ivWatch Model 400: Effect of Catheter Depth

ivWatch Study ID: IVW-CLR-CS02-400

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Number of subjects: 28

Number of IV sites: 56

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Abstract/Informational Paragraph:

The Effect of Catheter Depth Study was performed to investigate how catheter depth affects the sensitivity of the ivWatch device. In the design of the ivWatch Sensor Cable, optical models were developed assuming the infiltrate was located approximately 3-5 mm beneath the skin, which is a common depth for peripheral IV veins. These models suggested the sensitivity of the ivWatch device should decrease as the infiltrate is placed deeper into the tissue. This study empirically investigated the relationship between depth and the performance of the ivWatch device. Catheters were placed adjacent to veins in the forearms of healthy adult volunteers. The tip of these catheters were placed next to veins between 2 and 8 mm deep using ultrasound imaging. The tissue was then infiltrated up to 30 mL of isotonic saline solution. The ivWatch Model 400 detected 100% (29/29) of the infiltrations placed within 5mm of the skin surface. The device sensitivity decreased for greater depths. The 5-7mm depth class had a sensitivity of 38% (5/13) and the 7-9mm depth class had a sensitivity of 50% (7/14). A linear regression analysis demonstrated that the presence of a hyperechoic fascia above the catheter tip (as seen in the ultrasound image) corresponded to a smaller infiltration signal. This effect was more dominant than depth alone suggesting that this tissue boundary acts to confine the fluid to deeper regions in the tissue making the detection of the infiltration more difficult.