

Date: 21.04.2021

Field Safety Notice EXHALYZER D

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

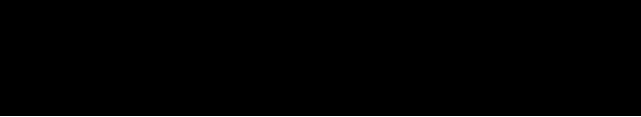
Contact details of local representative
Acertys Healthcare nv, Oeyvaersbosch 12, BE-2630 Aartselaar, Tel: +32 3 870 11 11, www.acertys.com
MATREL d.o.o., Baštijanova 9a, HR-10 000 Zagreb, Tel: +385 1 3633 055, www.matrel.hr
TECHNOPROCUR CZ, spol. s r.o., Lipova 524, 252 43 Pruhonice, Tel: +420 241 716 024, www.technoprocur.cz
Intramedic A/S, Gentoftegade 118, 2. Sal, 2820 Gentofte, Tel: +45 7023 6162, www.intramedic.dk
Timik Medical Oy, Innopark 2, Vankankäthe 7, 13100 Hämeenlinna, Tel: +358 757 580 860, www.timik.fi
Adhesia Division Diagnostics, 26, Rue de la montée, 68820 Flaxlanden, Tel : +33 3 89 06 14 44, www.adhesia.com
ECO PHYSICS GmbH, Gildenweg 6, D-50354 Hürth, Tel: +49 2233 46055 00, www.ecophysics.de
ANNOX Ltd., 3 Cowper Crescent, Hertford, Herts, SG14 3DY, Tel: +44 1 992 534 643, www.annox.co.uk
Analytical Instruments S.A., 9, Tzavella str., 152 31 K. Chalandri/Athens, Tel: +30 210 67 48 973, www.analytical.gr
Med-Pro Hungary kft., Perényi út 8/b, 1037 Budapest, Tel: +36 1 250 1463, www.med-pro.hu
Sormedica Co. Ltd, Kuzmos str. 28, 08431 Vilnius, Tel: +370 (5) 219 57 10, www.sormedica.lt
Medical Graphics Italia Srl, Via Simone d'Orsenigo, 21, 20135 Milano, Tel: +39 02 54 12 03 43, www.medgraphics.it
AkuMed A.S., Østjensjøveien 27, Postboks 6253, Etterstad, 0603 Oslo, Tel: +47 22 07 52 20, www.akumed.no
PRO VITA Polska Sp. z o.o. Sp.K., Ul. Parafialna 1, 47-100 Strzelce Opolskie, Tel: +48 77 462 13 00, www.sprzetmedyczny.pl
PULMOCOR, Rua José Joaquim de Freitas, 253, PO Box 46, 2751-901 Cascals, Tel: +35 1 214 841 840, www.pulmocor.pt
MIKRO+POLO, Zabrebska 22, Maribor 2000, Tel: +38 626 14 33 00, www.mikro-polo.si
SANRO Electromedicina S.A., Ctra. de Húmera 10, 28224 Pozuelo de Alarcón (Madrid), Tel: +34 (91) 352 92 44, www.sanro.com
Intramedic AB, Sjöängsvägen 1C, 192 72 Sollentuna, Tel: +46 8 409 03 800, www.intramedic.se
ECO PHYSICS, INC., 3915 Research Park Drive Suite A-3, Ann Arbor, MI 48108-2200, Tel: +1 734 998 1600, www.ecophysics-us.com
Fairport Ltda, Rua Jacarandá 293, 04926-160 São Paulo -SP, Tel: +55 11 9 8293 9715, www.fairport.com.br
Ascencia Pty. Limited, 2/21 Howleys Road, Notting Hill VIC 3168, Tel: +61 3 9545 1371, www.ascencia.com.au
Bioline Tech Co. Ltd., Room 1209, Rongke Wangjing Center, Building A, Chaoyang District, Beijing 100102, Tel: +86 10 58404176, www.bioline-tech.com
Farasa Mehr Co. Ltd., No: 10, 3rd Floor, Arash Building, Mohseni Square, 1547934471 Tehran, Tel: +98 21 2225 8496
Eldan Electronic Instruments Co.Ltd., 6 Hashiloach Street, Petach-Tikva 49170, Tel: +972 3 9371144, www.eldan.biz
Al Essa Medical & Scientific Equipment Co. Wll, 118 Sector C, Street 38, Shuwaikh Ind. Are, 13036 Safat, Tel: +965 96965535, http://www.alessakuwait.com
Barzan Medical Supplies, 9 ahmed bin ali st., Doha, Bin Omran 4961 qa, Tel: +974 44410270, www.barzanmedical.com
TEKNIKEL Ticaret ve Sanayi A.S., Piyalepaşa Bulvarı, Kastel Is Merkezi, C-Blok Kasimpasa, Istanbul, Tel: +90 212 254 7400, www.teknikel.com

Field Safety Notice (FSN)
EXHALYZER D

1. Information on Affected Devices *	
1	1. Device Type(s) *
.	Pulmonary function testing device
1	2. Commercial name(s)
.	EXHALYZER D
1	3. Unique Device Identifier(s) (UDI-DI)
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1	4. Primary clinical purpose of device(s) *
.	Pulmonary Function Testing
1	5. Device Model/Catalogue/part number(s) *
.	M3024 with option M3024-12 (N2-MBW)
1	6. Software version
.	Spiroware 3.3.0 or previous versions
1	7. Affected serial or lot number range
.	All
1	8. Associated devices
.	None

2. Reason for Field Safety Corrective Action (FSCA) *	
2	1. Description of the product problem *
.	O2 and CO2 Sensor cross sensitivity
2	2. Hazard giving rise to the FSCA *
.	None, when correct normative values are used.
2	3. Probability of problem arising
.	All FRC / LCI measurements might be affected
2	4. Predicted risk to patient/users
.	No risk for patient or user
2	5. Further information to help characterise the problem
.	Using correct normative values does not lead to any misinterpretation of clinical outcome.
2	6. Background on Issue
.	Scientific publications as listed in the attached report summary.
2	7. Other information relevant to FSCA
.	-

3. Type of Action to mitigate the risk *		
3.	<p>1. Action To Be Taken by the User *</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input checked="" type="checkbox"/> Other: Software update by customer as soon as possible, latest at the next yearly maintenance or at the end of clinical trial </p> <p> <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>	
3.	2. By when should the action be completed?	As soon as possible, latest at the next yearly maintenance or at the end of clinical trial
3.	<p>3. Particular considerations for: Choose an item.</p> <p>-</p>	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 31.05.2021
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection </p> <p> <input checked="" type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Software update available for download</p>	
3	6. By when should the action be completed?	As soon as possible, latest at the next yearly maintenance or at the end of clinical trial
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
3	<p>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?</p> <p>Choose an item.</p>	

4. General Information *	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN -
4.	3. For Updated FSN, key new information as follows: -
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: -
4	6. Anticipated timescale for follow-up FSN
4.	7. Manufacturer information (For contact details of local representative refer to page 0 of this FSN)
	a. Company Name ECO PHYSICS AG
	b. Address CH-8635 Duernten
	c. Website address www.ecomedics.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes
4.	9. List of attachments/appendices: AM21-022-Report Summary V11
4.	10. Name/Signature 

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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