GETINGE

January 2026

URGENT MEDICAL DEVICE CORRECTION
CS100 IABP
CS300 IABP
Battery Cycle IFU Specifications for CS100/CS300
Reference Number: OT 1407189

Product Description:	Product Code/Part Number:	UDI Code:
SSU to update to this section to include only the specific part numbers distributed in country/region		
CS100 IABP	0998-00-3013-45 0998-UC-3013-45	10607567107790
CS100 IABP	0998-00-3013-53 0998-UC-3013-53	10607567107394
CS100 IABP	0998-00-3013-55 0998-UC-3013-55	10607567107295
CS100 IABP	0998-00-3013-57 0998-UC-3013-57	10607567107776
CS100 IABP	0998-00-3013-58 0998-UC-3013-58	10607567107622
CS100 IABP	0998-00-3013-61	10607567112671
CS100 IABP	0998-00-3013-62	10607567112664
CS100 IABP	0998-00-3013-64	10607567107509
CS100 IABP	0998-00-3013-65 0998-UC-3013-65	10607567107684
CS100 IABP	0998-00-3013-67 0998-UC-3013-67	10607567107486
CS100 IABP	0998-00-3013-68 0998-UC-3013-68	10607567107691
CS100 IABP	0998-00-3013-69 0998-UC-3013-69	10607567107769
CS100 IABP	0998-00-3013-83 0998-UC-3013-83	10607567107400
CS100 IABP	0998-00-3013-85	10607567108094
CS300 IABP	0998-00-3023-43	10607567112534
CS300 IABP	0998-00-3023-45	10607567108575
CS300 IABP	0998-00-3023-53 0998-UC-3023-53	10607567107882
CS300 IABP	0998-00-3023-55 0998-UC-3023-55	10607567112541
CS300 IABP	0998-00-3023-57 0998-UC-3023-57	10607567108254
CS300 IABP	0998-00-3023-58 0998-UC-3023-58	10607567108339
CS300 IABP	0998-00-3023-61 0998-UC-3023-61	10607567108278
CS300 IABP	0998-00-3023-62	10607567108292
CS300 IABP	0998-00-3023-64 0998-UC-3023-64	10607567108308
CS300 IABP	0998-00-3023-65	10607567108322

Product Description:	Product Code/Part Number:	UDI Code:
	0998-UC-3023-65	
CS300 IABP	0998-00-3023-67 0998-UC-3023-67	10607567112619
CS300 IABP	0998-00-3023-68 0998-UC-3023-68	10607567108353
CS300 IABP	0998-00-3023-69 0998-UC-3023-69	10607567108377
CS300 IABP	0998-00-3023-83 0998-UC-3023-83	10607567108285
CS300 IABP	0998-00-3023-85	10607567108247
CS300 IABP	0998-00-3023-94	10607567108315

Distributed Affected Serial Number:	All	
Device:	CS100	CS300
Manufacturing Dates:	2003-2019	2007-2020
Distribution Dates:	2005-2020	2012-2020

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Field Safety Corrective Action for the CS300 and CS100 Intra-Aortic Balloon Pumps (IABP) to provide information regarding device battery cycle time.

Identification of the issue:

Datascope recently completed additional testing on the CS100/CS300 batteries and identified the battery runtime and cycle specifications contained in the devices' Instructions for Use (IFU) need to be updated. No CS100/CS300 IABP performance deficiencies were identified. See the current IFU Specifications as well as the updated IFU Specifications in the table below:

Current IFU Specifications	UPDATED IFU Specifications
IFU Section 11.9.2 Specifications: -Approximately 3 hours (180 min) with new battery 90 bpm, 22±5°C -2.25 hours(135min) minimum (120bpm, 22 ± 5°C) **IFU Section 7.7 Batteries:** -Replace batteries as required. Batteries should be replaced after 100 full discharge cycles, at no more than three (3) year intervals, or if run time is less than the minimum run time (see Specifications Section).	**IFU Section 11.9.2 Specifications:** -2.25 hours(135min) minimum (120bpm, 22 ± 5°C) **IFU Section 7.7 Batteries:** - Batteries should be replaced every 3 years or if the Battery Runtime Test fails during Preventive Maintenance

CS100/CS300 batteries should be replaced every three (3) years, rather than based on discharge cycles. Testing was conducted to verify that batteries continue to deliver adequate therapy throughout their three-year lifespan, provided preventative maintenance is performed as scheduled. However, if preventative maintenance is not performed as scheduled, battery performance may fall below the required 135 minutes of therapy at 120 BPM. The instruction to replace the device battery every three (3) years, or sooner if it does not meet specifications during Preventive Maintenance, has been included in the Service

Manual for the CS100 and CS300 IABP devices since product launch in July 2003 and June 2007, respectively.

Testing also found that new and previously used batteries both run at a minimum of 135 min at 120 BPM over the three-year period. As such, the reference to a difference in runtimes between new and used batteries at different beats per minute (bpm) is unnecessary and potentially confusing ("used" is defined as a battery which has completed one [1] discharge cycle), hence we are updating the IFU statement to remove "Approximately 3 hours (180 min) with new battery 90 bpm, 22±5°C" and to remove the reference to new batteries and to reflect a singular runtime.

The IFU Specifications have been updated in Appendix A to reflect this change and are listed above.

From October 1, 2020, to October 31, 2025, a total of three (3) complaints were reported to Datascope regarding batteries that did not meet the current IFU specifications. Two (2) complaints were received regarding batteries that did not meet the specification of 100 discharge cycles. There were no deaths, serious injuries, or other adverse events associated with these complaints. One (1) complaint was received regarding batteries that did not meet the 180-minute runtime specification for new batteries. There was no patient involvement and therefore no death, serious injury, or adverse event associated with this complaint.

Risk to Health:

Even if the customer is not aware of the reduced battery runtime (anticipated 180 minutes at 90 bpm of therapy for new battery versus an actual 135 minutes at 120 bpm for battery having undergone at least 1 discharge cycle), the hospital use environment provides multiple mitigations, such as continuous availability of AC power, access to replacement batteries, and availability of alternate IABP consoles, that significantly limit both the likelihood and duration of any resulting therapy interruption.

However, during external (inter-hospital) transport, if the customer does not anticipate the reduced battery runtime (135 minutes versus the expected 180 minutes), a therapy interruption may occur if the transport duration exceeds the available battery capacity within the transport vehicle. Such an interruption of therapy may result in hemodynamic instability.

Updated Battery Specifications:

Please see Appendix A of this letter for updated battery specification information.

Actions to be taken:

Our records indicate that you may have one or more CS300 and/or CS100 Intra-Aortic Balloon Pumps in your facility.

- Please forward this information to all current and potential CS300 and/or CS100 Intra-Aortic Balloon Pump users within your facility.
- Confirm Users are aware of IFU clarifications for batteries. There is no indication that battery cycles need to be monitored. Replace CS100/CS300 batteries (Part #: 0146-00-0039) every three years, and when a battery fails the Battery Runtime Test. No additional Preventative Maintenance or testing is required.
- Complete and sign the attached Response Form to acknowledge that you have received and understand this notification. Return the completed form to [add SSU contact information].

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Adverse events or quality problems experienced with the use of any of the products mentioned in this document may be reported to local Competent Authorities. Please follow the current regulations on adverse event reporting in your country.

We apologize for any inconvenience this correction may cause. If you have any questions, please call Datascope/Getinge Customer Support [add SSU contact information].

Sincerely,

Ojas Zatakia

Senior Director Quality Assurance & Regulatory Compliance

APPENDIX A
Updated CS300 and CS100 Intra-Aortic Balloon Pump Battery Specification

IFU Section 11.9.2 Specifications:
-2.25 hours(135min) minimum (120bpm, 22 ± 5°C)

IFU Section 7.7 Batteries:
- Batteries should be replaced every 3 years or if the Battery Runtime Test fails during Preventive Maintenance

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January 2026

URGENT MEDICAL DEVICE CORRECTION RESPONSE FORM

CS100 IABP

CS300 IABP

Battery Cycle IFU Specifications for CS100/CS300

Reference Number: OT 1407189

CS100: 2005-2020 / CS300: 2012-2020

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Correction Notice for the CS300 and CS100 Intra-Aortic Balloon Pumps. Please ensure that all users of the CS300 and CS100 Intra-Aortic Balloon Pump 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:_____

Return the completed form to [add SSU contact information].