ivWatch Model 400: The Effect of Sensor-to-Catheter Distance

ivWatch Study ID: IVW-CLR-CS12-400

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Chesapeake IRB ID: 00010217

Number of subjects: 23

Number of IV sites: 46

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Abstract/Informational Paragraph:

The Effect of Sensor-to-Catheter Distance Study was performed to understand how the distance separating the ivWatch Sensor and catheter tip (infiltration origin) affect the sensitivity and the detected volume of notifications issued by the ivWatch Model 400. Twenty-three (23) healthy adult volunteers were enrolled, and each participant received two peripheral IVs in each forearm. Each catheter was placed immediately adjacent to a typical vein used for IV therapy with ultrasound guidance. The ivWatch Receptacle was placed next to each IV site. The distance separating the sensor from the catheter tip were randomized prior to starting the study. The separation distance ranged from 10 to 50 mm. The saline was infiltrated at a rate of 60 mL/hr. Each infiltration (i.e. the infusion pump) was stopped once the corresponding ivWatch device issued a red notification or the total infiltrated volume reached 100 mL. The infiltration sensitivity was 100%, 100%, 90%, 88.9%, and 77.8% for 10 mm, 20 mm, 30 mm, 40 mm, and 50 mm separation distance, respectively. The median detection volume was 2.78, 7.68, 12.33, 21.66, and 32.75 mL for 10 mm, 20 mm, 30 mm, 40 mm, and 50 mm separation distances, respectively. The detected volume was proportional to the catheter-to-sensor distance squared, as expected for fluid collecting in tissue and diffusing in all directions from the origin of the infiltration. The results of this study demonstrate that the ivWatch device can work effectively even if the sensor is not placed in close proximity to the catheter tip. These results also demonstrate why the instructions for use state the distance separating the catheter tip and sensor cable should be minimized for optimal performance.