

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. #32102

To: Healthcare Administrator / Risk Manager
Director of Neonatology/L and D/Nurse Manager
Director of Biomedical Engineering

RE: **Giraffe and Panda Warmers with Integrated Resuscitation System (iRes) and Giraffe Stand-alone Infant Resuscitation Systems**

Safety Issue

GE HealthCare has become aware of a potential issue involving the air-oxygen blender knob shaft on certain integrated and stand-alone Resuscitation systems. In some cases, the blender knob shaft can loosen, which can affect the delivered oxygen concentration. If this occurs, the system can deliver an oxygen concentration that does not match the intended concentration set by the user, potentially resulting in hypoxia or hyperoxia in the patient.

Actions to be taken by Customer/User

1. Inspect all of your Giraffe, Panda Warmers with Integrated Resuscitation System (iRes), and Giraffe Stand-alone Infant Resuscitation System devices following the instructions in Appendix 1 to determine if the device has an affected blender listed in Appendix 2.
2. If the device has an affected blender listed in Appendix 2, remove the unit from patient use and contact a GE HealthCare Service Representative at the number listed below.
3. If a device with an affected blender must be used prior to being corrected by GE HealthCare, follow the instructions below:
 - A. Follow the instructions in the Panda Warmer and/or Giraffe Warmer User Manuals, including all pre-use checkout instructions (M1110737 and M1110734 Chapter 8 Pre-use checkout and setup procedures) and the Giraffe™ Stand-alone Infant Resuscitation System User Manual (M1226780 Chapters 4 and 5 Checkout and Use). These manuals also include the following requirements and warnings:
 - Pre-use checkout: Before each operation, inspect the resuscitation system for damage, such as broken knobs and fittings or gauges with indicator needles that are not at 0.
 - Do not do the pre-use checkout procedure, service, or calibrate the device with the patient in the device. Make sure all pre-use checkout procedure steps are correctly completed before each patient use. If a step fails, do not use the device.
 - B. Perform the blender Multipoint Oxygen Concentration Check as described in Section 2.5.1 of the Service Manual M1128929.

- C. If the pre-use checkout passes and the Multipoint Oxygen Concentration Check meets specifications, GE HealthCare recommends oxygen concentration should be verified with an independent oxygen analyzer on a frequent basis until the unit is corrected.
- D. If the pre-use check does not pass (e.g., the blender knob is loose) or the Multipoint Oxygen Concentration Check does not meet specifications, remove the unit from patient use.

Note: User and service manuals are available on the Customer Documentation Portal:
<https://www.gehealthcare.com/support/manuals>.

- 4. Please evaluate existing service stock for affected blenders. The blender model number and serial number are visible on the packaging. The serial number is visible on the blender. Quarantine any blenders with model number M1091607-R if the serial number is listed in Appendix 2.
- 5. Please complete and return the attached Acknowledgement Form electronically via FMI 32102 Digital CRF or print, fill out manually, scan, and email to FMI.32102@gehealthcare.com.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Affected Product Details

Below listed products are impacted only if M1091607-R blender was installed during the last Preventive Maintenance. No action is required for units where an M1091607-X or M1091607 was used during last Preventive Maintenance. See the affected blender serial number list in Appendix 2.

Product	Ref#	GTIN Number
Giraffe™ Stand-alone Infant Resuscitation System	2082663-001 2082663-002 M1241424*	00840682100151 00840682100175
Giraffe™ Warmer with Integrated Resuscitation System (iRes)	M1118179	00840682103923
Panda Warmer with Integrated Resuscitation System (iRes)	M1112198	V2.0 (Hybrid) 00840682152716 V1.0 (US) 00840682152709
Panda Freestanding warmer	2063568-001	00840682103916
Service Blender Includes Standoffs and Knob	M1091607-R	NA

*NOTE: Some products were shipped prior to the implementation of UDI and may not contain a Global Trade Item Number (GTIN)

Intended Use:

The Integrated Resuscitation and Standalone Infant Resuscitation Systems provides the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes

practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures during manual ventilation to the infant. These are clinical practices that represent the established standard of care. Resuscitation may be required whenever an infant fails to establish effective, adequate breathing patterns necessary to meet tissue oxygen demands and/or to rid the body of carbon dioxide.

Product Correction

GE HealthCare will correct all affected products 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.

Service Centre UK - Patient Care Solutions :

Phone : 0800 387 377

Email : askuktechnicalsupport@gehealthcare.com

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

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare



Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

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: _____

No affected serial numbers were identified at this Facility

Affected Serial Numbers:

Blender Serial Number	Serial # of the Giraffe and Panda Warmers with Integrated Resuscitation System (iRes) and or Giraffe Stand-alone Infant Resuscitation Systems

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

To complete this form electronically, please scan the QR Code below or click this link:

<https://gehealthcare-svc.my.site.com/publicForm/s/?formId=aGjUr000003ARbV>



To complete this form via email, scan or take a photo of the completed form and email to:

MIC.FMI32102@gehealthcare.com



Appendix 1: Blender Identification Procedure

To determine if you have an affected blender serial number, remove the back panel of the resuscitation system. The serial number will be visible on the back of the blender. Review Appendix 2 to confirm if the serial number is listed as an affected blender. Record the information as required in the Medical Device Notification Acknowledgement Form.

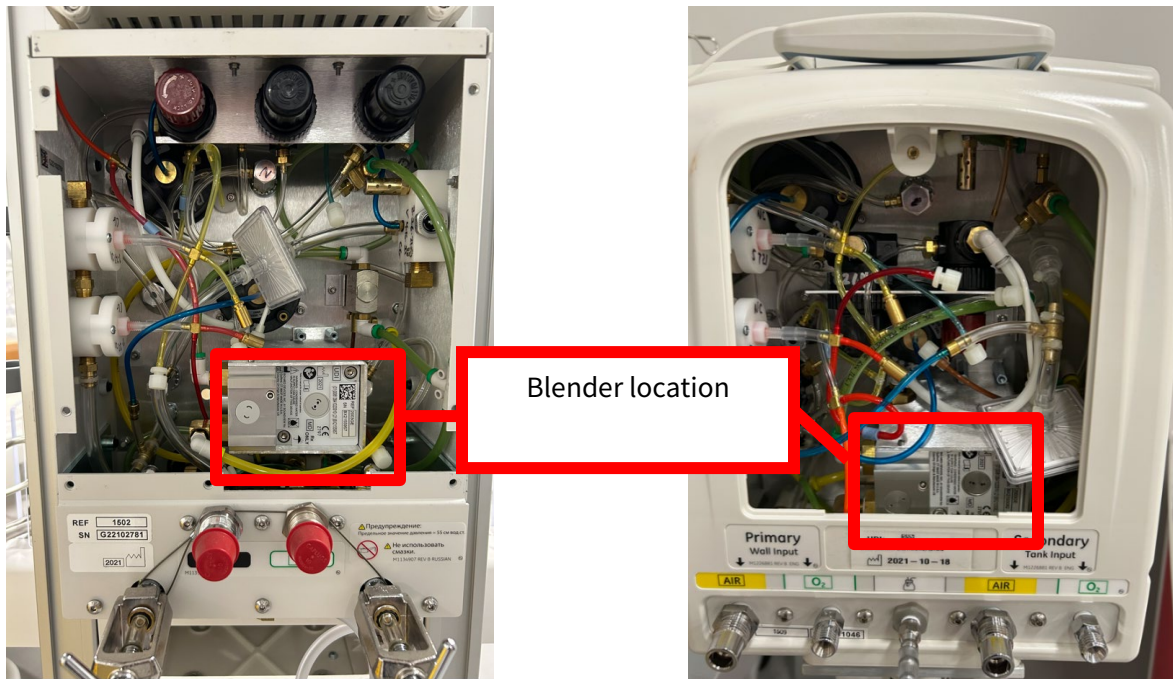


Figure 1: Giraffe™ and Panda Warmer with Integrated Resuscitation System / Giraffe™ Stand-alone Infant Resuscitation System with the back panel removed.

Figure 2: Giraffe™ Stand-alone Infant Resuscitation System with the back panel removed.

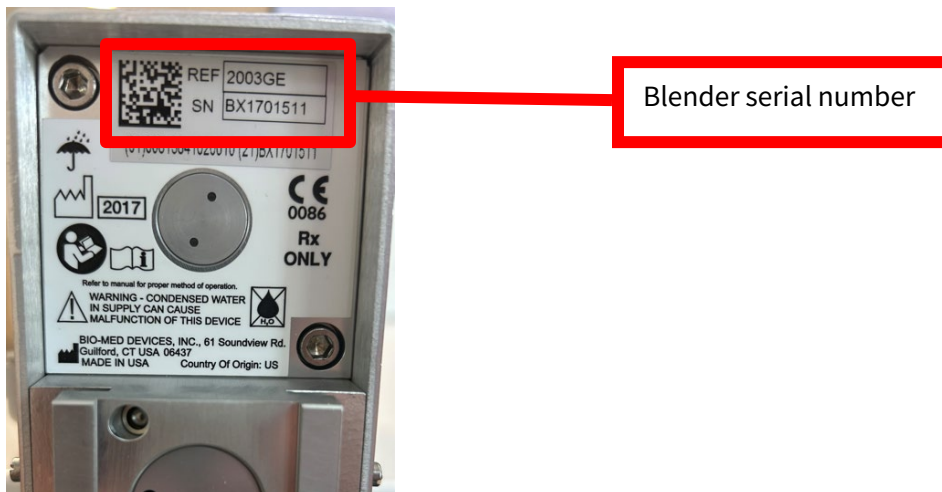


Figure 3: Picture of the location of the blender serial number.

Appendix 2: Affected Blender Serial Number List

Note: Blenders with serials numbers not in this list are not affected.

12105790	136W08B	355P09B	B1102015	B1202740	B1208736
7979700385	141J09B	B1003093	B1102405	B1203408	B1208739
002I08B	142W09B	B1003112	B1102571	B1203414	B1208759
002X08B	144J08B	B1003124	B1103145	B1203520	B1209463
008S10B	144N08B	B1003140	B1103159	B1203557	B1209467
008Y09B	149Q09B	B1003143	B1103251	B1203643	B1209641
013S09B	163608B	B1003147	B1103256	B1203892	B1209642
016A09B	169D08B	B1003153	B1103422	B1203905	B1209647
019J09B	169G08B	B1003343	B1103434	B1203909	B1209796
037E08B	169H08B	B1003452	B1103576	B1203913	B1209956
038D10B	172308B	B1003550	B1103710	B1203917	B1211743
038N08B	175P08B	B1003867	B1103850	B1204710	B1211784
042F10B	185I08B	B1003944	B1103856	B1205518	B1211907
042S10B	185Q08B	B1004844	B1103968	B1205537	B1212670
042T10B	189808B	B1004861	B1104440	B1205804	B1212683
045808B	189A09B	B1005029	B1104441	B1205820	B1212706
047I08B	189C08B	B1005036	B1104450	B1206201	B1212817
047J08B	189F09B	B1005422	B1104651	B1206909	B1300102
054C10B	193L08B	B1005534	B1104658	B1206948	B1300110
054I10B	193N08B	B1005560	B1104764	B1207178	B1300126
054L10B	195D09B	B1005571	B1105179	B1207180	B1300416
054N09B	195E09B	B1005839	B1105180	B1207181	B1300430
054O09B	195J09B	B1006102	B1105232	B1207189	B1300805
054U10B	195K09B	B1006304	B1105244	B1207201	B1300812
055D09B	198H08B	B1006935	B1105418	B1207202	B1300830
055V09B	210U09B	B1007078	B1105548	B1207215	B1300858
061K09B	218N09B	B1007220	B1105806	B1207240	B1300919
068W10B	219C09B	B1007262	B1106117	B1207308	B1302107
077M09B	219K09B	B1007383	B1106789	B1207555	B1302132
078M09B	220E08B	B1007528	B1106812	B1208045	B1302133
078S09B	226F08B	B1007605	B1106823	B1208066	B1302180
084I10B	244L09B	B1101215	B1107074	B1208067	B1302527
084J10B	260X09B	B1101224	B1107357	B1208068	B1302583
092G08B	266M08B	B1101241	B1107360	B1208069	B1302593
099F08B	267808B	B1101445	B1107581	B1208102	B1302945
100E08B	280F09B	B1101446	B1107658	B1208104	B1302983
100R08B	281H09B	B1101862	B1201361	B1208141	B1303084
104A09B	285J07B	B1101869	B1201601	B1208296	B1303098
133D08B	295J09B	B1101998	B1202187	B1208702	B1303453
136708B	338K07B	B1102011	B1202199	B1208729	B1303454
B1303492	B1310237	B1404760	B1408533	B1503611	B1505842
B1303581	B1400022	B1404786	B1409022	B1503644	B1505843

B1303854	B1400237	B1404925	B1409048	B1503665	B1505879
B1303868	B1400243	B1404981	B1409051	B1503667	B1505884
B1304069	B1400264	B1405020	B1409052	B1503673	B1505899
B1304357	B1400278	B1405213	B1409053	B1503687	B1505954
B1304374	B1400292	B1405218	B1409324	B1503698	B1505981
B1304450	B1400760	B1405542	B1409509	B1504073	B1505990
B1304518	B1400771	B1405558	B1409533	B1504076	B1505992
B1304564	B1400946	B1405574	B1409546	B1504078	B1505994
B1304570	B1401757	B1405576	B1409569	B1504339	B1505997
B1304574	B1401785	B1405577	B1409588	B1504538	B1506198
B1304751	B1401893	B1405589	B1409590	B1504754	B1506203
B1305163	B1402142	B1405601	B1409722	B1504755	B1506208
B1305175	B1402162	B1405608	B1409731	B1504761	B1506209
B1305213	B1402168	B1405621	B1501314	B1504765	B1506215
B1305215	B1402196	B1405622	B1501652	B1504800	B1506216
B1305337	B1402198	B1405629	B1501657	B1504919	B1506220
B1305363	B1402224	B1405630	B1501675	B1504951	B1506237
B1305523	B1402504	B1405649	B1501686	B1504999	B1506240
B1306066	B1402854	B1405688	B1501693	B1505000	BX1101219
B1306068	B1403053	B1405909	B1502040	B1505085	BX1501179
B1306078	B1403079	B1405998	B1502054	B1505090	BX1501323
B1306902	B1403128	B1406104	B1502157	B1505091	BX1501350
B1307502	B1403140	B1406186	B1502195	B1505093	BX1501429
B1307514	B1403155	B1406190	B1502200	B1505096	BX1501514
B1307526	B1403230	B1406191	B1502616	B1505301	BX1501668
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BX1601518	BX1602925	BX1605701	BX1702874	BX1705061	BX1801608
BX1601519	BX1602932	BX1605835	BX1702894	BX1705155	BX1801610
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BX1601523	BX1602935	BX1606148	BX1703023	BX1705376	BX1801663
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BX1602195	BX1603377	BX1701666	BX1703703	BX1705920	BX1802902
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BX1803153	BX1804372	BX1806187	BX1902137	BX1903411	BX1904812
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BX1803316	BX1804548	BX1806636	BX1902235	BX1903525	BX1905103
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BX1803334	BX1804655	BX1901149	BX1902300	BX1903624	BX1905112
BX1803346	BX1804660	BX1901170	BX1902302	BX1903650	BX1905116
BX1803352	BX1804761	BX1901173	BX1902426	BX1903688	BX1905124
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BX1803368	BX1804870	BX1901178	BX1902475	BX1903819	BX1905155
BX1803369	BX1804950	BX1901206	BX1902557	BX1903845	BX1905168
BX1803371	BX1804960	BX1901227	BX1902562	BX1903851	BX1905174
BX1803373	BX1805024	BX1901229	BX1902572	BX1903875	BX1905175
BX1803381	BX1805032	BX1901233	BX1902576	BX1903878	BX1905176
BX1803440	BX1805035	BX1901254	BX1902579	BX1903947	BX1905220
BX1803517	BX1805142	BX1901299	BX1902605	BX1903952	BX1905238
BX1803518	BX1805259	BX1901323	BX1902679	BX1903971	BX1905245
BX1803635	BX1805260	BX1901429	BX1902692	BX1903982	BX1905247
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BX1803690	BX1805404	BX1901614	BX1902749	BX1904081	BX1905253
BX1803709	BX1805411	BX1901719	BX1902809	BX1904093	BX1905254
BX1803741	BX1805418	BX1901881	BX1902828	BX1904124	BX1905258
BX1803759	BX1805423	BX1901889	BX1902847	BX1904148	BX1905308
BX1803769	BX1805445	BX1901892	BX1902874	BX1904170	BX1905313
BX1803771	BX1805449	BX1901901	BX1902907	BX1904224	BX1905390
BX1803837	BX1805486	BX1901938	BX1902933	BX1904255	BX1905449
BX1803839	BX1805487	BX1901960	BX1902941	BX1904290	BX1905497
BX1803840	BX1805648	BX1901969	BX1902960	BX1904302	BX1905553
BX1803845	BX1805701	BX1901978	BX1902989	BX1904355	BX1905589
BX1905733	BX2001513	BX2002267	BX2003019	BX2004024	BX2004388
BX1905859	BX2001520	BX2002268	BX2003042	BX2004030	BX2004413
BX1905866	BX2001528	BX2002282	BX2003067	BX2004031	BX2004426
BX1905954	BX2001617	BX2002286	BX2003140	BX2004032	BX2004443
BX1905976	BX2001620	BX2002290	BX2003151	BX2004043	BX2004454

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