stryker

URGENT:
Field Safety Notice: RA2023-3211897

LIFEPAK CR2 Defibrillator

Attn:

Recall Number: RA2023-3211897

January 2023

Product affected*

Catalog Numbers		Product	Part Numbers		Distribution Dates
99512-000112	99512-000397	**LPCR2**	CR2-2-000126	CR2-2-000411	**10/04/2022 – 10/14/2022**
99512-000371	99512-000398		CR2-2-000385	CR2-2-000412	
99512-000372	99512-000399		CR2-2-000386	CR2-2-000413	
99512-000374	99512-000484		CR2-2-000388	CR2-2-000498	
99512-000387	99512-000485		CR2-2-000401	CR2-2-000499	
99512-000388	99512-000490		CR2-2-000402	CR2-2-000504	
99512-000390	99512-000514		CR2-2-000404	CR2-2-000529	
99512-000395	99512-000961		CR2-2-000409	CR2-2-000980	
	99512-001459			CR2-2-001476	

Please see Appendix A for list of affected serial numbers.

Product description The LIFEPAK CR2 defibrillator is an automated external defibrillator (AED).

Product issue Stryker has discovered through customer complaints that some cellular LIFEPAK CR2 devices have incorrect cellular settings. With this issue, the device will not be able to connect to the cellular network. **There is no impact to the device's ability to deliver therapy.**

Potential risks There is no associated health or patient risk with this issue and there have been no reports of adverse events.

Actions needed

1. Please check your internal inventory to locate the affected product listed on the attached business reply form.
2. Stryker recommends that you continue to use your CR2, as the incorrect cellular settings does not interfere with the device's ability to deliver therapy.
3. To confirm receipt of this Medical Device Notice and understanding of the provided information, please email the enclosed Business Reply Form (BRF) by XXXXX XX, 2023 to <insert local email address>.

4. Once the BRF is received, a Stryker Representative will contact you to arrange for correcting the cellular settings.
5. There are no additional actions that users can and should take.
6. Maintain awareness of this communication internally until all required actions have been completed within your facility.
7. Inform Stryker if any of the subject devices have been distributed to other organizations by contacting Stryker Representative.

If you have any questions or concerns, please contact Stryker Representative <insert local phone number> or by email <insert local email address>.

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

Once again, please email <insert local email address> the enclosed Business Reply Form to acknowledge receipt of this notification.

•Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Attachments:

- LPCR2 Business Reply Form
- Appendix A – List of affected Serial Numbers

Business Reply Form

Account number:
Account name:
Account Address:

LIFEPAK CR2 Defibrillator

Recall Number: RA2023-3211897

January 2023

Response is required; Please complete and sign this form.
Email the completed form <insert local email address> by XXXXX XX, 2023.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog Numbers		Product	Serial Number(s)*	Quantity on hand
99512-000112	99512-000397			
99512-000371	99512-000398	**LPCR2**		
99512-000372	99512-000399			
99512-000374	99512-000484			
99512-000387	99512-000485			
99512-000388	99512-000490			
99512-000390	99512-000514			
99512-000395	99512-000961			
	99512-001459			

Please see Appendix A for list of affected serial numbers.

- ☐ I confirm receipt of the Medical Device Notice and understand the information provided.
- ☐ I have checked my inventory and:
  - Yes, we have affected device(s)
  - No, we don't have affected device(s)

If you no longer have the device on hand, what was the final disposition of the product:
Additional Comments:

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			

Appendix A – List of Affected Serial Numbers

50190497	50190504	50190519	50191168	50191173	50191179	50191180
50190307	50190357	50190358	50190364	50190374	50190411	50190419
50190463	50191171	50191183	50199569	50199577	50199690	50199702
50199706	50199793	50199859	50199869	50199876	50199879	50199951
50199994	50200037	50200041	50200043	50200055	50200060	50200069
50200139	50200167	50200190	50202329	50203175	50203186	50203187
50203190	50203193	50203194	50203196	50203448	50203450	50203453
50203454	50203456	50203458	50203459	50203460	50203466	50203468
50203470	50203471	50203473	50203475	50203477	50203478	50203479
50203482	50203484	50212625	50212666	50212667	50212670	50212678
50212682	50190239	50190240	50190241	50190242	50190244	50190246
50190247	50190248	50190249	50190252	50190288	50190289	50190290
50190291	50190293	50190294	50190302	50190303	50190304	50190305
50190306	50190308	50190309	50190310	50190343	50190345	50190346
50190347	50190355	50190359	50190362	50190367	50190369	50190370
50190372	50190375	50190379	50190381	50190384	50190386	50190388
50190390	50190392	50190396	50190397	50190398	50190399	50190400
50190401	50190402	50190403	50190404	50190405	50190407	50190408
50190409	50190410	50190413	50190414	50190415	50190416	50190417
50190418	50190420	50190425	50190428	50190429	50190430	50190431
50190433	50190435	50190440	50190458	50212575	50212602	50212608
50212612	50212622	50212645	50212646	50212650	50212652	50212655
50212657	50212663	50212668	50212671	50212672	50212677	50212683
50212685	50212686	50212687	50212689	50212691	50212692	50212693
50212694	50212695	50212696	50212697	50212698	50212699	50212700
50212701	50212702	50212703	50212705	50212706	50212708	50212710
50212711	50212712	50212713	50212714	50212717	50212722	50212724
50212736	50212761	50212879	50212893	50212895	50212897	50212899
50212902	50212904	50212910	50212912	50212918	50212924	50212926
50215551	50212573	50212704	50212707	50212721	50190432	50190434
50190438	50190441	50190442	50190444	50190445	50190454	50190465
50190468	50212723	50190365	50190412	50190427	50190439	50190467
50190469	50190470	50190471	50190472	50190473	50190475	50190476
50190487	50190493	50212718	50190363	50190474	50190478	50190480
50190481	50190483	50190485	50190486	50190488	50212716	50212720
50212725	50212726	50190477	50190479	50190489	50190492	50190494
50190499	50191167	50191175	50199797	50212216	50212571	50212684
50212889	50212890	50212896	50212898	50212901	50212903	50212905
50212907	50212913	50212908	50215559	50215669	50190496	50190503
50190505	50190755	50190803	50191158	50191161	50191164	50191165
50191172	50191176	50191177	50191178	50190245	50190251	50190349
50190366	50190484	50190490	50190491	50190495	50190501	50190717
50191160	50191162	50191166	50191169	50191170	50191174	50191181
50191182	50191184	50191185	50191186	50191187	50191188	50191189
50191190	50191191	50191192	50191193	50191195	50199563	50199567
50199573	50199574	50199587	50199588	50199595	50199601	50199606

50199611	50199616	50199620	50199629	50199632	50199633	50199670
50199680	50199683	50199685	50199695	50199700	50199707	50199711
50199712	50199714	50199718	50199742	50199767	50199780	50199809
50199818	50199824	50199828	50199833	50199842	50199853	50199861
50199862	50199864	50199872	50199873	50199884	50199891	50199948
50199964	50199972	50199981	50199988	50199991	50199998	50200003
50200011	50200017	50200019	50200022	50200036	50200039	50200040
50200053	50200056	50200066	50200076	50200084	50200137	50200159
50200162	50200166	50200175	50200193	50200195	50200198	50200201
50200203	50200209	50200213	50190466	50190482	50199571	50199870
50199966	50199979	50199983	50199999	50200002	50200029	50200058
50200064	50200138	50200157	50200158	50200164	50200168	50200180
50200183	50200202	50215509	50215519	50215556	50215571	50215694
50200009	50203170	50203174	50215515	50215518	50215521	50215523
50215552	50215562	50215579	50215676	50215557	50215570	50215573
50215714	50215743					