

# URGENT FIELD SAFETY NOTICE: RA2021-2600240

## ACTION REQUIRED

### LIFEPAK® CR2 Defibrillator

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® CR2 Defibrillator.

February 26, 2021

Dear Valued Customer,

Stryker is conducting a voluntary action to notify customers that received LIFEPAK CR2 devices. Please forward this notice to all your sites, trainers and users.

#### **Description of issue**

Stryker has received complaints that the LIFEPAK CR2 lid magnet has dislodged from the device, which may result in premature battery depletion. This issue has the potential to result in the inability for the device to turn on if the user does not use the on/off button or if the battery has fully depleted. There have been two adverse events associated with this issue where the patients ultimately expired.

The lid magnet is the primary means by which the device will turn on and off when the lid is opened or closed. If the lid magnet is missing, the device battery can deplete prematurely, even if the device is not powered on.

When the magnet is missing, the user can still use the power button to turn the device on and off. The device will automatically turn off within five minutes after being powered on if no patient is detected by the device.

**If you identify that your device has a missing lid magnet, you may continue to use your LIFEPAK CR2 device according to the operating instructions and the supplemental labeling attached to this letter until replacement part is received.**

#### **Stryker's planned actions**

The company is notifying all LIFEPAK CR2 customers of this potential safety issue. We are requesting that all LIFEPAK CR2 devices be inspected according to the instructions provided in this letter to ensure the lid magnet is present. A replacement lid and battery will be provided at no charge for any device identified to have a missing magnet which may have begun prematurely depleting the battery. In addition, replacement lids will be provided at no charge for affected devices with lids identified to have a manufacturing discrepancy.

#### **Required customer actions**

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and product in use at your facility to determine if you have any affected product identified in this letter.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
  - a. Please provide contact details so that Stryker can inform the recipients appropriately.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.

- a. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
6. Inspect all LIFEPAK CR2 devices to verify Green Readiness Indicator on device flashes every 6 seconds and the lid magnet is present according to the lid magnet inspection instructions at the end of this notification letter. If any devices are found with Readiness Indicator not flashing or the lid magnet missing, contact your designed Stryker Representative. **Refer to guidance chart in Attachment 1 for further clarifications.**
7. Review the LIFEPAK CR2 Supplemental Instructions attached to this notification letter and retain this document as supplemental labeling for your device(s).
8. Continue to check device readiness **at least monthly** in accordance with the LIFEPAK CR2 Operating Instructions, Maintaining a State of Readiness (pp. 77-78) and the instructions provided herein.  
Device readiness is indicated by:
  - All Devices: Green Readiness Indicator on device flashes every 6 seconds. If device is not ready, the Readiness Indicator will not flash.
  - Devices with Wireless Connectivity: In addition to the green flashing Readiness Indicator on the device, the LIFELINKcentral AED Program Manager or LIFENET System will generate a monthly status report that the device is READY.Please see LIFEPAK CR2 Operating Instructions, Maintaining a State of Readiness (pp. 77-78) for complete instructions.
9. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you longer have any of the subject devices in your physical inventory.
10. Return the completed form to your nominated Stryker Representative (indicated below) for this action.
  - a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Beatriz Gonçalves

Position: Senior Specialist, RAQA

E-mail: [raqa.uk@stryker.com](mailto:raqa.uk@stryker.com) / [beatriz.goncalves@stryker.com](mailto:beatriz.goncalves@stryker.com)

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, 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 cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

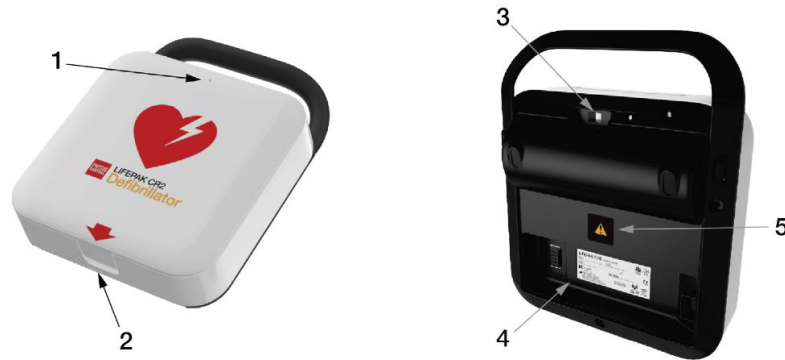


Nina Goddard  
RAQA Manager UK Benenord

**Stryker UK**

Stryker House, Hambridge Road, Newbury, Berkshire. RG14 5AW | P +44 1635 262400 | [stryker.com](http://stryker.com)

**Identification of impacted product**

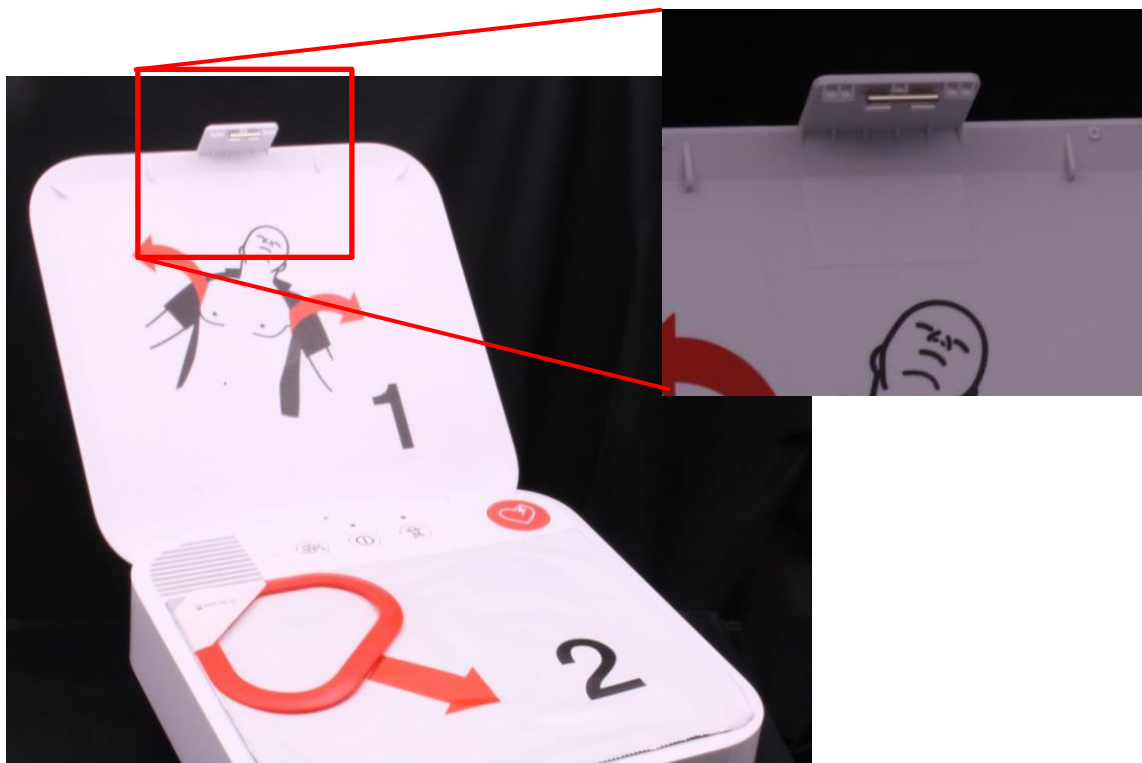


ITEM	FEATURE	DESCRIPTION
1	<b>Readiness indicator</b>	The green LED flashes every 6 seconds if the defibrillator is ready for use.
4	<b>Battery compartment</b>	The serial number label is located in the battery compartment. To view the serial number, remove the battery.

Note: Please refer to page 30 on your LIFEPAK CR2 Operating Instructions for further guidance.

**Lid Magnet Inspection Instructions**

1. Open the LIFEPAK CR2 lid
2. Inspect lid magnet clip for presence of magnet as shown in figure below



**URGENT FIELD SAFETY NOTICE: RA2021-2600240  
BUSINESS REPLY FORM**

**LIFEPAK ® CR2 Automated External Defibrillator (AED) Device List**

I acknowledge receipt of the Field Safety Notice for RA2021-2600240 and can confirm that:

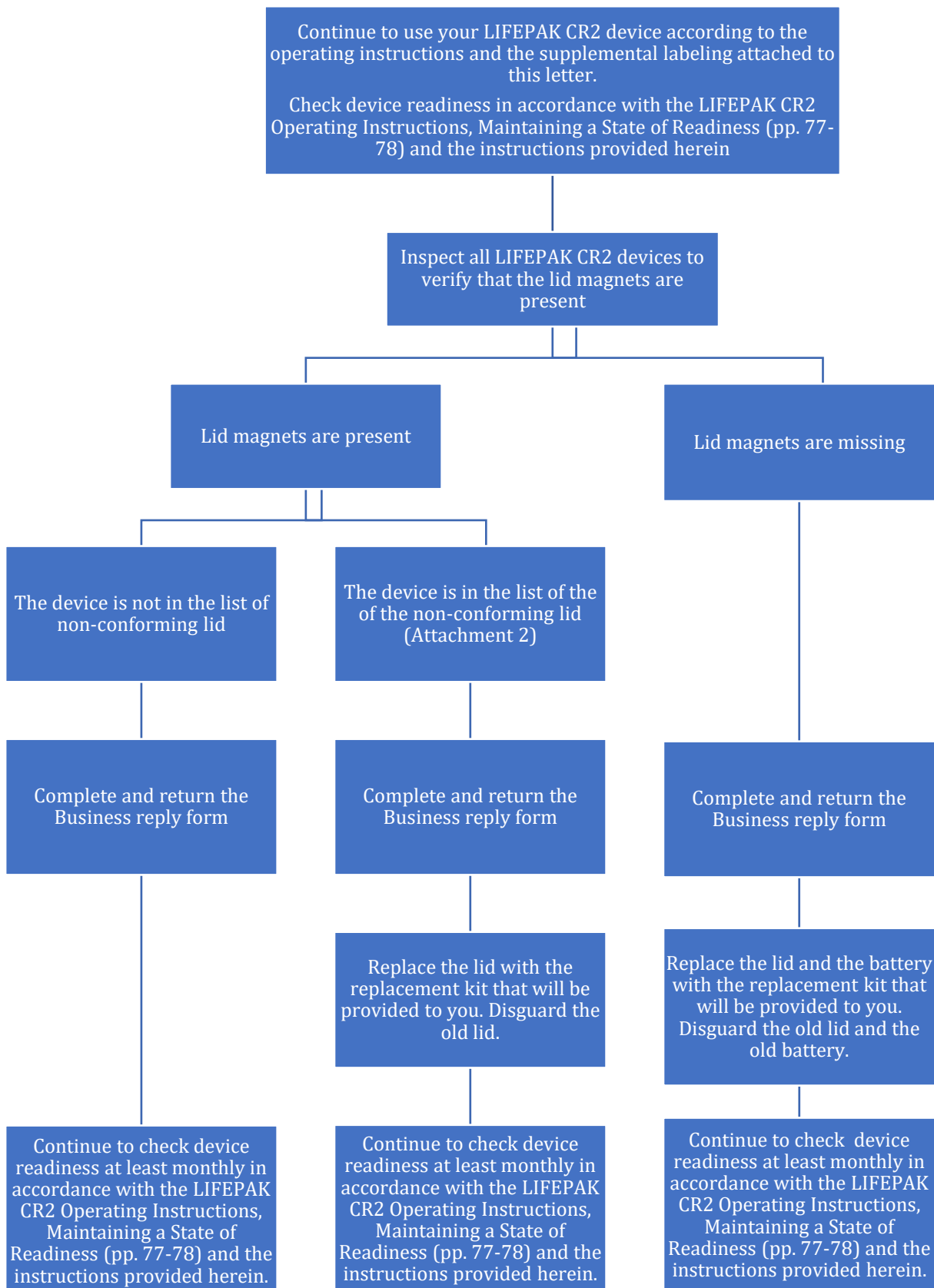
Serial Number*	Lid has Magnet Intact		SN is in the list of Attachment 2	
	Yes	No	Yes	No
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Please attach additional sheet if needed.

We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
<b>Please sign and return this form to acknowledge receipt of product notice.</b>			
Name of Hospital / Organization		Department	
Contact Name		Address	
Contact Title			
<b>Contact Signature</b>		E-mail Address	
Contact Phone No.		Date	

**PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, [raqa.uk@stryker.com](mailto:raqa.uk@stryker.com) and [beatriz.goncalves@stryker.com](mailto:beatriz.goncalves@stryker.com)**

**URGENT FIELD SAFETY NOTICE: RA2021 - 2600240**  
**Attachment 1: Customer's actions guidance chart**



**URGENT FIELD SAFETY NOTICE: RA2021 - 2600240**

**Attachment 2: List of affected serial numbers with no-conform lid distributed in UK and Ireland**

47963358	47997677	47999373	48021140	48048293	48051064	48153682	48156615	48161893	48243295
47972713	47997682	47999423	48021159	48048380	48051082	48153690	48156632	48161900	48243297
47976248	47997690	48012636	48021207	48048382	48051095	48153700	48156675	48161910	48243342
47978241	47997723	48013219	48021210	48048386	48051106	48153703	48156711	48161915	48243343
47978596	47997743	48013309	48036415	48048501	48051124	48153706	48156724	48162264	48243345
47981940	47997757	48013373	48037423	48048503	48051133	48153710	48156740	48162395	48243346
47987837	47997774	48013406	48038622	48048504	48051158	48153715	48156746	48195162	48243347
47988007	47997803	48013487	48038624	48048505	48051163	48153717	48156763	48197284	48243392
47988029	47997810	48013536	48038658	48048926	48051174	48154592	48156776	48197752	48243438
47988046	47997845	48013565	48038700	48048969	48051184	48154600	48156792	48197840	48243440
47988058	47997852	48013579	48038722	48049000	48051187	48154608	48156878	48197864	48243456
47988230	47997862	48013589	48039013	48049002	48051197	48154644	48156892	48197933	48243457
47988593	47997941	48013657	48039059	48049014	48051205	48154668	48156897	48197938	48243468
47988772	47998007	48013791	48039069	48049086	48051211	48154723	48156899	48197941	48243469
47990552	47998014	48013835	48039321	48049087	48051216	48154734	48156909	48198006	48243612
47990558	47998027	48013888	48039427	48049146	48051288	48154757	48156921	48198042	48243635
47990567	47998037	48013965	48039444	48049151	48051296	48154779	48156932	48198086	48243640
47990600	47998059	48014023	48039470	48049849	48051305	48154880	48156935	48198094	48243668
47990742	47998071	48014073	48040024	48049856	48051324	48154889	48156949	48198102	48243745
47990750	47998128	48014102	48040048	48049868	48051336	48154895	48156979	48223987	48243769
47990761	47998185	48014108	48040065	48049901	48051357	48154900	48157325	48235835	48243771
47990811	47998267	48014148	48040079	48049917	48051370	48155011	48157579	48236020	48246504
47991129	47998303	48014161	48040145	48049918	48051388	48155017	48157814	48236024	48269548
47991147	47998472	48014180	48040392	48049934	48051395	48155083	48157821	48236038	48269727
47992261	47998498	48014205	48040412	48049936	48051409	48155104	48157825	48236066	48270040
47994402	47998506	48014225	48040678	48050011	48051441	48155110	48157831	48236071	48275928
47994479	47998539	48014230	48040984	48050015	48051498	48155128	48157836	48236072	48275952
47995271	47998590	48015717	48041007	48050038	48053030	48155237	48157860	48236263	48275984
47995416	47998607	48015768	48041040	48050048	48053056	48155299	48157865	48236266	48275994
47996182	47998649	48015793	48041044	48050091	48145177	48155368	48157880	48236354	48276347
47996524	47998653	48015865	48041058	48050096	48145211	48155391	48157900	48236411	48374260
47996577	47998664	48017950	48041061	48050115	48145219	48155421	48157940	48237479	48374381
47996600	47998704	48017952	48048083	48050157	48145488	48155527	48158037	48237536	48375127
47996615	47998798	48019504	48048086	48050158	48145574	48155545	48158048	48237817	48375154
47996617	47998803	48019560	48048182	48051005	48145743	48155547	48159223	48237830	48375206
47997574	47998851	48019575	48048228	48051027	48145785	48156471	48159240	48237931	48375208
47997635	47999074	48020767	48048229	48051030	48145954	48156493	48159251	48242196	48375226
47997652	47999189	48020873	48048290	48051031	48145959	48156502	48159364	48242559	48375244
47997665	47999204	48020886	48048291	48051050	48145974	48156603	48160467	48243107	48375252
47997670	47999359	48021121	48048292	48051060	48152599	48156613	48161887	48243181	48375259

48375268	48384283	48385212	48388667
48375298	48384286	48385234	48388696
48375306	48384289	48385240	48388788
48375309	48384339	48385250	48388796
48375312	48384385	48385260	48388827
48375356	48384390	48385265	48388836
48375407	48384396	48385271	48388846
48375695	48384398	48385277	48388868
48375947	48384402	48385279	48388871
48382118	48384404	48385459	48388876
48382287	48384408	48385556	48388885
48382295	48384422	48385621	48388889
48382350	48384441	48385628	48388893
48383657	48384445	48385698	48388902
48383689	48384450	48386132	48388905
48383724	48384468	48386138	48388908
48383734	48384505	48386155	48388928
48383742	48384539	48386566	48388937
48383783	48384546	48386589	48388938
48383905	48384567	48386594	48388944
48384143	48384839	48386639	48388954
48384149	48384844	48386645	48388965
48384157	48384852	48386661	48388971
48384163	48384862	48386991	48388973
48384169	48384878	48387895	48388981
48384210	48384888	48387903	48388985
48384211	48384908	48387913	48388999
48384213	48384913	48387927	48389007
48384217	48384923	48387948	48389025
48384221	48384943	48387951	48389032
48384231	48384954	48387959	48389037
48384234	48384959	48387978	48389051
48384241	48384970	48388000	48389055
48384263	48384985	48388056	48392755
48384267	48385059	48388113	
48384271	48385135	48388479	
48384275	48385182	48388662	