Month, Year

FIELD SAFETY NOTIFICATION

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP)

Reference Number: OT 1162381

Model Number	UDI	Model Name	Serial/Lot Numbers
0998-00-0800-XX 0998-UC-0800-XX	SSU to update to Correspond with Part Number distributed in country	Cardiosave Hybrid	All
0998-00-0800-XX 0998-UC-0800-XX	SSU to update to Correspond with Part Number distributed in country	Cardiosave Rescue	All
Manufacturing Dates:		December 2011- Current	
Distribution Dates:		Since March 06, 2012	

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 the Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP) devices. This correction is due to the Instructions for Use (IFU) provided with the IABPs 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.

Issue Description

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				

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 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.
- When the necessary IFU translations are completed, 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 Pumps (IABP) 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 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 regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

_____

[redacted]
Sr. Director, Quality Assurance
Getinge/Datascope Cardiac Assist

[Month DD, YYYY]

FIELD SAFETY NOTIFICATION

Reference Number: OT 1162381

Datascope Cardiosave Intra-Aortic Balloon Pumps (IABP)

0998-00-0800-XX / 0998-UC-0800-XX- CARDIOSAVE HYBRID

0998-00-0800-XX / 0998-UC-0800-XX- CARDIOSAVE HYBRID

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 **Cardiosave Hybrid Intra-Aortic Balloon Pumps** 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