Microbial Ingress Performance - Comparison of BD Insyte™ Autoguard™ BC Shielded IV Catheter with Blood Control Technology to Medikit Supercath™ 5 and BD Insyte™ Autoguard™ Shielded IV Catheter without Blood Control Technology

Study Summary
1. This study examined whether adding a blood control valve to peripheral intravascular catheters (PIVs) would increase the number of microorganisms that can be recovered from the devices when these microorganisms were deliberately introduced into the device.
2. This study was powered to show a statistically significant difference between PIVs with and without blood control valves (60 devices/group).
3. For both the low and high concentrations of *S. epidermidis* the Medikit Supercath™ 5 device had significantly higher numbers of microorganisms recovered compared to the other devices tested.
4. There was no significant difference in this study between BD Insyte™ Autoguard™ BC shielded IV catheter with blood control technology and BD Insyte™ Autoguard™ shielded IV catheter without blood control technology.
5. Further work will be required to determine whether the statistical differences shown in this study are clinically relevant.

Introduction
With the introduction of blood control technology into the BD Insyte Autoguard shielded IV catheter family of products, it was necessary to understand the effects these new technologies have on catheter flushing and the potential for bacterial growth. The BD Insyte Autoguard BC catheter with blood control technology product is designed to reduce blood exposure during the placement of the PIV. The device has been engineered for improved performance during flushing, and microbial ingress or bacterial growth testing was used to evaluate this performance. This study compared three devices: BD Insyte Autoguard BC (BD IAG BC), Medikit Supercath 5 (Medikit S5), and a catheter without blood control technology, BD Insyte Autoguard (BD IAG).

Procedure
Each device to be tested was inserted into a simulated vein filled with blood, the catheter was advanced, and the needle was removed. A BD Q-Syte™ Luer Access Split Septum device was secured to the catheter hub. Then, the assembly was removed from the vein and ½ mL of a suspension of bacteria (*Staphylococcus epidermidis*) was injected into the catheter through the BD Q-Syte device. Next a flush syringe was secured to the BD Q-Syte device, and the system flushed with 3 mL of saline. After 24 hours incubation at 35° C, bacteria in the catheter assemblies were quantitatively cultured. Two bacterial concentrations were used in these studies: 10^3 and 10^6 CFU/mL. These concentrations were intended to simulate a high level of clinical contamination and an elevated concentration to identify differences between devices. For reference, it is estimated that between 10 to 100 bacteria would be transferred to the device during touch contamination.

Results
Figure 1 shows the average number of recovered bacteria for each device.

Statistical Analysis
Data were transformed into Log2. ANOVA was used to compare the groups. For both inoculum levels, the Medikit S5 device had significantly higher numbers of microorganisms recovered compared to the BD IAG BC and the BD IAG catheters.

The BD IAG BC device with blood control technology was not significantly different from the BD IAG device without blood control technology for either inoculum.

Conclusions
Two different PIVs with blood control technology were compared in the laboratory. The devices had significantly different results demonstrating that not all blood control PIVs perform the same. The BD IAG BC device does not increase bacterial growth risk as compared to a standard IV catheter without blood control technology.

Although the conditions of this laboratory testing simulated those expected to be encountered in clinical practice as described, the relationship between this testing and actual clinical outcomes has yet to be established.

![Figure 1. Recovered CFU Comparison](image-url)