Aidplex ScolioSense Device Installation Instructions
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ScolioSense™

SCOLIOSIS TREATMENT
REVOLUTIONIZED

aidplex

Device Installation Instructions

This manual is about installing the **ScolioSense** device of AIDPLEX SCOLIOSIS, under the trade name **ScolioSense**, a product of Aidplex. It includes instructions for storing the device and instructions for installing it.
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 t to which the medical device can be safely exposed

Contents

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.

*included in the device packaging

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 by 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 by the scoliosis patient and by the 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 undergoing treatment with a scoliosis brace.
- The **ScolioSense** device should only be installed onto braces and only by authorized personnel who have followed an installation training program.
- The **ScolioSense** device must not be physically 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.

Device installation instructions

The ScolioSense device can support up to 3 sensors for the scoliosis brace. During installation, the manufacturer must determine the pressure points of the brace and specify the exact areas where the sensors will be placed, the number of sensors, and finally the area where the device will be installed, following the guidelines below.

1. Choose an installation point

The device should be positioned so that:

- It does not disturb the patient
- It undergoes as little strain as possible

Two installation methods are recommended for ScolioSense:
1. External installation: For braces that were already manufactured and are in use by patients.
2. Internal installation: For braces that are yet to be manufactured.

1.1 External Device Installation

Figure 1.

A recommended installation point is usually the curve formed by the biggest angle of the patient's scoliosis, Figure 1.

Peel off the protective film from the installation tape to expose the sticky surface, Figure 2.

Figure 2.

Stick the special installation tape to the selected installation point.

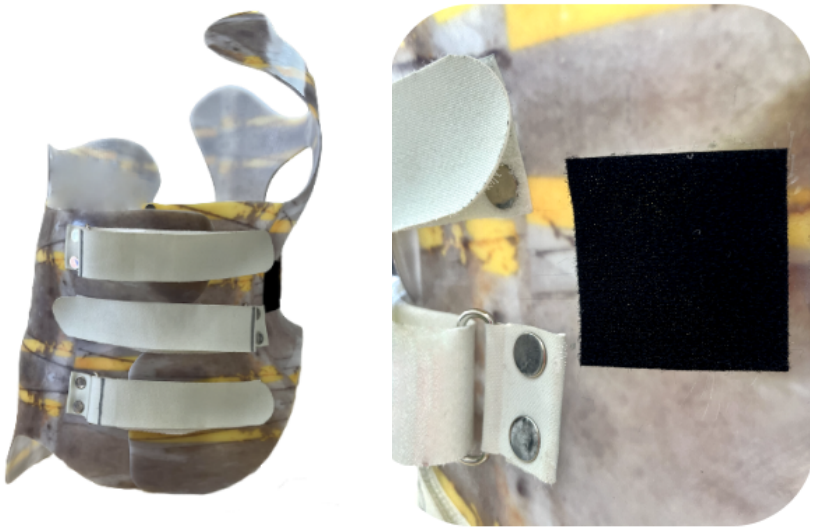

Figure 3.

1.2 Internal Device Installation

For the internal installation of the device, a Type-C Female to Type-C Male angled USB

Figure 4.

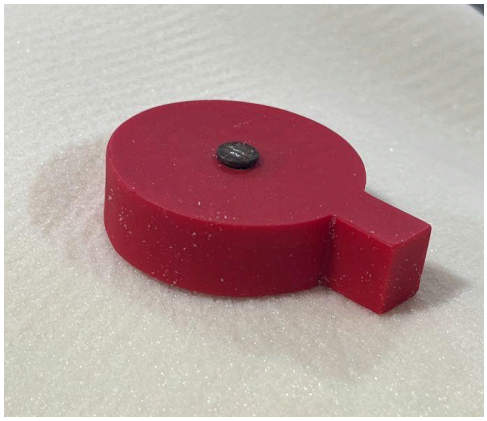

Figure 5.

adapter should be used for charging the device, Figure 4, as well as a mold for creating the recess at the installation point of the device, Figure 5.

The recommended area for the internal installation of the device is an area where an appropriate recess can be created for placing the device, Figure 6.

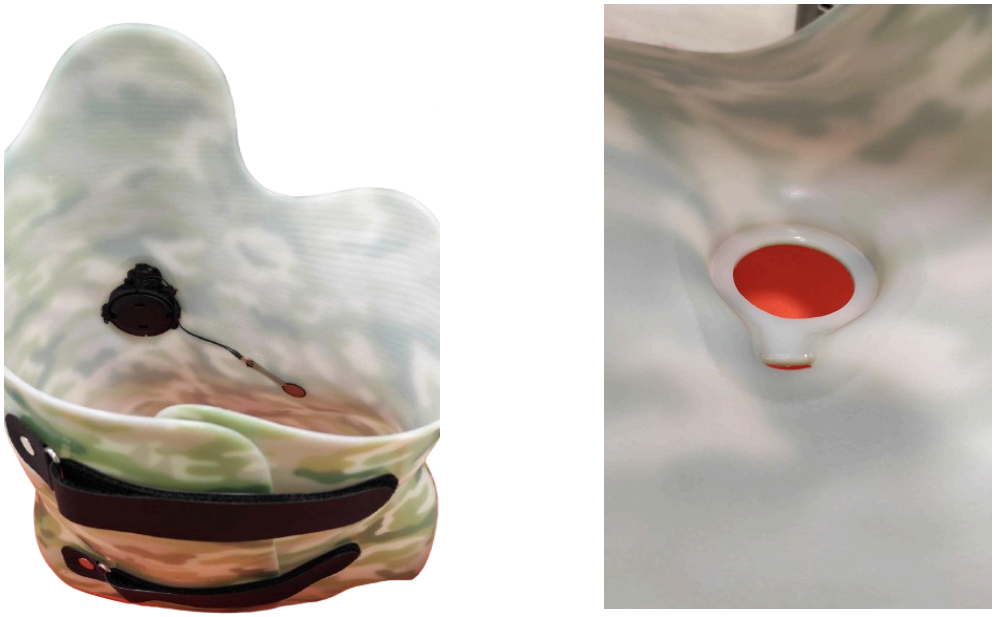

Figure 6.

To create the recess, you should:

- Use the provided mold, Figure 7.

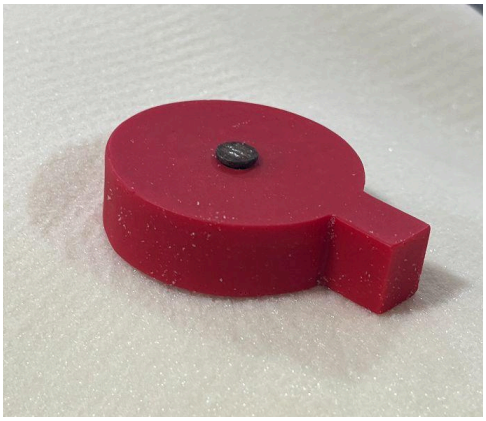

Figure 7.

- Secure the mold on the cast using a screw, with the socket side facing up (point A), Figure 8.

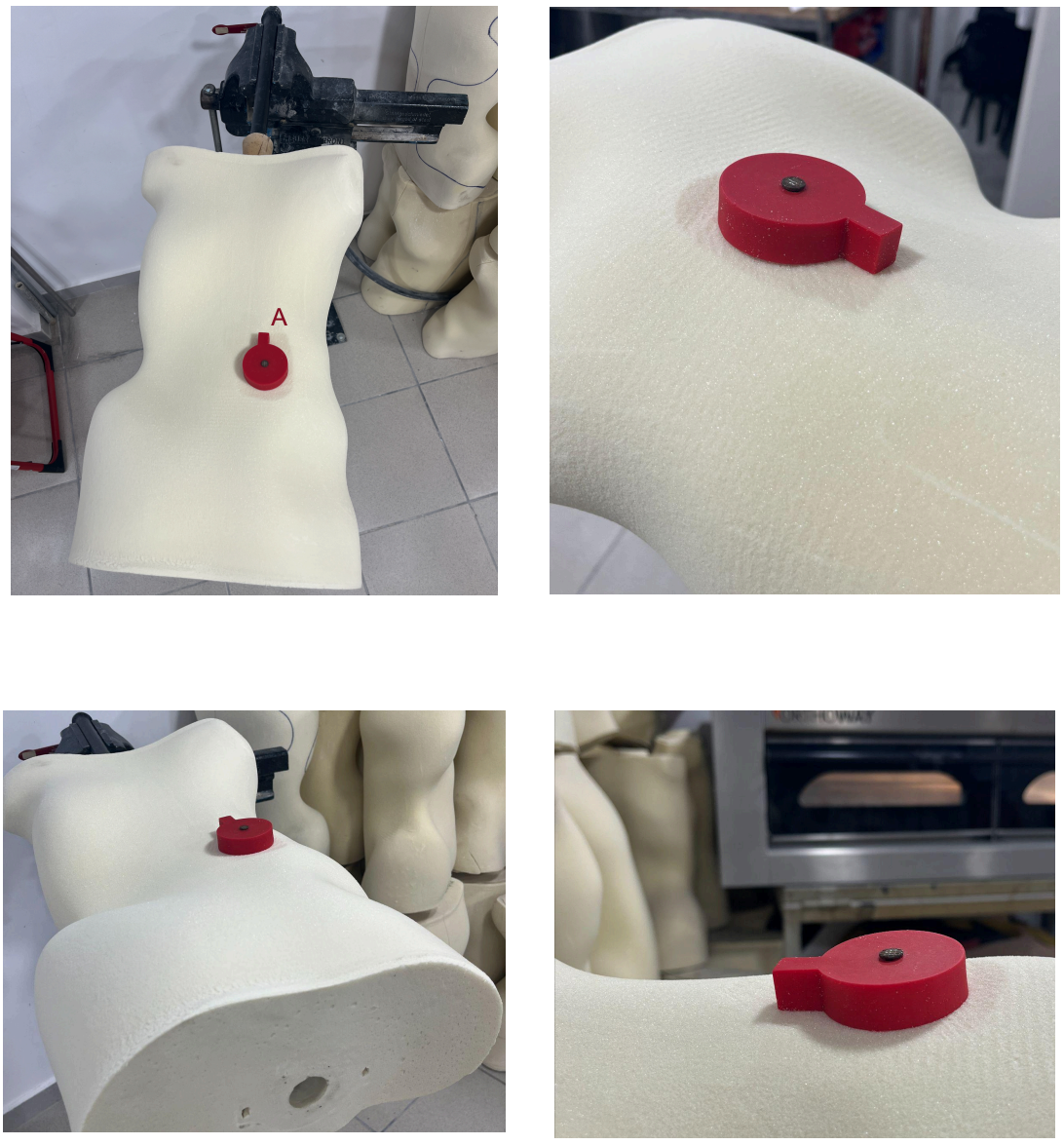

Figure 8.

- Once the plastic sheet for the scoliosis brace has been properly heated, proceed with its placement, Figure 9.

Figure 9.

- When the brace has been removed from the cast and properly cut, two holes need to be created in the recess for the device. The first hole will be created to expose the device to allow easy access to the reset button and indicator lights, and the second hole will facilitate the insertion of the device's charging plug. Specifically:
    - For the first hole, use a conical hole saw or stepped drill bits to gradually create a hole with a diameter of 40mm. Then, smooth the hole with sandpaper or other appropriate tool, Figure 10.

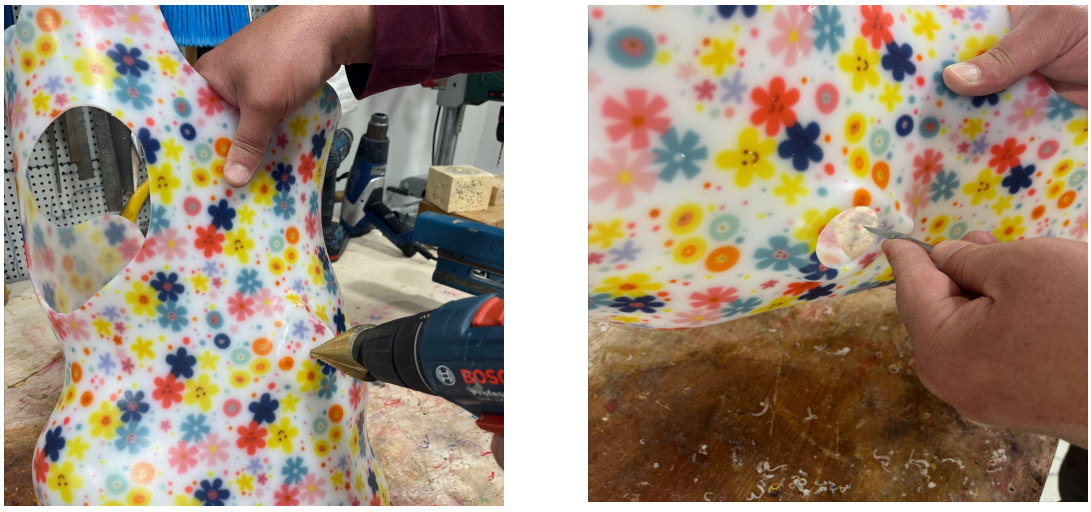

Figure 10.

- Make small holes at the socket location to aid in creating the final hole for the charging adapter, Figure 11.

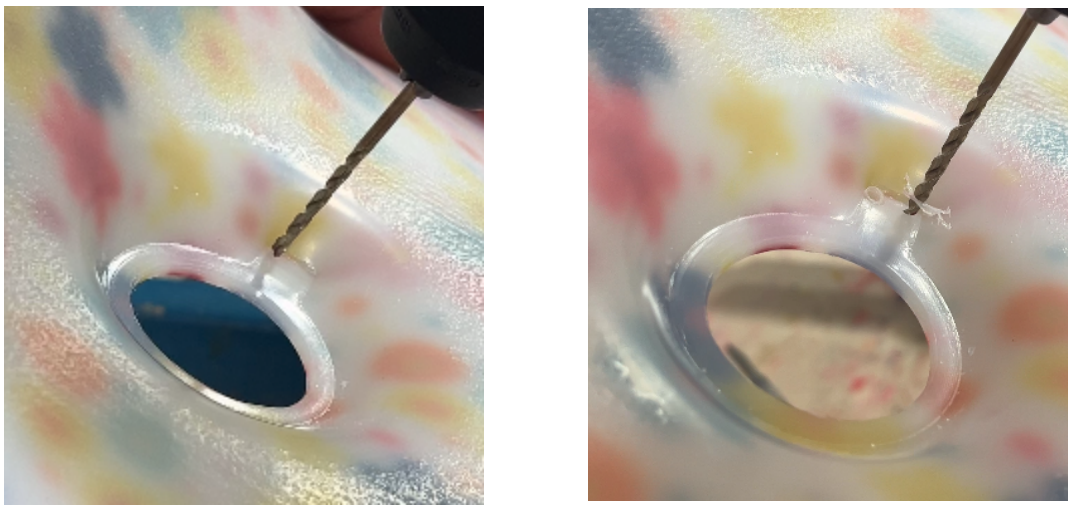

Figure 11.

- To create the hole for the adapter, heat a flat metal object (such as a screwdriver or blade) with a width equal to or slightly smaller than the USB socket and apply pressure at the location until the hole is formed, Figure 12.

Figure 12.

Connect the device to the Type C adapter and place it into the recess of the brace, so that the Type C plug is accessible on top of the device. Check if the device and plug are aligned and fit correctly into the recesses of the brace, Figure 13.

Figure 13.

2. Preparing the sensors for installation

The pressure sensors must:

- Not have any creases in either the tail or the round area of the sensor.
- Not come into contact with adhesives as they may corrode plastics (e.g., rubber cement, epoxy resin, etc.).
- Have their active surface facing the brace and the adhesive-black surface facing the plunger of the brace, Figure 14.

Figure 14.

3. Selection of area for sensors' installation

Sensors are placed at the pressure points of the brace. Typically, pads are placed at these points. The sensors are positioned between the brace and the pad or foam* (in cases where pads are not present). The active surface of the sensors should face the brace, and the adhesive-black surface should face the pad of the brace.

****Important**:**
You can select up to 3 points where sensors can be placed. If you choose points that are close to each other, the system will record the user's wearing time based on the pressures exerted in that specific area of the brace.
This may result in the total recorded wearing time being equal to or less than the actual wearing time by the patient, as depending on body posture, adequate pressure may not be exerted in that specific area to be recorded.
To ensure accurate recording of the desired pressure points and of the total wearing time of the brace, it is important to install an additional sensor in the diametrically opposite area to record pressures and overall usage in case the patient's body distributes the pressure differently (during sleep or exercise).

***Foam**: Soft polyethylene lining material for orthopedic applications (recommended material 7W690 Waforlen of 2mm).
Properties of recommended foam:
Operating temperature: 110 - 130 °C
Hardness: approx. 30 Shore A
Density: 0.14 g/cm³

In the case that:
- The brace has pads: The sensors should be placed under the pads.
- The brace does not yet have pads but will be installed later (mainly for new braces): The sensors should be placed at the points where the pads will be installed and covered with foam. The pads should be placed over the foam.
- The brace will not have pads: The sensors should be placed at the pressure points and covered with foam.

If none of the above cases correspond to the installation method you desire, please contact us (see Contact Information).

Sensor Preparation:

1. Place the sensor in the center of the pad or foam without adhering to it.
2. Outline the sensor with a 2cm distance from the sensor using a marker to create a safety zone for the sensor from the adhesive materials of the pad or foam to the brace, Figure 15.

Note: If the above dimensions (small pads or foam) cannot be followed, the safety zone for the sensor should be minimized with care to avoid contact with adhesive materials.

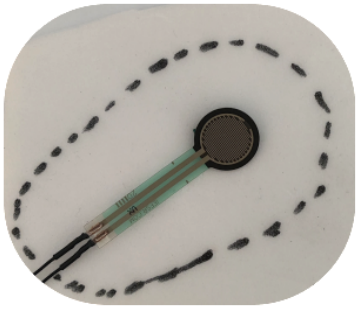

Figure 15.

4. Installation of the sensors

Each sensor should be taped to the brace using masking tape, Figure 16. Next, check the pressure recording of the sensor using the ScolioSense application (see Device Installation Inspection Instructions).
Check if the sensor is preloaded by observing the ball movement in the preview stage in the ScolioSense application. If the sensor is preloaded it should be adhered using the black adhesive tape to the pad within the designed perimeter due to the surface of the brace, Figure 15. Then, the tail of the sensor should be secured with masking tape or electrical tape onto the pad, leaving the sensor head uncovered, Figure 17.

However, if preloading still occurs, the sensor should be moved to the nearest point from the point of interest until the preloading is zero.

*__Preloading__: When a sensor records pressure values without applying any pressure.

CAUTION:

- Sensors should not be placed on highly curved surfaces that cause bending of the sensor head.
- There should be no creases in either the masking tape or the sensor, as these can cause preloading, resulting in incorrect pressure readings.
- Ensure that the sensors do not record pressure without any being applied by using the ScolioSense application (see Device Installation Inspection Instructions).

Figure 16.

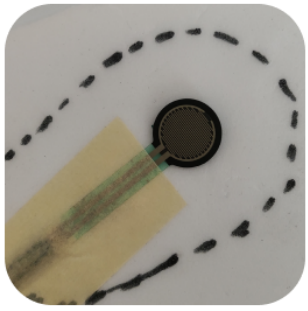

Figure 17.

5. Cable installation

To install the cables, choose one of the following options:

5.1 Installation of Cables Outside the Scoliosis Brace

At the end of each sensor, suitable holes (5mm in diameter) should be made in the brace, 2cm from the sensor, so that the cables can pass outside the brace, Figure 18.

Figure 18.

Next, the cables should be covered with insulation tape up to the point where the device is installed, Figure 19.

Figure 19.

Finally, if the device is installed outside the brace, 2 holes (5mm) should be made, and the cables should be properly routed through them to protect them from tensile stress, as shown in Figure 20.

Alternatively, if the device is installed inside the brace, one hole (5mm) should be made to allow the cables to enter the inside of the brace at the device's location.

CAUTION: The holes for the sensor cables should be below the device installation point.

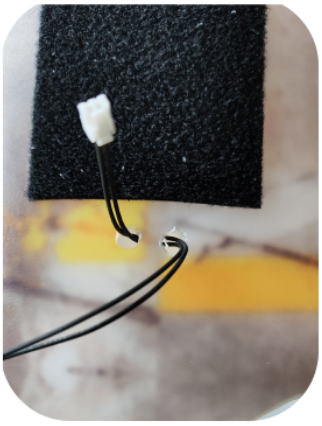

Figure 20.

5.2 Installation of Cables Inside the Scoliosis Brace

Secure the cables with foam to prevent any injury to the patient. The foam should cover the entire surface of the sensor cable, Figure 21.

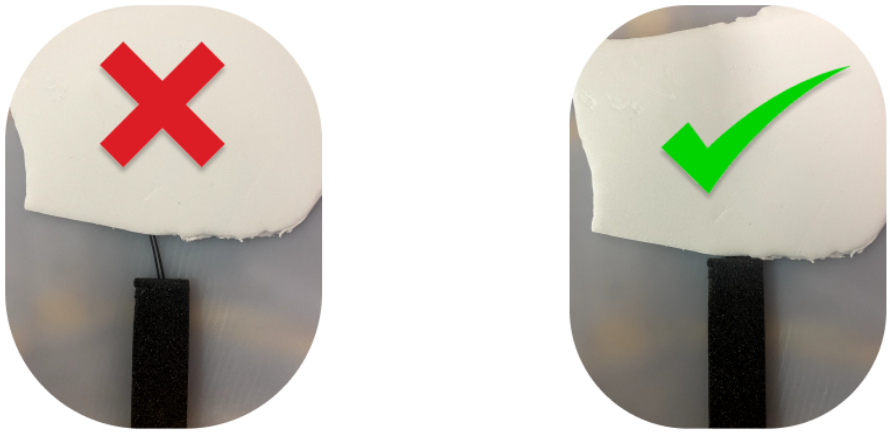

Figure 21.

At the end of the routing, if the device is installed outside the brace, a hole (5mm) should be made to connect the cables to the device, Figure 22.

CAUTION: The holes for the sensor cables should be below the device installation point.

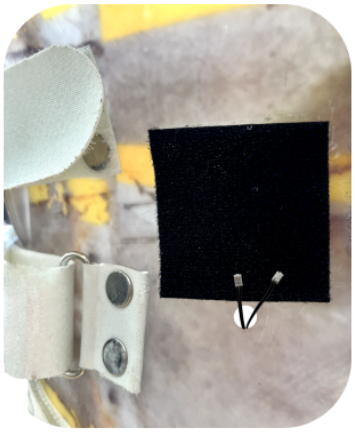

Figure 22.

Alternatively, if the device is installed inside the brace, the cables should be covered with foam up to the connection point with the device, as shown in Figure 23.

Figure 23.

6. Preparation of pressure pads installation

To prepare for the installation of the pads or foam, the adhesive material for the pad or foam should be applied around the designed perimeter, following the material's instructions, Figure 24.

CAUTION: The sensor (active surface and tail) should not come into contact with the adhesive material of the pad or foam.

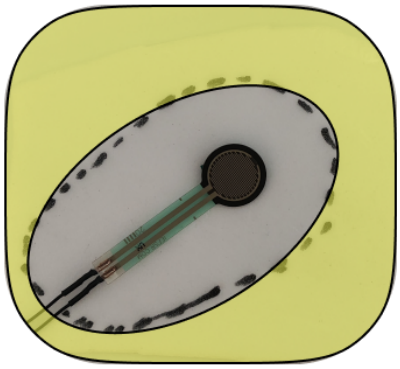

Figure 24.

7. Installation of pressure pads

Install the pad or foam at the selected pressure point. Ensure that the sensor is completely covered by the pad or foam, Figure 25.

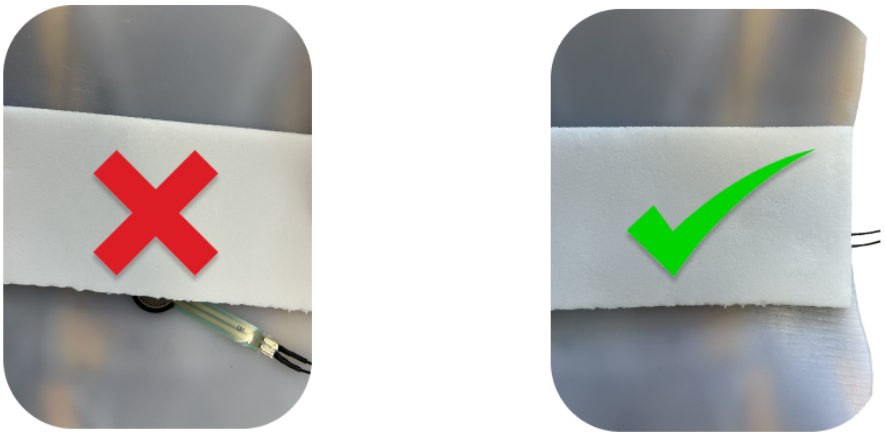

Figure 25.

8. Connecting the Sensors to the Device

Connect the sensors to the device in order, Figure 26.

Figure 26.

Important: In case of a change in the number of sensors, the sensors must follow the connection sequence 1, 2, 3.

Example 1: If a patient had 3 sensors and it is decided to remove the 2nd sensor, then the 3rd sensor should be moved to position 2.
Example 2: If a patient had 3 sensors and it is decided to remove the 1st sensor, then the remaining sensors should be moved to positions 1 and 2, respectively.
Example 3: If a patient had 3 sensors and it is decided to remove both the 1st and 2nd sensors, then the 3rd sensor should be moved to position 1.

9. Cable management

Wrap the excess cable around the dedicated slot of the portable device, Figure 27.

Figure 27.

The sensor cables can be gathered by wrapping them around the slot located at the bottom of the device. The device has 4 points that can be used for the entry or exit of the cables to and from the slot for gathering, Figure 28.

Figure 28.

10. Securing the Device at the Installation Point

10.1 Securing External Installation

Peel off the protective surface from the special installation tape (round tape) of the device to reveal the adhesive surface, and stick it to the back of the device, Figure 29.

Figure 29.

Next, install the ScolioSense device on the brace, Figure 30.

Figure 30.

10.2 Securing Internal Installation

Once the cable placement is complete and no cables are protruding from the device (see Cable Management), you should first connect the angled adapter of the charging plug so that access to the charger is at the front side of the device. Then, secure the device in the designated slot using silicone, Figure 31.

CAUTION: The silicone should not cover the cable management slot or the sensor plugs of the device.

Figure 31.

Finally, cover the installation point with a pad or foam, ensuring that the device does not come into contact with the adhesive materials, Figure 32.

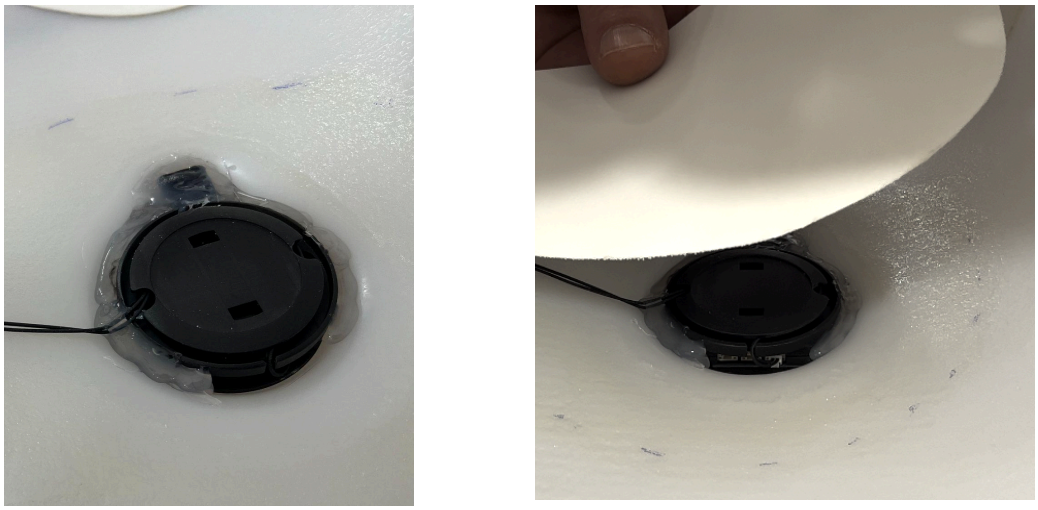

Figure 32.

Below is a complete example of an internal installation, Figure 33.

Figure 33.

Activation Instructions for the ScolioSense Device

Activate the device by connecting it to a USB-C cable to charge. The device only needs to remain connected for charging until the two green indicators flash.

Attention: Each device is charged to storage mode (60%) by Aidplex. After disconnecting the charging cable, if the blue indicator remains on, it means the device is ready to pair with a patient and perform the calibration process through the web platform. Otherwise, if the blue indicator does not remain on, the device needs to be charged for at least 30 minutes (partial charging).

Figure 34.

Device Installation Check Instructions

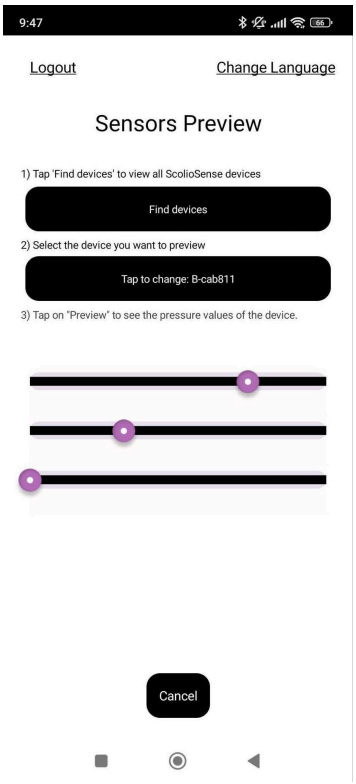

Figure 35.

To preview the sensor pressures and ensure the correct placement of the system in a brace, the ScolioSense app must be installed on the responsible installer's mobile device.

Important: After activating a device, you should attempt to update the device to the latest version using the DFU ScolioSense app (see Device Update Instructions).

The steps for checking the preloading and system response in the use of the brace are described below:

1. Install the ScolioSense app on your mobile device or tablet from the App Store or Google Play Store.
2. Login using the credentials of the ScolioSense.com web platform.
3. Search for the ScolioSense device by pressing the "Find Devices" button.
4. Select the ScolioSense device for testing (the device name is found inside its box).
5. Select "Preview" to view the sensor response.
6. Ensure that the balls move when pressure is applied to the pistons with sensors.
7. Ensure that the balls do not move when no pressure is applied to the pistons with sensors and the brace is in an upright position.

Device Update Instructions

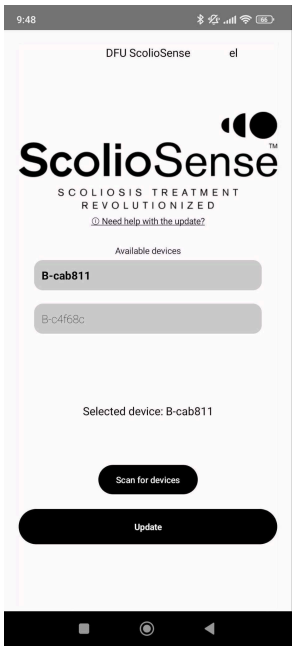

Figure 36.

After activating a device, it is important to check for any software updates. The steps to update a ScolioSense device are described below:

1. Install the DFU ScolioSense app on your mobile device or tablet from the App Store or Google Play Store.
2. Login using the credentials of the ScolioSense.com web platform.
3. Search for the ScolioSense device by pressing the “Scan for Devices” button.
4. Select the ScolioSense device for updating (the device name is found inside its box).
5. Update the device by pressing the “Update” button.

Spare parts

- Velcro tape
- **ScolioSense** device sensors
- Type-C Female to Type-C Male angled USB adapter

General Storage Conditions

Storage, packaging, and transport

- Temperature: -10 ºC to 25 ºC
- Air humidity: 30% to 75%

Contact info

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