

# IABP system analysis

## Comparison of Volume Displacement and Inflate/Deflate Time

Intra-aortic balloon counterpulsation (IABP) is the most frequently employed method of assistance for patients with left ventricular (LV) failure. Over 125,000 intra-aortic balloons (IAB) are placed worldwide annually. Although the IABP is an adjunctive rather than primary therapy, many studies have shown that counterpulsation has a positive impact on patient outcome.

The effectiveness of IABP is determined by several factors such as IAB size relative to the aorta (occlusivity), ability to track arrhythmias, speed of inflation and deflation and proper timing of IAB inflation and deflation within the cardiac cycle. While speed is important, the ability to displace volume is the actual event which determines the effectiveness of augmentation and unloading. The purpose of this test is to quantify the performance (speed) and volume delivery of two commercially available IAB catheters on several different IABP consoles.

**Methods:** Experiments were performed using the TMS (Test Measurement System, Arrow International, Everett, MA.) This system is a heated water bath with the ability to measure IAB/IABP performance parameters. These measurements include inflation/deflation speed and total volume displaced by the IAB. This system is used to provide data for FDA 510(k) regulatory review. Data was collected on a standard PC via a data acquisition card at 250Hz. Data was imported into Excel for storage and graphing.

**Test protocol:** An Arrow IAB-04840U or IAB-05840U (8 Fr. 40cc IAB) was used for all tests. The data represents the average of 10 IAB catheters on each console. IABP systems tested were the Arrow ACAT® 1 PLUS, Arrow AutoCAT™, and Datascope® System 98. All IABP systems were operating in their latest configuration. The test was performed under standard FDA regulatory measurement conditions. These include bath heat 98.6 degrees (37°C), system pressure at midpoint of the IAB (75 mmHg) and heart rates varied from 60 to 200 bpm.

The IAB was connected to each IABP console as recommended by the manufacturers' instructions for use, using the standard driveline tubing included in the IAB package. Each IABP console was connected to the Fogg ECG simulator as specified in each operator's manual.

Timing was set to ensure a 50% inflated and 50% deflated cycle time. Purge or fill cycles were instituted on all pumps to ensure optimal performance of each IABP system, as per manufacturer's instructions.

Volume displacement is measured in cc's and is based on the displacement of water during IAB inflation. Inflation and deflation times are calculated based on the volume displacement curve which is generated from the TMS. The inflation and deflation times are measured from the 10 to 90% points on the inflation or deflation curve. All inflation and deflation time is shown in msec. Total cycle time is the sum of inflation and deflation times.

**Summary of Results:** Data from each IABP console was recorded. The following 4 traces are shown on the graphs:

- Bar 1: Volume displaced in ccs
- Bar 2: Total cycle time in msec
- Bar 3: Deflate time in msec
- Bar 4: Inflate time in msec

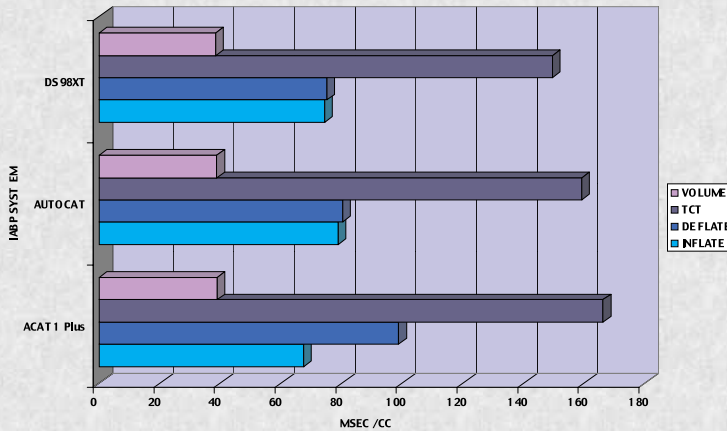
ACAT® and AutoCAT™ displaced .5cc more volume than the Datascope® System 98. The ACAT® was substantially faster on inflation than the other systems.

When you compare the actual volume displacement per msec, the performance of all of these systems is similar.

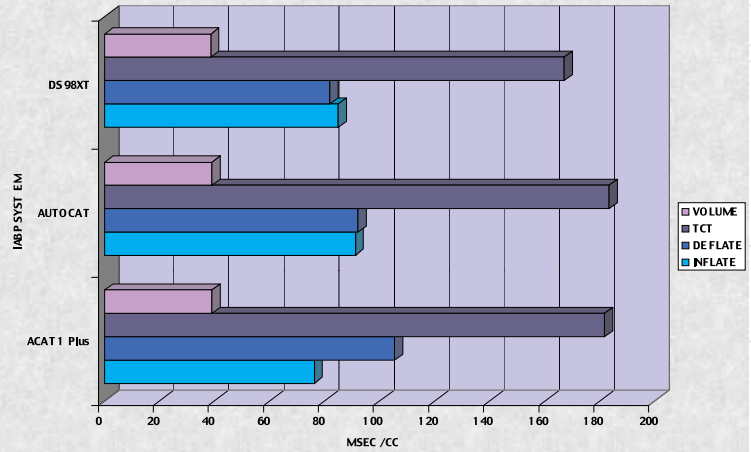
IABP SYSTEM	IAB-04840U	IAB-05840U
ACAT®	.235cc/msec	.216cc/msec
AutoCAT™	.244cc/msec	.213cc/msec
D/S 98	.257cc/msec	.231cc/msec

The IAB-04840U is slightly faster than the IAB-05840U, but the 5840U had slightly higher volume displacement. This is likely due to the difference in IAB design and dimensions.

**IAB-04840-U PERFORMANCE**  
**VOLUME DISPLACEMENT AND SPEED**  
 Average of Heart Rates from 60 to 180 BPM @ 75 MMHG



**IAB-05840-U PERFORMANCE**  
**VOLUME DISPLACEMENT AND SPEED**  
 Average of Heart Rates from 60 to 180 BPM @ 75 MMHG



**Conclusion:** The Arrow IABP systems (ACAT® 1 PLUS and AutoCAT™) provided more volume displacement on both IAB's than the D/S 98. This could result in slightly better augmentation in the clinical environment. The ACAT® had the fastest inflation time.

When the volume delivery per msec is calculated, the performance of the systems is basically similar and well within accepted performance standards for IABP systems.

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