[Month DD, YYYY]

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Reference Number: OT 1210922

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP) with Ultrasonic Doppler

Product Name	**CARDIOSAVE Hybrid – Ultrasonic Doppler**	
Product Code	**0154-01-0001, Ultrasonic Doppler**	
UDI-DI	**N/A – Doppler is Cardiosave Hybrid Accessory**	
Manufacturing Dates for All:	**0154-01-XXXX, Ultrasonic Doppler**	**Manufactured since 12-Dec-2012**
Distribution Dates for All:	**0154-01-XXXX, Ultrasonic Doppler**	**Distributed since12-Dec-2012**

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for the Ultrasonic Doppler supplied with Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP) devices. Ultrasonic Dopplers 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 registrations and labeling, Datascope/Getinge identified that the IFU supplied with Ultrasonic Dopplers to customers in affected countries is not available in the local language required by regulation in affected countries.

The Ultrasonic Doppler IFU is currently supplied in English only.

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 that is installed with the Ultrasonic Doppler.

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 Hybrid 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 Hybrid IABP Users of this Ultrasonic Doppler IFU translation issue.

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

Albanian	Bulgarian	Chinese	Croatian	Czech	Danish
Dutch	Estonian	Finnish	French	German	Greek
Hungarian	Italian	Japanese	Korean	Latvian	Lithuanian
Macedonian	Norwegian	Polish	Portuguese	Romanian	Russian
Serbian	Slovak	Slovenian	Spanish	Swedish	Turkish
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 1210922

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP) with Ultrasonic Doppler

DISTRIBUTION DATES:

0154-01-XXXX, Ultrasonic Doppler 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 Cardiosave Hybrid Intra-Aortic Balloon Pumps with Ultrasonic Doppler** 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