

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:

Description of the problem:

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+ | 160310-04-0135 |
| 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 |
| FeNO+ | 161007-04-0364 |



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| FeNO+ | 161010-04-0365 |
| FeNO+ | 161011-04-0370 |
| FeNO+ | 161012-04-0372 |
| FeNO+ | 161013-04-0373 |
| 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+ | 170327-04-0142 |
| FeNO+ | 170407-04-0136 |
| FeNO+ | 170412-04-0188 |
| 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+ | 170829-04-0410 |
| FeNO+ | 170911-04-0420 |
| 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+ | 180417-04-0198 |
| FeNO+ | 180502-04-0212 |
| FeNO+ | 180503-04-0213 |
| 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+ | 181203-04-0032 |
| FeNO+ | 181215-04-0044 |
| FeNO+ | 190102-04-0047 |
| 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 |