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Product Name: eVu TPS System

Device Name: eVu Senz App iOS

REF

SA4520

EC REP

EMERGO EUROPE Westervoortsedijk 60,

6827 AT Arnhem The Netherlands

Manual No/Rev: SA4521 v.1.0.1.0 (August 2023)

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Labeling Symbols



Operating instructions (consult accompanying documents)

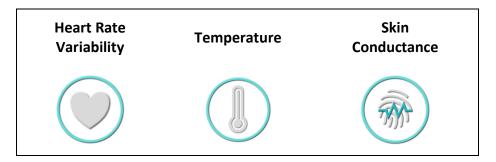
Medical Device

eVu Senz - eVu TPS

How This Works

Research shows that slow, relaxed breathing encourages a balanced nervous system and promotes calm awareness, increased focus, and decreased stress. eVu Senz is a self-training application that encourages these states by having you follow the on-screen breath pacer with way

With the aid of the eVu TPS finger device, the eVu Senz app provides feedback on three of your body's biosignals:



As you learn to comfortably produce full, even breaths at a rate of 5 - 7 per minute, your increased relaxation response will express itself as:

- An increase in heart rate variability.
- An increase in finger temperature.
- A decrease in skin conductance.

An increased stress response would express itself with the biosignals reacting in the opposite direction from the trends described above.

eVu Senz scores your ability to produce this relaxation response based on simultaneously increasing your heart rate variability and temperature readings, as well as decreasing your skin conductance. The better you are producing this ideal response, the more points you will score during the session. The system will also gently let you know when your biosignals are improving through visual icon cues and feedback music.

If breathing between five and seven breaths per minute is uncomfortable, change the breath pacer speed in the **Settings** tab. You can practice taking relaxed even breaths at a higher respiration rate, and later lower the breathing pacer speed when you are comfortable.

We encourage you to use this app in a comfortable environment, free of distractions. Scores may improve when you are cultivating positive feelings and thoughts. If you practice often, you

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will find the breathing task easier, and you will score more points. You can also choose to ignore the breath pacer and practice gaining points using your own relaxation method.

The units of measurement for the three biosignals are as follows:

- Heart rate variability: percent of total power for the low spectral frequency, often abbreviated as %LF.
- Finger temperature: degrees Celsius or Fahrenheit.
- Skin conductance: μSiemens

Do not worry about understanding the biosignals' units. eVu Senz does the work of letting you know when you are doing well or not. It can also display the biosignals as success index values between 0 and 100.

For Best Results

If your fingertips are too cold, it can be difficult for the eVu TPS device to get an accurate reading. Ideally, use the device and eVu Senz app in a room at about 20 °C or 68 °F.

Intended Purpose

The complete eVu TPS® system includes the eVu TPS device and the eVu Senz® app. It is intended for visualization and real-time feedback (biofeedback) of physiological parameters to assist a patient in developing a degree of conscious control over typically involuntary functions. It is intended for relaxation training and to provide information to aid in stress reduction.

Note: It is not intended for monitoring, diagnosis, or treatment. Furthermore, it is not intended to measure quantitatively the value of physiological parameters. Measurements are relative to each other, indicating short-term trends rather than absolute values.

Caution: US Federal Law restricts the device to sale by or on the order of a licensed health-care practitioner.

Wearing the eVu TPS

To correctly place the eVu TPS device on your finger, follow the instructions below. Refer to the accompanying images.

1. Attach the fabric strap to the eVu TPS device, by slipping the two loops from one end of the strap onto the two outer hooks of the eVu TPS device.



2. Apply the eVu TPS device to your finger, with the writing on the label oriented upward and with the "On" button pointing toward your hand. You can try using the eVu TPS on any finger, but the index and middle fingers are recommended for best results. The device should be placed near the end of your finger. The two metal plates on the underside of the device should be resting against your skin, for best results, against fleshy parts of the finger.





3. Secure the eVu TPS device to your finger by wrapping the fabric strap around your finger and back over the eVu TPS device. Use the appropriately positioned hole to attach the strap to the central hook on the side of the device.

Choose a hole that holds the eVu TPS device comfortably and securely. It is too tight if it is uncomfortable, and it is too loose if it constantly shifts positions or falls off.



When properly fastened, the fabric strap will cover the eVu TPS device logo, but the indicator light will be visible when the device is on.

When the eVu TPS device is in use during the **Practice** or **Train** sessions, the blue light will slowly flash.

Charging the eVu TPS

The eVu Senz displays the battery level of the connected device at the top right of the screen.

When the icon changes from green to red, it is a good idea to recharge the eVu TPS device.



Use the charger provided with the device. No other charger is supported for charging the eVu TPS.



To charge the eVu TPS device:

1. Plug the charging cable in the device's charging jack, which is adjacent to the "On" button.



2. Plug in the charger.

3. When the eVu TPS device is charging, a green light is visible. When the device is fully charged, the green light turns off.



Note: You cannot charge the eVu TPS device when you are using it or wearing it.

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Connecting the eVu Senz App and the eVu TPS Device

Before starting a Practice or Training session, you need to connect the eVu TPS device to the eVu Senz app via Bluetooth. The eVu Senz app guides you through the process.

Tips:

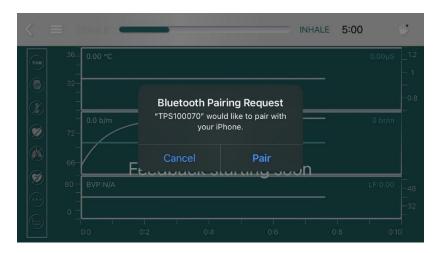
- Make sure to read and follow the safety instructions in the eVu TPS User Guide.
- Make sure the eVu TPS device is charged.
- Make sure your iOS device is charged and turned on.

Pairing the eVu TPS and your iOS Device

- 1. Strap the eVu TPS to your finger.
- 2. Turn it on and wait for the blue light to begin flashing.
- 3. Launch the app.
 - A pop-up message asks you to turn on Bluetooth in your iOS settings if it is off.
- 4. Turn on Bluetooth in the iOS **Settings > Bluetooth** menu.
- 5. Return to the eVu Senz Home page.
- 6. Tap **Practice** or **Train**.

Note: Practice is available whether you are logged in or not. Train is available only if you are logged in.

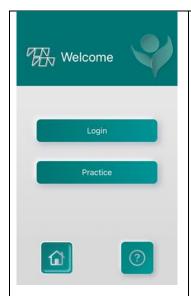
- 7. Tap **Signal View** or **Rewards View**.
- 8. The Bluetooth Pairing Request may pop up the first time you run the application.



- 9. Tap **Pair** to pair the device.
- 10. Continue with the training session.

Starting Up

Before logging into eVu Senz, you have access to the Help, Login and Practice screens.



Tap the **Help** icon to view the instructions manual for all aspects of using the eVu Senz app, arranged in several detailed tabs.

Tap the **Home** icon on the Help screen, or any other screen, to return to the Home screen.

The version of the app is displayed at the top of the screen.

Practice



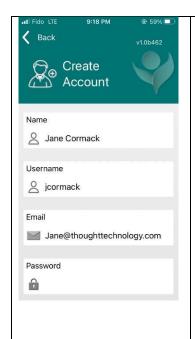
You can begin a Practice session without logging in. Just connect your device as described in the preceding section *Connecting to eVu Senz With the eVu TPS Device*. Tap Practice and select Signal View or Rewards View.

Note: The biosignal data from Practice sessions will not be saved, and you will not be able to review the results.

Logging In and Signing Up



The **Login** button gives you access to the Login screen and to the Sign-up screen. Tap **Sign-up** to create an account



Enter your information in the following fields and tap **Sign-up**:

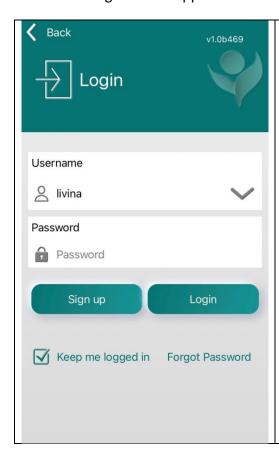
- Name
- Username
- Email
- Password
- Confirm password
- Clinician name
- Clinician email

Select **Keep me logged in** so that if you exit the eVu Senz app, you can re-enter it without entering your username and password. This option is selected by default. If it is unselected, you must remember your username and password each time you start the eVu Senz app. Explicitly choosing the Logout option logs you out of your profile. You must provide your username and password to log in.

Logging In

To log in to your account:

- 1. Go to the eVu Senz Home screen.
- 2. Tap **Login**. The Login screen appears.

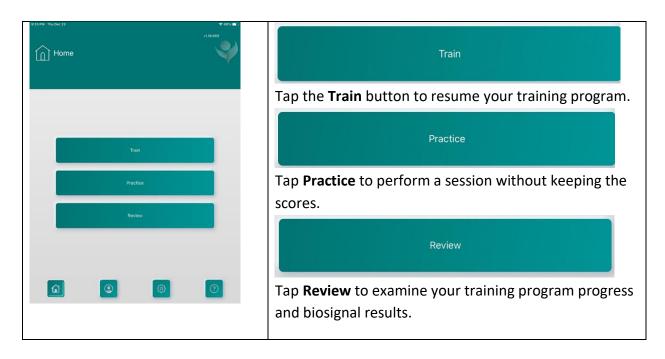


3. Enter your username and password and tap **Login**.

If you have forgotten your username and password, click **Forgot Password** and enter the email address you provided when you created your profile. The app will send an email containing your username along with a temporary password that can be used to log into your profile.

Select **Keep me logged in** so that if you exit the eVu Senz app, you can re-enter it without entering your username and password. This option is selected by default. If it is unselected, you will have to remember your username and password each time you start the eVu Senz app. Note that even if you select Keep me logged in, explicitly choosing the Log out option will log you out of your profile and it will be necessary to provide your username and password to log in.

Once logged in, you have access to more options.



Make sure the eVu TPS is strapped to your finger, turned on, and paired to your tablet or smartphone before selecting Train. Refer to the eVu *TPS User Guide* for instructions on the device pairing process.



Account Profile

Tap the **Account** icon to access the eVu Senz Account menu with the following options:

New Program to start a new training program and select a different length or difficulty level. If you have already started a training program, you can use this option to create a new one with different parameters. If you start a new program, you can no longer train within the previous program.

Profile update to update your profile information, including name, email, clinician's name, and clinician's email.

Change password to change the password stored in your current user profile.

Report to send a copy of the program results to the email address entered in the profile as "Clinician email." If this email address is missing or invalid, it can be added or corrected through the **Profile update** option.

About to view information on the app, such as the unique device identification (UDI), number, the reference number and lot, the manufacturer's address, and the date of publication.

Logout logs out the current user from the app. After logging out, to view results or continue training under your user profile, you must log in again by providing your username and password.

Settings

Tap the **Settings** icon to define parameters for your training and practice sessions, in Signal view and Rewards View.

Current eVu TPS device: choose the eVu TPS device used for training. This setting is only used if more than one eVu TPS device is paired to the device.

Display value: choose to show the biosignals as success index values, signal values, or hidden completely at the beginning of the session. When signal values are chosen, the following unit values are used:

- A Heart rate variability: percent of total power (a value between 0 and 100%) for the low spectral frequency (also known as LF).
- Temperature: degrees in Celsius or Fahrenheit.
- Skin conductance: microSiemens.

The success index is a measure ranging from 0 to 100 where 100 is the top score. The success index increases based on your relaxation goal being achieved. In other words, for heart rate variability, the index will increase as percent power of LF increases, for temperature, the index will increase as temperature increase and for skin conductance, the index will increase as skin conductance decreases.

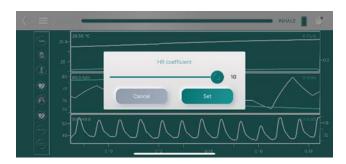
Auto disconnect timeout: set how long the app maintains its Bluetooth connection to an eVu TPS device when not in a Training or Practice session. Shorter time settings conserve eVu TPS device battery life.

Breath pacer: set the length of each segment in the breath pacer cycle. Inhale time, post inhale time, exhale time, and post exhale time can each be specified.

Breath pacer	
Inhale time:	
	3.1s
Post inhale time:	
•	0.4s
Exhale time:	
	5.1s
Post exhale time:	
0	0.4s

Note: During a session, you can toggle the breath pacer sound on or off. This can help to guide you through the breath cycle.

HR coefficient: Apply the Heart Rate (HR) coefficient to smooth the normal beat to beat Heart Rate waveform if you prefer a smoother looking signal.



Move the slider to the right toward 10 to increase the smoothness. The default is 6. Tap **Set** to apply the value.

Note: The Heart Rate coefficient is also available from the Settings menu in Signal.

Temperature unit: choose between Fahrenheit and Celsius temperature scales.

Music: choose among the selections of feedback music.

Note: The music can be turned on or off from within the Settings menu in Rewards View.

Annie	•
Acoustic guitar	C
Organ (sustain)	C
Ocarina (sustain)	C
Harp	C
Marimba	C
Perc Organ (sustain)	C
Musette (sustain)	C
Slow string (sustain)	С
Wood block	C

Proportional Tone: choose from a variety of proportional tones to add feedback to sessions in Signal View. The pitch of proportional tones changes as the live signal line rises and falls.

Tap **Play** to listen to a sample. You can switch to a different tone during a live session.

Note: The proportional tone can be modified in Signal View as well.

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Complete the Program

Training within the eVu Senz app is enhanced with an integrated training program in the Reward view. A program is a series of ten training sessions, with identical durations. The program goal is to achieve a predefined number of points overall ten sessions. Points are scored by producing a relaxation response, where your heart rate variability and temperature readings increase, and your skin conductance decreases. Following the breath pacer with slow, moderate breathing facilitates this response. If you feel at all dizzy, do not breathe as deeply. The better you are at producing this ideal response, the more points you will score during each session and over the whole program.

The session time and program goal are defined immediately before the first training session of a new program. If you have never run a training session before with the app, the program settings will be specified when you click the **Train** button for the first time.

Success index data from completed training sessions is saved and can be examined in review mode. After a program is completed, a new one can be started. Programs and their features are only accessible after logging in.

You can abandon your current training program and start a new program by going to the **eVu Senz** menu, at the top-left of the screen, and selecting **New Program**. The data from the previous incomplete program remains saved for review.

Practice sessions do not contribute to the score or goal of the program.

Training

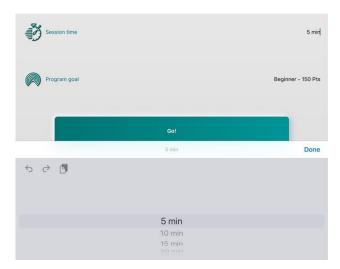
Tap **Train** on the Home screen to begin a training session. Then, select the type of training session, **Signal View**, or **Rewards View**.

Next, for both types, the app connects to the eVu TPS. If more than one eVu TPS is paired to the device, you must select the right eVu TPS.

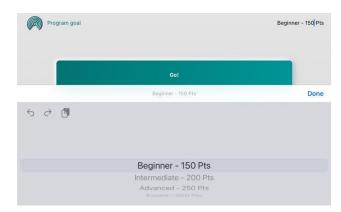
If this is your first-time training or you have completed one program and are ready to start another, the **New Program** menu appears before the countdown begins. In this menu, select the information specified below for your training program:



Connected Device: Normally you do not have to adjust this setting. If you have more than one eVu TPS device paired to your device, select the right eVu TPS for your training.



Session Time: Choose how long you want each training session to last. They can be as short as five minutes or as long as 60 minutes.



Program Goal: Choose a training level and the number of points to use as your training goal for the entire program. A beginner goal is appropriate if you are new to slow, relaxed even breathing. A more difficult goal is appropriate for someone who has practiced this type of activity before.

During training, try to keep your hand as still as possible. Movement makes it hard for the eVu TPS device to properly read your biosignals. If you move your hand too much, a red shaking hand symbol will appear at the top right of the screen. When there is no significant movement, the hand will return to its gray color.



If the eVu TPS device falls off your finger or is removed during a training session, the hand icon black eVu TPS area at the top right of the device's screen will blink as shown to reflect this.



Beginning a Session in Signal View or Rewards View

Every session begins with a 64-second calibration period. After this, training starts, and the app's features are activated. The following options are available in both Signal View and Rewards View during a session. To access them, tap the sidebar icon in the top left corner of the screen:

Disconnect

Music on

Pacer sound on

Pacer

HR coefficient

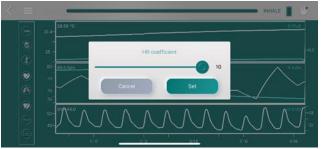
Disconnect: tap to disconnect the eVu TPS from the device and return to the Home page.

Music on /off: tap to turn the music on or off. In Rewards View, when Music is on, the proportional tones do not play.

Pacer sound on / off: turn on the pacer sound to guide you through the breath cycle.

Pacer: modify the length of the inhale, post inhale, exhale, and post exhale times before or during a session.

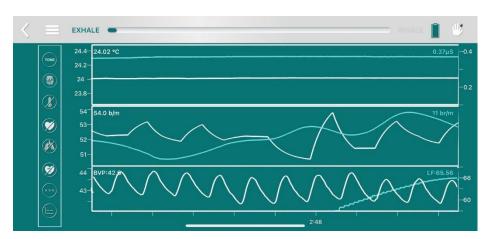
HR coefficient: If the Heart Rate signal appears choppy, apply the HR coefficient to make it look smoother.



Move the slider to the right toward 10 to increase the smoothness. The default is six. Tap **Set** to apply the value.

Note: The Heart Rate Coefficient is also available from the main Settings menu.

Signal View



Signal View presents three line graphs representing the live signal for the following:

- Temperature and skin conductance
- Respiration and heart rate
- Raw pulse waveform and heart rate variability

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Labels for each modality are shown on the top left and top right of the graphs along with your current values.

When the session starts, a proportional tone plays providing audio feedback for your skin conductance level.

For feedback on a different modality, tap the corresponding button on the left. This mutes the sound on the current selection and plays the tone for the new one. Only one modality can be active at a time. To mute the tone for the active modality, tap the active button. A line is drawn through the button to indicate it is inactive.

Tap **Tone** to select a different tone.

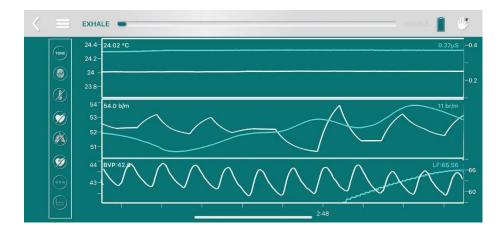
The pitch for the tone rises and falls for the active modality, to reflect your relaxation response, as follows:

For all tones, except Music

- If your skin conductance rises, the pitch rises.
- If your finger temperature rises, the pitch falls.
- If your respiration rate rises, the pitch rises.
- If your heart rate rises, the pitch rises.
- If your low frequency level rises, the pitch falls.

If you select **Music** as a tone, the volume increases and decreases for the modalities, as follows:

- If your skin conductance rises, the volume decreases.
- If your finger temperature rises, the volume increases.
- If your respiration rate rises, the volume decreases.
- If your heart rate rises, the volume decreases.
- If your low frequency level rises, the volume increases.

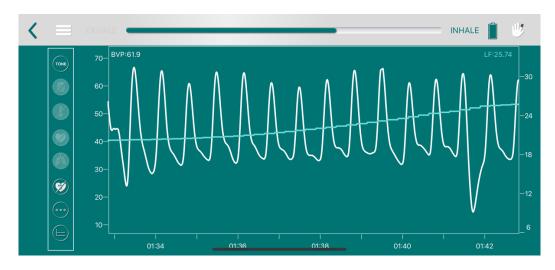


If you do not want audio feedback, deselect all the icons on the left.

To concentrate on taking slow even breaths, follow the breath pacer at the top of the screen. Add sound by tapping the side menu icon at the top of the screen and selecting **Pacer sound on**. This can help to guide you through the breath cycle, inhale, post inhale, exhale, and post exhale.

The respiration line flow depends on the three-directional movements of eVu TPS device. To get the respiration wave, relax the finger with the eVu TPS strapped to it and place it on the top of your stomach. The signal line will follow your respiration pattern. The label will show the number of breaths you take per minute. When you breathe at about six breaths per minute, you will notice the heart rate and respiration signals rise and fall together with a bit of lag, which is ideal.

Tap a graph to expand it to full screen.



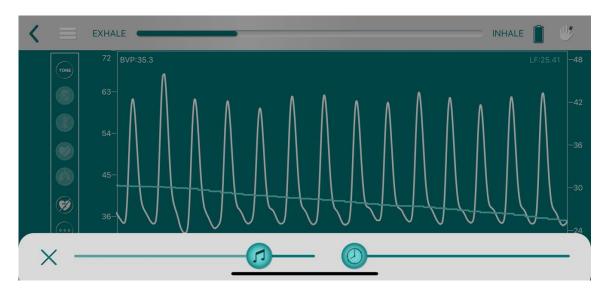
Then when you are ready to return to the three-graph layout, tap the arrow that appears on the left. In full-screen mode, you can play tones only for the modalities related to the displayed graph.



Tap the ellipsis icon at the bottom left of the screen to show the sliders for the tone sensitivity and the time scale. They are hidden by default.

Use the sliders at the bottom of the screen. Move the left slider to the right to increase the sensitivity of the proportional tones and y-axis, and the right slider to adjust the x-axis time base of the graph.

Tap the center icon once or multiple time to reset the chosen signal line position, sequentially from center to near bottom to near top. This will also change the corresponding tone pitch.



Note: in practice sessions on tablets, the x axes display the time. This is replaced by a countdown timer in training sessions and is not shown on smartphones. When it is available, use the right slider to modify the x-axis (time base).

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Rewards View

For a successful session in Rewards View, follow the breath pacer line with your breathing:

Inhale as the dark green line rises.

Exhale as the dark green line falls.



Do your best to produce moderate, relaxed breaths from the diaphragm, to maximize your relaxation response. If you experience dizziness, breathe less deeply.

The following three symbols for your biosignals are displayed throughout the training session:

Temperature

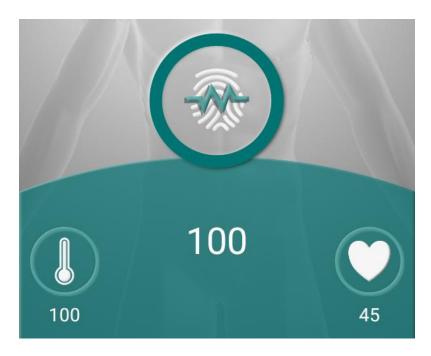
Heart Rate Variability



Skin Conductance



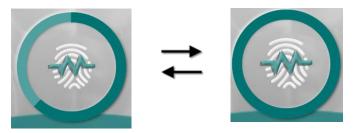
Depending on how *Display Value* is defined in Settings, the current value for each biosignal is indicated as a value or by the extent of highlighting on the Success Index circle. Tap the central icon to change between displaying the signal value with units or the success index. If the signal values were hidden, tap the central icon to show them. It is impossible to re-hide the numbers during a live session. This must be done through the general settings.



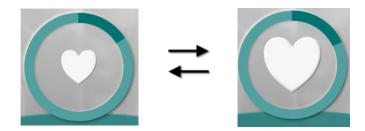
When a symbol is in the center of the screen, the app highlights that biosignal with three additional feedback cues. To select a different biosignal for the center position, tap on the symbol for that signal. These cues are based on an increasing relaxation response or an increasing stress response:

Success meter: this is the colored ring surrounding the biosignal symbol. The extent to
which you can activate your relaxation response is reflected in the extent of highlighting
on the ring.

The more highlighting there is in the ring = the better you are doing.



• **Symbol size**: the biosignal symbol grows or shrinks based on whether the signal is expressing an increased relaxation response or an increased stress response. For example, heart rate variability increases as a response to relaxation, and the symbol grows larger. Increased stress decreases heart rate variability, and the symbol shrinks. When the symbol grows large = you are doing well.



 Feedback music: when the biosignal is responding to an increased relaxation response, the session music is easily heard. When the biosignal responds to an increased stress response, the session music is heard only faintly.
 Louder feedback music = you are doing well.

Feedback music is available during the session. To mute or un-mute the session music, go to the **eVu Senz** menu at the top-left of the screen in mid-session and toggle the **Music on/ Music off** options. By default, the feedback music is muted at the beginning of a training session.

The breath pacer can also include a sound to guide the breath cycle, inhale, post inhale, exhale, and post exhale. To mute or un-mute the pacer sound, go to the **eVu Senz** menu at the top-left of the screen in mid-session and toggle the **Pacer Sound On/ Pacer Sound off** option. This is useful if you are training with your eyes closed or when not looking at your device's screen.

Your point total for the session is displayed in the lower-right corner of the screen. You are awarded one point for each biosignal that is maintained for 10 seconds in the desired relaxed condition.

The training exercise ends when the session countdown timer reaches zero. The timer is visible in the lower-left corner. At the end of the exercise, you will be able to see the results of the session and compare it to previous sessions of your program.

If a training session is abandoned before the timer reaches zero, nothing is saved for the session.

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Practice

The **Practice** session is a limited version of the **Training** session. See the **Training** topic to learn more.

No biosignal data is saved during a practice exercise and no review mode is available. Because the practice session is not part of the training program, it includes fewer on-screen features: there is no session timer and there is no tracking of points. You can quit from a practice session whenever you want.

Make sure to strap the eVu TPS device to your finger and to pair it with your tablet or smartphone before selecting **Practice**. Refer to the *eVu TPS User Guide* for details on the device pairing process.

Perform a practice session for a trial run and a chance to explore the app's features.

Review

Click the **Review** button to examine your program's progress results regardless of whether the sessions were recorded in Signal View, Rewards View, or a combination of the two.

The top half of the screen displays results derived from each biosignal, averaged from all sessions of the program. These success index averages illustrate how your body's nervous system is expressing an increasing relaxation or stress response for the entire program. The closer the values are to 100, the better you were at eliciting the relaxation response.

Success Index Averages:



Beneath the success index averages is the **Points to Goal** bar and number. This shows the number of points you have scored (in green) and how many more points you need to achieve the Program Goal (in gray) that was set when you started this program.



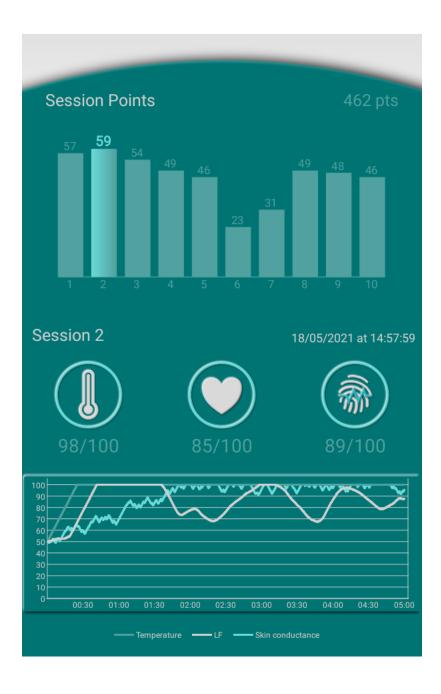
If you have run more than one program, swipe left and right to switch between programs.

On the lower half of the screen, the session point bars show the number of points you have scored during each training session. The more points you scored in each session, the better you did.

Tapping on a biosignal symbol reveals the number of points that biosignal contributed to the total points.



Swipe the graph up to examine each training session in detail. A line graph appears indicating the session changes made during the session for the success of each biosignal. This refers to the proportion of time, during the session, that your nervous system was expressing an increasing relaxation response. The three biosignal icons representing the average readings for the session are shown above the line graph.



Each biosignal of the line graph represents your body's relaxation and stress response. Each line moves upward toward the 100% maximum when your body is successfully relaxing, and each line moves toward the 0% minimum when your body is exhibiting a stress response. You are doing well when you get the lines to move toward 100% and remain at higher values. Each biosignal responds at different rates and sensitivities, so do not worry if a certain signal is more difficult to raise than another.

Swipe left and right to view a different session in the same program. The bar graph highlighted in green indicates the session being displayed in detail below.

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About

About eVu Senz

Requirements for Use

eVu Senz requires an eVu TPS device and a Bluetooth-enabled iOS device. User profile setup requires an email address.

Copyright Notices and Acknowledgement

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The following libraries are used under license from their respective authors, under terms of the Apache 2.0 license:

Swift-SMTP, ©2021 Kitura.

The following libraries are used under license from their respective authors, under terms of the MIT license:

IQKeyboardManager, ©2019 Mohd Iftekhar Qurashi.

ActionOver, ©2020 Andrea Miotto.

SendGrid-Swift, ©2020 SendGrid.

AlertToast, ©2022 Elai Zuberman.

Last update: August, 2023

NOTICE TO USERS IN THE EUROPEAN UNION

Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions for Use and the competent authority of the Member State in which the user and/or patient is established.