[Month DD, YYYY]

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Reference Number: OT 1162381

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP)

Product Name	**CARDIOSAVE Hybrid & Rescue – All Plug Variants**
Product Code & UDI	

Product Name	Product Code	UDI #
CARDIOSAVE RESCUE, 3.1 EDITION	0998-00-0800-85	10607567113449
CARDIOSAVE HYBRID, 3.1 EDITION	0998-00-0800-65	10607567113432
CARDIOSAVE HYBRID - TYPE "N" PLUG	0998-00-0800-36	10607567114187
CARDIOSAVE HYBRID, TYPE B PLUG	0998-00-0800-53	10607567108391
CARDIOSAVE RESCUE	0998-00-0800-83	10607567108407
CARDIOSAVE RESCUE, CHINESE	0998-00-0800-75	10607567112312
CARDIOSAVE HYBRID W/ E/F PLUG	0998-00-0800-55	10607567108414
CARDIOSAVE HYBRID, TYPE G PLUG	0998-00-0800-52	10607567108438
CARDIOSAVE HYBRID, TYPE I PLUG	0998-00-0800-45	10607567108421
CARDIOSAVE HYBRID TYPE K PLUG	0998-00-0800-34	10607567111940
CARDIOSAVE HYBRID TYPE J PLUG	0998-00-0800-32	10607567111117

Manufacturing Dates for All:	**0998-00-0800-XX CARDIOSAVE Hybrid – All Plug Variants**	**Manufactured since 12-Dec-2012**	
Distribution Dates for All:	**0998-00-0800-XX CARDIOSAVE Hybrid – All Plug Variants**	**Distributed since 12-Dec-2012**	

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP) devices. IABPs distributed within affected countries are provided with Instructions for Use (IFU) that are not available in local language translation. This voluntary Correction only affects the countries where IFUs are required in a language other than English. Updated IFUs will be made available in the manner described below when translation is complete.

Identification of the issue:

During an internal review of Datascope's Cardiosave IABP registrations and labeling, Datascope/Getinge identified that the IFU supplied with IABPs to customers in affected countries is not available in the local language required by regulation in affected countries.

The Cardiosave IABP IFU is currently supplied in the following languages:

Chinese	Czech	Danish	Dutch	English	Finnish
French	German	Hungarian	Italian	Japanese	Korean
Norwegian	Polish	Portuguese	Russian	Slovak	Spanish
Swedish	Turkish				

Risk To Health:

The IFU not being available in the local language does not pose a risk to health, as it does not impact the user's ability to properly use the device.

Actions to be taken by the user:

Our records indicate that you may have one or more Cardiosave IABPs in your facility.

NO DEVICES NEED TO BE RETURNED.

- Complete and sign the attached Response Form (Page X) 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.

- Datascope/Getinge expects the necessary IFU translations will be completed by September 30, 2025. At which point we will provide a copy to your facility in your local language.

- The IFU that is currently in your possession can be used until an updated IFU in your local language is provided. If you have any questions or need clarification regarding any IFU content, please contact your local Datascope/ Getinge Sales/Service Unit (SSU) representative to obtain assistance.

    - <SSU add local contact information to this letter>

Please forward this information to all current and potential Cardiosave 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.

Actions to be taken by Datascope/Getinge:

Datascope/Getinge is initiating this Medical Device Correction to notify Cardiosave IABP Users of this IFU translation issue.

Datascope/Getinge is currently working to translate the IFUs to the following local languages required by affected country requirements.

Albanian	Bulgarian	Croatian	Estonian	Georgian	Greek
Kazakh	Latvian	Lithuanian	Romanian	Serbian	Slovenian
Ukrainian					

Once the translation is completed, Datascope/Getinge will provide the IFU to your facility in your local language.

We apologize for any inconvenience this Medical Device Correction may cause.

Sincerely,

_____

Ojas Zatakia
Sr. Director, Quality Assurance
Getinge/Datascope Cardiac Assist

[Month DD, YYYY]

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Reference Number: OT 1162381

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP)

DISTRIBUTION DATES:

0998-00-0800-XX CARDIOSAVE Hybrid – All Plug Variants

Distributed since 12-Dec-2012

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE]

I acknowledge that I have read and understand this Medical Device Correction Letter for the affected **Datascope Intra-Aortic Balloons (IAB)** at this facility. I confirm that all users of the above-mentioned products 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/discarded our affected product:

Circle one **YES** **NO**

We have sold/moved our affected product to another facility:

Circle one **YES** **NO**

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 INSERT LOCAL SSU FAX NUMBER or by EMAIL to INSERT LOCAL SSU EMAIL ADDRESS