[Month DD, YYYY]

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Reference Number: OT 1210924

Datascope Intra-Aortic Balloons (IAB)

Product Name	**Linear, Mega, Sensation, & Sensation Plus Intra-Aortic Balloons (IAB)**
Product Code & UDI	

Model	Product Code	UDI
Linear 7.5fr 25cc	0684-00-0478-01	10607567106526
Linear 7.5fr 34cc	0684-00-0479-01	10605767106557
Linear 7.5fr 40cc	0684-00-0480-01	10607567106564
MEGA 7.5fr 30cc	0684-00-0294-01	10607567107950
MEGA 7.5fr 40cc	0684-00-0295-01	10607567107974
MEGA 8fr 50cc	0684-00-0296-01	10607567108001
Sensation 7fr 34cc	0684-00-0469-01	10607567106755
Sensation 7fr 40cc	0684-00-0470-01	10607567106779
Sensation Plus 7.5fr 40cc	0684-00-0568-01	10607567108063
Sensation Plus 8fr 50cc	0684-00-0576-01	10607567108605

Distributed Affected Lot Number:	**N/A**	
Manufacturing Dates for All:	**Intra-Aortic Balloons (IAB)**	**Manufactured since 01-Feb-2022**
Distribution Dates for All:	**Intra-Aortic Balloons (IAB)**	**Distributed since 01-Feb-2022**

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for Intra-Aortic Balloons (IAB). IABs 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 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 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					

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 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 is available in your local language is provided. If there are any questions on IFU content that your facility needs clarification on, please contact your local Datascope/ Getinge Sales/Service Unit (SSU) representative to obtain assistance.

    - <SSU add local contact information to this letter>

- 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.

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.

Actions to be taken by Datascope/Getinge:

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				

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 1124885

Datascope Intra-Aortic Balloon (IAB)

DISTRIBUTION DATES: Distributed since 01-Feb-2022

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