

To whom it may concern

Dear Customer,

In view of the situation with the Novel Coronavirus (2019-nCoV), we hereby want to provide guidance on appropriate infection prevention and control (IPC) measures for the use of Intra-Aortic Balloon Pumps (IABP) when treating patients with a confirmed or suspected infection.

As a first step, make sure to stay up-to-date with information published on the World Health Organization (WHO) website regarding patient management:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patientmanagement>

With the current COVID-19 pandemic there are many questions on how to clean and disinfect capital equipment in hospitals. Getinge is making major efforts to contribute to the containing of this infection and treating patients.

Getinge has a project underway that will update the Cardiosave IABP Instructions for Use, disinfection instructions, later this year. Taking into consideration the current situation with the fast spreading COVID-19 virus, we want to share with you some of these recommendations immediately.

Please, follow the standard protocol established in your hospital for the proper procedure of cleaning and disinfection of capital equipment as well as the **guidelines below for all Getinge Intra-Aortic Balloon Pumps (Cardiosave, CS100 and CS300):**

Pre-Cleaning the System and Accessories

Pre-cleaning involves removing gross soil and larger debris from the system and accessories. Use an alcohol free, bleach free, acid free, phenol free, acetone free, and ammonia free quaternaly based detergent for example, Sani-Cloth® AF3 Germicidal Disposable Wipes, or Clinell® Universal Wipes to remove all gross soil from the unit (including display and touchscreen) and accessories (e.g. ECG and blood pressure cables). Pay special attention to small gaps around controls, seams, vent grates, and any other hard to reach areas. Use as many wipes as needed to effectively remove all gross soil. Use a small low lint or lint free swab

containing the detergent to remove all gross soil from tight crevices and gaps such as the area outlining the on/off button.

Cleaning the System and Accessories

After pre-cleaning is complete, using the identified wipes and detergent described above, continue cleaning the unit and accessories by wiping and using the top to bottom, clean to dirty approach. Use a small low lint or lint free swab containing the detergent to clean tight crevices and gaps such as the area outlining the on/off button. If the wipe you are using becomes dry or dirty, replace with a new wipe and continue cleaning.

Inspect the unit and accessories for visible soil, if any soil is present, continue cleaning using the previously stated techniques until no visible soil exists. When cleaning is complete, wipe the unit using a lint free cloth moistened with warm deionized water to remove any detergent residue. After cleaning is complete, allow the unit to air dry.

Disinfection

After a thorough cleaning, the unit needs to be disinfected. To disinfect your Getinge IABP, Getinge recommends using an alcohol-free, bleach-free, acid-free, phenol-free, acetone-free, and ammonia-free quaternary based detergent (appropriate for intermediate level disinfection), for example, Sani-Cloth® AF3 Germicidal Disposable Wipes, or Clinell® Universal Wipes” (follow the instructions located on the detergent container). Follow the instructions of the manufacturer of the disinfectant. Allow treated surfaces to remain wet for at least three [3] minutes. Treated surfaces need to remain wet for a minimum of three [3] minutes for full effectiveness.

Getinge remains committed to helping you deliver optimal IABP therapy and to safely operate the hardware necessary in this pandemic restrictive environment. We thank you for your continued support as well as your continued work on patient therapy and safety.

Sincerely,

Getinge