May 2026

FIELD SAFETY NOTICE

Reference Number: OT 1210922

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP), CS 100 Intra-Aortic Ballon Pumps (IABP), and CS300 Intra-Aortic Ballon Pumps (IABP) with Maquet-Branded D900 Ultrasonic Doppler and Maquet-Branded D900 Ultrasonic Dopplers sold separately.

Product Name	**CARDIOSAVE Hybrid, CS100, and CS300 – Maquet-Branded D900 Ultrasonic Doppler**
Product Code	**0154-01-0001, Maquet-Branded D900 Ultrasonic Doppler**
UDI-DI	**N/A – Doppler is a Cardiosave Hybrid, CS100, and CS300 Accessory**
Manufacturing Dates for All:	**Since 12-Dec-2012**
Distribution Dates for All:	**Since 12-Dec-2012**

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for the Maquet-Branded D900 Ultrasonic Doppler supplied with Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP), CS100 IABP, and CS300 IABP devices, and can be purchased separately. Maquet-Branded D900 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.

Identification of the issue:

During an internal review of Datascope's Cardiosave registrations and labeling, Datascope/Getinge identified that the IFU supplied with Maquet-Branded D900 Ultrasonic Dopplers to customers in affected countries is not available in the local language required by regulation in affected countries.

Previously, the Ultrasonic Doppler IFU was 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, CS100 IABPs, and/or CS300 IABPs in your facility that is installed with the Maquet-Branded D900 Ultrasonic Doppler, and/or a separate Maquet-Branded D900 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 and have received the updated Doppler IFUs with the translation in your local language.
- 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.

Please forward this information to all current and potential Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP), CS100 IABP, CS300 IABP, and Maquet-Branded D900 Ultrasonic Doppler 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, CS100 IABP, CS300 IABP, and Maquet-Branded D900 Ultrasonic Doppler Users of this Ultrasonic Doppler IFU translation issue.

Two IFUs are enclosed with this Field Safety Notice that contain the following translations:

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

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

Sincerely,

Ojas Zatakia

Sr. Director, Quality Assurance

Getinge/Datascope Cardiac Assist

[May 2026]

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Reference Number: OT 1210922

Datascope Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP), CS 100 Intra-Aortic Ballon Pumps (IABP), and CS300 Intra-Aortic Ballon Pumps (IABP) with Maquet-Branded D900 Ultrasonic Doppler and Maquet-Branded D900 Ultrasonic Dopplers sold separately. DISTRIBUTION DATES:

0154-01-0001, Maquet-Branded D900 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, CS100 Intra-Aortic Balloon Pumps, and/or CS300 Intra-Aortic Balloon Pumps with Maquet-Branded D900 Ultrasonic Doppler** and/or a separate Maquet-Branded D900 Ultrasonic Doppler at this facility. I confirm that all users of the above-mentioned products at this facility have been notified accordingly.

I confirm that I have received the two Doppler IFUs that contain the translations for my local language.

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