



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188 USA

May 27, 2022

GEHC Ref. # 34128

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

RE: **Avance CS², Avance CS² Pro, and Aisys CS² Anesthesia Systems base can have a crack which can fracture if excessive load is applied, resulting in a tip or overbalance of the anesthesia device**

This document contains important information for your product. 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.

Safety Issue

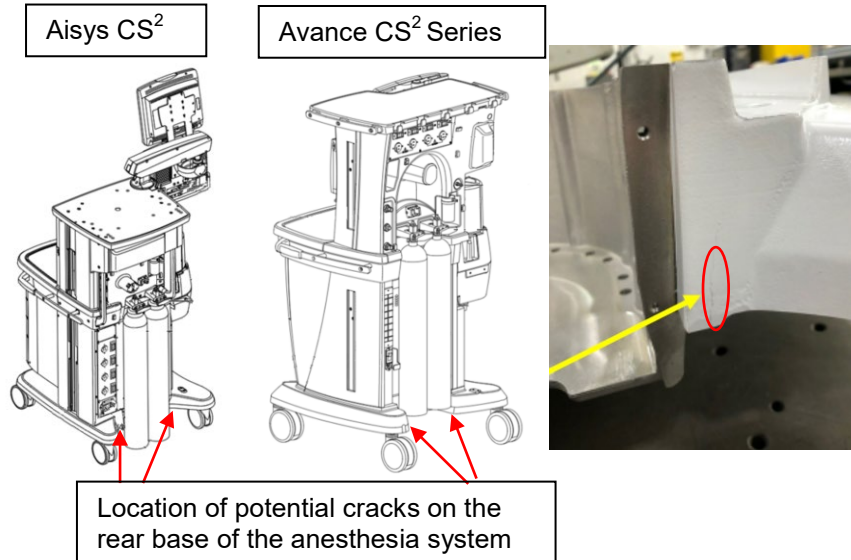
Avance CS², Avance CS² Pro, and Aisys CS² Anesthesia Systems base can have a crack in a specific location in the rear of the anesthesia system. If excessive load is applied to the anesthesia device (for example when the device is being moved over a threshold), a cracked base could potentially fracture, resulting in a tip or overbalance of the anesthesia system, which can result in potential injury if it falls on a person.

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

Actions to be taken by Customer / User

You can continue to use your anesthesia system by following the below instructions prior to use:

- 1) Inspect the anesthesia system for cracks at the rear of the base as shown in the pictures below.



- 2) If no cracks are observed, you can continue to use your anesthesia system.
- 3) If you observe a crack at the rear of your anesthesia system as shown in the picture above, contact your GE Healthcare Service Representative.

You can continue to use your system under the following conditions:

- Limit the movement of your system. If the anesthesia system is required to be moved, use care on uneven flooring/threshold and ensure the floor is clear of obstacles (cables, power cords, etc.).
 - Do not exceed the recommended weight limit for equipment mounted or supported by the anesthesia system.
- 4) Complete the attached Medical Device Notification Acknowledgement Response form and send to: FMI34128.BASECRACKS@ge.com

**Affected
Product
Details**

Avance CS² and Avance CS² Pro Anesthesia Systems:
P/N:1009-9050-000 - GTIN: 00840682102322
Aisys CS² Anesthesia Systems:
P/N: 1011-9050-000 – GTIN: 00840682102292
See attached Appendix for a list of affected systems.

Intended Use:

The GE Datex-Ohmeda Anesthesia Systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

**Product
Correction**

GE Healthcare will inspect and correct if required 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 at 1-800-437-1171 or your local Service Representative.

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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



GE Healthcare

GEHC Ref. # 34128

**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.

*Customer/Consignee

Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

Please complete the requested information and send back via one of the methods below.

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff 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: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: FMI34128.BASECRACKS@ge.com



APPENDIX Affected Avance CS² and Avance CS² Pro Anesthesia Systems

APKA00600	APKA01237	APKA01325	APKA01370	APKA01414	APKA01456	APKA01500	APKA01568
APKA00601	APKA01238	APKA01326	APKA01371	APKA01415	APKA01457	APKA01501	APKZ00267
APKA00602	APKA01239	APKA01327	APKA01372	APKA01416	APKA01458	APKA01504	APKZ00524
APKA00789	APKA01240	APKA01328	APKA01373	APKA01417	APKA01459	APKA01505	APKZ02234
APKA00790	APKA01241	APKA01329	APKA01374	APKA01418	APKA01460	APKA01506	
APKA00795	APKA01242	APKA01330	APKA01375	APKA01419	APKA01461	APKA01507	
APKA00796	APKA01243	APKA01331	APKA01376	APKA01420	APKA01462	APKA01508	
APKA00797	APKA01244	APKA01332	APKA01377	APKA01421	APKA01463	APKA01509	
APKA00864	APKA01245	APKA01333	APKA01378	APKA01422	APKA01464	APKA01510	
APKA00867	APKA01246	APKA01334	APKA01379	APKA01423	APKA01465	APKA01511	
APKA00868	APKA01247	APKA01335	APKA01380	APKA01424	APKA01466	APKA01512	
APKA00869	APKA01248	APKA01336	APKA01381	APKA01425	APKA01467	APKA01525	
APKA00945	APKA01249	APKA01337	APKA01382	APKA01426	APKA01469	APKA01537	
APKA00993	APKA01250	APKA01338	APKA01383	APKA01427	APKA01470	APKA01538	
APKA01055	APKA01251	APKA01339	APKA01384	APKA01428	APKA01471	APKA01539	
APKA01056	APKA01252	APKA01340	APKA01385	APKA01429	APKA01472	APKA01540	
APKA01057	APKA01253	APKA01341	APKA01386	APKA01430	APKA01473	APKA01541	
APKA01112	APKA01254	APKA01342	APKA01389	APKA01431	APKA01474	APKA01543	
APKA01113	APKA01255	APKA01343	APKA01390	APKA01432	APKA01475	APKA01544	
APKA01114	APKA01256	APKA01344	APKA01391	APKA01433	APKA01476	APKA01545	
APKA01124	APKA01257	APKA01345	APKA01392	APKA01434	APKA01477	APKA01546	
APKA01125	APKA01258	APKA01346	APKA01393	APKA01435	APKA01478	APKA01547	
APKA01126	APKA01288	APKA01347	APKA01394	APKA01436	APKA01479	APKA01548	
APKA01127	APKA01289	APKA01348	APKA01395	APKA01437	APKA01480	APKA01549	
APKA01128	APKA01290	APKA01349	APKA01396	APKA01438	APKA01481	APKA01550	
APKA01129	APKA01291	APKA01352	APKA01397	APKA01439	APKA01482	APKA01551	
APKA01130	APKA01292	APKA01353	APKA01398	APKA01440	APKA01483	APKA01552	
APKA01131	APKA01293	APKA01355	APKA01399	APKA01441	APKA01484	APKA01553	
APKA01132	APKA01298	APKA01356	APKA01400	APKA01442	APKA01485	APKA01554	
APKA01133	APKA01299	APKA01357	APKA01401	APKA01443	APKA01486	APKA01555	
APKA01139	APKA01300	APKA01358	APKA01402	APKA01444	APKA01487	APKA01556	
APKA01140	APKA01301	APKA01359	APKA01403	APKA01445	APKA01488	APKA01557	
APKA01141	APKA01302	APKA01360	APKA01404	APKA01446	APKA01489	APKA01558	
APKA01203	APKA01303	APKA01361	APKA01405	APKA01447	APKA01490	APKA01559	
APKA01204	APKA01304	APKA01362	APKA01406	APKA01448	APKA01491	APKA01560	
APKA01205	APKA01318	APKA01363	APKA01407	APKA01449	APKA01492	APKA01561	
APKA01208	APKA01319	APKA01364	APKA01408	APKA01450	APKA01493	APKA01562	
APKA01210	APKA01320	APKA01365	APKA01409	APKA01451	APKA01494	APKA01563	
APKA01211	APKA01321	APKA01366	APKA01410	APKA01452	APKA01495	APKA01564	
APKA01228	APKA01322	APKA01367	APKA01411	APKA01453	APKA01496	APKA01565	
APKA01229	APKA01323	APKA01368	APKA01412	APKA01454	APKA01498	APKA01566	
APKA01230	APKA01324	APKA01369	APKA01413	APKA01455	APKA01499	APKA01567	

Aisys CS² Anesthesia Systems

APWA00734	APWA01413	APWA01552	APWA01634	APWA01676	APWA01720	APWA01768	APWA01813
APWA00735	APWA01414	APWA01553	APWA01635	APWA01677	APWA01721	APWA01769	APWA01818
APWA00736	APWA01415	APWA01554	APWA01636	APWA01678	APWA01722	APWA01770	APWA01819
APWA00737	APWA01443	APWA01555	APWA01637	APWA01679	APWA01723	APWA01771	APWA01820
APWA00738	APWA01444	APWA01556	APWA01638	APWA01680	APWA01724	APWA01772	APWA01821
APWA00739	APWA01445	APWA01557	APWA01639	APWA01681	APWA01725	APWA01773	APWA01822
APWA00740	APWA01447	APWA01567	APWA01640	APWA01682	APWA01726	APWA01774	APWA01823
APWA01111	APWA01487	APWA01568	APWA01641	APWA01685	APWA01727	APWA01775	APWA01824
APWA01112	APWA01488	APWA01569	APWA01642	APWA01686	APWA01728	APWA01776	APWA01825
APWA01113	APWA01491	APWA01570	APWA01643	APWA01687	APWA01729	APWA01777	APWA01826
APWA01114	APWA01492	APWA01591	APWA01644	APWA01688	APWA01730	APWA01778	APWA01827
APWA01115	APWA01493	APWA01592	APWA01645	APWA01689	APWA01731	APWA01779	APWA01828
APWA01116	APWA01508	APWA01593	APWA01646	APWA01690	APWA01732	APWA01780	APWA01829
APWA01133	APWA01509	APWA01594	APWA01647	APWA01691	APWA01733	APWA01781	APWA01830
APWA01162	APWA01510	APWA01602	APWA01648	APWA01692	APWA01734	APWA01782	APWA01831
APWA01163	APWA01514	APWA01603	APWA01649	APWA01693	APWA01735	APWA01784	APWA01832
APWA01197	APWA01515	APWA01605	APWA01650	APWA01694	APWA01736	APWA01785	APWA01833
APWA01198	APWA01516	APWA01609	APWA01651	APWA01695	APWA01737	APWA01786	APWA01834
APWA01199	APWA01517	APWA01610	APWA01652	APWA01696	APWA01738	APWA01787	APWA01835
APWA01200	APWA01518	APWA01611	APWA01653	APWA01697	APWA01739	APWA01788	APWA01836
APWA01201	APWA01519	APWA01612	APWA01654	APWA01698	APWA01740	APWA01789	APWA01837
APWA01202	APWA01520	APWA01613	APWA01655	APWA01699	APWA01741	APWA01790	APWA01838
APWA01203	APWA01521	APWA01614	APWA01656	APWA01700	APWA01742	APWA01791	APWA01839
APWA01204	APWA01522	APWA01615	APWA01657	APWA01701	APWA01743	APWA01792	APWA01840
APWA01207	APWA01523	APWA01616	APWA01658	APWA01702	APWA01744	APWA01793	APWA01841
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APWA01215	APWA01525	APWA01618	APWA01660	APWA01704	APWA01746	APWA01795	APWA01843
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