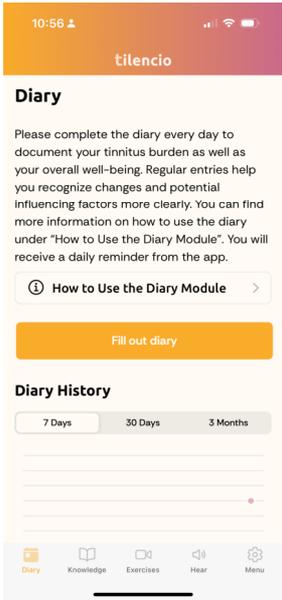
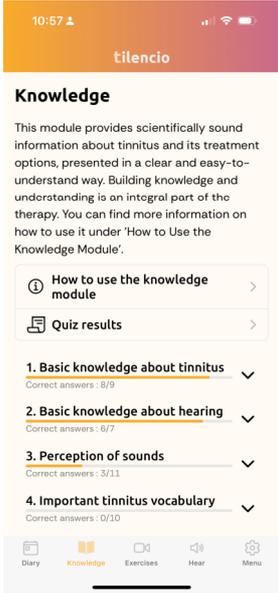
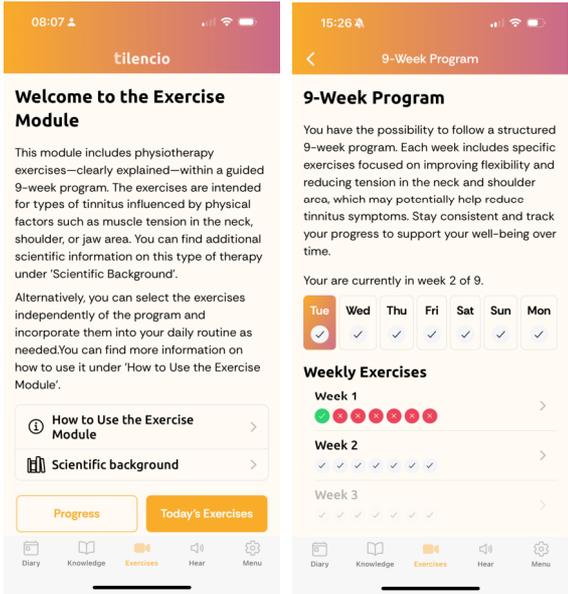
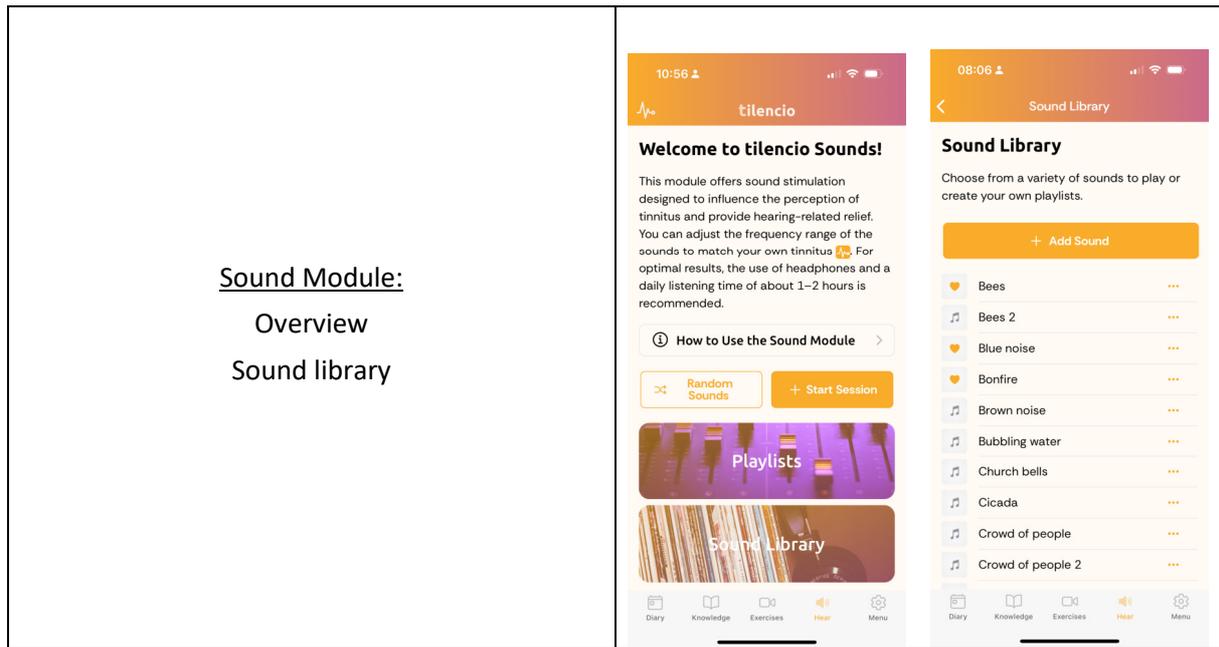


Instructions for Use

TILENCIO

<p><u>Start screen</u></p>	
<p><u>Diary Module</u></p>	

<p style="text-align: center;"><u>Knowledge Module</u></p>	
<p style="text-align: center;"><u>Exercise Module:</u> Overview 9-Week Program</p>	



Sound Module:
Overview
Sound library

These instructions were put together with great care. If you should still find details here, which do not agree with how the system is handled, we would appreciate it if you let us know so that we can correct the discrepancies as quickly as possible.

Should there be a serious incident or undesirable side effects during handling and use of the product which are not specified in these instructions for use, please report these to us with a detailed description of the incident or side effects. Please use the contact details below for this purpose.

The specifications and figures in this user manual are subject to change due to optical or further technical developments.

All trademarks named and shown are trademarks of the respective proprietor and are recognized as being protected.

Reprinting, translation and duplication - even of excerpts – require the written permission of the manufacturer.

Information about the product and the manufacturer



Product name: silencio

A product of be-on-market GmbH

Lilienstrasse 33

91244 Reichenschwand

Germany

Version of these instructions for use

Document Version 03, dated 02.02.2026

The version of the instructions for use can also be found elsewhere in the instructions for use, e.g. in the footer.

Applicable software version

These Instructions for Use apply to software version 01.01.

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1. Scope of Delivery

1.1 Standard Scope of Delivery

Part/Trade Name	Description	Part/Order Number
tilencio	Mobile stand-alone software	

Table 1.1: Standard Scope of Delivery

There are no accessories, replacement parts or consumable parts needed for the use of the device.

2. Product Description

2.1 Intended Purpose

tilencio is a mobile stand-alone software designed for users with tinnitus symptoms. The symptoms of the condition are monitored through questionnaire-based documentation and treated using various recognized therapeutic methods. Additionally, the user is provided with information to learn more about the condition and potential self-management techniques.

2.2 Intended Patient Population

tilencio is intended to be used by adults (18+ years) with chronic subjective tinnitus.

2.3 Medical Indications

tilencio is intended to be used by persons with chronic subjective tinnitus.

2.3.1 Contraindications

To date, there are no known contraindications for the use of **tilencio**.

2.4 Intended User

tilencio is intended to be used by humans with tinnitus symptoms. The user is a lay person.

2.5 Intended Use

2.5.1 Intended place of operation

tilencio is a mobile application and can be used anywhere, for example at home, outdoors or at work.

2.5.2 Intended use environment

There is no specific use environment, as the device is a software product.

2.5.3 Intended body site of application

There is no specific body site of application, as the device is a software product.

2.5.4 Intended duration and intended frequency of use

There is no general limit for the intended duration or intended frequency of use.

Diary module: There is no limit for the duration of use or intended frequency of use of this module.

Hear module: There is no limit for the duration of use or intended frequency use of this module.

Knowledge module: The intended frequency of use is one lesson per day over 12 weeks. After 12 weeks the user can still work with the knowledge module.

Exercise module: The intended frequency of use is 3 exercises per day over 9 weeks. After 9 weeks the user can still use the exercise module.

2.5.5 Precautions/Warnings

Hear module:

Volume warning:

Pay attention to the set volume, protect your ears from loud sounds. Listen at no more than 85 decibels (dB), which corresponds to average street noise.

2.6 Clinical claims

Claim	Linguistic Variations
<i>Symptom relief in general</i>	
Reduction of tinnitus burden	<ul style="list-style-type: none"> - tilencio is a medical smartphone app for the treatment of chronic tinnitus that reduces tinnitus stress and enables patients to better manage the condition. - Reduction of tinnitus burden - tilencio: The digital solution for tinnitus relief - Digital solution for alleviating tinnitus burden
Fast reduction of tinnitus burden	- Reduction of tinnitus burden possible after just 6 weeks
<i>Knowledge Module</i>	
Significant reduction of tinnitus symptoms by using the Knowledge Module	- Better comprehension will help patients to better cope with tinnitus burden.
<i>Hear Module</i>	
Significant reduction of tinnitus symptoms by using the Hear Module	
<i>Exercise Module</i>	
Up to 30% of all tinnitus cases are attributable to somatic or somatosensory causes.	- Up to 30% of all tinnitus symptoms have somatic causes
Significant reduction of somatosensory tinnitus burden	- The Exercise Module provides physiotherapeutic exercises designed to help reduce tinnitus symptoms, particularly those related to somatic causes.
<i>Combination of multiple therapies</i>	
Greater and/or faster reduction of tinnitus burden through the combination of different therapies.	<ul style="list-style-type: none"> - Scientific studies show that combinations of different forms of therapy achieve significantly better results than single therapy approaches - Fast and greater reduction of tinnitus stress through a combination of different therapies
<i>Combination with Hearing Aids</i>	
Combination with Hearing Aids possible	- The app can be optimally combined with hardware solutions such as hearing aids

Claim	Linguistic Variations
	- Reduction of tinnitus burden

2.6.1 Non-clinical Claims

Claim	Linguistic Variations
<i>Data Protection</i>	
High data protection standards	<ul style="list-style-type: none"> - Data protection is our top priority. All personal and medical data is always transmitted between the server backend and the app in encrypted form and stored in encrypted form - Your data stay your data. Data protection is a top priority for us. All personal and medical data between server backend and app is transferred encrypted and stored encrypted and never leaves the tilencio application. We do not sell or trade your data.
<i>Multilingual</i>	
tilencio is available in at least 8 languages.	<ul style="list-style-type: none"> - tilencio is the only certified tinnitus app in Germany available in 8 languages. More languages will be available in the future. - tilencio is currently available in eight languages: German, English, French, Spanish, Dutch, Greek, Italian and Turkish. More languages will follow shortly.
<i>General</i>	
<p>tilencio - the affordable digital solution for tinnitus*</p> <p>* compared to benchmark products</p>	<ul style="list-style-type: none"> - With tilencio, we are launching the most comprehensive tinnitus app with a compelling price/performance ratio in the market for digital health applications. - tilencio offers the most comprehensive therapy approach of all tinnitus apps
tilencio is a medical device	<ul style="list-style-type: none"> - tilencio is an approved class IIa medical device. - tilencio is a CE certified device.
tilencio - the most comprehensive digital, solution for tinnitus relief	

Claim	Linguistic Variations
<i>Sound Module</i>	
More than 50 natural and synthetic sounds are included.	
Adjustable sound frequency	- Sounds are adjustable to your individual tinnitus frequency
<i>Diary</i>	
Self-Awareness and Symptom monitoring	<ul style="list-style-type: none"> - Keep track of your personal tinnitus burden. A short questionnaire will assist you every day to capture your individual perception of your tinnitus and how it develops over time. - Keep track of symptoms, potential triggers and spot trends over time. - The Diary module is designed to help you track your tinnitus symptoms and general well-being on a daily basis. - Answering daily questions helps to reflect on your condition and identify patterns or triggers (e.g., stress, noise exposure, sleep quality). - It builds awareness around how lifestyle or environment affects your tinnitus, which is key for self-management. - Better understanding of the effectiveness of treatments or interventions. - The Diary module can serve as a valuable tool for observing and managing your tinnitus symptoms over time.

2.7 Functional Description

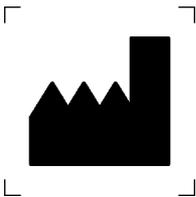
tilencio is a medical device designed to support individuals suffering from tinnitus by alleviating symptoms through a structured and interactive approach. The application incorporates multiple modules, each serving a specific function in tinnitus management.

Modules and their Functions

- **Diary Module (“Diary”)**: This module has no clinical relevance. It allows users to document their tinnitus-related experiences by answering structured questions. Users can revisit past diary entries and track their symptom progression over time. A graphical representation of tinnitus intensity helps visualize patterns and changes, assisting in better symptom management.
- **Knowledge Module (“Knowledge”)**: This module provides structured psychoeducational content on tinnitus through a **12-chapter program**, designed to be completed over **12 weeks**, with **one lesson per day**. Each chapter contains **seven lessons**, covering different aspects of tinnitus management. At the end of each chapter, users complete a **quiz** to reinforce their understanding. These quizzes can be taken **multiple times**, and users receive **feedback** to support their learning. The module is designed to improve understanding of tinnitus and enhance coping strategies. The content has been reviewed by medical professionals to reflect the current state of research and ensure up-to-date scientific validity.
- **Listening Module (“Hear”)**: This module provides various soundscapes that users can play to help manage tinnitus symptoms. It includes nature sounds, everyday sounds, and customizable audio options. Users can create and manage personal playlists, add and remove sounds, and play them in an endless loop for continuous relief. The ability to import custom sound files further enhances personalization.
- **Exercises Module (“Exercise”)**: This module offers structured exercises designed to help alleviate tinnitus symptoms. Each exercise is accompanied by a video demonstration for guided practice. Additionally, a structured **nine-week program** allows users to track their progress easily. Users can restart the program at any time to continue their tinnitus management journey.

tilencio is available in several languages, allowing users to choose their preferred language. The app includes an easy-to-use **language switch feature**.

2.7.1 Labeling

Symbol	Significance
	<p>Company logo and trademark</p>
	<p>Manufacturer name and address Supplementary see EN ISO 15223-1</p>
	<p>Medical Device Symbol Indicates that the product in question is a medical device</p>
	<p>UDI-Symbol displays a carrier containing information about a unique product identification Consists of: (01) <UDI-DI><product name> (8012) <Software version></p>
	<p>CE label for Class II products, the quarter-digit identification number of the involved Notified Body is indicated</p>

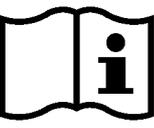
Symbol	Significance
	<p>The inspection of the accompanying documents is a binding act for this medical device.</p> <p>Supplementary see EN 20417</p>
	<p>Warning</p> <p>(Warnings have their origin in risk assessment. They are necessary to draw the user's attention to residual risks or sources of danger. All warnings are listed in Chapter 3 below each other.)</p>

Table 2.1: Labelling

3. Safety Instructions

Read these instructions for use carefully. They are part of the device and have to be available at all times. Do only use the device for the intended purpose described in this document (see chapter 2.1).

For your own safety and according to the requirements of the Medical Device Regulation, please observe the following:

WARNING: Important safety or performance information or immediate response from operator required.

CAUTION: Other important information with or without the need of operator response.

3.1 General remarks

Hint	<p>Internet connection:</p> <p>The app requires an active internet connection.</p>
------	--

Table:3.1: General remarks

3.2 Operation of the Device

Hints	<p><u>Resetting the 9-week program in the Exercise module:</u></p> <p>How to use the Exercise Module:</p> <p>Please note: this action will permanently delete all current progress and cannot be undone or restored.</p> <p>Settings:</p> <p>Deleting and resetting will erase all your progress in the 9-week exercise program.</p>
-------	---

	<p>Delete Account:</p> <p>Deleting your account is permanent and cannot be undone. All of your data will be removed, and you will lose access to your account.</p>
	<p>Volume Warning:</p> <p>Pay attention to the set volume, protect your ears from loud sounds. Listen at no more than 85 decibels (dB), which corresponds to average street noise.</p>

Table 3.2: Operation of the Device

3.3 Side Effects and Contraindications

There are currently no known side effects in relation to the device.

There are currently no known contraindications in relation to the device

4. Initial Operation

4.1 Installation

Download the app from the official app store and install it on a compatible mobile device. See chapter 6 Required Equipment for compatible mobile devices.

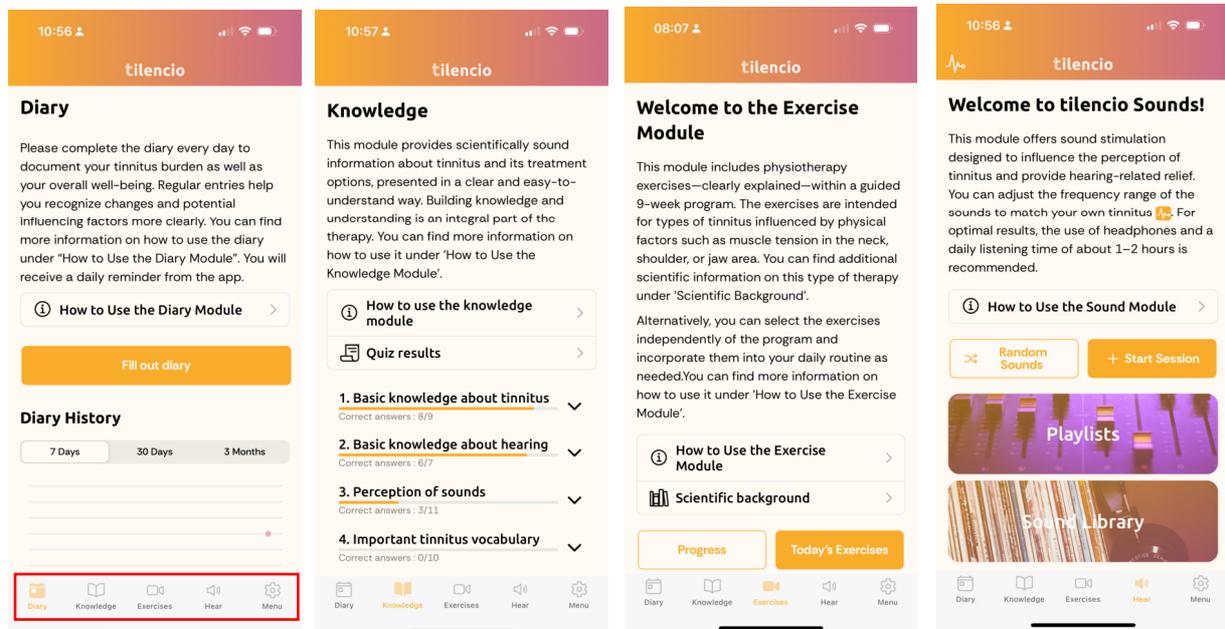
4.2 Configuration

Registration: Create a personal account with your mail address and a password and select a preferred language.

License: Enter your license key to use all the modules of the application.

5. Operation

The app consists of four modules: Diary, Knowledge, Hear, and Exercise. Each module offers a specific function to support tinnitus management—ranging from daily symptom tracking, psychoeducational content, and therapeutic soundscapes to guided exercises. The user can interact with the modules individually or in combination, depending on personal preferences and needs.



The menu bar at the bottom of the screen shows which different modules are available for selection. Clicking on the respective symbol takes you to the relevant module.

There is also a settings menu where you can view and permanently delete your profile, change your password and adjust your settings.

5.1 Module "Diary"

Document tinnitus-related experiences and track progression with graphical visualizations.

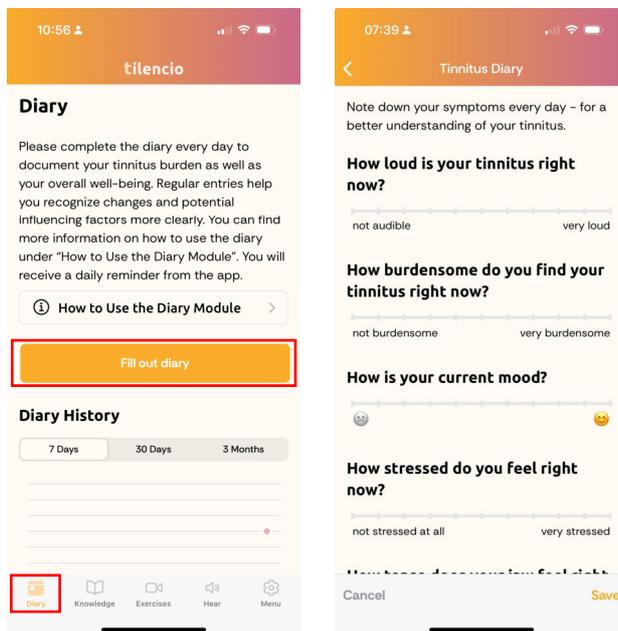
How to Use the Diary Module

The Diary module is designed to help you track your tinnitus symptoms and general well-being on a daily basis. Here's how to make the most of each feature:

1. Complete Your Daily Entry

You can create a new diary entry at any time to record how much your tinnitus is currently affecting you and how you feel. To do this, click on the *Fill out diary* button. When you have finished filling in the entry, tap on *Save* at the end of the page. Regular daily entries help you to better recognize changes over a longer period of time. If you wish, you can give each entry its

own name at the end of the diary entry – this makes it easier to find specific situations or events later on.

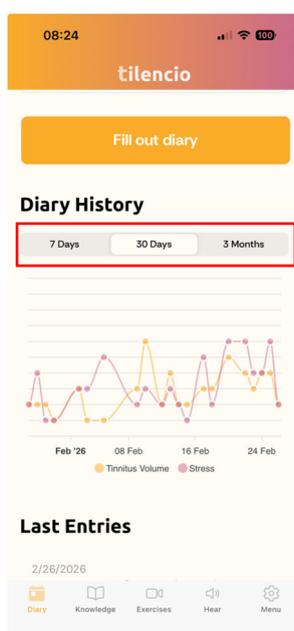


2. View Past Entries

All your diary entries are saved in a list at the bottom of the page. You can scroll through this list anytime to review how your symptoms and experiences have changed over time. If necessary, individual entries can also be deleted.

3. Track Trends with the Chart

The Diary module contains a chart displaying trends in your tinnitus volume and stress levels. This chart updates with each new entry, offering an overview of how these parameters develop over time. You can view the history over 7 days, 30 days, or 3 months by clicking on the corresponding tab above the chart. Reviewing this chart can help you identify possible triggers or



patterns. If you have made several diary entries on a single day, the chart will show the average value of the individual entries.

4. Daily Reminders

To help you keep up with regular entries, you can set up notifications once a day at times that work best for you. You can customize the time of the reminder in the app settings under *Notifications*. Please allow notifications in your smartphone's system settings so that this feature can be activated.

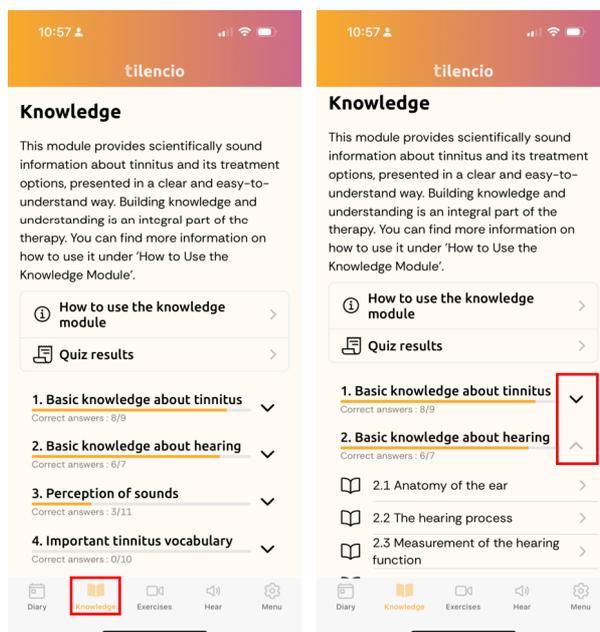
5.2 Module “Knowledge”

How to Use the Knowledge Module

The Knowledge Module is designed to help you better understand your tinnitus and cope with it more confidently in everyday life. Its content is an important part of the treatment, guiding you step by step through reliable, easy-to-follow information.

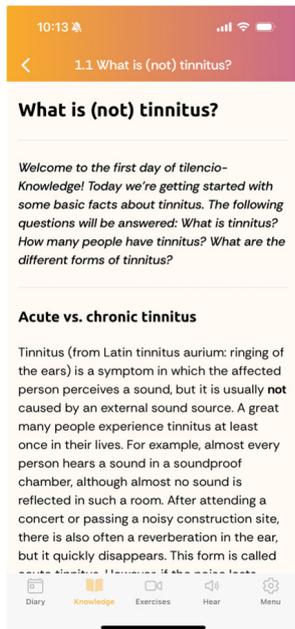
1. Overview

The module consists of 12 chapters, each containing 7 lessons. To view the lessons in a chapter, tap on the arrow icon to the right of the chapter name. This will expand the section and display all 7 lessons. You can close the chapter view again at any time by clicking the arrow once more. You can work through the lessons at your own pace. A steady routine—such as completing one lesson per day—is recommended. This way, you can finish each chapter within a week.



2. Working Through Chapters and Lessons

Read the lessons in each chapter in order. Each lesson is clearly structured and focused on the essentials, making it easier to understand and absorb the material.



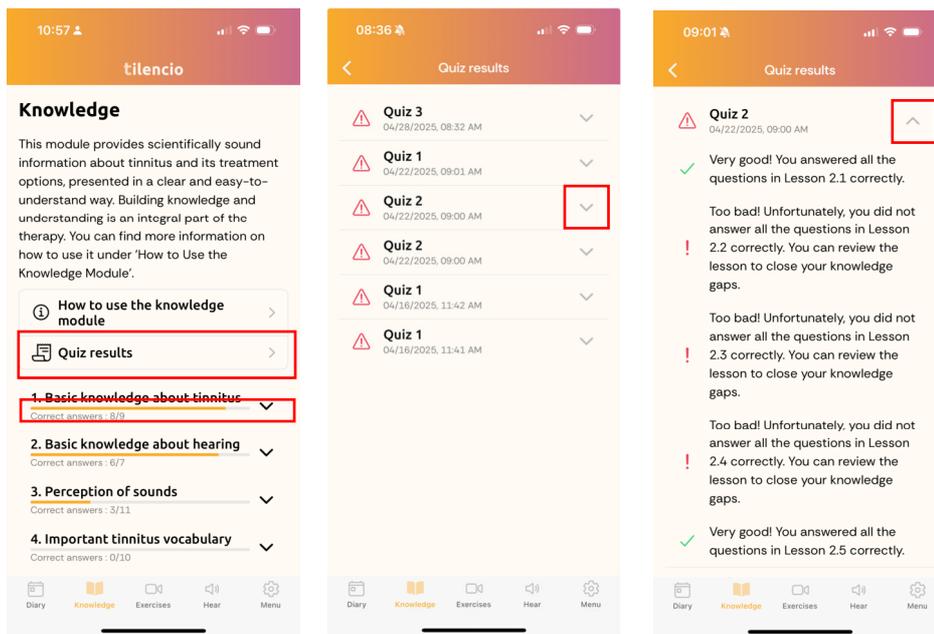
3. Chapter-End Quiz

At the end of each chapter, you will find a short quiz. It helps you to check what you have learned from the chapter. The results are for your own guidance only—there is no minimum score required. Once you've completed a quiz, the next chapter will be unlocked. You can repeat any quiz as often as you like if you want to refresh your knowledge.

4. Progress and Quiz Results

Below each chapter, a bar shows how many quiz questions you answered correctly. This overview can help you decide whether you want to review a chapter again. You can find all complete quizzes under *Quiz results*. There you can revisit individual results later or delete them if needed. The results are sorted chronologically, with the most recent at the top.

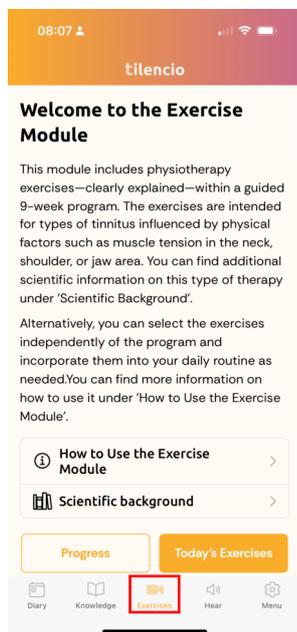
To see more detailed feedback on your performance, tap on the arrow next to a quiz result. This expands the view to show which topics you answered correctly and where there may be room for improvement. Click the arrow again to collapse the view.



5.3 Module “Exercise”

How to Use the Exercise Module

The Exercise Module supports you with physiotherapy-based movements that are commonly used when tinnitus is influenced by muscular factors. It’s designed so you can explore the exercises flexibly and at your own pace. The following features are available:



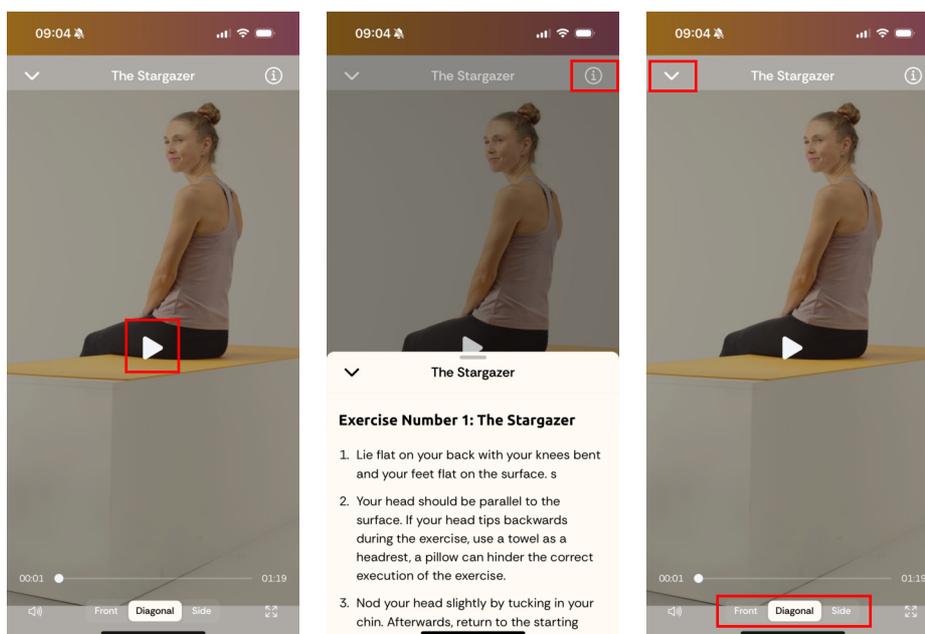
1. Access to all videos

All available exercises are clearly listed at the bottom of the menu page. You can select and watch each video individually - depending on your needs, symptoms, or personal preference.

2. Using the exercise videos and video player

The video player includes several features to make learning the exercises easier:

- **Play and pause**
Tap the play or pause button in the center of the video. If you tap anywhere on the screen again, the button will disappear; tap once more to bring it back.
- **View step-by-step instructions**
Tap the info icon (“i”) in the top right to open the detailed written guidance for each exercise. You’ll find all movements clearly explained, so you can perform the exercise correctly even without the video.
- **Turn sound on or off**
Tap the speaker icon in the bottom left to enable sound or mute it.
- **Switch perspectives**
At the bottom of the screen, you can choose different viewing angles (*Front*, *Diagonal*, *Side*). This allows you to watch the exercise from the perspective that makes it easiest to follow.
- **Close the video**
To exit the video, tap the downward arrow in the top left corner of the screen.

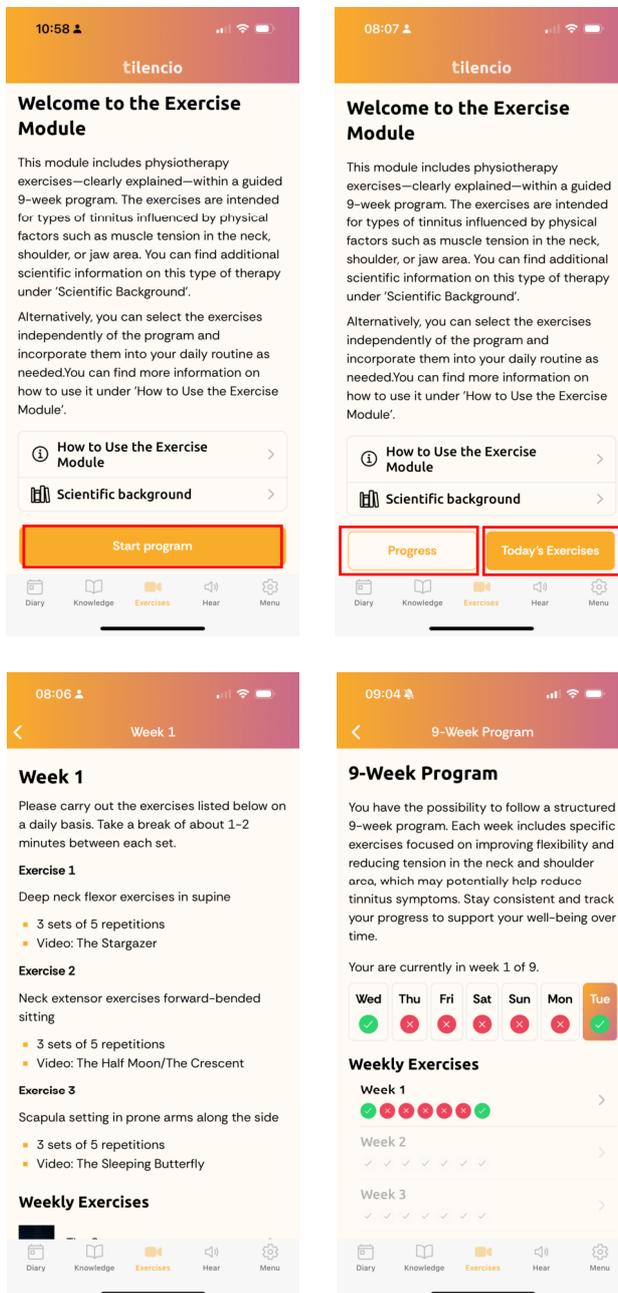


3. The 9-week program

A recommended 9-week program is available to help you structure your training. It guides you week by week with selected exercises designed to systematically support your progress.

- **Start the program**
Tap *Start program* to begin the structured training. The program will guide you through the planned weeks and exercises in a clear sequence.
- **View today’s exercises**
In *Exercises today*, you’ll see the exercises scheduled for the current day. Once you’ve completed them all, tap *Exercises completed* at the bottom of the page so your session is saved and correctly reflected in your progress.
- **Check your progress**

Tap *Progress* at any time to see which week you're in and which days you've already completed exercises. This overview helps you stay consistent and keep track of your training routine.

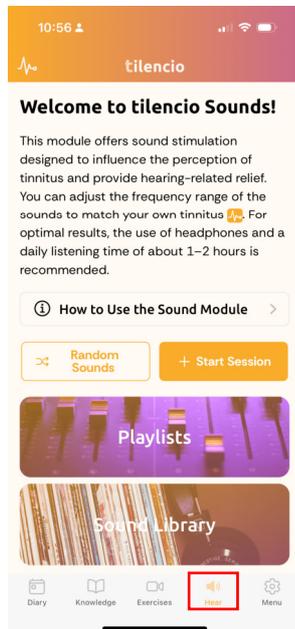


- **Reset the program**

If needed, you can restart the program at any time. You'll find this option in the app settings under *Exercises*, which will take you back to Week 1. Please note: This action will permanently delete all current progress and cannot be undone or restored.

5.4 Module “Hear”

Play therapeutic sounds, create and manage playlists, and import custom audio files.

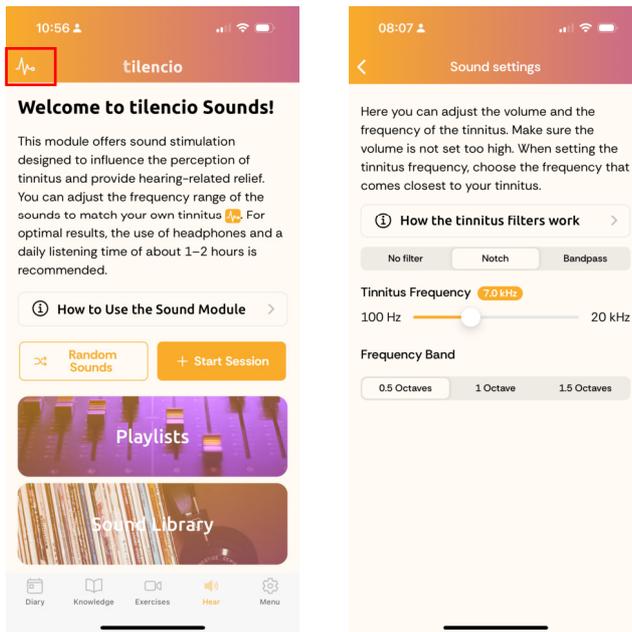


How to use the Hear module

tilencio Sounds offers you various options to use audio to support your tinnitus management. You can use both pre-made sounds and your own and organize them to suit your preferences. The most important functions at a glance:

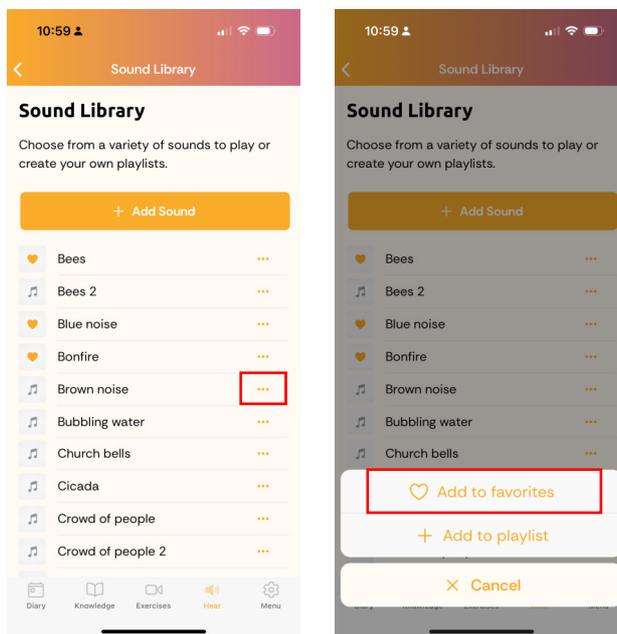
1. Set tinnitus frequency

Using the frequency icon in the top left corner of the screen, you can tailor audio playback to the (estimated) frequency range of your tinnitus. Use the slider to set your tinnitus frequency, select the desired frequency band, or switch the adjustment off entirely if needed. The frequency can also be adjusted at any time in the player itself if you want to make fine adjustments while listening.



2. Sound library

The Sound Library contains all sounds currently available in the app. You can play any sound directly or call up additional options via the three dots.



3. Sound Session

Tap *Start Session* to begin a guided sound therapy session. You'll be asked two short questions about your current tinnitus condition. After answering, you can choose a sound from the list and begin playback.

Once you close the sound player, you'll again have the option to answer follow-up questions to reflect on your listening experience.

4. Manage favorites

Mark frequently used sounds as favorites to find them more quickly. You can do this either directly in the audio player using the heart icon, or in the sound library via the three dots (*Add to favorites*). Favorites can of course be removed again: Tap the three dots next to the sound and select *Remove from favorites*.

5. Add your own sounds

You can upload additional sounds from your phone into the app. To do so, tap *Add sound* in the Sound Library and select a suitable file. (*Supported file formats: m2a, m3a, mp2, mp2a, mp3, mpga*)

6. Create and manage playlists

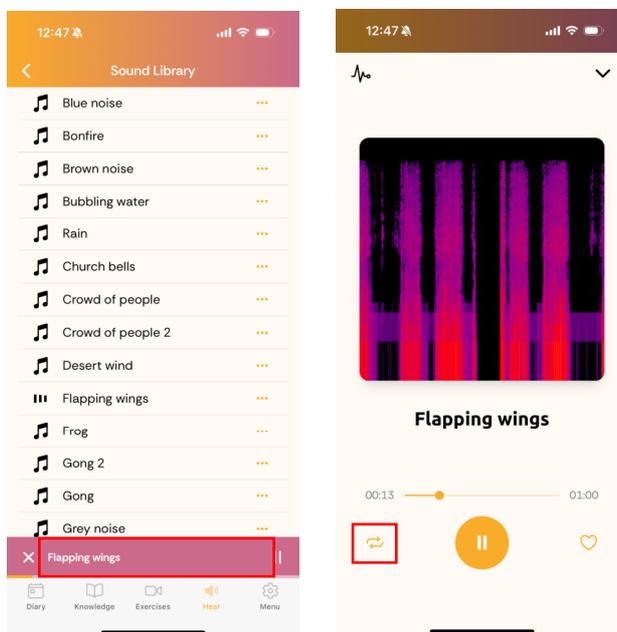
In addition to the pre-made playlists, you can create your own:

- Tap *New playlist* in the playlist's menu
- Enter a name and confirm with *Create*
- Within the playlist, tap *Add sounds* to select any sounds you like

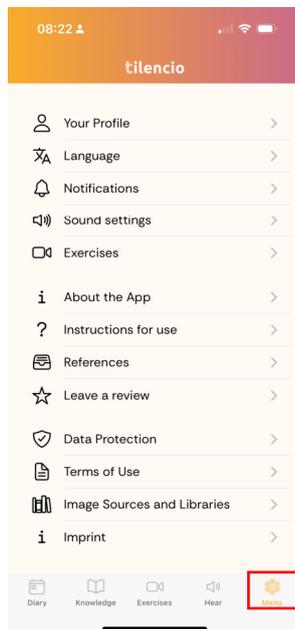
You can rename or delete playlists at any time if you no longer need them. Simply open the playlist and tap the three dots in the top right corner.

7. Loop a sound continuously

In the player, you can play sounds on a continuous loop. Open the audio player in full-screen mode by tapping it in the center. The endless loop is activated by tapping on the symbol with the two circular arrows at the bottom left.



5.5 Settings



1. Your Profile

In *Your Profile*, you can:

- Edit your first name and last name
- Enter and activate a new licenses key if your license has expired
- Change your password by tapping on *Change Password*
- Delete your account permanently

Please note: If you choose to delete your account, all saved progress and personal data will be lost and cannot be restored.

2. Language

Here you can change the app language by tapping on the desired language. tilencio is available in eight different languages, and you can change your preference at any time.

3. Notifications

In *Notifications* you can:

- Enable or disable notifications (must be allowed in your device's system settings first)
- Set the time for a reminder, helping you stay on track with diary entries or exercises.

4. Sound Settings

Within the *Sound Settings* you can:

- Adjust your tinnitus frequency
- Modify the frequency band to further personalize your sound therapy experience

5. Exercises

Here you can reset the 9-week program.

Please note: Resetting the program will permanently delete your progress, and it cannot be recovered.

6. Instruction for Use

The Instruction for Use is available directly in the Settings menu. Here, you can access detailed guidance on how to use each module and feature of the app.

6. Required equipment

To use silencio, you need an internet-enabled smartphone with the operating system Apple iOS 14.0 or higher or Android OS 5.1 or higher.

Also, internet access is required, and an e-mail address is needed for the registration of a user account.

7. Malfunctions and their Removal

Malfunction	Cause of the malfunction	Removal of the malfunction
User not able to login	Not registered yet	Create an account with your credentials (e-mail address and password)
User not able to login	Wrong credentials	Make sure to use the correct credentials (e-mail-address and password)
User not able to login	Forgot password	Please contact us via email: support@healthstudyclub.de
Fill out diary not possible	Diary already filled out	You can only make a diary entry every 7 hours; you can change your current entry by clicking on "Edit entry" or wait until 7 hours have passed since the last entry and fill out a new entry.
Functions cannot be used	License has expired	Renew your license in the settings (Your Profile → License)

If you have any technical questions, please contact us by email: support@healthstudyclub.de.

8. Maintenance/Disposal

8.1 Maintenance

No physical maintenance is required. Keep the device on which the app is installed updated and in good working condition. If your mobile device gets lost or you choose to switch the mobile device, you can login into your account with the same credentials. Your license is linked to your account and remains valid even if you change devices. Please note: Only the diary entries are saved under your account. You will lose your individual settings, your progress and your personal sounds.

8.2 Putting out of Operation and Disposal

The account can be deleted within the settings in the menu.

The app can be uninstalled at any time. No special disposal conditions apply.

9. Declaration of Conformity

Declaration of Conformity

(according to Regulation (EU) 2017/745 on medical devices, annex IV dated May 2017)

be-on-market GmbH
SRN: DE-MF-000006151
Lilienstraße 33
91244 Reichenschwand
Germany

declares under its sole responsibility that the product

Basis-UDI-DI: 426067671_HSC_tilencio_JR

tilencio

Intended Purpose:

tilencio is a medical device software designed to support individuals suffering from tinnitus by alleviating symptoms through a structured and interactive approach.

UDI-DI: 4260676710436

Valid for software version: 1.x

Valid until: Next major release

to which this declaration relates is in conformity with the following regulation:

Evaluation procedure according to Regulation (EU) 2017/745 on medical devices, annex IX and related laws.

Classification according to Regulation (EU) 2017/745 on medical devices, annex VIII:

Standalone software class IIa according to classification rule 11

This product has been CE-labelled due to the fulfilment of the general safety and performance requirements according to Regulation (EU) 2017/745 on medical devices, annex I.



TÜV SÜD PRODUCT
SERVICE GMBH
Ridlerstraße 65
80339 München,
Germany

be-on-market GmbH, Stefan Bolleiningger, Digital, Unterschrieben von

Stefan Bolleiningger

Datum: 2025.04.07 11:19:46

tilencio_Declaration of Conformity_20250407

01_00_002_Declaration of Conformity_V01

Printed version is not subject to change management. Always use the up-to-date document.

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be-on-market GmbH
Lilienstrasse 33
91244 Reichenschwand
Germany

IMPORTANT!

In the event of serious incidents in connection with the use of the product, you must inform the manufacturer and the responsible authority.