[Month DD, YYYY] via [INSERT METHOD]

URGENT FIELD SAFETY NOTICE
THIS IS AN UPDATE TO PREVIOUSLY INITIATED ACTIONS for FSCAs
MAQUET CARDIOSAVE Hybrid and MAQUET CARDIOSAVE Rescue

Product Description:	Product Code/Part Number:	UDI Code:
Cardiosave Hybrid	0998-00-0800-31 0998-UC-0800-31	10607567109053 N/A
Cardiosave Hybrid	0998-00-0800-32	10607567111117
Cardiosave Hybrid	0998-00-0800-33 0998-UC-0800-33	10607567109008 N/A
Cardiosave Hybrid	0998-00-0800-34	10607567111940
Cardiosave Hybrid	0998-00-0800-35	10607567109107
Cardiosave Hybrid	0998-00-0800-36	10607567114187
Cardiosave Hybrid	0998-00-0800-45	10607567108421
Cardiosave Hybrid	0998-00-0800-52 0998-UC-0800-52	10607567108438 N/A
Cardiosave Hybrid	0998-00-0800-53 0998-UC-0800-53	10607567108391 N/A
Cardiosave Hybrid	0998-00-0800-55 0998-UC-0800-55	10607567108414 N/A
Cardiosave Hybrid	0998-00-0800-65	10607567113432
Cardiosave Rescue	0998-00-0800-75	10607567112312
Cardiosave Rescue	0998-00-0800-83	10607567108407
Cardiosave Rescue	0998-00-0800-85	10607567113449

Distributed Affected Lot Number:	All
Manufacturing Dates:	Since December 2011
Distribution Dates:	Since March 06, 2012

Dear insert Healthcare Professional title,

Datascope Corp., a subsidiary of Getinge, is notifying customers of an **update to the below previously submitted** Field Safety Corrective Actions for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP). This notification does not apply to customers based in the United States.

Manufacturers Report #	Issue #	Short Description	Risk To Health
2249723-09/20/2018-002-C	1	Altitude Issue	Hemodynamic instability
2249723-05/17/2019-001-C	2	Battery Usage, Charging, Maintenance and Storage	Hemodynamic instability
2249723-03/01/2021-001-C	3	Cybersecurity Vulnerabilities – Ripple20	Patient Health/Clinical data cannot be transmitted or received
2249723-08/13/2021-002-C	4	Helium over-reporting	Hemodynamic instability
	5	Shutdown Upon Battery Removal	Hemodynamic instability
2249723-01/24/2023-002-C	6	Code 111/ Code 112	Hemodynamic instability
2249723-06/02/2023-012-C	7	Battery Docking Issues	Hemodynamic instabiltity

Datascope/Getinge has developed a software correction to mitigate these issues and the software upgrade is now available. Your device may already have been corrected with this software upgrade—see below instructions to confirm your current Software Revision. If your device has not already been corrected, a Datascope/Getinge service representative will contact you to schedule the installation of the updated software. This work is being done at no cost to your facility.

The Cardiosave Intra-Aortic Balloon Pump is an electromechanical system used to inflate and deflate intra-aortic balloons. It provides temporary support to the left ventricle via the principle of counterpulsation as stated in the Instructions For Use.

Risk to Health:

No new risk is presented as part of this update.

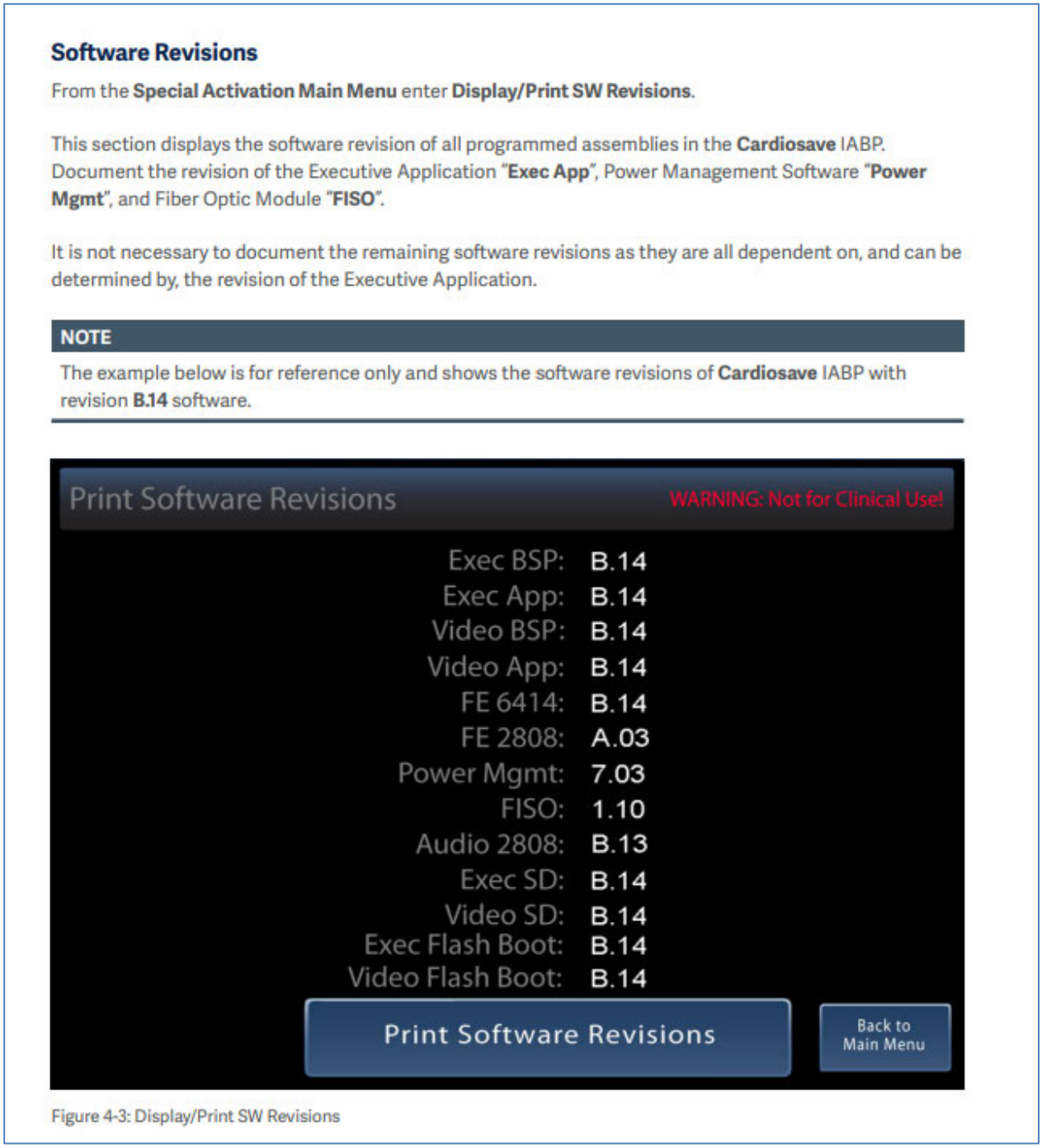
Actions to be taken by the User related to all issues provided in this notification:

A review of our records indicates that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in your facility.

1. Examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.
2. Identify the Software Revision currently installed on your affected devices. Refer to Figure 1 below for instructions on how to identify the revision of software currently installed on your device.
    - If each of your affected devices have software revision D.00 or D.01, your devices have been corrected for purposes of the above Field Safety Corrective Actions.
        i. Getinge/Datascope sent a separate Field Safety Corrective Action notice to customers on [date] (FSCA 2249723-11/16/2022-001-C) regarding the

potential for blood to enter into the Cardiosave Hybrid and Rescue IABPs, for which software revision D.01 was released as a correction. D.01 contains each of the corrective updates from D.00 and adds the correction for a blood back event.

- If any of your devices have software revision lower than D.00 or D.01 (e.g.: B.XX or C.XX), your device still requires the software update and has not yet been corrected.



Software Revisions

From the **Special Activation Main Menu** enter **Display/Print SW Revisions**.

This section displays the software revision of all programmed assemblies in the **Cardiosave** IABP. Document the revision of the Executive Application "**Exec App**", Power Management Software "**Power Mgmt**", and Fiber Optic Module "**FISO**".

It is not necessary to document the remaining software revisions as they are all dependent on, and can be determined by, the revision of the Executive Application.

NOTE

The example below is for reference only and shows the software revisions of **Cardiosave** IABP with revision **B.14** software.

Figure 4-3: Display/Print SW Revisions

Figure 1: Instructions for identifying your IABP device's current Software Revision.

3. If your device has not been corrected with the updated Software Revision, **please continue to follow the instructions as listed in the original notifications until your devices have**

had their software updated. Please contact your local Getinge Representative if you need an additional copy of the original notifications.

4. Complete and sign the attached Response Form (Page 5) 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.

5. Datascope/Getinge service representative will contact you to schedule the installation of the updated software. You may also contact your local Getinge Service representative at XXXXXXX. This work is being done at no cost to your facility.

Please forward this information to all current and potential Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) 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.

This voluntary correction notification only affects the products listed on page 1; no other products are affected by this voluntary correction.

We apologize for any inconvenience these Field Safety Corrective Actions may cause. If you have any questions, please contact your local Datascope/Getinge representative.

Sincerely,

[Name]
[Title]
Getinge

[Month DD, YYYY]

THIS IS AN UPDATE TO THE PREVIOUSLY INITIATED ACTION

URGENT FIELD SAFETY NOTICE – MEDICAL DEVICE RESPONSE FORM
FSCAs 2249723-09/20/2018-002-C, 2249723-05/17/2019-001-C, 2249723-03/01/2021-001-C, 2249723-08/13/2021-002-C, 2249723-01/24/2023-002-C, 2249723-06/02/2023-012-C

MAQUET CARDIOSAVE Hybrid and MAQUET CARDIOSAVE Rescue

Distribution Dates: since March 6, 2012

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

I acknowledge that I have reviewed and understand this Field Safety Corrective Action **update** for the affected Cardiosave Intra-Aortic Balloon Pump(s) at this facility for this issue.

I confirm that all Users **and Nurse Educators** of the Cardiosave Intra-Aortic Balloon Pump(s) at this facility have been notified accordingly.

☐ All affected devices at this facility have been updated to software revision D.00 or higher.

☐ Affected devices at this facility have not yet been updated.
If device software has not been updated, please list the Serial Number(s) at this facility that require update:

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 Cardiosave Hybrid and/or Rescue Intra-Aortic Balloon Pump(s):
Circle one **YES**
If yes, are all units scrapped? Circle one **YES** **NO**

We have sold/moved Cardiosave Hybrid and/or Rescue Intra-Aortic Balloon Pump(s) to another facility:
Circle one **YES** **NO** **If yes indicate Serial Number(s):** _____
If yes, were all units sold? 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

Getinge