

24. Junij 2019

Varnostno opozorilo

Trgovsko ime izdelka, ki je predmet tega obvestila : FeNO+
FSCA- identifikator : FSCA NC 502
Vrsta ukrepa : *Korektivni ukrep*

Namenjeno: Vsem uporabnikom, uvoznikom in distributerjem Medisoft FeNO +

Podrobnosti o napravah na katere se obvestilo nanaša:

Vsi aparati FeNO+, proizvedeni po 1. februarju 2015, ki imajo vgrajeno MNO-LO NO elektrokemično celico. Prav tako predhodni aparati nadgrajeni s tem analizatorjem. Seznam serijskih števil naprav na katere se nanaša to obvestilo je na voljo na spodnji povezavi;

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

Opis težave:

Tveganja pregrevanja baterije, ki vzdržuje polarizacijo NO analizatorja, ni mogoče 100% izključiti. Verjetnost da pride do pregrevanja je zanemarljiva, vendar bo Medisoft vseeno zamenjal baterije, da se izogne kakršnemokoli tveganju. Seznam naprav na katere se obvestilo nanaša je priložen temu dokumentu.

Tehnična podrobnost:

Proizvajalec baterij preizkusi izdelek s polnjenjem s 3C (360mA) v 8 urah brez posledic požara ali eksplozije. Baterija v napravi FeNO je polnjena z 1,3333C (160mA) manj kot 2 uri, nato pa integrirano vezje prekine polnjenje, ko je baterija napolnjena do 96,5%, in ohrani polnilni tok 25 µA, dokler polnost baterije ne pade pod 66,5 %, ko se začne ponovno polnjenje s 160mA. Enak testni sistem, kjer so NO celice polarizirane pred testiranjem, se uporablja interno, ta sistem je neprekinjeno priključen 24 ur na dan in uporablja enako baterijo, brez poslabšanja, požara ali eksplozije.

Priporočeni ukrepi, ki jih mora izvesti uporabnik:

Konec delovnega dneva izklopite napravo, kot je navedeno v navodilih za uporabo.

Pošiljanje tega varnostnega opozorila:

To varnostno opozorilo bo vsem uporabnikom naprav v Franciji in Belgiji poslal Medisoft, za druge države pa bodo vsi distributerji FeNO +, ki so prodali naprave po februarju 2015, neposredno v stiku s postopkom in vsemi tehničnimi vidiki in načinom organizacije intervencije.

Prosimo, upoštevajte to opozorilo in posledično ukrepajte v primernem časovnem obdobju, da zagotovite učinkovitost popravnih ukrepov (če je primerno).

Medisoft načrtuje, da bo z potrebnimi ukrepi v tej zvezi zaključil do decembra 2019.

Kontakt odgovorne osebe:

Eric Dion. Vodja kakovosti, Medisoft S.A., eric.dion@medisoft.be , 0032 82 223020

Spodaj podpisani potrjuje, da je bila s tem obvestilom seznanjena pristojna agencija (Zaključni odstavek).

Eric Dion
Vodja kakovosti Medisoft S.A.



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Seznam naprav (razvrščenih po naraščajočem vrstnem redu)

Naprava	Serijska številka
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
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FeNO+	160610-04-0243
FeNO+	160616-04-0247
FeNO+	160617-04-0252
FeNO+	160620-04-0253
FeNO+	160621-04-0251
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FeNO+	160705-04-0277
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FeNO+	160902-04-0332
FeNO+	160914-04-0344
FeNO+	160915-04-0353
FeNO+	161004-04-0356
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FeNO+	161007-04-0364



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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
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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
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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+	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
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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
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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
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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
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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
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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
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FeNO+	180919-04-0330
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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
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FeNO+	190205-04-0083
FeNO+	190221-04-0106
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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