

Urgent Field Safety Notice

Commercial name/Model: BeneHeart C Series

FSCA-identifier: CP2403-JH04564

Type of action: Software upgrade

2024-06-14.

Attention: [Hospital/Distributor Name]

Dear Sir or Madam,

Through the continuous monitoring of products distributed by Mindray, we have become aware of a potential issue that may be associated with certain devices of the BeneHeart C Series Automated External Defibrillator. This letter is intended to provide you with information as follows:

Details on affected devices:

The affected serial numbers (SN) of the BeneHeart C Series Automated External Defibrillator can be identified from the label. The serial numbers of the affected devices are listed **in appendix 1**.

Description of the problem:

Mindray has identified the affected BeneHeart C Series Automated External Defibrillator might not provide required patient defibrillation therapy. The reason for this failure is due to incorrect function configurations.

To date, Mindray has not received any report of serious incidents such as death or serious injury due to the above issue.

Advise on action to be taken by the CUSTOMER / USER:

1. Please pass the Field Safety Notice (FSN) to all those who need to be aware within your organization or to any organization where the affected BeneHeart C Series Automated External Defibrillators have been delivered.
2. After you receive this Field Safety Notice, please confirm that if you have any BeneHeart C Series Automated External Defibrillators on the affected list, please discontinue use of the device and contact us. Mindray service team will repair the problem as soon as possible.
3. Return the Field Safety Notice Acknowledgement Form to Mindray confirming that the Field Safety Notice has been read and understood.

Advise on action to be taken by the distributor:

1. Please pass the Field Safety Notice (FSN) to all those who need to be aware within your organization or to any organization where the affected BeneHeart C Series Automated External Defibrillators have been delivered.
2. If your organisation has any BeneHeart C Series Automated External Defibrillators on the affected list, please do not sell or install these devices to your customers. Mindray's service team will contact you as soon as possible to provide software and upgrade instructions. If you have any questions regarding the software upgrade process, please contact our local Mindray service team.
3. Return the Field Safety Notice Acknowledgement Form to Mindray confirming that the Field Safety Notice has been read and understood.

Transmission of this Field Safety Notice:

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

Contact reference person:

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your local Mindray Customer Service Engineer or designated Technical Support Engineer – [hilfe](#).

Contact: [hilfe](#), *National Service Manager- Germany*
E-Mail: hilfe@mindray.de

This Notice has been notified the appropriate Regulatory Agency.

Signature:

Emily Zhao

Representative of PMS Quality Center

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South, High-tech Industrial Park,
Nanshan, Shenzhen 518057, P.R. China
Tel: 0086 755 81887277
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Commercial name/Model: BeneHeart C Series

FSCA-identifier: CP2403-JH04564

Type of action: Software upgrade

Please fill in this form and return this confirmation by E-mail or Fax immediately.

Contact: [hilfe](#), *National Service Manager- Germany*

E-Mail: hilfe@mindray.de

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

Appendix list

No	Commercial Name	Serial Number of products	No	Commercial Name	Serial Number of products
1	BeneHeart C2	AE7-29069443	28	BeneHeart C1A Fully	AF3-14001356
2	BeneHeart C2	AE7-2A069538	29	BeneHeart C1A Fully	AF3-1B003515
3	BeneHeart C2	AE7-34076099	30	BeneHeart C1A Fully	AF3-22004845
4	BeneHeart C2	AE7-34076157	31	BeneHeart C1A Fully	AF3-22004862
5	BeneHeart C2	AE7-34076176	32	BeneHeart C1A Fully	AF3-22005091
6	BeneHeart C2A Fully	AE9-19001284	33	BeneHeart C1A Fully	AF3-24007798
7	BeneHeart C2A Fully	AE9-19001303	34	BeneHeart C1A Fully	AF3-25008962
8	BeneHeart C2A Fully	AE9-19001349	35	BeneHeart C1A Fully	AF3-28013354
9	BeneHeart C2A Fully	AE9-26003872	36	BeneHeart C1A Fully	AF3-28014583
10	BeneHeart C2A Fully	AE9-27004355	37	BeneHeart C1A Fully	AF3-28015156
11	BeneHeart C2A Fully	AE9-28004515	38	BeneHeart C2	AE7-18021585
12	BeneHeart C2A Fully	AE9-2B005292	39	BeneHeart C2	AE7-18021601
13	BeneHeart C2A Fully	AE9-2B005369	40	BeneHeart C2	AE7-19023185
14	BeneHeart C1A	AF1-19018070	41	BeneHeart C2	AE7-19023193
15	BeneHeart C1A	AF1-21027151	42	BeneHeart C2	AE7-19023195
16	BeneHeart C1A	AF1-21027159	43	BeneHeart C2	AE7-19023210
17	BeneHeart C1A	AF1-21027166	44	BeneHeart C2	AE7-19023219
18	BeneHeart C1A	AF1-22028173	45	BeneHeart C2	AE7-19023247
19	BeneHeart C1A	AF1-22028185	46	BeneHeart C2	AE7-19023262
20	BeneHeart C1A	AF1-22028243	47	BeneHeart C2	AE7-19023267
21	BeneHeart C1A	AF1-22028244	48	BeneHeart C2	AE7-19023270
22	BeneHeart C1A	AF1-22028827	49	BeneHeart C2	AE7-19023271
23	BeneHeart C1A	AF1-34066627	50	BeneHeart C2	AE7-19023273
24	BeneHeart C1A	AF1-34066716	51	BeneHeart C2	AE7-26052443
25	BeneHeart C1A	AF1-36069497	52	BeneHeart C2	AE7-26053131
26	BeneHeart C1A Fully	AF3-14001328	53	BeneHeart C2	AE7-28063554
27	BeneHeart C1A Fully	AF3-14001339	54	BeneHeart C2	AE7-29068041

55	BeneHeart C2	AE7-2B070667	96	BeneHeart C1A	AF1-24035180T
56	BeneHeart C2	AE7-2B070672	97	BeneHeart C1A	AF1-24035268T
57	BeneHeart C2	AE7-2B070694	98	BeneHeart C1A	AF1-24035276T
58	BeneHeart C2	AE7-2B070701	99	BeneHeart C1A	AF1-24035295T
59	BeneHeart C2	AE7-32075075	100	BeneHeart C1A	AF1-24035321T
60	BeneHeart C2	AE7-32075078	101	BeneHeart C1A	AF1-24035333T
61	BeneHeart C2	AE7-32075082	102	BeneHeart C1A	AF1-24035341T
62	BeneHeart C2	AE7-34076042	103	BeneHeart C1A	AF1-26044772
63	BeneHeart C2A Fully	AE9-19001339	104	BeneHeart C1A	AF1-26046784
64	BeneHeart C2A Fully	AE9-19001346	105	BeneHeart C1A	AF1-28056411T
65	BeneHeart C2A Fully	AE9-19001360	106	BeneHeart C1A	AF1-28056457T
66	BeneHeart C2A Fully	AE9-19001372	107	BeneHeart C1A	AF1-28056471T
67	BeneHeart C1A	AF1-13012400	108	BeneHeart C1A	AF1-28056472T
68	BeneHeart C1A	AF1-13012417	109	BeneHeart C1A	AF1-28056485T
69	BeneHeart C1A	AF1-19019623	110	BeneHeart C1A	AF1-28056500T
70	BeneHeart C1A	AF1-19019642	111	BeneHeart C1A	AF1-28056516T
71	BeneHeart C1A	AF1-19019644	112	BeneHeart C1A	AF1-28056531T
72	BeneHeart C1A	AF1-19019653	113	BeneHeart C1A	AF1-28056533T
73	BeneHeart C1A	AF1-19019688	114	BeneHeart C1A	AF1-28056543T
74	BeneHeart C1A	AF1-19019692	115	BeneHeart C1A	AF1-28056544T
75	BeneHeart C1A	AF1-19019708	116	BeneHeart C1A	AF1-28056553T
76	BeneHeart C1A	AF1-19019722	117	BeneHeart C1A	AF1-28056557T
77	BeneHeart C1A	AF1-19019745	118	BeneHeart C1A	AF1-28056574T
78	BeneHeart C1A	AF1-19019747	119	BeneHeart C1A	AF1-28056594T
79	BeneHeart C1A	AF1-1A022998	120	BeneHeart C1A	AF1-29058775T
80	BeneHeart C1A	AF1-1B024744T	121	BeneHeart C1A	AF1-29058795T
81	BeneHeart C1A	AF1-1B024745T	122	BeneHeart C1A	AF1-29058797T
82	BeneHeart C1A	AF1-1B024756T	123	BeneHeart C1A	AF1-29058843T
83	BeneHeart C1A	AF1-1B024763T	124	BeneHeart C1A	AF1-29058876T
84	BeneHeart C1A	AF1-1B024767T	125	BeneHeart C1A	AF1-29058880T
85	BeneHeart C1A	AF1-1B024773T	126	BeneHeart C1A	AF1-29058883T
86	BeneHeart C1A	AF1-1B024803T	127	BeneHeart C1A	AF1-29058889T
87	BeneHeart C1A	AF1-1B024807T	128	BeneHeart C1A	AF1-29058893T
88	BeneHeart C1A	AF1-1B024811T	129	BeneHeart C1A	AF1-29058911T
89	BeneHeart C1A	AF1-1B024816T	130	BeneHeart C1A	AF1-29058932T
90	BeneHeart C1A	AF1-1B025462	131	BeneHeart C1A	AF1-29058944T
91	BeneHeart C1A	AF1-21027737	132	BeneHeart C1A	AF1-29058967T
92	BeneHeart C1A	AF1-21027764	133	BeneHeart C1A	AF1-29058984T
93	BeneHeart C1A	AF1-21027766	134	BeneHeart C1A	AF1-29058994T
94	BeneHeart C1A	AF1-21027770	135	BeneHeart C1A	AF1-29058996T
95	BeneHeart C1A	AF1-21027777	136	BeneHeart C1A	AF1-29058998T

137	BeneHeart C1A	AF1-29059011T	166	BeneHeart C1A	AF1-36069519
138	BeneHeart C1A	AF1-29059038T	167	BeneHeart C1A	AF1-36069558
139	BeneHeart C1A	AF1-34066618	168	BeneHeart C1A	AF1-36069573
140	BeneHeart C1A	AF1-34066643	169	BeneHeart C1A	AF1-36069589
141	BeneHeart C1A	AF1-35067166T	170	BeneHeart C1A	AF1-36069593
142	BeneHeart C1A	AF1-35067170T	171	BeneHeart C1A	AF1-36069597
143	BeneHeart C1A	AF1-35067178T	172	BeneHeart C1A	AF1-36070807
144	BeneHeart C1A	AF1-35067197T	173	BeneHeart C1A Fully	AF3-15001649
145	BeneHeart C1A	AF1-35067236T	174	BeneHeart C1A Fully	AF3-15001682
146	BeneHeart C1A	AF1-35067241T	175	BeneHeart C1A Fully	AF3-15001734
147	BeneHeart C1A	AF1-35067247T	176	BeneHeart C1A Fully	AF3-1B003510
148	BeneHeart C1A	AF1-35067269T	177	BeneHeart C1A Fully	AF3-24007697
153	BeneHeart C1A	AF1-35067332T	178	BeneHeart C1A Fully	AF3-24007698
154	BeneHeart C1A	AF1-35067333T	179	BeneHeart C1A Fully	AF3-24007738
155	BeneHeart C1A	AF1-35067347T	180	BeneHeart C1A Fully	AF3-28015439
156	BeneHeart C1A	AF1-35067361T	181	BeneHeart C1A Fully	AF3-28015445
157	BeneHeart C1A	AF1-35067369T	182	BeneHeart C1A Fully	AF3-28015474
158	BeneHeart C1A	AF1-35067450T	183	BeneHeart C1A Fully	AF3-28015475
159	BeneHeart C1A	AF1-35067454T	184	BeneHeart C1A Fully	AF3-34021514
160	BeneHeart C1A	AF1-36069034	185	BeneHeart C1A Fully	AF3-34021519
161	BeneHeart C1A	AF1-36069147	186	BeneHeart C1A Fully	AF3-34021562
162	BeneHeart C1A	AF1-36069209	187	BeneHeart C1A Fully	AF3-36024119
163	BeneHeart C1A	AF1-36069489	188	BeneHeart C1A	AF1-26044692
164	BeneHeart C1A	AF1-36069494	189	BeneHeart C1A	AF1-34066714
165	BeneHeart C1A	AF1-36069496	190	BeneHeart C1A	AF1-35067162