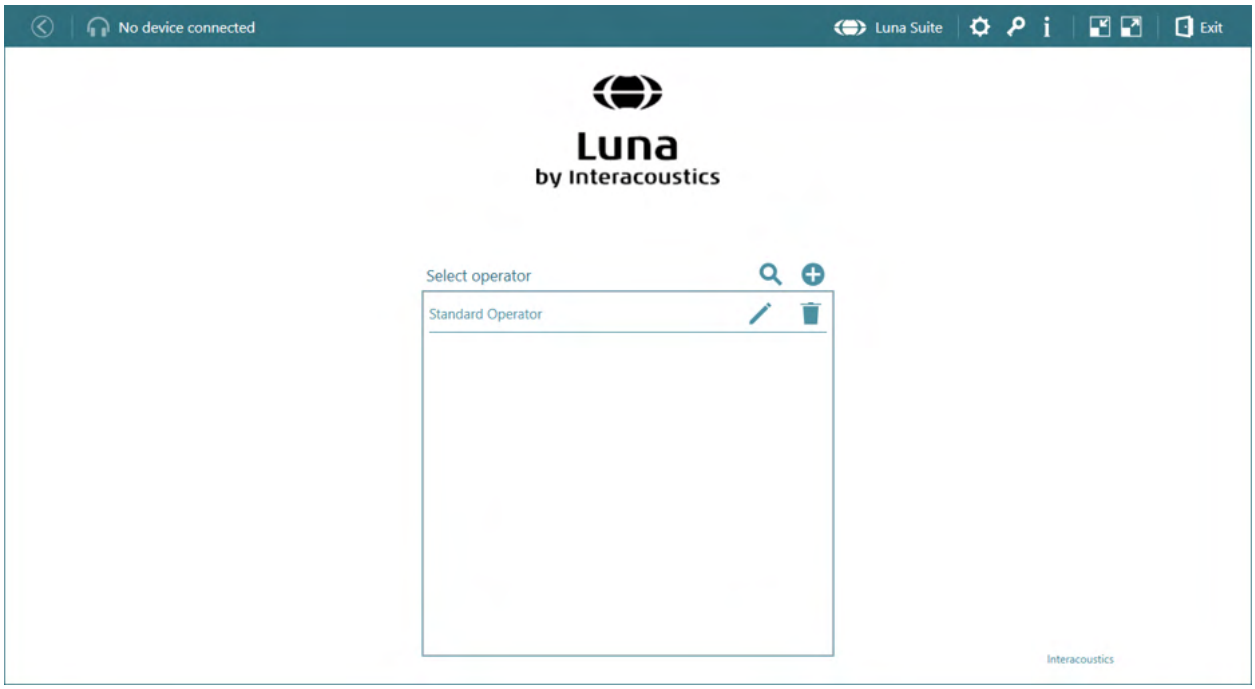


The Luna Suite will not be functional before the license key has been entered.

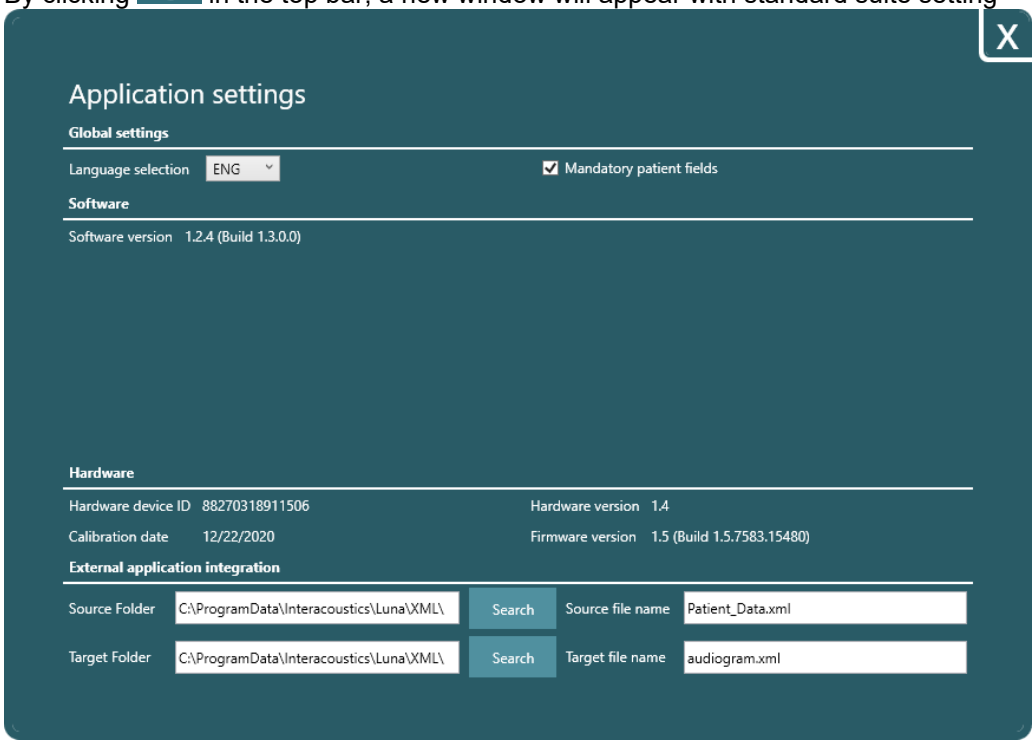
3 Operating instructions

3.1 Suite setup

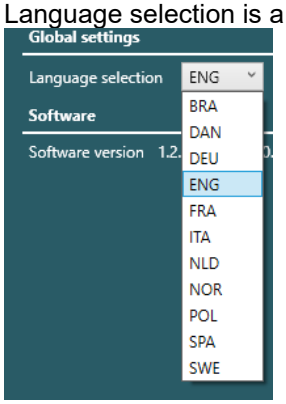
When the license has been activated for the Luna headset, the front-page window will now look like this:



By clicking  in the top bar, a new window will appear with standard suite setting



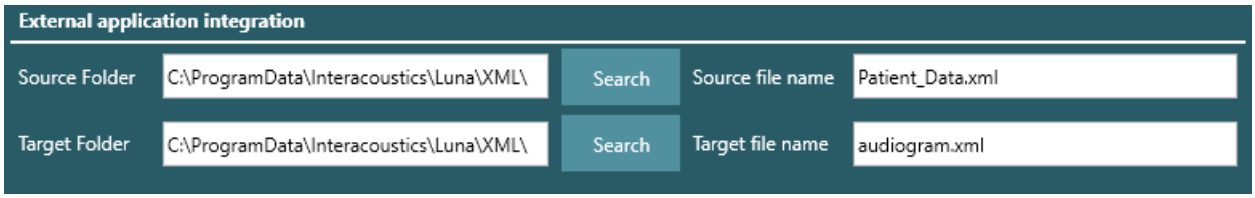
Language selection is a drop-down menu with all available languages for the Suite.



When changing the language, the Suite must be closed and restarted before changes are made.

When checked off, the mandatory fields for operator and patient are no longer marked red, and operator and patient can be created without any mandatory fields.

This field will show information regarding the headset and Suite.

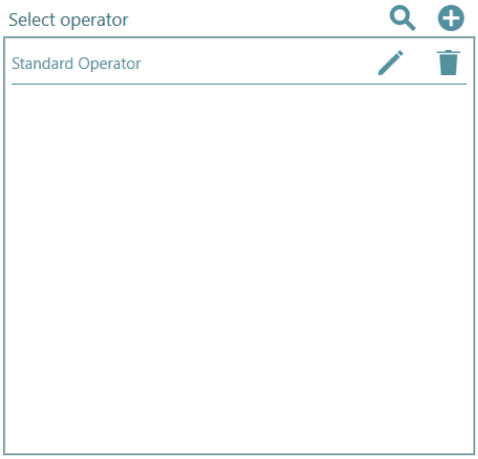


Here it is possible to change the folder to where patient data can be exported. When search is clicked, a new pop-up window from Windows File Explorer will open, and it is possible to choose a path directly on the PC.

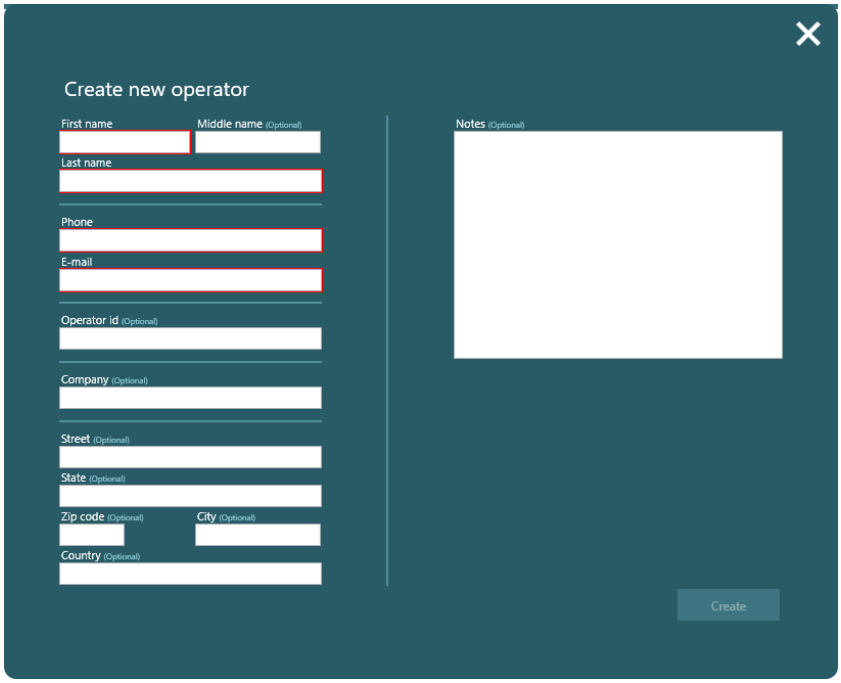
By clicking  in the top bar, the Instructions for Use will open in a new window in the language selected under global settings.

3.2 How to create an operator

A standard operator will always be present, when the license key has been activated. There is no information to this operator, but it can be changed, or it is possible to delete the operator.



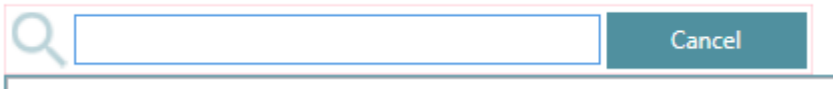
Create new operator – A new pop-up window opens, when this icon is clicked.



If Mandatory patient fields are checked under settings, there will also be mandatory fields for operator – here shown with red boxes. If they are not filled, the “Create” button will not be active.
Notes written in here will only be visible here.
All optional information will be shown in the PDF file under “Printed by”
First and last name will be shown in the PDF file under “Performed by”

Search for an operator already in the system. Search can be made with either first or last name, results will be shown either way.

When clicked, a search bar appears

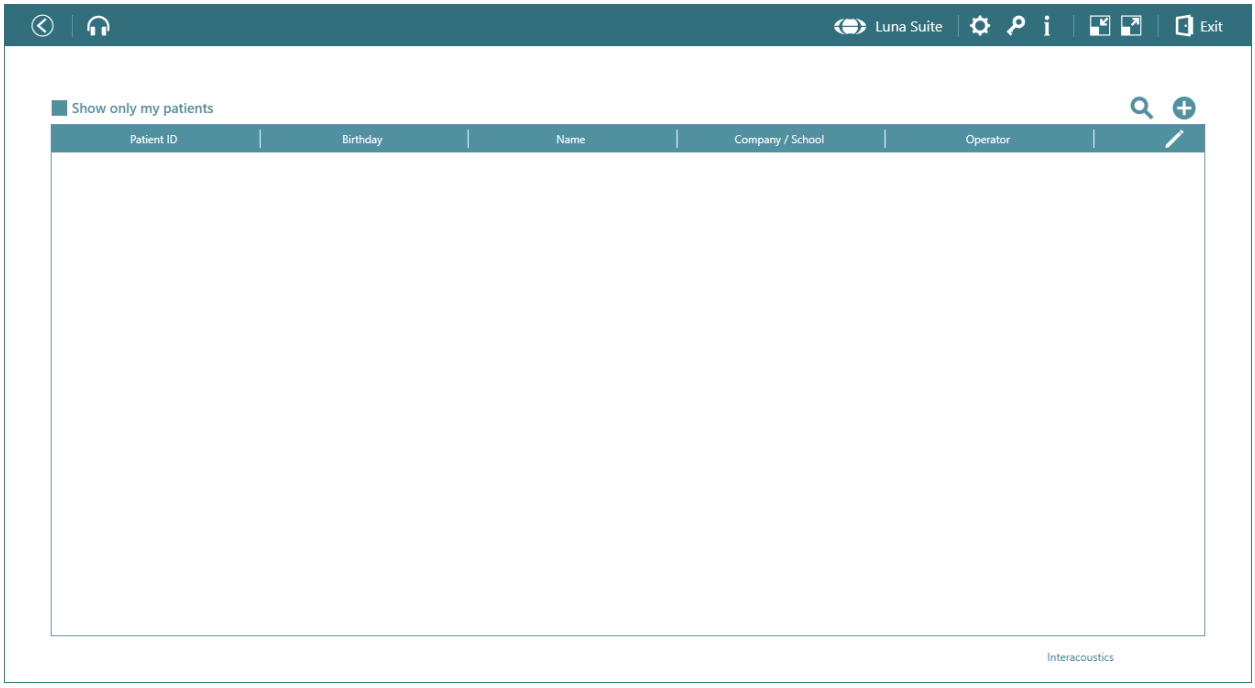


Clicking this allows the user to edit the operator.

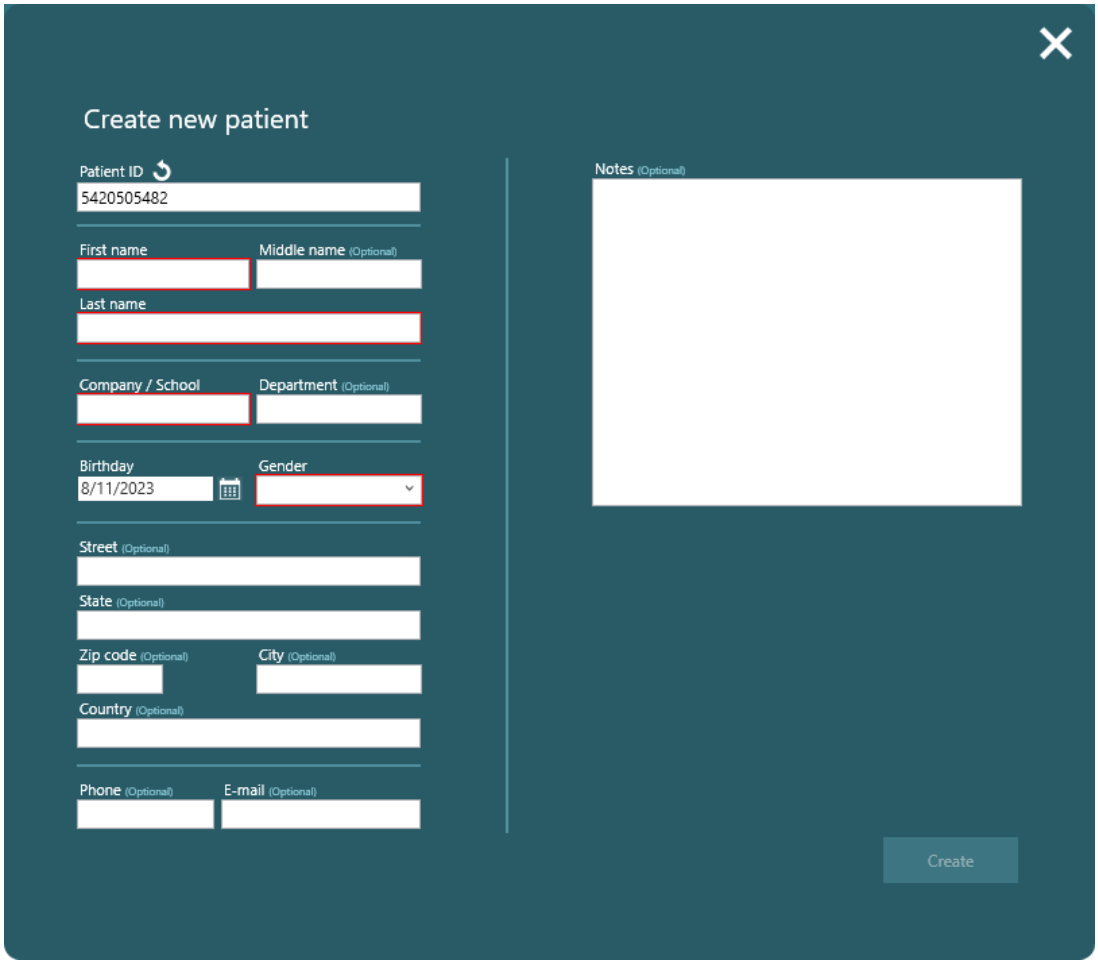
This will delete the operator with a pop-up asking if the user is sure that they want to delete the operator and settings.

3.3 How to create a new patient

When choosing an operator, it is now possible to create a patient under the operator.



Create new patient – A new pop-up window opens, when this is clicked.



- If Mandatory patient fields are checked under settings, mandatory fields marked with red need to be filled before the “Create” button will be active.
- Notes written in here will only be visible here.
- Patient ID can be random numbers that the system provides itself or the user can change them to birthday date, social security numbers or other numbers.
- Optional fields will not be shown in printout.

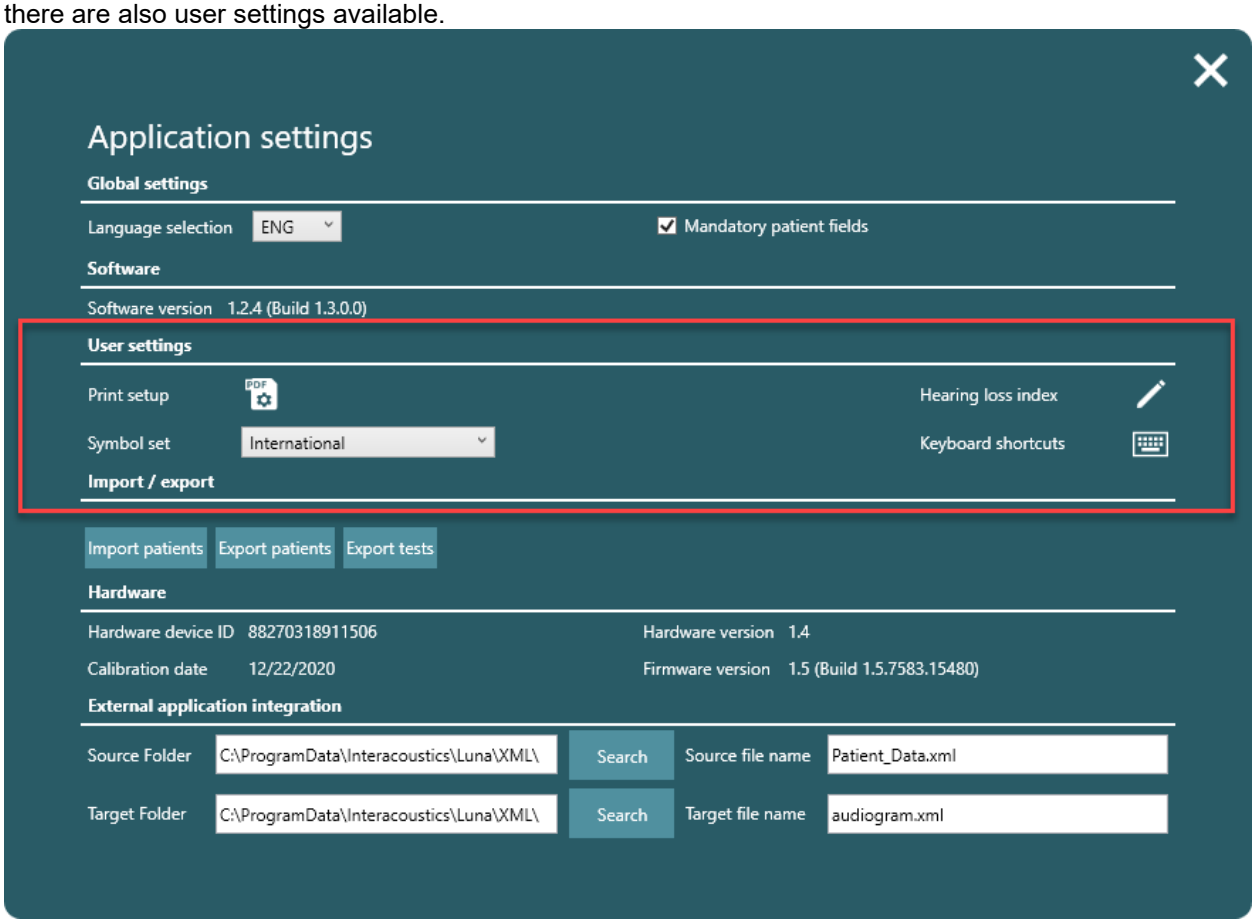
This will delete the patient with a pop-up asking if the user is sure that they want to delete the patient and settings. If the patient has been exported and saved on the PC, it is only the patient information that is saved and not the tests.

Search for an operator already in the system. It does not matter if it is the first or last name that is being typed.

By clicking the icon in the top bar with patients, it becomes possible to edit what information should be shown about the patients.

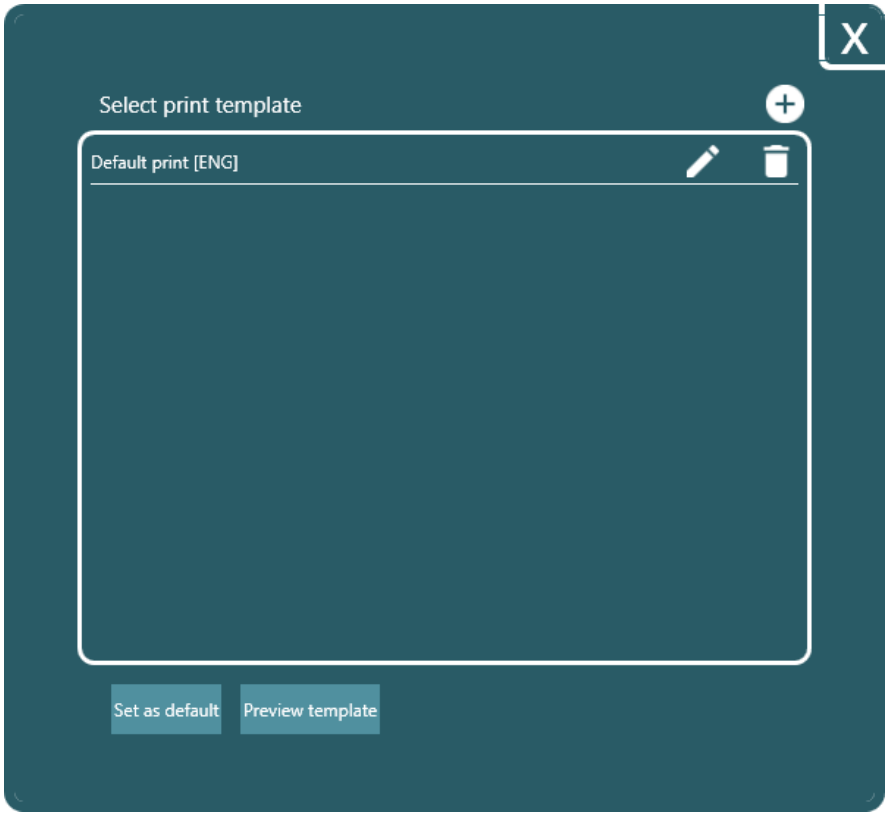
3.4 User settings

In the front page of the patient overview, it is still possible to click the settings wheel in the top bar. Now there are also user settings available.



3.4.1 Print setup

By clicking the PDF icon  , settings for printout will open in a new window.

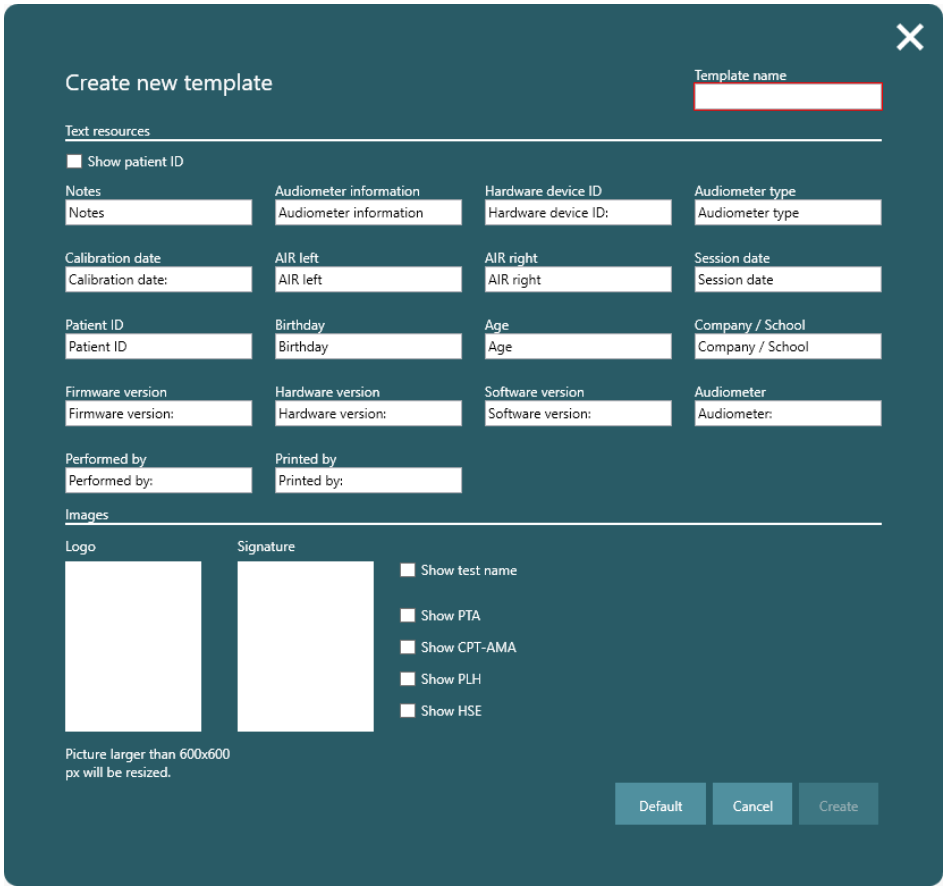


Create new print template

Edit existing print template

Delete print template

Select a template and set it for default to be the one used when printing to PDF.



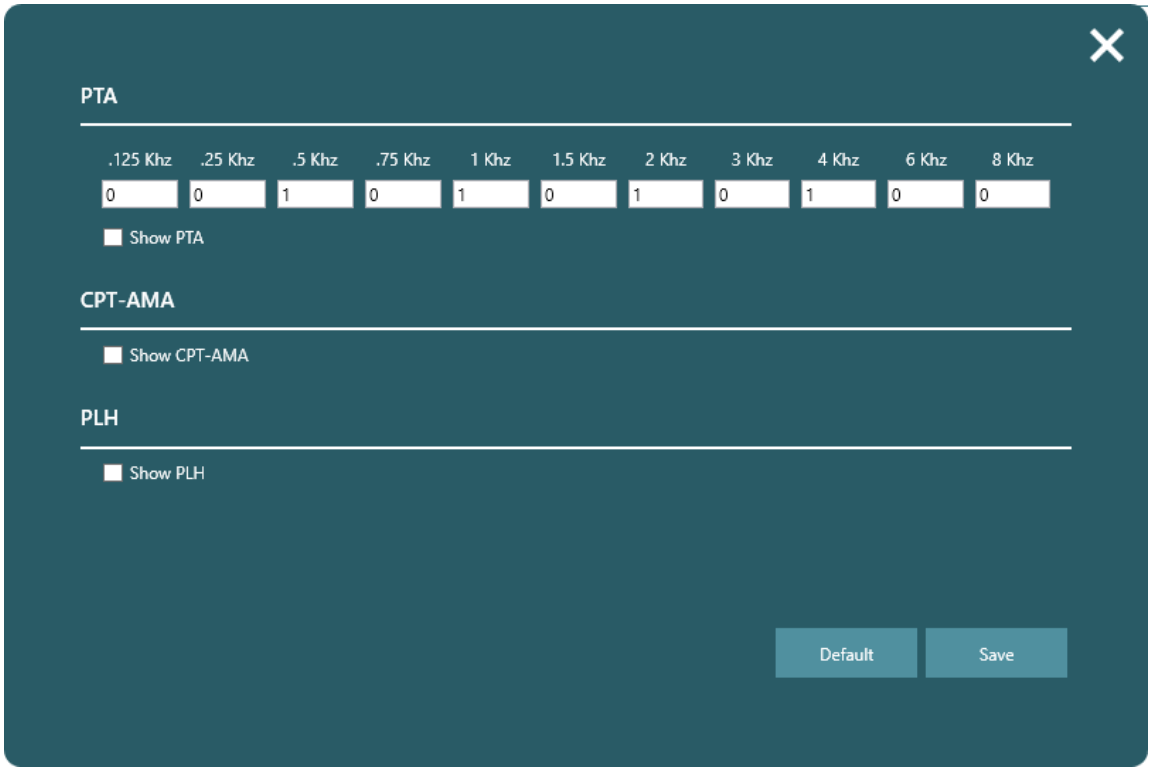
The only mandatory field in the print template is the Template name.
When clicking on the field under Logo and Signature, a popup window from file explorer will open. This gives the option to upload the logo and signature to the print template.

3.4.2 Symbol set

This setting is for future development and will not change anything yet.

3.4.3 Hearing loss index

By clicking the pen in application settings, a new pop-up window will appear with setting for PTA, CPT-AMA, PLH.



PTA can be weighed as the clinic wishes. By default, it is set for 1 at 500 Hz, 1, 2 and 4 kHz.
CPT-AMA will be calculated according to below table:

Table CPT-AMA

HV [dB HL]	500Hz	1kHz	2kHz	4kHz
10	0.2	0.3	0.4	0.1
15	0.5	0.9	1.3	0.3
20	1.1	2.1	2.9	0.9
25	1.8	3.6	4.9	1.7
30	2.6	5.4	7.3	2.7
35	3.7	7.7	9.8	3.8
40	4.9	10.2	12.9	5.0
45	6.3	13.0	17.3	6.4
50	7.9	15.7	22.4	8.0
55	9.6	19.0	25.7	9.7
60	11.3	21.5	28.0	11.2
65	12.8	23.5	30.2	12.5
70	13.8	25.5	32.2	13.5
75	14.6	27.2	34.0	14.2
80	14.8	28.8	35.8	14.6
85	14.9	29.8	37.5	14.8
90	15.0	29.9	39.2	14.9
95	15.0	30.0	40.0	15.0
100	15.0	30.0	40.0	15.0

PLH shift from baseline, which is an initial test. PLH is evaluated by comparing two sets of tests based on the PLH table.

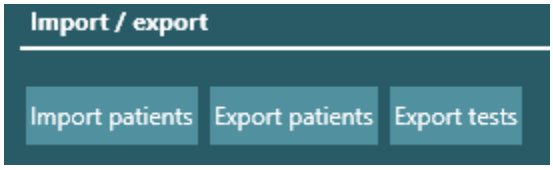
3.4.4 Keyboard shortcuts

 Clicking the keyboard will give access to see and edit the PC shortcut keys.

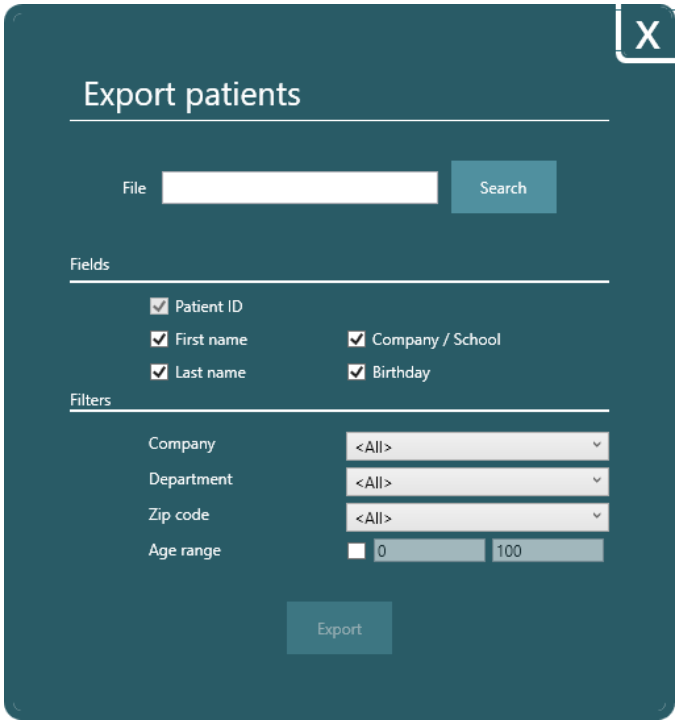
Action	Shortcut key
Frequency up	Right arrow
Frequency down	Left arrow
dB level down	Up arrow
dB level up	Down arrow
Signal type	S
Step size	T
Ear side	E
Tone	Space
Delete	Delete
Heard	W
Not heard	Q
Left ear	L
Right ear	R

3.4.5 Import/export functions

It is possible to import patients to the Luna Suite. They must be saved in XML files to be able to be read in the Luna suite. Only correct files will be shown when searching for patients to import.



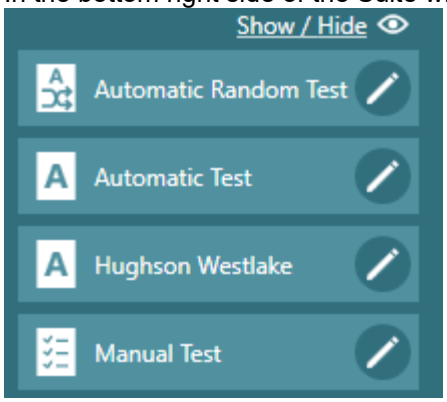
When clicking “export patients”, it is possible to export all patients or just some, by choosing export filters. By choosing filters it is possible to export patients in smaller groups or separately. If no filters are set, all patients will be exported to the same file.



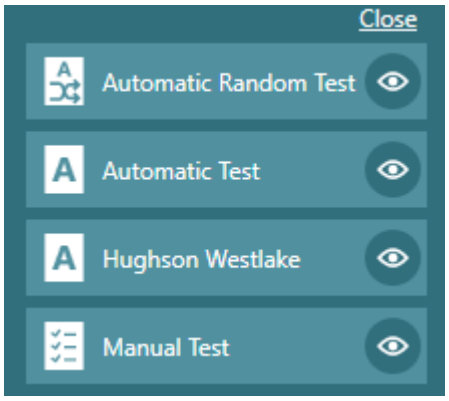
When exporting tests, it is possible to choose dates of tests, to filter them. Otherwise all tests from the chosen patient will be exported.

3.5 Tests

In the bottom right side of the Suite window, all available tests will be visible.



Above the tests, the text Hide/show can be clicked to make the option for Hide/show tests available.



The ones with eye icon next to them, are the ones that are visible. To hide a test, the eye icon must be clicked to remove the test. When changes are made, the close button at the top will collapse the edit mode and only show the tests chosen.

Click  to enter test setup

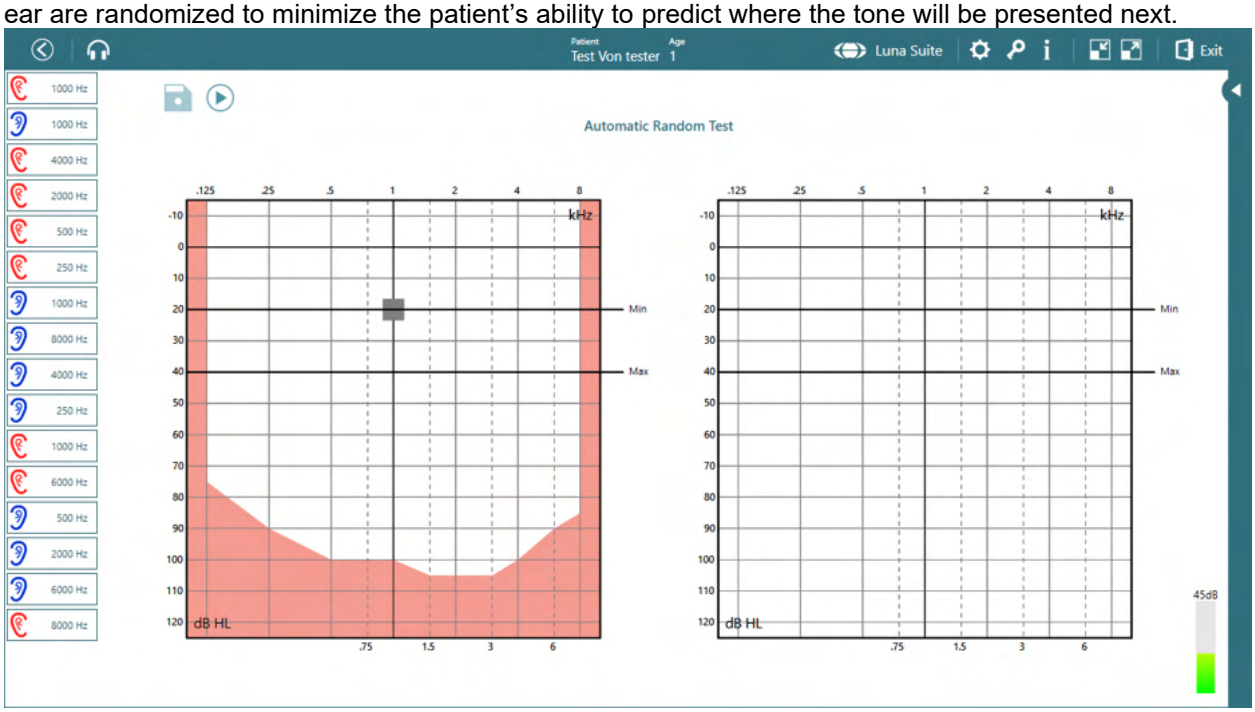
3.5.1 Ambient noise

An ambient noise bar will be visible in the bottom right corner for all test windows to indicate when the test can be performed in acceptable noise and when the noise levels are too high in the surroundings. The levels will vary depending on which frequency is being tested and is in compliance with ISO 8253.

Green color indicates acceptable noise levels.
Yellow indicates slightly too much noise, and adjustments in surroundings should be made.
Orange indicates not acceptable levels for testing.

3.5.2 Automatic Random Test

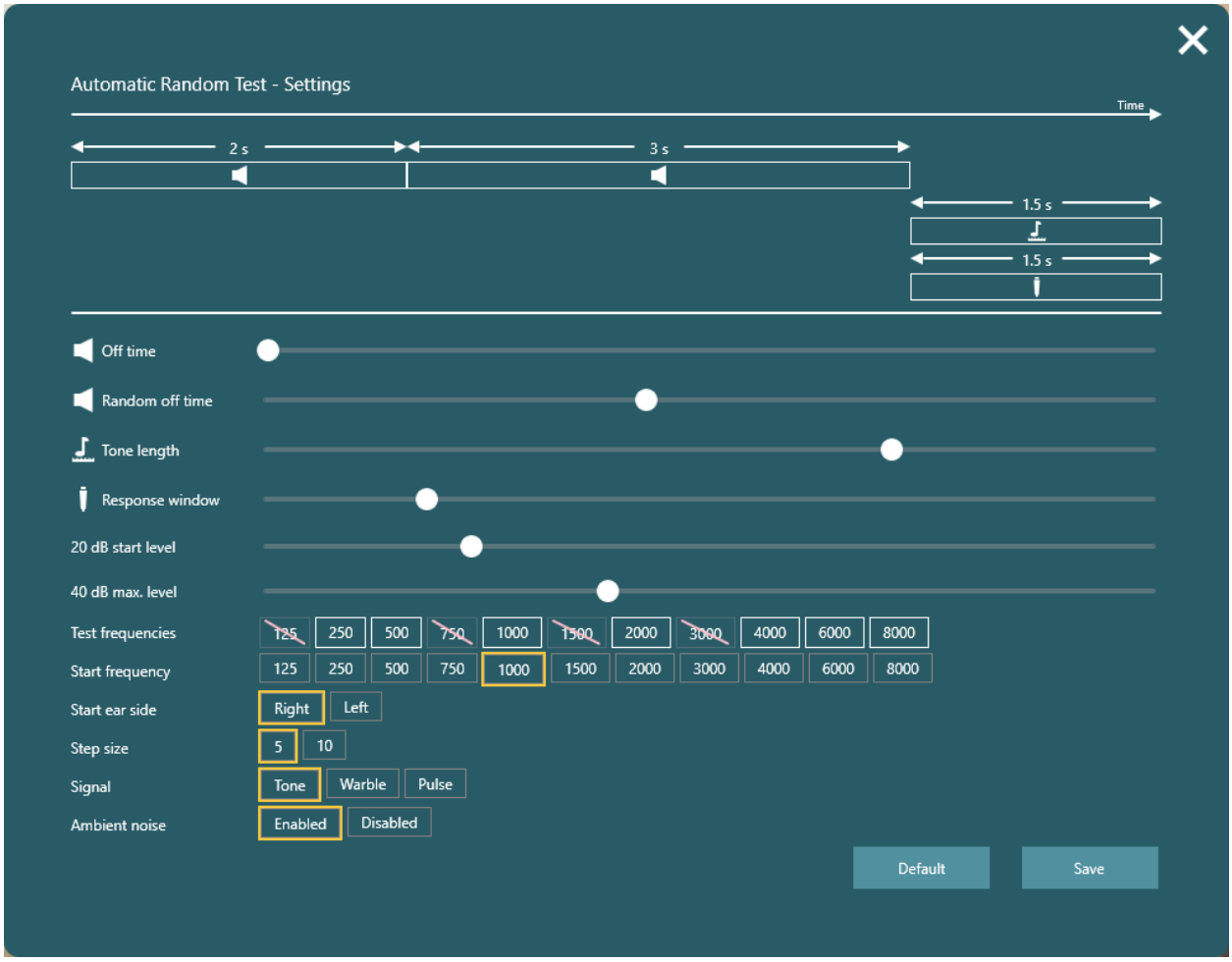
With the Automatic Random Test, it is possible to do an automatic test where both frequencies and test ear are randomized to minimize the patient's ability to predict where the tone will be presented next.



Selected frequencies are shown in the left side bar.
The minimum and maximum levels are marked with black lines in the audiogram to indicate the test section.

To start the test,  must be clicked. When the test is running, the button will change to pause option. When the test is complete, the floppy disk icon will be available to click to save the results.

Next to the floppy disk, will be an edit symbol  which will allow the user to retest the frequencies, if there are any doubts about the result.
At the bottom of the screen, a small panel will appear where the tone can be activated by clicking the microphone, and the frequencies can be changed by using the mouse or by touch to place the marker to selected frequency and intensity.



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 must answer.

20 dB start level:	This setting decides the minimum start dB level for each frequency. 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.
Ambient noise	By enabling Ambient noise, a monitor bar will appear to show the user the noise level. The bar changes color depending on the noise level.

3.5.3 Automatic Test

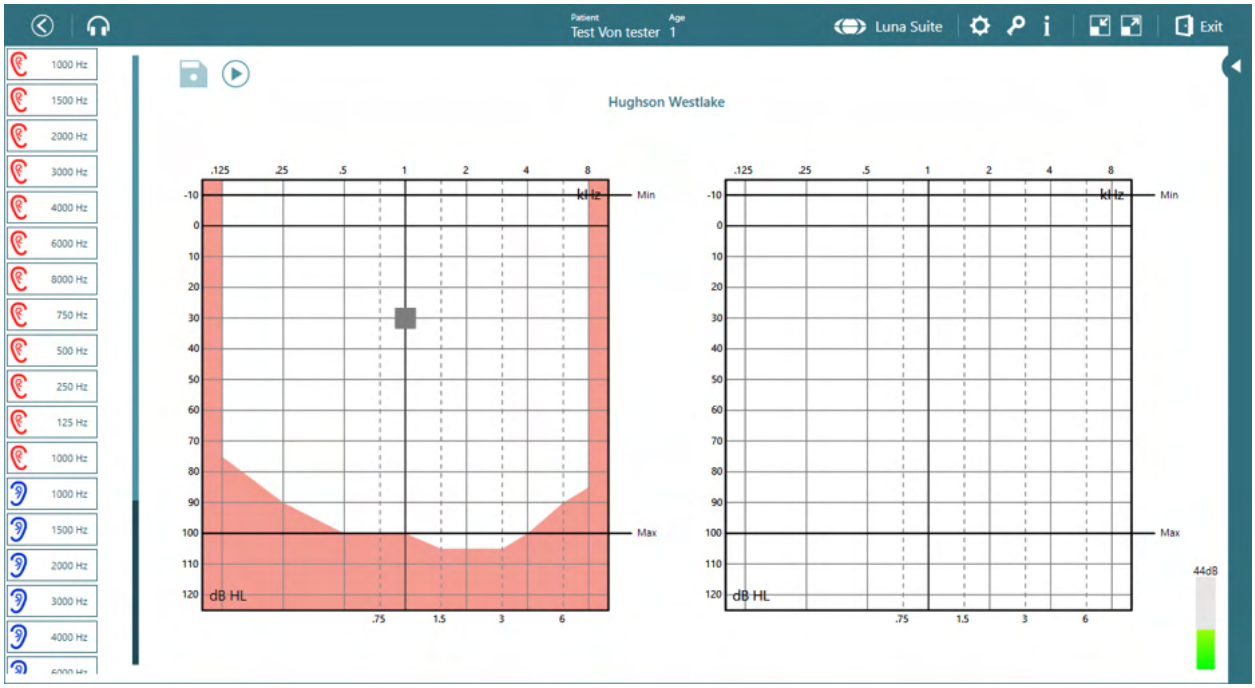
The Automatic Test will allow the user to instruct the client and start the test with no need to do any further before the test is done. It is possible in settings to choose which frequencies need to be tested. It is also possible when entering the test to uncheck the frequencies that is not needed, so only the important frequencies will be tested. This is done in the right side of the test screen by clicking on the frequency that is not needed, and it will be greyed out to show it will not be tested.
This can also be done during test.

Settings and tests screen will be like Automatic Random Test – See section 3.5.2

3.5.4 Hughson Westlake Test

Hughson Westlake is an automatic pure tone threshold test procedure. The correct test result is determined from 2 out of 3 similar responses (or 3 out of 5) to the tone. The test starts at 1000 Hz and at the chosen dB level. Intensity will increase in 5 dB steps and decrease by 10 dB.

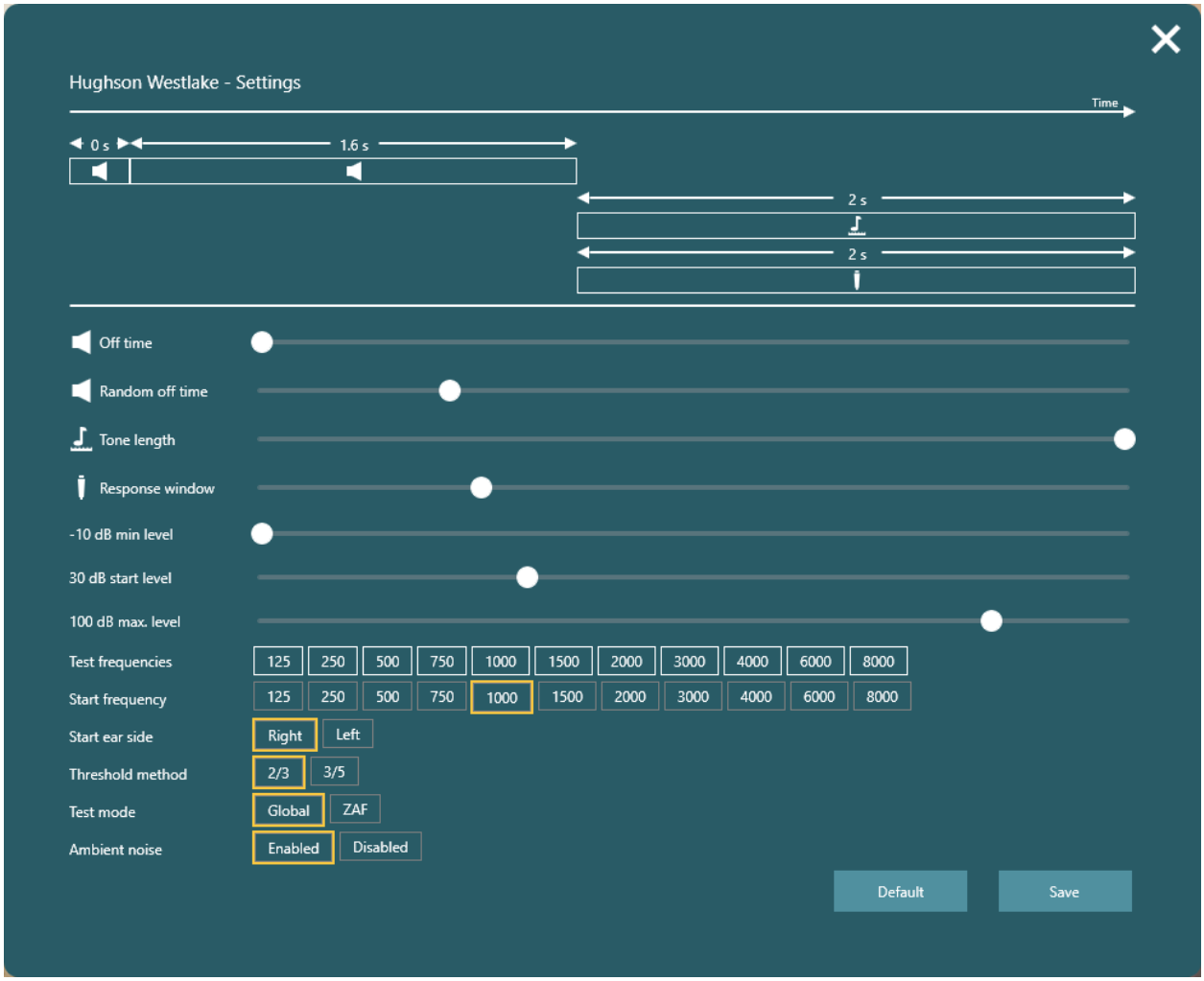
Test screen



Selected frequencies are shown in the left side bar.
The minimum and maximum levels are marked with black lines in the audiogram to indicate the test section.

To start the test,  must be clicked. When the test is running, the button will change to pause option. When the test is complete, the floppy disk icon will be available to click to save the results.

Next to the floppy disk will be an edit symbol  which will allow the user to retest the frequencies if there are any doubts concerning the result.
At the bottom of the screen, a small panel will appear where the tone can be activated by clicking the microphone, and the frequencies can be changed by using the mouse or by touch to place the marker to selected frequency and intensity.

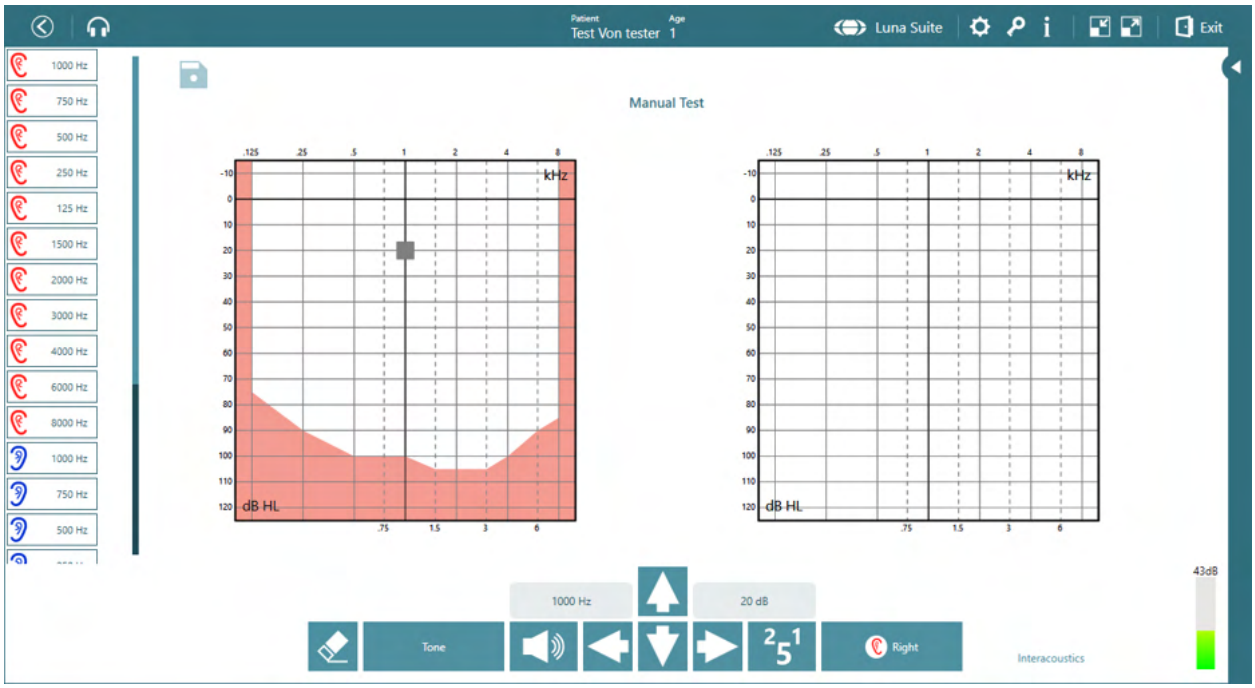


Off time	2 – 7 sec.	Time with no tone, recommended setting: 0.
Random off time	0 – 7 sec.	An extra time off, added to the ”Off time”, making it more difficult for the patient to figure out when the tone is present. The extra random time will vary throughout the test randomly. Example: If the Off time 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.
X dB min. level		The lowest intensity the system will test to. If this is set for 10 dB, no frequencies will be tested below 10 dB
X dB start level		Will start the test tone at this level for each frequency
X dB maximum level		Your dB will never exceed X 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	Left or right.
Threshold method	You may choose between 2/3 and 3/5. Depending on how many similar answers you want before changing frequency.
Test mode	Global will always be default. ZAF is a special setting for South Africa

3.5.5 Manual Test

The manual test allows the user to control the testing. This is done by performing the audiometry while using keyboard strokes or function keys on screen directly in the Suite.



On the right side, all test frequencies are shown and can be disabled or enabled, if needed.

 After the test is done, the floppy disc is clicked to save the test

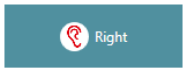
 deletes the threshold that is marked with the grey box

This allows the user to toggle between test signals: Tone, Warble and Pulse

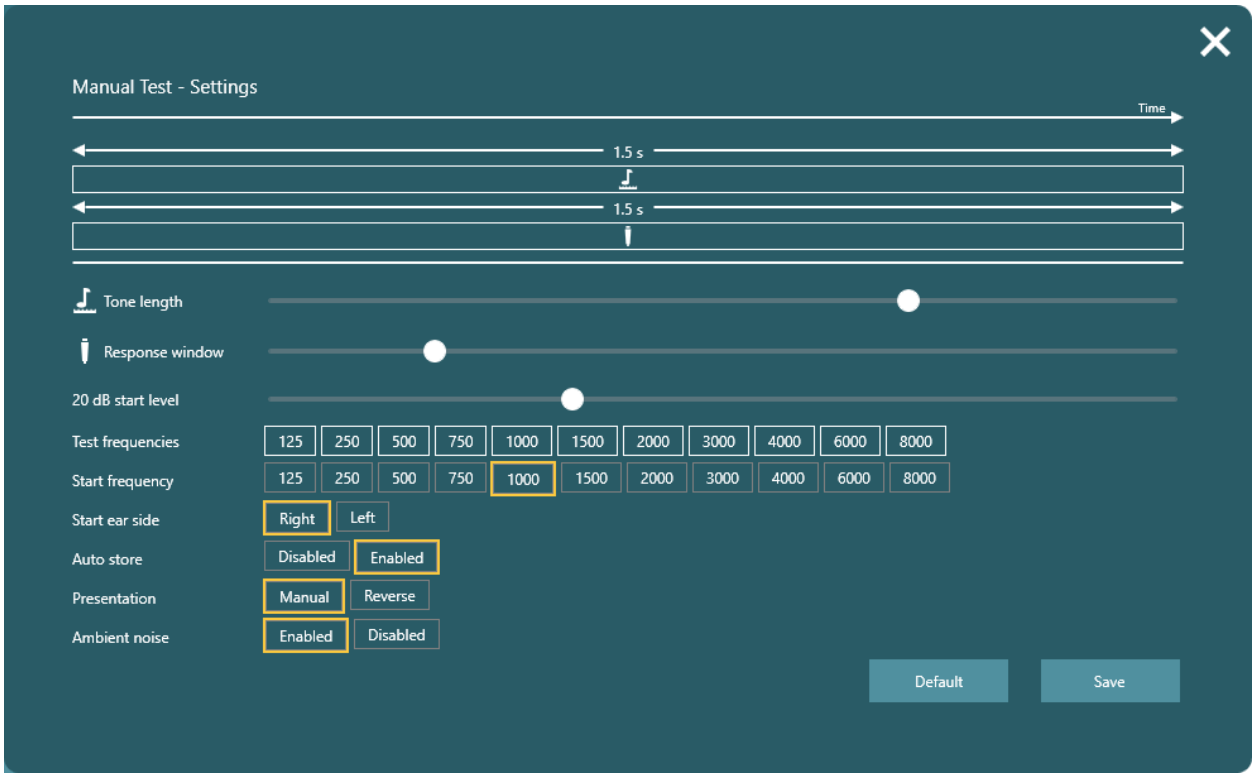
 Send the test tone when clicked. This can also be activated by using spacebar on the keyboard

 The arrows are used to navigate in frequencies and intensities. Arrows on keyboard can also be used

Changes step size. 1-, 2- or 5-dB step size is available.



Changes between right and left ear. Keyboard strokes are L and R for this command.



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	Start level for each frequency
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 ear side		Right will be set as default
Autostore		Allows the system to set the mark for when the patient response. If no response is registered, the mark for no response will be set instead.

3.5.6 Table view with pass/refer criteria

When going to setting for the automatic test and automatic random test, it is possible to change the view from graph view to table view by setting start and stop intensity to the same. This is relevant if you wish to make a quick estimation of the hearing by performing a one intensity screening. The result will be shown as pass/refer and not with dB as in graph mode.

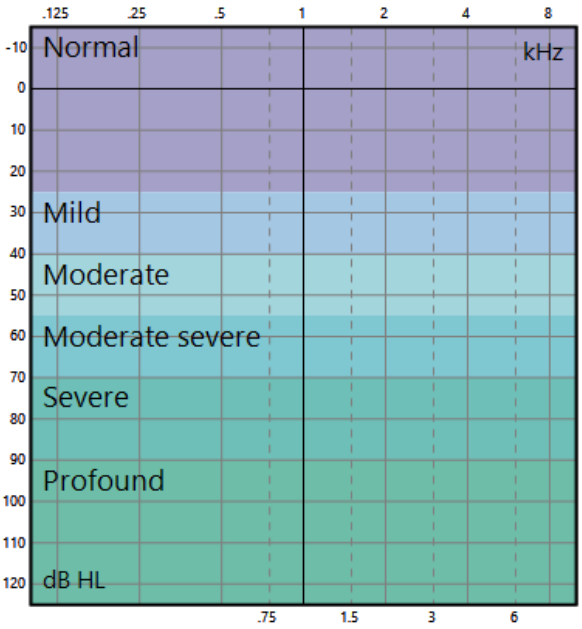
Right	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	6000 Hz	8000 Hz
20 dB HL	REFER	REFER	PASS	REFER	PASS	PASS	PASS

Left	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	6000 Hz	8000 Hz
20 dB HL	PASS	PASS	PASS	REFER	REFER	PASS	REFER

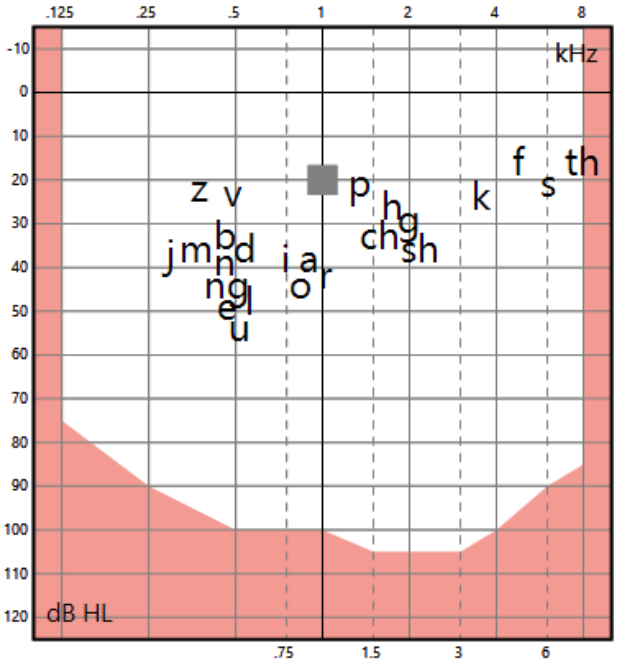
3.6 Overlays

In the left side of the Suite, a fold out menu is available with different overlays and features for the audiogram

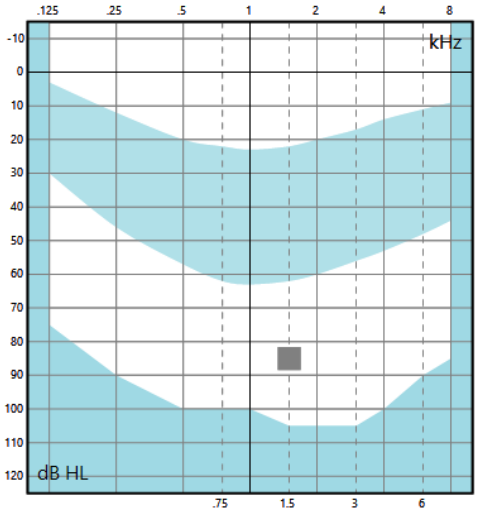
The top one will display the severity overlay



The next overlay shows the phonemes to illustrate to the user and client which phonemes are outside the audible field.



The speech banana will indicate in which area the speech is located, and will give the user and client a tool to discuss speech understanding.



 By clicking this icon in the foldout bar, the audiograms will change sides so the left will be shown left, and the right will be shown to the right, if clicked.

 /  Clicking this icon will combine the two audiograms and show the measures on the same audiogram graph. This can help the user compare the two ear sides.

4 Maintenance

4.1 General maintenance procedures

Your Luna may be gently cleaned by means of a soft cloth dampened with lukewarm 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 meet 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

Recommended cleaning and disinfection solutions

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

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 24 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 centre 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 these for a particular purpose or application.

5 General technical specifications

Medical CE-mark:	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745. 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)+AMD1:2020
	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. Noncondensing

5.1 Technical specifications

	Transducers
[A]	– two earphones
[A]	Hearing levels from -10 to 105 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 follows IEC60601-1-2:2014, emission class B group 1+AMD1:2020.

NOTICE: There are no deviations from the collateral standard and allowances uses NOTICE: All necessary instruction for maintaining compliance regarding 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, except for 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 *Instrument* **(Luna)** is intended for use in the electromagnetic environment specified below. The customer or the user of the *Instrument* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Instrument*** 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 ***Instrument*** 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 *Instrument*.			
The ***Instrument*** **(Luna)** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Instrument*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Instrument*** 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 ***Instrument*** **(Luna)** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Instrument*** 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the ***Instrument***.
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 Line to line +2 kV Line to earth	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	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***Instrument*** requires continued operation during power mains interruptions, it is recommended that the ***Instrument*** 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.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the I***nstrument*** contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***Instrument*** **(Luna)** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Instrument*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***Instrument,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	$d = \frac{3,5}{Vrms}\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{V/m}\sqrt{P}$ 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 ***Instrument*** is used exceeds the applicable RF compliance level above, the ***Instrument*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***Instrument.*** [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

Opr. dato:	af:	Rev. dato: 30.01.2023	af:	Rev. nr.:	
2014-03-07	EC		MHNG	5	

Company: _____

Address: _____

_____

Phone: _____

e-mail: _____

Address
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo
Poland

Mail:
rma-diagnostics@dgs-diagnostics.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 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.