

STIM onTrack™ Instructional Guide



These instructional materials are intended for informational purposes only and do not constitute medical advice. If you have any questions regarding your treatment plan, contact your physician or medical professional.

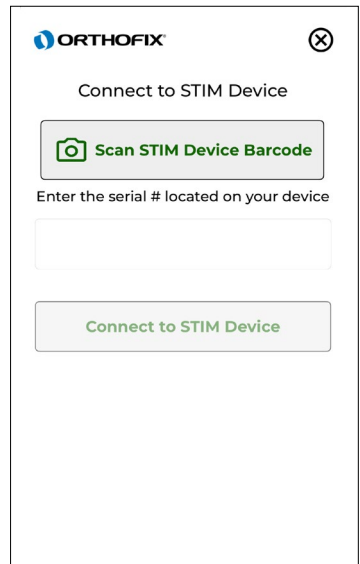
About STIM onTrack

The STIM onTrack™ app is a patient friendly accessory available for you to use with your Orthofix Bone Growth Therapy Device (STIM Device). The app encourages you to adhere to treatment sessions prescribed by your physician. It features a daily treatment reminder and a device usage calendar to help you take an active role in your bone healing recovery. Studies show that patients who are more involved with their follow-up care have an overall better recovery experience and outcomes. At the time of device delivery, your Orthofix representative will help you download the application to your mobile device.

Connecting the STIM onTrack App to Your Bone Growth Therapy Device

In order for the STIM onTrack app to connect to your STIM Device, the device must be on and providing a treatment or charging the battery.

1. The first time you launch (open) the STIM onTrack app, you will be prompted to 'Connect to STIM Device'.
2. Enter the serial number barcode on your bone growth therapy device by pressing the button 'Scan STIM Device Barcode' or by manually typing in the numbers in the open text box.
3. Push the 'Connect to STIM Device' button. Wait until the Treatment Screen appears as this is an indication that the device has paired with the app successfully.

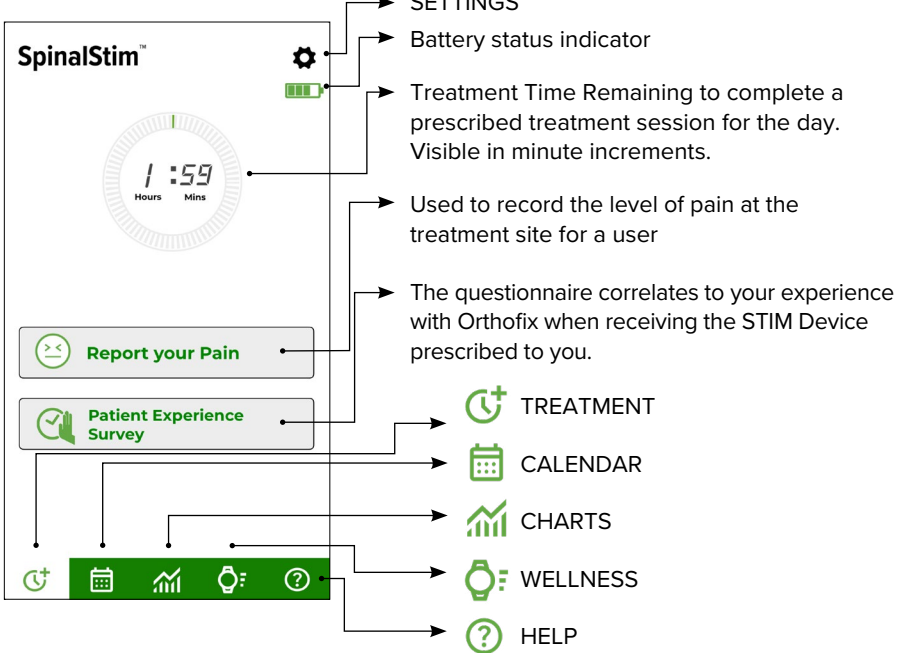


⚠ Note: The Orthofix STIM onTrack app is supported on iOS and Android devices. The STIM Device will not communicate with any other device or app other than the official Orthofix STIM onTrack app from Orthofix. The app is available on the Apple App Store and Google Play Store.

⚠ Note: Bluetooth on your smartphone or tablet must be turned on before downloading the STIM onTrack application.

⚠ Note: Update your device software for best app experience.

Treatment Tab



Device Notification

Treatment Completed

Once you have finished your treatment for the day, this message will appear on your STIM onTrack app while the device is automatically shutting off.



Device Not Connected

This message will appear when your STIM Device is not connected to the STIM onTrack app. Click the troubleshooting icon for details.



Bluetooth Turned Off

This message will appear when the Bluetooth on your smart phone is turned off or permission to use Bluetooth is disabled.



Device Expired

Your STIM Device will expire after 365 days of use. Contact your physician or Orthofix Patient Care for more details.



Low Device Battery

If the device is connected and the battery is low at any point during your treatment, this message will appear on your STIM onTrack app.



Device Charger Not Supported

If the device is not charged with an Orthofix-supplied Power Charger, this message will appear on your STIM onTrack app.



Calendar Tab

The Calendar Tab on the STIM onTrack app shows the duration of time you have worn the device beginning with the initial treatment day. This information is visible by:

- Calendar overview
- Daily treatment details
- Patient usage data summary

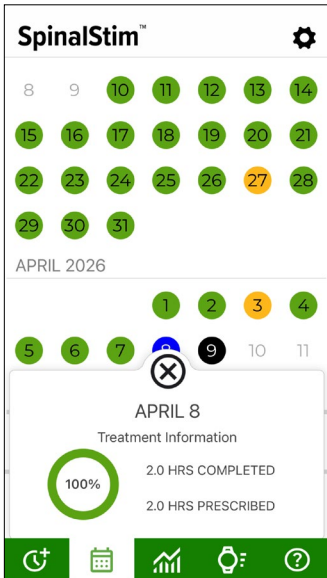
Calendar Overview

During daily treatment, while the app is open, you will notice a light yellow circle highlighting the current day on the calendar. Once the prescribed treatment for the day is completed, the circle will change from light yellow to light green.

Calendar Color Key:

- Current Day (prior to treatment)
- Day Selected to Review Details
- No Treatment Completed
- Partial Treatment Completed (same day)
- Completed Full Treatment (same day)
- Partial Treatment Completed
- Completed Full Treatment

Once a date on the calendar has passed and/or the STIM Device has been turned on and connected to the app, a dark red, yellow, or green circle will highlight the date to indicate no, partial, or full treatment for that day.



Daily Treatment Details

When you select a date on the calendar, the Daily Treatment Information will appear. It will display a summary of how many hours you used the device in comparison to the treatment hours prescribed by your physician. The Treatment Information pop-up also gives the percentage of the hours completed compared to the hours prescribed.



Patient Usage Data Summary

Total Days of Treatment - The number of days you have worn the device for the full time prescribed.

Days Since Start of Treatment - The total number of days you have had the device to wear for treatment.

Compliance Percentage - The percentage of days you have fully completed the prescribed treatment compared to the number of days since the start of treatment.

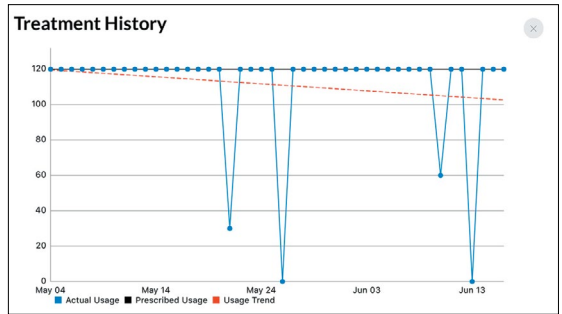
The patient usage data will be synced to the STIM onTrack app each time that the STIM Device is on for treatment or charging as long as the paired mobile app is open and in close proximity. Last paired date will be updated to the date data was synced.

This section will show an approximate calculation if you complete the current day treatment with the app open.

⚠ Note: The calendar functions by scrolling up and down for Apple device and side to side for an Android device.

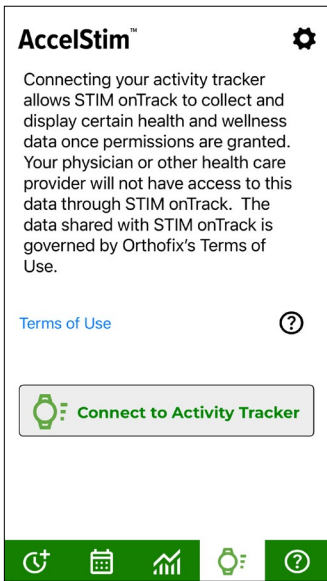
Charts Tab

The Charts Tab on the STIM onTrack app includes Treatment Compliance and Visual Analogue Scale (VAS) tools which enable you to share the treatment history, and your quality of life with pain related to your surgery or injury. The details displayed are from information provided throughout your treatment and can be shared with your prescribing physician.



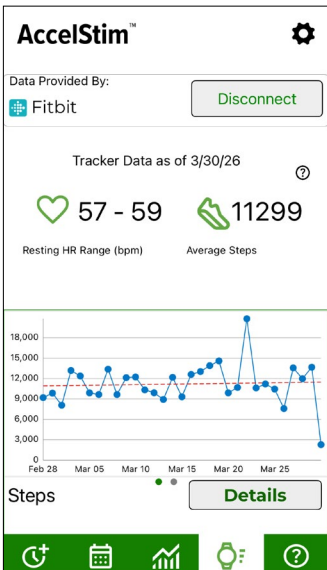
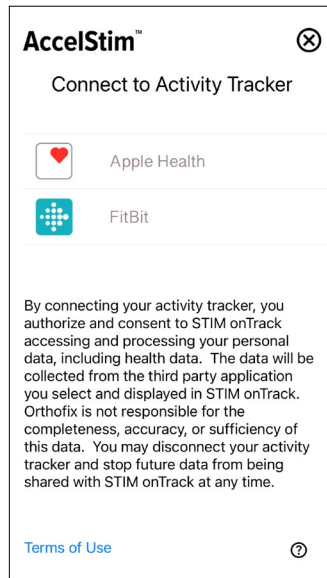
→ **Navigate to Generate Care Report (PDF) -** Generating a care report allows you to save an electronic copy of your treatment, and pain level.

Wellness Tab



The Wellness tab on the STIM onTrack app allows you to connect to your smart watch. The trackers available for pairing are Apple Health, and Fitbit. Please note for Android phones, only Fitbit is available.

➔ **Connect to Activity Tracker** - This initiates pairing with the activity tracker and takes you to the 'Connect to Activity Tracker' screen where the specific tracker can be selected.



Select the type of activity tracker to connect to STIM onTrack. Follow the prompts to connect to your tracker. Please note that account setup is done via Apple or Fitbit.

After pairing with a tracker, step count and heart rate will be displayed. The summary above displays a heart rate range and average step count for the past seven days.

➔ **Disconnect** - The 'Disconnect' button will disconnect the paired tracker from STIM onTrack and return to the first screen above. You can reconnect to the same or other tracker at any time.

⚠ **Note:** Wellness data will appear from the connected activity tracker the following day after an average is calculated.

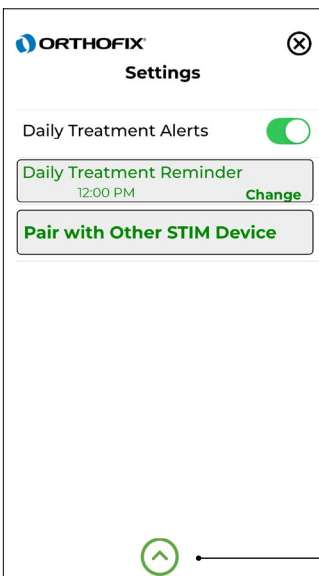
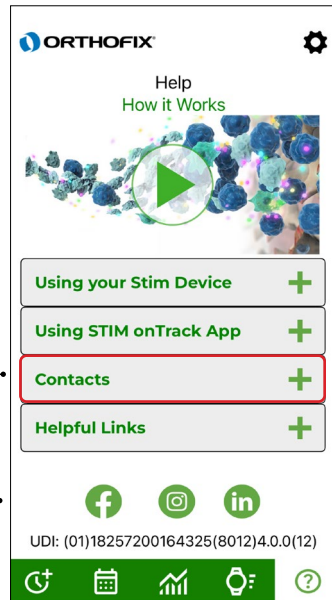
Help Tab and Settings

The Help Tab displays contact information and website links to resources to help patients during their recovery.

The contact numbers provided, are one-touch calling on your smartphone and give you the ability to contact your Orthofix Sales Representative and/or Patient Care.

Users can now utilize in-app messaging to connect with Patient Care.

Follow Orthofix on social media to stay up to date on product news!



⊗ – Exit out of Settings Tab

Daily Treatment Alerts - Slide the button to turn on a daily treatment reminder.

Time of the daily Treatment Reminder - This section displays the current reminder time and is only visible if the Daily Treatment Alerts are on.

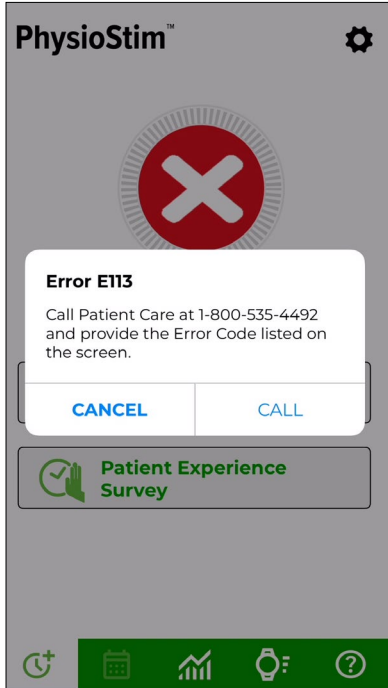
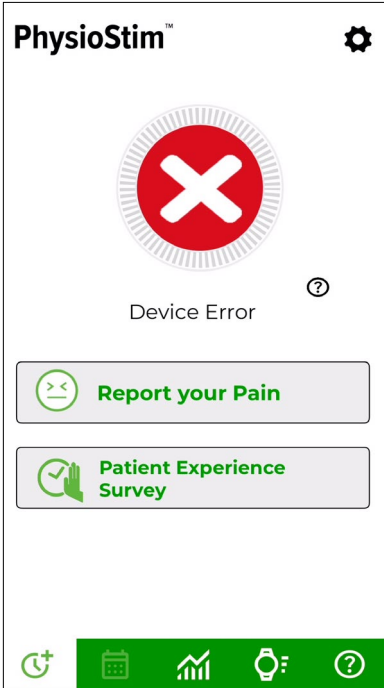
Pair with Other Stim Device - This section will display the currently paired device and the 'Disconnect' button while the device is actively connected. When the device is not connected, the 'Pair with Other STIM Device' button will be displayed.

Management Mode - Settings used only by an authorized Orthofix Representative.

⚠ Note: Changes to the prescribed time will affect the compliance of the next treatment session.

Device Error Messages

The Error Message means that your STIM Device is not functioning properly. Please contact Patient Care at 800.535.4492. Your Patient Care Representative will ask for the Error Code, which begins with the letter E and is followed by 3 digits. This code allows the Patient Care Representative to determine why your STIM Device is not functioning properly. In the absence of cellular service, the 'CALL' button will not be shown.



Additional Error Codes

Code	Exception Name	Definition
E300		An unexpected exception has occurred
E301	Clock Exception	The main high speed clock oscillator is not started or a problem was detected with the HSE (clock security detection).
E302	State Machine Exception	Unexpected condition where a system software state or event was not supported or invalid. SWERR, Software Exception
E303	Event Processor Exception	The system software main event thread has failed to initialize. TIM5 peripheral or associated clock probably an issue.
E304	Charge Fault	The dedicated battery charger IC safety timers have expired indicating several possibilities of a charge fault including battery failure, main circuit failure, or charger circuit failure.
E305	PVD	The programmable voltage detector has detected a very low MCU source voltage, system brownout detection.
E306	CRC Exception	Configuration data (MFG, Rep, Device, or Battery) calculated CRC-32 does not match. Can also be attributed to a RTC reset/re-initialization.
E307	RTC Not Configured	The RTC backup memory is either not configured or has become corrupt. During manufacture the RTC must be initialized via USB.
E308	RTC Not Running	The RTC timer failed to start. The low- speed system clock may be dysfunctional.
E309	Battery Level Low Exception	Will not be displayed on the LCD screen. This Exception is logged in the system device log when the "Battery Low" threshold is reached.
E310	Battery Standby	Battery level too low (occurs in settings mode). Custom Exception number used in treatment mode (EXXXXXXXX).
E311	Treatment Start Exception	An exception occurred attempting to start the LIPUS treatment.
E312	Not Manufactured Exception	The device manufacturing configuration is not programmed or may be invalid.
E313	RTC Rollback Exception	The device date predates the last "usage date" by at least one day. Possibly the time zone was changed via external software.
E314	Memory Full Exception	Usage data memory is completely full (or the last location is used). No more than 384 days may be stored.
E315	Expired Exception	This indicates that the number of days elapsed since the first patient treatment day is greater than 365 days.
E316	Treatment Save Exception	Usage data failed to write to flash memory. Flash, persistent, memory Exception.
E317	Transducer Voltage Exception	The system detects a transducer driver voltage out of range exception.
E318	Transducer Open Circuit	The system detects a low current condition in the transducer hardware
E319	Transducer Short Circuit	The system detects a high current condition in the transducer hardware
E320	Display Exception	A parameter to one of the display functions was not valid.
E321	TS Controller Exception	An error was encountered initializing the touchscreen controller
E322	ADC Threshold Exception	A battery threshold for the currently selected battery type and selected device type is invalid or not populated.
E323	Treatment Monitor Verification Exception	Either treatment RAM corrupted while treatment was ongoing, or a critical treatment rule failed verification (example: Prescribed Time must always be between or equal to the device Min/Max limits).

Cybersecurity for the STIM onTrack app

The STIM onTrack app is available to download from the Apple App Store and Google Play Store. The latest version of the mobile app can be found on the Apple App Store and Google Play Store list and can be verified on the last 3 digits of the UDI on the Help Tab.

The STIM onTrack app uses a secure Bluetooth connection to pair with your STIM Device. This data with any survey data is saved on the mobile device and is then transferred to the STIM MD™ Physician Portal using HTTPS secure link. To avoid any cybersecurity risk, always keep the phone locked with a strong passcode. The app does not store any personal information. The STIM onTrack app works in conjunction with STIM Device.

If the device is no longer needed, patients are welcome to remove the app from their mobile device. If the storage of the app is cleared due to any reason, the data can be restored* by pairing the app with the STIM Device.

The STIM onTrack app shows various alerts in case of any connectivity error or error identified on STIM Device that is transferred over Bluetooth. For any questions regarding the alerts, contact Patient care at the phone number provided on the Help Tab in the app.

If you suspect any cyber-attack on the mobile device, contact Patient Care at 800.535.4492. In case of a cybersecurity event, Orthofix will reach out to the patient on the number provided on file. A copy of mobile app software bill of materials (SBOM) may be requested by calling Patient Care.

*Activity tracker data can be restored by logging into the tracker account.

* Information collected via the STIM onTrack app is not intended for the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions.

BoneGrowthTherapy.com/privacy-policy/

STIM onTrack™ Mobile App Patent No. U.S. 10,238,867

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