ivWatch Model 400: The Effect of Infiltration Rate

ivWatch Study ID: IVW-CLR-CS03-400

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Number of subjects: 24

Number of IV sites: 48

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Abstract/Informational Paragraph:

The Effect of Infiltration Rate Study was performed to understand how the infiltration rate affects the performance of the ivWatch device, as measured by the infiltration signal and detection volume required to generate a red notification. Twenty-four (24) healthy adult volunteers were pseudo-randomly selected to receive two IVs in either (1) each forearm or (2) the dorsal aspect of each hand. One site was infiltrated at a relatively fast rate for adults (100 or 150 mL/hr); the other site was infiltrated at slow rate of (5 or 50 mL/hr). Five mL/hr is a generally accepted KVO (Keep Vein Open) rate to prevent the formation of thrombus within the catheter leading to an occlusion. A subcutaneous injection of 10 mL of isotonic saline solution was performed for each site modeling the worst-case infiltration condition of a bloodless infiltrate. All sites in this study generated a red notification resulting in a sensitivity of 100% for each rate. The volume of infiltrate required to generate a red notification increases for faster rates. For 5 mL/hr, the majority of infiltrations were detected by 0.9 mL. For 150 mL/hr, approximately 5.7 mL were required to detect most of the infiltrations. This trend is associated with the smoothing and low pass filtering of the ivWatch algorithm.