[Month DD, YYYY] via [INSERT METHOD]

UURGENT FIELD SAFETY NOTICE
MEDICAL DEVICE REMOVAL
CARDIOSAVE Battery Pack, Li-Ion

Part Number (REF)	Serial numbers (SN)
0146-00-0097	SSUs to fill in using final ship history
Manufacturing Dates:	September 06, 2017 to March 04, 2021
Distribution Dates:	SSUs to fill in using final ship history

Dear Hospital Contact,

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:

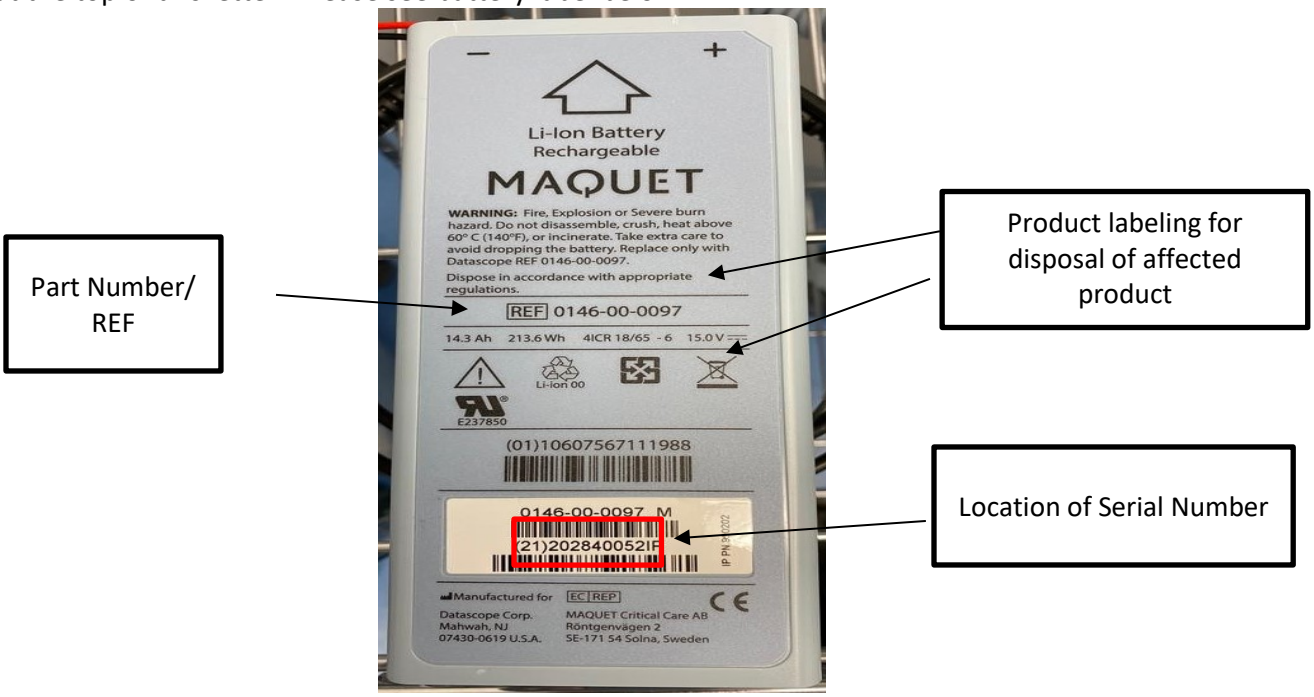

Figure 1:

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 on page 4 to acknowledge that you have received this notification.
- Return the completed form to Atrium/Getinge to INSERT LOCAL SSU EMAIL ADDRESS or by faxing the form to INSERT LOCAL SSU FAX NUMBER.

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,

_____

Recall Coordinator Name

Recall Coordinator Title, Regulatory Affairs and Field Action Compliance Getinge

Month DD, YYYY]

URGENT FIELD SAFETY NOTICE - MEDICAL DEVICE REMOVAL RESPONSE FORM

CARDIOSAVE Battery Pack, Li-Ion

FAX BACK TO: INSERT LOCAL SSU FAX NUMBER or EMAIL TO: INSERT LOCAL SSU EMAIL ADDRESS

DISTRIBUTION DATES: SSUs to fill in using final ship history

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Removal Notice for the Cardiosave Li-Ion Battery Pack with Part Number/REF Number 0146-00-0097. Please ensure that all users of the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) at this facility have been notified accordingly.

Please dispose of affected batteries properly in accordance with local statutes and the labeling on the battery pack. Please refer Figure 1 on page 2.

☐ Please check this box if you no longer have the affected device at your facility.

Please provide the required information and signature below and return this form to Getinge even if you no longer have the affected device at your facility.

List of Affected Cardiosave Li-Ion Battery Pack at your facility

Part Number/ REF Number	Serial number(s)	Battery will be properly disposed? (Yes/No)
0146-00-0097		

Facility Representative Information:

Facility Representative:

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State: _____

Return the completed form by FAX to INSERT LOCAL SSU FAX NUMBER **or by EMAIL to** INSERT LOCAL SSU EMAIL ADDRESS