



SOZO[®]

by impedimed[®]

SOZOhub

Instructions for Use



ImpediMed Limited

ABN 65 089 705 144

Unit 1
50 Parker Court
Pinkenba Qld 4008
Australia

Phone: + 61 7 3860 3700
Fax: + 61 7 3260 1225
Email: enquiries@impedimed.com
Website: <http://www.impedimed.com/>

For assistance with product set up please review the help videos at <https://www.impedimed.com>. For other assistance, or to report product issues, please contact ImpediMed by email at tsu@impedimed.com or by phone at: + 877 247 0111.

EC

REP

MediMark Europe Sarl
11 rue Emile ZOLA,
B.P. 2332, 38033 Grenoble Cedex 2
France



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Introduction

SOZO

SOZO: A bioimpedance spectroscopy device for use on human patients, utilizing ImpediMed's patented BIS technology in a user-friendly format to allow quick and accurate measurement of fluid levels. This can be used as an "early warning" monitor for determining changes in the fluid status of patients with fluid management problems.

SOZO consists of hardware connected over Bluetooth to the SOZO app on a supplied tablet. Please refer to LBL-507, the SOZO Instructions for Use, for more information on setting up and using the system, tablet and app.

SOZOhub

The SOZOhub database is intended to support use of the SOZO system and SOZO app by storing measurement data taken using the SOZO device. SOZOhub also provides all of the user accounts (usernames and passwords) that are used to log in to the SOZO app as well as access the patient data and measurements.

SOZOhub also has a web front end that allows optional reporting functionality and data export features that is not available within SOZOapp.

The user interface for SOZOhub is accessed using a web browser. This could be a web browser on the computer where SOZOhub is installed, a web browser on another computer within the same network as the SOZOhub, or the tablet on which the SOZOapp is installed.

Accessing the SOZOhub database

SOZOhub Installer

The SOZOhub installation program must be run before the SOZOhub web portal can be accessed. Please refer to LBL-505, the SOZOhub installer instructions for use.

Accessing SOZOhub: Web Portal

SOZOhub is accessed via any device (computer or tablet) that can run a web browser and is connected to your facility network. It is not limited to the desktop or laptop computer on which SOZOhub was installed.

The web address used to access the portal will be created when the SOZOhub installer has been run. Enter the web address into a browser to continue. SOZOhub is compatible with Chrome or Firefox web browsers only.

Login screen

Log In To Your Account

Username

clinician

Password

.....|

Language

English (US)



Log In

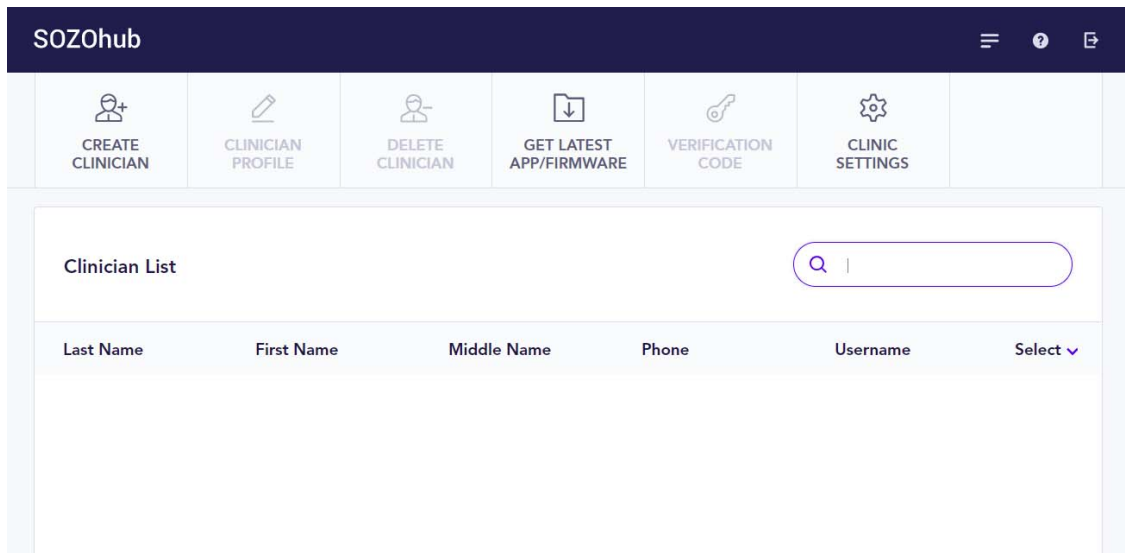
The login screen is where both SOZOhub IT administrators and clinicians log in using their user ID and password.

The administrator password is created during the initial setup of SOZOhub.

Administrator Functionality

Administrator Login

After the administrator logs in for the first time, the SOZOhub should show an empty database.



Please note that the administrator will not be able to access patient data through SOZOhub; only the clinicians can access this data.

General Navigation

To access the list of clinicians at any time in SOZOhub, click on the first icon in the top banner:



To access the help page (which includes web links, email addresses for ImpediMed support and latest SOZOhub version), click the second icon in the top banner:



To log out, click the third icon in the top banner. This will revert back to the login screen. Please note that the app will time out 60 minutes after login and revert back to the login screen.

Create clinician accounts.

SOZOhub

CREATE CLINICIAN

CLINICIAN PROFILE

DELETE CLINICIAN

GET LATEST APP/FIRMWARE

VERIFICATION CODE

CLINIC SETTINGS

Clinician Details

First Name

Required

Username

Required

Last Name

Required

Password

Required

Middle Name

Confirm Password

Required

Country Code

Phone Number

Create Clinician

After entering details into this page, click 'Create Clinician'. This can be repeated for all clinicians onsite who will be using the SOZO device by clicking 'Clinician List' to return to the Clinician List, and repeating the above exercise. The Clinician List will fill out as each new profile is created.

Modifying Clinician Profile

Check the box next to the clinician whose details need to be modified, then click 'Clinician Profile'

SOZOhub

CREATE CLINICIAN

CLINICIAN PROFILE

DELETE CLINICIAN

GET LATEST APP/FIRMWARE

VERIFICATION CODE

CLINIC SETTINGS

Clinician List

tcclinician

Last Name	First Name	Middle Name	Phone	Username	Select
clinician	test		+1 8675309	tcclinician	<input checked="" type="checkbox"/>

This will go to the detailed clinician profile where any applicable entries can be modified and re-saved:

SOZOhub

CREATE CLINICIAN

CLINICIAN PROFILE

DELETE CLINICIAN

GET LATEST APP/FIRMWARE

VERIFICATION CODE

CLINIC SETTINGS

Clinician Details

First Name

test

Required

Phone Number

8675309

Last Name

clinician

Required

Username

tcclinician

Middle Name

Reset Password

Country Code

United States (+1)

Save Changes

The password can also be modified in this page by clicking 'Reset Password'.

The image shows the SOZOhub web application interface. A modal dialog titled "Set New Password" is open in the center. It contains two input fields: "Password" and "Confirm Password", both with placeholder text. Below these fields is a blue "Save" button. The background is a dimmed view of the "CLINICIAN PROFILE" page. The top navigation bar includes "CREATE CLINICIAN", "CLINICIAN PROFILE" (active), and "CLINIC SETTINGS". The "Clinician Details" form on the background includes fields for "First Name" (test), "Last Name" (clinician), "Middle Name", and "Country Code" (United States (+1)). There are also "Reset Password" and "Save Changes" buttons visible on the right side of the form.

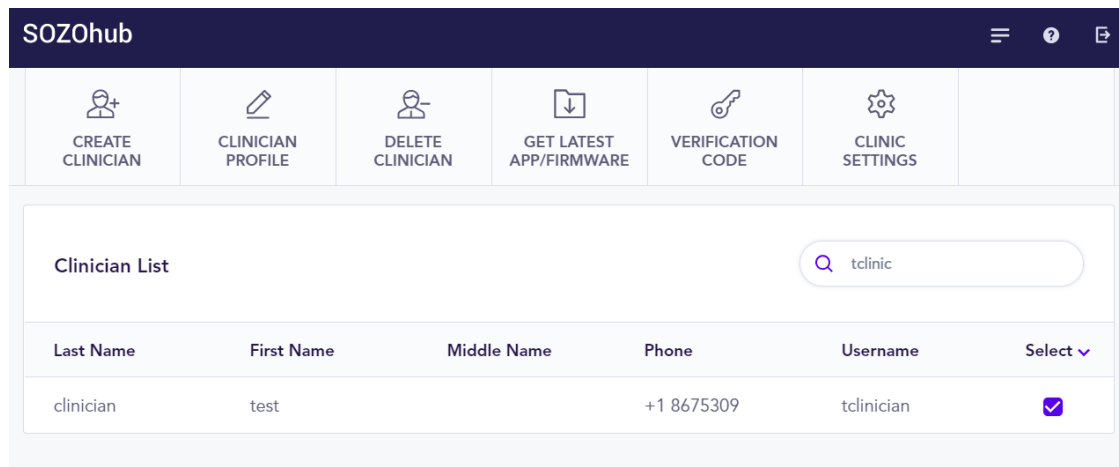
After making modifications, click 'Save'. The following success screen should appear:

The image shows the SOZOhub web application interface after a successful update. A modal dialog titled "Success" is open in the center. It features a green checkmark icon, the word "Success" in bold, and the message "Clinician's details changed successfully". Below this is a blue "OK" button. The background is a dimmed view of the "CLINICIAN PROFILE" page. The top navigation bar now includes "CREATE CLINICIAN", "CLINICIAN PROFILE" (active), "DELETE CLINICIAN", "GET LATEST APP/FIRMWARE", "VERIFICATION CODE", and "CLINIC SETTINGS". The "Clinician Details" form on the background is the same as in the previous image, with fields for "First Name" (test), "Last Name" (clinician), "Middle Name", and "Country Code" (United States (+1)). There are also "Reset Password" and "Save Changes" buttons visible on the right side of the form.

Clicking "Clinician List" will return back to the main administrator dashboard:

Deleting Clinician Profile

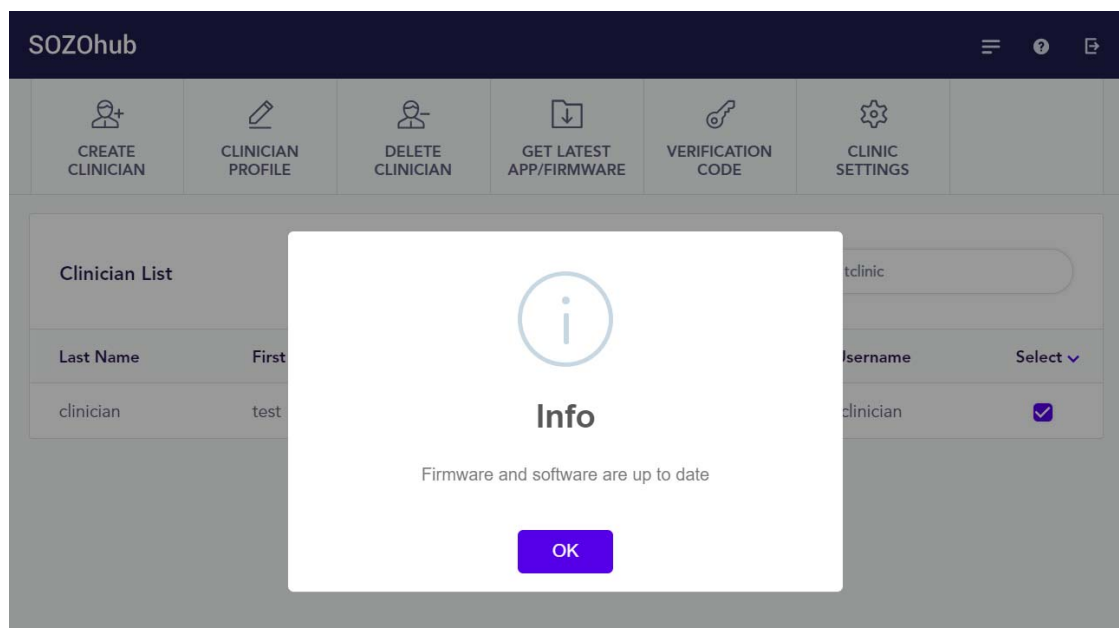
To delete a profile, simply check the box for all profiles that need to be deleted, and click the button marked 'Delete Clinician':



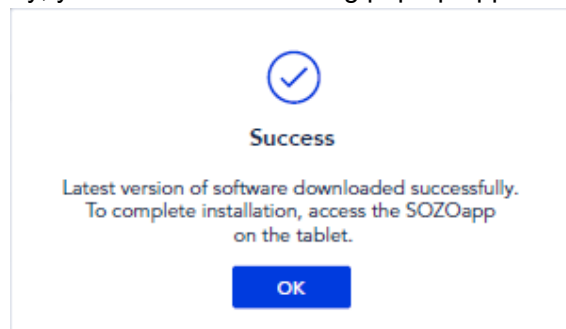
This will prompt a warning pop-up that requires your acknowledgment to proceed.

Updating Software and Firmware

From the administrator dashboard, the SOZOapp software and SOZO system firmware can be updated by clicking the button marked 'Update Software' and 'Update Firmware'. This will prompt a check with SOZOcloud to confirm that your software is up-to-date; if it is, you will see the message below:



If a newer version of the software or firmware is available, the SOZOhub software will download it automatically; you will see the following pop-up appear:



The SOZOapp will need to be accessed separately to allow updates to take place.

Search Clinician

SOZOhub

CREATE CLINICIAN

CLINICIAN PROFILE

DELETE CLINICIAN

GET LATEST APP/FIRMWARE

VERIFICATION CODE

CLINIC SETTINGS

Clinician List

tclin|

Last Name	First Name	Middle Name	Phone	Username	Select
clinician	test		+1 8675309	tclinician	<input type="checkbox"/>

In the event that multiple clinician profiles are created, the administrator can search for a specific profile by entering text into the ‘Search Clinician’ field. This will limit the number of available clinicians based on the search terms provided.

Verification Code

During initial setup, the SOZOapp and tablet will need to link to the local SOZOhub by setting a connection path from their SOZOapp login screen.

To ensure a secure pairing process, a one-time verification code will need to be generated by the site administrator. Select the clinician who is logging in for the first time and have them press “Set Connection Path” on the SOZOapp login screen. From the administrator SOZOhub portal, the site administrator will select the clinician and click “Verification Code”, which will create and display a 10-digit code. The site administrator will provide that to the clinician, as well as the local SOZOhub address, to be entered in SOZOapp.

SOZOhub Verification Code
screen:

Verification Code

tclinician 0503894765

OK

Verification code resets every 15 mins.

SOZOapp connection path
screen:

Set Connection Path

SOZOhub Path

http://yourclinicname.mysozohub.com

Username

tclinician

Clinician Password

.....

SOZOhub Verification Code

0503894765


Note: Administrator must generate a verification
code through SOZOhub


Authenticate


Clinic Settings/Adding Site Logo


The site administrator may add a clinic logo to the SOZOhub installation. This logo will appear on any clinic reports that are printed through SOZOhub (for further information on reports, see later in this user guide). To add the logo, the administrator will first need to click on 'Clinic Settings' from the main screen. This will bring up the following screen:


SOZOhub


CREATE CLINICIAN

CLINICIAN PROFILE


DELETE CLINICIAN

GET LATEST APP/FIRMWARE

VERIFICATION CODE

CLINIC SETTINGS

Report Logo Settings



Maximum Size 1MB
File supported format PNG

Revert

Browse

Save

To select a new logo, click 'Browse' and find the appropriate hospital image. It will need to be less than 1MB and in file format .png. Once selected, click 'Save'.

Clicking 'Revert' will change the logo back to the stock SOZO image shown above.

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Clinician Functionality

Clinician Login

From the same login screen as the administrator, enter the clinician username and password as created by the administrator. This will open the patient dashboard screen displaying all patients with data stored in the local SOZOhub database.

The screenshot shows the SOZOhub Patient Dashboard. At the top is a dark blue header with the 'SOZOhub' logo on the left and three icons (hamburger menu, help, and share) on the right. Below the header is a row of seven buttons: 'PATIENT DASHBOARD' (with a clock icon), 'CREATE PATIENT' (with a person icon), 'DELETE PATIENT' (with a person icon and a minus sign), 'BILLING REPORT' (with a document icon), 'EXPORT' (with a document icon and 'XLSX' text), 'REPORT/PRINT' (with a printer icon), and 'LICENSING STATUS' (with a document icon). Below these buttons is a 'Patient List' section. It features a search bar with a magnifying glass icon and the text 'Search Patient'. Below the search bar is a table with the following columns: 'Last Name', 'First Name', 'Date of Birth', 'Sex', 'MRN', 'Last Assessment', and 'Select' (with a dropdown arrow). The table contains one row of data: 'A Measurem...', 'Example', 'Fri, 1975 May 2', 'Female', an empty 'MRN' field, 'Mon, 2018 May 14 12...', and a checkbox.

Last Name	First Name	Date of Birth	Sex	MRN	Last Assessment	Select
A Measurem...	Example	Fri, 1975 May 2	Female		Mon, 2018 May 14 12...	<input type="checkbox"/>

Note that at initial setup this screen will not have any patients listed. Patients can be created either in SOZOhub, or through the SOZOapp on the supplied tablet.

General Navigation

To access the list of patients at any time in SOZOhub, click on the first icon in the top banner:



To access the help page (which includes web links, email addresses for ImpediMed support and latest SOZOhub version), click the second icon in the top banner:



To log out, click the third icon in the top banner. This will revert back to the login screen. Please note that the app will time out 60 minutes after login and revert back to the login screen.

Create Patient

From the patient list, click on 'Create Patient'.

This will bring up a blank 'Patient Dashboard' screen. Fill in all required fields and assessment types appropriate for the patient. If L-Dex assessment type is selected, additional patient-specific information is required – please review the L-Dex User Guide for more information.

Once all details are entered, click 'Create Patient'. The patient list will be automatically updated and measurements can now be taken from SOZOapp.

Please note that patients may also be created within SOZOapp, in a similar manner.

Viewing Patient Dashboard

Within SOZOhub, check the box on the right hand side to select an individual patient. This will allow the patient dashboard to be accessed. To access the patient dashboard, click the button marked 'Patient Dashboard'

A brief summary of patient information is supplied in the patient dashboard:

SOZOhub

PATIENT DASHBOARD

HISTORY

RESULTS

PROFILE

REPORT/PRINT

Patient Details

Last Name

A Measurement

First Name

Example

Date of Birth

Fri, 1975 May 2

Sex

Female

MRN

Last Assessment

Mon, 2018 May 14 12:20

Assessment Type

✓ L-Dex® Analysis for Lymphedema

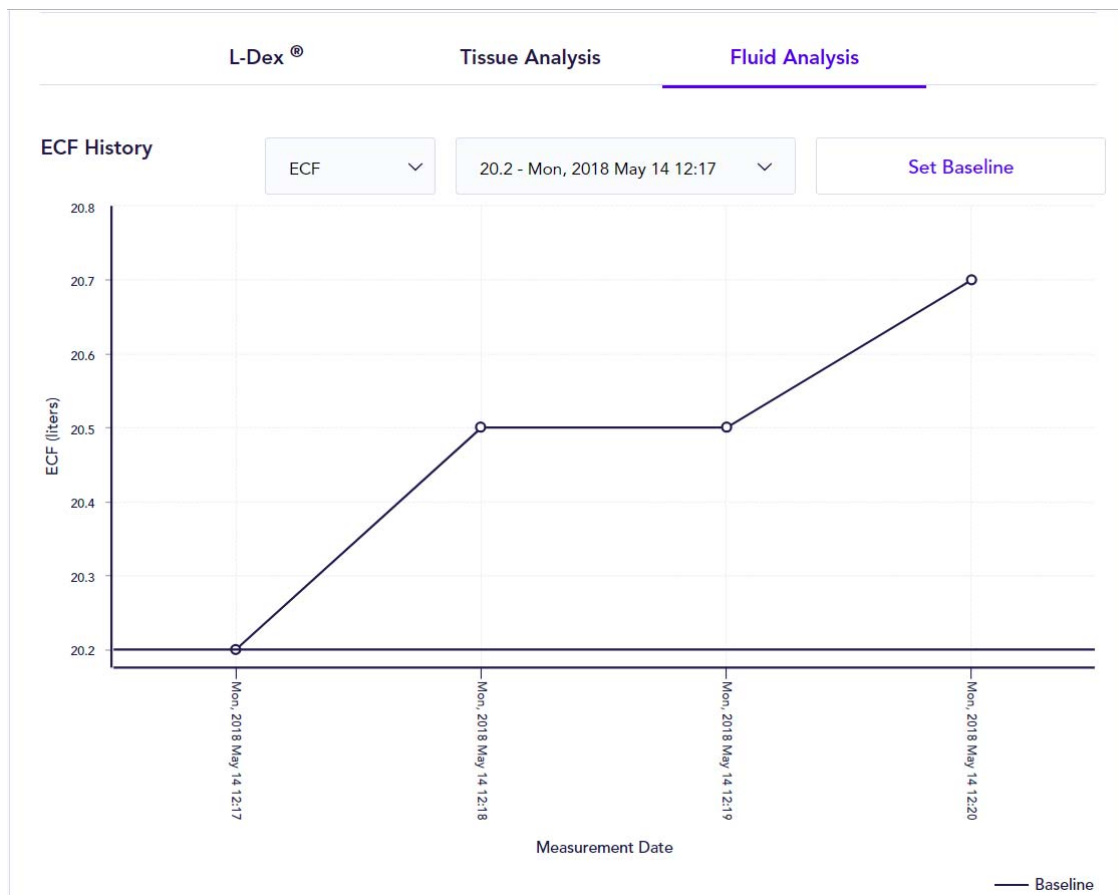
✓ Tissue Analysis for Body Composition

✓ Fluid Analysis for Heart Failure and General Fluid Status Monitoring

From here, the patient's recorded measurements history can be assessed against a baseline, individual measurements can be reviewed, or the patient's personal data reviewed/edited.

Review of Historical Data

To review the trending and set baseline measurements for the patient, click button marked 'History'.



Baseline scores can be set for analysis by selecting a timepoint from the drop-down menu and clicking on 'Set Baseline'. This will save the selection as the baseline score that all subsequent measurements are compared against.

For tissue analysis, a baseline score can be set for Fat Free Mass and Hy-Dex® values. For fluid analysis, baseline scores can be set for ECF values.

The baseline allows for comparison of historical measurement values against a specific value that, in your clinical opinion, represents a 'normal' state for the user. This will allow changes in the patient's fluid levels to be assessed over time.

Review Individual Measurements

To review results from individual timepoints, click button marked 'Results'.

SOZOhub

PATIENT DASHBOARD

HISTORY

RESULTS

PROFILE

REPORT/PRINT

Patient Details

Last Name

A Measurement

First Name

Example

Date of Birth

Fri, 1975 May 2

Sex

Female

MRN

Last Assessment

Mon, 2018 May 14 12:20

Measurements

Date

Mon, 2018 May 14 12:20

Mon, 2018 May 14 12:19

This will bring up a list of all measurements taken for the patient, arranged chronologically with the most recent measurement at the top. Selecting one of the readings will open the summary of the measurement taken on that time and date, allowing access to the analyses that were performed.

Please note that if your site no longer maintains licenses for all assessment types, you will still be able to view the assessments that were previously made while the licenses were in effect.

Review/Edit Patient's Personal Details

To review the patient's demographic details, click button marked 'Profile'. This will open the following screen:

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SOZOhub

?

PATIENT DASHBOARD

HISTORY

RESULTS

PROFILE

REPORT/PRINT

Patient Details

First Name

Required

Example

Date of Birth

Required

Fri, 1975 May 2

Last Name

Required

A Measurement

Sex

Required

Female

Middle Name

HEIGHT (ft. in)

Required

5

9

Medical Record Number (MRN)

Email

Country Code

Postal Code

All form fields can be edited by clicking on them and editing the text. The drop-down menus can be opened and the appropriate value selected.

Patient weight cannot be modified, but will reflect the weight that was entered at the last measurement.

The assessment types available for a patient are based on site licenses. It is recommended that the patient only have relevant assessment types selected. Each assessment type selected will be displayed in the SOZOapp at the time of measurement, or in patient history/results presented within SOZOhub.

Once all changes have been made to the profile, click 'Save Changes'. Please note the following:

- If patient height has been modified the following warning will appear.

A warning dialog box with a yellow circular icon containing an exclamation mark. Below the icon, the word "Warning" is displayed in bold. The text inside the dialog asks: "Do you want to calculate historical results using the revised height or the height entered at time of measurement?". At the bottom, there are two buttons: "Height at measurement" (grey) and "Revise height" (purple).

Clicking 'Height at measurement' will maintain old assessments according to the height entered at the time. This is appropriate for patients whose height is changing as a function of age.

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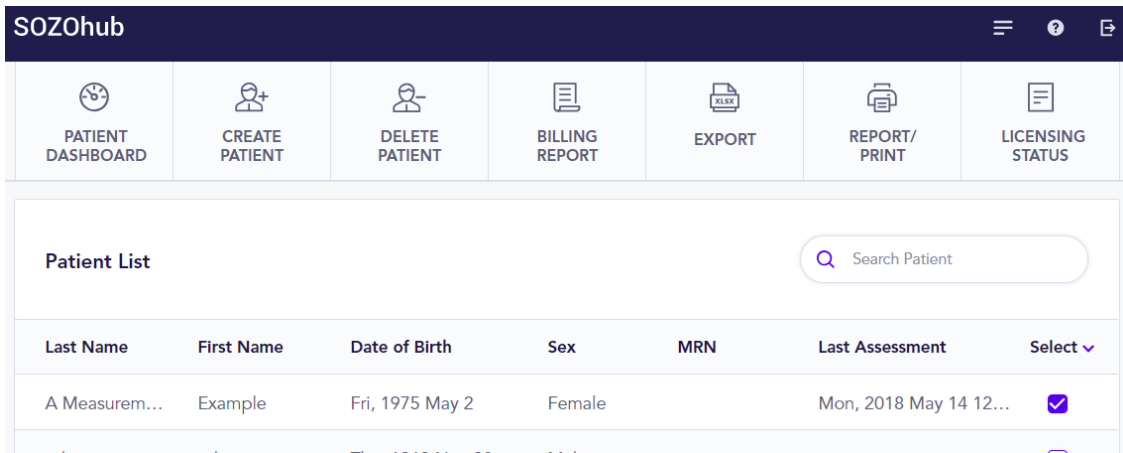
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Clicking 'Revise height' will recalculate all old assessments according to the new height being saved. This is appropriate when patient height has been entered incorrectly and measurements already taken. Old measurements can then be revisited through patient history.

- L-Dex specific data (at-risk limb, dominant limb) is only available when L-Dex assessments are selected. Please note that de-selecting L-Dex assessments will grey out the selections, and they will not be saved.
- If assessment types have been added, you will be given the opportunity to recalculate past results retrospectively by reviewing patient history.
- If assessment types have been removed, patient history will not be modified; however, new measurements will be limited to those assessment types that are selected.

Deleting patients

From the Patient Dashboard, select one or more patients to delete:



The screenshot shows the SOZOhub Patient Dashboard. At the top, there is a navigation bar with the SOZOhub logo and several icons: Patient Dashboard, Create Patient, Delete Patient, Billing Report, Export, Report/Print, and Licensing Status. Below the navigation bar is a 'Patient List' section with a search bar labeled 'Search Patient'. The patient list is a table with the following columns: Last Name, First Name, Date of Birth, Sex, MRN, Last Assessment, and Select. The first row shows a patient named 'A Measure...' with first name 'Example', date of birth 'Fri, 1975 May 2', sex 'Female', and last assessment 'Mon, 2018 May 14 12...'. The 'Select' column for this row has a checked checkbox. The second row is partially visible, showing 'adam' as the last name and 'adam' as the first name.

Last Name	First Name	Date of Birth	Sex	MRN	Last Assessment	Select
A Measure...	Example	Fri, 1975 May 2	Female		Mon, 2018 May 14 12...	<input checked="" type="checkbox"/>
adam	adam	Thu, 1962 Nov 29	Male			<input type="checkbox"/>

Clicking 'Delete Patient' will bring up the following warning:



Warning

Are you sure you want to delete the selected patient(s)?

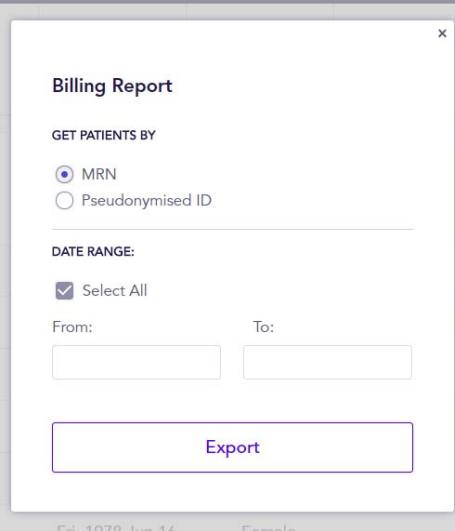
NO

YES

Click 'Yes' to proceed if the patient profile is to be deleted. Note that patient data will not be recoverable after deletion, including measurement data.

Billing Report

Billing Reports will allow clinicians to track total usage of their SOZO system over time. From the patient list, click on 'Billing Report' to bring up the following screen:

A screenshot of a web application window titled "Billing Report". The window has a close button (X) in the top right corner. Inside the window, there is a section "GET PATIENTS BY" with two radio buttons: "MRN" (selected) and "Pseudonymised ID". Below this is a "DATE RANGE:" section with a checked checkbox labeled "Select All". Underneath are two input fields labeled "From:" and "To:". At the bottom of the form is a large button labeled "Export". The window is overlaid on a blurred background of a patient list.

The list can be arranged by patient MRN or (for more security in reports) pseudonymised IDs, and either within a selected date range, or since the creation of the SOZOhub at the facility.

Click on 'Export' to export data from the SOZOhub database into an Excel spreadsheet that can be downloaded and reviewed offline.

Export

The export function allows one or more patient's SOZO data to be exported into an Excel spreadsheet and reviewed offline. Select one or more patients from the patient list and click 'Export' to bring up the following pop-up:

Export Settings

ASSESSMENT TYPE:

☐ L-Dex®
 ☐ Hy-Dex®

☐ Tissue Analysis
 ☐ Report Summary

☐ Fluid Status

DATA TYPE:

☐ Results Simplified Data
 ☐ Results Full Data

DATE RANGE:

☒ Select All

From:

To:

DATA FORMAT:

☐ Row per patient
 ☐ Row per measurement

ADDITIONAL SETTINGS:

☐ Show De-identified SOZOhub ID
 ☐ Show Patient Identifying Details
 ☐ Show Additional Patient Details
 ☐ Show Device/Measurement info

Export

Select options and click 'Export' to download an Excel spreadsheet containing the desired data.

Assessment types: individual assessment types can be selected. Alternately, click on 'Report Summary' which will fill out all other fields in the pop-up and proceed to 'Export'.

Data types: Simplified data will limit the exported results to SOZO outputs. The Full Data will include raw data from the measurements.

Date range: 'Select all' will include all results ever taken for the selected patient(s). Alternately, enter a date range to limit the reported results.

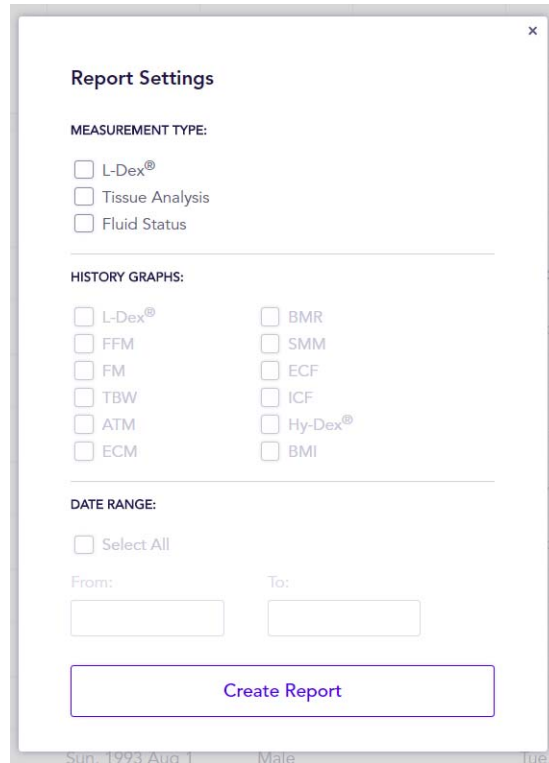
Data format: Selecting per-patient will result in measurements for an individual arranged into a single row in the Excel spreadsheet. Selecting per-measurement will result in each measurement for an individual arranged into separate rows.

Additional settings: Each selection will add the relevant information to the final generated report.

Please note that if multiple patients are selected, each patient data will be incorporated into the single Excel worksheet.

Patient Reports

To create a printable pdf for an individual patient, select a patient from the patient list and click the button marked 'Report/Print'. The following pop-up will appear:



The image shows a 'Report Settings' pop-up window. It contains three sections: 'MEASUREMENT TYPE' with checkboxes for L-Dex®, Tissue Analysis, and Fluid Status; 'HISTORY GRAPHS' with checkboxes for L-Dex®, FFM, FM, TBW, ATM, ECM, BMR, SMM, ECF, ICF, Hy-Dex®, and BMI; and 'DATE RANGE' with a 'Select All' checkbox and 'From'/'To' date input fields. A 'Create Report' button is at the bottom. The window has a close button (X) in the top right corner. At the bottom of the window, there is a status bar showing 'Sun, 1993 Aug 1' and 'Male'.

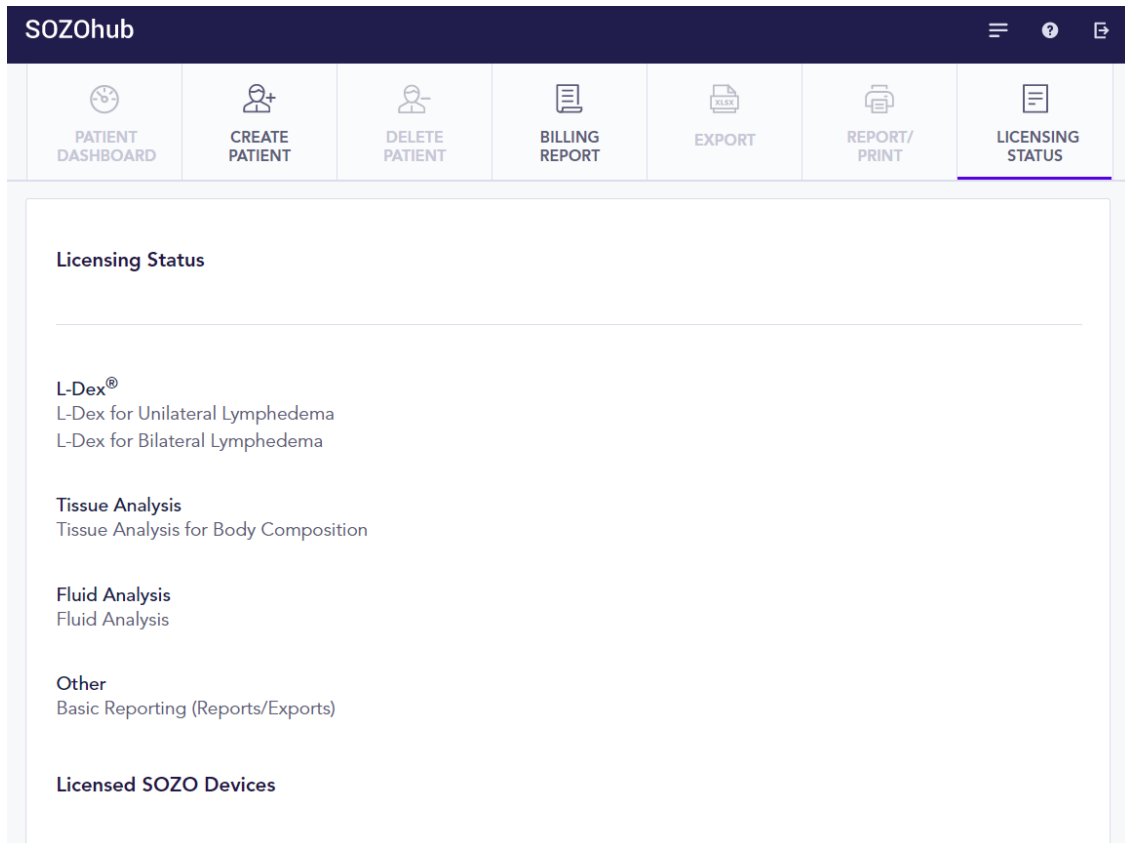
At least one field must be selected to allow a report to be generated.

History graphs are optional, and require the appropriate measurement type to be selected; i.e., the L-Dex history graph can only be selected if L-Dex measurement type is selected. If history graphs are required for the report, a data range will need to be selected before the report can be generated.

Once the fields are selected, click 'Create Report' to generate a pdf that can be downloaded and printed.

Licensing Status

At any time, the clinical can identify what licenses are available for the site by clicking on 'Licensing Status' to bring up the following screen:



Only the licenses presented on the SOZOhub License Status page are available at the site. If a licence is not available, a measurement may still be taken, but the assessment for that measurement may not be available. Once a license is granted, the clinician will be allowed to select that assessment type for the patient and all previous readings taken will be re-calculated to show assessments for all historical measurements.

To ensure that licenses are up to date, the SOZOhub must connect to SOZOcloud at least once every thirty days. If the SOZOhub has been disconnect from SOZOcloud for more than 30 days, all licenses will be revoked and no measurement will be possible. A warning will be presented to the user upon login if the SOZOhub has not connected to SOZOcloud for 14 days or longer.

To add measurement types, please call ImpediMed Customer Support to amend the agreement with your facility.