



URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Depolyment>

GEHC Ref #34066

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

Affected product: **imtmedical AG, EVair Compressor** (an optional accessory to GE Healthcare Engstrom Carestation, Engstrom Pro, and CARESCAPE R860 ventilators)

Dear Customer,

This letter is to notify you that the manufacturer of the EVair Compressor, imtmedical AG, is conducting a field corrective action involving the imtmedical AG, EVair Compressor, which is an optional accessory to GE Healthcare Engstrom Carestation, Engstrom Pro, and CARESCAPE R860 ventilators. GE Healthcare is implementing the field corrective action as to these affected GE Healthcare ventilators.

A copy of the imtmedical AG notice is included in this mailing. Please review the imtmedical AG notice carefully as it provides greater detail of the issue, including information on how to identify whether your device is affected. If you have any questions regarding this field correction or the identification of an affected EVair Compressor, please contact GE Healthcare Service or your local Service Representative.

Toll Free number: LCS: 8004292222 SaudiArabiaServiceCenter@ge.com

Please ensure that all potential users and supervisors at your facility are made aware of this correction notice immediately. If you have transferred this device to another location, please forward a copy of this notice to them and notify GE Healthcare of the device's new location as soon as possible.

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

We apologize for any inconvenience this action may have caused and thank you for your continued cooperation and support.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Date of Letter Deployment: June 25, 2015

imtmedical Reference no. 2015_1

imtmedical AG
 Regulatory Affairs Department
 Gewerbestrasse 8
 9470 Buchs
 Switzerland

To: GE Healthcare
Attn: Chad Melotte, Supplier Quality Lead Engineer

RE: Important **customer safety notice** regarding the field corrective action of EVair compressors used as optional accessory to GE Healthcare ventilators

imtmedical has recently become aware of a potential safety issue due to potential hardware failures associated with the EVair accessory compressors for the Engström Carestation, Engström Pro, and CARESCAPE R860 ventilators. **Please ensure that all potential users are made aware of this safety notification and the recommended actions.**

Safety Issue imtmedical has identified that potential friction of cables and tubing internal to the EVair compressor may result in an inability for the compressor to output compressed air. There is a potential for temporary oversupply of oxygen to the patient as a result of this failure because the GE Healthcare ventilators are designed ventilate with 100% oxygen in the case of loss of input air supply pressure. **There are no reports of patient or user injury related to this issue.**

Safety Instructions You can continue to use EVair compressors with GE Healthcare ventilators. If a compressor exhibits a failure resulting in a low air supply pressure alarm on the ventilator, use of the compressor should be discontinued. Repair will be required.

Affected Product Details EVair compressors (M1230847, M1230849) that were provided to GE Healthcare by imtmedical prior to May 30, 2015 may be affected by this issue. See the serial number list provided in the appendix for a full list of affected devices.

Product Correction imtmedical will provide GE Healthcare with field correction kits (REF 302.810.000) to GE Healthcare. GE Healthcare will contact all affected customers, and correct all affected systems.

Contact Information For questions or concerns regarding this notification, please contact imtmedical at sales@imtmedical.com.

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

Sincerely,

Hans-Jörg Reinhold
 Regulatory Affairs Manager
 imtmedical AG




imtmedical ag
 Gewerbestr. 8 · CH-9470 Buchs SG
 Tel. +41 81 750 66 99 · Fax +41 81 750 66 95

Date of Letter Deployment: June 25, 2015

imtmedical Reference no. 2015_1

Appendix

Part A

REF

M1230849

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
1.	10013	2.	10236	3.	10467	4.	10713
5.	10014	6.	10237	7.	10468	8.	10714
9.	10015	10.	10238	11.	10469	12.	10715
13.	10016	14.	10239	15.	10470	16.	10716
17.	10017	18.	10240	19.	10471	20.	10717
21.	10018	22.	10241	23.	10472	24.	10718
25.	10019	26.	10242	27.	10473	28.	10719
29.	10020	30.	10243	31.	10474	32.	10720
33.	10021	34.	10244	35.	10475	36.	10721
37.	10022	38.	10245	39.	10476	40.	10722
41.	10023	42.	10278	43.	10477	44.	10723
45.	10024	46.	10279	47.	10478	48.	10724
49.	10025	50.	10280	51.	10479	52.	10725
53.	10026	54.	10281	55.	10480	56.	10726
57.	10027	58.	10282	59.	10481	60.	10727
61.	10028	62.	10283	63.	10482	64.	10728
65.	10029	66.	10284	67.	10483	68.	10729
69.	10030	70.	10285	71.	10484	72.	10730
73.	10031	74.	10286	75.	10485	76.	10731
77.	10032	78.	10287	79.	10486	80.	10732

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
81.	10033	82.	10288	83.	10487	84.	10733
85.	10034	86.	10289	87.	10488	88.	10734
89.	10035	90.	10290	91.	10489	92.	10735
93.	10036	94.	10291	95.	10490	96.	10736
97.	10051	98.	10292	99.	10491	100.	10737
101.	10052	102.	10293	103.	10492	104.	10738
105.	10053	106.	10294	107.	10493	108.	10739
109.	10054	110.	10295	111.	10494	112.	10740
113.	10055	114.	10296	115.	10495	116.	10741
117.	10056	118.	10297	119.	10496	120.	10742
121.	10057	122.	10298	123.	10497	124.	10743
125.	10058	126.	10299	127.	10498	128.	10744
129.	10059	130.	10300	131.	10499	132.	10745
133.	10060	134.	10301	135.	10500	136.	10746
137.	10061	138.	10302	139.	10501	140.	10747
141.	10062	142.	10303	143.	10506	144.	10748
145.	10063	146.	10304	147.	10507	148.	10749
149.	10064	150.	10305	151.	10508	152.	10750
153.	10065	154.	10306	155.	10509	156.	10751
157.	10066	158.	10307	159.	10510	160.	10752
161.	10067	162.	10308	163.	10511	164.	10753

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
165.	10068	166.	10309	167.	10512	168.	10754
169.	10069	170.	10310	171.	10513	172.	10755
173.	10070	174.	10311	175.	10514	176.	10756
177.	10071	178.	10312	179.	10515	180.	10757
181.	10072	182.	10313	183.	10516	184.	10758
185.	10073	186.	10314	187.	10517	188.	10759
189.	10074	190.	10315	191.	10518	192.	10760
193.	10075	194.	10316	195.	10519	196.	10761
197.	10076	198.	10317	199.	10520	200.	10762
201.	10077	202.	10318	203.	10521	204.	10763
205.	10078	206.	10319	207.	10522	208.	10764
209.	10079	210.	10320	211.	10523	212.	10765
213.	10080	214.	10321	215.	10524	216.	10766
217.	10081	218.	10322	219.	10525	220.	10767
221.	10082	222.	10323	223.	10526	224.	10768
225.	10083	226.	10324	227.	10527	228.	10769
229.	10084	230.	10325	231.	10528	232.	10770
233.	10085	234.	10326	235.	10529	236.	10771
237.	10086	238.	10327	239.	10530	240.	10772
241.	10087	242.	10328	243.	10531	244.	10773
245.	10088	246.	10329	247.	10532	248.	10774

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
249.	10089	250.	10330	251.	10533	252.	10775
253.	10090	254.	10331	255.	10534	256.	10776
257.	10091	258.	10332	259.	10535	260.	10777
261.	10092	262.	10333	263.	10536	264.	10778
265.	10093	266.	10334	267.	10537	268.	10779
269.	10094	270.	10335	271.	10538	272.	10780
273.	10095	274.	10336	275.	10539	276.	10781
277.	10101	278.	10337	279.	10540	280.	10782
281.	10102	282.	10338	283.	10541	284.	10783
285.	10103	286.	10339	287.	10542	288.	10784
289.	10104	290.	10340	291.	10543	292.	10785
293.	10105	294.	10341	295.	10544	296.	10786
297.	10106	298.	10342	299.	10545	300.	10787
301.	10107	302.	10343	303.	10546	304.	10788
305.	10108	306.	10344	307.	10547	308.	10789
309.	10109	310.	10345	311.	10548	312.	10790
313.	10110	314.	10346	315.	10549	316.	10791
317.	10111	318.	10347	319.	10550	320.	10792
321.	10112	322.	10348	323.	10551	324.	10793
325.	10113	326.	10349	327.	10552	328.	10794
329.	10114	330.	10350	331.	10553	332.	10795

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
333.	10115	334.	10351	335.	10554	336.	10796
337.	10116	338.	10352	339.	10555	340.	10797
341.	10117	342.	10353	343.	10556	344.	10798
345.	10118	346.	10354	347.	10557	348.	10799
349.	10119	350.	10355	351.	10558	352.	10800
353.	10120	354.	10356	355.	10559	356.	10801
357.	10126	358.	10357	359.	10560	360.	10802
361.	10127	362.	10358	363.	10561	364.	10803
365.	10128	366.	10359	367.	10562	368.	10804
369.	10129	370.	10360	371.	10563	372.	10805
373.	10130	374.	10361	375.	10564	376.	10806
377.	10131	378.	10362	379.	10565	380.	10807
381.	10132	382.	10363	383.	10566	384.	10808
385.	10133	386.	10364	387.	10567	388.	10809
389.	10134	390.	10365	391.	10568	392.	10810
393.	10135	394.	10366	395.	10569	396.	10811
397.	10136	398.	10367	399.	10570	400.	10812
401.	10137	402.	10368	403.	10571	404.	10813
405.	10138	406.	10369	407.	10572	408.	10814
409.	10139	410.	10370	411.	10573	412.	10815
413.	10140	414.	10371	415.	10574	416.	10816

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
417.	10141	418.	10372	419.	10575	420.	10817
421.	10142	422.	10373	423.	10576	424.	10818
425.	10143	426.	10374	427.	10577	428.	10819
429.	10144	430.	10375	431.	10578	432.	10820
433.	10145	434.	10376	435.	10579	436.	10821
437.	10146	438.	10377	439.	10580	440.	10822
441.	10147	442.	10378	443.	10581	444.	10823
445.	10148	446.	10379	447.	10582	448.	10824
449.	10149	450.	10380	451.	10583	452.	10825
453.	10150	454.	10381	455.	10584	456.	10826
457.	10151	458.	10382	459.	10585	460.	10827
461.	10152	462.	10383	463.	10586	464.	10828
465.	10153	466.	10384	467.	10587	468.	10829
469.	10154	470.	10385	471.	10588	472.	10830
473.	10155	474.	10386	475.	10589	476.	10831
477.	10156	478.	10387	479.	10590	480.	10832
481.	10157	482.	10388	483.	10591	484.	10833
485.	10158	486.	10389	487.	10592	488.	10834
489.	10159	490.	10390	491.	10593	492.	10835
493.	10160	494.	10391	495.	10594	496.	10836
497.	10161	498.	10392	499.	10595	500.	10837

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
501.	10162	502.	10393	503.	10596	504.	10838
505.	10163	506.	10394	507.	10597	508.	10839
509.	10164	510.	10395	511.	10598	512.	10840
513.	10165	514.	10396	515.	10599	516.	10841
517.	10166	518.	10397	519.	10600	520.	10842
521.	10167	522.	10398	523.	10601	524.	10843
525.	10168	526.	10399	527.	10602	528.	10844
529.	10169	530.	10399	531.	10603	532.	10845
533.	10170	534.	10400	535.	10604	536.	10846
537.	10171	538.	10400	539.	10605	540.	10847
541.	10172	542.	10401	543.	10606	544.	10848
545.	10173	546.	10402	547.	10607	548.	10849
549.	10174	550.	10403	551.	10608	552.	10850
553.	10175	554.	10404	555.	10609	556.	10851
557.	10176	558.	10405	559.	10610	560.	10852
561.	10177	562.	10406	563.	10611	564.	10853
565.	10178	566.	10407	567.	10612	568.	10854
569.	10179	570.	10408	571.	10613	572.	10855
573.	10180	574.	10409	575.	10614	576.	10856
577.	10181	578.	10410	579.	10615	580.	10857
581.	10182	582.	10411	583.	10616	584.	10858

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
585.	10183	586.	10412	587.	10617	588.	10859
589.	10184	590.	10413	591.	10618	592.	10860
593.	10185	594.	10414	595.	10619	596.	10861
597.	10186	598.	10415	599.	10620	600.	10862
601.	10187	602.	10416	603.	10621	604.	10863
605.	10188	606.	10417	607.	10622	608.	10864
609.	10189	610.	10418	611.	10623	612.	10865
613.	10190	614.	10419	615.	10624	616.	10866
617.	10191	618.	10420	619.	10625	620.	10867
621.	10192	622.	10421	623.	10626	624.	10868
625.	10193	626.	10422	627.	10627	628.	10869
629.	10194	630.	10423	631.	10628	632.	10870
633.	10195	634.	10424	635.	10629	636.	10871
637.	10196	638.	10425	639.	10630	640.	10872
641.	10197	642.	10426	643.	10631	644.	10873
645.	10198	646.	10427	647.	10632	648.	10874
649.	10199	650.	10428	651.	10633	652.	10875
653.	10200	654.	10429	655.	10634	656.	10876
657.	10201	658.	10430	659.	10635	660.	10877
661.	10202	662.	10431	663.	10636	664.	10878
665.	10203	666.	10432	667.	10637	668.	10879

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
669.	10204	670.	10433	671.	10638	672.	10880
673.	10205	674.	10434	675.	10639	676.	10881
677.	10206	678.	10435	679.	10640	680.	10882
681.	10207	682.	10436	683.	10641	684.	10883
685.	10208	686.	10438	687.	10642	688.	10884
689.	10209	690.	10439	691.	10643	692.	10885
693.	10210	694.	10440	695.	10644	696.	10886
697.	10211	698.	10441	699.	10645	700.	10887
701.	10212	702.	10442	703.	10646	704.	10888
705.	10213	706.	10443	707.	10647	708.	10889
709.	10214	710.	10444	711.	10648	712.	10890
713.	10215	714.	10445	715.	10649	716.	10891
717.	10216	718.	10446	719.	10674	720.	10892
721.	10217	722.	10447	723.	10675	724.	10893
725.	10218	726.	10448	727.	10676	728.	10894
729.	10219	730.	10449	731.	10677	732.	10895
733.	10220	734.	10450	735.	10678	736.	10896
737.	10221	738.	10451	739.	10679	740.	10897
741.	10222	742.	10452	743.	10680	744.	10898
745.	10223	746.	10453	747.	10681	748.	10899
749.	10224	750.	10454	751.	10682	752.	10900

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
753.	10225	754.	10455	755.	10683	756.	10901
757.	10225	758.	10456	759.	10684	760.	10902
761.	10226	762.	10457	763.	10685	764.	10903
765.	10227	766.	10458	767.	10686	768.	10904
769.	10228	770.	10459	771.	10687	772.	10905
773.	10229	774.	10460	775.	10688	776.	10906
777.	10230	778.	10461	779.	10689	780.	10907
781.	10231	782.	10462	783.	10690	784.	10908
785.	10232	786.	10463	787.	10701	788.	10909
789.	10233	790.	10464	791.	10710	792.	10910
793.	10234	794.	10465	795.	10711	796.	10911
797.	10235	798.	10466	799.	10712	800.	10912
801.	10913	802.	10959	803.	11005	804.	11051
805.	10914	806.	10960	807.	11006	808.	11052
809.	10915	810.	10961	811.	11007	812.	11053
813.	10916	814.	10962	815.	11008	816.	11054
817.	10917	818.	10963	819.	11009	820.	11055
821.	10918	822.	10964	823.	11010	824.	11056
825.	10919	826.	10965	827.	11011	828.	11057
829.	10920	830.	10966	831.	11012	832.	11058
833.	10921	834.	10967	835.	11013	836.	11059

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
837.	10922	838.	10968	839.	11014	840.	11060
841.	10923	842.	10969	843.	11015	844.	11061
845.	10924	846.	10970	847.	11016	848.	11062
849.	10925	850.	10971	851.	11017	852.	11063
853.	10926	854.	10972	855.	11018	856.	11064
857.	10927	858.	10973	859.	11019	860.	11073
861.	10928	862.	10974	863.	11020	864.	11074
865.	10929	866.	10975	867.	11021	868.	11075
869.	10930	870.	10976	871.	11022	872.	11076
873.	10931	874.	10977	875.	11023	876.	11077
877.	10932	878.	10978	879.	11024	880.	11078
881.	10933	882.	10979	883.	11025	884.	11079
885.	10934	886.	10980	887.	11026	888.	11080
889.	10935	890.	10981	891.	11027	892.	11097
893.	10936	894.	10982	895.	11028	896.	11098
897.	10953	898.	10983	899.	11029	900.	11099
901.	10954	902.	10984	903.	11030	904.	11100
905.	10955	906.	11001	907.	11031	908.	11101
909.	10956	910.	11002	911.	11032	912.	11102
913.	10957	914.	11003	915.	11049	916.	11103
917.	10958	918.	11004	919.	11050	920.	11104

Part B
REF
M1230847

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
1.	10012	2.	10262	3.	10665	4.	10951
5.	10037	6.	10263	7.	10666	8.	10952
9.	10038	10.	10264	11.	10667	12.	11081
13.	10039	14.	10265	15.	10668	16.	11082
17.	10040	18.	10266	19.	10669	20.	11083
21.	10041	22.	10267	23.	10670	24.	11084
25.	10096	26.	10268	27.	10671	28.	11085
29.	10097	30.	10269	31.	10672	32.	11086
33.	10098	34.	10270	35.	10673	36.	11087
37.	10099	38.	10271	39.	10702	40.	11088
41.	10100	42.	10272	43.	10703	44.	11089
45.	10121	46.	10273	47.	10704	48.	11090
49.	10122	50.	10274	51.	10705	52.	11091
53.	10123	54.	10275	55.	10706	56.	11092
57.	10124	58.	10276	59.	10707	60.	11093
61.	10125	62.	10277	63.	10708	64.	11094
65.	10246	66.	10650	67.	10709	68.	11095
69.	10247	70.	10651	71.	10937	72.	11096
73.	10248	74.	10652	75.	10938	76.	11113
77.	10249	78.	10653	79.	10939	80.	11114

Consecutive no.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE	Cont.	SN Prefix: GE
81.	10250	82.	10654	83.	10940	84.	11115
85.	10251	86.	10655	87.	10941	88.	11116
89.	10252	90.	10656	91.	10942	92.	11117
93.	10253	94.	10657	95.	10943	96.	11118
97.	10254	98.	10658	99.	10944	100.	11119
101.	10255	102.	10659	103.	10945	104.	11120
105.	10256	106.	10660	107.	10946	108.	11121
109.	10257	110.	10661	111.	10947	112.	11122
113.	10258	114.	10662	115.	10948	116.	11123
117.	10259	118.	10663	119.	10949	120.	11124
121.	10260	122.	10664	123.	10950	124.	11125
125.	10691	126.	10692	127.	10693	128.	10694
129.	10695	130.	10696	131.	10697	132.	10698
133.	10261						