SOZOhub
Instructions for Use

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For EU Customers: All products at the end of their life may be returned to ImpediMed for recycling.

For patent(s) and/or patent application(s) see: https://www.impedimed.com/patents/

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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 netword 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

    ••••••••••
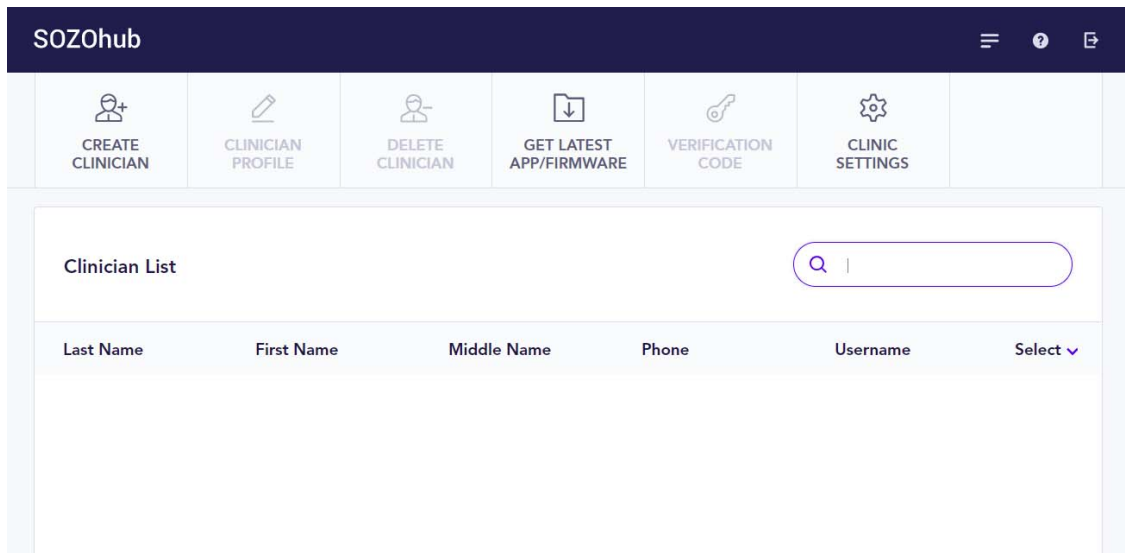
Language

    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.

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'

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

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

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

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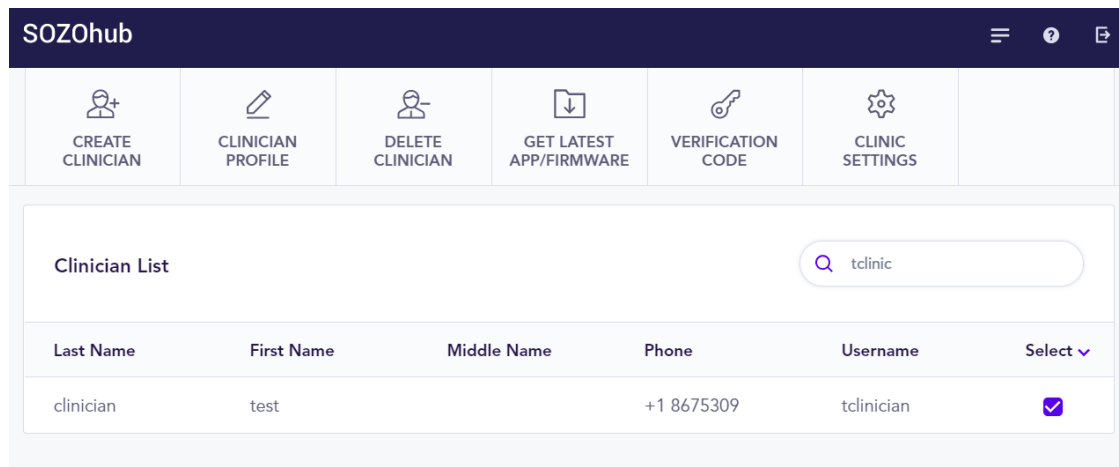
This will prompt a warning pop-up that requires your acknowledgment to proceed.

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:
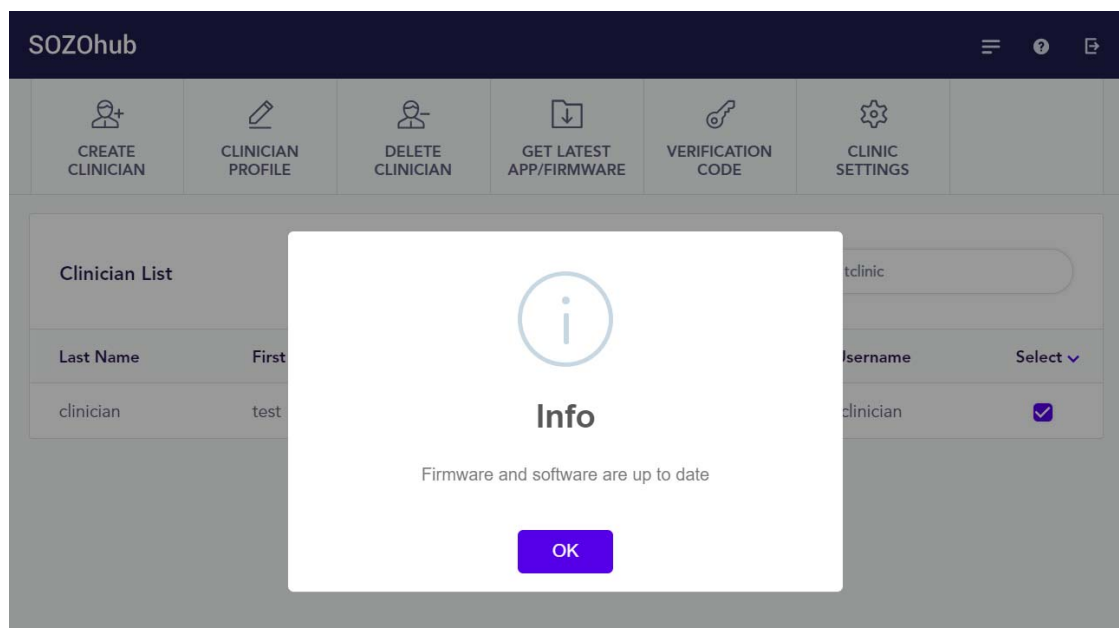
If a newer version of the software or firmware is available, the SOZOhub software will download it automatically; you will see the following pop-up appear:
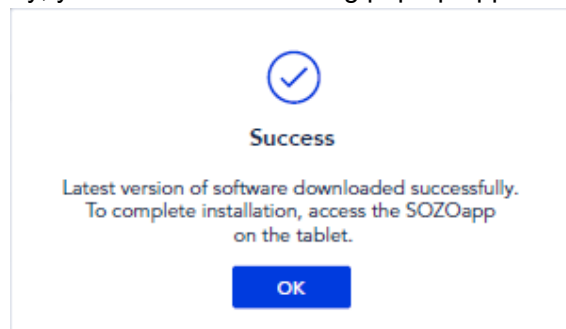
The SOZOapp will need to be accessed separately to allow updates to take place.

Search Clinician

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

ittp://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:

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.

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.

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:

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'.

The tabs will allow selection of the assessment types (L-Dex, Tissue or Fluid Analysis) selected for the patient.

Depending on what licenses are used at your facility, not all of the options may be available.

Within each tab, clinical outputs can be viewed individually as a trend line on a graph. Each module has different outputs that can be trended, for example:
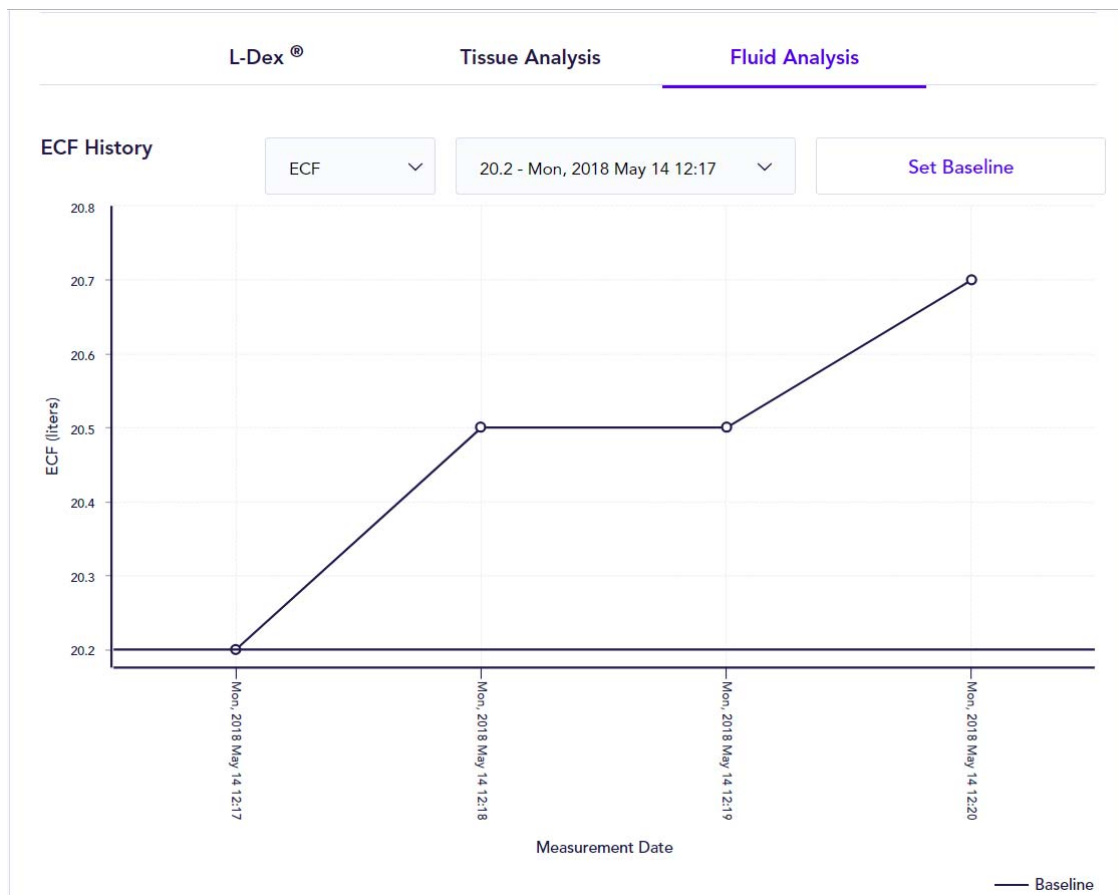
Baseline scores can be set for analysis by selecting a timepoint from the drop-down menu and clicking on 'Set Baseline'. This will save the selection as the baseline score that all subsequent measurements are compared against.

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'.

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:

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

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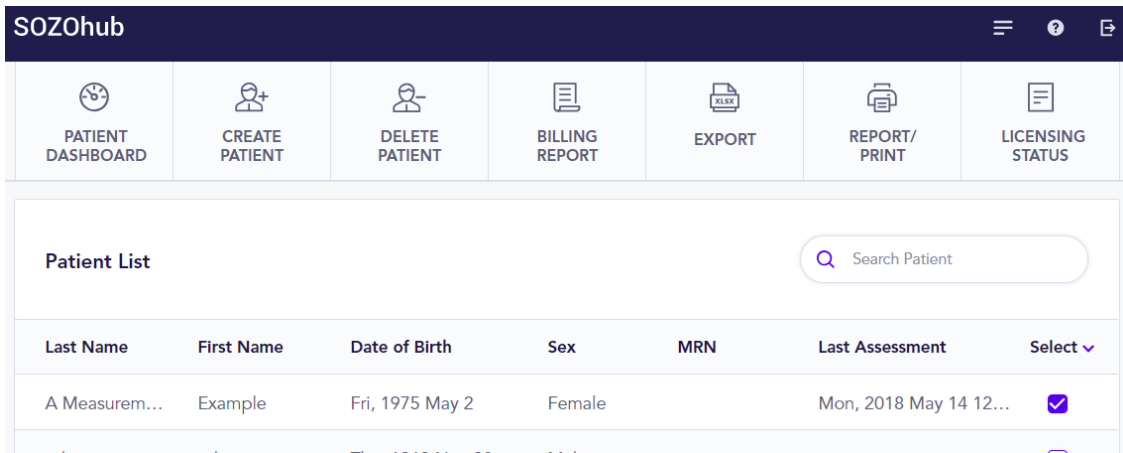
Clicking 'Revise height' will recalculate all old assessments according to the new height being saved. This is appropriate when patient height has been entered incorrectly and measurements already taken. Old measurements can then be revisited through patient history.

- 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:

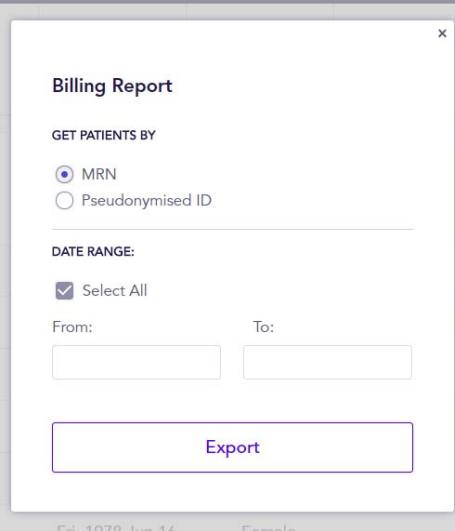

Clicking 'Delete Patient' will bring up the following warning:

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:

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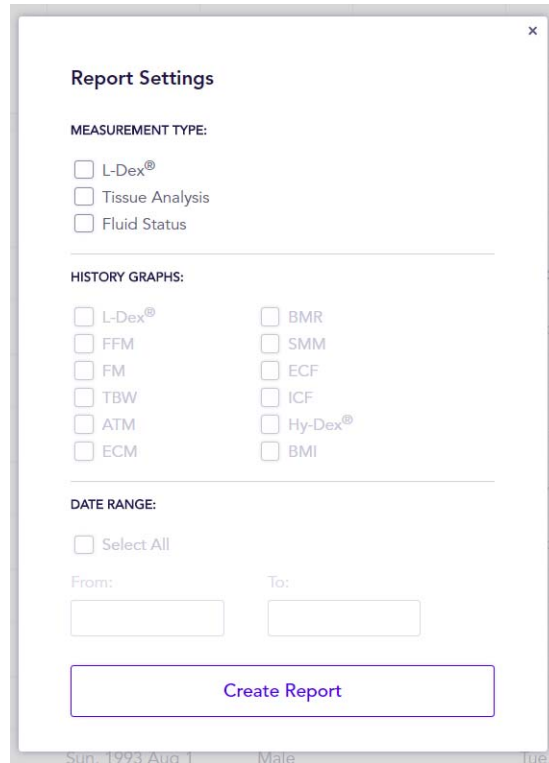
Data format: Selecting per-patient will result in measurements for an individual arranged into a single row in the Excel spreadsheet. Selecting per-measurement will result in each measurement for an individual arranged into separate rows.

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:


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:
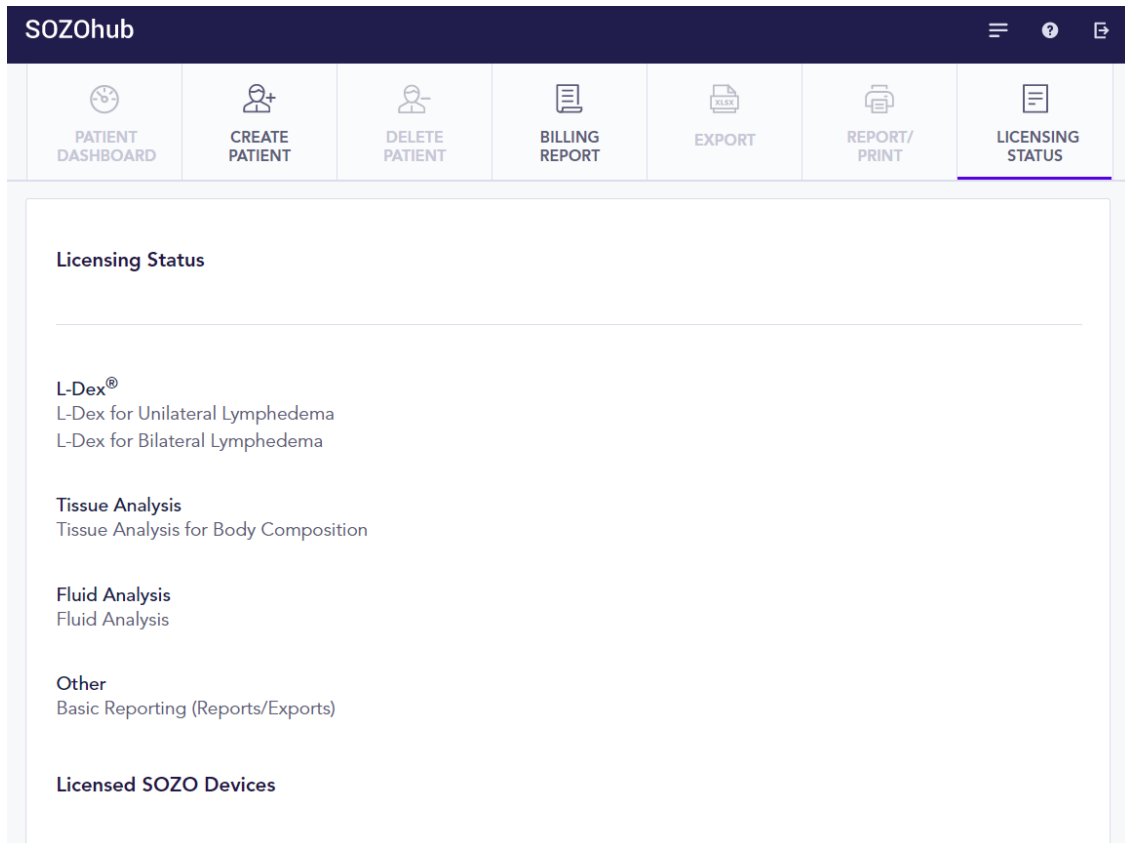
Only the licenses presented on the SOZOhub License Status page are available at the site. If a licence is not available, a measurement may still be taken, but the assessment for that measurement may not be available. Once a license is granted, the clinician will be allowed to select that assessment type 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.