OPOS[1] User Manual

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1 Table of Contents

2 OPOS[1] Product Description

OPOS[1] is a system used by clinicians in the field of orthotics and prosthetics to track the amount of time that an orthotic or prosthetic device is worn by a patient. It also includes basic activity level tracking via step count. The main intention of OPOS[1] is to provide clinicians with an accurate portrayal of how well their patients are following the prescribed schedule of use in order to improve ambulatory outcomes and intervene, if necessary.

The system is composed of:

- A wearable compliance sensor that is lightweight and low-profile and can be mounted directly to the orthosis/prosthesis via a flexible sticker-like enclosure, or it can be embedded into the thermoplastic or carbon-fiber shell of the orthosis/prosthesis.
- A mobile application used for wireless data transmission, data recording, and data visualization
- A cloud database used to store data for all practices using OPOS[1]

The sensor is mounted to the orthosis/prosthesis at the point of service. The sensor is connected to a user's mobile phone via a mobile app to allow for remote monitoring, or it can function as a data logger and store the data locally until it can be downloaded at the next appointment. The clinician views the patient data and summary reports using a mobile application. Patient data can be exported to share with other members of the clinical care team and attach to the patient's electronic medical record. Clinicians and practice owner can view reports that show global trends in patient data over time.

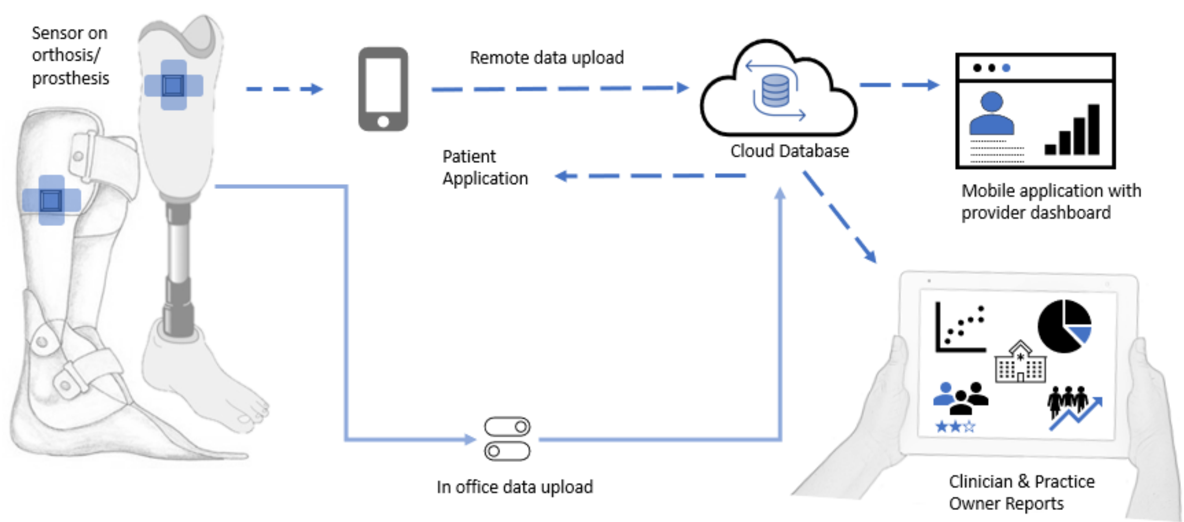


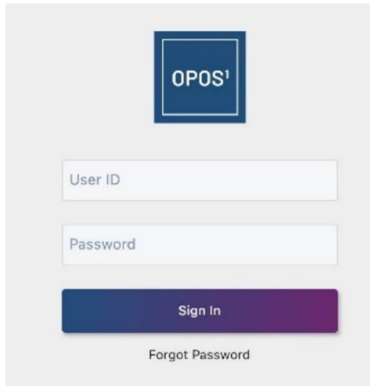
Figure 1: OPOS[1] System Diagram

3 OPOS[1] Application Usage Guide

The screenshots below show a step-by-step navigation through the application.

3.1 Log in

The application requires login each time it is opened for security purposes. User ID is the email address. Password is set by user at first login. See the Resetting Password section for information on resetting passwords.

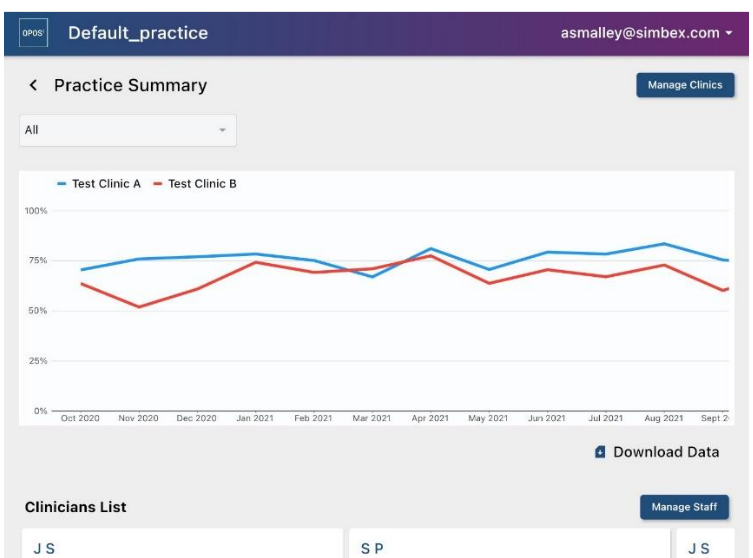


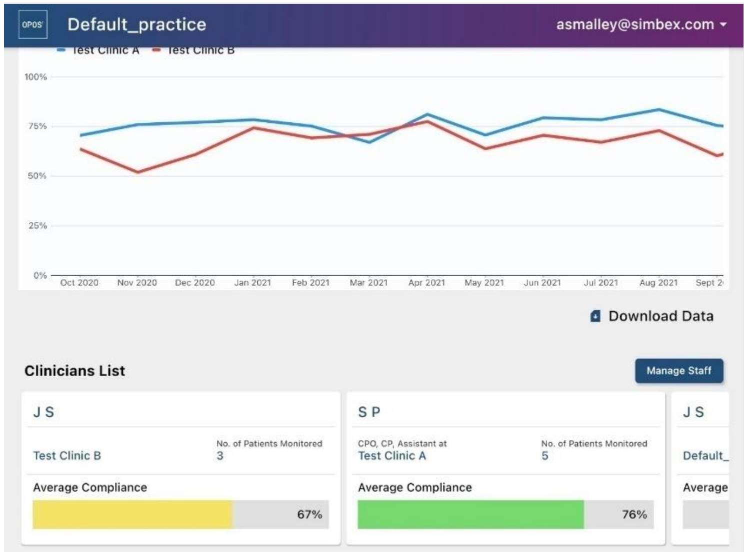
3.2 Practice Summary Page

Practice Admin accounts are directed to the Practice Summary page after log-in. The Practice Summary page displays compliance percentage data over time for each clinic within the practice. The dropdown selection allows customization of the display. Cards below the chart show clinician summary data.

Actions available from the Practice Summary page:

- Show compliance data over time for selected clinics (clinic dropdown)
- Add/edit clinics (MANAGE CLINICS)
- Add/edit staff (MANAGE STAFF)
- View Clinician Dashboard page (select the clinician's card below the graph)
- Download .csv of practice summary data (DOWNLOAD DATA)



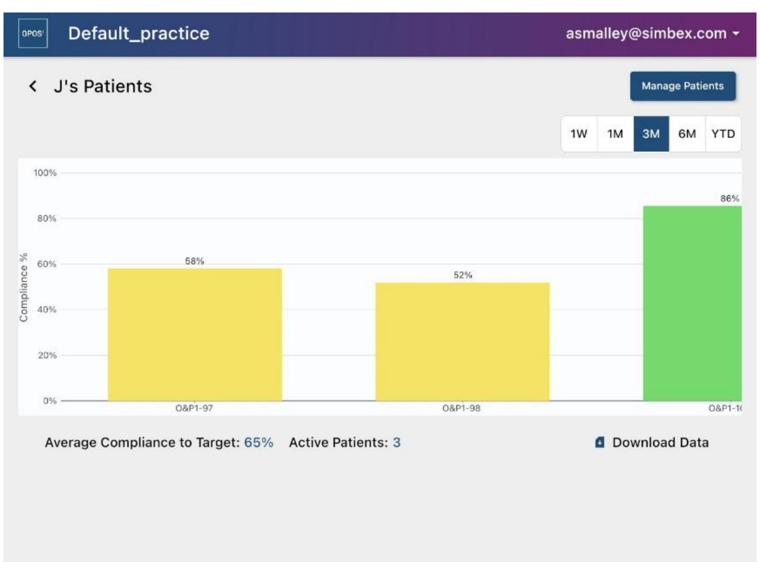


3.3 Clinician Dashboard page

Clinicians are directed to their Clinician Dashboard page immediately after log-in. Practice Admin navigate to the Clinician Dashboard page by selecting the clinician card from the Practice Summary page. The Clinician Dashboard page shows the compliance percentage of that clinician's patients.

Actions available from Clinician Dashboard page:

- Add/edit patients (MANAGE PATIENTS)
- Timebox data (1W, 1M, 3M, 6M, YTD)
- Navigate to patient page (Select patient ID in bar chart)
- Download .csv of practice summary data (DOWNLOAD DATA)

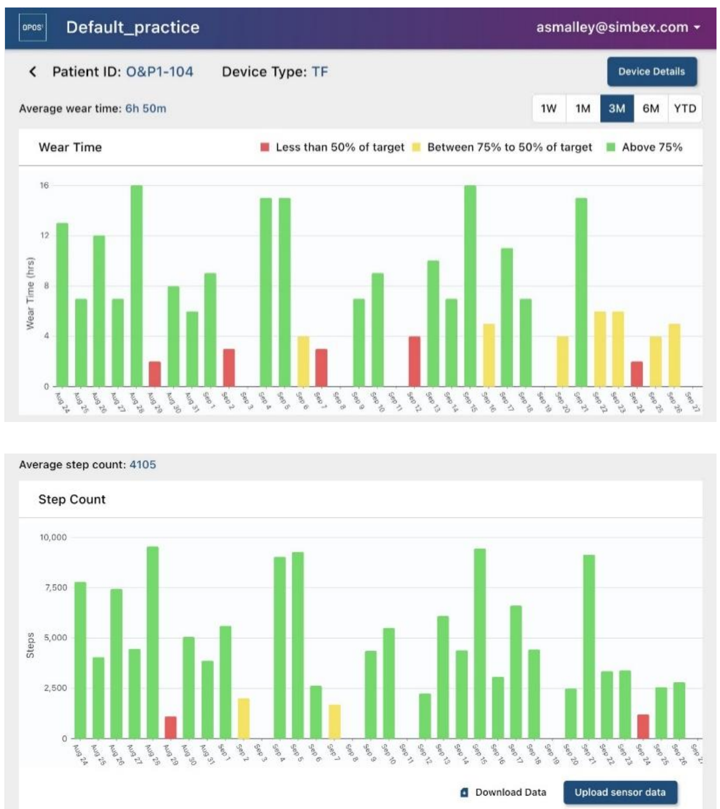


3.4 Patient page

Patients are directed to the patient page after log-in. Clinicians and Practice Admin navigate to patient page by selecting patient ID within the Clinician Dashboard chart. The patient page shows the individual patient's wear time and step count data over time. Patients who access this page are not shown the DEVICE DETAILS button.

Actions available from the Patient page:

- Connecting and activating/deactivating sensors (DEVICE DETAILS)
- Setting break-in period (DEVICE DETAILS)
- Setting wear time and step count targets (DEVICE DETAILS)
- Timebox data (1W, 1M, 3M, 6M, YTD)
- Upload sensor data (UPLOAD SENSOR DATA)
- Download .csv of patient data (DOWNLOAD DATA)



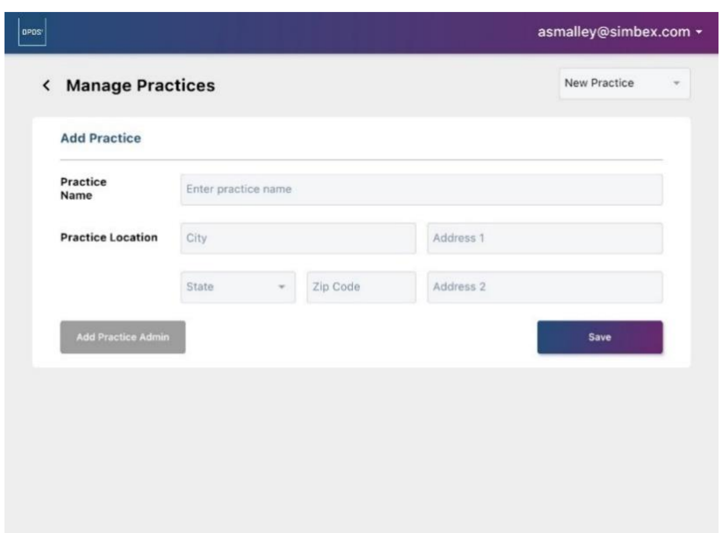
3.5 Resetting passwords

Users can reset passwords by selecting FORGOT PASSWORD on the login screen. They are then prompted to input their User ID (email address). A reset email with a temporary password is sent to their email address. When they navigate back to the login screen, the temporary password is used to log in. The user should then reset their password.

3.6 Adding a practice

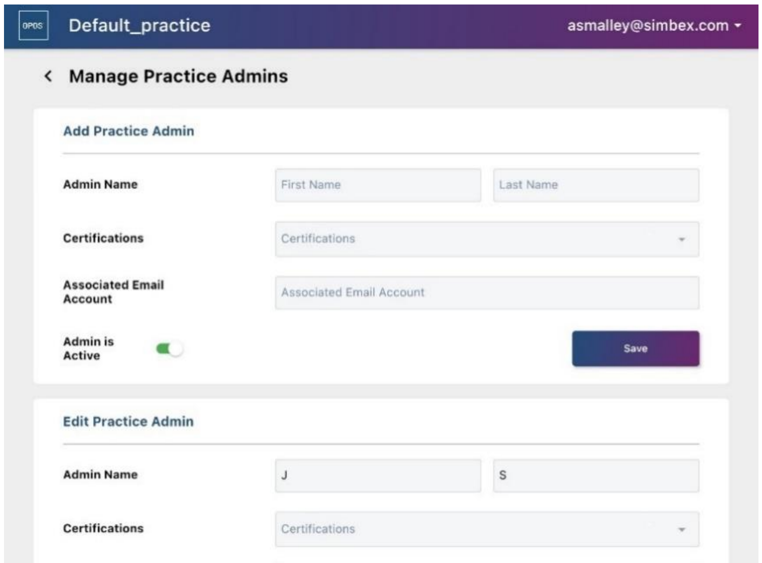
Only System Administrators can add new practices. A navigation screen with two options is the first page seen after a System Administrator logs in.

Selecting the option to **MANAGE OPOS1 PRACTICES** opens the Manage Practices screen, where the System Administrator can add a new practice. This same screen also allows the System Administrator to edit existing practices by selecting a practice name from the dropdown list at the top right corner of the screen.



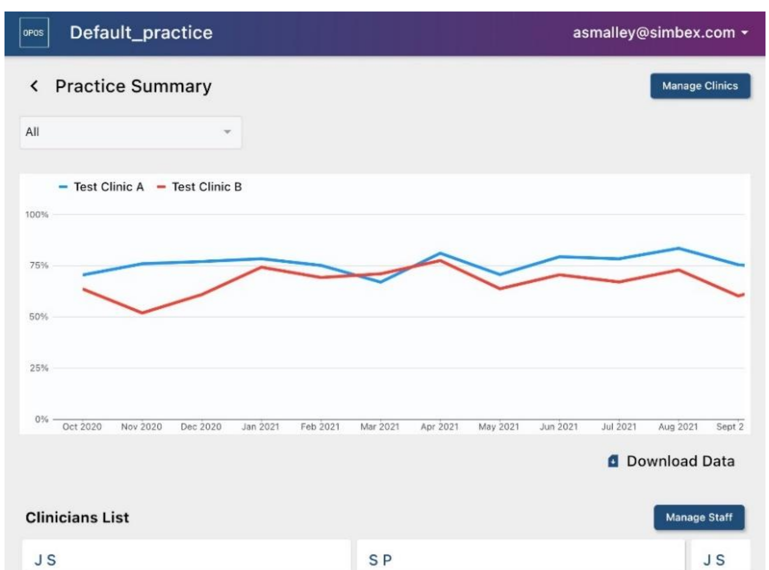
3.7 Adding a practice admin

After the System Administrator adds a new practice, they need to add at least one Practice Admin to that practice. Once a Practice Admin is added to a practice, that person can login and begin populating their practice with user accounts (additional Practice Admins, Clinicians and Patients).

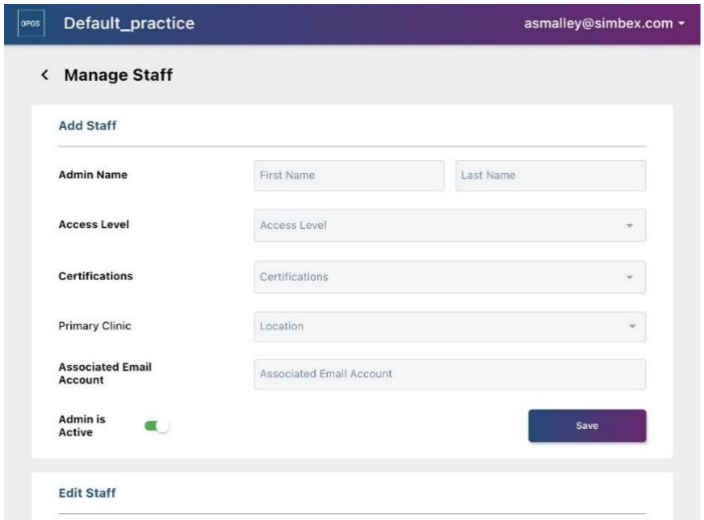


3.8 Adding/ editing users

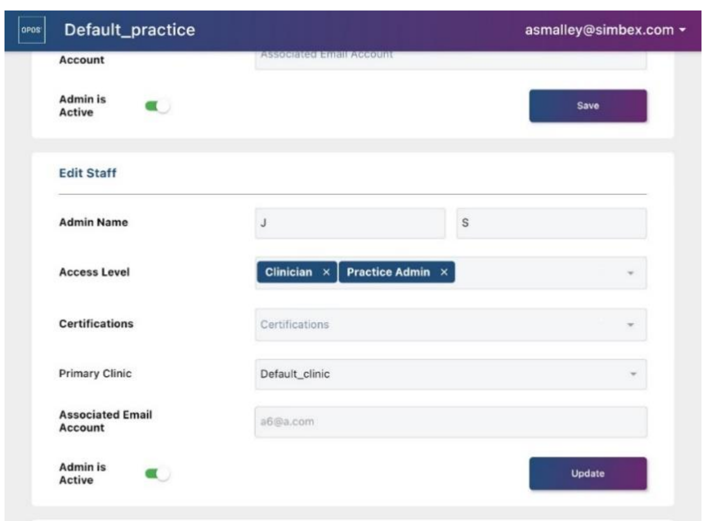
Practice Admins can add and edit staff accounts by selecting MANAGE STAFF in the Practice Summary page.



Within the Manage Staff form, the dropdown fields in access level and certifications allow for multiple selections. The Primary Clinic field allows only one choice from the list of clinics within that practice. This selection determines which clinic displays that clinician's data on the Practice Summary page.

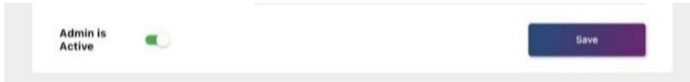


If a user is designated as a Practice Admin only, they can view all areas of the application but cannot have patients assigned to them. If the user is both a Practice Admin and a Clinician, they can view all areas of the application and can be assigned their own patients. If a user is a Clinician only, they can view the data of the patients that have been assigned to them.



3.9 Deactivating users

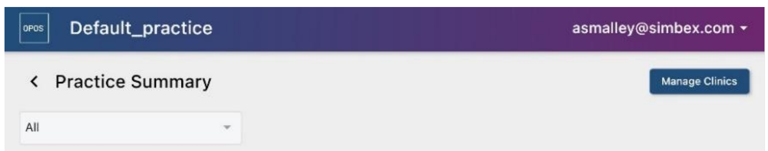
Staff accounts can be deactivated by Practice Admins by toggling the *User is Active* switch at the bottom Left corner of the Edit Staff form.



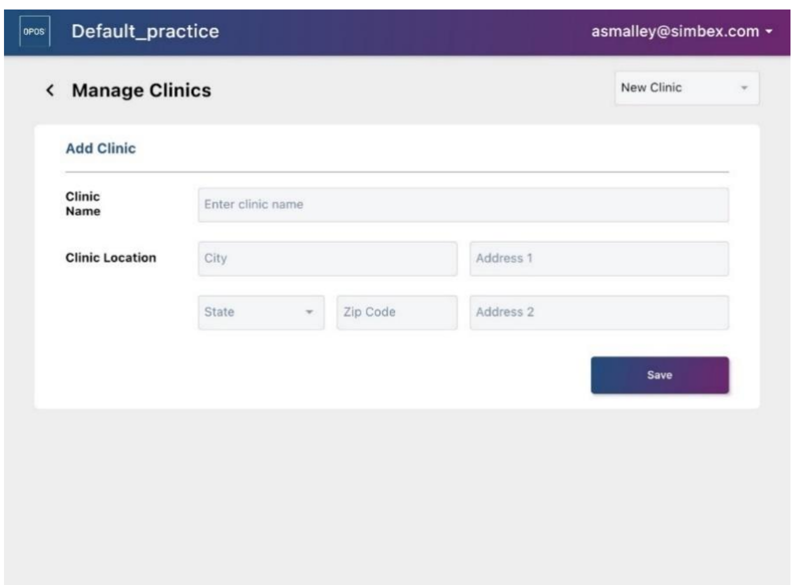
All changes to the staff form are saved by selecting Update. If a staff account is not *active*, that person's data is not displayed on the Practice Summary screen. If that staff member becomes *active* again (or if a Practice Admin wants to view that clinician's data in the Practice Summary screen) the toggle can be switched back on.

3.10 Adding/editing clinic locations

Practice Admins can add or edit clinic locations within their own practice by selecting the Manage Clinics button at the top right corner of the Practice Summary screen.

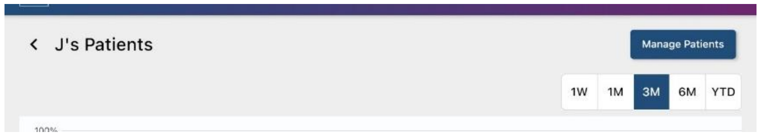


The default form on the Manage Clinics screen is to add a new clinic. Existing clinics can be edited by selecting from the dropdown list at the top right corner of the screen.

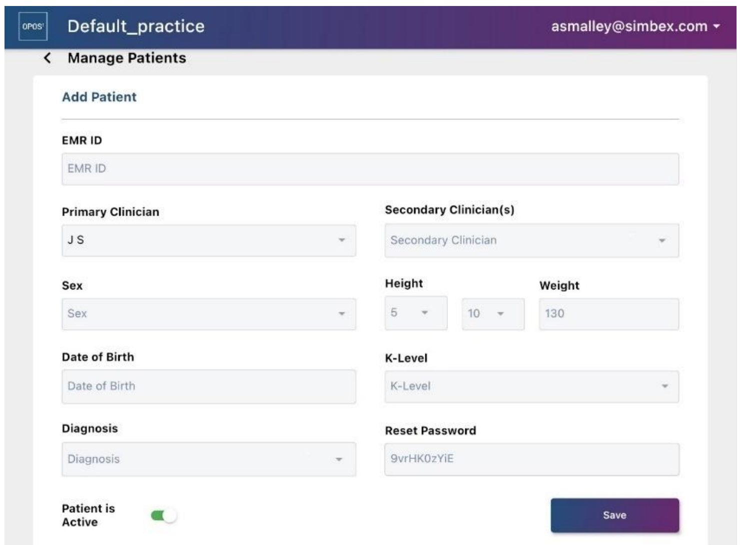


3.11 Adding/editing patients

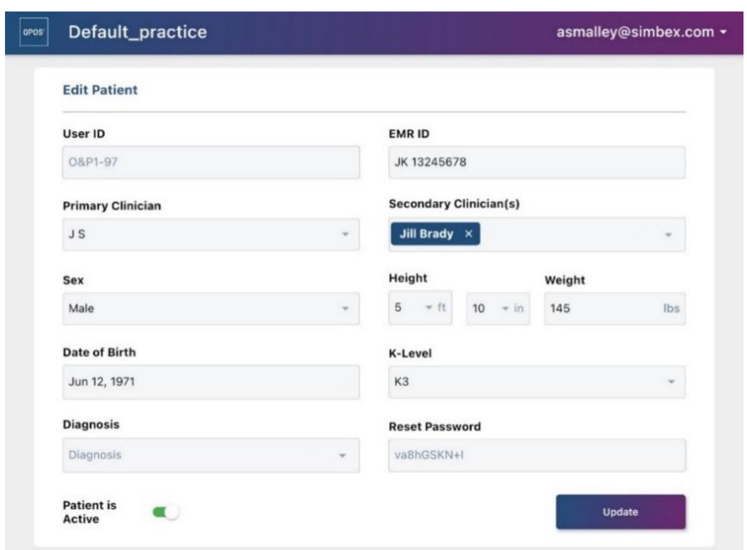
Clinicians and Practice Admins can add or edit patient accounts via the clinician summary page. The Manage Patients button on the top Right corner navigates to the add/edit patient form.



Patient accounts default to *active*, but the switch on the lower left portion of the patient form can be toggled to mark the patient as *inactive*. A patient should be marked as inactive if they are not currently using an OPOS[1] sensor on their Orthotic or Prosthetic device. Inactive patient accounts will not display in the clinician summary page.

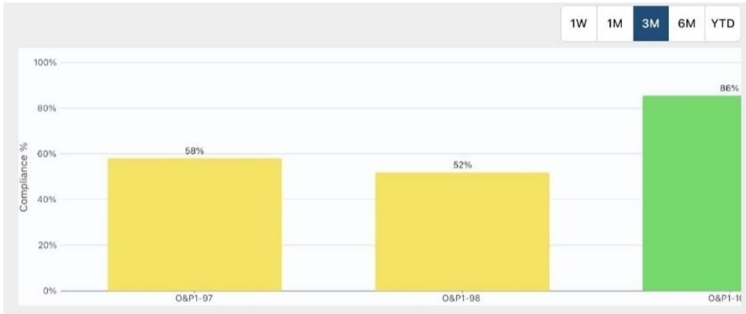


Existing patient information can be edited in the same screen. Use the **UPDATE** button to save changes.

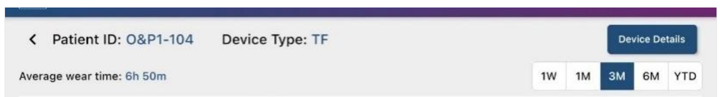


3.12 Adding a sensor to a patient

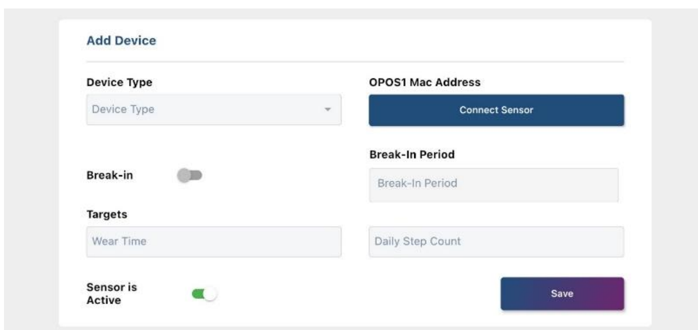
Once a patient has been added to the system, navigate to their patient page by selecting their **PATIENT ID** under the bar graphs on the clinician summary page.



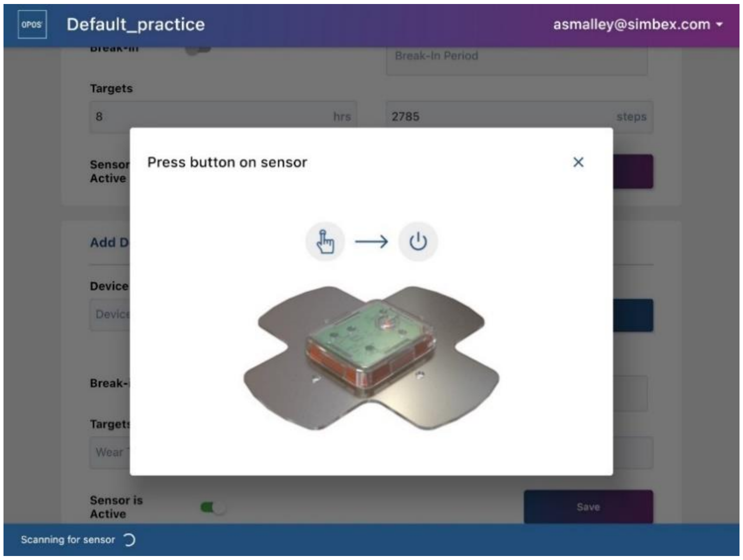
On the patient page, select **DEVICE DETAILS** to view the add/edit device form.



Select the type of orthotic/prosthetic device from the dropdown and select **CONNECT SENSOR**.



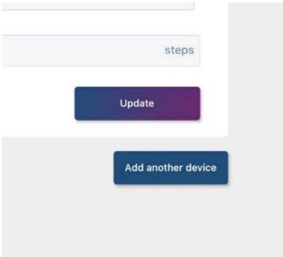
A pop-up will instruct you to push the button on the sensor that you are trying to connect. Once the connection is established, the OPOS[1] MAC address field will automatically populate. Press **SAVE** before navigating away from this page.



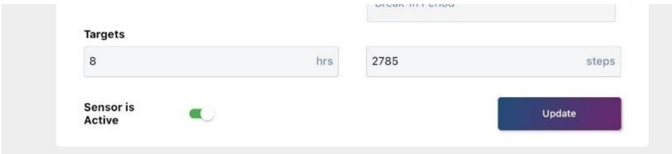
Note: Each sensor can only be added to 1 patient under typical use case scenarios. If an edge-case occurs where a sensor needs to be used for more than 1 patient (for example, during product testing), the database must be modified each time the sensor is reassigned in order to ensure that there is no duplicate entry.

3.13 Deactivating a sensor

If the patient already has one connected sensor and it needs to be replaced, another sensor can be added using <u>**ADD ANOTHER DEVICE**</u> button on the same form.



Be sure to deactivate the previous sensor by toggling the <u>**SENSOR IS ACTIVE**</u> switch. Each patient can only have one *active* sensor at a time.



3.14 Designating targets

In the device details form, the wear time hours and step count targets can be set and updated whenever necessary. The targets fields are inactive when the break-in period is activated. Use the **UPDATE** button to save changes.

3.15 Setting break-in periods

Set the device break in period by toggling the break-in switch and selecting a date for the break-in to end.

During the break in period, the wear time and step count targets are not active.

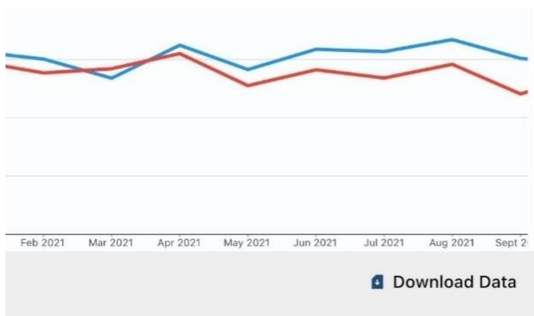
Patient's wear time and step count are tracked but not assigned a compliance %. Because there is no compliance %, the data from the break in period is displayed as grey bars and it is not captured in the Clinician Dashboard or Practice Summary pages. The data collected during the break in period should help the clinician determine realistic target values for wear time and step count.

3.16 Refreshing sensor data

Patients who use the mobile application will be able to upload their sensor data from within the app by using the **UPLOAD SENSOR DATA** button in the lower Right corner of the patient page. If patients have not been using the application, sensor data can be uploaded by the clinic staff by pushing the button on the OPOS[1] sensor or by using the **UPLOAD SENSOR DATA** button.

3.17 Downloading .csv files

Practice Summary, Clinician Dashboard and Patient pages all have the option to download a .csv file of the data on that page. When a user selects **DOWNLOAD DATA**, an excel sheet of the data from that page is emailed to the user's email address.



4 OPOS1 Sensor Installation Guide

4.1 Adhesive Installation

Clean the wall of the Orthotic/Prosthetic with isopropyl alcohol and allow to dry. Orient sensor so that power symbol will be upright when worn. Remove backing to expose adhesive. While pulling the wings on the left and right tight, wrap the sensor tightly around the Orthotic/Prosthetic. Pull the top and bottom wings tight and press to adhere. Firmly rub all of the wings to ensure full adhesion, especially in the corners and around the edges of the circuit board cavity.

If necessary, trim the wings back to fit on the Orthotic/Prosthetic. Leave at least 5/8" of material beyond the edge of the circuit board cavity.

4.2 Sewn/Riveted Installation

Orient sensor so that power symbol will be upright when worn. Remove backing to expose adhesive. Attach PET back seal to exposed adhesive to seal sensor and cover adhesive. Use the holes provided or sew through the material of the wings to attach to a strap.

If necessary, trim the wings back to fit on the Orthotic/Prosthetic. Leave at least 5/8” of material beyond the edge of the circuit board cavity.

4.3 Changing the Battery

Remove sensor assembly from Orthotic/Prosthetic by carefully pulling at the corners. Work your way around each wing until the sensor pulls off easily. Remove any adhesive covering the back side of the circuit board cavity to expose the circuit board. Remove back pad and flex the circuit board cavity open to free the circuit board. Slide the battery out of the open side of the holder and remove from circuit board completely.

Install new battery into the holder. Note the proper polarity as marked on the battery and holder.

5 Federal Communications Commission (FCC) Compliance

The following statements apply to the OPOS[1], as required by the FCC:

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: —Reorient or relocate the receiving antenna. —Increase the separation between the equipment and receiver. —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. —Consult the dealer or an experienced radio/TV technician for help. (Part 15.105)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation (Part 15.19)

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment. (Part 15.21)