# ivWatch SmartTouch Sensor: Device Verification for Infiltrated Tissues

ivWatch Study ID: IVW-CLR-CS22-400

Investigators: William J. Naramore, Susan Brown, MSN, MSED, BA, VA-BC, Gregory J. Schears, M.D., Marisa A. Cole

Advarra IRB ID: 00030567

Number of subjects: 128

Number of IV sites: 256

Date: December 2018

**Abstract/Informational Paragraph:**

The Device Verification for Infiltrated Tissues was performed to compare the infiltration detection sensitivity of the ivWatch SmartTouch and Fiber Optic Sensors side-by-side and to evaluate processing algorithms to optimize detection performance. A total of 133 adult volunteers were enrolled in the study for a total of 128 accepted case studies. After prepping and cleaning the site, the physician placed the catheter next to the vein using ultrasound guidance. The ivWatch Sensor Receptacle or SmartTouch Sensor was placed near the tip of the catheter and the site was dressed with an occlusive dressing. This process was repeated for the second IV site. The sensitivity and detection volume performance characteristics of SmartTouch and Fiber Optic Sensors appear to be equivalent based on the results in this verification study. The measured sensitivity was greater for the SmartTouch versus Fiber Optic Sensor, but this difference is mainly due to several Fiber Optic Sensors that were incorrectly placed over a vein. Also, the sensitivity was lower at 2 cc/hr compared to other rates for both sensors. This result may indicate local absorption of the infiltrated fluid at a rate similar to the infusion rate. The SmartTouch Sensor is capable of issuing notifications at smaller volume than the Fiber Optic Sensor with the SmartTouch-specific optimized algorithm. An analysis of the SmartTouch and Fiber Optic Sensors with the Model 400 Fiber Optic Sensor-specific algorithm shows there was no significant difference in detection volume. The similarity in detection volume when analyzing with the same detection algorithm parameters confirms equivalence in the optical design of the sensors.