September 2021

URGENT MEDICAL DEVICE REMOVAL

CARDIOSAVE Battery Pack, Li-Ion

Part Number (REF)	Serial numbers (SN)				
0146-00-0097	192054036IP	181458323PE	202566731IP	202536430IP	192172046IP
	191935520IP	181458923PE	181460723PE	181533830PE	192221049IP
	191832314IP	192134743IP	181362411PE	181653442PE	202383918IP
	181706044PE	202810846IP	192174946IP	181653742PE	192173046IP
	202268605IP	192240650IP	181437521PE	191824513IP	192174046IP
	191983523IP	202363210IP	181462023PE	192062136IP	202372818IP
	192069438IP	192145043IP	202410920IP	192100141IP	181594332PE
	181725430IP	181459023PE	192076438IP	192233550IP	181527430PE
	181526630PE	181460223PE	181460823PE	192244450IP	192030329IP
	202254801IP	192097841IP	202373118IP	202314108IP	191831014IP
	181458423PE	202373518IP	192175546IP	202381318IP	202395219IP
	181460023PE	181461923PE	181542330PE	202380318IP	191960122IP
	191918620IP	181459923PE	202316408IP	181441322PE	192084938IP
	202259701IP	181460123PE	181458823PE	192167546IP	202462222IP
	202368411IP	192224949IP	192181146IP	181650741PE	192178446IP
	202370911IP	192212749IP	181642839PE	192032629IP	202252001IP
	202679137IP	192235150IP	202475424IP	192179546IP	192199347IP
	181458723PE	191843014IP	202391419IP	202382218IP	192238650IP
	181459123PE	202390519IP	181461023PE	202373718IP	202651535IP
	202341809IP	202403919IP	202346109IP	181584332PE	192121242IP
	171178321PE	191883318IP	191892119IP	191894819IP	202621733IP
	181459223PE	171308141PE	171320448PE	192192247IP	202389519IP
	171263233PE	202536630IP	181376217PE	191992724IP	192217649IP
	192201047IP	192205547IP			
Manufacturing Dates:	September 06, 2017 to March 04, 2021				
Distribution Dates:	September 23, 2017 to August 17, 2021				

Dear Risk Manager,

Datascope/Getinge is initiating a voluntary Medical Device Removal for a limited number of Cardiosave Li-Ion Battery Packs with Part Number/REF Number 0146-00-0097 used with Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to the potential risk of unexpected short battery runtime.

Note: Only battery runtime is impacted. When using AC power, Cardiosave IABP will work as expected and performance is not impacted.

If a patient is supported on Cardiosave with affected battery(ies) and adequate alternative power sources (hot-swapping batteries or AC power) are unavailable, therapy may be interrupted. Both Cardiosave Hybrid and Rescue IABP monitors display battery life to the user, prompting intervention with low battery alarms when alternative power sources are indicated. The Cardiosave touchscreen displays the charge level for each battery and displays an alarm message (with audible tone) when approximately 30 minutes of operating time remain with additional notifications every 5 minutes until battery power is depleted. An alerted user would have the opportunity to seek alternative power to avoid therapy interruption. The patient populations most at risk are those being transported on battery power and those who are more vulnerable to any interruption in counter pulsation therapy when relying on battery power.

Identification of the issue:

Cardiosave Lithium-Ion Batteries (0146-00-0097) did not meet the minimum runtime requirement per Getinge's internal Product Specification. These nonconforming batteries were inadvertently released to customers.

Datascope/Getinge is aware of six complaints for batteries with the potential to run less than the 60 minute runtime per specifications. There have been no adverse events reported that are related to this issue.

The scope is limited to Cardiosave Li-Ion Battery Pack (0146-00-0097) with Serial Numbers listed at the top of this letter. Please see battery label below:

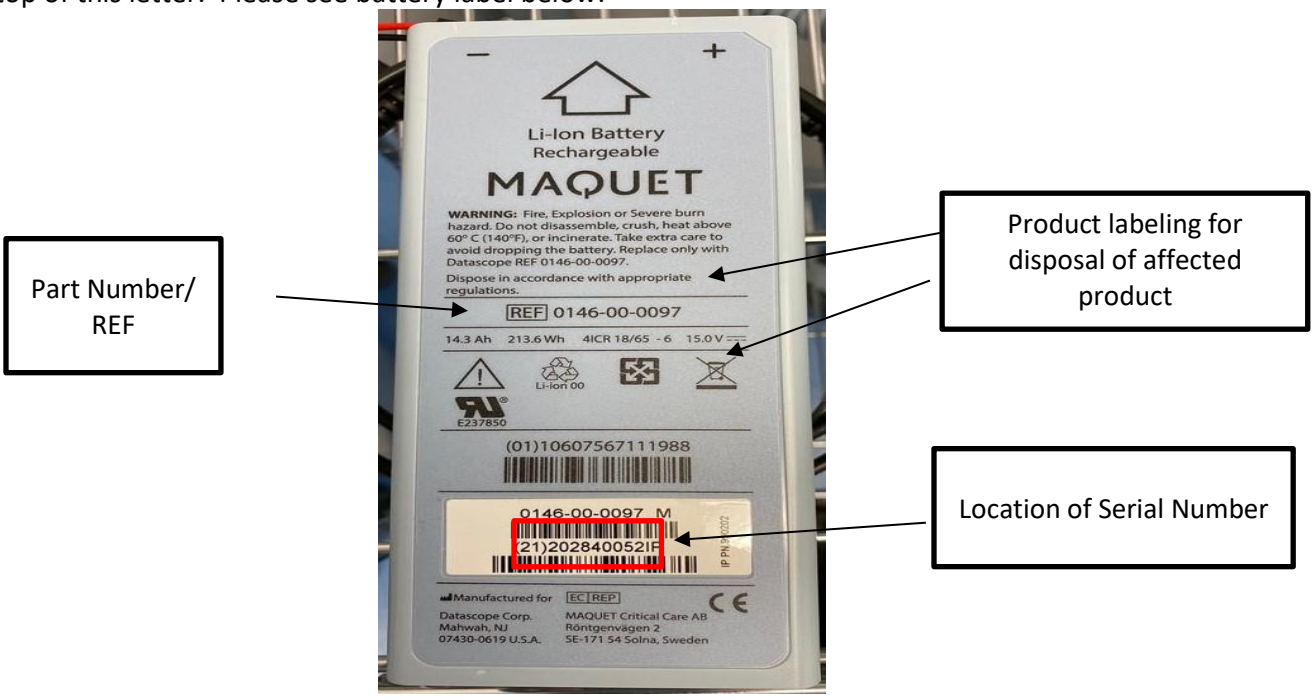

Figure 1:

Our records indicate that your facility has received one or more of the Cardiosave Li-Ion Battery Packs that are affected by this recall.

Actions to be taken:

- Please examine your inventory immediately to determine if you have any of the Cardiosave Li-Ion Battery Packs with Part Number/REF Number 0146-00-0097 and with Serial Numbers matching those listed at the top of this letter.
- Replace any affected battery with an unaffected battery, and remove affected product from areas of use.
- Should you have affected product, you are eligible for credit or a replacement at no cost to your facility upon receipt of Response Form (see page 4).
- To get your free replacement battery we need you to provide a ship to contact and your acknowledgment on page 4 that the defective battery will be disposed once you receive the replacement battery pack.
- Please dispose of affected batteries properly in accordance with local statutes and the labeling on the battery pack. Please see Figure 1.
- Please forward this information to all current and potential Cardiosave Hybrid and Cardiosave Rescue IABP users within your hospital / facility.
- If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.
- Please complete and sign the attached URGENT FIELD SAFETY NOTICE MEDICAL DEVICE REMOVAL– RESPONSE FORM FORM on page 4 to acknowledge that you have received this notification.
- Return the completed form to Getinge.

This Urgent Medical Device Removal only affects the product listed on page 1; no other products are affected.

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your local Datascope/Getinge representative

Sincerely,

Rachana Patel
Regulatory Affairs and Field Action Compliance Specialist
Getinge
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Wayne, NJ 07470