Aidplex ScolioSense Online Platform Instructions for Use

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# Online Platform Instructions for Use

This manual is about the **ScolioSense** online platform of AIDPLEX SCOLIOSIS, under the trade name **ScolioSense**, a product of Aidplex. The information content is owned by Aidplex and is provided only for the operation of Aidplex devices and software.

This manual is subject to change.

Last edition:https://scoliosense.com/Home/SupportEN.

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# Introduction

#### **Intended Use:**

The AIDPLEX SCOLIOSIS is a system designed to ensure the good quality of use of scoliosis braces. It is intended to be used in combination with another medical device e.g. (Boston back brace, Cheneau brace, Rigo-Cheneau brace, custom-made braces). The system provides the ability to secure and assure the quality of the treatment of scoliosis with a brace and the ability to remind the patient about the appropriate fitting of the brace based on the instructions of the supervising clinician.

It consists of three subsystems:

- a wearable device with analog and/or digital sensors (e.g. pressure sensors) retrofitted on any type of scoliosis back brace,
- a mobile application for patients with scoliosis to track the wearing time of their brace and to remind them to continue wearing the brace as indicated by their clinician, and
- a web application for their supervising clinicians to assure the adherence to treatment of their patients, the quality of their wearing time based on the correct fitting of their patients' braces.

AIDPLEX SCOLIOSIS, under the trade name of **ScolioSense** consists of: the wearable device (**ScolioSense** device), the mobile application (**ScolioSense** app) and the web application (**ScolioSense** online platform).

To install the **ScolioSense** device, you need:

- 1. The ScolioSense\* device.
- 2. One to three pressure sensors\*.
- 3. A square and a round piece of velcro tape to install the device\*.
- 4. A special foam cover for the sensor cables.

# The company

**Aidplex** operates in the health sector intending to improve the quality of life of patients. More information: <a href="https://www.aidplex.com">www.aidplex.com</a>.

<sup>\*</sup>included in the device packaging

# Important safety note

## **CONTRAINDICATIONS**

The **ScolioSense** device is not intended for:

- Any other use besides a scoliosis brace.
- Direct contact with the body, open wounds, burned tissue, near the eyes, and near fractures.
- Different conditions beyond scoliosis and for patients who are not **ScolioSense** users.

The web application is not intended for:

- Any other use than the supervising clinician and authorized personnel.
- Use as a patient list for different conditions.

The mobile application is not intended for:

- Any other use than the scoliosis patient and user of the Aidplex system with the permission of the qualified clinician.
- Simultaneous use from multiple mobile devices.

#### **INDICATIONS**

ScolioSense is indicated for:

- Scoliosis patients undergoing treatment with the use of a brace and using the ScolioSense app and the ScolioSense device.
- Supervising clinicians with scoliosis patients undergoing treatment with the use of a brace using the **ScolioSense** online platform.
- Ensuring and assuring the course of scoliosis treatment with the use of a brace.
- Ensuring the fitting and use of the brace in accordance with the instructions of the supervising clinician.
- Reminding the patient about the appropriate fitting of the brace based on the instructions
  of the supervising clinician.

# WARNINGS AND PRECAUTIONS

- Any use of the ScolioSense other than as indicated is prohibited.
- The ScolioSense online platform should only be used by supervising clinicians and authorized personnel.
- The ScolioSense app should only be used by scoliosis patients who are being treated with a brace.
- The **ScolioSense** device should only be installed on braces and only by authorized personnel who have followed an installation training program.
- The **ScolioSense** device must not be opened by unauthorized personnel.
- Patients should not interfere with connecting or disconnecting the sensors from the wearable device.
- The process of fitting the brace (calibration) inside the online platform should not be
  used to determine the fitting of the brace, but only to capture the appropriate fitting as
  defined by the supervising clinician.
- The calibration process in the **ScolioSense** online platform should not be used to determine the fitting of the brace, but only to capture the appropriate fitting as determined by the supervising clinician.

# **General Operating Conditions**

#### Operating environment

To access the online platform, the user must have a web browser and an Internet connection. **ScolioSense** supports recent versions of Google Chrome, Mozilla Firefox, Apple Safari, Microsoft Edge, and on iOS and Android mobile devices.

## ScolioSense Online Platform

#### **User Qualifications**

**ScolioSense** is intended for patients with scoliosis, who wear a brace, and their supervising clinicians. The **ScolioSense** app and the **ScolioSense** device are used by patients. The **ScolioSense** online platform is used by medical or authorized personnel.

#### Description

The online platform has 7 pages:

- 1. Login page: Login to the platform.
- 2. Registration page (Register): Registering on the platform.
- 3. Patient Page (Dashboard): The main page of the **ScolioSense** online platform. Contains a patient summary as well as summary charts with patient information.
- 4. Patient Details page: Contains detailed information about the patient and his treatment.
- 5. Patient Edit page: The user can edit the patient information.
- 6. Profile page: The user can change their information and password for the **ScolioSense** online platform.
- 7. Help page (Help): The user can read the updated instructions for using the online platform.

#### Getting started

To visit the **ScolioSense** online platform, visit <u>www.scoliosense.com</u>.

#### **New User Registration**

To register on the **ScolioSense** online platform, use this <u>link</u>. You will need to fill in your email address, and a representative of **Aidplex** will contact you to set up the account.

# Thank you for your interest!

Already Have Account? Login now

The registration process for Doctors and Manufacturers is currently closed.

To stay updated please provide us with your email address, and we will notify you accordingly when you are eligible to apply.

Enter your email address

Notify me

#### User account login

After creating your account, you can log in to the **ScolioSense** online platform using this <u>link</u> by filling in your login details.

# Login

Enter your email address and password to login on the ScolioSense platform for Doctors and Manufacturers.

demo@aidplex.com

Remember Me

Forgot your password?

New to ScolioSense? Join now

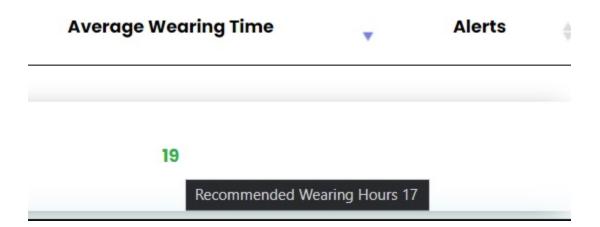
#### Patient Page

#### Patient page for clinicians

Under this section, you can see your list of patients. The list contains the First Name, Last Name, Scoliosis Type, Average Wear Time (of the brace), and Alerts.

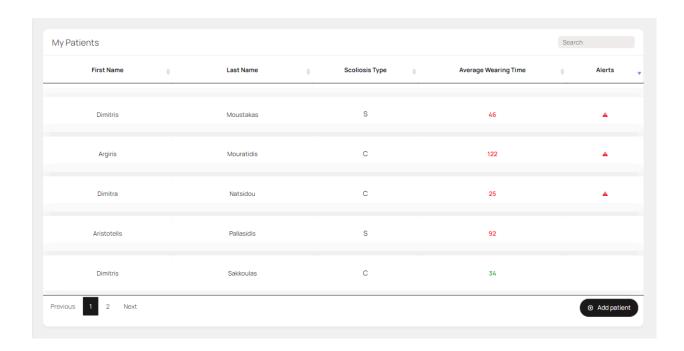
**Type of Scoliosis:** The type of scoliosis is classified as S or C.

**Average Wearing Time:** The measurement appears Green when it meets the recommended time, otherwise it appears Red. Hovering the cursor over the measurement shows the number of recommended usage hours of the brace.



**Alerts:** Alerts indicate if the patient has had no data for the past 3 or 7 days. These alerts appear in orange in the first [1] case, while in red in the second [2] case.





- 1. By pressing the "+ Add patient" button at the bottom of the patient list, you can create a <a href="new patient account">new patient account</a> on the platform.
- 2. Through the search bar, you can easily and quickly search for your patients.

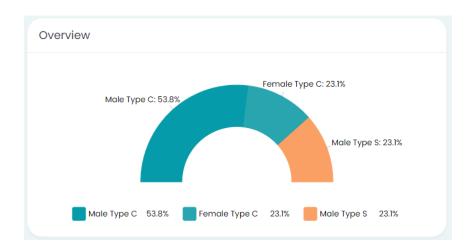
At the bottom of the Patient Page, there are 2 summary charts:

#### Adherence

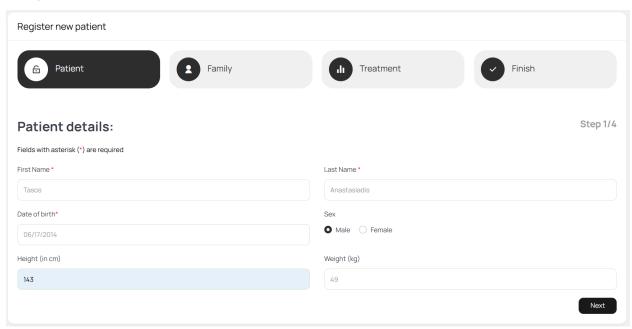


- 1. Adherent
- 2. Non-adherent

Type of scoliosis by gender (Overview)



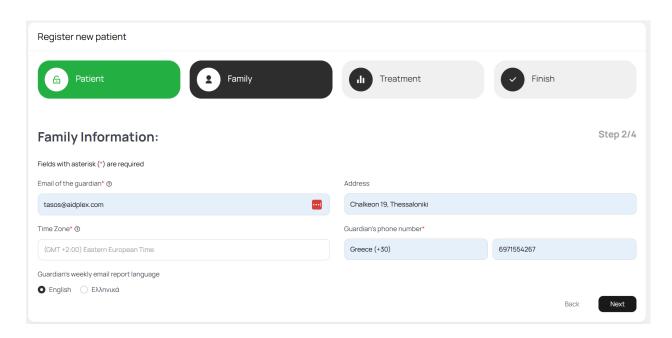
#### Add patients



In the **Account Patient Information Details** section for registering a patient, you should fill in the following information:

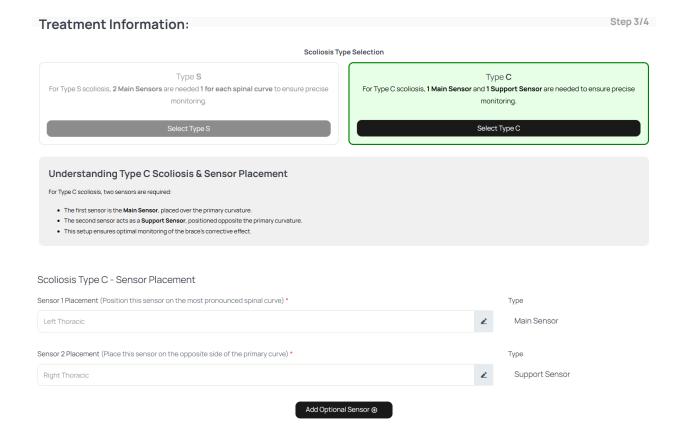
- 1. First Name
- 2. Last Name
- 3. Date of Birth
- 4. Gender
- 5. Height
- 6. Weight

All required fields are marked with an asterisk (\*)



In the Family Information step, enter the guardian's email address, phone number, home address, time zone, and select the preferred language for the guardian's weekly report. Remember that all required fields must be filled in to continue. Click Next to proceed to the treatment details.

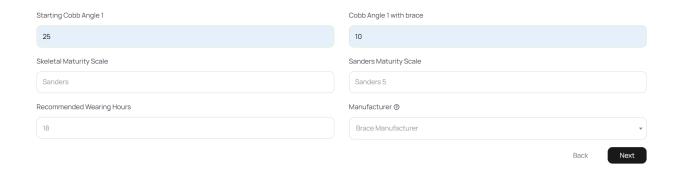
- 1. Guardian's Email Address (This will be used to log into the ScolioSense app)
- 2. Guardian's Phone Number
- 3. Home Address
- 4. Time Zone
- 5. Report Language



In the **Treatment Information** step, select the type of scoliosis (**Type S** or **Type C**). Both types of scoliosis require **at least two sensors**.

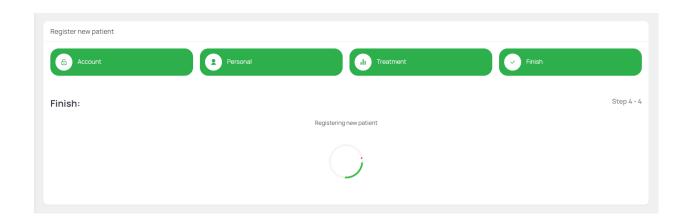
- 1. **Type S Scoliosis** involves two spinal curves and requires **two main sensors**, placed at the apex of each curve.
- 2. **Type C Scoliosis** involves a single spinal curve and requires:
  - One sensor placed at the apex of the curve.
  - One sensor placed on the opposite side.
     The support sensor monitors the total daily fitting time but does not determine whether the brace was worn in an adjusted or non-adjusted pressure ranges.

You can add another sensor by clicking the Add Optional Sensor



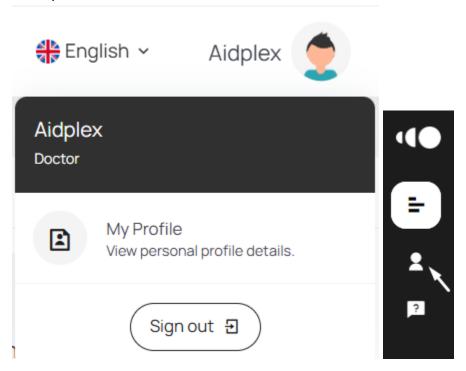
Additionally, configure the Cobb angles, the recommended wearing hours, the skeletal maturity scale (Risser or Sanders), and select the orthotist or clinician responsible for this patient.

Once the process is completed, an automated email will be sent to the patient's email address.



#### My account (My Profile)

To view your account, select either your name in the top right and then select My Profile option or the profile icon from the side menu.

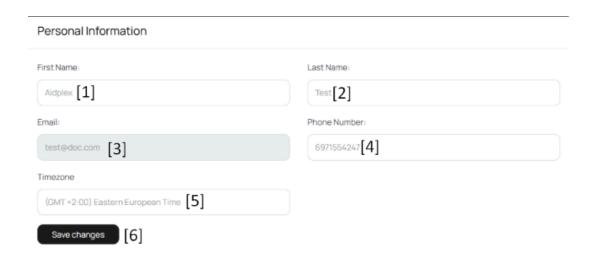


Through the profile screen, you can change the following:

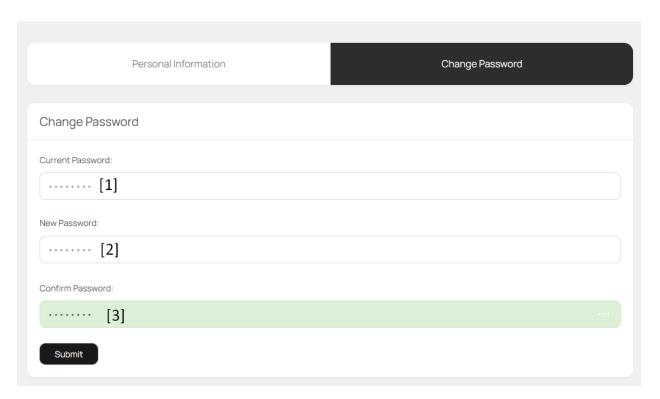
- 1.Name
- 2.Surname
- 4. Telephone Number
- 5.Timezone

**Important:** The Email[3] address cannot be changed. In case you wish to change your email address, please contact the support department at support@aidplex.

To save your changes, you should select the "Save Changes" button[6].



If you wish to change your login password, you should select the "Change Password" tab[6]



To change your password, you must enter your current password[1].

If the password is incorrect, a message will appear, as shown below.

You should then enter the new code in the section "New Password" [2] and confirm it in the field "Confirm Password" [3].

#### Current Password: Your password was incorrect.

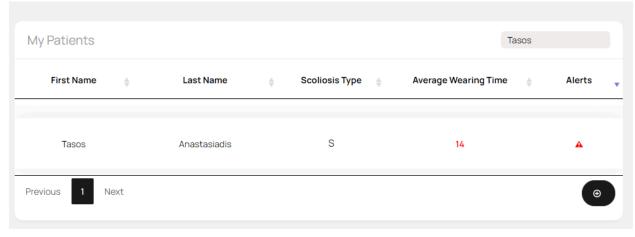
\*\*\*\*\*\*\*

To save the new password, you should select the "Submit" button.

#### Patient tab (Patient details)

#### Patient tab for clinicians

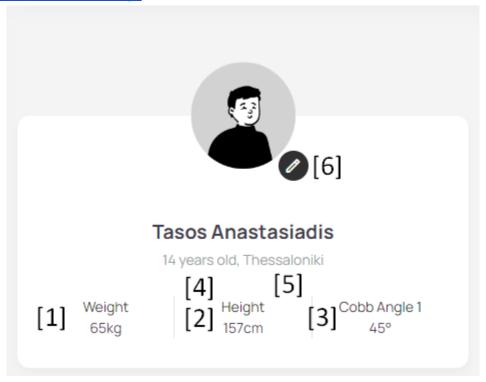
To see detailed information about a patient, you should select the patient from the list on the patient page.



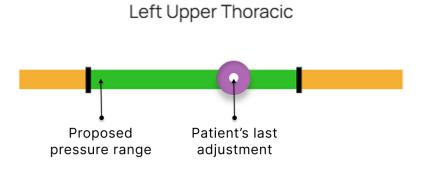
The first part of the screen shows personal information about your patient, such as:

- 1. Weight
- 2. Height
- 3. Current Cobb angle, (in case the patient has S-type scoliosis, then both Cobb angles are displayed),
- 4. Age
- 5. Location of the patient

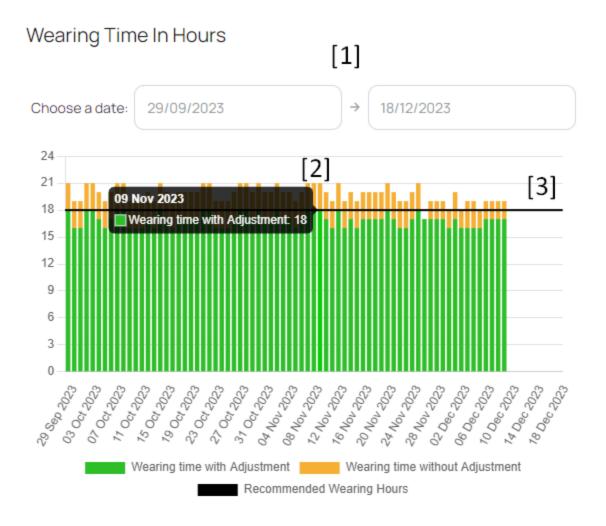
You can edit your patient details by pressing the "Edit" button[6] as seen below through the Patient details modification page.



Below the patient's personal information, the sensor pressure graphs display the recommended pressure range in green. The last brace adjustment is indicated with a purple marker, while orange sections indicate pressure readings outside the optimal range.



Next to the patient information is the patient brace usage summary graph. Each bar represents one day. The hours of use with the appropriate fitting of the brace[2] are represented in light green and the hours without in orange. Hovering over a bar shows more information about that day. The black line[3] refers to the appropriate hours of use of the brace. At the top of the chart, you can set a custom range of days[1].



Next, to the usage graph, information related to the treatment course is presented such as:

- 1. The date that the treatment has started (date of enrollment in the **ScolioSense platform**)
- 2. Risser or Sanders classification
- 3. The Cobb angle
- 4. The Cobb angle while using the brace (in the case that the patient has S-type scoliosis, then both Cobb angles appear).

Finally, to start the <u>Brace setting-Calibration</u> you should press the button **Start Calibration**[1].

# Status Started on 29 September 2023 Risser classification Stage 4 Starting Cobb Angle 1 45 Cobb Angle 1 with brace 43 Starting Cobb Angle 2 27 Cobb Angle 2 with brace 23 Calibrated by: Demo Doctor Start Calibration

#### Pressure Chart Page (Adjustment graph)

Selecting the Adjustment history button on the patient tab takes you to the Adjustment graph page.



The graphs below show each sensor's upper (dotted line) and lower limit (continuous line) generated during the brace setting-Calibration. The points within the chart indicate the fitting of the patient's brace.



#### Edit patient page

Through the "Edit patient page", you can edit the patient's information.

The patient can be deleted with the button "Remove Patient"[1].

**CAUTION:** The procedure of deleting a patient is **irreversible!** 

To change a patient's **ScolioSense** device, you must select the **Change ScolioSense** device[2]. After changing the device, another calibration is required.

In case you change the number of sensors or the positions of the sensors, then another calibration is required[3].

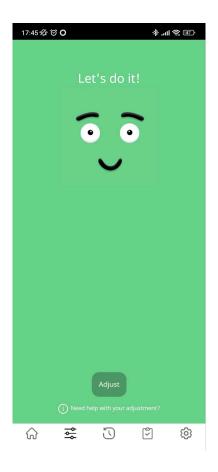
To save the changes, you should select the button "Submit"[4].

In case you do not wish to save the changes, you can transfer to the patient's details without saving by pressing "Cancel Without Saving".



#### **Brace setting-Calibration**

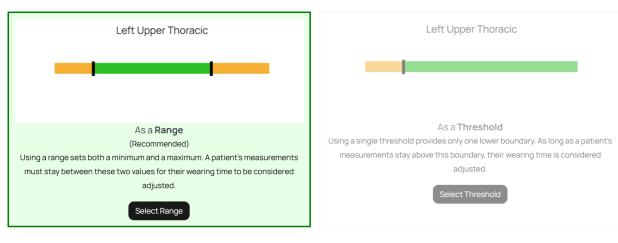
To adjust the sensors, the patient should wear the brace and be in an upright position. The correct fitting of the brace is defined by the user of the **ScolioSense** online platform. The patient must have the **ScolioSense** app installed on their mobile device, be logged into the app, and have an active Internet connection with Location and Bluetooth services enabled. The patient must also be on the adjustment page.



#### **Calibration Type**

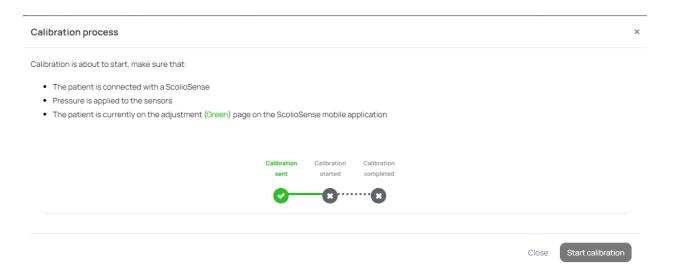
- Range Calibration (Recommended): Sets both the minimum and maximum pressure limits. The patient's pressure readings must remain within this range to be classified as adjusted.
- Threshold Calibration: Sets only a minimum pressure limit. Readings above this threshold are considered adjusted.

#### Select a Method: Range vs. Threshold

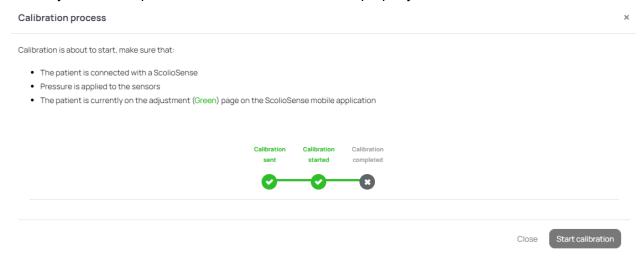


Once you have fitted the patient's brace in the desired position, you should press the button, **Start calibration.** 

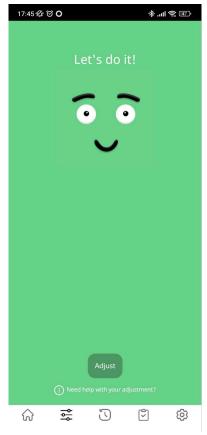
Then a notification is sent to the mobile device of the patient and the process of the calibration starts.



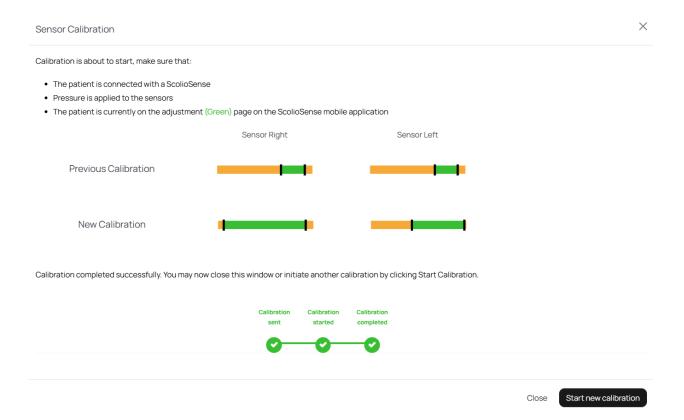
During the calibration process, the patient should take two deep breaths and then breathe normally so that the pressure limits of the sensors are properly set.



The process of setting up the brace is shown below through the **ScolioSense** app in an Android environment. The process is completed automatically.

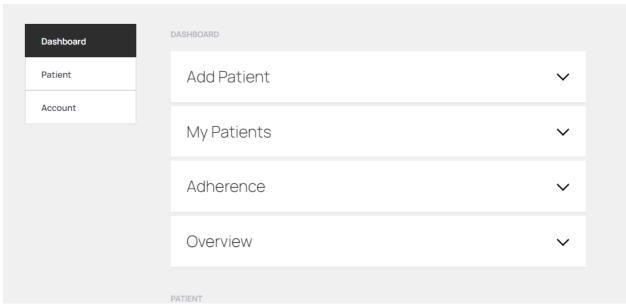


After the calibration process is completed, the window will refresh and the limits of the previous and new calibration will be displayed. The pressure range for recommended use is displayed in green, while the non-recommended range is displayed in orange.



#### Help

Through the help page, you can learn more about all the functions of the **ScolioSense** online platform, as well as ways to deal with possible problems.

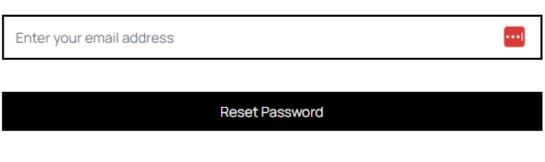


#### Forgot password

In case you can't remember your password, you can retrieve your password by clicking at this link.

# Forgot Password

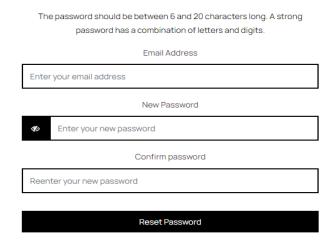
Please enter your email address and we'll send you an email with instructions to reset your password.



Back

In the next few minutes, an email is sent containing a link to the page to create a new password. After filling in the new password and selecting "Reset Password" you can enter the platform with your new password.

#### **Reset Password**



#### **Email Report**

ScolioSense supports sending a weekly report via email to the patient's guardian. The report includes the wearing time per day for the previous week.

Reports are sent every Sunday at 18:00. If the guardian wishes to stop receiving these emails, they can visit the following link: <a href="https://scoliosense.com/Report/Stop">https://scoliosense.com/Report/Stop</a>.

There, they can enter their email address and click the "Unsubscribe" button. A confirmation email will be sent to verify the unsubscription.

# Unsubscribe from Weekly Report Emails

Please enter your email address below to stop receiving weekly report emails from ScolioSense.

you@example.com

Unsubscribe

You can re subscribe the weekly email report **here**.

A sample weekly report



# ScolioSense weekly report

Tasos for the period 26/06 - 02/07:

Thursday 26/06: 24 hours Friday 27/06: 24 hours Saturday 28/06: 24 hours Sunday 29/06: 24 hours Monday 30/06: 24 hours Tuesday 01/07: 24 hours Wednesday 02/07: 0 hours

Total: 144 hours

Average: 21 hours per day

This is an automated message from the ScolioSense system. To stop receiving these messages, <u>click here</u>.

# Troubleshooting

Problem	Coping
No connection is made to the platform	Contact Aidplex.
Brace calibration is not performed	<ol> <li>Make sure the ScolioSense app has the Location and Bluetooth services enabled and an active Internet connection.</li> <li>Make sure the ScolioSense app is open, and the patient is on the adjustment page.</li> <li>In case the ScolioSense app responds to the</li> </ol>

	platform's calibration request but the process terminates unexpectedly, then:  a. Turn off the Location and Bluetooth services of the patient's device, and then turn the above services back on.  b. Restart the <b>ScolioSense</b> app. Close the app from the background and try again.  4. In case the <b>ScolioSense</b> app does not respond to the calibration request of the platform then:  a. Log the patient out of the <b>ScolioSense</b> app and then log the patient into the <b>ScolioSense</b> app.  b. Uninstall the <b>ScolioSense</b> app and reinstall it on the patient device.  If the problem persists, contact Aidplex.
The patient did not receive his registration email from the platform	<ol> <li>Ensure that an email has been delivered to the address provided by the patient, both in the inbox and in the spam folder.</li> <li>Make sure that the address given by the patient is entered correctly in the platform.</li> <li>Delete the patient from the platform and create a new patient account.         If the problem persists, contact Aidplex.     </li> </ol>

# Legal information

**Aidplex** disclaims all liability for any loss of data, loss of profits, or any other loss or damage suffered by the end customer.

The **ScolioSense** device is warranted for 2 years from purchase when used in accordance with this manual.

**Aidplex** can proceed with the replacement of a **ScolioSense** device (if deemed necessary) free of charge, in the case of an active warranty.

**Warning:** The warranty is **not** applied if any part of the device is modified or replaced by personnel, that is not authorized by **Aidplex** or its authorized representative.

Aidplex does not guarantee any therapeutic results when using ScolioSense.

# Service policy

Whenever the **ScolioSense** product is repaired, settings may change or data loss may occur on the device.

#### Warning

Before sending for repair, the data of the **ScolioSense** device should be synchronized through the **ScolioSense** app (if possible), to ensure the maintenance of its data.

**Aidplex** has a support team for **ScolioSense**, which you can contact every day during the hours 10.00 - 18.00 (Greek Time), except Saturdays, Sundays, and Holidays, via the telephone number +302316014433 or via email: support@aidplex.com for any questions or product related problem.

# Warning

**ScolioSense** is a Class 1 Medical Device, an accessory of the scoliosis brace, which is a Class 1 Medical Device as well.

**ScolioSense** must be used in accordance with the instructions for use.

Failure to do so may result in injury.

Users are responsible for the way they are using **ScolioSense**.

Please check the **Aidplex** or **ScolioSense** website periodically for available information regarding contraindications, risks, or side effects related to **ScolioSense**.

**ScolioSense** does not offer treatment advice or any medical diagnosis.

Aidplex does not guarantee any therapeutic results when using ScolioSense.

#### Contact info

Address: 40 Vasileos Irakleiou Street, Thessaloniki, 54623

Phone: +302316014433 Email: info@aidplex.com