Vibrosonic harmonize®

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Introduction

We are pleased you've chosen a product from Vibrosonic GmbH.

These electronic instructions are part of Vibrosonic harmonize® version 1.2.0 dated

08/05/2025.

A copy of this document is available as a PDF version at:

http://www.vibrosonic.com/support/harmonize-hilfe.

A printed version is available on request from Support at Vibrosonic GmbH within 7 working days (contact details below).

You can find the version identifier of your current installation of Vibrosonic harmonize[®] on the <u>help</u> tab of the software.

These instructions contain information on the following topics:

Introduction

- Instructions and explanation of symbols
- Important safety information
- **Product safety instructions**
- Special features of the Hearing Contact Lens®
- <u>Software-Installation</u>

Operating Vibrosonic harmonize®

- <u>General structure of Vibrosonic harmonize®</u>
- <u>Customer management</u>
- <u>Audiogram management</u>
- <u>Session management</u>
- Device list
- <u>Help</u>

Manufacturer information:



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Data protection

This software collects confidential, legally protected or personal data according to EU-GDPR. The customer data exported is password encrypted by the software. With reference to the EU-GDPR, we would like to emphasize that unauthorized copying or distribution of this software and the information contained herein is not permitted.

We would also like to emphasize that the content of this software – particularly the customer database – must be deleted if the purpose for which it was stored no longer applies.

Instructions and explanation of symbols

	Warnings: The text marked with this symbol must be read before using the device.
i	Note: Text marked with this symbol contains important information on handling the hearing system and its product safety.
Res of the second se	Observe the instructions: Indicates that it is essential to read the instructions before use.
	Manufacturer: Denotes the manufacturer of the medical device product according to the Regulation (EU) 2017/745 on medical devices. Its name and address are given next to the symbol. If applicable, a date is indicated underneath this symbol which corresponds to the date of manufacture of the product.
CE 0483	CE mark: The product complies with the requirements of the Regulation (EU) 2017/745 on medical devices. The four-digit number indicates the identification number of the notified body.
MD	Medical device: Identifies a medical device.
REF	Catalogue number: Specifies the manufacturer's catalogue number so that a particular medical device can be identified.
LOT	Lot number: A lot number links an item to information that the manufacturer considers relevant for the traceability of a product. In the case of software, this may be the version of the software.

Important safety information

The Hearing Contact Lens [®] and ear canal module may only be handled by a Vibrosonic-certified ENT doctor. As parts of Vibrosonic alpha are worn inside the ear canal and on the eardrum, insertion or maintenance by an unqualified person may result in injury to the eardrum, middle ear and/or inner ear.
Vibrosonic harmonize [®] may only be used by a specialist with hearing aid acoustician training or comparable qualification. If operated by unqualified persons, there is a risk of irreversible hearing damage resulting from hearing aid amplification set too high over a prolonged period.

Product safety instructions

	Vibrosonic hearing systems use the Vibrosonic Hearing Contact Lens® – rather than a loudspeaker – to create the sound impression. The customer wears the individual components of Vibrosonic hearing systems on the eardrum or inside the ear canal. To ensure customers have the best possible outcome, important instructions must be followed Thereforeplease read these instructions carefully and in particular the section "Special features of the Vibrosonic Hearing Contact Lens"
E	Also familiarize yourself with the instructions for the Vibrosonic hearing system to be fitted. You can access it as well as the technical data sheet of the system via the Vibrosonic harmonize [®] help function or directly at <u>https://vibrosonic.com/support/harmonize-hilfe</u> .
Í	Only compatible programming adapters and cables may be connected. Currently, Vibrosonic harmonize® supports HI-PRO USB, HI-PRO 2 and Noahlink programming adapters. Information on the support provided by the hearing systems to be programmed can be found in the relevant operating instructions of the hearing system.
i	Any serious incident according to the Medical Device Regulation (EU) 2017/745 for medical devices (MDR) must be reported to Vibrosonic GmbH and the responsible authority of the country of residence. A serious incident is the occurrence of an untoward medical incident within the context of a medical device which directly or indirectly led, might have led or leads to any of the following:
	 death of a patient, user or third party serious deterioration of the health condition of a patient, user or third party

Cyber security instructions



As the **user of this software**, you must **ensure** that you take the appropriate measures to safeguard customer data. Make sure that all Windows accounts are password protected.

Ensure that only **individuals authorized** to access customer and fitting data have **access** to this PC and that a secure Windows password protection is in place. Additionally, set up hard drive encryption to protect against physical access.

Explanation: The central database (if configured) is located at \Users\Public\Documents\vibroFTS.db and can be accessed by anyone with access to this PC.



User-specific databases (if configured accordingly) are located under \Users\[Username]\Documents\Harmonize and are subject to Windows access control. Even if the software has not been configured to use a central database for all users, such a setup can be created *at any time by anyone with access to the PC*. For this, only a valid database file needs to be placed at C: \Users\Public\Documents\vibroFTS.db.

Users who launched Vibrosonic harmonize® before a central database was configured will automatically continue to use their personal database. New users will subsequently use the central database by default, even if the use of separate databases was configured during installation.

Intended Use

Vibrosonic harmonize[®] is used to configure the hearing systems distributed by Vibrosonic and to adapt their acoustic amplification characteristics to the customer's individual hearing loss. The software may only be used in conjunction with supported hearing systems from Vibrosonic (see <u>Supported Hearing Systems</u>) and only by qualified personnel (audiologists, hearing care professionals).

Medical Information

Medical indications and contraindications as well as a clinical benefit of Vibrosonic harmonize® are derived only from it's use in conjunction with a supported hearing system (see <u>Supported Hearing Systems</u>). The same applies to side effects, risk factors and residual risks. Therefore, for this information please refer to the instructions for use of the connected hearing system.

Special features of the Hearing Contact Lens®

Your customer is wearing the loudspeaker of the hearing systems fitted using Vibrosonic harmonize[®], the Hearing Contact Lens[®], directly on the eardrum. In natural hearing, sound hits the eardrum at the end of the ear canal and causes it to vibrate. The Hearing Contact Lens[®] developed by Vibrosonic GmbH works on the same principle: Rather than loudspeakers in the ear that reproduce sound, sound is transmitted by direct mechanical stimulation of the ear system. The result is a natural listening experience.



Vibrosonic alpha consists of three essential components:

- the Hearing Contact Lens®
- an ear canal module
- the sound processor

The sound processor contains the electronics, battery, and microphones. The sound processor and the ear canal module are connected to each other via the magnetic cable. The customer can make and break this connection himself to remove the sound processor as necessary. The Hearing Contact Lens[®] and ear canal module are designed to remain inside the ear canal permanently and are connected by the connecting cable.

This new way of creating sound impressions give rise to some specifics when fitting Vibrosonic hearing systems.

The most important facts in a nutshell:

- *Regular checkups* must be arranged with a *Vibrosonic-certified ENT doctor*.
- Ask your customer regularly if he suspects a change in the fit of the Hearing Contact Lens[®]
 e.g., as a result to a check-up appointment with the ENT doctor, or if he has noticed a change in sound volume. In both cases a *new calibration* is required.
- If Vibrosonic harmonize[®] *indicates poor performance* of the Hearing Contact Lens[®] even after several calibration attempts, the customer should be referred to a *Vibrosonic-certified ENT doctor*.
- Only work with *acoustic audiograms obtained without the Hearing Contact Lens*[®] in place.

The Hearing Contact Lens® from Vibrosonic is only suitable for patients over 18 years of age. Your customer must also schedule regular checkups with a Vibrosonic-certified ENT doctor. This ensures that the hearing system functions optimally. Check-ups may require the Hearing Contact Lens® to be repositioned. As the Hearing Contact Lens[®] – similar to a contact lens for the eyes – adheres to the eardrum merely by a liquid film, its position may change under certain circumstances. The same applies when the Hearing Contact Lens[®] is repositioned by an ENT doctor. This can significantly change the sound impression experienced by your customer.

Therefore please ask your customers regularly if the sound volume of the hearing system has changed noticeably or if the ENT doctor has performed any repositioning. Vibrosonic harmonize[®] will remind you of this. In either case, as well as for the First Fit of the device, the hearing system should be recalibrated. For this purpose, an in-situ measurement of the client's hearing threshold is performed, using the hearing system.

Information on this can be found in the section <u>Calibration of the hearing system</u>. Please also recalibrate the device in case you are unsure whether the required sound levels are obtained. Vibrosonic harmonize[®] will show you if the target levels can be reached and then continues using the newly determined calibration curve during fitting.

Important: If, despite repeated calibration attempts, Vibrosonic harmonize[®] keeps signalling insufficient performance of the Hearing Contact Lens[®], the customer should be referred to a Vibrosonic-certified ENT doctor to check the position.

Please also note that acoustic audiometry with a Hearing Contact Lens® in place has its limitations, as it leads to slight attenuation of the direct sound. *Therefore, in order to obtain optimal fitting results, only enter audiograms recorded without the Hearing Contact Lens® in place.* When using a new audiogram, Vibrosonic harmonize® also requires the hearing system to be recalibrated, as the Hearing Contact Lens® must have been repositioned for correct acoustic audiometry.

Declaration of Conformity

Vibrosonic GmbH hereby declares that the product Vibrosonic harmonize[®] complies with the Regulation (EU) 2017/745 on medical devices (MDR). The complete text of the declaration of conformity is available directly from the manufacturer.

Software - Installation

Open the file harmonize-setup_v1.2.0.exe with a double click

In case a Windows Defender message appears, please click**More Information**. *Important:* "Unknown issuer" is displayed here, as Vibrosonic GmbH has not registered Vibrosonic harmonize[®] with Microsoft.

Therefore, please make sure you have received the software package directly from the Vibrosonic homepage or directly from Vibrosonic on a data carrier

Once you have ensured this, click the **Execute anyway** button. Select the language to be used during installation. The installation program then checks whether all prerequisites for installation are met and shows a notification if required components are not yet installed on your computer (e.g., the .NET framework).

In this case the installation prgram provides an option to install the required packages.

III Vibrosonic harmonize® Setup			×
Prerequisites Select which prerequisites will be insta	alled		\odot
Name Image: Instant ins	Required	Found Installed	Action Skip Must Install
Advanced Installer	< Back	Next 3	> Cancel

Data protection statements and licensing information is displayed for each of the installed components. If you agree with this, click **Install**.

Hicrosoft Windows Desktop Runtime - 5.0.1 (x86)-Installer

Microsoft	Windows Desktop Runtime - 5.0.1 (x86)
	Windows Desktop Runtime
	The .NET Windows Desktop Runtime is used to run Windows Forms and WPF applications, on your computerNET is open source, cross platform, and supported by Microsoft. We hope you enjoy it!
.NET	By clicking Install, you agree to the following terms. <u>Privacy Statement</u> <u>Licensing Information for .NET</u>
	Install Close

After successfully installing all additionally required components, you reach the welcome dialog of the Vibrosonic harmonize[®] installation program. Please carefully read the safety instructions in particular.

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To start installing Vibrosonic harmonize[®], click **Next**, select an installation directory, and confirm it with **Next**.

In the subsequent dialog you can select components and features to be installed that you may need using Vibrosonic harmonize[®]:

(() Vibrosonic harmonize® Setup	×
Optional features to install	
Select the features to be installed	y
 ✓ Vibrosonic harmonize ✓ On Semiconductor Communication Accelerator Adaptor Use global database for all users 	
< Back Next >	Cancel

The following features are available:

- Vibrosonic harmonize installs the basic program of Vibrosonic harmonize[®]. You should only deselect it if Vibrosonic harmonize[®] is already installed and you have started the setup to install additional features.
- The On Semiconductor Communication Accelerator Adaptor component is necessary for Vibrosonic harmonize® to work. Only deselect it if you have already installed it.
- To give all Windows users access to a common database, you can select *Use global database for all users* .

In the default configuration, a separate customer database is created for each Windows user once the software is started, which can only be accessed by this user.

Important: Please make sure that **all** Windows users create a secure password on their computer and remove unused Windows users! Also ensure that all Windows users are authorized to access the patient data stored in the database in accordance with the applicable data protection guidelines.

Select this database and then click **Next**.

The installation program now informs you that you must take the appropriate measures to protect the customer data stored in the database.

(Vibrosonic harmonize® Setup	×
Important: Use Windows Passwords!	\mathfrak{S}
Please ensure that all user accounts are secured with a Windows password! Also ensure that only individuals authorized to access patient data a granted access - even when configuring Vibrosonic harmonize® to separate databases for each Windows user. For more information of security, please refer to the user manual.	re use n IT
Vibrosonic 	ncel

After reading the text, click **Next**.

The Vibrosonic harmonize[®] licence terms as well as the third-party components used are displayed. Please read them carefully.

If you agree to the licence agreements, click **I accept the licence agreement** and confirm with **Next**.

Preparations for installation are now complete.

Confirm the start of the installation by clicking **Install**.

Depending on which components you selected for installation in the last step, the installation wizards for these components are now started in succession. Follow the instructions for the

wizards displayed on the screen.

Note: If you have already installed individual components, you may be given the choice to *Repair* or *Remove* them.

In this case, select **Repair**. If newer components (e.g., HI-PRO drivers) are already installed on your system, you can easily cancel the installation.

Note: The drivers for the programming adapter used are supplied with your programming adapter. They must be installed separately from Vibrosonic harmonize[®].

Once all components have been installed, you will be notified. Click **Finish** to exit the Vibrosonic harmonize[®] installation program.

There is now a shortcut to the software on your desktop.



A Windows reboot might be required before programming adapters installed with the software can be used.

System requirements

Minimum requirements:

Operating system: Windows 10 (64 bit) CPU: 1 GHz RAM: 2 GB for 64 bit Hard disk: 128 GB Graphics: DirectX 9 or higher

Internet connection (online update)

Compatible programming adapters

The following programming adapters are compatible with Vibrosonic harmonize®:

- Hi-Pro USB / Hi-Pro 2
- NOAHlink

Please also check in the user manual of the hearing systemwhich programming adapters it supports.

The drivers for the programming adapter used are supplied with your programming adapter. They must be installed separately from Vibrosonic harmonize[®].

Please refer to the operating instructions of the respective programming adapter.

Supported Hearing Systems

The following Vibrosonic hearing systems are compatible with Vibrosonic harmonize®:

- Vibrosonic alpha

This section contains information about the general structure of Vibrosonic harmonize[®]. The **main window** is presented below.



The main window is roughly divided into four panes:

Vibrosonic harmonize Q Customers Example Audiogram Vibrosonic Provide Audiogram Provide Audiogram	•	 The main menu ribbon (top left) 							
🛛 🗘 Customers 🛛 🕁 Audiogram 💿 🗸 Session 🦧 Devices 🕜 Help		W Vibrosonic harmon	ze						
		Q Customers	Audiogram	€ Session	R Devices	Help			

• The live device display (top right)



• The display of the current customer details (on the right)

Customer details

Address:

John Smith 32 Reading Rd. B26 3QJ Birmingham

Assigned hearing aids

Vibrosonic alpha (SN:4211734) R Vibrosonic alpha (SN:4202666) L

Last audiogram

[dB]

• The workspace (in this example: selecting the Customers tab)

and some

Vibrosonic harmonize			
Q Customers 🔁 Audiogram	Session 🎢 De	vices 🕜 Help	
Add Edit Delete Customer management			
Customer management			
First name:		Last name:	Birthday:
John		Smith	01.01.1951
Jane		Smith	03.03.1952

The main menu ribbon, live device display and the current customer details are displayed continuously regardless of the tab selected in the main menu. The display in the workspace depends on the current selection of tabs in the main menu ribbon, in which the software functions currently required (Customer management, Audiogram management, Session management and execution, a list of Vibrosonic harmonize[®] compatible hearing aids, Help) can be called up. Information on these functions can be found in the respective chapters.

All functions of the software are always executed for the *current customer*. The *current customer* can be selected in customer management by clicking on the relevant entry in the customer list. The display of customer details continuously shows which person is selected as the *current customer* and also a summary of that person's customer details.

The live device display / management of connected hearing systems

If the **continuous scan** function is enabled in the live display of hearing systems, it shows you continuously whether a Vibrosonic hearing system is connected to the computer via a compatible programming device.

It also shows whether this programming device is assigned to a customer from the customer database and is used to manage these assignments.



If a connected hearing system is not displayed (as shown here in the screenshot), make sure that

- Continuous scan is enabled
- the programming device used has been connected before starting Vibrosonic harmonize[®] and is compatible with both, Vibrosonic harmonize[®] and the hearing system connected
- the drivers for the programming device used have been installed and are working properly

To connect a hearing system proceed as follows:

Plug the programming cable (connected to the Vibrosonic hearing system) into the connection socket of the programming device labelled Left or Right according to the customer's ear side.

Please check that the device is connected to the PC and switched on.

Now connect the hearing system to the programming cable.

Live display of the hearing system connected:

Hearing systems not yet assigned to a customer are now displayed with a green hearing aid icon. Clicking the icon assigns the device to the *current customer*.



Alternatively, the device is automatically assigned to the *current customer* once it is used in a new session for this customer. You can find information on how to select the current customer in the chapter <u>Customer management</u>.

When moving the mouse over the icon, a tool tip appears, which displays the serial number of the device. The programming adapter used for connection is displayed under the product name.

If a device is already assigned to a customer, the name of the customer is also shown in the live display.

If the customer is not the current customer, the following icon appears:



By clicking this button, the customer is automatically selected as the *current customer*.



If a connected **device is assigned to the** current customer, a red hearing aid icon is displayed.



By clicking this button, the existing assignment of the hearing system can be cancelled.

R	Continuous scan				
Vibrosonic alpha HI-PRO John Smith	ľ2	Vibrosonic alpha HI-PRO John Smith			
	L Ji	Inassign the device from this customer: ohn Smith ibrosonic alpha (SN 4211734)			



If the L/R symbol appears, the Left and Right side of the hearing system have been

reversed when connecting to the programming device.

In this case, please exchange the Left and Right sides.

Important: This function does not work for devices that have not yet been assigned to a customer, as assignment to the correct ear side is made when the hearing system is connected for the first time based on the connection used on the programming device.

Customer / Customer Management

Under the **Customers** tab you find all the **Customer management** functions.

III Vibro	osonic harmoni	ze				
R	Customers	Audiogram	€ ● Session	Devices	? Help	
Add	Edit Dele	te Customer export import management				
Cus	stomer r	management	t			
First na	me:			Last na	me:	Birthday:
John				Smith		01.01.1951
Jane				Smith		03.03.1952

Here you can:

- search for a customer
- select a customer as *current customer*
- create or delete new customers
- edit a customer's personal data
- export or import customer data

In Vibrosonic harmonize[®], **all** software actions are executed for the *current customer*, i.e., the last customer selected in Customer management. You can select a customer entry by searching in the **Customer management** customer list, either manually or by using the search screen and marking it by clicking it once.

	J	ohn Sm 🔊
Last name:	Birthday:	
Smith	01.01.1951	

After marking a customer as the *current customer*, an overview of the **customer details** of the *current customer* is displayed on the right of the main window.



For more information on the following functions, see the relevant subchapters of this section:

Add customers

Edit customers

Delete customers

Export/Import customers

Search customers

Add customers

To create a new customer, on the **Customers** tab \Re tab, click the **Add** button \Re .

Enter the required data and confirm your entry with **Save**.

If you click the **Cancel** button, you discard all unsaved changes and arrive back at the main window.

	🕊 John Smith			—	×
	Customer	details			
-	First name:	John	Last name:	Smith	
t	Address:	32 Reading Rd.			
26	Zip code:	B26 3QJ	City:	Birmingham	
16	Birthday:	1/1/1951	Phone:	+44 7871 330 1234	
1	Insurance:				1
	Insurance Status:		Insurance No.:		
		Save		Cancel	

Edit customers

To change customer details, select the customer in **Customer management** and click the **Edit**

button R.

Alternatively, open the dialog by double-clicking the relevant customer entry in **Customer management**.

	🕊 John Smith			— C) ×
	Customer	details			
1	First name:	John	Last name:	Smith	
t	Address:	32 Reading Rd.			
26	Zip code:	B26 3QJ	City:	Birmingham	
	Birthday:	1/1/1951 15	Phone:	+44 7871 330 1234	
1	Insurance:				
l	Insurance Status:		Insurance No.:		
		Savo		Cancol	
l		Save		Cancel	

You can now change the data in the relevant fields and then confirm the changes by clicking the **Save** button.

If you don't want to apply the changes after all, click the **Cancel** button.

Delete customers

If you want to delete a customer's data, select the customer in **Customer management** and click the **Delete** button in the **Customer 's** tab.

A deleted customer cannot be restored!

Export/Import customers

You can import or export customer files using the Import customers A and Export

customers A buttons.

These functions are used to transfer customer and fitting data between hearing aid acousticians, e.g., if your customer's address has changed. All audiograms and fitting sessions available in the database are exported and can be re-imported later.

Important: Please follow all data protection guidelines when passing on customer data. You may not pass on these data without the customer's consent!

To export a customer, click the **Export customers** ¹A button.

The exported customer data is encrypted with a password that you must assign.

Please only use **secure passwords** for this purpose and **only** enter the password **unobserved**, as the input is displayed in plain text!

<u>A lost password cannot be restored! Please remember your password!</u>

To import, click the **Import customers** A button.

After selecting the record to be imported, you are now prompted to enter the password set for the file earlier.

Again, only enter the password unobserved, as the input is displayed in plain text!



After entering the correct password, all the customer's data (customer details, audiograms, session results) is restored from the imported record.

Search customers

To search for a customer, enter the required name in the search screen in Customer

management.

The customer searched for then appears in Customer management and can be selected as the *current customer* as usual by clicking it once.

Q Customers	Audiogram	Session	Devices	? Help			
* <u>A</u> <u>A</u> <u>A</u>	R 1 R 1 R						
Custome	export import r management						
Customer	Customer management						
						John Sm 🔎	
First name:			Last name	e:	Birthday:		
John			Smith		01.01.1951		

Audiogram Management

On the **Audiogram's** tab you find an overview of all the audiograms created so far for the *current customer*. Here you can also:

Add audiograms

Edit audiograms

Delete audiograms

Further information on these functions are found in the relevant subchapters of this section.

Add audiograms





Here you can enter the following audiometric data for the *current customer*:

- AC Air Conduction
- BC Bone Conduction
- DL Discomfort Level

First select the required audiogram type (AC, BC or DT) that you want to edit. You can then add a data point to the active curve or modify existing points by left clicking the relevant frequency on the sound audiogram that corresponds to the required level. To remove a point, right-click the point you want to remove (*Note: The appropriate audiogram type must be selected* – for example, to remove a data point from the AC audiogram, the mode for editing the AC audiogram must be active). One by one, proceed in this way for all audiogram types to be stored.

Typically audiograms display data for the **right ear side** in **red** on the left of the chart and data for the **left ear side** in **blue** on the right of the chart.

To apply the complete audiogram (AC, BC, DT) of one ear side to the other ear side, click the following buttons.



Caution: ALL audiogram data is applied, and existing data may be overwritten.



The audiograms can then be further processed as described above.



It is also possible to remove all the points created of an audiogram by clicking the button.

By clicking the **Save** button, the settings are applied and stored in the database together with the creation date.

To cancel the process without saving, click the **Cancel** button.

Edit audiograms

The **Edit** button can be used to make changes to an existing audiogram from the *current customer*. First select the *current customer* in the Customer management tab and switch to

Audiogram management 🔛 . Select the audiogram to be edited from the history displayed.

Audiogram



Using the Edit button, the audiogram you have selected will be opened for editing.



Editing the audiogram is now possible in the same way as described in the Add section.

Delete audiograms

To completely delete an audiogram, select the current customer in Customer management,

switch to Audiogram management and select the audiogram to be deleted from the history displayed there.

Audiogram

History:

12/18/2020 12/23/2020 3/23/2022



To delete the entry, click the **Delete** or

<u>A deleted audiogram cannot be restored!</u>

Session Management

in the **Session** tab vou can access Session management in Vibrosonic harmonize[®]. Here you can start a new fitting session for the *current customer*. A *session history* is displayed, from which you can obtain information about all previous fitting sessions you have performed with the *current customer*.



Besides the creation date of the session, the hearing systems used, and the correponding serial numbers, you have direct access to the calibration data used in the respective session (**show calibration**). This information will be helpful during communication with Vibrosonic Customer Service in the event of problems.

By clicking the button you can display the final gain settings active after the selected session. This allows you to easily restore previous hearing aid settings if needed or use them for orientation during a new fitting session.

For more information on Session Management, see the following sections:

Start / Add / Display sessions Calibration of the hearing system The fitting window - Automatic first fit The fitting window - General operating functions The fitting window - General operating functions The fitting window - Manual first fit The fitting window - Fine adjustment The fitting window - Fine adjustment The fitting window - Working with programs The fitting window - Setting up automatic program selection The fitting window - Logging The fitting window - Using previous session results or device settings The fitting window - Simulation mode Deleting a session

Start / Add / Display sessions

there are two ways to start a new session for the *current customer*:

- 1) Simply click the **Add** button directly in Session management. You will always do this for new customers.
- Alternatively you can load a previous session performed with the same customer and use it as a starting point for a new session. Select the required session in Session management and select Show:



Session management

ID	Date	Left side hearing aid

You can now review all settings that were active at the end of the selected session. Editing the hearing system's current settings is not possible at this point.



To allow this, click the **New session** button in the loaded session window:

Regardless of how you started the new session, you are now prompted to select an audiogram to use for the new session.

Available audiograms are displayed in a list with the creation date on the right of the window. The most recent audiogram is at the bottom of the list and is preselected.

At this point you can still add a new audiogam to the list using the 📴 button.



Select the required audiogram and click the **Continue** button.

The connection dialog opens. Here you are prompted to select the hearing systems to be used for the new session.

onnect device:		Connect device:	
Vibrosonic alpha HI-PRO	connect	Vibrosonic alpha HI-PRO	connect
r simulate a device:		or simulate a device:	
Simulate		Simul	ate
Right side hearing aid		Left side hearing aid	

In the example, **Vibrosonic alpha** is used for both ears and is connected to the PC via a **HI-PRO** programming adapter.

Note: During an ongoing fitting session, the **Continuous scan** function is **disabled**. If a hearing system is not displayed in the connection dialog despite correct connection of the programming cables, please press the **Refresh** button:



Further information: Only hearing systems are displayed that are either not yet assigned to a customer or are assigned to the current customer selected for the session. Hearing systems already assigned whose left and right sides have been swapped, will not be displayed. If your devices are not listed as required, check for the correct connection, and update the display with the **Refresh** button. (Try this several times, if necessary: After reconnecting the programming cable, it may take a few seconds before the device is detected)

Continue

Now click the **Connect** button to select a hearing system to use during the session. Perform this step for both ear sides, if necessary.

The hearing systems connected now appear in the connection dialog under "Right hearing aid" and "Left hearing aid".

Now confirm your selection with **Continue**.

Calibration of the hearing system

After having started a new session and having selected an audiogram including the required hearing systems, you have now arrived at the calibration dialog. You can now check the calibration of the hearing systems connected and perform recalibration, if necessary. If the hearing system has been calibrated before, the graphic shown presents you with a chart of the hearing aid calibration together with the underlying audiogram data (acoustic audiogram and

calibration audiogram / in-situ audiogram). This graphic can be **saved** and might be useful when communicating with Vibrosonic Support in the event of problems with the device. <u>Note:</u> The acoustic audiogram is not displayed in dB(HL), but in dB(SPL) and therefore differs in the representation of the audiogram previously entered.

A short checklist displays whether the device has been calibrated before, when the last calibration took place, and whether the audiogram used in the session and the audiogram used for calibration match. If this is not the case, a new calibration must be performed before Vibrosonic harmonize[®] allows fitting to be started.

Every device should always be recalibrated if a change in the fit of the Hearing Contact Lens® to the eardrum (coupling) is suspected. This may occur after a check-up with an ENT doctor or if the customer has noticed a general change in sound volume. Therefore, please check this with your customer at each session – Vibrosonic harmonize® will remind you.



By clicking the **Calibrate** button, start the function for calibrating a hearing system by recording an in-situ audiogram (in the following referred to as *calibration audiogram*). Use the arrow keys on your keyboard to navigate, and the space bar to play a sound at the selected level and frequency to determine your customer's hearing thresholds. Please record the thresholds, at least for the frequencies stored in the acoustic audiogram used.

Once a frequency and level has been selected, the corresponding stimulus is played as long as you keep pressing the space bar. The last level played at a particular frequency is stored as a data pointin the calibration audiogram.

Important: In the default setting, loud sounds are at the top of the chart, while quiet sounds are at the bottom. You can change this setting by clicking the button at the left of the chart. Any red areas displayed cannot be selected for safety reasons, as these would lead to levels significantly above your customer's hearing threshold with the Hearing Contact Lens® working properly.

Once you have determined the *calibration audiogram* at least for the frequencies specified in the acoustic audiogram, click the **Save** button.



The software will then run a short test to estimate the feedback path. Please notify the customer that a brief sound will occur, which may be momentarily uncomfortable.

Once the calibration and feedback measurement are complete, the software will show the response of the Hearing Contact Lens[®] as a black line in a chart. Ideally, this line should stay entirely within the green area. The chart will also display the calibration audiogram you entered, along with the reference acoustic audiogram used for comparison.

If the response is not within the green display area, this could indicate that the performance of the Hearing Contact Lens[®] is too low and a warning message appears.

In this case, please check the displayed response carefully and repeat the in-situ measurement, if necessary. If the response remains outside the green display area after renewed recalibration attempts, you should refer your customer to a Vibrosonic-certified ENT doctor to check the correct position and functionality of the Hearing Contact Lens[®].

If the calibration of all hearing systems used in the session has been successful, click the **Continue** button to go to the fitting window.

The fitting window - Automatic first fit

After successfully completing calibration, the fitting window is opened. You are now asked whether you would like to perform an automatic **First Fit**.

Provided you confirm the First Fit, Vibrosonic harmonize[®] will calculate target gains using the fitting formula displayed (here CAMEQ2-HF, in short: CAM2) and optimally adapt the device settings to the formula. Both target curves and fitting results are then displayed in the session window. The last fitting formula used in the fitting window is used here.

Vibrosonic harmonize[®] currently only supports the use of CAMEQ2-HF, as other fitting formulas generally do not specify the high frequency ranges supported by the Hearing Contact Lens[®]. Information on CAMEQ2-HF can be found at:

Brian C.J. Moore, Brian R. Glasberg & Michael A. Stone (2010), Development of a new method for deriving initial fittings for hearing aids with multi-channel compression: CAMEQ2-HF, International Journal of Audiology, 49:3, 216-227, DOI: 10.3109/14992020903296746

Important: The First Fit settings cannot be immediately heard by the customer: You should always check changed settings first and then present them to the customer using the **Preview** button without saving them permanently in the hearing system. Furthermore, the automatic First Fit is performed exclusively in the main program (Program A), since only this program is used by default. No program automation is preconfigured. If you want to configure programs or program automation, you will find information on how to do this in the following sections <u>The fitting</u> <u>window - Working with programs</u> und <u>The fitting window - Setting up automatic program</u> <u>selection</u>.

If you decide not to perform a First Fit , Vibrosonic harmonize[®] will use the settings saved on the device.

The display takes into consideration the latest calibration – gain curves shown may therefore differ from those set during the last fitting session.

The fitting window - General operating functions

The following figure shows a typical display of the fitting window:



Here, Vibrosonic harmonize[®] displays the current gain settings of the hearing systems connected. The hearing systems used are displayed at the top left and top right of the window.

In the lower part of the window the following buttons are found:

Preview:

Changed settings are presented to the customer, but not saved on the device. When the device is restarted, the settings from the start of the session are restored. After changing any setting, this button must always be clicked before the customer can hear the changes.

Finish:

Your selected settings are written to the hearing system's permanent memory, the session ends, and the results of the session are stored in the session history. You are also prompted to specify a location for a PDF fitting report of the session result.

Cancel:

This brings you back to the start page – the device settings from the start of the session are restored. All settings of the current session up to that point, including the calibration performed, are lost.

The **Display** field allows you to switch between different display modes:



You can use the drop-down menu to switch between a display of the Insertion Gain, the Real Ear Aided Gain, or the Frequency Response. These parameters are displayed for input sound pressures of 40, 60 and 80 dB(SPL).

In addition, you can select from the following options:

- First fit target individual target curves calculated from the fitting formula (blue)
- Previous configuration settings saved on the device during the last completed session (purple)
- Loaded session settings from a loaded session (red).

These settings match the "Previous configuration" if the loaded session was also the last session performed with the device.

- Current session settings currently made (green) these settings are presented to the customer as a **Preview** or are written to the device when the session is closed; they are **always** displayed.
- In addition, there is the option to display the maximum possible OSPL 90.
- In addition, there is the option to display the maximum gain before feedback (MGBF) in the Real Aided Gain and Insertion Gain view (orange).

The MGBF graph is only available when a real hearing aid system is connected. Since feedback cannot be measured during simulation, the feedback graph cannot be displayed in simulation mode.

The fitting window - Manual first fit

In the fitting window, you can always manually perform a First Fit for the hearing system's program currently selected .

The fitting formula can be selected from a drop-down menu under "First Fit":

FirstFit —		
CAM2		~
•	•	

However, Vibrosonic currently only supports the CAMEQ2-HF fitting formula.

The First Fit is triggered by clicking the appropriate arrow button (e.g., left arrow to perform a First Fit for the left side only).

Important: The First Fit settings cannot immediately be heard by the customer: You should always check changed settings first and then present them to the customer using the **Preview** button without saving them permanently. Also please note that the First Fit is performed exclusively in the program currently selected.

The fitting window - Fine adjustment

After the First Fit, Vibrosonic harmonize[®] allows you to fine-tune all gain settings of the hearing system To do this, you can configure

- the equalizer
- the settings of the compression stage
- the wideband gain (AGCo)
- <u>FBC</u>
- Noise Reduction

Using the compression channels and AGCo, your are also able to configure the wideband and narrowband output limits of the device.

Equalizer

Individual frequency ranges can be amplified or attenuated in the **Equalizer** tab.



The frequency range can be precisely adjusted in 1dB steps by moving the sliders. The selected frequency range appears in purple in the output level / gain chart.

Several equalizers can be combined into one control (slider) by clicking the **Simple, Medium** or **Complex** buttons.



In the *Complex* mode, Vibrosonic alpha offers 49 equalizer controls.

When switching to *Medium* or *Simple*, 3 or 5 equalizers are combined into one slider, respectively

Compression



Vibrosonic harmonize[®] allows you to set the compression by hovering over a required frequency range using the cursor. The relevant area is then marked with a purple band in the gain/output level chart. At the same time a small window opens, in which the input/output curve of the compressor is displayed. The sliders allow you to directly shift the knee points of the compression as well as the gain for high and low levels. Also, it is possible to enter the corresponding values directly into the table.

The Compression tab allows you to set the maximum output levels of the hearing system. Simply enter the required values in the fields marked with **MPO**. Please note that the values of the MPO setting indicate the attenuation as compared to the maximum output level technically possible. Accordingly, the input of negative values is expected here. You can see the effects of your settings from the corresponding output SPL graph and the greyed-out area displayed, which represents the current level limit. During first fit a starting configuration for **MPO** is automatically applied.

AGCO

In the AGCo tab, you can configure Wideband Gain and a wideband level limit (Output Limit),

in addition to frequency band related settings of gain and maximum level. During first fit a starting configuration for the **Output Limit** is automatically applied.

Wideband Gain	0 dB	
Output Limit	0 dBFS	

FBC

In the **FBC** tab, you can start a feedback measurement for the connected hearing aid system, separately for the right and left side. This measurement is used to estimate the feedback path. Feedback cancellation can be turned on or off. During the first fit, feedback cancellation is automatically turned on if needed. This is the case, if the target amplification is higher than the estimated feedback path. You can set the feedback cancellation individually for each hearing aid program.



Noise Reduction

In the **Noise Reduction** tab, you can turn the function on or off for the connected hearing aid system, separately for the right and left side. You can choose how much background noise should be reduced using the **Maximum Reduction (dB)** setting. Noise reduction can be configured individually for each hearing aid program.

The **Reduction Rate (dB/s)** controls how quickly the system reacts to changes in background noise. This setting applies to all hearing aid programs.

During first fit a starting configuration for noise reduction is automatically applied.



The fitting window - Working with programs

Vibrosonic harmonize[®] offers basic functions to assign different gain settings to different hearing aid programs and to configure an automatic program selection mode. This function is disabled in the start-up settings of Vibrosonic hearing systems – by default only one hearing

aid program is assigned. To assign additional programs besides the main program (*Program A*), for example *Program B*, first select it in the program selection menu (see following figure).



Important: Make sure that you have presented any changes made in the previous program to your customer using the Preview button – otherwise it is not possible to switch programs. This is in your customer's interest, as the current session settings for the selected program are automatically enabled on the device when switching programs.

To perform First Fit and fine adjustment, you can then proceed as previously described for the main program. Once your customer is satisfied with the program's gain settings, the next step is to define how the program is to be used: If the customer is to be able to access the program manually by using a button on his hearing system you must select the **Enable program** setting for this program (see following figure) – otherwise the program cannot be accessed manually.



If you want the program to be used exclusively by the device program automation, remove the relevant tick, and set up program automation. However, programs can also be manually accessible and used by program automation at the same time.

Note: If intermediate programs are disabled, they are simply skipped when the program selection switch is clicked. Example: If Program B is disabled, but Programs A and C are enabled, the device jumps from Program A to Program C when the program selection switch is clicked.



The fitting window - Setting up automatic program selection

To set up program automation, first select the **Programs** button.

Now select the program in which your customer would like to start program automation. If you select *Program A*, program automation is started as soon as the customer switches to this program for example. **Important:** The program selected for this purpose must be enabled for manual selection (*Enable program*).

Then select how the program channels of the hearing system are to be assigned to the different surroundings that the program automation can distinguish. These are:

- o Quiet surroundings
- Noisy surroundings
- o Speech
- Speech with background noise
- o Music
- Windy surroundings

The following figure shows a setting in which program automation is enabled by calling up *Program A*. Gain settings stored in *Program A* are used in *quiet surroundings* as well as for *speech*, *whereas* switching to *Program B* only takes place in *noisy surroundings*. It is possible, but not necessary, to also switch *Program B* to manually selectable using the **Enable program** option.

Equalizer Compression AGC	O Programs Logging						
Automatic program launch	Automatic program Jaunch Program A Vitomatic program control						
, laterine program lateri		Quiet enviroment	Program A 🗸	Speech in noisy enviroment	None	~	
Start delay	20 c	Noisy enviroment	Program B 🗸	Music	None	~	
	50 5	Speech	Program A 🗸	Windy enviroment	None	~	
			New session	Cancel	review Finish		

Start delay controls the minimum time that should elapse after enabling the automatic program before the first program switch takes place.

The fitting window - Logging

In the *Logging* tab you can use the *Load long term log* button to see how long a connected device has been used and how long it remained in a particular hearing aid program.



To generate the relevant data, the logging function must be enabled by placing the relevant tick (see the following figure). The function can be disabled by removing the tick.



The following figure shows an example of the long-term log display.

The usage time per program is displayed in the format **TT.hh:mm:ss** (days.hours:minutes:seconds).



To reset the count to zero, use the **Reset log data** function.

By changing the **Logging interval**, you can define how often the device checks which program it is currently in. This allows you to influence the period over which the measurement data can be stored.

The fitting window - Using previous session results or device settings

If you have used a hearing system for the session that has been fitted before, in the current session you can easily restore the results of the last session performed with the device, even after the device has been recalibrated. Similar to a manual First Fit, you can automatically adjust the session settings to the previous device configuration under **Generate device parameters** by clicking the *purple* arrow button.

Generate device parameters					
•	•••	•			
-	••				

If you have loaded a previous session prior to starting a new one, you can reset the gain settings of the current session to those of the loaded session by clicking the *red* arrow buttons.

The colours of the buttons correspond to those of the gain curves for which the settings are to be adjusted.

The fitting window - Simulation mode

To start a session in simulation mode, start a new session and select an audiogram as usual. In the connection dialogue that opens next, do not click on "Connect", but select the "Simulate" button for the required wearing side instead.

	e	_	\times
Select a hearing aid	for this session		
			L
	Connect device:		
0			
U			
	or simulate a device:		
	Simulate		
	Left side hearing aid		

From the list opened, select the required device and click **Simulate** once more. Perform this step for both ear sides, if necessary.

or simulate a device:	or simulate a device:
Simulate	Simulate
Right side hearing aid	Left side hearing aid
Vibrosonic alpha Simulation	Vibrosonic alpha Simulation
	Continue

The simulated devices are now displayed as hearing systems selected for the session. You can work with them as usual except that the calibration function inlcuding the feedback measurement and the MGBF graph are not available.

Deleting a session

To **delete** a session of the *current customer* from the session history, select the corresponding



Session management

5				
ID	Date	Left side hearing aid	Right side hearing aid	
12	3/25/2022 5:52 PM	Vibrosonic alpha (SN: 4202666) L	Vibrosonic alpha (SN: 4211734) R	show calibration
13	4/2/2022 12:43 PM	Vibrosonic alpha (SN: 4202666) L	Vibrosonic alpha (SN: 4211734) R	show calibration
14	4/2/2022 1:03 PM	Vibrosonic alpha (SN: 4202666) L	Vibrosonic alpha (SN: 4211734) R	show calibration

The **Devices** tab **%** displays all hearing systems available in Vibrosonic harmonize[®]. This list can be refreshed using the **Scan Library** button

Help / Updates

In the **Help** area **?** you can access help on how to use Vibrosonic harmonize® as well as the

hearing systems fitted with the software.

The following information and functions are available:



Furthermore you can find the version identifier of your installation of Vibrosonic harmonize® right below the Vibrosonic logo.

<u>Update</u>

Update

When started, Vibrosonic harmonize® automatically checks if updates are available and offers

to install them as appropriate. You can also run the check manually under the Help tab 😗.