[Month DD, YYYY] via FedEx

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION

Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

Product Description:	Product Code/Part Number:	UDI Code:
Cardiosave Hybrid	0998-00-0800-31 0998-UC-0800-31	10607567109053 N/A
Cardiosave Hybrid	0998-00-0800-32	10607567111117
Cardiosave Hybrid	0998-00-0800-33 0998-UC-0800-33	10607567109008 N/A
Cardiosave Hybrid	0998-00-0800-34	10607567111940
Cardiosave Hybrid	0998-00-0800-35	10607567109107
Cardiosave Hybrid	0998-00-0800-45	10607567108421
Cardiosave Hybrid	0998-00-0800-52 0998-UC-0800-52	10607567108438 N/A
Cardiosave Hybrid	0998-00-0800-53 0998-UC-0800-53	10607567108391 N/A
Cardiosave Hybrid	0998-00-0800-55 0998-UC-0800-55	10607567108414 N/A
Cardiosave Hybrid	0998-00-0800-65	10607567113432
Cardiosave Rescue	0998-00-0800-75	10607567112312
Cardiosave Rescue	0998-00-0800-83	10607567108407
Cardiosave Rescue	0998-00-0800-85	10607567113449

Distributed Affected Lot Number:	**All**
Manufacturing Dates:	**December 2011 to June 30, 2017**
Distribution Dates:	**March 6, 2012 to July 20, 2017**

Dear Hospital Contact,

Datascope Corp., a subsidiary of Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to an issue that could affect IABP performance:

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

An unexpected shutdown of the IABP may occur due to a failure of the connection between the Coiled Cord cable (part number 0012-00-1801) and the Cable Assembly backplane (part number 0012-00-1796) to the Coiled Cord cable which provides the communication between the display head and base unit. Please refer to images below.

Unexpected shutdown due to failure of the Coiled Cord cable and Cable Assembly backplane to Coiled Cord cable

Identification of the issue:
Datascope/Getinge has received complaints reporting Cardiosave IABPs unexpectedly shutting down.

An internal investigation of the complaints determined an unexpected shutdown may be due to damaged Coiled Cable Cords [part numbers 0012-00-1801 and 0012-00-1796] that provide bidirectional communication between the display head and base unit. Please refer to images below for reference.

Datascope/Getinge has received 25 reported complaints of damaged Coil cords resulting in unexpected shutdown over a 2 year period.

There have been 0 adverse events reported.

Risk to Health:
An unexpected shutdown and resulting interruption to therapy may threaten the hemodynamic stability of the supported patient.

User Actions to be taken now:

1. Prior to use of the Cardiosave IABP, inspect the coiled cable cord to ensure that there is no visible damage.

Old Pump Console Coiled Cord Connection:

New Pump Console Coiled Cord Connection:

Figure 1: Representative picture of both the old and new Coiled Cable cord design.

2. Should you experience an unexpected shutdown of the Cardiosave IABP during therapy, utilize another IABP to continue therapy. Until an alternative IABP is located

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you may attempt to restart the IABP. If the IABP remains non-operational, immediately remove from the patient care environment for further product evaluation.

3. If your device remains inoperable, please contact your service representative to identify the cause and take the necessary actions required.

Type of Action by the Company:
Datascope/Getinge has developed a hardware correction to address this issue. It is important to note that this issue is limited to units distributed prior to July 24, 2017. A Datascope/Getinge service representative will contact you to schedule the installation of the correction if your unit is affected as the correction kit becomes available. This work will be done at no cost to your facility.

Actions to be taken by the User related to the issue provided in this notification:

A review of our records indicates that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.

Please complete and sign the attached URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION - RESPONSE FORM (Page 4) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy or by faxing the form to your local Datascope/Getinge Representative or office.

Please forward this information to all current and potential Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) users within your hospital/facility.

If you are a distributor who has shipped any affected products to customers, please forward this letter to their attention for appropriate action

This voluntary correction notification only affects the products listed on page 1; no other products are affected by this voluntary correction.

We apologize for any inconvenience this Medical Device Correction may cause. If you have any questions, please contact your local Datascope/Getinge Representative or office.

Sincerely,

[FULL NAME]
[TITLE]
Getinge

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION – RESPONSE FORM
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

[ADD ACCOUNT#
FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

I acknowledge that I have reviewed and understand this Urgent Medical Device Correction Letter regarding unexpected shutdown due to failure of the Coiled Cord cable and Cable Assembly backplane to Coiled Cord cable related to the affected Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s) at this facility.

I confirm that all users of the Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s) at this facility have been notified accordingly.

Please provide the required information and signature below.

Facility Representative Information:

Signature:_____ **Date:**_____

Name:_____ **Phone:**_____

E-Mail Address:_____

Title:_____ **Department:**_____

Hospital Name:_____

Address, City and State: _____

We have scrapped our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s):
Circle one **YES** **NO** **If yes, list Serial Numbers:** _____

We have sold/moved our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) to another facility:
Circle one **YES** **NO** **If yes, list Serial Numbers:** _____

If you answered YES above: please provide new facility information below.

New Facility Name:_____

New Facility Address:_____

New Facility Contact Name:_____ **New Facility Phone #:** _____

Return the completed form by FAX to XXXXXXX or by EMAIL to
xxxxxxxxx@getinge.com

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