SilentCloud

Operating instructions for the SilentCloud v1

English

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician, audiologist or other hearing healthcare professional.

CE 0123

Table of Contents

Introduction

Welcome to SilentCloud!

We have compiled a large portfolio of different tinnitus evaluations and therapies into a single system for you.

You will have access to 17 modules of education and counseling, which you will receive in 15-20 minutes.
Then we offer you 40 modules of cognitive behavioral therapy (iCBT).

The iCBT sessions provide a lot of useful information, counselling sessions and many exercises to help you relax and fall asleep more easily. Each of these sessions is designed to be completed in about 20 minutes.

You can repeat all the exercises as many times as you like, because we add each of the completed exercises to the exercise toolbox.

We also have included 3 Sound Therapies, that are called, Basic-, Tailored Sound- and Tailored Tonal Sound Therapy.

The SilentCloud System is a prescription only medical device. There are the above therapies that we can offer to you, however they do require the prescription of a Healthcare Professional or ENT (Ear, Nose and Throat Physician).

Fitting and Programing of therapies can ONLY be performed by qualified healthcare professionals, that are

- (a) familiar with tinnitus treatment, and

- (b) have completed the SilentCloud HCP Training, and

- (c) are associated with HCP office or clinic, which has been qualified by SilentCloud

- (c) that have been granted access by SilentCloud to the HCP Dashboard.

Patients can only use those therapies, for which they have obtained a prescription. Only after such prescription is entered and confirmed in the SilentCloud System, the HCP can start fitting / programing any of the respective therapies into the patient's mobile device (Therapy Release).

You should use the sound therapies for the duration as fitted and programmed by your Health Care Professional . Clinical research has shown that our sound therapies can significantly reduce tinnitus distress. We have targeted sound therapies for tonal or atonal tinnitus.

Please read this user manual thoroughly before using the SilentCloud app for the first time, no further training will be required.

Regarding any residual risk, please consult the sections Side Effects, Warnings and Precautions.

If you have any questions, please contact your hearing care professional, which you can select during the course of using SilentCloud.

Let's get started!

General information

Intended use

The SilentCloud in combination with a Tinnitus Management Program is a therapeutic software tool for the treatment of chronic subjective tinnitus for home use.

The target population for SilentCloud are adult tinnitus patients over 18 years.

The SilentCloud is intended to provide relief from the disturbance of chronic subjective tinnitus, while using the device.

The SilentCloud is fitted and programmed by a qualified healthcare professional familiar with tinnitus treatment.

Contraindications

There is the following contraindication for the use of SilentCloud.

- Severe mental disorders

If you suffer from a **serious mental disorder** or are uncertain about it, **you should not use SilentCloud**, but consult your family doctor, a psychologist or psychotherapist. In case of illness or suspicion of a serious mental disorder, **talking to a doctor or psychotherapist is** essential.

Please note, SilentCloud is a support in the management of a burden of chronic subjective tinnitus and cannot replace professional therapy by a psychologist or psychotherapist.

In addition, there are the following contraindications to the use of sound therapy. In the event that one or more of these contraindications occur, sound therapy should not be used.

- Auditory Hallucinations
- Symptomatic Hearing Disorders
- Morbus Meniere
- Brainstem Diseases
- Psychiatric Disorders
- Other Insufficiently treated Serious Comorbidities, (e.g. active infection, malignant cancer, active neurological pathologies)
- Temporomandibular Joint Disorders
- Objective Tinnitus
- Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear within the previous 90 days
- History of sudden or rapidly progressive hearing loss within the previous 90 days
- History of semicircular canal dehiscence syndrome
- Active Cervical Pain
- Active Sore Throat

Side - Effects

For the sound therapy the following possible side effects are known.

- transient increase of tinnitus
- transient additional atonal noise
- transient additional tinnitus tone
- transient increase in tinnitus burden
- transient increase in loudness
- tinnitus frequency shift
- transient headaches
- transient increase of anxiety
- tinnitus frequency increased to >10 kHz
- transient discomfort
- transient itching of ear canals
- transient otalgia

Instructions

Please read the user manual before using SilentCloud for the first time.

The descriptions refer in each case to the illustration on the right of the text.

Warnings

We have limited the Maximum Sound Output Level of SilentCloud. We also have limited the maximum possible therapy duration to 6 hours per day. However, maximum sound output of your mobile device can lead to a high noise-exposure level. Listening to sounds at high volume beyond 8 hours per day can potential permanent damage your hearing.

Inform your hearing care professional immediately if you experience any side effects or your tinnitus is getting worse.

Precautions

When using the SilentCloud system, you have to use the same mobile device and same headphones for both the fitting and programming sections and the therapy application sections, as the programming is based on your individual mobile device/headphone combination.

The SilentCloud app has been developed and tested for use by a single user. Do not use the SilentCloud App with other people. It is important that your therapy in the SilentCloud App is approved by your healthcare provider only. Incorrect settings can lead to side effects that may affect your tinnitus.

Do not use your SilentCloud while driving a vehicle or performing any activity that requires your full attention.

Use the SilentCloud app in a quiet and silent environment.

Use the SilentCloud app at low volume first and then slowly adjust the volume.

Sound therapies in particular should be used at a volume just above the hearing threshold.

Press the Mute button, Pause button, or remove your headphones immediately if your SilentCloud App unexpectedly emits loud, atypical, or unusual sounds.

If you have any questions about using the SilentCloud app, please contact your hearing care professional.

Please note: Protect your phone with a PIN or other measures to ensure that only you have access to your private data on your mobile device.

System Requirements

SilentCloud can be installed and used on the following devices:

Apple Devices:

- o   iPhone 6s or higher
- o   iOS v14.5 or higher
- o   Standard Display Zoom mode supported only
- o   You need an Apple Play Store Account (Apple ID)
- o   Device must be able to connect to the internet

Android Devices:

- Device needs to support Google Play Store

- Android 9 or higher

- min. Screen resolution of

- You need a Google Play Store Account

- Device must be able to connect to the internet

General functions

The SilentCloud App is a therapeutic software tool for the treatment of chronic subjective tinnitus for home use and is designed to provide you with relief from chronic subjective tinnitus.

Interruption of the therapy

If you have to interrupt the therapy for a longer period of time (e.g. for more than one month), we recommend that you complete a THI questionnaire before and after the break to document your tinnitus symptoms.

Installation and Use of SilentCloud App

How to Install SilentCloud on your Phone

To install SilentCloud on your mobile phone, visit your App Store (e.g., Google Play Store or Apple App Store) and search for SilentCloud. Follow the instructions to install SilentCloud on your phone.

Starting the SilentCloud App for the first time

After installation of SilentCloud app, you first have to find the SilentCloud icon **(1)** to start the app.

On iOS devices newly installed app can be found on your last screen, swipe with one finger from right to left to get to the last screen, where you will find the SilentCloud icon **(1)**.

On Android devices, swipe up from the bottom of your screen to the top. Now you can swipe with one finger from right to left to get to the last screen, where you will find the SilentCloud icon **(1)**.

Tap the SilentCloud icon **(1)** to start the app.

Closing the SilentCloud App

Normally, it is not necessary to close the SilentCloud app, but if an app won't respond or seems frozen, you can close it, then open it again. You should close an app only if it's unresponsive.

On iOS devices the way you close an app depends on the type of device that you have.

For iPhone X and later, from the Home Screen, swipe up from the bottom of the screen and pause in the middle of the screen.

Swipe right or left to find the SilentCloud app.

Swipe up on the app's preview **(1)** to close the app.

For iPhone SE, iPhone 8 and earlier, and iPod touch, double-click the Home button to show your most recently used apps.

Swipe right or left to find the SilentCloud app.

Swipe up on the app's preview **(1)** to close the app.

On Android devices, from the Home Screen, tab the III button.

Swipe right or left to find the SilentCloud app.

Swipe up on the app's preview to close the app.

Administrative steps

Selection of the country

Please select your country **(1)** and continue by pressing the button **(2).**

You will find your respective country at button **(1), e.**g. Belgium. Press the area where your country name appears and continue in the registration process with button **(2).**

Note: the language of the SilentCloud app is based on the language set on the mobile device and is independent of the country selection.

Registration

In the next step you can register with SilentCloud **(1)** or log in if you have already done so **(2)**.

Register

On the registration main screen you have the option to register an account with SilentCloud, by using your existing Google **(1)** or Apple **(2)** Accounts or another email address **(3)** of your choice (see next steps).

Please enter your email address in the area **(1)** first and then press the button **(2)** to receive a verification code.

With the button **(3)** you can cancel the process.

If you are already logged in, you only need to log in by pressing the button **(4).**

If you have received your verification code by e-mail, please enter it in the area **(1)** and confirm it again by pressing the button **(2)**.

If you need a new verification code, you can request it again using the button **(3).**

You can cancel this process by pressing the button **(4)**.

If you are already logged in, you only need to log in using the button **(5).**

This is what the screen will look like once you have entered your verification code **(1).**

You then only need to confirm this by pressing button **(2).**

In the next step of the registration process, please enter a password in area **(2)** and confirm it by entering the **same** password again in area **(3)**.

The privacy policy can be accessed via the link of the button **(4)** (see next figure). You confirm that you have read it by ticking the box on the left **(4)**. You must also accept the data protection declaration by ticking the box **(5).**

Only then can you continue with the registration using the button **(6).**

Important Note: Please note that the password must contain 8-16 characters, with 3 out of 4 of the following: Lowercase letters, uppercase letters, numbers and one of the following symbols: @ # $ % ^ & * - _ + = [ ] { } | \ : ' , ? / ` ~ " ( ) ; .

The data protection declaration can be found under the following link www.silentcloud.com/privacypolicy.

With the button **(1)** you can go back to the SilentCloud App.

Log in

In the last step, enter your name in the button **(1)** and your password in the button **(2).** To continue, press the button **(3)**.

Privacy policy

The privacy policy can be viewed at the following link: www.silentcloud.com/privacypolicy.

Successful registration

The screen of your successful registration will look as follows and you can complete the registration process by pressing the button **(1).**

Subscription

Introduction

You can use plenty of content without subscription. All sections of our **All about Tinnitus** program is freely available.

If you want to have access to sound therapy and iCBT, subscription gets necessary.

Please note, which therapies will be available for you depends also on the prescription by your ENT and tinnitus expert.

First, the subscription process is explained to you on an information screen. You can continue by pressing the button **(1)** or you can go back to the main menu by pressing the button **(2)**.

Options

When selecting Subscribe in the previous screen, you will be introduced to the different options for your subscription, see **(1)** and **(2)**.

If you had an active subscription before and for example changed your phone, you can also use the function Restore Purchase **(3)**.

You also can go back to the previous screen by pressing the button **(4)**.

Subscription through Apple or Play Store

Depending on your phone and its operating system you will be requested to identify yourself with your Apple Store or Google Play Store account **(1)**.

You can also cancel this process by pressing the cancel button **(2)**.

Confirmation of Subscription

When you have finished the subscription process, you will be informed by a smaller information window. Size and content can be different depending on your operating system.

Please confirm by pressing the button **(1)**.

Settings

You can reach the settings via the button **(1)**.

On the Settings page, you can call up a lot of information and initiate actions.

By pressing the buttons **(1)**, you can call up the operating instructions and download a blank prescription form.

By pressing the buttons **(2)** you can access your personal profile and make changes. Furthermore, you can unsubscribe from SilentCloud and revoke your consent to data usage.

By pressing the button **(3)** you can delete your account and your data completely.

By pressing the button **(4)** you can restore a previous subscription to SilentCloud.

In the buttons area **(5)** you can find the Privacy Policy and Terms of Use.

By pressing the button **(6)** you can reach information about the app's manufacturer and get references to medical literature. At the very bottom you can also find the version number of SilentCloud.

Questionnaires

Introduction

Each module begins with a short introduction.

You reach the main menu from the introduction via the button **(1).**

You start the questionnaire by pressing the button **(2)**.

Answering the questions

For each question, please select the answer that best fits your current situation. To do this, press the corresponding button **(1)**.

You can change your answer at any time by selecting a different button.

Confirm your answer by pressing the lower button **(2)**.

Navigation within the questionnaire

At the top you will see information that allows you to navigate within the questionnaire.

In the middle **(1)** you can see which question you are currently on and how many questions you have to answer in total.

If you want to cancel the completion of the questionnaire, press the button **(2)**.

If you want to go back to an earlier question, press the button **(3).**

Cancellation of the questionnaire

If you have to stop filling out the questionnaire, you will be informed that the answers to questions you have already completed will be lost.

To cancel the completion of the questionnaire, confirm by pressing the button **(1).**

If you want to continue filling in the questions, press the button **(2)**.

Result of the questionnaire

After you have completed all the questions, you will be given a summary of the results of the questionnaire **(1).**

You can stop filling out the questionnaire by pressing the lower button **(2)**. Your results will be saved.

Different question types and answer options

The different questionnaires also contain different answer options, which are briefly explained below.

Single answer

For this type of question, please choose an answer that seems most correct to you, e.g. **(1).**

Use the button **(2)** to move on to the next question.

Questions where only one answer can be selected are used exclusively in the following questionnaires:

- THI
- HQ
- GAD-7
- PHQ-9
- WHO-5

and partially used in the following questionnaires:

- TSCHQ
- Medication
- Pitch Matching

Multiple responses

Questions in which several answers can be selected are used in the context of cognitive behavioral therapy.

Answer on a scale

For questions where you select a number on a scale **(1),** please slide your finger over the button **(2)** until the desired number becomes darkly visible.

Use the button **(3)** to switch to the next question.

Questions that require the answer to be selected from a list will be

used exclusively in the following questionnaires:

- TFI

and partially used in the following questionnaires:

- TSCHQ
- Medication

Answer from a list

For questions where you can select from a list **(1)**, slide your finger across the control panel **(2)** until the answer you want to select appears dark.

Use the button **(3)** to continue in the questionnaire.

Questions that require a text to be entered are sometimes used in the following questionnaires:

- Medication

Enter your own text

For these questions that require text entry **(1)**, go to the button **(2)** and type in the term using your mobile phone keypad. Use the button **(3)** to go to the next question.

Clinic Selection

Introduction

Below you will find the description of the clinic finder.

To begin, read the explanations on your display and then start the Clinic Finder by pressing the buttons **(1)** – Get Started to Select a Shop, or Skip, which skip finding a Shop for now.
US and Ireland only, will also show the Button labelled Digital Journey.

Location services

In the next step, you will be asked to allow the use of your current location using the button **(1).** This will allow you to locate the nearest clinic.

Map view

In the map view you can see nearby clinics **(1)** and select them.

Information about your clinic

You will now receive detailed information on the clinics and can view each of them by sliding the button **(2)**. Then select one of the clinics by pressing the button **(1).**

Confirmation of the selected clinic

Now you only need to confirm the selected clinic by pressing the button **(1)** or you can go back one step with the help of the button **(2).**

Start screen

The home screen, also labeled "Activities", is your primary point of contact in SlientCloud. From here you can access all content and get an overview of your achievements so far.

Activities screen

You always get to the start screen via the button **(1)** on the bottom left. The start screen contains changing content, here e.g. a button to reach section 3 of Education & Counseling, your Sound Therapy, which in this example is not yet unlocked, access to iCBT, which is also not yet unlocked and access to a welcome screen.
You can also book a free consultation.

Furthermore, a contact to your hearing care professional can also be established via this start screen. To do this, also tap Messages **(2)**.

Also remember to slide up the visible buttons in the home screen **(1)** so that you can see all the available buttons. In this case, you will find the "My Journey" section as the fifth button.

Welcome screen

On the home screen, you will find (in our example as the fourth post) a welcome screen with some important information for you to read through.

Use the button **(1)** to return to the start screen.

Journey

Under the "Journey" button is an illustration of the many therapy options in SilentCloud.

Press the button **(1)** to return to the start screen.

Exercises

You can access your exercises via the button **(1)** in the lower menu bar. These are arranged chronologically. Scroll up the exercise buttons to reach all available exercises.

Counseling

You can access your Counseling sections via the button **(1)** in the lower menu bar. These are arranged chronologically. Scroll up the buttons for the Counseling sections to reach all available sections.

Settings

You can switch to the "Settings" area using the button **(1)** at the top left.

Messages

This section describes the function of the Messages module in SilentCloud.

Introduction

Please read the on-screen text first before continuing **(1)**. You can return to your other activities using the button **(2).**

Loading new messages

By pressing the button **(1)** you can recall older messages.

If you want to return to the program, press the button **(2)**.

Write new message

Start of a new message

If you want to send a new message, press the button **(1)**.

Use the button **(2)** to go back in the program.

Select new message

In the following step, possible messages appear that you can select **(1)**.

Press the button **(2)** to return to the previous screen.

Confirm selection

If you have chosen one of the messages (e.g. (**1**)), please confirm it by clicking **(2)** or delete **(3) it** again if you want to choose another message.

New message visible

Once you have selected and confirmed a message, it will appear on your screen as follows **(1)**.

You can select further messages with button **(2)** and go back in the program with button **(3).**

Notification on new message

Read new message

If you receive a reply, you will be notified and your message **(1)** will appear on the screen.

With button **(2)** you can go to the message selection and with button **(3)** you go back in the program.

iCBT & Counseling

SilentCloud contains both a module with 17 sections from the area of general information on tinnitus and advice on dealing with tinnitus (Education & Counseling) and a module with 40 sections from the area of Cognitive Behavioral Therapy (CBT) with elements of mindfulness teaching.

The respective sections contain similar controls, which are described here for both modules together.

The functions are described on the basis of the Education & Counseling module, but are to be used for the modules of CBT.

Introduction

In the upper, middle area of your screen **(1)** you can see which section of the module you are currently in. Please read the text and continue using the button **(2).** If you would like to end the chapter, tap the button **(3)** to return to the main menu.

Voice-Overs

In some modules there are voice-overs that you can start by pressing the button **(1).** With the button **(2)** further down you can achieve a display of the spoken text to read along additionally.

Use the button **(3)** to move back one page.

Press the button **(4)** to continue in the program.

Use the button **(5)** to return to the main menu.

If you have activated the text display **(1)**, your screen will look like this:

When the voice-over is activated, this symbol **(1)** appears.

In the colour gradient of the green circle **(2)** you can then see how far the playback of the text has progressed.

You can move the text to be read along **(1)** in order to remain parallel to the spoken text. The pause button remains accessible at all times.

Only when the text has been pushed all the way to the top can the button be reached which displays the next content of the following chapter **(1)**.

Questions and answers

After the chapter you have read or listened to, a question **(1)** will appear, which you should answer using the two buttons **(2)** and **(3).**

Press the button **(4) to** continue in the program.

Below is an explanation **(1)** of your answer.

You can then continue with the button **(2).**

Longer texts

Longer texts that fill more than one page must be pushed up with your finger **(1)** so that you can finish reading them.

Only at the very end of the longer text the button **(1)** becomes visible, which allows to switch to the next content.

Animation

Some sections also contain animations that either start automatically or can be started using the button **(1).**

After that, the animations **(1)** run automatically and do not have to be stopped.

Calling other modules

Further content such as questionnaires or longer relaxation exercises can be accessed via the larger buttons **(1).** Some modules have to be executed (e.g., questionnaires or hearing tests) before proceeding. In this case, the button **(2)** would be greyed out as long as the module has not yet been performed. In other cases, the module can be used later (e.g., at bedtime), in which case button **(2)** is activated and usable. We recommend to use all modules.

All larger modules can also be accessed via the main menu.

Medication

Introduction

To begin, please read the information on your screen.

Press button **(1)** to return to the main menu and press button **(2)** to continue in the sequence.

Instructions

By pressing the button **(1)** you activate a blue highlighted field where you can type in the substance of your medicine.

Name of the active substance

Please type in this field **(1)** the name of the substance of your drug using the keyboard visible below. As soon as the program recognizes the substance, suggestions will be made and the name will be completed automatically **(2)**.
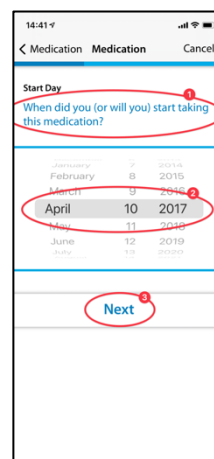
Start of medication

Here we ask you to set the approximate time when you start taking your medication **(1)**.

By swiping over the button **(2),** you can select the month, the day and the year, viewed from left to right. To do this, move your finger up or down in the button **(2)** to reach the desired date.

Use the button **(3)** to continue in the program.

Questions

In this step we ask you to answer questions **(1).** Here you select your respective answer by tapping the button **(2).**

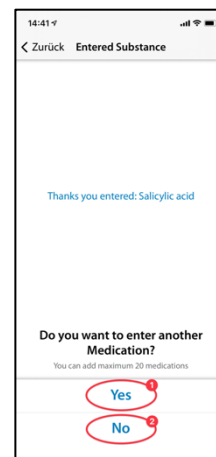Press the button **(3)** to continue in the module.

With the button **(4)** you can end the module, whereby your previous entries of this part are not saved.

Adding more medication

If you are taking more than one medicine at the same time, you can enter more information by pressing the button **(1)** and proceed exactly as you did when entering your first medicine.

If you do not want to list another drug, press the button **(2)**.

Sound Finder

Introduction

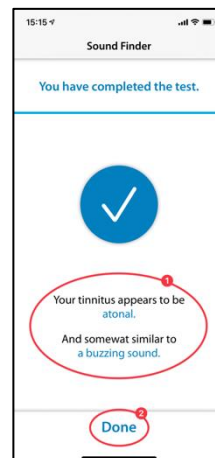Please read the explanation on your screen at the beginning and then press the button **(1)** to continue.

Pairwise comparison of the tones

Now you will be presented with two different tones each. Please select the one that is most similar to your tinnitus **(1)**. By pressing the buttons **(2)** and **(3)** you activate the respective tone and can also adjust the volume with the volume slider **(4)** according to your wishes. If you have selected the more similar tone after listening to it, it remains highlighted in blue **(2)** or **(3)** and you confirm by pressing the button **(5)**. If you want to test the tone pair again, you can stop the process and go back one step with the button **(6).**

Result

Your test result then appears on the display **(1)** and you can continue by pressing the button **(2).**

Adjustment of the Basic Sound Therapy
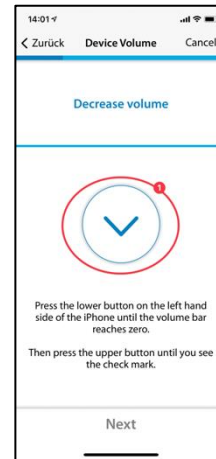
Introduction

To start the program, operate the button **(1)**.

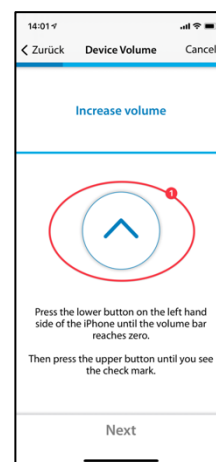With the button **(2)** you can return to the main menu.

Adjusting the volume

Volume reduction

Reduce the volume on the outside of your phone to zero. The change in colour of the button **(1)** tells you when this has been achieved.
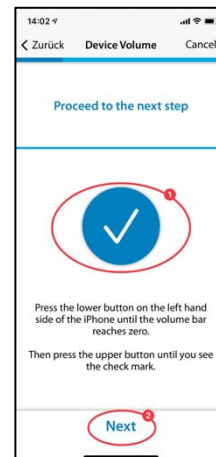
Raising the volume

If the volume is at the minimum position, increase the volume of your phone again to about a medium level until the button **(1)** changes color to blue.

Correct volume

When you have reached the correct volume for the test, a blue circle with a tick **(1)** appears on your display.

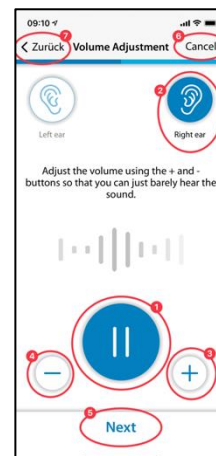Only when the tick is visible can you continue by pressing the button **(2).**

Setting threshold right ear

By pressing the button **(1)** a tone sounds at the right ear **(2)**. Using the buttons **(3)** and **(4),** please adjust the volume so that you can just barely hear the sound.
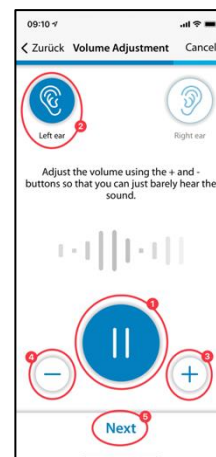
You can continue in the program using the button **(5).** If you want to cancel the module **(6)**, the previous setting will not be saved.

By means of the button **(7)** you can go back in the program.
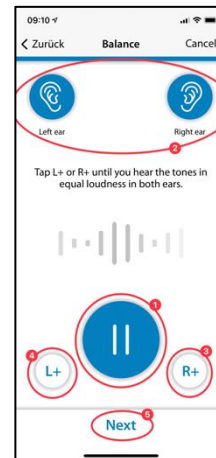
Setting threshold left ear

Now, by pressing the button **(1), the** tone sounds on the left ear **(2)**. Please use the buttons **(3)** and **(4)** to adjust the tone so that you can just hear it and continue with the button **(5) in** the sequence.

Balance adjustment

In this step you start the tone **(1)** and adjust the volume of the tone by pressing the buttons **(3)** and **(4)** so that it sounds equally loud on both ears **(2).**
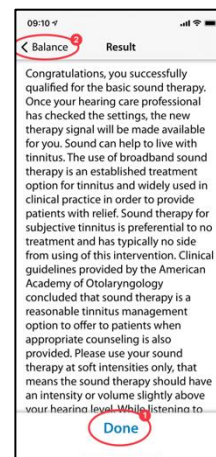
With the help of the button **(5)** you can continue in the module.

Result

Please read the explanation and close the module by tapping the button **(1).**

If you want to change the balance of your sound again, press the button **(2)**.
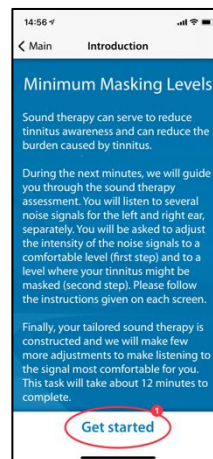
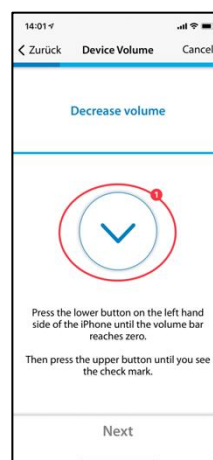# Adjustment of the Tailored Sound Therapy

Introduction

Read the following instruction and start the module by pressing the button **(1)**.
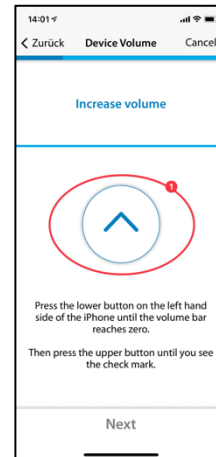

Adjusting the volume

Volume reduction

Reduce the volume on the outside of your phone to zero by pressing the button **(1).**
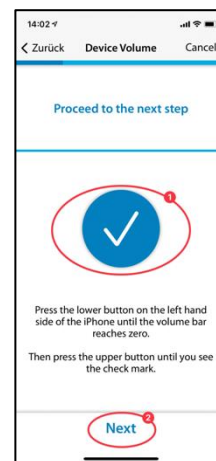
Raising the volume

If the volume is at the minimum position, increase the volume of your phone again to about a medium level using button **(1)**.
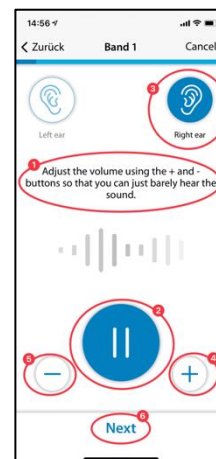
Correct volume

When you have reached the correct volume for the test, a blue circle with a tick **(1)** appears on your display.

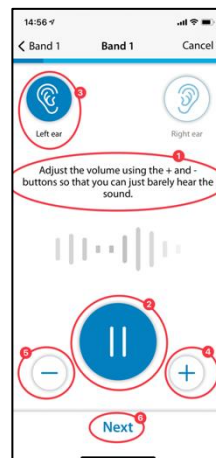Only when the tick is visible can you continue by pressing the button **(2).**

Volume 1 - Right Ear

First read the instruction **(1)** before you start the tape with the sound button **(2)**. The signal will now sound in your right ear **(3).** By pressing the buttons **(4)** and **(5),** please adjust the volume of the signal so that you can just hear it. Continue with the button **(6).**

Volume 1 - Left Ear

Again, first read the instruction **(1)** before you start the tape with the button **(2).** The signal will now sound in your left ear **(3)**. By pressing the buttons **(4)** and **(5),** please adjust the volume of the signal so that you can just hear it. Continue with the button **(6).**
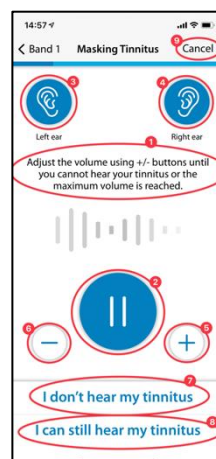
Volume 1 - Both Ears

Also in this step please read them instruction **(1)** first. By pressing the button **(2)** you start the signal, which you now hear on both ears **(3)/(4).**

With the help of the buttons **(5)** and **(6)** please adjust the volume so that you can no longer hear your tinnitus or the maximum volume is reached.
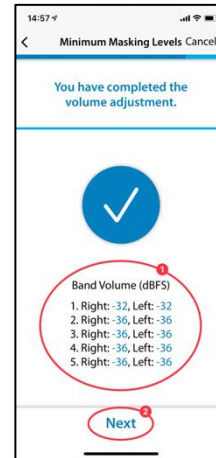
Then tap button **(7)** or **(8)**, depending on whether you still perceive your tinnitus or not. With button **(9)** you can delete the last step.

Note: tapes 2-5 are adjusted accordingly.

Result

In this step you will be shown the results of your volume determination **(1)**. Continue in the program using the button **(2).**
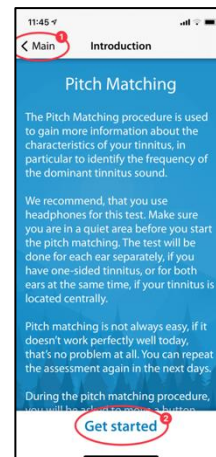
Pitch Matching

Introduction

Each module begins with a short introduction.

You can access the main menu from the introduction page via button **(1).**

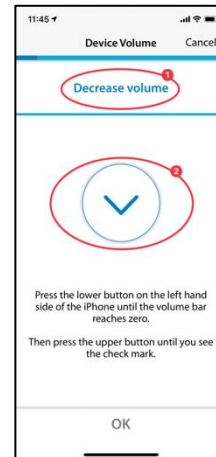You start the pitch matching by pressing the button **(2).**

Adjusting the volume

The next step is to set the volume to a medium value.
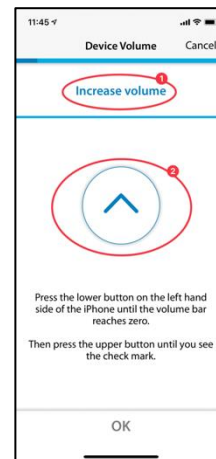
Setting the volume to minimum

To do this, first reduce the volume to the minimum level using the buttons on the side of your smartphone.

Increase the volume

Then increase the volume using the side buttons until the symbol in the middle of the screen **(2)** changes to a tick (OK sign).
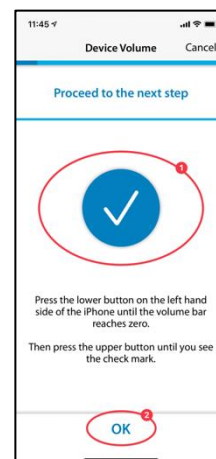
If you have increased the volume too much, the arrow **(2)** in the middle of the screen changes direction and indicates that you need to reduce the volume slightly. This is also indicated to you via the text **(1).**

Medium volume reached

If you see this symbol **(1)**, you have the correct volume setting.

Continue pitch matching by pressing the button **(2).**
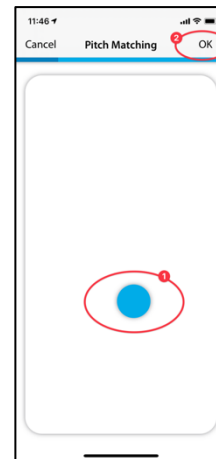
Setting the comparison tone

The goal of the initial pitch matching is to identify a tone that sounds as similar as possible to your tinnitus.

First pass

To do this, place your finger on the blue dot in the middle **(1).** Moving the blue dot to the **right makes the** sound louder.

By moving the blue point **(1) upwards,** the tone becomes higher. Thus, by moving the blue point **(1),** you can adjust the tone to your tinnitus as far as possible.
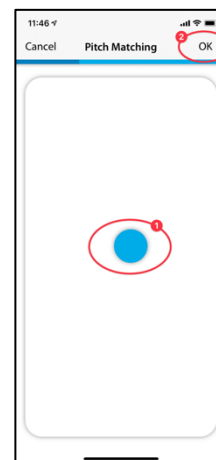
Once you have reached the best match, release the blue dot **(1)** and confirm your tone by pressing the button **(2)**.
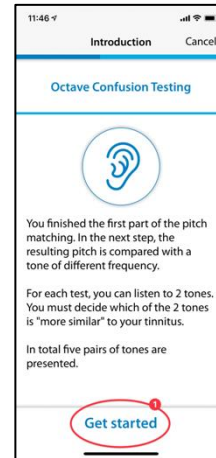
Second round

The second pass again confirms the tone you have determined by again placing your finger on the blue dot **(1)** and moving it to change the volume as well as the pitch.

If you hear a tone that sounds as similar as possible to your tinnitus, release the blue dot **(1)** and then confirm by pressing the button **(2).**

Explanation of the next step

In the next part, you will be presented with two tones and you will decide which one is more similar to your tinnitus. A total of 5 pairs of tones follow. You start the following test by pressing the button **(1)**.
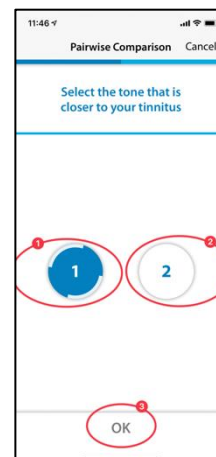
Pairwise comparison

By tapping the buttons **(1)** or **(2),** a different tone sounds in each case. You can listen to it as often as you like to decide which of the two tones is more similar to your tinnitus.

The sound you tap **(1)** or **(2)** appears in blue when it is played.

Once you have decided which tone seems more similar to you, tap it **(1)** or **(2)** and the area appears in blue. Then confirm your decision by pressing the button **(3)**.
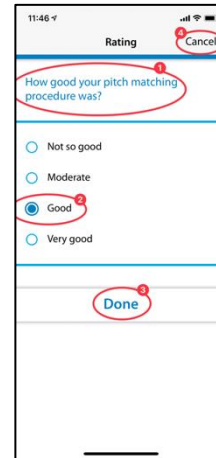
Repeat this process until you have heard all 5 tone pairs and selected the tone most similar to your tinnitus.

Closing Question

In the following we ask you to read the question in the upper part of the screen **(1)**, choose an answer by tapping the buttons in front of the respective answer **(2)** and finally proceed by pressing the button **(3)**.

You can cancel the pitch matching at any time by pressing the button **(4)**.
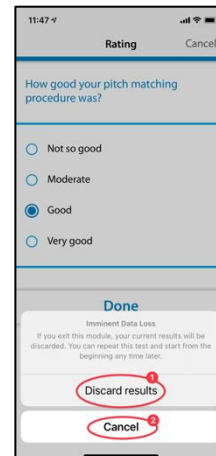
Aborting the Pitch Matching

If you exit the module at any time by confirming with button **(1)**, your previous data will not be saved**.**

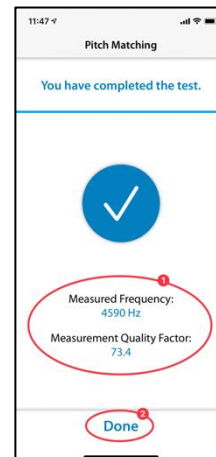You can repeat the test after it has been cancelled.

By pressing the button **(2)** you can interrupt the abort process and return to the current position in the module.

Result

When the tests are finished, the result of your test will appear on your screen **(1)**.

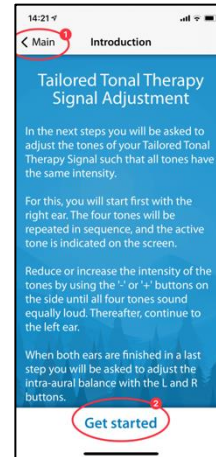By tapping the button **(2)** you continue with the rest of the program.

Adjustment of the tonal therapy signal

Introduction

The steps for adjusting the tonal therapy signal are described below.

Please read the explanations before you start using the button **(2).**
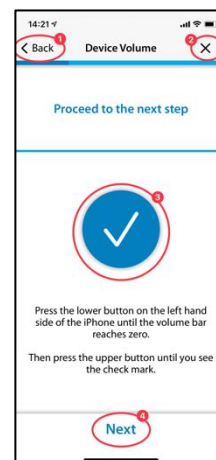
Press the button **(1)** to return to the main menu.

Volume adjustment

Please reduce the volume to zero on the side of your mobile phone. Then carefully increase the volume again until the tick appears in the blue circle **(3)**.

With the button **(1)** you can go back one step and leave the module by pressing the button **(2).**

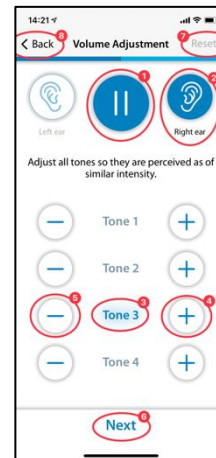Continue the sequence by pressing the button **(4).**

Setting the four stimulation tones for the right ear

Use the button **(1)** to start playing the four stimulation tones for your right ear first **(2)**. If, for example, you want to change the third tone **(3),** you can change its volume with the buttons **(4)** and **(5)** so that the volume seems similar to the other three tones. Continue in this way with all four tones. Eventually, all tones should sound the same to you.

Press the button **(6)** to continue in the sequence.

You can delete your settings again using the button **(7).**

Press the button **(8)** to go back in the program.

The volume of the four individual tones for the left ear is set accordingly.

Adjusting the signal balance

This step is about setting the volume of the stimulation tones the same for both ears **(2)** and **(3).**

Use the button **(1)** to start playing the tones. By pressing the buttons **(4)** and **(5)** you adjust the volume of the left and right ear respectively so that the stimulation tones are heard equally loudly in both ears.

Press the button **(6)** to continue in the sequence.

Use button **(7)** to delete your current settings and button **(8)** to return to the program.

Closing

At the end you only need to read the text and can continue the program with the help of the button **(1).**

Press the button **(2)** to return to the balance setting if you want to change it again.
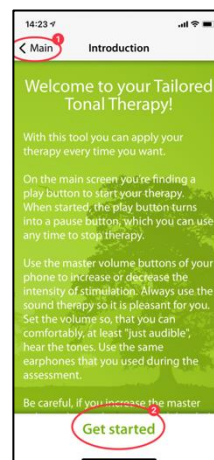
Application of sound therapy

The following section describes the steps for using sound therapy.

Introduction

Use the button **(1)** to return to the main menu.

To correctly perform the application of sound therapy, please first read the instructions on

your screen. To do this, slide the text further up to its end.

Pressing the button **(2)** takes you to the sound therapy start screen.
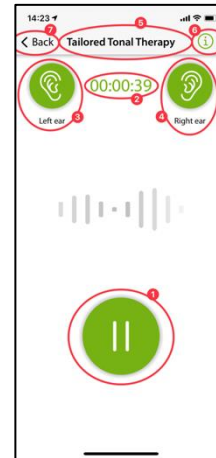
Application of sound therapy

With the start button **(1)** your sound therapy starts and changes to a pause button. At the same time the duration of the therapy time **(2)** is displayed.

The green background indicates which ear **(3)** and **(4)** is receiving the sound stimulation.

In the upper center **(5)** you see your current position in the module.

By pressing the button **(6)** you will get more information about the sound therapy.
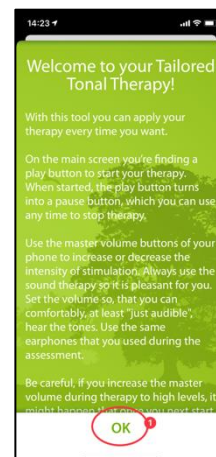
Use the button **(7) to** return to the main menu.

Information

To read the text in full, please slide it up the screen.

If you have read the information to the end, confirm this with the OK button **(1)** at the bottom.

HCP Fitting / Programming

Introduction

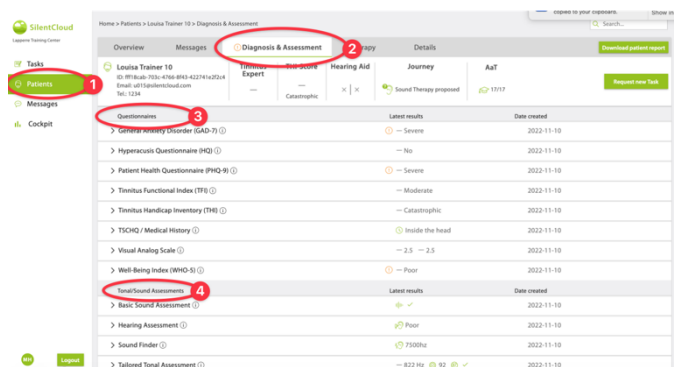Fitting and Programing of therapies can ONLY be performed by qualified healthcare professionals, that are

(a) familiar with tinnitus treatment, and

(b) have completed the SilentCloud HCP Training, and

(c) are associated with HCP office or clinic, which has been qualified by SilentCloud

(c) that been granted access by SilentCloud to the HCP Dashboard.

Patients can only use those therapies, for which they have obtained a prescription.

> i.   *First, the HCP must enter the patient's prescription into SilentCloud System before any of the actually prescribed therapy can be programmed/fitted or edited and released into respective Patient device.*
>
> ii.   *Then, the HCP assigned to a respective patient will review all relevant data that have been collected for a respective patient, i.e. THI, TFI, VAS, GAD-7, PHQ-9, scores and individual response details.*
>
> iii. *The patient will also, either face-to-face or remotely, complete sound therapy assessments, guided by the HCP, who reviews the recorded data, and may ask patients to repeat certain assessments, (which the HCP find important or relevant) guided by the HCP or the HCP can schedule another appointment to see the patient. The HCP communicates either face-to-face (directly) or via message or email with his/her patients.*
>
> iv.   *Finally, only after the HCP is satisfied with the various therapy parameters, that he/she wants program into the patient device, then he/she will program such fitting to the patient's device. Until such time, the patient cannot use any therapy on his/her device. **Note:** The HCP can also stop or edit therapies – any of the therapies at any time.*

Patient List on HCP Dashboard

In the Patient List **(1)** the HCP can select the patient to be fitted / programmed. Then, on the HCP Dashboard in the Tab Diagnostics & Assessment **(2)** the fitting HCP can review all of the detailed questionnaire data **(3)** collected and all the individual data recorded during the therapy sound assessments **(4)** prior to fitting / programming the respective patient device.
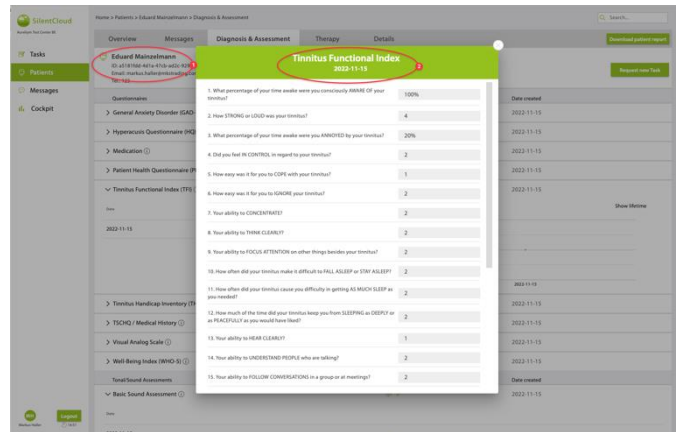
In the Patient List **(1)** the HCP can review all relevant details for all completed questionnaires (such TFI **(2)**), assessments, included the evolution of scores as well as the entire patient history as recorded by SilentCloud.

Request Patient to do a new or repeat a task

At any time, and especially prior to fitting / programming, the HCP can ask the patient to repeat anyone of the questionnaires or therapy sound assessments, i.e. "Request new Task". The data of such repeated tasks are again recorded in the dataset of the particular patient and reviewed by the HCP.
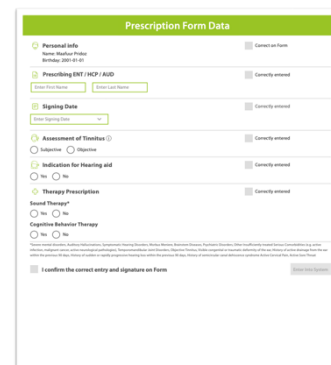
The HCP interacts with the patients either directly face-to-face or via the messaging tool. "New Task Requests" are sent to patient's SilentCloud App.

Furthermore, the HCP can see all other patient related information in the Overview and Details Tabs.

HCP enters Prescription

In order to fit / program the patient device, the HCP has to first enter the "prescription" information into the system.

The SilentCloud System will not allow any fitting / programing of any therapy of the patient device, by the HCP, before the respective "Prescription" has been entered.
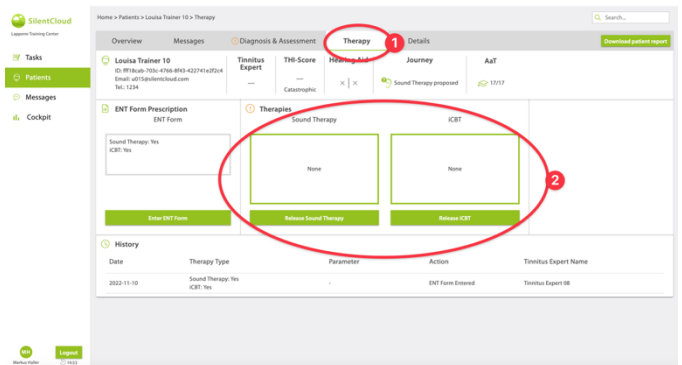
HCP Programming / Fitting - Patient Device

The HCP can select and program any of those therapies into patient's device, which are (a) prescribed and (b) for which that patient has successfully demonstrated eligibility.
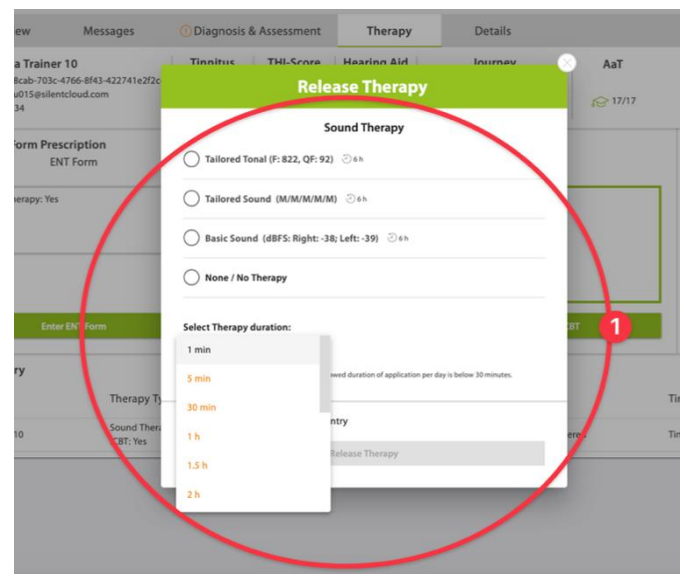
For each of the eligible therapies, the HCP reviews relevant parameters, such as Pitch Frequency, Masking Bands, etc. prior to programming the patient device. The HCP may also ask the patient to repeat anyone of the assessments.

The HCP can choose between up to three sound therapies and/or Counselling (CBT) **(2)** in the Therapy Tab of the HCP Dashboard **(1)**.
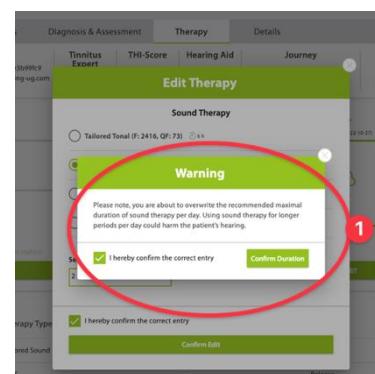

For each of the Sound Therapies, that HCP wants program into the device, the *SilentCloud* System will calculate a NIOSH compliant maximum allowed therapy duration. The HCP can select any duration, that is less than or equal to the maximum allowed duration **(1)**.

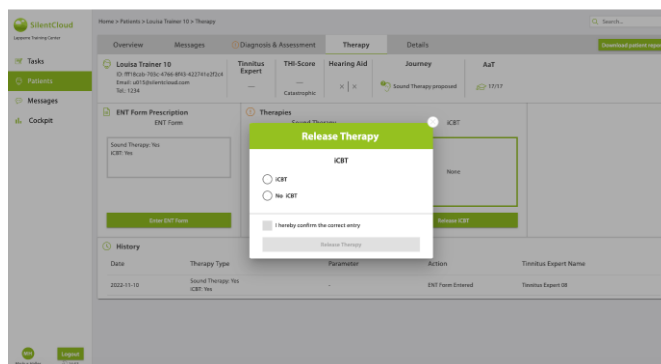The HCP can also deactivate (stop) any therapy at any time – NONE / No Therapy.

Should the HCP after careful review of the patient's dataset believe, that a sound therapy duration, longer than the maximum allowed duration, would be more appropriate for the particular patient, he/she will be shown the warning on the right **(1)**.

Only after the HCP completes all the above steps and accepts and confirms his fitting / programming for the patient, then the therapy is "released" to the patient's device.

The HCP may also, after careful review of the patient's dataset, release, edit or stop the counselling therapy, i.e. CBT.

The HCP can also deactivate (stop) any CBT at any time – No CBT.

Technical Specifications

- Mobile Patient App is usable at your Own Mobile Device with iOS v14 or higher or Android v9 or higher
- Dimensions: not applicable since software only product
- Sound Presentation
  - Sampling rate: 48.000 Hz
  - Output: Digital through iOS/Android integrated sound chip
  - Output Range zero to max output as defined by HCP (max output of device combinations ≤ 110 dB, device controls, that only therapy application is allowed, that does not harm the hearing)
- Adjustability of sound presentation during sound administration
  - +/- buttons: 1-2 dB FS
  - L/R buttons: 1-2 dB FS
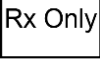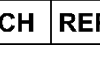- Frequency Bands for Basic Sound Therapy
  - Pink noise
- Frequency Bands for Tailored Sound Therapy
  - Band 1: 100 – 3.700 Hz
  - Band 2: 3.700 – 5.300 Hz
  - Band 3: 5.300 – 7.700 Hz
  - Band 4: 7.700 – 12.000 Hz
  - Band 5: 12.000 Hz – 15.000 Hz
  - Within band: white noise
  - Stop band attenuation: 60 dB
- Pitch Matching Procedure
  - Frequency Boundaries: 200 – 14.000 Hz
  - Verification passed with Quality Factor ≥ 20%
- Tailored Tonal Therapy Signal
  - Number of tones: 4, sinusoidal tones, Hanning windows
  - Frequency range: 0.74 – 1.4 times tinnitus frequency
  - Repetition Rate: 1.5 Hz
  - Tone duration: 150 ms
- Psychometric Assessments
  - Tinnitus Handicap Inventory (THI)
  - Tinnitus Functional Index (TFI)
  - Visual Analogue Scale (VAS)
  - Patient Health Questionnaire (PHQ-9)
  - General Anxiety Disorder Questionnaire (GAD-7)
  - Hyperacusis Questionnaire
  - World Health Organization Five Will-Being Index (WHO-5)
- Psychoacoustic Assessments
  - Pitch Matching
  - Sound Administration
- The following aspects are not applicable since SilentCloud is a medical software only:
  - MRI safety
  - Storage Conditions and Shelf Life
  - Cleaning & Disinfection
  - Information on microbiological state
  - Information on packaging
  - Information on sterilization method
  - Information on reusable device
- Preventive inspection and maintenance to be performed including the frequency of such maintenance measures for non-implantable parts: not applicable
- Information on reusable device: not applicable since SilentCloud is medical software

Symbols

This section describes icons used in SilentCloud.

Symbol	Meaning
MD	medical device
REF	Reference number
SN	Serial number
(factory symbol)	Manufacturer
(instructions symbol)	See operating instructions
CE 0123	European conformity marking incl. Notified Body number
Rx Only	Federal (USA) law restricts this device to sale by or on the order of a physician, audiologist or other hearing healthcare professional.
CH | REP	Swiss authorised representative (CH-REP)
UK | REP	UK authorised representative (UK-REP)

Contact

Manufacturer	**UK | REP**	**CH | REP**
Aureliym GmbH	**Ikidenya LTD**	**SWISSTINNITUS AG**
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www.aureliym.com		www.swisstinnitus.ch

Note: if you have any problems, please contact your tinnitus expert of choice directly.