impedimed

FSN Ref: Manufacturer's ref number **2023-01**

Date: 03 August 2023

Urgent Field Safety Notice

SOZO® Bilateral Arm L-Dex® Software (Software v1.4, 4.1 and 5.0)

For Attention of all the customers who are using SOZO bilateral arms L-Dex feature from the SOZO software, for SOZO software versions 1.4, 4.1, and 5.0.

Contact details of local representative (name, e-mail, telephone, address etc.) *
Richard Hines Senior Manager of Regulatory Affairs, ImpediMed Inc. 5900 Pasteur Court, Suite 125 Carlsbad, CA 92008 USA Email: rhines@impedimed.com P: +1 760-585-2104

impedimed

FSN Ref: Manufacturer's ref number **2023-01**

Urgent Field Safety Notice (FSN)
SOZO® Bilateral Arm L-Dex® Software (Software v1,4, 4.1 and 5.0)
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	The SOZO bilateral arms L-Dex feature from the SOZO software, for SOZO software versions 1.4, 4.1, and 5.0. The SOZO Bioimpedance System can detect fluid levels of patients to assist physicians in determining a patient's condition and has been CE Marked as a Class IIa device since 2019. SOZO is primarily utilized for potential or current lymphoedema patients to assist in monitoring patient fluid changes. The potential fluid changes that are associated with possible lymphoedema in the limbs are calculated with the SOZO software and displayed to the clinician and patient as an "L-Dex" score. Below is the ImpediMed Inc. SOZO system indication for use statement for Lymphoedema, a potential side effect of breast cancer treatment. Lymphoedema is a swelling in the limbs caused when the lymphatic system is damaged by the irradiation, damage, or removal of lymph nodes in the arm or leg that is adjacent to the side where tumors were diagnosed and treated. Lymphoedema does not typically occur in an adjacent limb unless tumors are discovered on that side and treated through surgery or radiation. In addition, prophylactic mastectomies do not regularly result in lymphoedema in the adjacent arm. Lymphoedema is categorized as either unilateral (one side) or bilateral (both sides of the body).
1.	2. Commercial name(s)
	SOZO® Bilateral Arm L-Dex® Software (Software v1.4, 4.1 and 5.0)
1.	3. Unique Device Identifier(s) (UDI-DI)
	SOZO System: ++B2772726995SR
1.	4. Primary clinical purpose of device(s)*
	Lymphoedema Bioimpedance Spectroscopy is for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular volume differences between the limbs, and is presented to the Clinician on an L-Dex scale as an aid to their clinical assessment of lymphoedema. The L-Dex Assessment is only indicated for patients who will have, or who have had, lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated.
1.	5. Device Model/Catalogue/part number(s)*
	Add as Appendix if necessary.
1.	6. Software version
	Software v1.4, 4.1 and 5.0
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	The SOZO system consists of several components. The SOZO system itself includes a hand unit with electrodes for the left and right hands, a foot unit with electrodes for the left and right feet, a stand that allows for patients to be measured in a standing position, and a cord which connects both the hand and foot units.

	The system also includes a tablet computer with the SOZOapp (SOZO specific app for control of system and data) installed that is used to control the SOZO system, view patient data, and transmit/receive patient data from the cloud. A web-based site, MySOZO.com allows clinicians and other SOZO users to view and analyze patient data. And finally, patient data is stored and calculated in an Amazon Web Services (AWS) cloud database that can be accessed via either the SOZOapp or MySOZO.com.

2	**Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	The reasons for the voluntary defect correction of the bilateral arm assessment feature from the software are the following: - In some cases, patients are being assessed using the incorrect L-Dex assessment type. Most frequently, patients at unilateral risk of lymphoedema are incorrectly being assessed using the bilateral arm L-Dex assessment. As a result of the investigations into the incorrect patient L-Dex assessment types stated above, ImpediMed discovered that the L-Dex bilateral arm assessment does not have the same level of sensitivity to help detect subclinical signs of lymphoedema as the L-Dex unilateral arm assessment.
2.	2. Hazard giving rise to the FSCA*
	Risk to Patent Health: If a true unilateral patient (approximately 90% of all potential lymphoedema patients) has their patient profile selected to bilateral measurement, the lack of sensitivity to detect subclinical lymphoedema within the L-Dex bilateral arm assessment will likely not identify a fluid change commensurate with the patient's actual lymphoedema condition. This can be corrected for true unilateral patients by setting the patient profile to unilateral L-Dex parameters which will effectively monitor fluid changes in the patient. For true bilateral patients (approximately 10% of the potential lymphoedema population) with tumors and treatment in both breasts, bilateral L-Dex will not provide enough sensitivity to accurately detect subclinical fluid changes in the patient's arm, requiring the physician to recommend more frequent clinical examination and directly conducting patient symptom assessment. If diagnosed early enough, lymphoedema is treatable, and in many cases, reversible. Common treatments include use of a compression sleeve on the impacted limb for a period of weeks.
2.	3. Probability of problem arising
	Health Hazard Evaluation: Based on a clinical assessment from Dr. Chirag Shah, an oncologist at the Cleveland Clinic with significant expertise in both lymphedema and the ImpediMed Inc. SOZO L-Dex technology, there is a reasonable probability that the population at greatest risk utilizing bilateral L-Dex arm will result in some medically reversible or transient adverse health consequences. In addition, according to Dr. Shah, there is also a remote probability that the overall patient population utilizing SOZO L-Dex will experience medically reversible or transient adverse health consequences.
2.	4. Predicted risk to patient/users
	Per Dr. Shah, it is unlikely that either the overall patient population or the patient population at greatest risk who utilize SOZO L-Dex will experience any adverse events because of the bilateral sensitivity issue. Dr. Shah's recommendation is the at-risk patient population (true bilateral patients) will require clinical examination and symptom assessment
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	In some cases, patients are being assessed using the incorrect L-Dex assessment type. Most frequently, patients at unilateral risk of lymphoedema are incorrectly being assessed using the bilateral arm L-Dex assessment.

	As a result of the investigations into the incorrect patient L-Dex assessment types stated above, ImpediMed discovered that the L-Dex bilateral arm assessment does not have the same level of sensitivity to help detect subclinical signs of lymphoedema as the L-Dex unilateral arm assessment.
2.	7. Other information relevant to FSCA
	Communication and Training Plan: As the plan to deactivate the bilateral L-Dex licenses is being organized and completed, a communication and training plan will be rolled out to communicate the pending changes to the software and to train users on how to identify potential true unilateral and potential true bilateral lymphoedema patients and align their SOZO patient profiles accordingly. It will be critical to align the patient profiles properly to address whether patients are true unilateral or true bilateral patients, as their treatment plans will be different and unilateral patients have more accurate L-Dex assessments with profiles that reflect their unilateral condition. The communication plan will consist of multiple email communications notifying customers and users of the situation (utilizing an email read receipt process), along with a follow up with customers either by phone, via video conference, or through a walk-in visit to the customer, as necessary. Training will include training clinical personnel on how to update potential or existing true unilateral arms patient profiles to reflect the patient's condition, while potential or existing true bilateral patients will have their treatment plans amended to include more frequent clinical examinations and symptom assessment. This communication and training plan will prioritize the customers with the most patients, SOZO bilateral licenses, users, and SOZO devices to effectively address the most patients and users simultaneously.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Align their SOZO patient profiles accordingly. It will be critical to align the patient profiles properly to address whether patients are true unilateral or true bilateral patients, as their treatment plans will be different and unilateral patients have more accurate L-Dex assessments with profiles that reflect their unilateral condition.	
3.	2. By when should the action be completed?	*Immediate Solution – deactivation of the bilateral L-Dex licenses* The most recent versions of the SOZO software are 4.1 and 5.0. As an immediate corrective action, all SOZO bilateral arm software licenses will be deactivated remotely by ImpediMed. This will disable all existing bilateral L-Dex licenses in the field until a more sensitive bilateral L-Dex software version can be deployed. The SOZO software is utilized by both the MySOZO.com web-based system and the SOZO app, tablet-based software.

3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Other: D*eactivation of the bilateral L-Dex licenses*	
3	6. By when should the action be completed?	*Deactivation of the bilateral L-Dex licenses : Immediately*
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

4. General Information*

4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	ImpediMed Inc.
	b. Address	5900 Pasteur Court, Suite 125Carlsbad, CA 92008 USA
	c. Website address	Only necessary if not evident on letter-head.

4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Reply Form
4.	10. Name/Signature	Richard Hines Senior Manager of Regulatory Affairs, ImpediMed Inc. Email: rhines@impedimed.com

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Field Safety Notice
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2023-01
FSN Date*	03 August 2023
Product/ Device name*	SOZO® Bilateral Arm L-Dex® Software (Software v1.4, 4.1 and 5.0)
Product Code(s)	N/A
Batch/Serial Number (s)	Software v1.4, 4.1 and 5.0

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty: N/A	Lot/Serial Number: N/A	Date Returned (DD/MM/YY):
		Qty: N/A	Lot/Serial Number: N/A	Date Returned(DD/MM/YY):
		N/A	Comments: N/A	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty: N/A	Lot/Serial Number: N/A	
		Qty: N/A	Lot/Serial Number: N/A	
		N/A	Comments:	
☐	No affected devices are available for return/	Customer to complete or enter N/A		

	destruction	
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	rhines@impedimed.com
Customer Helpline	+1 760-585-2104
Postal Address	ImpediMed Inc. Richard Hines, Senior Manager of Regulatory Affairs 5900 Pasteur Court, Suite 125 Carlsbad, CA 92008 USA
Web Portal	www.impedimaed.com
Fax	+1-760-804-9245
Deadline for returning the customer reply form*	31 August 2023

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.