GETINGE

Date 2 Oct 2019 Via FedEx

URGENT MEDICAL DEVICE RECALL – REMOVAL
Low Level Output Cable – Interface to Philips Monitor For Use With Cardiosave and CS300 Intra-Aortic Balloon Pumps (IABPs)
Product Mislabeling

Product Code/Part Number:	0012-00-1589-03
Distributed Affected Lot Number:	10000493876
Manufacturing Date:	January 2019
Distribution Dates:	February 28, 2019 – March 26, 2019

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL DATASCOPE/GETINGE LOW LEVEL OUTPUT CABLE – INTERFACE TO PHILIPS MONITOR USERS WITHIN YOUR HOSPITAL / FACILITY. IF YOU HAVE FURTHER DISTRIBUTED ANY OF THE AFFECTED PRODUCTS, FORWARD THIS INFORMATION TO THE RECIPIENT.

Dear Risk Manager,

Datascope/Getinge is initiating a voluntary recall-removal involving one lot of the Low Level Output Cable – Interface to Philips Monitor recommended for use with Cardiosave and CS300 IABPs. Datascope/Getinge has identified that one lot of Low Level Output Cable – Interface to Philips Monitor, labeled as part number 0012-00-1589-03, was received from the supplier with an incorrect Cable in the packaging. The packaging contained a Low Level Output Cable – Interface to GE Monitor, part number 0012-00-1589-04.

The monitor connector designs are different, preventing cables 0012-00-1589-03 (Interface to Philips Monitor, see figure 1 on page 2) and 0012-00-1589-04 (Interface to GE Monitor, see figure 2 on page 2) from being interchangeable. The cable connector to Philips monitor is more circular while the cable connector to GE monitor is rectangular.

D012-00-1589-03

Figure 1

D012-00-1589-04

Figure 2

Identification of the issue
Datascope/Getinge became aware of this issue through customer complaints.

Risk to Health
Being unable to connect the IABP to an external monitor will not affect the pump's ability to provide therapy function to the patient. The IABP is able to generate its own signals and has an independent display on the device itself; therefore, there is no health risk to the patient or user of the device.

To date, Datascope/Getinge has not received any adverse events regarding this issue.

Actions to be taken:
Our records indicate that you have received an affected Low Level Output Cable – Interface to Philips Monitor from lot 10000493876. Please complete the steps below:

- Please examine your inventory immediately, remove and quarantine any affected product.
- If you have un-used affected product, please contact Getinge Customer Service at 1-888-627-8383 (press option 2, then option 1) between the hours of 8 AM and 6 PM Eastern Standard Time to request a material authorization number (RMA) and shipping instructions. Pack the product to be returned with the appropriate return documents and, using the shipping

instructions provided, arrange for pickup with the designated delivery service provider. Replacement product or a credit will be issued for your return.

- Please enter the quantity and RMA number provided by Customer Service in the spaces provided on the URGENT MEDICAL DEVICE RECALL – REMOVAL Response Form on Page 4 of this letter, if you are returning products to Datascope/Getinge.

- Please complete and sign the attached URGENT MEDICAL DEVICE RECALL – REMOVAL RESPONSE FORM (page 4) to acknowledge that you have received this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy to [redacted] or by faxing the form to 1-973-807-9290.

This voluntary recall only affects the Low Level Output Cable – Interface to Philips Monitor, 0012-00-1589-03 with lot 10000493876; no other products are affected by this voluntary recall.

This recall 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

We sincerely apologize for any inconvenience this recall may cause.

If you have any questions, please contact your Datascope/Getinge representative or call the Datascope/Getinge Customer Service at 1-888-627-8383 (press option 2, then option 1), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

Sincerely,

[redacted]

Marylou Insinga
Senior Specialist, Regulatory Affairs and Field Action Compliance
Getinge