September 21, 2021

URGENT MEDICAL DEVICE REMOVAL

CARDIOSAVE Battery Pack, Li-Ion

Part Number (REF)	Serial numbers (SN)						
0146-00-0097	171097810PE	181513630PE	191806513IP	191956322IP	192175646IP	192241550IP	202401619IP
	171100310PE	181526530PE	191822513IP	191968223IP	192179046IP	192245250IP	202403719IP
	171101010PE	181609237PE	191831214IP	191968723IP	192179246IP	202266705IP	202416720IP
	171102210PE	181642339PE	191848115IP	191969623IP	192185446IP	202279305IP	202482724IP
	171218521PE	181642639PE	191852615IP	191971023IP	192187947IP	202280605IP	202535330IP
	171255732PE	181645841PE	191853415IP	191972823IP	192190247IP	202321308IP	202552831IP
	171264133PE	181646041PE	191860615IP	192004724IP	192195547IP	202323808IP	202593632IP
	171277935PE	181659242PE	191863015IP	192018828IP	192196247IP	202330609IP	202599332IP
	171318548PE	181661142PE	191872616IP	192081138IP	192196447IP	202334109IP	202599432IP
	171325749PE	181673143PE	191874716IP	192083838IP	192196647IP	202367411IP	202617233IP
	171337749PE	181694244PE	191902319IP	192084038IP	192200647IP	202369811IP	202651035IP
	171339849PE	181694644PE	191904319IP	192098341IP	192200947IP	202371511IP	202654636IP
	171345550PE	181703744PE	191908720IP	192099841IP	192204947IP	202386519IP	202719740IP
	171348550PE	181705244PE	191910720IP	192103741IP	192205847IP	202388319IP	202723440IP
	181405120PE	181706344PE	191912520IP	192104141IP	192210249IP	202389819IP	202725540IP
	181440222PE	181721730IP	191915920IP	192104541IP	192216649IP	202389919IP	202782744IP
	181474326PE	181748032IP	191922620IP	192106442IP	192220349IP	202394719IP	202791944IP
	181477426PE	191778911IP	191943120IP	192107842IP	192220749IP	202398619IP	
	181487828PE	191787312IP	191955422IP	192155645IP	192224349IP	202400219IP	
	181492328PE	191790412IP	191956122IP	192173146IP	192225649IP	202401419IP	
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:

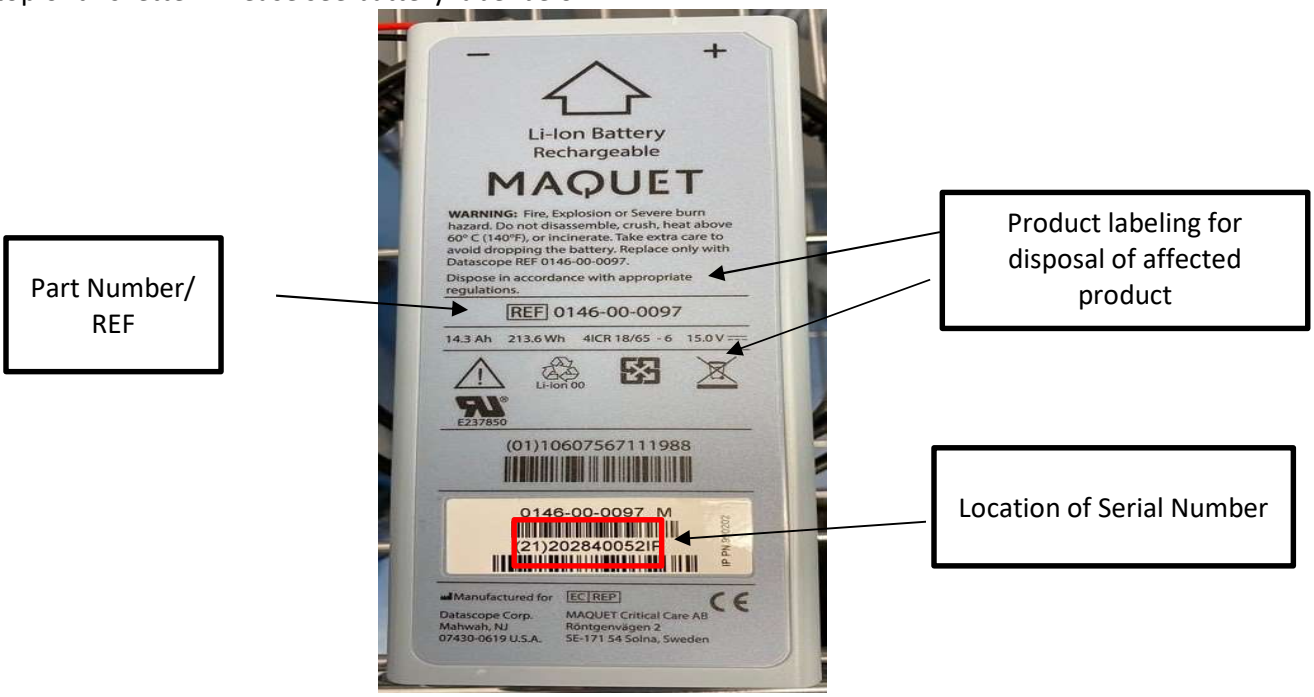

Figure 1:

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. 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.
- Whether you have affected product or not, please complete and sign the attached URGENT MEDICAL DEVICE REMOVAL – RESPONSE FORM (page 4) to acknowledge that you have received this notification and disposed properly of the affected product. Return the completed form to Getinge by e-mailing a scanned copy to Li-Ionbattery.Datascope@getinge.com or by FAX to 877-446-3360.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program using one of the following methods:

- **Online:** www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax:** 1-800-FDA-0178

We apologize for any inconvenience this Medical Device Removal may cause. If you have any questions, please contact your Datascope/Getinge representative or, for technical questions, please contact Customer Service (at 1-888-943-8872, options 2), Monday through Friday, between the hours of 8:00a.m. and 6:00p.m. EST.

This notification is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

_____

Rachana Patel
Regulatory Affairs and Field Action Compliance Specialist
Getinge
45 Barbour Pond Drive
Wayne, NJ 07470