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Addendum to: Cardiosave IABP Operating Instructions – Clinical Considerations
IAB IFU Balloon Membrane Perforation

For use of Cardiosave Hybrid IABP and Cardiosave Rescue IABP with Linear, Mega, Sensation, Sensation Plus, Yamato Plus-R, Trans-Ray and Trans-Ray Plus IABs.

A. Balloon Membrane Perforation

Balloon membrane perforation may be caused by:

- Contact with a sharp instrument.
- Fatigue failure due to unusual (biaxial) folding of the balloon membrane during use.
- Contact with calcified plaque resulting in abrasion of the surface and eventual perforation.

If perforation occurs, blood may be visible in the IAB catheter. If balloon membrane perforation occurs or is suspected it may also be evidenced by: 1) bright red blood, dried blood particles or serosanguineous fluid seen in the extracorporeal tubing or catheter extender; 2) a sudden change in the diastolic augmentation pressure waveform and/or 3) certain IAB pump alarms. Do not bypass these alarms, and pay close attention to the alarm notifications. The following Cardiosave alarms are designed to assist the user to identify and address a perforated balloon earlier, which may prevent blood from traveling into the IABP:

- Autofill Failure – Blood Suspected
- Autofill Failure
- Gas Gain in IAB Circuit
- Gas Loss in IAB Circuit
- IAB Catheter Restriction

Periodically check the IAB catheter tubing for blood both throughout therapy and when the above alarms occur. If any blood is noted or perforation is suspected, the following procedure must be performed immediately:

1. Stop pumping by placing IABP console in Standby.
2. Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate.
3. Clamp extracorporeal tubing between white y-fitting and male connector.
4. Notify physician, and prepare for IAB catheter removal.
5. Consider IAB catheter replacement, if the patient's condition warrants.
6. If blood is suspected of having entered the pump, take pump out of service. It should be evaluated before use in another patient by Biomed/Technical Service to determine if replacement of contaminated components is necessary.

WARNINGS

- If you continue to pump an IAB catheter with a leak, gaseous embolic injury of organs may result or a large blood clot may form within the balloon membrane requiring surgical removal of the IAB catheter.
- Do not inflate the IAB using a syringe or any other means if a balloon membrane leak is suspected.
- Should an IAB membrane perforation occur, blood may be permitted to travel into the IABP console. To prevent blood loss and damage to the IABP console, stop therapy, disconnect catheter extender tubing from the IABP console, and clamp the extracorporeal tubing.
- Perforation of an IAB membrane may indicate that the patient's vascular condition may induce abrasion or perforation in subsequent IAB membranes.
- An unexpected shutdown due to a blood back event may threaten the hemodynamic stability of the supported patient as the User is left unaware to the status of the IABP. Additionally, any subsequent attempts to use a console that experienced a blood back event without reconditioning may delay future therapy delivery.
- The user and subsequent maintenance or service personnel can be exposed to an unexpected biohazard should proper containment precautions not be taken.
- Subsequent patients may be exposed to an unexpected biohazard should an impacted console not be appropriately serviced prior to use.

For the Cardiosave Intra Aortic Balloon Pump:

- During hospital use, it is advised another Cardiosave be available to provide therapy should the Cardiosave in use be compromised.
- It is advised not to transport a patient receiving counterpulsation therapy via Cardiosave unless the clinician deems the benefit of transport outweighs the risk of unexpected shutdown.

Note: The length of time a balloon membrane can survive such contact with plaque or unusual folding is unpredictable. A leak in an IAB catheter within the bloodstream may allow gas to enter the patient's bloodstream which may result in patient injury. Large perforations are rare, therefore the small quantity of gas released is usually asymptomatic. The rate of incidence at each individual hospital may be influenced by the degree of vascular disease in that patient population, by the location of the IAB catheter in the aorta, or by using a balloon membrane size inappropriate for the specific patient.

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