

24 June 2019

Field Safety Notice

Commercial name of the affected product : FeNO+
FSCA-identifier : FSCA NC 502
Type of action : *Corrective action*

Attention: All users, importers and distributors of Medisoft FeNO+

Details on affected devices:

All FeNO+ manufactured from 01 February 2015, equipped with MNO-LO nitric oxide electrochemical cell.
Or previous devices upgraded with this analyser.

List of the serial numbers of the concerned devices available hereunder;

https://www.medisoft-ftp.be/index.php?option=com_content&view=article&id=21

Description of the problem:

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A risk of overheating of the battery who keep the polarization of the nitric oxide analyser could not be excluded at 100%, the probability is nearly inexistent however, Medisoft prefer to proceed with the replacement of the component to avoid any risk. The list of the affected devices is joined to this document.

Technical detail:

The manufacturer of the battery test the product with a charge of 3C (360mA) during 8 hours without consequences of fire or explosion. The battery in the FeNO is charged with 1.3333C (160mA) for less than 2 hours, after this the IC stop the charge when the battery is charged at 96.5% and keep a trickle current of 25µA until the charge of the battery go under 66.5%, were the charge restart at 160mA. An identical test system were the NO cells are polarized before testing of the device is used internally, this system is continuously powered 24h/day, and use the same battery without deterioration, fire or explosion.

Advise on action to be taken by the user:

Power down the device at the end of the day, as preconized in the instructions for use.

Transmission of this Field Safety Notice:

This Field Safety Notice will be sent by Medisoft to all the user of the device for France and Belgium, for other countries all the distributors of the FeNO+ who have sold a device after February 2015 will be contacted directly, with the procedure and all technical aspects and the way to organise the intervention.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate).

Medisoft plan to close the related actions for December 2019.

Contact reference person:

Eric Dion. QaRa Manager, Medisoft S.A., eric.dion@medisoft.be , 0032 82 223020

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (Closing paragraph)

Eric Dion
QaRa Medisoft S.A.

List of devices (sorted in ascending order)

Device	Serial Number
FeNO+	140220-04-1765
FeNO+	140513-04-1873
FeNO+	140514-04-1873
FeNO+	140515-04-1873
FeNO+	140516-04-1873
FeNO+	141125-04-0023
FeNO+	141203-04-2026
FeNO+	150203-04-0002
FeNO+	150220-04-0057
FeNO+	150226-04-0142
FeNO+	150259-04-0085
FeNO+	150317-04-0144
FeNO+	150318-04-0114
FeNO+	150319-04-0115
FeNO+	150320-04-0116
FeNO+	150330-04-1913
FeNO+	150331-04-1913
FeNO+	150401-04-0155
FeNO+	150407-04-0145
FeNO+	150408-04-0206
FeNO+	150409-04-0212
FeNO+	150410-04-0172
FeNO+	150413-04-0198
FeNO+	150417-04-0222
FeNO+	150528-04-0248
FeNO+	150528-04-0258
FeNO+	150529-04-0260
FeNO+	150601-04-0263
FeNO+	150602-04-0264
FeNO+	150629-04-0232
FeNO+	150629-04-0291
FeNO+	150630-04-0291
FeNO+	150701-04-0292
FeNO+	150702-04-0292
FeNO+	150703-04-0292
FeNO+	150706-04-0303
FeNO+	150707-04-0303



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FeNO+	150708-04-0295
FeNO+	150727-04-0289
FeNO+	150728-04-0325
FeNO+	150827-04-0361
FeNO+	150922-04-0375
FeNO+	150929-04-0383
FeNO+	150930-04-0384
FeNO+	151008-04-0391
FeNO+	151009-04-0403
FeNO+	151012-04-0392
FeNO+	151013-04-0393
FeNO+	151103-04-0011
FeNO+	151103-04-0416
FeNO+	151104-04-0417
FeNO+	151105-04-0420
FeNO+	151106-04-0421
FeNO+	151109-04-0443
FeNO+	151201-04-0012
FeNO+	151202-04-0028
FeNO+	151203-04-0037
FeNO+	151204-04-0040
FeNO+	151215-04-0047
FeNO+	151216-04-0048
FeNO+	151217-04-0049
FeNO+	151218-04-0050
FeNO+	151221-04-0051
FeNO+	151222-04-0052
FeNO+	160104-04-0032
FeNO+	160126-04-0089
FeNO+	160201-04-0095
FeNO+	160202-04-0096
FeNO+	160210-04-0100
FeNO+	160216-04-0107
FeNO+	160222-04-0109
FeNO+	160225-04-0112
FeNO+	160226-04-0033
FeNO+	160304-04-0122
FeNO+	160304-04-0131
FeNO+	160307-04-0132
FeNO+	160308-04-0133
FeNO+	160309-04-0134



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FeNO+	160311-04-0136
FeNO+	160317-04-0146
FeNO+	160318-04-0147
FeNO+	160321-04-0148
FeNO+	160322-04-0149
FeNO+	160323-04-0145
FeNO+	160324-04-0153
FeNO+	160325-04-0154
FeNO+	160329-04-0155
FeNO+	160330-04-0156
FeNO+	160331-04-0157
FeNO+	160401-04-0158
FeNO+	160408-04-0172
FeNO+	160411-04-0168
FeNO+	160412-04-0165
FeNO+	160413-04-0166
FeNO+	160414-04-0167
FeNO+	160426-04-0195
FeNO+	160524-04-0231
FeNO+	160525-04-0234
FeNO+	160603-04-0240
FeNO+	160610-04-0243
FeNO+	160616-04-0247
FeNO+	160617-04-0252
FeNO+	160620-04-0253
FeNO+	160621-04-0251
FeNO+	160629-04-0275
FeNO+	160705-04-0277
FeNO+	160711-04-0286
FeNO+	160714-04-0289
FeNO+	160718-04-0082
FeNO+	160811-04-0315
FeNO+	160812-04-0316
FeNO+	160901-04-0328
FeNO+	160902-04-0332
FeNO+	160914-04-0344
FeNO+	160915-04-0353
FeNO+	161004-04-0356
FeNO+	161005-04-0359
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FeNO+	161024-04-0385
FeNO+	161025-04-0387
FeNO+	161108-04-0004
FeNO+	161125-04-0008
FeNO+	161129-04-0024
FeNO+	161130-04-0025
FeNO+	161201-04-0022
FeNO+	161202-04-0028
FeNO+	161205-04-0030
FeNO+	161221-04-0051
FeNO+	161222-04-0041
FeNO+	161223-04-0046
FeNO+	161228-04-0040
FeNO+	161230-04-0054
FeNO+	161269-04-0052
FeNO+	170109-04-0062
FeNO+	170123-04-0071
FeNO+	170124-04-0071
FeNO+	170125-04-0071
FeNO+	170126-04-0071
FeNO+	170127-04-0071
FeNO+	170131-04-0093
FeNO+	170201-04-0079
FeNO+	170209-04-0089
FeNO+	170210-04-0090
FeNO+	170213-04-0091
FeNO+	170214-04-0092
FeNO+	170221-04-0125
FeNO+	170222-04-0123
FeNO+	170228-04-0088
FeNO+	170303-04-0131
FeNO+	170306-04-0132
FeNO+	170307-04-0133
FeNO+	170308-04-0120
FeNO+	170309-04-0121
FeNO+	170310-04-0122
FeNO+	170312-04-0124



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FeNO+	170413-04-0189
FeNO+	170414-04-0190
FeNO+	170418-04-0218
FeNO+	170424-04-0187
FeNO+	170502-04-0249
FeNO+	170503-04-0250
FeNO+	170504-04-0251
FeNO+	170505-04-0232
FeNO+	170506-04-0238
FeNO+	170508-04-0233
FeNO+	170509-04-0234
FeNO+	170510-04-0235
FeNO+	170511-04-0236
FeNO+	170512-04-0222
FeNO+	170515-04-0261
FeNO+	170522-04-0266
FeNO+	170523-04-0259
FeNO+	170524-04-0269
FeNO+	170529-04-0237
FeNO+	170608-04-0272
FeNO+	170609-04-0273
FeNO+	170612-04-0274
FeNO+	170613-04-0275
FeNO+	170614-04-0276
FeNO+	170615-04-0287
FeNO+	170619-04-0309
FeNO+	170620-04-0339
FeNO+	170626-04-0327
FeNO+	170627-04-0337
FeNO+	170704-04-0310
FeNO+	170705-04-0338
FeNO+	170713-04-0345
FeNO+	170713-04-0417
FeNO+	170714-04-0350
FeNO+	170808-04-0367
FeNO+	170809-04-0377
FeNO+	170811-04-0376
FeNO+	170814-04-0375



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FeNO+	170912-04-0349
FeNO+	170925-04-0385
FeNO+	170926-04-0439
FeNO+	170927-04-0440
FeNO+	170928-04-0441
FeNO+	171002-04-0442
FeNO+	171003-04-0443
FeNO+	171010-04-0456
FeNO+	171115-04-0022
FeNO+	171116-04-0023
FeNO+	171117-04-0024
FeNO+	171122-04-0027
FeNO+	171123-04-0028
FeNO+	171208-04-0053
FeNO+	171213-04-0071
FeNO+	171214-04-0072
FeNO+	180109-04-0082
FeNO+	180110-04-0083
FeNO+	180111-04-0084
FeNO+	180112-04-0099
FeNO+	180122-04-0109
FeNO+	180214-04-0133
FeNO+	180221-04-0136
FeNO+	180223-04-0137
FeNO+	180226-04-0146
FeNO+	180227-04-0147
FeNO+	180228-04-0148
FeNO+	180305-04-0149
FeNO+	180306-04-0150
FeNO+	180312-04-0168
FeNO+	180313-04-0169
FeNO+	180314-04-0170
FeNO+	180315-04-0171
FeNO+	180316-04-0172
FeNO+	180319-04-0173
FeNO+	180404-04-0189
FeNO+	180406-04-0191
FeNO+	180409-04-0192
FeNO+	180416-04-0197



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FeNO+	180504-04-0214
FeNO+	180507-04-0215
FeNO+	180508-04-0216
FeNO+	180514-04-0218
FeNO+	180522-04-0236
FeNO+	180523-04-0237
FeNO+	180524-04-0238
FeNO+	180525-04-0239
FeNO+	180611-04-0260
FeNO+	180612-04-0261
FeNO+	180621-04-0264
FeNO+	180625-04-0269
FeNO+	180626-04-0270
FeNO+	180718-04-0286
FeNO+	180719-04-0287
FeNO+	180806-04-0295
FeNO+	180807-04-0296
FeNO+	180810-04-0303
FeNO+	180830-04-0315
FeNO+	180903-04-0317
FeNO+	180904-04-0318
FeNO+	180913-04-0325
FeNO+	180917-04-0327
FeNO+	180918-04-0328
FeNO+	180919-04-0330
FeNO+	180920-04-0331
FeNO+	181004-04-0343
FeNO+	181018-04-0355
FeNO+	181022-04-0357
FeNO+	181105-04-0001
FeNO+	181106-04-0002
FeNO+	181112-04-0008
FeNO+	181121-04-0017
FeNO+	181121-04-0018
FeNO+	181124-04-0020
FeNO+	181127-04-0025
FeNO+	181128-04-0026
FeNO+	181129-04-0027



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FeNO+	181215-04-0044
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FeNO+	190104-04-0050
FeNO+	190107-04-0051
FeNO+	190108-04-0052
FeNO+	190109-04-0053
FeNO+	190110-04-0055
FeNO+	190114-04-0059
FeNO+	190115-04-0060
FeNO+	190116-04-0061
FeNO+	190117-04-0062
FeNO+	190118-04-0036
FeNO+	190121-04-0069
FeNO+	190124-04-0075
FeNO+	190128-04-0076
FeNO+	190204-04-0082
FeNO+	190205-04-0083
FeNO+	190221-04-0106
FeNO+	190222-04-0107
FeNO+	190306-04-0119
FeNO+	190311-04-0123
FeNO+	190312-04-0128
FeNO+	190319-04-0138
FeNO+	190324-04-0148
FeNO+	190328-04-0149
FeNO+	190412-04-0168
FeNO+	190516-04-0191
FeNO+	190603-04-0203
FeNO+	190605-04-0205
FeNO+	190606-04-0206
FeNO+	190607-04-0208
FeNO+	190618-04-0221