Electromedical Products International, Inc.

FSN Ref: **FSCA Manufacturer Ref: CAR 07-01-2019**

Date: July 9th, 2019

Urgent Field Safety Notice
Electromedical Products International Inc 's "Alpha Conducting Solution"

For Attention of*: **Alpha Conducting Solution Users and Distributors**

Contact details of local representative (name, e-mail, telephone, address etc.)*

Distributor Name & Address	Contact Name	Country	Phone number and email address
Piniol Therapie Erlistrasse 2 , 6403 Kussnacht am Rigi	Sandra Schonbachler	Switzerland	(41) 41 854 18 17 sandra.schoenbaechler@piniol.ch
Premed Chemin Rey 11C La Plaine 1283	Prema Kumar	Switzerland	41791095424 kumarprem1@gmail.com
Electro-Zeutika GmbH BGM-Jakob-Karg-Str. 33 Grasbrunn 85630	Bjoern Schaefer	Germany	(49)81063778935 bjoern.schaefer@electro-zeutika.de
Iben Smith-Ulnits Hoptrup Vandkaer 39 Haderslev 6100	Iben Smith-Ulnits	Denmark	45 22 42 58 08 iben@i-bensmith.dk
Mossawi Mohammad S.A.R.L. Life Trading and Development Cite Freri 3, Lot B, El Hamiz D.E.B. Alger	Mossawi Mohammad	Denmark	213 21 877 585
BioforMed Aesthetic SL C/Amadeo Arias 15 - 7A Valladolid 47014	Claudio Tassi	Spain	+39 3355823165 bioformed.aesthetic@gmail.com
Servitron 200SL C/SAan German 6 Bis Local 9 Madrid	David Martinez	Spain	dpm.health@hotmail.com

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Distributor Name & Address	Contact Name	Country	Phone number and email address
The Microcurrent Site Ltd Unit 3, Upstairs Brookside Sawtry Hunts PE28 5SB	Steve Hutchinson	United Kingdom	1487208041 steve@themicrocurrentsite.co.uk
Zagoridis Georgios "Neuvexis Healthcare" 24 Chalkidikis Street Thessaloniki 54643	George Zagoridis	United Kingdom	(30) 6949 335 074 zagoridis@neuvexis.com
TradeMed d.o.o Trg. JF Kennedya 6b Zagreb 10000	Natko Geres	Croatia	385-1-2444-656 natkogeres@gmail.com
Mediwel Kft. - Nepessy Judit H-1037 Budapest Vorosvari ut 107. fszt.	Judit Nepessy	Hungary	36-20779 4074 judit.nepessy@mediwel.hu
BITS Sas Via G. Matteotti 19 Villasanta	Tommaso Calini	Italy	+39 339 6510055 tcalini@bitsol.eu
UAB Meda LT Šaltalankiu 14-4, Klevines vs. Avižieniu sen Vilnius 14180	Kazimieras Zakevicius	Lithuania	370 5 246 0054 info@meda-lt.lt
ARGUS RT Ltd 15E Unijas Str. Riga LV1039	Eduards Arajs	Latvia	37129203393 eduards.arajs@argus.lv
EEG Professionals BV Vestdijk 61 5611 CA Eindhoven 5611	Derk Mulder	Netherlands	040-2364111 d.mulder@ggzgroep.nl
Microstim Nederland BV Mitchamplein 1A 7556 SC Hengelo Hengelo 7556	Jacquelien Fekkes	Netherlands	074 2504669 braindynamics@gmail.com

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Urgent - Field Safety Notice (FSN)
Electromedical Products International Inc – "Alpha Conducting Solution"

1. Information on Affected Devices*

1.1. Device Type(s)*

Alpha Conducting Solution is a solution used with the Alpha-Stim M & AID devices to assist with electrical conductivity.
Alpha-Stim devices are electrotherapy stimulation devices for the treatment of anxiety, insomnia, depression and pain. Product is not sterile.

1.2. Commercial name(s)

"Alpha Conducting Solution" , "ACS" , "ACSR" (ACS Refill)

1.3. Unique Device Identifier(s) (UDI-DI)

1.4. Primary clinical purpose of device(s)*

Alpha Conducting Solution is an accessory to the Alpha-Stim devices.
It is applied in drops to the portion of the device that attaches to the patient to increase electrical conductivity.

1.5. Device Model/Catalogue/part number(s)*

ACS (15 ml) and ACSR (250 ml)

1.6. Software version

Not relevant.

7. Affected serial or lot number range

Product	Model /size	Lot Number	Manufacturing Date
Alpha Conducting Solution	ACS 15 ml	081914-15	June, 2014
		111715-15	October, 2015
		070116-15	July 2016
		020117-15	February, 2017
		080117-15	August, 2017
		010118-15	January, 2018
		041618-15	April, 2018
		041618A-15	April, 2018
		071618-15	July, 2018
		102018-15	October, 2018
	ACSR 250 ml	032014-25	February 2014
		060515-25	May, 2015
		101615-25	October 2015
		011716-25	November, 2015
		021317-25	February, 2017
		080117-25	August, 2017
		010118A-25	January, 2018
		041618-25	April, 2018
		071618-25	July, 2018
		102018A-25	October, 2018

1	Within context of the FSCA e.g. for IVD reagents and platforms. NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	The product may not have the capability to effectively control the contamination of the conducting solution over time. The products failure to prevent contamination could lead to injuries associated with, but not limited to, the following: Candida albicans, Aspergillus Niger, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus.
2.	**2. Hazard giving rise to the FSCA***
	There have been no reports of harm or injury due to this event; risk of occurrence is small. Customers should be cautious that the product may not have the capability to effectively control the contamination of the conducting solution over time. The products failure to prevent contamination could lead to injuries associated with, but not limited to, the following: Candida albicans, Aspergillus Niger, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus. Solution should not be used; it should be discarded.
2.	**3. Probability of problem arising** Improbable
2.	**4. Predicted risk to patient/users**
	Overall risk to patient is “LOW”.
2.	**5. Further information to help characterize the problem**
	EPI has received no complaints or notices of harm due to Alpha Conducting Solution. Solution supplier, Pharmaceuticals Innovations, also has not received any notices of harm.
2.	**6. Background on Issue**
	EPI was contacted by our solution supplier, Pharmaceutical Innovations, that the solution failed antimicrobial stability testing. They indicated no complaints or harm were received due to the solution, but a voluntary recall of the product was deemed necessary.
2.	7. Other information relevant to FSCA

FSN Ref: CAR 07-01-2019

FSCA Manufacturer Ref: CAR 07-01-2019

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** **X Identify Solution** X **Quarantine Device** ☐ Return Device X **Destroy Solution** ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	**2. By when should the action be completed?**	**Immediately**
3.	3. Particular considerations. Is follow-up of patients or review of patients' previous results recommended? **No follow up is needed.** **No complaints or notices of harm have occurred.** **Risk of a problem arising is very small/low.** **Discontinuing use should mitigation the concern.**	
3.	**4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)**	**Recommended, but not required**
3.	**5. Action Being Taken by the Manufacturer** **X Product Removal** ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None **EPI is asking customers to stop using the product and distributors to cease sales immediately.** **This constitutes a product removal by asking customers to dispose of the material.** **There is no expectation that product needs to be returned to the manufacturer.**	
3	6. By when should the action be completed? See table for communication action as follows:	

	Customer Type	1st communication	Examples needed:	2nd communication
	Distributor	**Email**	- Email message	Repeat 1st contact after 4 weeks if effectivity was not achieved
	Patient& Clinical	• **Email, bulk service provider including weblink** • **Postal mail if no phone number or email address is found**	- Email message	After 4 weeks, if effectivity was not achieved EPI will evaluate if phone call or postal mail if no phone number or email address is found ; or if another email note is the correct action.
	EPI Website		- Web page - form	
3.	7. Is the FSN required to be communicated to the patient /lay user?			**YES, end user should stop using the "Alpha Conducting Solution" and destroy the product.**
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?			
	Email message and link to EPI website will provide direction			

FSN Ref: CAR 07-01-2019 FSCA Manufacturer Ref: CAR 07-01-2019

	4. General Information*	
4.	**1. FSN Type***	**RECALL.**
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows:	
	Summarize any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item.
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	E.g. patient management, device modifications etc.	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	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:	If extensive consider providing web-link instead.
4.	**10. Name/Signature**	Insert Name and Title here and signature below

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) **Please transfer this notice to other organizations** 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 or its distributor or local representatives**, **and the National Competent Authority of Health of your country, if appropriate, as this provides important feed-back.***

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