ivWatch SmartTouch Sensor: The Effect of PIV Depth and Site

ivWatch Study ID: IVW-CLR-CS25-400

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Number of subjects: 64

Number of IV sites: 128

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Abstract/Informational Paragraph:

The Effect of PIV Depth and Site was performed to further understand how the depth and site of the catheter in a subject's tissue affects the performance of the SmartTouch Sensor. A total of 65 adult volunteers were enrolled in the study for a total of 64 accepted case studies. There were two parts to the study including 1) a site portion where IV site locations, hand, forearm and AC, were investigated with randomly assigned infiltration rates and 2) a depth portion where tissue was investigated at different catheter placement depths on the forearm. For the site portion of the study (part 1), configurations that specified IV site location and infiltration rate were assigned randomly for subjects. Possible IV locations included hand, forearm, and AC and infiltration rates were 5, 50, 100, and 150 mL/hr. For the depth portion of the study (part 2), subjects were screened for subcutaneous tissue depth on the forearm prior to configuration. The investigation of catheter depth and site location on the performance of the ivWatch SmartTouch Sensor provided several important insights. As expected from previous studies with the ivWatch Fiber Optic Sensor, the detection volume decreases for infiltrated tissues closer to the skin surface. This occurs because a greater proportion of the detected photons propagate through the shallow layers of tissue relative to the deeper layers. When the catheter is placed deeper, it takes more time for the fluid to diffuse into the sensors sensitive area. This was also observed in the IV site location portion of the study because catheters placed in the AC were on average 91% and 61% deeper than catheters placed in the hand and forearm sites, respectively. The depth coefficients from the linear regression models show a detection volume increase of about 0.65 mL per mm depth. As observed in previous studies, one of the most significant predictors for sensitivity was the presence of a fibrous fascia separating the sensor and the end of the catheter tip. This fascia is expected to inhibit the diffusion of the infiltrate to more shallow layers (closer to the skin) where the device sensitivity is highest. Additionally, the fascia could potentially interfere with the infrared signal, reducing the observed signal change. In all of the cases where a notification was not issued, a significant fascia is observed in the ultrasound images.