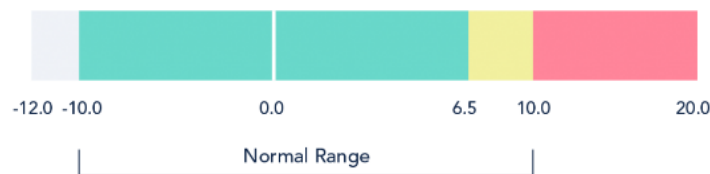


INTRODUCTION:

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 measures the electrical signal that travels through the fluid surrounding the cells which make up the muscle and tissue of the limbs. The amount of this fluid increases as lymphedema develops. Increased fluid means the electrical signal will travel more easily through the limb. An L-Dex device compares how easily the electrical signal travels in the unaffected versus the affected (or at-risk) limbs and generates an L-Dex value from this comparison.

The L-Dex value indicates the difference in the amount of extracellular fluid in the unaffected limb versus the affected limb. The values are displayed on an L-Dex scale against a matched “healthy” group as an aid in a clinician’s assessment. An L-Dex measurement is taken and the score is plotted on a graph similar to what is shown below.



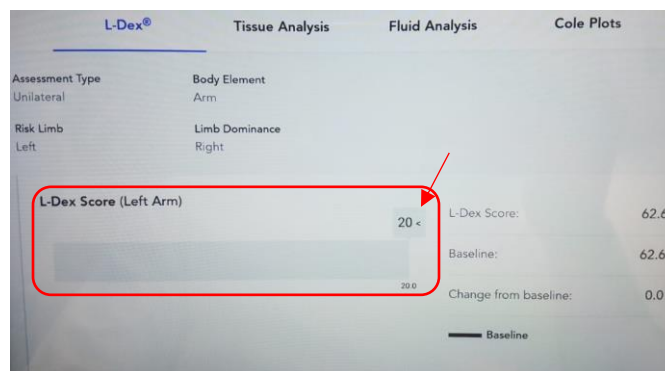
The range of L-Dex values.

*Note: L-Dex values that lie outside the normal range may indicate the early signs of lymphedema and values that have changed +6.5 L-Dex units from baseline may also indicate early lymphedema. The L-Dex scale is a tool to assist in the clinical assessment of lymphedema by a medical provider.

ISSUE DESCRIPTION:

ImpediMed has become aware of a display issue when the L-Dex score exceeds the range (-12 to +20). The result **20<** will be displayed in the upper right corner of the graph.

The value that is shown on the scale is presented incorrectly; it should be presented as **>20**. See below image illustrating the error in the display.



**Note: If a patient's L-Dex score is significantly above a normal range and that elevated score is selected as the baseline (e.g. a baseline score greater than 30 L-Dex units), the entire chart will be shaded grey. The grey area represents L-Dex scores that are more than 10 units lower than the baseline. This can reduce your ability to use the color chart effectively. While the baseline can be changed, it cannot be removed in versions 2.0.1

and prior, so it is not recommended to select a baseline that represents an elevated L-Dex score outside the normal range.

AFFECTED PRODUCTS:

- | | | | |
|---|--|--------------------------|--------------------------------|
| <input checked="" type="checkbox"/> SOZO Analyzer | <input checked="" type="checkbox"/> Software | Version: 2.0.1 and prior | <input type="checkbox"/> U400 |
| <input type="checkbox"/> SFB7 | <input type="checkbox"/> Electrodes (gel backed) | | <input type="checkbox"/> Other |

INSTRUCTIONS:

No action is required at this time; for information purposes only.

CONTACT INFORMATION:

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