Month, Year

URGENT MEDICAL DEVICE CORRECTION

Datascope Cardiosave Hybrid Intra-Aortic Balloons (IAB)

Model Number	UDI	Model Name	Serial/Lot Numbers
0684-00-0478-01	10607567106526	Linear 7.5fr 25cc	All
0684-00-0478-02	10607567106533	Linear 7.5Fr. 25cc IAB (with APA)	All
0684-00-0479-01	10605767106557	Linear 7.5fr 34cc	All
0684-00-0479-02	10607567106540	Linear 7.5Fr. 34cc IAB (with APA)	All
0684-00-0480-01	10607567106564	Linear 7.5fr 40cc	All
0684-00-0480-02	10607567106571	Linear 7.5Fr. 40cc IAB (with APA)	All
0684-00-0294-01	10607567107950	MEGA 7.5fr 30cc	All
0684-00-0294-02	10607567107967	MEGA 7.5Fr. 30cc IAB (with APA)	All
0684-00-0295-01	10607567107974	MEGA 7.5fr 40cc	All
0683-00-0295-02	10607567107981	MEGA 7.5Fr. 40cc IAB (with APA)	All
0684-00-0296-01	10607567108001	MEGA 8fr 50cc	All
0684-00-0296-02	10607567108018	MEGA 8Fr. 50cc IAB (with Statlock & APA)	All
0684-00-0469-01	10607567106755	Sensation 7fr 34cc	All
0684-00-0470-01	10607567106779	Sensation 7fr 40cc	All
0684-00-0568-01	10607567108063	Sensation Plus 7.5fr 40cc	All
0684-00-0576-01	10607567108605	Sensation Plus 8fr 50cc	All
Manufacturing Dates:		Since 01-Feb-2023	
Distribution Dates:		Since 01-Feb-2023	

Dear Risk Manager,

The purpose of this letter is to advise you that Datascope, a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for Intra-Aortic Balloons (IAB). The Instructions for Use (IFU) and Blood Back Addendum provided with the IABs are not provided in the required local languages. This voluntary correction only affects the countries where IFUs are required in a language other than English.

Issue Description

During an internal review of Datascope's Datascope's Linear, Mega, Sensation, and Sensation Plus IAB registrations and labeling, Datascope/Getinge identified that the IFU supplied with IABs to customers in affected countries is not available in the local language required by regulation in affected countries.

The IAB Catheter IFUs and Blood Back Addendum document are currently supplied in the following languages:

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

Risks 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.

Customer Actions:

Our records indicate that you may have one or more IABs 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.
- 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 IAB 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.

Additional Information

Datascope/Getinge is initiating this Medical Device Correction to notify IAB 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	Georgian	Kazakh	Romanian
Serbian	Ukrainian				

Datascope/Getinge is currently working to translate the Blood Back Addendum document to the following local languages required by affected country requirements.

Albanian	Georgian	Kazakh	Serbian	Ukrainian

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

_____

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

[Month DD, YYYY]

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Reference Number: OT 1210924

Datascope Intra-Aortic Balloon (IAB)

Distributed since 01-Feb-2023

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