

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 34139

To: Chief of Anesthesia
Health Care Administrator/Risk Manager
Director of Biomedical/Clinical Engineering

RE: **Tec 6 Plus and Tec 800 series vaporizers can deliver reduced concentration of volatile anesthetic agent**

Safety Issue

GE HealthCare has recently become aware that, due to a manufacturing issue, certain Tec 6 Plus and Tec 800 series vaporizers can deliver less anesthetic agent than the vaporizer dial setting. If the vaporizer is not used in conjunction with an anesthetic agent monitor, this can result in insufficient anesthetic effect which could result in patient movement during surgery and/or intraoperative awareness.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer/User

You can continue to use the vaporizer in accordance with the instructions in the User Reference Manual (URM) and the actions described below:

1. Perform the Output Concentration Check described in **Appendix 1** for every impacted vaporizer (see Affected Product Details in this letter).
 - If a vaporizer passes the Output Concentration Check, you can continue to use that vaporizer. GE HealthCare recommends use of anesthetic agent monitoring during vaporizer use.
 - If a vaporizer fails the Output Concentration Check, you can continue to use that vaporizer with anesthetic agent monitoring until GE HealthCare corrects the vaporizer.
 - If a vaporizer fails the Output Concentration Check and anesthetic agent monitoring is **not** available, **remove the vaporizer from service**.
2. Please complete and return the attached Medical Device Notification Acknowledgement Response Form to ARC.FMI34139@gehealthcare.com
3. Please ensure all potential staff in your facility are made aware of this safety notification and the recommended actions.
4. Please retain this document for your records.

**Affected
Product Details**

Tec 6 Plus, Tec 820, and Tec 850 Vaporizers.
See **Appendix 2** for a list of affected serial numbers.

Product	Ref #	GTIN Number
Tec 6 Plus	1107-9601-000	00840682112536
	1107-9602-000	00840682112659
	1107-9603-000	00840682112574
	1107-9604-000	00840682112925
	1107-9610-000	00840682112864
	1107-9612-000	00840682113236
	1107-9616-000	00840682113069
	1107-9617-000	00840682112666
	2066835-001	00840682112857
	2069767-001	00840682112505
	2078800-001	00840682112512
	2091008-001	00840682112437
	2091009-001	00840682112802
	M1098876	00840682112710
	M1145610	00840682112765
	M1220023	00840682112789
	M1220854	00840682112826
	M1221495	00840682115902
M1233992	00840682112451	
Tec 820 ISO	1177-9820-ISO	00840682124744
Tec 820 SEV	1177-9820-SEV	00840682124720
Tec 850 ISO	1177-9850-ISO	00840682124751
Tec 850 SEV	1177-9850-SEV	00840682124737

Intended Use

The Tec 6 Plus Vaporizer adds desflurane inhalant anesthetic vapor to the medical gasses supplied to a patient. The Datex-Ohmeda vaporizer should be used in anesthesia systems equipped with a Selectatec® Series Manifold only. The North American Dräger Vaporizer should be used in anesthesia systems equipped with an exclusion manifold. Both variants of the Tec 6 Plus Vaporizer must be supplied with dry medical gas and be connected to a suitable AC power supply. The Tec 6 Plus Vaporizer is designed to meet UL 2601-1, EN 60601- 1 and IEC 601-2-13.

The Tec 820 and Tec 850 Vaporizers are designed for use in continuous flow techniques of inhalation anesthesia. They are available in isoflurane and sevoflurane. Each vaporizer is agent specific and is clearly labeled with the anesthetic agent for which it is designed. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed for use only with Selectatec Series Manifolds.

**Product
Correction**

All affected products will be corrected at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Scott Kelley
Chief Medical Officer
GE Healthcare

Appendix 1: Output Concentration Check

1. Connect the vaporizer to an anesthesia machine.
2. Make sure the vaporizer is at room temperature (approximately 21°C or 70°F).
3. Ensure the airway gas module has been calibrated prior to checking the vaporizer concentration.
4. Ensure a Low P leak check on the anesthesia machine being used has been performed and passed. (Refer to the corresponding anesthesia machine User's Reference Manual.)
5. Connect the gas sampling adaptor to the Inspiratory port of the breathing system.
6. Connect the inspiratory limb of a patient circuit to the other end of the gas sampling adaptor.
7. Connect the expiratory limb of the patient circuit to the expiratory port of the breathing system.
8. Ensure the wye of the patient circuit is occluded.
9. Ensure scavenging is functioning.
10. Ensure a manual ventilation bag is on the bag arm.
11. Place the breathing system in bag mode.
12. Set the APL Valve to ~ 10 cmH₂O.
13. Ensure that the vaporizer to be tested is locked on the manifold and filled with agent to approximately the half-full line. Note: If vaporizer is dry (first time fill), add anesthetic agent and wait for at least 45 minutes before performing the check.
14. Set the oxygen output of the anesthesia machine to a flow of 5 ± 0.5 L/min.
15. Set the vaporizer to the Dial Setting position as indicated in the table below for the vaporizer being tested.
16. Deliver small breaths by gently squeezing the manual bag.
17. After approximately 1 minute determine if the readings are within the specified Vol % tolerances as indicated below.
 - i. If the readings are within the tolerances, the vaporizer has PASSED the Output Concentration Check.
 - ii. If the readings are outside of the tolerances, the vaporizer has FAILED the Output Concentration Check.
18. Record the Serial Number of each vaporizer that failed the test in the Medical Device Notification Acknowledgement Response Form attached to this Urgent Medical Device Correction Letter.

	Acceptable Output Range per ISO 80601-2-13	
Tec 6 Plus (Desflurane) Dial Setting	Min Vol%	Max Vol%
6%	4.8	7.8

	Acceptable Output Range per ISO 80601-2-13	
Tec 820/850 (Isoflurane or Sevoflurane) Dial Setting	Min Vol%	Max Vol%
3%	2.4	3.9

Appendix 2: Tec 6 Plus and Tec 820/850 Vaporizer - Affected Serial Number List

TEC 6 PLUS AFFECTED SERIAL NUMBERS

AESB07001	AESC18001 through AESC18013	AESD07001 through AESD07013
AESB10007 through AESB10008	AESC19001 through AESC19016	AESD08001 through AESD08014
AESB11014	AESC20001 through AESC20010	AESD08016 through AESD08017
AESB23021	AESC21001 through AESC21035	AESD09003 through AESD09004
AESB24010	AESC22001 through AESC22018	AESD09006 through AESD09009
AESB33008	AESC22020	AESD09011 through AESD09018
AESB33013	AESC23001 through AESC23037	AESD10001 through AESD10002
AESB33026	AESC23039 through AESC23051	AESD10004 through AESD10010
AESB37011	AESC24001 through AESC24030	AESD10012 through AESD10021
AESB40007	AESC25001 through AESC25032	AESD11001 through AESD11016
AESB40017	AESC26001 through AESC26005	AESD12001 through AESD12028
AESB40023	AESC27001 through AESC27018	AESD13001 through AESD13034
AESB49025	AESC28001 through AESC28027	AESD14001 through AESD14021
AESC02001	AESC29001 through AESC29032	AESD15001 through AESD15003
AESC03005	AESC30001 through AESC30024	AESD15005 through AESD15017
AESC04023	AESC31001 through AESC31016	AESD16001 through AESD16004
AESC05025	AESC32001 through AESC32020	AESD16006 through AESD16013
AESC06026	AESC33001 through AESC33014	AESD16015 through AESD16019
AESC06034	AESC34001 through AESC34010	AESD17001 through AESD17008
AESC08003	AESC35001 through AESC35018	AESD18001 through AESD18011
AESC08006 through AESC08007	AESC36001 through AESC36007	AESD19002 through AESD19016
AESC08022	AESC36009	AESD20001 through AESD20032
AESC09010	AESC37001 through AESC37028	AESD21001 through AESD21033
AESC09018	AESC38001 through AESC38022	AESD22001 through AESD22032
AESC09024	AESC39001 through AESC39020	AESD23001 through AESD23026
AESC09033	AESC40001 through AESC40004	AESD24001 through AESD24008
AESC09037	AESC42001 through AESC42025	AESD24010 through AESD24022
AESC10003	AESC43001 through AESC43028	AESD25001
AESC10009	AESC44001 through AESC44020	AESD25004
AESC10011	AESC45001 through AESC45015	AESD25006 through AESD25022
AESC10013	AESC46001 through AESC46007	AESD26001 through AESD26006
AESC10017 through AESC10018	AESC46009 through AESC46022	AESD26008 through AESD26021
AESC10020	AESC47001 through AESC47016	AESD28001 through AESD28004
AESC10022	AESC48001 through AESC48030	AESD29001 through AESD29027
AESC10025 through AESC10026	AESC49001 through AESC49028	AESD30001 through AESD30037
AESC10029	AESC50001 through AESC50026	AESD31001 through AESD31007
AESC10032 through AESC10033	AESC51001 through AESC51011	AESD31009 through AESD31017
AESC11003 through AESC11025	AESD01001 through AESD01017	AESD31019
AESC13001 through AESC13026	AESD02001 through AESD02015	AESD31021 through AESD31038
AESC14001 through AESC14020	AESD03001 through AESD03019	AESD31040 through AESD31051
AESC15001 through AESC15022	AESD04001 through AESD04017	AESD32001 through AESD32006
AESC16001 through AESC16015	AESD05001 through AESD05012	AESD32010
AESC17001 through AESC17014	AESD06001 through AESD06014	AESD33002 through AESD33003
AESD33011	AESD37004 through AESD37021	AESD38019 through AESD38020

AESD33014 through AESD33024	AESD37023 through AESD37032	AESD39002
AESD34002 through AESD34009	AESD37035 through AESD37040	AESD39014
AESD34011 through AESD34018	AESD38001 through AESD38007	AESD39017
AESD36001 through AESD36010	AESD38009	AESD39021 through AESD39022
AESD37001 through AESD37002	AESD38017	AESY40038

TEC 820/850 ISOFLURANE AFFECTED SERIAL NUMBERS

SQAA01702	SQAC00534 through SQAC01510	SQAD01216 through SQAD01217
SQAC00240	SQAD00001 through SQAD00699	SQAD01219
SQAC00303	SQAD00701 through SQAD00823	SQAD01221 through SQAD01223
SQAC00454	SQAD00828 through SQAD01048	SQAD01225
SQAC00492 through SQAC00509	SQAD01051 through SQAD01184	SQAD01228 through SQAD01233
SQAC00511 through SQAC00515	SQAD01186 through SQAD01193	SQAD01235 through SQAD01241
SQAC00517 through SQAC00519	SQAD01195 through SQAD01204	SQAD01247
SQAC00521 through SQAC00522	SQAD01207 through SQAD01210	SQAD01257
SQAC00524 through SQAC00530	SQAD01213	

TEC 820/850 SEVOFLURANE AFFECTED SERIAL NUMBERS

SQBB05615	SQBC00922	SQBC01108 through SQBC01109
SQBB05655	SQBC00924	SQBC01111 through SQBC01112
SQBB05948	SQBC00930	SQBC01114 through SQBC01115
SQBB05960	SQBC00949	SQBC01117
SQBB06409	SQBC00970	SQBC01119 through SQBC01121
SQBC00401	SQBC00980	SQBC01129
SQBC00456	SQBC00984	SQBC01135 through SQBC01138
SQBC00465	SQBC00997 through SQBC01001	SQBC01148 through SQBC01149
SQBC00493	SQBC01004	SQBC01156 through SQBC01157
SQBC00508	SQBC01009	SQBC01159 through SQBC01170
SQBC00514	SQBC01019	SQBC01172
SQBC00553	SQBC01021	SQBC01178 through SQBC01179
SQBC00566	SQBC01024	SQBC01181 through SQBC01182
SQBC00596	SQBC01030 through SQBC01031	SQBC01187 through SQBC01190
SQBC00608	SQBC01033	SQBC01193 through SQBC01195
SQBC00619	SQBC01037	SQBC01197 through SQBC01199
SQBC00622 through SQBC00623	SQBC01040 through SQBC01043	SQBC01203
SQBC00644	SQBC01045	SQBC01206
SQBC00657	SQBC01049	SQBC01209
SQBC00659	SQBC01061	SQBC01214 through SQBC01215
SQBC00787	SQBC01074	SQBC01217
SQBC00804	SQBC01077	SQBC01224
SQBC00843	SQBC01088	SQBC01227
SQBC00848	SQBC01095	SQBC01229 through SQBC01232
SQBC00886	SQBC01101	SQBC01234 through SQBC01244
SQBC00901	SQBC01105 through SQBC01106	SQBC01246 through SQBC01249
SQBC01251 through SQBC01255	SQBD01978 through SQBD02315	SQBD02878 through SQBD02903

SQBC01257 through SQBC01277	SQBD02317 through SQBD02422	SQBD02905 through SQBD02906
SQBC01279 through SQBC01281	SQBD02424 through SQBD02425	SQBD02908 through SQBD02924
SQBC01283	SQBD02427 through SQBD02429	SQBD02926 through SQBD02928
SQBC01286 through SQBC01288	SQBD02431 through SQBD02439	SQBD02930 through SQBD02935
SQBC01290 through SQBC01296	SQBD02441 through SQBD02442	SQBD02937 through SQBD02941
SQBC01298 through SQBC01299	SQBD02444 through SQBD02445	SQBD02943 through SQBD02956
SQBC01303 through SQBC01308	SQBD02448 through SQBD02450	SQBD02958 through SQBD03259
SQBC01310	SQBD02452	SQBD03278 through SQBD03285
SQBC01312	SQBD02454 through SQBD02455	SQBD03287 through SQBD03297
SQBC01316	SQBD02457 through SQBD02462	SQBD03299 through SQBD03362
SQBC01320 through SQBC01323	SQBD02464 through SQBD02469	SQBD03364 through SQBD03403
SQBC01325 through SQBC01336	SQBD02471	SQBD03405 through SQBD03477
SQBC01338 through SQBC01345	SQBD02473 through SQBD02477	SQBD03479 through SQBD03542
SQBC01347 through SQBC01354	SQBD02479	SQBD03544 through SQBD03586
SQBC01358 through SQBC01361	SQBD02481 through SQBD02490	SQBD03588 through SQBD03589
SQBC01364 through SQBC01604	SQBD02492 through SQBD02493	SQBD03591 through SQBD03649
SQBC01606 through SQBC01650	SQBD02495 through SQBD02502	SQBD03651 through SQBD03686
SQBC01652 through SQBC01655	SQBD02504 through SQBD02550	SQBD03688 through SQBD03724
SQBC01658 through SQBC02379	SQBD02552 through SQBD02577	SQBD03726 through SQBD03816
SQBC02582 through SQBC02607	SQBD02579 through SQBD02584	SQBD03818 through SQBD03820
SQBC02609 through SQBC02721	SQBD02586 through SQBD02621	SQBD03822 through SQBD03824
SQBC02723 through SQBC03488	SQBD02623	SQBD03826 through SQBD03827
SQBC03490 through SQBC03562	SQBD02625	SQBD03830 through SQBD03842
SQBC03564 through SQBC03567	SQBD02627	SQBD03844 through SQBD03885
SQBC03569 through SQBC03593	SQBD02629 through SQBD02657	SQBD03887 through SQBD03943
SQBC03595 through SQBC03600	SQBD02659 through SQBD02663	SQBD03945 through SQBD03990
SQBC03602 through SQBC03642	SQBD02665 through SQBD02676	SQBD03992 through SQBD03997
SQBC03644 through SQBC03646	SQBD02679 through SQBD02683	SQBD03999 through SQBD04000
SQBC03648 through SQBC04414	SQBD02686	SQBD04002 through SQBD04005
SQBC04435 through SQBC05470	SQBD02688	SQBD04007
SQBC05473	SQBD02690 through SQBD02694	SQBD04009 through SQBD04014
SQBC05475 through SQBC05484	SQBD02696 through SQBD02700	SQBD04016 through SQBD04067
SQBC05488	SQBD02703 through SQBD02716	SQBD04069 through SQBD04075
SQBC05491	SQBD02718 through SQBD02752	SQBD04077 through SQBD04094
SQBC05495 through SQBC05496	SQBD02754 through SQBD02781	SQBD04097 through SQBD04099
SQBC05498 through SQBC05500	SQBD02783 through SQBD02785	SQBD04101 through SQBD04136
SQBC05502 through SQBC05505	SQBD02787 through SQBD02809	SQBD04138 through SQBD04165
SQBC05508 through SQBC05815	SQBD02811 through SQBD02822	SQBD04167 through SQBD04179
SQBD00001 through SQBD00983	SQBD02824 through SQBD02854	SQBD04181 through SQBD04198
SQBD01004 through SQBD01976	SQBD02856 through SQBD02863	SQBD04215 through SQBD04234
SQBD04200 through SQBD04213	SQBD02865 through SQBD02876	SQBD04236 through SQBD04248

SQBD04250	SQBD04632	SQBD04904
SQBD04254	SQBD04634 through SQBD04636	SQBD04906 through SQBD04909
SQBD04256 through SQBD04272	SQBD04638 through SQBD04644	SQBD04911
SQBD04274 through SQBD04285	SQBD04646 through SQBD04651	SQBD04913
SQBD04287 through SQBD04295	SQBD04655 through SQBD04656	SQBD04915
SQBD04297 through SQBD04304	SQBD04658	SQBD04918 through SQBD04921
SQBD04306 through SQBD04320	SQBD04664	SQBD04926 through SQBD04928
SQBD04322 through SQBD04331	SQBD04666	SQBD04930 through SQBD04934
SQBD04333 through SQBD04383	SQBD04668	SQBD04937 through SQBD04957
SQBD04385 through SQBD04396	SQBD04672 through SQBD04674	SQBD04959 through SQBD04970
SQBD04398 through SQBD04404	SQBD04676 through SQBD04678	SQBD04972 through SQBD04978
SQBD04407 through SQBD04408	SQBD04680 through SQBD04683	SQBD04980 through SQBD04985
SQBD04410 through SQBD04414	SQBD04685 through SQBD04687	SQBD04987 through SQBD04988
SQBD04416 through SQBD04477	SQBD04689	SQBD04990 through SQBD05001
SQBD04479 through SQBD04490	SQBD04694 through SQBD04698	SQBD05003
SQBD04492 through SQBD04497	SQBD04702 through SQBD04703	SQBD05005 through SQBD05007
SQBD04499	SQBD04707 through SQBD04713	SQBD05009 through SQBD05011
SQBD04501	SQBD04717 through SQBD04718	SQBD05013 through SQBD05024
SQBD04503	SQBD04720 through SQBD04726	SQBD05026 through SQBD05041
SQBD04505 through SQBD04506	SQBD04729 through SQBD04732	SQBD05044 through SQBD05047
SQBD04508	SQBD04735 through SQBD04736	SQBD05049
SQBD04511	SQBD04738 through SQBD04747	SQBD05051
SQBD04513 through SQBD04516	SQBD04751	SQBD05053 through SQBD05056
SQBD04518 through SQBD04519	SQBD04753 through SQBD04764	SQBD05059 through SQBD05078
SQBD04521 through SQBD04523	SQBD04769 through SQBD04773	SQBD05081 through SQBD05107
SQBD04525 through SQBD04526	SQBD04775 through SQBD04776	SQBD05109 through SQBD05118
SQBD04528 through SQBD04533	SQBD04778 through SQBD04786	SQBD05120 through SQBD05131
SQBD04535	SQBD04790 through SQBD04792	SQBD05133 through SQBD05148
SQBD04540 through SQBD04542	SQBD04794 through SQBD04796	SQBD05151
SQBD04544 through SQBD04545	SQBD04798 through SQBD04799	SQBD05153 through SQBD05154
SQBD04547	SQBD04804 through SQBD04805	SQBD05160
SQBD04550 through SQBD04551	SQBD04808	SQBD05162 through SQBD05163
SQBD04553	SQBD04811	SQBD05169 through SQBD05171
SQBD04559 through SQBD04560	SQBD04815	SQBD05173
SQBD04562 through SQBD04563	SQBD04817	SQBD05176
SQBD04565 through SQBD04571	SQBD04820 through SQBD04823	SQBD05181
SQBD04573 through SQBD04578	SQBD04826	SQBD05183
SQBD04581 through SQBD04585	SQBD04828	SQBD05185 through SQBD05186
SQBD04588 through SQBD04596	SQBD04830	SQBD05195 through SQBD05196
SQBD04598 through SQBD04607	SQBD04832	SQBD05199
SQBD04609	SQBD04834 through SQBD04838	SQBD05202 through SQBD05204
SQBD04611 through SQBD04616	SQBD04841	SQBD05206
SQBD04618 through SQBD04619	SQBD04885	SQBD05209
SQBD04621 through SQBD04623	SQBD04889 through SQBD04891	SQBD05214
SQBD04625 through SQBD04627	SQBD04894	SQBD05216
SQBD04629 through SQBD04630	SQBD04896 through SQBD04901	

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

We acknowledge receipt and understanding of the Urgent Medical Device Correction Notice. We've checked all the vaporizers within scope of this action, those with serial numbers (SN) listed below **failed** and require replacement. All other vaporizers passed.

List affected vaporizer SN's			

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: ARC.FMI34139@gehealthcare.com.

