June 17, 2019 via FedEx

URGENT MEDICAL DEVICE CORRECTION
Datascope Intra-Aortic Balloon Pumps (IABP)
Battery Usage, Charging, Maintenance and Storage Instructions

AFFECTED PRODUCT	PART NUMBER	DISTRIBUTION DATE
Cardiosave Hybrid IABP **Cardiosave Rescue IABP** **CS300 IABP** **CS100 IABP**	All	All

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL CARDIOSAVE HYBRID, CARDIOSAVE RESCUE, CS300 and CS100 INTRA-AORTIC BALLOON PUMP (IABP) USERS WITHIN YOUR FACILITY.

IF YOU ARE A DISTRIBUTOR WHO HAS SHIPPED ANY AFFECTED PRODUCTS TO CUSTOMERS, PLEASE FORWARD THIS DOCUMENT TO THEIR ATTENTION FOR APPROPRIATE ACTION.

Dear Customer,

This is to notify you that the Datascope IABP devices(s) (Cardiosave Hybrid IABP, Cardiosave Rescue IABP, CS300 IABP and CS100 IABP) your facility may have received from Getinge are part of a field correction initiated May 16, 2019. This field correction is being conducted to ensure that all IABP users follow each device's Operating Instructions Manual for recommendations on usage, charging, maintenance and storage of the batteries, as battery run times and discharge cycles vary between IABP models. If battery maintenance is not performed per the Operating Instructions Manual for each IABP, the battery may provide less than the expected minimum run time of operating power per battery. In addition, Getinge will proactively reach out to all customers to help ensure this field correction is adequate and effective to reduce IABP shutdown while operating on battery power.

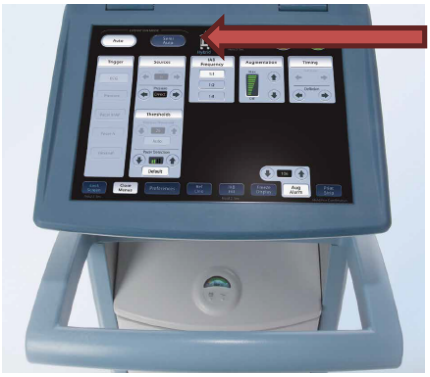
There have been five patient deaths reported since March 2016, although the deaths cannot be definitively attributed to the device shutting down while operating on battery power.

There is patient risk of hemodynamic instability due to sudden interruption or temporary suspension of therapy. In patients with mild to moderate hemodynamic compromise, inotropic agents can provide sufficient hemodynamic support while the unit is reconnected to an AC source or alternative therapy is initiated. Therefore, an interruption of the therapy would be unlikely to lead to a life-threatening situation. However, in critical patients with severely compromised hemodynamic function dependent on continuous circulatory support, an interruption or delay in IAB support as a result of an unexpected shutdown or failure to initiate therapy can occasionally/likely have more severe consequences that can be life threatening.

Immediate Interim actions to be taken by User:

- Ensure the IABP is plugged into an AC power outlet whenever possible during patient use to prevent the battery from depleting.
- Ensure the IABP is plugged into an AC power outlet when the system is not in use. The batteries should be kept at a full charge even when the IABP is not in use.
- When transporting patients within or between facilities, please refer to the IABP Operating Instructions Manual for recommendations on portable/battery operation. For example:

- Prior to portable operation, the battery should be fully charged
- For Cardiosave Rescue and Cardiosave Hybrid only:
    - Additional charged batteries should be on hand during transport
    - Ensure the batteries are properly seated in the battery compartment/charger and the IABP Console is completely seated/secured into the IABP Cart
        - For Cardiosave Hybrid, you can verify if the Console is completely seated in the IABP cart by the indicator on the display:



If the word "**Hybrid**" is displayed, then the IABP console is secured into the IABP cart.

If the word "**Rescue**" is displayed, then the IABP console is not secured into the IABP cart

- Check battery run time and replace batteries as required, as recommended in each IABPs Operating Instructions Manual. A reduction in run time can occur over a battery's life for reasons such as age, storage temperature and discharge depth. Batteries should be replaced:
    - After reaching the maximum number of charge-discharge cycles
    - When the battery provides less than the minimum specified run time
    - If the battery is broken, cracked, leaking or damaged
    - When the labeled lifetime of the battery is reached

    NOTE: Batteries for the Cardiosave Hybrid and Cardiosave Rescue IABPs sold before June 2015 should be replaced immediately as the labeled lifetime for these batteries is 4 years. Replacement batteries can be ordered through your sales or service representative. To determine the date of manufacture for all Cardiosave batteries, refer to attached document, '*Cardiosave Lithium-ion Battery Pack' ML-0795*.

    NOTE: CS100/CS300: Informational messages on the display screen provide information to the operator regarding the batteries. The **Battery Maintenance Required** message indicates that the IABP internal battery requires maintenance. The Battery test due date or Battery Replacement Date predate the current system date at startup or the internal battery has a total accumulated discharge time in excess of 100 total discharge cycles.

    For all replacement batteries, ensure only Datascope approved/sourced batteries are installed/used.

In case of a sudden shutdown of an IABP such as battery depletion is related to the static condition (no inflating or deflating) of the balloon during the interruption of therapy, it is important to note the following WARNING in the Operating Instructions for all Datascope IABPs:

WARNING: The patient balloon should not remain inactive in the patient (i.e., no inflating or deflating) for more than 30 minutes, due to the potential for thrombus formation.

In the unlikely event that this situation was to occur, transfer the patient to an alternative Datascope IABP. If an alternative Datascope IABP is unavailable; manually inflate the IAB with air or helium and immediately aspirate.

Please refer to the IAB Instructions for Use, Manually Inflating and Deflating a Catheter. The IAB Instructions for Use reiterates that a catheter should not remain inactive for more than 30 minutes, due to the potential for thrombus formation. Alternatively, the IAB could be removed.

To support our customers in this field correction, Getinge will execute the following Corrective Actions:

Initial Action - Cardiosave Hybrid IABP, Cardiosave Rescue IABP, CS300 IABP and CS100 IABP:

- A Getinge representative will contact each consignee to schedule a training visit with your facility to review a recently developed battery operations, care and maintenance reference guide specific to the IABP(s) based on the Operating Instructions Manual(s) provided with each device.
- Electronic Post Market Surveillance training effectiveness will be conducted by Getinge to proactively evaluate the effectiveness of each customer's training and battery knowledge as well as capture customer feedback/experiences related to user experience for the IABP(s).

Additional Actions - Cardiosave Hybrid IABP, Cardiosave Rescue IABP:

- Getinge is currently developing a Cardiosave battery maintenance software upgrade targeted for early 2020. This updated software requires FDA clearance and once completed, a Getinge Service representative will contact you to schedule the installation of the updated software. This work will be done at no cost to your facility.
- NOTE: A similar software upgrade was released for the CS300 IABP and CS100 IABP in 2017. If you are unsure whether your IABP has been updated with the released software upgrade, please contact your Getinge Sales & Service Office with the Model and Serial number of the IABP. The Sales & Service Office will determine if the IABP software has been updated.

Please complete the attached Urgent Medical Device Correction Response Form (page 4) to acknowledge that you have received this Medical Device Field Correction letter. Please fax the completed form to 1-866-340-5660 or send via email to: IABPBattery2019@getinge.com.

This Medical Device Correction is being made with the knowledge of the U.S. Food and Drug Administration.

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.

- Online: https://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

Maquet/Datascope apologizes for any inconvenience you may experience as a result of this Medical Device Correction. For technical questions, please contact Technical Support Department (at 1-888-627-8383 and press 3), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. EST.

Thank you for your cooperation and immediate assistance.

Sincerely,

Tina M. Evancho

Tina Evancho
Manager, Regulatory Affairs and Field Action Compliance
Getinge

Cardiosave Lithium-ion Battery Pack

Determining Date of Manufacture

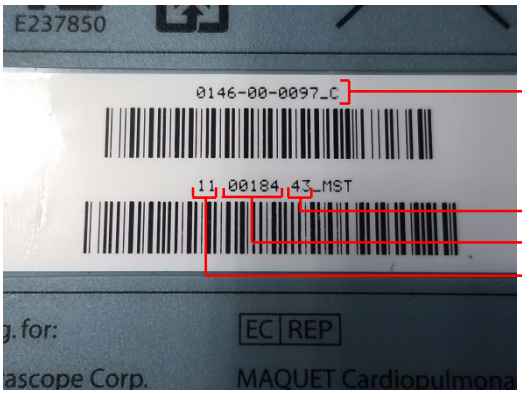
Cardiosave Lithium-ion Battery Pack

A white barcode label is affixed to the top of each Cardiosave Lithium-ion Battery Pack. This barcode label provides information such as part number, serial number, and year and week of manufacture. Refer to the example below for barcode label placement.

Example barcode label placement

Determining Date of Manufacture

Each barcode label provides information in the form of two barcodes. The first barcode is the Datascope Corp. part number of the Cardiosave Lithium-ion Battery Pack. The second barcode is coded with the year of manufacture, battery pack serial number, and week of manufacture.



In the above example, the Datascope Corp. part number for this battery pack is **0146-00-0097**. The serial number is **00184**, and it was manufactured in the week **43** of **2011**. The letters after the serial number vary.

NOTE

The year and week of manufacture will always be a two digit number, and the serial number will always be a five digit number.