

Aidplex ScolioSense Device and Mobile Application Instructions

Document version: 5

Manufacturer: Aidplex

Last modified: 21-10-2024



Device and Mobile Application Instructions











The manual is about the **ScolioSense** device and the mobile application, **ScolioSense** app 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>.

ScolioSense Device Label's Symbols

Symbol	Illustration
	Indicates the manufacturer of the medical device
	Indicates the manufacturer's batch code so that the batch can be identified
	Indicates the manufacturer's catalog number so that the medical device can be identified
	Indicates the temperature limits to which the medical device can be safely exposed
	Operator notification or operator action is required to avoid undesirable consequences
	Indicates the need for the user to consult the instructions for use
	CE conformity marking: marking by which the manufacturer declares that a device complies with the applicable requirements set out in this regulation and other applicable Union harmonization legislation that provides for its installation
	Indicates that the product is a medical device
	Indicates unique device identifier information
	Indicates the humidity range to which the medical device can be safely exposed

Contents

ScolioSense Device Label's Symbols	2
Contents	3
Introduction	4
The company	4
Important safety note	5
CONTRAINDICATIONS	5
INDICATIONS	5
WARNINGS AND PRECAUTIONS	6
Spare parts	6
General Operating Conditions	7
Operating environment	7
Storage, packaging and transport	7
Use	7
ScolioSense	7
User Qualifications	7
Benefits	7
ScolioSense app	8
Description	8
Specifications	8
Installation	9
Getting started	9
User account login	9
First connection	9
Home page	10
Adjustment	11
History	14
Achievements	14
Settings	14
Change application language	14
Check for updates	14
Troubleshooting	15
Personal Data Management	15
Terms and Conditions	15
Feedback	15
Account Logout	15
ScolioSense Device	16
Description	16
Specifications	16
Installation	17

Getting started	17
Indicator Light Statuses ScolioSense	17
Troubleshooting	18
Legal information	19
Warranty Terms	19
How to repackage the product for return	21
Signs of material degradation	21
Some of them but not limited may include:	21
Service policy	22
Warning	22
Contact info	22

Introduction

Thank you for choosing an **Aidplex** product.

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 **ScolioSense** consists of: the wearable device (**ScolioSense** device), the mobile application (**ScolioSense** app) and the web application (**ScolioSense** online platform).

The company

Aidplex operates in the health sector intending to improve the quality of life of patients. More information: www.aidplex.com.

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.

Spare parts

- Special installation tape
- **ScolioSense** device sensors

General Operating Conditions

Operating environment

The **ScolioSense** device works throughout the brace usage. Patients should ensure that the **ScolioSense** device is charged so that there is no loss of data during treatment while using **ScolioSense**. The **ScolioSense** app is suitable for Android and iOS devices, which require Location services and Bluetooth to be enabled to communicate with the **ScolioSense** device, as well as an available internet connection to communicate with the entire **ScolioSense**.

Storage, packaging and transport

- Temperature: -10 °C to 25 °C
- Air humidity: 30% to 75%

Use

- Temperature: -10 °C to 40 °C
- Air humidity: 30% to 75%

ScolioSense

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.

Benefits






ScolioSense enables the patient to oversee in real-time the usage of the brace with the **ScolioSense** app. It also checks the fitting of the brace through the application based on the instructions of the clinician. At the same time, by observing the measurements of the **ScolioSense** device, the clinician is able to oversee the course of the treatment, through the **ScolioSense** online platform.

ScolioSense app

Description

The **ScolioSense** app helps patients understand and follow the prescribed treatment.

The **ScolioSense** app consists of 7 screens:

1. Language selection: Language selection when first installing the app on a mobile device.
2. Login: Login to the application through the email used for the registration of the patient, and the password that was created by the patient.
3.  Home: Presents the daily usage hours of the brace, training questionnaires, and the battery status of the **ScolioSense** device.
4.  Adjustment: Includes the adjustment process, which visualizes the appropriate fitting of the brace. In addition, the process of determining the correct fitting of the brace by the clinician is carried out.
5.  History: Provides detailed information about the usage of the brace over the past 30 days.
6.  Achievements: Presents the achievements and badges, earned by adhering to the treatment.
7.  Settings: Presents functions for feedback, changing language, updates, managing personal data, logging out, and troubleshooting the application.

Specifications

Minimum Requirements of **ScolioSense** app:

Operating system	<ul style="list-style-type: none">● Android: 8.1+● iOS: 11+
Connectivity	<ul style="list-style-type: none">- Bluetooth (BLE)- GPS- Internet Connection

Installation

The **ScolioSense** app is installed from Play Store and App Store for Android and iOS devices.



To connect the patient to the **ScolioSense** app, the clinician must register the patient's details with a valid email address through the online platform. An email is then sent to the patient with instructions to create a password.

Important:

The **ScolioSense** app must be installed and updated throughout treatment with the brace.

Getting started

For the **ScolioSense** app to work properly, you must have the Location, Bluetooth, and Internet connection services enabled to connect and transfer data to the **ScolioSense** device.

Important: In case the device has not been activated by the manufacturer, you should connect it to a charger with a USB-C cable. The device should remain connected until the LED indicator blinks twice in green color.

User account login

To log in to the **ScolioSense** app, you will need to use the email and your password as mentioned in the Description section.

First connection

When using the **ScolioSense** app for the first time:

- You will be asked to connect the **ScolioSense** app to the **ScolioSense** device, that has been installed on your brace.

To connect the **ScolioSense** device to the **ScolioSense** app, you must:

1. Be close to the brace
2. Enable the mobile device's Bluetooth, Location, and Internet services.

3. Select the name of your **ScolioSense** device in the pop-up screen of available devices, that will appear in the **ScolioSense** app. Note that the name of the **ScolioSense** device is placed under the cover of the package in the form of “B-xxxxxx”.
4. Pair with the device using a pairing code. The code is written under the name of the **ScolioSense** device.
5. Confirm your selection by following the instructions in the **ScolioSense** app.
Note: In case the application does not prompt you to enter the device code or if the connection fails for any other reason, you should go to your mobile’s Bluetooth devices and search (scan) to find your ScolioSense device. Then, select pair. You can find Bluetooth devices in your mobile settings or, in most cases, by long-pressing the Bluetooth icon in the activation window.

Home page





Find information about:





- the total usage time of the brace.
- the recommended hours of use.

To synchronize the data with the device, you need to swipe down on the screen.

You can learn more information on how to use the brace and the treatment process through the daily quiz in the **ScolioSense** app.

The battery percentage is displayed in the **ScolioSense** app by pressing the battery icon.

Icon	Description
	Daily quiz
	Daily brace usage time
	Visualization of the time of use and the goal set by the clinician
Battery Indications	
	Full

	Half charged
	Battery low
	Charging
	Unknown value

Adjustment

It offers assistance in following the instructions given by the clinician for the fitting and use of the brace.

For fitting the brace, there are three modes available:

1. **Preview**

It is only available before the first calibration of the brace, which is performed by the clinician. The message “Contact your clinician to use this feature” is displayed on the screen, and the “Preview” button is available. Selecting the “Preview” button displays the current fitting of the brace.

2. **Calibration**

It is performed only by the clinician, through the **ScolioSense** online platform, to calibrate the device to the appropriate fitting. Throughout the process, you should be on the “Adjustment” screen, and follow the clinician's instructions.

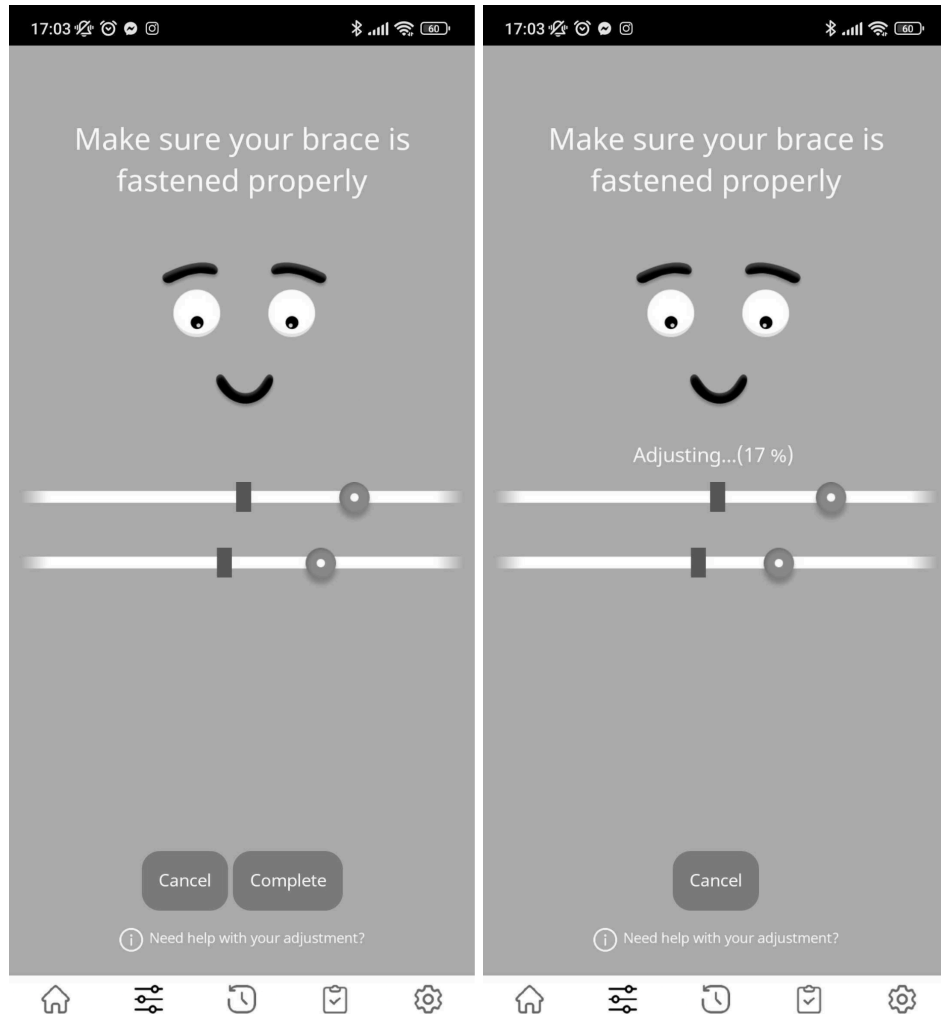
Attention: ScolioSense must not be used as a tool to fit the brace in the appropriate fitting, the patient must follow their doctor's instructions on how to properly fit the brace.

3. **Adjustment**

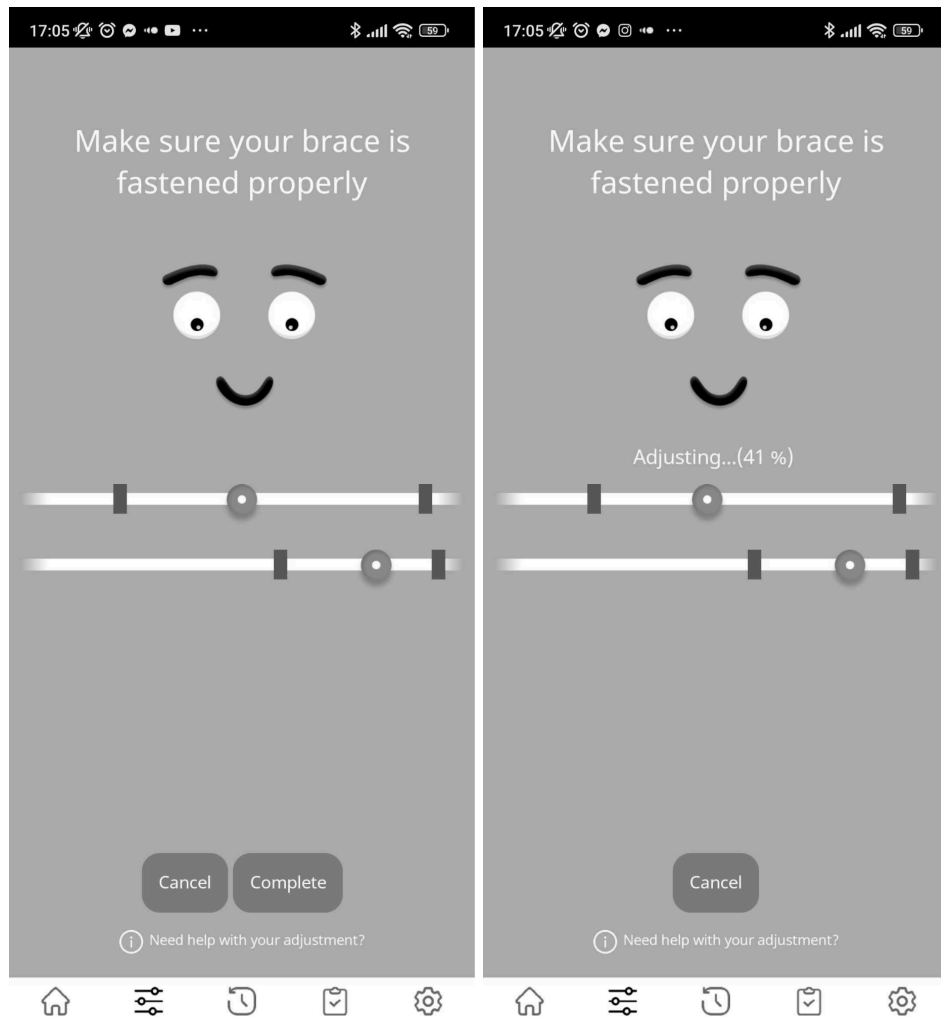
It is available after the first device calibration (see 2). The “Adjust” button is available on the screen. Wear the brace as directed by your clinician, and select the button. The current fitting of the brace is displayed by the dots, that appear on the screen. The vertical lines represent the recommended fitting of the brace. You should fit your brace to the appropriate fitting, according to the clinician's instructions.

Attention: ScolioSense must not be used as a tool to fit the brace in the appropriate fitting, the patient must follow their doctor's instructions on how to properly fit the brace.

- Example of an adjustment: The clinician selects to use only the lower threshold.



- Example of an adjustment: The clinician selects to use a range (both lower and upper thresholds).



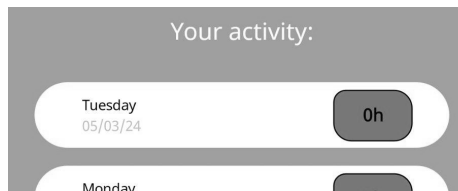
Once you have adjusted the brace correctly, select “Complete” and wait until the process is completed.

Please note that:

- **The ScolioSense device must be operating.**
- **The mobile device's Bluetooth services must be activated.**
- **Be in an upright position during the adjustment.**

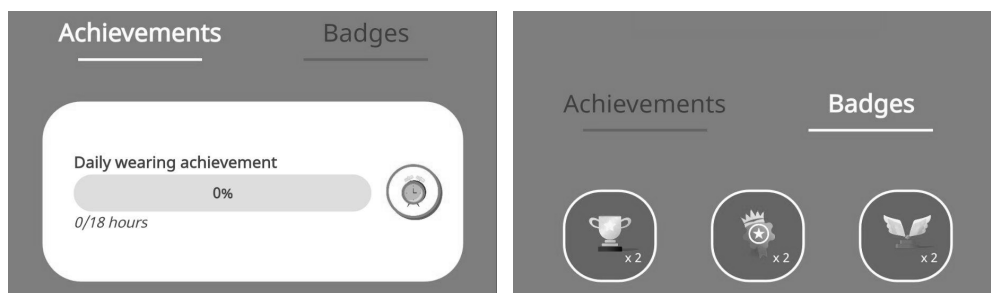
History

Presents information about the brace usage in the previous 30 days. You can see detailed information by selecting the specific day.



Achievements

It displays the awards and the progress of the achievements you have unlocked, following the treatment process.



Settings

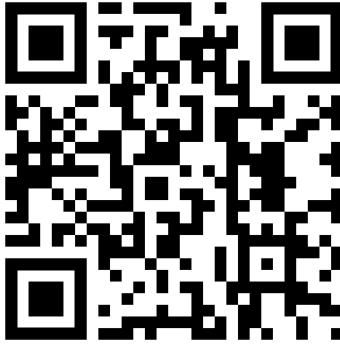
Change application language

Select the operating language of the application.

Check for updates

Select "Check for updates" to check and install available updates of both the app and the ScolioSense device.

Important: If updates are available for the device, the app will prompt you to install the ScolioSense DFU app, through which the device will be updated. The ScolioSense DFU app is available for Android and iOS devices.



Attention: Follow the steps in the DFU ScolioSense app to update the device. In case of an error during installation (permanent purple indication), you should restart the device by pressing the reset button, and repeat the pairing process of the device with the mobile device (Location services must be enabled).

Instructions for use

View available ScolioSense user guides.

Troubleshooting

Follow the on-screen instructions to detect any incorrect readings from the sensors.

Important:

1. **Don't** wear the brace while troubleshooting.
2. The **ScolioSense** device should be powered on.
3. Turn on the Bluetooth services of the mobile device.

Personal Data Management

You can choose the Privacy Policy to be informed regarding the management of your personal data, or contact gdpr@aidplex.com to delete them.

Terms and Conditions

Select "Terms and Conditions" to be informed about the terms of use and conditions of the application.

Feedback

Select "Report" and send comments and observations about the **ScolioSense**.

Account Logout

Select "Logout".

ScolioSense Device

Description

The **ScolioSense** device uses up to 3 analog and/or digital sensors (e.g. pressure sensors) retrofitted on any type of scoliosis back brace, and records in real-time the hours of usage of the brace and the recommended use as instructed by the clinician.

In addition, it allows the patient to adjust their brace based on the clinician's instructions. The **ScolioSense** device uses a rechargeable battery, that lasts 21 days*, which charges using a Type-C cable and a charger (not included).

* Battery life depends on frequency of use.

The **ScolioSense** device has a reset function. Momentarily press the reset button located in the small opening on the top of the device using a suitably sized object. The light should blink green twice.

Attention: After restarting the device, the process of pairing the device with the mobile device should be repeated (Location services must be enabled).

Specifications

Connectivity	BLE (Bluetooth Low Energy)
Weight	20gr (+/-1gr)
Dimensions (diameter x height)	52 x 15 mm
Wireless detection range*	-16 dBm (up to 13 meters)
Wireless communication range*	-16 dBm (up to 7 meters)
Number of pressure sensors	1 to 3
Maximum sensor measurement force	5 kg
Battery life	21 days of use / 2 hours for full charge
Device power supply	Lithium polymer battery (Li-Po) 100 mAh

Wireless transmission frequency	2402 - 2480 MHz
Output radiated power	25.11 μ W

*The detection and communication range was measured outdoors, without impediments. Ideally, the transmitter/receiver distance should be <5 meters.

Installation

Installation of the **ScolioSense** device is performed by qualified personnel.

Important: Do not reposition or disconnect the **ScolioSense** device from the brace. Any actions performed by the user, except the device's restart process (reset), are not considered as intended use.

Getting started

At the first visit to the clinician, the first setup of the **ScolioSense** device takes place to use the **ScolioSense** app.

Important: The clinician should ensure that the **ScolioSense** device is functional by resetting the device and recognizing the sequence of 2 Green indicators. In case there is no sequence, the device should be charged for at least 30 minutes.

Indicator Light Statuses **ScolioSense**

Light Indication Description	Device Status
Constant Red indication	The device is charging (charging complete when the indicator stops).
Periodically flashing Red indication	Synchronization with the ScolioSense app. Perform the synchronization process by swiping down on the Home screen of the application. Do not turn off the ScolioSense app until the process is complete.
Green indication blinks twice	Reset the device. Attention: After restarting the device, the process of pairing the device with the mobile device should be repeated (Location services must be enabled).
Constant Blue indication	Awaiting the first calibration of the ScolioSense device.

Light Indicator Changes Colors (The indicator transitions from blue to purple, and then blinks twice in green)	Update the device software and reboot.
Periodically flashing Blue indication	Indication that may be associated with: <ol style="list-style-type: none"> 1. Confirmation that your device is the one connected with the ScolioSense app. 2. Running brace check procedure. 3. Data synchronization with the ScolioSense app.
Periodic Blue indication, and shift to Purple indication	The device has been notified to initiate the calibration of the fitting of the brace by the clinician. <u>Note:</u> If the <u>Purple indication</u> does not appear, then the process has not been completed correctly.

Troubleshooting

Problem	Troubleshooting
The ScolioSense app cannot connect to the device.	<ol style="list-style-type: none"> 1. Make sure Location and Bluetooth services are enabled on your mobile device. 2. Restart the ScolioSense app. Close the app from the background and turn off Location and Bluetooth services. Then re-enable the services and run the synchronization process. 3. Check if the ScolioSense device is charged. Restart the device by pressing reset. If the device responds, then it is on, otherwise, charge for >30 minutes. Attention: After restarting the device, the process of pairing the device with the mobile device should be repeated (Location services must be enabled).
The measuring of time of use is inaccurate.	<ol style="list-style-type: none"> 1. If the usage time is longer than the actual time, then you should perform the troubleshooting procedure in the settings screen of the ScolioSense app. Caution: You should not use the brace during the troubleshooting

	<p>process.</p> <ol style="list-style-type: none"> 2. If the usage time is less than the actual time, then: <ol style="list-style-type: none"> 2.1. On the home screen of the ScolioSense app, perform the synchronization process with the ScolioSense device. 2.2. On the control screen, confirm that the process is working. 3. Restart the ScolioSense device by pressing reset. Attention: After restarting the device, the process of pairing the device with the mobile device should be repeated (Location services must be enabled).
<p>The brace calibration process cannot be completed (the Purple indication does not light up, or the results are not displayed to the clinician).</p>	<ol style="list-style-type: none"> 1. If additional instructions appear in the ScolioSense App, follow them. 2. Make sure the number of sensors on the clinician's online platform is the same as that of the device. 3. Ensure adequate pressure is applied to all installed sensors throughout the brace calibration. 4. Restart the ScolioSense device by pressing reset. Attention: After restarting the device, the process of pairing the device with the mobile device should be repeated (Location services must be enabled).

In case your problem is not resolved, please contact Aidplex (see [Service policy](#)).

Legal information

Warranty Terms

This warranty does not apply if the product is:

- used with incompatible products.
- used for commercial purposes, such as rental.
- modified.
- damaged by accident, misuse, wear or any other cause not related to defective materials.

To receive warranty services, valid proof of purchase in the form of a sale invoice or receipt must be presented.

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**.

To initiate the return process, the customer must obtain a valid RMA (Return Material Authorization) number. RMA refers to the process of returning a product for refund, replacement, or repair during the product's warranty period. To obtain it, the customer should contact the procurement department, specifically the warehouse (see [Service Policy](#)).

When contacting the company, the customer is obliged to state the LOT Number (written on the product label), the device ID, and the date of purchase along with the proof of purchase of the product.

In the event of a product return within the warranty, the company is obliged to replace the product with a new one and conduct an investigation into the reasons why the device was deemed defective.

In the case of a product return outside the warranty, the company is not obliged to replace the product, but conducts an investigation into the reasons why the device was deemed defective. In this case, the company will contact the customer about the return process.

How to repackage the product for return

The customer is responsible for packaging the device to ensure their transport. Whenever possible, the customer should use the product's original packaging. The RMA number must appear on the shipping package. In addition, the customer should store the payment receipt inside the product packaging.

Signs of material degradation

Some of them but not limited may include:

- Scratches
- Broken parts due to falls or improper use
- Modification or replacement of any part of the device by unauthorized personnel
- Exposure to wet environment
- Underwater submersion
- Exposure to extreme temperatures

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