ivWatch Model 400: Infiltration Detection Performance when Placing Over Transparent Occlusive Dressing

ivWatch Study ID: IVW-CLR-CS15-400

Investigators: Garret T. Bonnema, Ph.D., Gregory J. Schears, M.D.

Chesapeake IRB ID: 00013715

Number of subjects: 24

Number of IV sites: 48

Date: October 2015

Abstract/Informational Paragraph:

A clinical study was performed to examine whether placing the ivWatch Sensor and Receptacle above common occlusive dressings impacts the infiltration detection performance of the ivWatch Model 400. Recent investigational work in pediatric hospitals has suggested that placing the sensor and Receptacle above the clear film of the occlusive dressing would simplify the initial setup for most effective sensor placement. A total of 24 adult volunteers participated in the study. The participant was given a pseudo-randomized study configuration that specified the IV site (hand or forearm) and occlusive dressing type (textured or non-textured). Each participant received two subcutaneous injections of isotonic saline solution. The Receptacle was placed over the occlusive dressing on one side (test site), and directly on the skin (control site) on the other side. The occlusive dressing side (right or left) was also specified in the random configuration. Overall, a red notification was issued for 47 of the 48 monitored sites prior to 10mL of volume being delivered into the tissue. The mean detection volume for control and test sites was 3.25 mL and 2.92 mL, respectively. A paired t-test indicated there was no statistical difference between the control and test sites ($p = 0.246$). The results of this study indicate that placing the ivWatch Sensor and Receptacle over clear occlusive dressings does not change the infiltration detection performance of the ivWatch Model 400.