

## **INTRODUCTION:**

The SOZOapp, SFT-013 and SFT-026 for the Android operating system was updated in version 3.0.0 to interface with the new cloud-based architecture of MySOZO.com. The SOZOapp provides the interface to the SOZO device and is required to take measurements. The SOZOapp also provides an interface for users to review results of patient measurements as they are taken and of past measurements. Individual measurements may be seen through a results screen and historical charted measurements may be seen through a history screen. For L-Dex measurements, a historical charted measurement is shown in both the results screen and in the history screen.

## **ISSUE DESCRIPTION:**

ImpediMed has become aware of a bug associated with the display of the L-Dex results in the following situation. All three of the following must be true for the bug to be in effect.

- Lymphedema Type: Bilateral Only; and
- when using the SOZOapp; and
- when reviewing an individual measurement

When these conditions exist, if the user takes a new measurement or reviews an individual result in the SOZOapp, the patient's associated data shown in the L-Dex History chart is erroneously displayed from right (oldest) to left (most recent). This data would normally be presented chronologically from left to right.

The potential impact of this bug is that users, expecting to see the most recent results charted on the right hand side of the graph, may not identify trends in the data displayed on the left hand side of the graph.

This bug does not affect any unilateral measurements, results shown in the SOZOapp history screen, or results shown on the MySOZO web-based interface.

The graphic below identifies the bug and the screen as taken from a screenshot of the SOZOapp after navigating to a specific L-Dex Bilateral result.

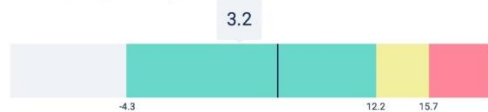
### Results

Last Name	First Name	Date of Birth	
Sex	MRN	Last SOZO Assessment	Assessment Date:
		21 May 2019 11:10	21 May 2019 11:10

L-Dex      Fluid Analysis      Tissue Analysis      Cole Plots

Assessment Type	Body Element	Limb
Bilateral	Leg	Both
Risk Limb	Limb Dominance	
Both	Right	

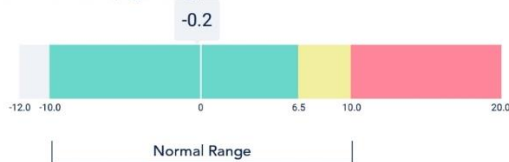
#### L-Dex Score (Left Leg)



L-Dex Score: 3.2  
Baseline: 5.7  
Change from baseline: -2.5

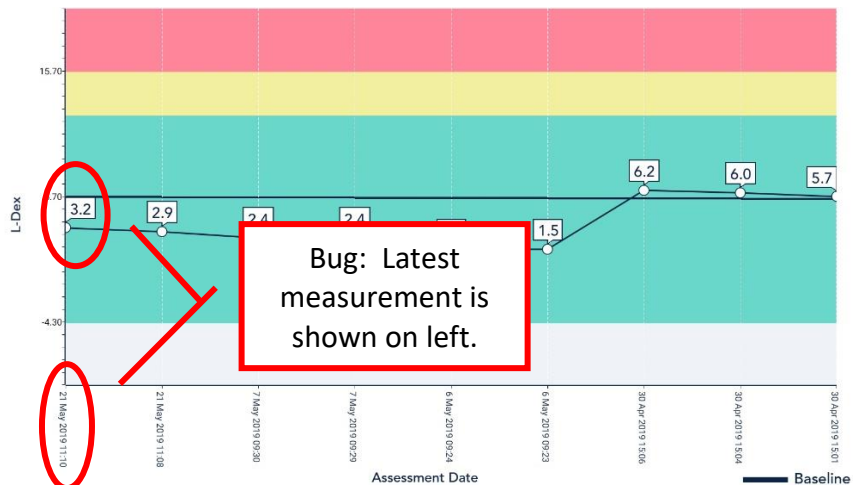
Baseline

#### L-Dex Score (Right Leg)



L-Dex Score: -0.2 (In normal range)  
Baseline: -  
Change from baseline: -

#### L-Dex History (Left Leg)



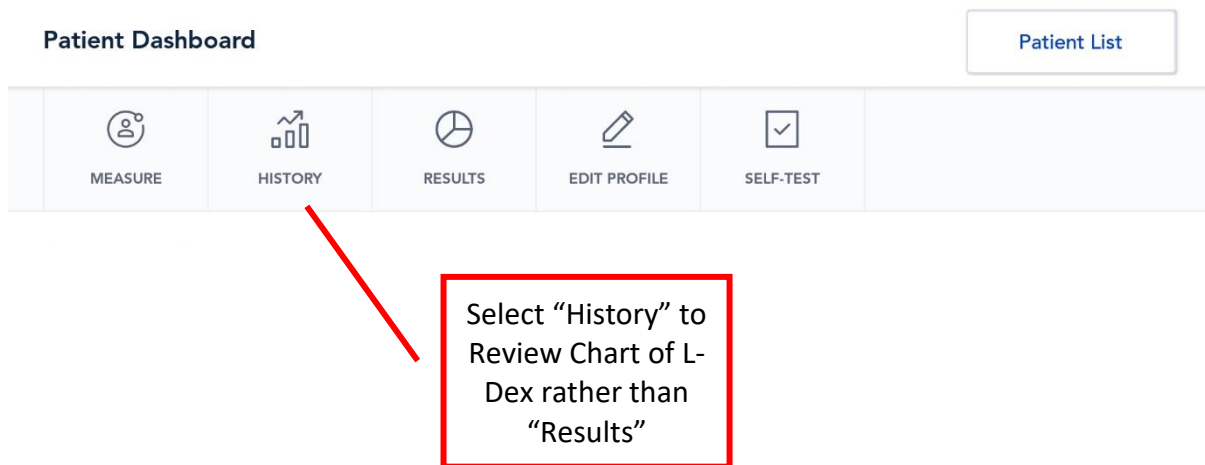
Bug: Latest measurement is shown on left.

**AFFECTED PRODUCTS:**

- SOZO Analyzer
- Software Version: v3.0.0
- U400
- SFB7
- Electrodes (gel backed)
- Other

**INSTRUCTIONS/ISSUE WORKAROUND:**

When reviewing bilateral L-Dex results in the SOZOapp, consult the actual reading value. When looking at the trend or historical results, it is strongly recommended that users navigate to the history screen from the patient dashboard as indicated in the figure below, rather than using the L-Dex History chart that is shown when the current measurement results are displayed. Since the bug is not present in the MySOZO web browser, alternatively, users may review a given patient’s L-Dex results and history using the MySOZO web interface.



**RESOLUTION TIMING:**

ImpediMed is working diligently to identify a fix for this issue and will deploy a software update to resolve the issue in the next software release, which is expected to occur in the next two months.

**CONTACT INFORMATION:**

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