

Urgent Medical Device Recall

30/40/50 CC IAB Volume Connectors
MANUFACTURER: Arrow International

APPENDIX B

When setting up and using the unit follow all instructions in the Operator's Manual.

1. As stated in the Operators Manual (See pages: 5-4 to 5-11 and 6-4 for ACAT1; 5-3 to 5-11 and 6-13 for AutoCAT 2 rev.2.21 and 5-3 to 5-11 and 6-13 for AutoCAT 2 rev 2.23.) this issue can be recognized immediately by verifying the VOLUME SETTING displayed on the screen of the ACAT 1 Plus and AutoCAT 2 Series IABP Console. The currently set volume of the IAB balloon pump catheter is shown in the Lower Right Area of the display, below the Hemodynamic values and above the HE tank bar graph. As soon as the IAB connector is securely connected, the volume of the corresponding IAB catheter and connector should be properly displayed in the area shown. The IAB volume is also printed on the recorder strip.



When setting up the IABP console for use, ensure that the following steps are completed.

2. **Verify** that all connections are made properly. This includes the ECG cables, Arterial Pressure connections (AP) and the IAB volume connector. (See pages: 5-4 to 5-11 and 6-4 for ACAT1; 5-3 to 5-11 and 6-13 for AutoCAT 2 rev.2.21 and 5-3 to 5-11 and 6-13 for AutoCAT 2 rev.2.23).

3. **Verify** that after the IAB connector of the IAB pump tubing assembly is attached to the IABP console, the volume setting is correct for the corresponding connector that is listed below. The volume settings are as follows for the each color coded connector below:

- a. **White Connectors: 30cc**
- b. **Blue Connectors: 40 cc**
- c. **Orange Connectors: 50 cc**



4. If the volume is properly displayed, no further action is required. **Set the AUG Alarm (see section 8b below)**: When the augmentation alarm is set and the Augmentation falls below the set limit, the IABP console will alert the clinician with an audible alarm and a screen message that states “AUG BELOW SET LIMIT”. This alarm will alert the clinician when the level of augmentation is not being provided to the patient. If this alarm occurs, the clinician should assess the patient and the IABP and verify that the IAB volume setting is set to the correct level. The IAB volume, that is shown on the screen and recorder should be verified as per your hospital policy, but at least every 2 hours as described in the operator’s manual.
5. If the volume is NOT properly displayed and reads 2.5cc on the AutoCAT 2 Series or 5.0cc on the ACAT 1 Series;
- a. **Disconnect and Reconnect the IAB Pump Tubing Assembly connector** making sure the IAB pump tubing assembly connector is fully seated in the receptacle.



- b. **Verify the IAB volume setting on the IABP.** If it is showing the correct volume, no further action is required.
6. If the IAB volume is still **INCORRECT**, you should replace the IAB Pump Tubing assembly with a tubing assembly of the same volume size.
 - a. **DISCONNECT** the IAB pump tubing assembly at the QUICK CONNECT on the balloon.
 - b. **REPLACE** with another appropriate size pump tubing assembly. Pump Tubing Assembly may be ordered from Arrow using 30cc (Part Number IAK-02696), 40cc (Part Number IAK-02695), and 50cc (Part Number IAK-02693).
 - c. **RECONNECT** to IABP and verify IAB volume setting is correct, as described above.

WARNING:

Use of an incorrectly sized IAB pump tubing assembly can result in under or over delivery of Helium to the IAB. This may reduce cardiac support or increase the risk of Helium embolism in the event of a leak in the IAB. This can also increase the risk of thrombus formation on the IAB balloon catheter that is implanted in the patient. If the thrombus formation is somehow dislodged from the catheter, it could potentially cause end organ damage or neurological deficits (i.e., stroke or transient ischemic attack).

Ensure that if an alternative pump tubing assembly is used, that it is the same volume as the pump tubing assembly that it is replacing.

7. If replacing the IAB pump tubing assembly with an assembly that does NOT correct the problem, change to another IABP console and notify your local Biomedical support staff or contact Teleflex Medical/Arrow IABP Worldwide Service.
8. Once pumping has been started take the following steps (if the pump is not performing properly refer to the operator's manual for proper operation of the IABP) :
 - a. **Assess** the AP waveform and note that Augmentation is present during IAB inflation. If the IAB volume is very low, Augmentation may not be present or may be very low. (See pages 5-14 to 5-18 and 9-15 to 9-18 for ACAT1; 6-16 to 6-18 and 8-20 to 8-22 for AutoCAT 2 rev.2.21; 6-18 and 8-24 to 8-26 for AutoCAT 2 rev2.23 for AP waveform/Timing assessment and assessment of augmentation).
 - b. **Set the AUG Alarm:** The augmentation alarm when set will alert the clinician with an audible alarm and a screen message that states "AUG BELOW SET LIMIT". This alarm will alert the clinician that the proper augmentation/pressure

is not being delivered to the patient. To set the augmentation alarm:

- i. **Press AP SELECT**
- ii. **Press AP Alarm**
- iii. **TURN AP Alarm ON**
- iv. **Verify AUG Alarm is selected**
- v. **Set AUG AP Alarm to appropriate value based on patient condition and hospital protocol.**
- vi. **See pages 10 to 11 for ACAT1; 3-33 to 3-34 for AutoCAT 2 rev.2.21 and 3-34 and 3-35 for AutoCAT 2 rev.2.23 for further information on the AP Alarm**

C. If the unit defaults to 2.5cc or 5cc volume (the inappropriate pumping volume) discontinue use of the pump tubing assembly - refer to, and follow, the instructions given in step 6 of this Appendix (B). The volume cannot be adjusted at the pump in this circumstance - this can only be corrected by replacing the pump tubing assembly.

9. Refer to the operator's manual for proper operation of the IABP.