Shenzhen Med-link Electronics Tech Co., Ltd.

Rev 2: February 2020

FSN Ref: FSN2024001 FSCA Ref: FSCA2024001

Date: 2024.06.28

Field Safety Notice
Device Commercial Name

For Attention of*:Users such as healthcare professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
Swiss Authorized Representative. Name: Share Info Suisse GmbH; Address: St. Leonhard-Strasse 35, 9000 St. Gallen, Switzerlan; E-mail: ch-rep@share-info.com

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Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Disposable Pulse Oximeter Probe is a compatible sensor for use with major brands of patient monitors and oximeter devices, as an accessory of the legally marketed oximeters or patient monitors on the EU market, the Disposable Pulse Oximeter Probe is indicated for continuous non-invasive monitoring of functional arterial oxygen saturation (SpO2) and pulse rate (PR) in hospital settings.
1.	2. Commercial name(s)*
	Disposable Pulse Oximeter Probe
1.	3. Primary clinical purpose of device(s)*
	Disposable Pulse Oximeter Probe is to be used for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.
1.	4. Device Model/Catalogue/part number(s)*
	Catalogue number: S0190M-LP

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Incident description from hospital: 1. Phlyctenoid redness on the top of the foot of a 35 SA (1.735 kg) premature newborn, at the sensor location, despite a change of position every 3 hours as recommended. 2. The incident did not result in serious harm to patients, users or third parties.
2.	2. Hazard giving rise to the FSCA*
	A mild injury, illness or impairment which can be treated with minimal or no intervention.
2.	3. Probability of problem arising
	From January 1st, 2021 to May 31st, 2024, 5,622,952 Disposable Pulse Oximeter Probes manufactured by our company were sold all over the world. Only 3 have reported similar adverse events. The probability of this hazard occurring is low.
2.	4. Predicted risk to patient/users
	Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics or impaired circulation, such as irritation, reddening, blistering or burns.

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 For neonates, or patients with poor peripheral blood circulation or sensitive skin, the healthcare professionals should inspect the sensor site more frequently. Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics or impaired circulation, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours.	
3.	2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**3. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Update the warning in IFU: "For neonates, or patients with poor peripheral blood circulation or sensitive skin, the healthcare professionals should inspect the sensor site more frequently. Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics or impaired circulation, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours."	

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? *	No
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	Shenzhen Med-link Electronics Tech Co., Ltd.
	b. Address	2nd, 4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
	c. Website address	https://www.med-linket.com/

4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *

	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.

Shenzhen Med-link Electronics Tech Co., Ltd.

Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN2024001
FSN Date*	2024.06.28
Product/ Device name*	PULSE OXIMETER SENSORS

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Contact Name*	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation	
Print Name*	
Signature*	
Date*	