Eyes Under the Skin

Fiber Optic Sensor White Paper

Continuous IV Site Monitoring

ivWatch, LLC, verifies that the content in this document is correct and accurate, reflecting the features of the product available at the time of writing. However, the content is subject to change without notice. Typographical errors, changes to screens or images, or other, minor device changes may occur that should not affect the understanding or operation of this device.

Note: For the most current release of this paper, refer to the digital version on the ivWatch website at www.ivWatch.com.

Trademarks
IVWATCH and SMARTTOUCH word marks and stylized “IV drip” design are registered trademarks owned by ivWatch, LLC in the United States of America and other jurisdictions elsewhere in the world.

Patents
ivWatch, LLC is the owner of United States Patent Numbers 9,326,686 and 7,826,890 that apply to the ivWatch Patient Monitor and ivWatch Sensors. Other patents are pending or granted in the United States of America and other jurisdictions elsewhere in the world. A list of the granted patents owned by ivWatch, LLC is provided on the ivWatch website at www.ivWatch.com/patents/. The ivWatch webpage is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act and provide notice under 35 U.S.C. §287(a).

For more information, please contact:
ivWatch, LLC | 700 Tech Center Parkway, Suite 300, Newport News, VA 23606, USA
Tel: (855) 489-2824 | Fax: (757) 224-5009 | www.ivWatch.com

All rights reserved. © ivWatch, LLC, 2022 DM-0000011 Rev. 5

Table of Contents

Introduction 4
Clinical Background of IV Therapy 8
Periodic Monitoring vs. Continuous Monitoring 10
Company Legacy 14
ivWatch Patents 16

About the Technology 18
The ivWatch Patient Monitor 18
The Fiber Optic Sensor Cable 20
How it Works 22
Infiltration Detection by the Perfect Clinician 25

Device Sensitivity 28
Early-stage Detection of Peripheral IV Infiltrations 30
Effect of Infiltration Rate on Infiltration Detection 34

Device Specificity 38
Alarm Fatigue 38
Minimizing Alarm Fatigue Associated with Infiltration Detection 39

Detecting Infiltrated IV Sites on Pediatric Patients 42
Non-alarming Phase 43
Alarming Phase 48

Additional Clinical Study Data Analysis of Volume of Infiltrations 52

Introduction

Peripheral intravenous (IV) catheter insertions are the most common invasive hospital procedures performed worldwide; however, failure rates of 35-50% still exist[1]—even in the best of hands. To have such a critical and high-volume medical procedure overshadowed by failure rates is unacceptable.

A common cause of peripheral IV failure (PIV) is infiltration and extravasation, which is when IV fluid leaks outside of the vein and into surrounding tissue.

Peripheral IV failures result in drug dosing errors, which can be costly, painful, and potentially deadly. There was no effective and proven solution to catch the failure at its earliest stage. Until now.

Peripheral IV infiltrations and extravasations are an unacceptable global problem with only one monitoring solution—ivWatch.

Improving Patient Outcomes One IV at a Time

ivWatch revolutionized peripheral IV site monitoring by developing the first and only medical device to detect infiltrations and extravasations earlier than the standard of care. With decades of experience, research, testing, and clinical application, the company delivered a groundbreaking solution to this largely unreported problem.

CLINICIANS NEED A RELIABLE PARTNER. CLINICIANS NEED A SOLUTION.

The company's tenacious pursuit of improving patient safety was the guiding principle when developing a first-of-its-kind continuous peripheral IV site monitoring solution. It all started in 1996 with an idea that has been continuously advanced for almost three decades now.

Patient Monitor

Generation 1
Investigational Device

Generation 2
Investigational Device

The idea that peripheral IVs could be continuously monitored noninvasively, leading to early detection of infiltration and extravasation, was the spark that ignited the company's pursuit of the solution.

ivWatch was awarded its first patent in 2010 following two phases of testing with collegiate partners across Virginia, and received numerous federal health grants. The company aggressively pushed forward with an eye on creating a commercially viable product and service.

With each design cycle, there was a never-ending approach to improving the product for optimal performance, which brought to life a continuous peripheral IV site monitoring system—the first major step in the fight against peripheral IV infiltrations and extravasations. With the system in demand, ivWatch soldiered on and successfully gained FDA clearance for adult patients in 2015, pediatric patients in 2016, and affixing the CE Mark in 2017. The outcomes were already changing for early adopters as adverse events began to decrease at various hospitals around the globe when ivWatch technology was incorporated into their best practices.

In a world where healthcare professionals are spread thin, clinicians need more than just a helping hand.

Indications for Use

The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 mL or less of optically clear infusates, as an adjunctive device to the clinical evaluation in the healthcare setting of adults and pediatrics with peripherally-inserted catheters (PIVs). The device is indicated to assess patients for subcutaneous infiltrations and extravasations but should not serve as a substitute for regular clinician assessment of the PIV site. The ivWatch Model 400 is intended for use by healthcare practitioners who have been trained in the use of the device.

ivWatch is always there to continuously monitor peripheral IV sites and help detect infiltrations and extravasations.

Clinical Background of IV Therapy

Of hospitalized patients, 60% to 90% will receive an IV catheter during their stay and half of those IVs will fail. Failures are due to infiltration, clots in the cannula, inflammatory response, separation of the cannula from the vein, and other reasons.[1] This is a reoccurring problem that is not preventable.

up to

90%

of hospitalized patients receive an IV[1]

50%

of peripheral IVs fail[1]

23%

of peripheral IV failures are due to infiltration[1]

A mean failure rate of nearly **50%** would be unacceptable for food processing, automobile driving, or cell phone use, let alone airplane flights, so why has it been accepted for the most commonly performed invasive hospital procedure worldwide?

In the words of Claire Rickard, one of the leaders of the clinical resite movement:

'Not just in our study but in many published works, the incidence of infiltration, occlusion, and accidental removal is disturbingly high. Up to **90%** of catheters fail before therapy is complete.'

– 2015 Journal of Infusion Nursing article, Helm et. al.[1]

Periodic Monitoring vs. Continuous Monitoring

Healthcare organizations have relied solely upon periodic monitoring of peripheral IVs to detect infiltrations or extravasations for decades. Seasoned members of healthcare staff may be able to pick up on an infiltration or extravasation with a cursory examination and communication with the patient.

However, not catching the issue early enough can cause:[2,3]

SKIN NECROSIS
AMPUTATION
COMPARTMENT SYNDROME
NERVE DAMAGE
MEDICATION DOSING ERRORS
SCARRING

Periodic Monitoring vs. Continuous Monitoring

Various medical products aim at reducing the risk of infiltration events—advanced dressings, securement devices, and even the placement of more invasive lines—but none of the available products can prevent peripheral IV infiltrations or extravasations. Peripheral IV infiltration/extravasation events are inevitable due to a variety of factors such as a patient's preexisting conditions, clinical status, medical diagnosis, medications given, age, etc.

ivWatch technology can detect issues with the peripheral IV site early enough to help limit serious damage, regardless of the factors.

Think about ivWatch like a seatbelt.

If you knew you could prevent death or serious damage with a preventative measure, wouldn't you want that level of protection for your patients?

On the topic of damages, peripheral IV infiltrations and extravasations can lead to costly negligence claims that are often resolved in favor of the patient and ultimately leave a long-lasting negative impact on the hospital. Damages paid out to patients have been recorded as high as $3.6 million in the last five years.[4]

Continuous peripheral IV site monitoring aligns with the evidence-based standard of care, helps avoid issues associated with infiltration/extravasation events, and reduces provider liability and costs.

Simply stated, ivWatch is the solution you need to help prevent negative outcomes for you, your patient, your staff, and your hospital.

Company Legacy

2001-2009

NIH Grant Phase 1 and Phase 2 testing with Eastern Virginia Medical School for animal research and University of Virginia for human subject research.

2010

NIH Grant Continuation with Virginia Commonwealth University Health for human subject research with hospital patients.

NOVEMBER | 2010
First patent for “optical detection of intravenous infiltration” granted by U.S. Patent and Trademark Office.

DECEMBER | 2010
ivWatch, LLC formed.

2012

Pediatric clinical study at Cincinnati Children’s Hospital Medical Center with 127 patients.

2013-2014

Clinical validation studies proved the ivWatch Patient Monitoring System to be highly sensitive and resulted in the development of an algorithm for patient motion. Results were used in FDA submission.

2015

FEBRUARY
First FDA clearance issued for Model 400 for adult patients.

2016

The ivWatch Patient Monitoring System launches with availability in the United States.

JULY | 2016
Conclusion of pediatric clinical study at Cincinnati Children's Hospital Medical Center with over 210 patients to aid in FDA clearance of ivWatch Patient Monitoring System for pediatric age group.

DECEMBER | 2016
Second FDA clearance issued for the ivWatch Patient Monitoring System, this one for pediatric patients. The products are now cleared for all ages.

2017

Received right to affix the CE Mark on the Model 400.

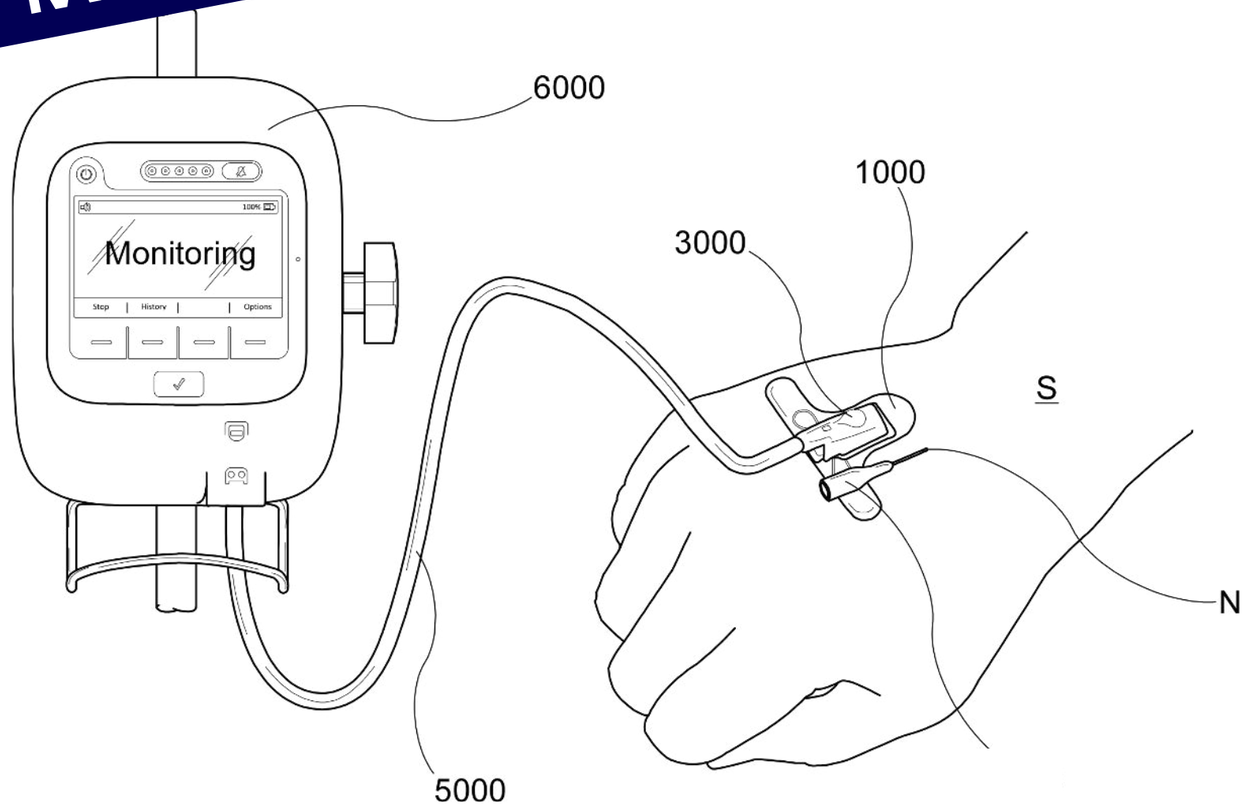
2019

Clinical validation studies begin for SmartTouch Sensor, the company’s miniaturized, disposable sensor and its accessories.

2020

SmartTouch Sensor and accessories received FDA clearance for all ages and the right to affix the CE Mark; product launches.

ivWatch Patents



As of 2022, the company has been granted over 60 patents worldwide. ivWatch paves the path forward with unmatched innovations in early detection technology for peripheral IV therapy. When it comes to early detection technology, no one has come close to replicating or even simulating this proprietary innovation.

U.S. Patent No.
7,826,890:

Optical detection of intravenous infiltration

Application filed on December 6, 2005
Patent granted on November 2, 2010

"An intravenous infiltration detection apparatus for monitoring intravenous failures, which applies an optical method coupled with fiber optics and algorithms for tissue optics to provide a means for noninvasive detection of intravenous infiltration surround the site of IV injection. In the invention, the tissue surrounding the injection site is exposed to a single-wavelength of electromagnetic radiation, and light is collected with only one detector. Changes in the relative intensity of the radiation reflected, scattered, diffused or otherwise emitted provide a means for monitoring infiltration. The invention provides routine, automated, continuous, and real-time monitoring for patients undergoing IV therapy."

U.S. Patent No.
9,326,686:

System and method for mitigating the effects of tissue blood volume changes to aid in diagnosing infiltration or extravasation in Animalia tissue

Application filed on July 30, 2013
Patent granted May 3, 2016

"A system including a sensor and a device coupled to the sensor. The sensor is configured to detect in Animalia tissue a first electromagnetic radiation extinction dominated by absorption of a first wavelength and a second electromagnetic radiation extinction dominated by scattering of a second wavelength. The device is configured to aid in diagnosing at least one of infiltration and extravasation in the Animalia tissue based on the first and second electromagnetic radiation extinctions detected by the sensor."

About the Technology

The ivWatch Patient Monitor

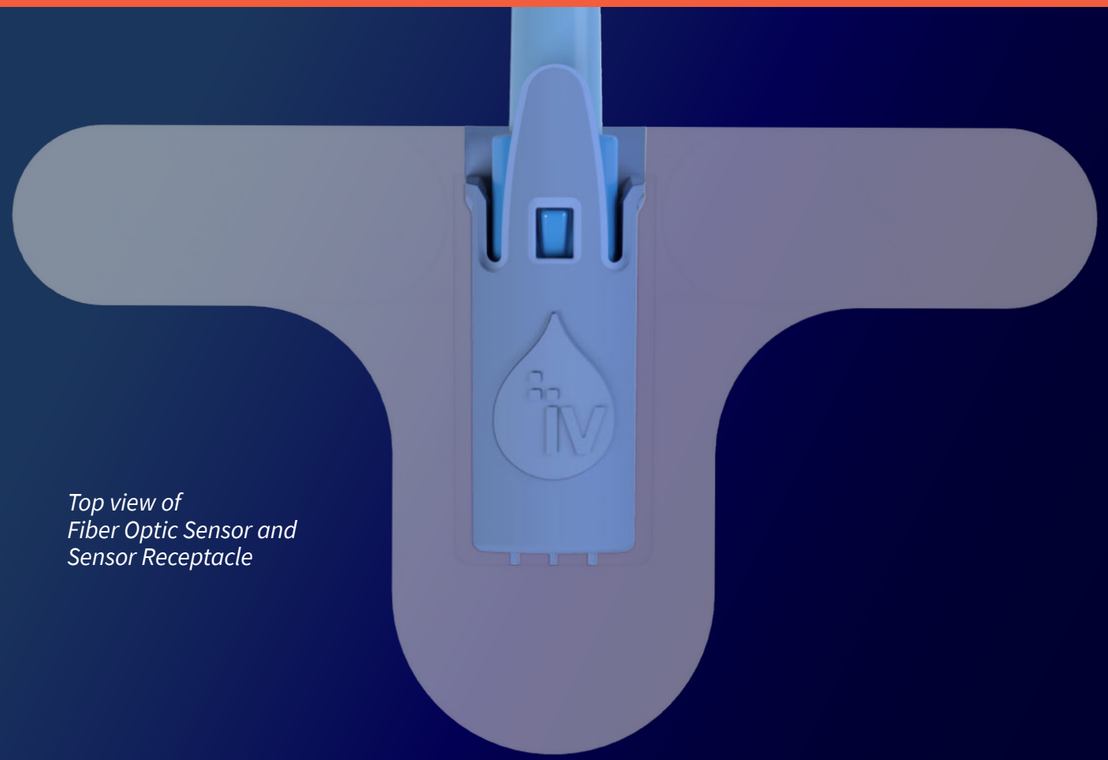
The ivWatch Patient Monitor was designed with direct input from clinicians to ensure easy setup, use, and interaction in both high-pressure settings and routine environments. The ivWatch Patient Monitor continuously assesses the status of the patient's peripheral IV using optical sensor technology and a proprietary signal processing algorithm to notify clinicians when IV fluid is leaking and pooling in the tissue adjacent to the peripheral IV insertion site. Clinicians receive real-time audible and visual notifications, often before visible signs of an infiltration are evident, which may help to reduce both liability and patient harm.

The ivWatch Patient Monitoring System helps clinicians provide the highest quality of care to every patient by detecting peripheral IV infiltrations and extravasations at their earliest stage.

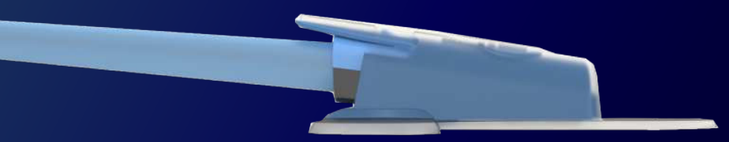
ivWatch System Components

1. ivWatch Patient Monitor
2. Extension Module*
3. SmartTouch Sensor*
4. Patient Cable*
5. Fiber Optic Sensor Cable
6. Sensor Receptacle

**Learn more in ivWatch's SmartTouch Sensor White Paper*



Top view of
Fiber Optic Sensor and
Sensor Receptacle



Profile view of Fiber Optic Sensor and Sensor Receptacle

The Fiber Optic Sensor Cable

The Patient Monitoring System includes the Fiber Optic Sensor Cable, which is cleared for use on all peripheral IV sites and for patients of all ages, sizes, and skin tones. The single-use Sensor Receptacle attaches to the Fiber Optic Sensor Cable for easy placement near the patient's IV site.

Sensor Notifications

Monitoring Normal Tissue

Yellow Check IV

Optical signal indicates a possible peripheral IV infiltration or extravasation

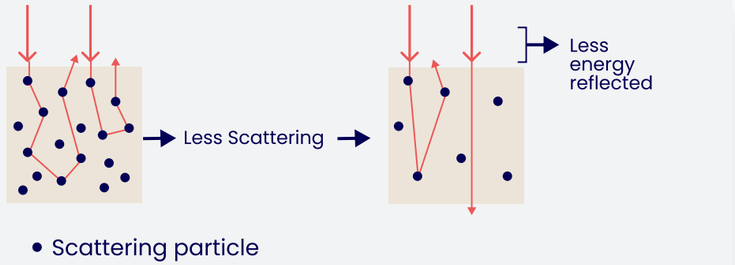
Red Check IV

Optical signal indicates a probable peripheral IV infiltration or extravasation

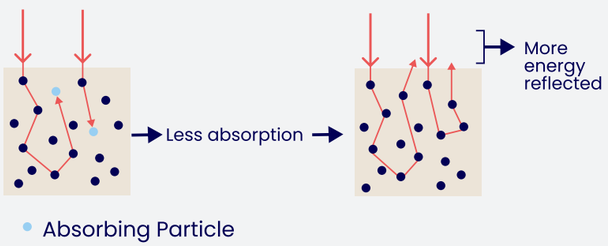
Principles of Operation

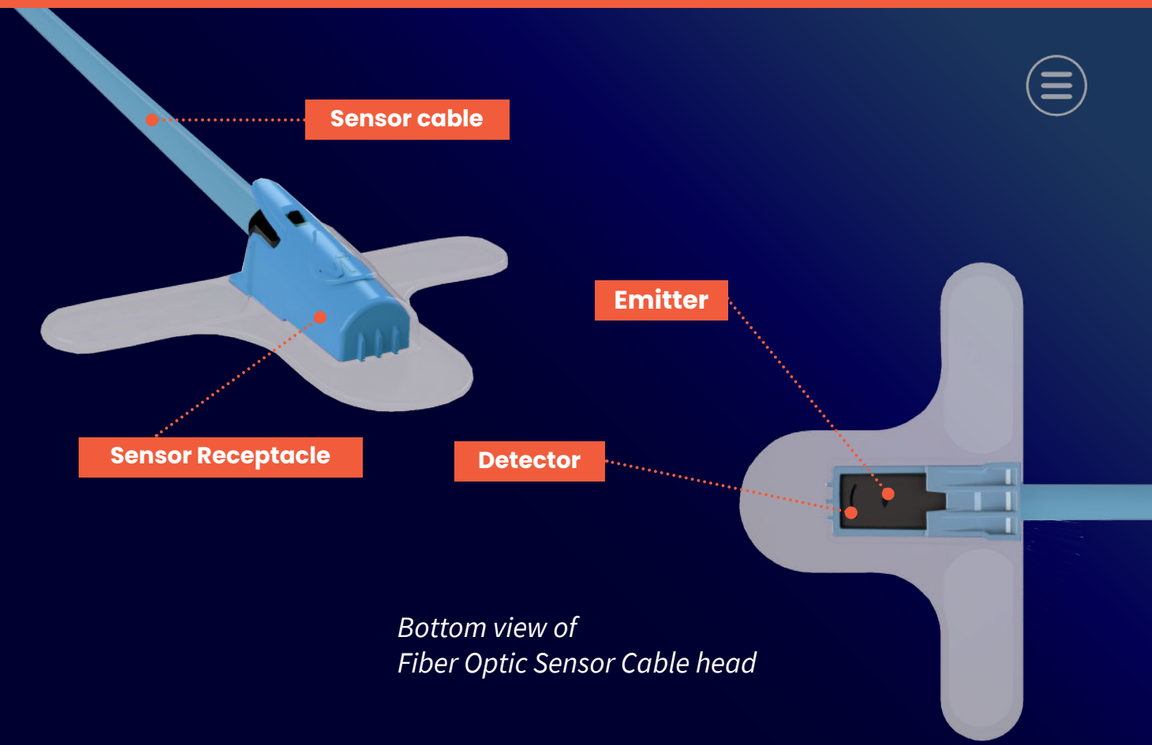
Before diving into the specifics of how ivWatch technology works, it's important to understand how particles of light move within tissue.

Light scatters when a photon, or particle of light, is redirected due to an interaction with some structure or particle in the tissue. Scattering structures in the tissue can include cells (e.g., blood cells, keratinocytes), fibers (e.g., collagen and elastin fibers), and cellular components (e.g., mitochondria, nuclei). When there are more scattering structures in the tissue, more energy will be reflected back to the surface. Likewise, if there are fewer scattering structures in the tissue, less energy will be reflected back to the surface.



Absorption occurs when the energy of the photon is absorbed by a structure in the tissue such as hemoglobin in blood or melanin in the epidermis. When there are more absorption structures in the tissue, less energy will be reflected back to the surface. Likewise, fewer absorption structures result in more energy reflected back to the surface.





Bottom view of Fiber Optic Sensor Cable head

Optical Sensor Technology

Diffuse reflectance refers to the measurement of photons that enter the skin tissue and then reflect back out after many scattering events. The Fiber Optic Sensor has an emitter and a detector to transmit and receive light signals to measure the changes in the optical properties and diffuse reflectance of the tissue near a peripheral IV site. The emitter transmits light to the tissue, and the detector, located a few millimeters away from the emitter, measures the reflected light signal. The reflected light signal primarily depends on the scattering and absorption properties of the monitored tissue.

The emitter allows two wavelengths of light to enter the tissue. One wavelength is in the near-infrared range, tuned to capture light scattering changes of infiltrated fluid. The other wavelength is in the visible range to provide information on patient motion, which can add noise (or uncertainty) to the infiltration signal measurement mainly due to movement of blood in microvessels under the skin surface. ivWatch's signal processing algorithm incorporates both wavelengths to provide high sensitivity and specificity for identifying infiltration events.

Figure 1 illustrates the typical path of photons measured in the diffuse reflectance signal. The figure shows an ultrasound image of normal tissue, with a few typical photon paths illustrated by colored arrows.

The illustration below the ultrasound shows how this corresponds to the ivWatch device. Once an infiltration is introduced to the tissue, the extra fluid causes the typical photon to travel a farther distance in between scattering events, which can be seen in **Figure 2**.

The ivWatch device detects the change in photon scattering in the diffuse reflectance signal and issues a Check IV notification.

When infiltrated fluid is present in the subcutaneous skin tissue, a significantly different diffuse reflectance signal occurs. Changes to diffuse reflectance are received by the Fiber Optic detector and are analyzed by ivWatch's proprietary algorithm to determine whether conditions indicate that an infiltration event may have occurred.

Ultrasound of Normal Tissue

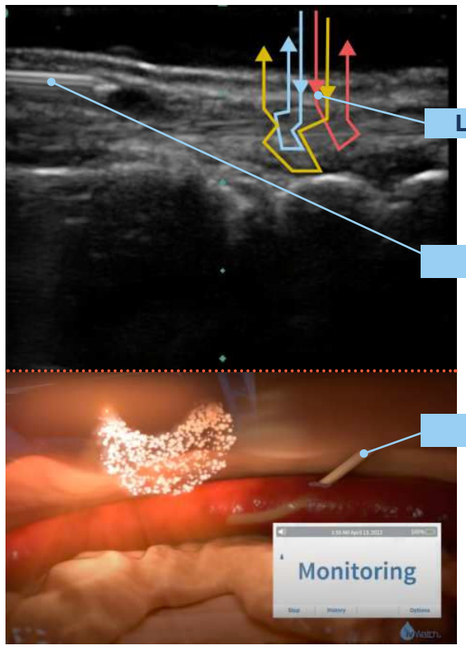


Figure 1. *Illustrations of photon paths in normal tissue.*

Ultrasound of Infiltrated Tissue

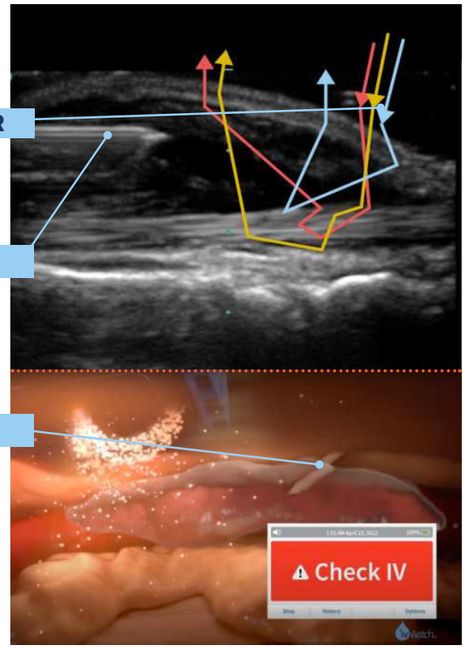
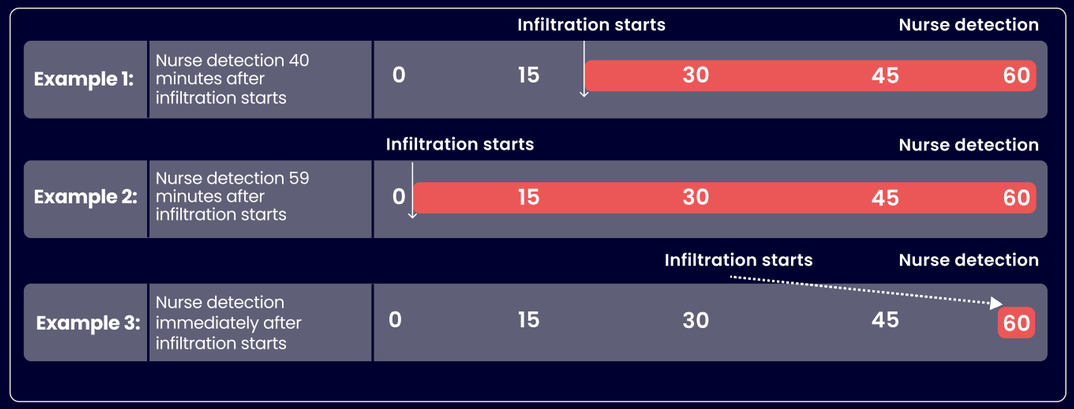


Figure 2. *Illustrations of photon paths in infiltrated tissue.*

Infiltration Detection by the Perfect Clinician

To be an effective product, ivWatch must detect early-stage infiltrations (less than 10 mL of fluid) significantly better than the current clinical standard of care. One way the technology is compared to the current nursing standard of care is through the concept of a "perfect clinician." A perfect clinician assesses the IV site hourly and perfectly classifies the IV site as normal or infiltrated, regardless of how much fluid has been infiltrated into the tissue. Comparing ivWatch technology to this concept is conservative, as it is almost impossible for a real clinician to reliably detect a small volume of infiltrated fluid like 0.2 mL with the naked eye.

Example detections by a perfect clinician, who measures the IV site hourly, are shown in the graphic below:



Early infiltration sensitivity is an important component in the comparison between the performance of the ivWatch device and the perfect clinician. Early infiltration sensitivity is the percentage of early-stage infiltrations (less than 10 mL of fluid) that are detected, either by the ivWatch device or the perfect clinician. To determine the early-infiltration sensitivity of both the ivWatch device and the perfect clinician, the following equations were used:

For the ivWatch device, early infiltration sensitivity (S_D) is defined as

$$S_D = \frac{Monitored\ sites\ that\ generate\ a\ true\ positive\ red\ notification\ in < 10\ mL}{Total\ number\ of\ monitored\ sites}$$

For the perfect clinician, the infiltration has the same probability of occurring at any time between clinical assessments. Therefore, the infiltration sensitivity of the perfect clinician (S_c) is given by

$$S_C = \min\ (100\%, \frac{V_{lim}}{R \cdot T_C} * 100\%)$$

where:

- V_{lim} is the 10 mL volume limit
- R is the infiltration rate in mL/hr
- T_c is the observation period in hours

For example, at 100 mL/hr (R=100), the perfect clinician making hourly assessments (T_C=1) of the IV site would be expected to detect 10% (infiltration sensitivity of the perfect clinician = S_C) of the infiltrations prior to 10 mL (V_{lim}=10). That is because the clinician only has 6 minutes to detect 10 cc of infiltrated fluid (or less) when it is flowing into the tissue at 100 mL per hour.

This example illustrates why the infiltration rate and fluid volume are such important factors in determining clinician sensitivity.

Figure 3 illustrates the infiltration sensitivity of a perfect clinician for different infiltration rates and observation periods, with the above example incorporated as an orange "X." The performance of the perfect clinician is limited by how frequently the site can be assessed. If the perfect clinician could monitor the site continuously (observation period = 0), the clinician's infiltration sensitivity would be perfect.

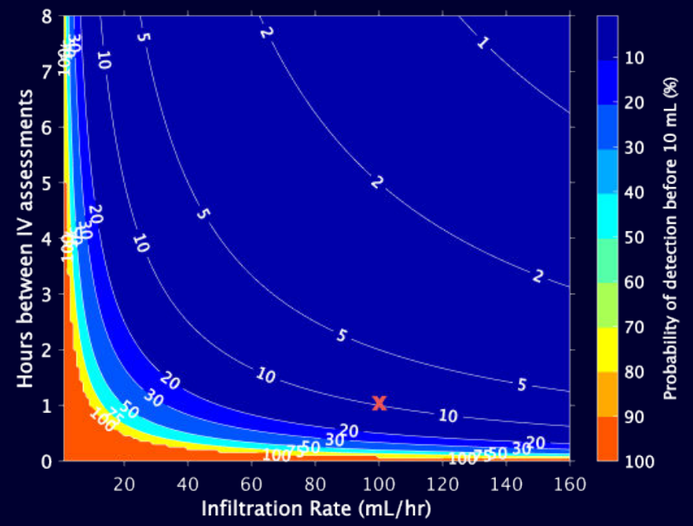


Figure 3. *The sensitivity of a perfect clinician for identifying early infiltrations (infiltrated volume < 10 mL).*

The frequency of peripheral IV site assessments can vary significantly in practice depending on the clinician's workload and the perceived risks to the patient.

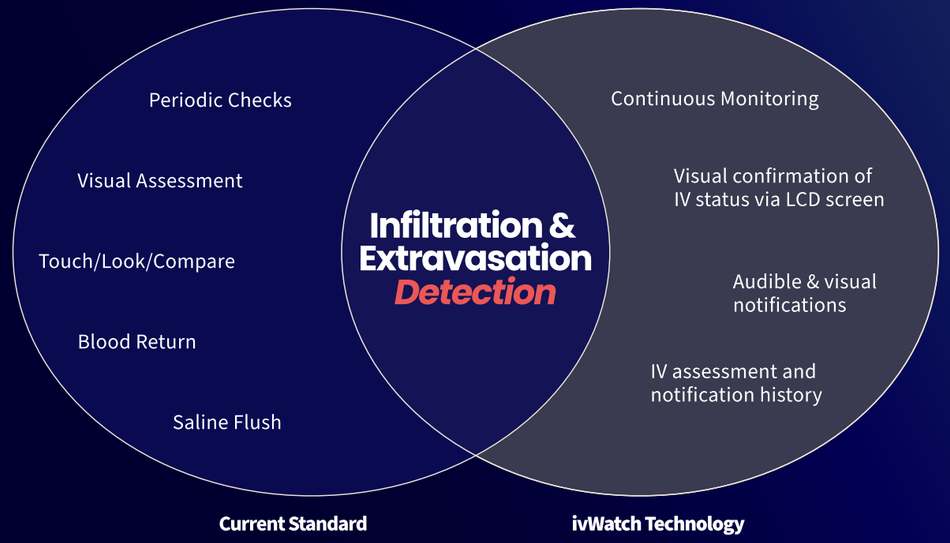
Table 1 includes the practice recommendation for peripheral IV site assessment frequency from the 2021 revision of the Infusion Therapy Standards of Practice, published by the Journal of Infusion Nursing. Discussions with hospitals and clinicians suggest most peripheral IV sites are checked either once per hour or less frequently depending on a variety of external factors.

Table 1. *Practice recommendation for inpatient and nursing facilities by the Infusion Nurses Society (INS) under Standard 42.*[2]

Assessment Frequency of Peripheral IV Catheters	Description
At least every 4 hours	• All patients with peripheral IV catheters
At least every 1 to 2 hours	• Critically ill patients • Sedated patients • Patients with cognitive deficits
At least every hour	• Neonatal patients • Pediatric patients
More frequently than every hour	• Patients receiving infusions of vesicant medications

The INS recommendations can be extremely difficult to obtain in the current medical environment, with high patient ratios, consistent short staffing, decreases in supplies, and increases in patient complexity. The addition of ivWatch technology does not replace the clinician's assessment of the peripheral IV site. It is there to monitor the peripheral IV site continuously between assessments, to let clinicians know early that something adverse is possibly happening in the tissue when the clinician cannot physically have eyes on the peripheral IV site. In the last 100 years, different technologies have evolved to help improve patient safety, not because clinicians are not experts or doing their jobs, but because they are human and are limited in what they are able to do and see.

Combined Detection: Clinician Assessment + ivWatch



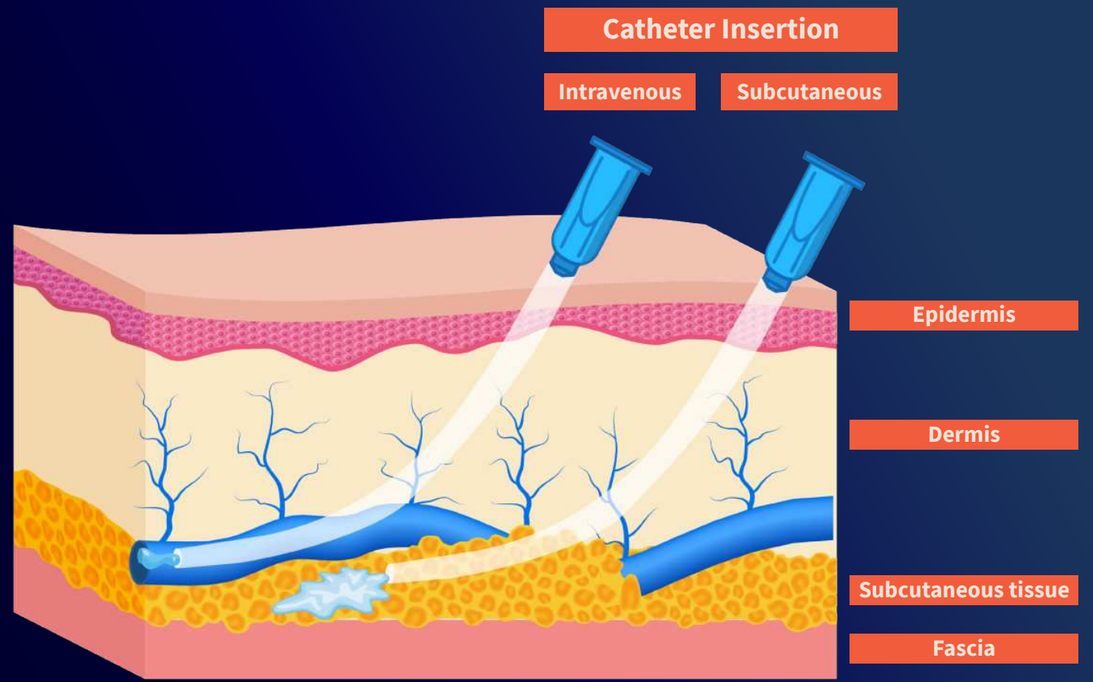
Like any medical procedure, IV placements come with their own set of increasingly high standards. No clinician can be perfect, but technologies like the ivWatch Patient Monitoring System can help clinicians achieve or exceed these standards. Every clinician wants the best for their patients, and it's our goal to help clinicians obtain and maintain the highest level of patient safety.

Device Sensitivity

Device sensitivity refers to the ability of the ivWatch Patient Monitoring System to correctly recognize an infiltrating peripheral IV site as infiltrating in less than 10 mL of fluid, in other words, a true positive. A high sensitivity means there are few missed infiltrations, or false negatives.

Even the most perfectly placed catheter can still go bad. And even a perfect clinician that checks the site every hour on the hour still needs help detecting infiltrations during the time they're not at the bedside.

The following study describes how device sensitivity was determined for the Fiber Optic Sensor Cable. This study utilized a subcutaneous injection method that closely approximates the conditions of a peripheral IV infiltration without exposing the research subject to additional risks and discomforts associated with puncturing a vein (e.g., ecchymosis, hematoma, phlebitis, thrombosis, or embolism).



The subcutaneous injections were performed by a physician using the same equipment as a peripheral IV procedure. After placement of the peripheral IV, an ivWatch Sensor Receptacle and Sensor Cable were positioned near the site. A short waiting period was needed for the ivWatch Patient Monitor to measure a baseline of non-infiltrated tissue before normal saline solution was injected into the subcutaneous tissue. The design of this study ensures that the number of true positives and therefore device sensitivity can be defined since it is known that each peripheral IV is infiltrated.

Early-stage Detection Of Peripheral IV Infiltrations

BACKGROUND

A clinical study approved by a central Institutional Review Board (IRB) was performed to measure the sensitivity of the ivWatch Model 400 for detecting early-stage infiltrations. Healthy adult volunteers received two peripheral IVs in either the dorsal aspect of the hand or the forearm. Enrollment criteria for a range of skin pigmentations and body types ensured a representative sample of the intended population of the device.

STUDY OBJECTIVES

Determine sensitivity

of the ivWatch Patient Monitor for detecting early-stage infiltrations (<10mL of isotonic saline solution).

Demonstrate performance

for different skin pigmentations, body types, infiltration rates, and common PIV locations.

Demonstrate statistically significant improvement

for detecting early-stage infiltrations in comparison to hourly observations by a perfect clinician (i.e., clinician with 100% infiltration detection accuracy)

PARTICIPANTS

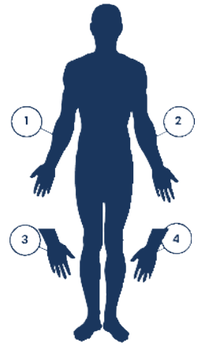
70

INFILTRATED IV SITES

140

MEASURED ATTRIBUTES FROM EACH RESEARCH SUBJECT

- ACTUAL WEIGHT
- ACTUAL HEIGHT
- SKIN PIGMENTATION
- BLOOD PRESSURE
- FOREARM CIRCUMFERENCE



SENSOR LOCATION

Each subject received two randomly placed IVs. One on each forearm or each dorsal aspect of the hand. See graphic to the left for the four possible sensor locations.

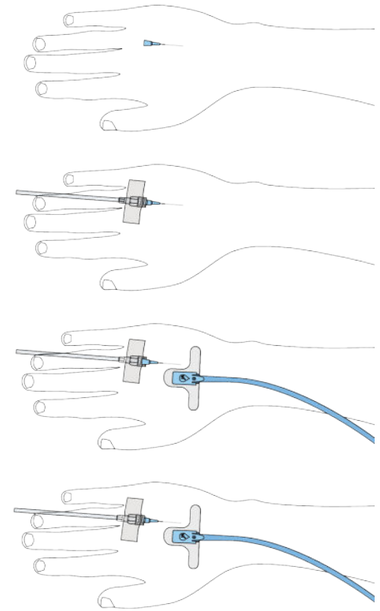
INFILTRATION TIMING

The infiltration was started randomly between five and 30 minutes after monitoring began on the ivWatch Patient Monitor.

IV PLACEMENT METHOD

The IV catheter was placed immediately adjacent to a typical vein using ultrasound guidance.

One of seven nurses performed the IV procedure.



ISOTONIC SALINE SOLUTION

All subjects were infused with 10 mL of isotonic saline solution. Infiltration rates were randomly selected between 5 mL/hr and 150 mL/hr.

DEMOGRAPHICS

GENDER

28 Male
42 Female

SKIN PIGMENTATION

40 Light skin
10 Medium skin
20 Dark skin

BODY MASS INDEX

1 Underweight
23 Normal
23 Overweight
23 Obese

SENSOR NOTIFICATION

The ivWatch Patient Monitor issued notifications if signals consistent with an infiltration were detected.

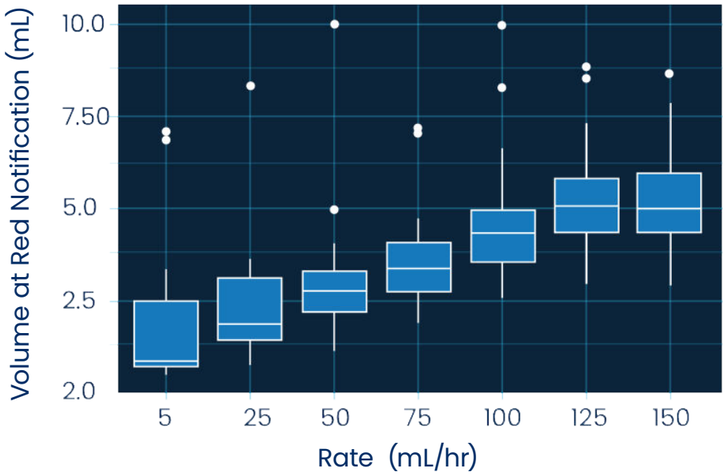
Monitoring
Normal Tissue

Yellow
Check IV

Red
Check IV

EFFECT OF INFILTRATION RATE

The detected volume is slightly larger (~5 mL) for faster rates compared to slower rates (1-2 mL).



SENSITIVITY

Red
Check IV

A red notification was issued for 96.4 % of the infiltrations, corresponding to 135 of 140 infiltrations.

96.4% | 95% Confidence Interval: 91.4 to 98.7%

Yellow
Check IV

A yellow notification was issued for 99.3 % of the infiltrations, corresponding to 139 of 140 infiltrations.

99.3% | 95% Confidence Interval: 95.5 to 99.96%

STUDY CONCLUSIONS

1. The red and yellow notifications issued by the ivWatch device were highly sensitive to PIV infiltrations and would alert clinicians to the early stages of an infiltrated PIV site.
2. The yellow and red notifications can often detect infiltrations faster than a perfect clinician assessing the site hourly (p-value less than 0.05 for rates ≥ 25mL/hr).
3. The device worked well for a range of common infiltration rates, skin pigmentations, body types (as measured by the body mass index), and ages.
4. No adverse events were recorded. No skin irritation or disruption to skin integrity was observed from the 140 sites of the study.

DATE OF STUDY

February 2014

SPONSOR

ivWatch, LLC

INVESTIGATORS

Gregory J. Schears, M.D.
Garret T. Bonnema, Ph.D.
William J. Naramore, B.S.

NURSES

Debbie Coles, RN
Mary Clare, RN
Erin Rock, RN BSN
Patricia Przybyl, RN
Sierra Knapp, RN
Tara Svadeba, RN BSN
Jeannette McGuirk, RN

INTERNAL PROTOCOL ID

IVW400CS-06

CHESAPEAKE IRB

Pro00009285

CONCLUSION

Effect of Infiltration Rate On Infiltration Detection

BACKGROUND

An IRB-approved clinical study was performed to assess the effect of infiltration rate on the detection of early-stage infiltrations.

Twenty-four healthy adult volunteers received two subcutaneous infusions of isotonic saline solution in either the forearms or the dorsal aspect of the hands. The catheter was placed immediately adjacent to a vein using ultrasound guidance. The rate of each infiltration was randomly selected between 5 and 150 mL/hr. The ivWatch Model 400 monitored each site and issued notifications if an infiltration was detected.

STUDY OBJECTIVES

1. Determine whether the infiltration rate has a significant effect on the measured infiltration signal.
2. Determine whether the hand infiltration signal differs significantly from the forearm infiltration signal.
3. Contribute study data to a database of ivWatch signals of infiltrated tissue.
4. Evaluate processing algorithms to optimize performance of future ivWatch devices

PARTICIPANTS

24

48

INFILTRATED IV SITES

MEASURED ATTRIBUTES FROM EACH RESEARCH SUBJECT

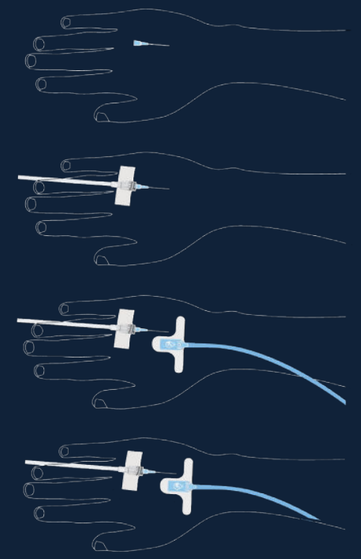
- ACTUAL WEIGHT
- ACTUAL HEIGHT
- SKIN PIGMENTATION
- BLOOD PRESSURE
- FOREARM CIRCUMFERENCE

ISOTONIC SALINE SOLUTION

All subjects were infused with 10 mL of isotonic saline solution. The infiltration was started after five minutes of monitoring by the ivWatch Patient Monitor. The infiltration rate for each IV site was randomly selected from one of four infiltration rates: 5 mL/hr, 50 mL/hr, 100 mL/hr, 150 mL/hr.

SENSOR LOCATION

Each subject received two IVs randomly placed on either the forearm or dorsal aspect of the hand.



IV PLACEMENT METHOD

Nurses performed the IV procedure. The IV catheter was placed immediately adjacent to the vein using ultrasound guidance.

SENSOR NOTIFICATION

The ivWatch Patient Monitor issued notifications if signals consistent with an infiltration were detected.

Monitoring
Normal Tissue

Yellow
Check IV

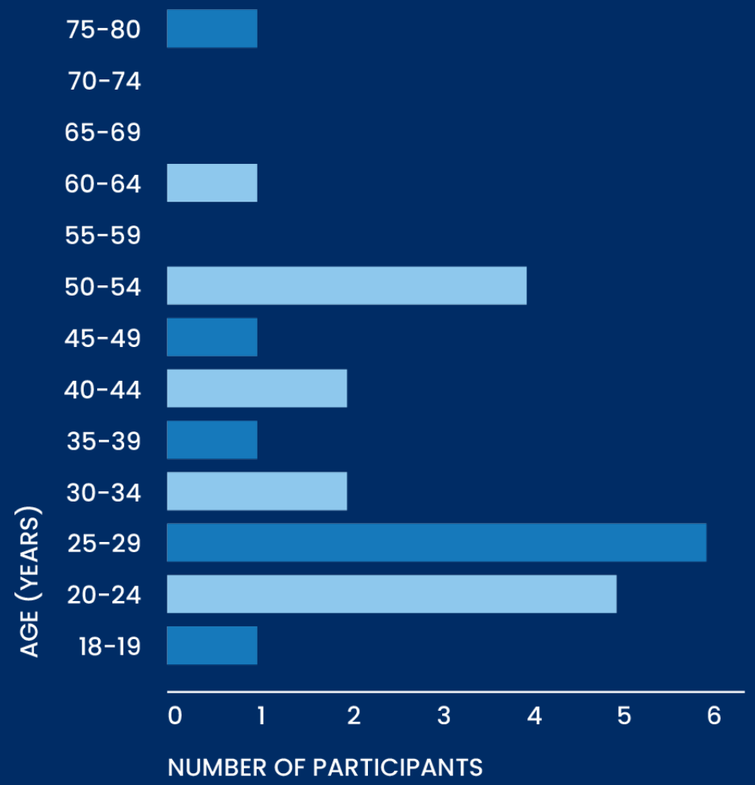
Red
Check IV

DEMOGRAPHICS

GENDER
13 Male
11 Female

BODY MASS INDEX
1 Underweight
8 Normal
6 Overweight
9 Obese

SKIN PIGMENTATION
10 Light skin
11 Medium skin
3 Dark skin



STUDY CONCLUSIONS

1. The red and yellow notifications were issued by ivWatch for all 48 infiltrations in this study prior to 10 mL infiltrated volume, corresponding to 100% detection sensitivity (95% Confidence Interval: 70-100%).
2. The average volume at the red notification was 1.7 mL, 3.0 mL, 3.7 mL, and 5.6 mL for 5, 50, 100, and 150 mL/hr.
3. The ivWatch Patient Monitor has a two-minute response time which results in larger detection volumes for faster infiltration rates.
4. No adverse events were recorded. No skin irritation or disruption to skin integrity was observed from the 48 sites of the study.
5. The measured patient attributes of gender, skin pigmentation, age, and body mass index did not have statistically significant impacts on the sensitivity or detection volume measured in the study.

DATE OF STUDY

October-November 2013

SPONSOR

ivWatch, LLC

INVESTIGATORS

Gregory J. Schears, M.D.
William J. Naramore, B.S
Garret T. Bonnema, Ph.D.

STUDY LOCATION

ivWatch, LLC
469 McLaws Circle
Williamsburg, VA 23185

INTERNAL PROTOCOL ID

IVW400CS-03

CHESAPEAKE IRB

Pro00008941

Device Specificity

Device specificity refers to the ability of the ivWatch Patient Monitoring System to correctly recognize normal tissue as not infiltrated, in other words, a true negative. A high specificity indicates there are few false positive results, meaning there are few notifications that identify the tissue as infiltrated when the tissue is not infiltrated.

Alarm Fatigue

Alarm fatigue is the result of clinicians being bombarded with an excessive number of clinical alarms from patient monitoring devices. It desensitizes clinicians to these alarms and leads to poor patient outcomes, including death.

In one study conducted in the fall of 2019 at the Jorvi Hospital Emergency Department, there were 28,176 alarms produced by eight devices, none related to ivWatch, over a four-week period. Only 695 or 2.5% of these alarms were acknowledged by the clinician.[6]

It is important to reduce the number of false alarms in the clinical setting as much as possible. Developed with the understanding of what causes false notifications, ivWatch aims to reduce alarm fatigue by ensuring the technology has high specificity.

Minimizing Alarm Fatigue Associated with Infiltration Detection

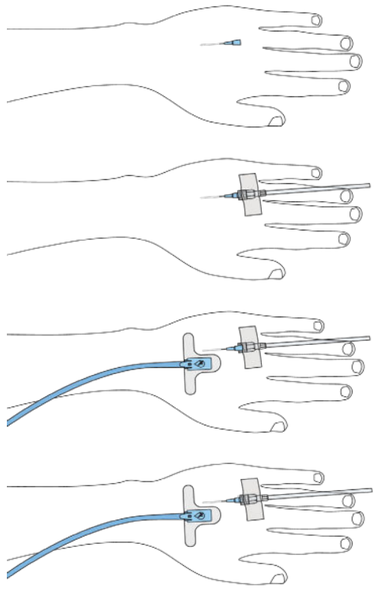
BACKGROUND

An IRB-approved clinical study was performed to measure the rate of false notifications issued by the ivWatch Patient Monitor.
Forty healthy adult volunteers were enrolled in a 24-hour study.

Each research subject was monitored from a site on either the forearm or the dorsal aspect of the hand.

STUDY ENVIRONMENT

The observation area included a hospital bed, television, and video camera. The video camera provided a record of the subject's motion activities throughout the study.



STUDY OBJECTIVES

1. Quantify the rates of red notifications and self-correcting yellow notifications when monitoring normal tissue.
2. Identify conditions that may cause a non-infiltration notification by the ivWatch Patient Monitor.
3. Demonstrate insensitivity of the device to interference with other near-infrared devices and common hospital activities such as blood pressure measurement.
4. Demonstrate safety of the device, specifically the impact of the Sensor Receptacle on skin.

SENSOR LOCATION

The ivWatch sensor was randomly placed on either the forearm or dorsal aspect of the hand. A VeinViewer ® was used to place the sensor immediately adjacent to a typical vein.

No catheterization was performed, but the site was dressed following standard protocols, with the tubing taped down.

SENSOR NOTIFICATION

The ivWatch Patient Monitor issued notifications if signals consistent with an infiltration were detected.

Monitoring
Normal Tissue

Yellow
Check IV

Red
Check IV

DEMOGRAPHICS

GENDER
24 Male
16 Female

SKIN PIGMENTATION
19 Light skin
11 Medium skin
10 Dark skin

BODY MASS INDEX
19 Normal
12 Overweight
9 Obese

1 IN 2
DAYS

A false yellow notification was issued at a rate of 0.51 notifications per day, or about one notification every two days.

0.51
95% Confidence Interval: 0.31 to 0.79

1 IN 4
DAYS

A false red notification was issued at a rate of 0.24 notifications per day, or less than one notification every four days.

0.24
95% Confidence Interval: 0.11 to 0.45

NON-INFILTRATION NOTIFICATION CONDITIONS

In an analysis of the surveillance footage, many of the red and yellow Check IV notifications were associated with motions of the research subject that either applied pressure to the site or applied force to the sensor cable/receptacle assembly. Most notifications were associated with sites on the hand. Device interference did not cause any false red or yellow notifications.

STUDY CONCLUSIONS

1. The red and yellow non-infiltration notification rates of 0.24 and 0.51/day, respectively, are sufficiently small suggesting a minimal impact on clinical alarm fatigue.
2. Many of the non-infiltration notifications in this study were associated with patient activities that applied a force to the site.
3. No red or yellow notifications were generated by the interference of common near-infrared devices.
4. No adverse events were recorded. No skin irritation or disruption to skin integrity was observed from the 40 sites of the study.

DATE OF PHASE

January 2014

SPONSOR

ivWatch, LLC

INVESTIGATORS

William J. Naramore, B.S
Garret T. Bonnema, Ph.D.

STUDY LOCATION

ivWatch, LLC
469 McLaws Circle
Williamsburg, VA 23185

INTERNAL PROTOCOL ID

IVW400CS-05

CHESAPEAKE IRB

Pro00009175

CONCLUSION

Detecting Infiltrated IV Sites on Pediatric Patients

STUDY INTRODUCTION

The Early Stage Detection of Peripheral IV Infiltrations study demonstrated the effectiveness of the ivWatch Model 400 in scenarios where it was known that an infiltration had occurred. A subsequent study was completed at the Cincinnati Children's Hospital Medical Center (CCHMC) to further analyze the product's effectiveness in a clinical environment. The study, which took place over an 11-month period, was broken up into two phases. In phase one, the ivWatch Model 400 was incorporated into the IV therapy of patients but did not notify clinicians of infiltration ("non-alarming" phase). This allowed investigators to analyze how the ivWatch Model 400 compared to clinicians' assessments in the early detection of IV infiltration. The ivWatch Model 400 did notify caregivers about infiltration events in the second phase of the study ("alarming" phase) allowing investigators to compare the results from the phase where no notifications were issued.

Pediatric patients are a high-risk population for IV infiltration due to their activity level, limited communication skills, and small limb size. An IRB-approved clinical study was performed to measure the performance of the ivWatch Model 400 device for detecting early-stage infiltrations on pediatric patients under the age of 18.

This study was conducted in two phases and was designed to measure several important metrics that describe the performance of the ivWatch device. Each site was continuously monitored during IV therapy and the IV was terminated if an infiltration was detected or other complications were identified.

Non-alarming Phase

BACKGROUND

In the non-alarming group, 156 children—from neonate (two weeks) to 17 years who required continuous IV therapy—received a subcutaneous infusion in various IV locations including the forearm, dorsal aspect of the hand, foot, or antecubital (AC) fossa. The rate, dosage, and solution of each IV therapy was determined by the medical protocols required to treat each child's specific condition. Each site was continuously monitored during IV therapy and the yellow and red Check IV notification data was collected. However, in order to evaluate the data against study objectives, the ivWatch visible/audible Check IV infiltration notifications were not enabled on each ivWatch Patient Monitor and were not analyzed until after the clinician-confirmed extravasation events.

NON-ALARMING PHASE STUDY OBJECTIVES

1. Compare the current standard of care, including routine nurse IV assessment by nursing staff with the ivWatch technology by analyzing the time between the ivWatch device detection and nurse confirmation.
2. Determine how many of the nurse-confirmed infiltrations/extravasations were detected by the ivWatch device.

PARTICIPANTS

156

MONTHS

7

MEASURED ATTRIBUTES FROM EACH RESEARCH SUBJECT

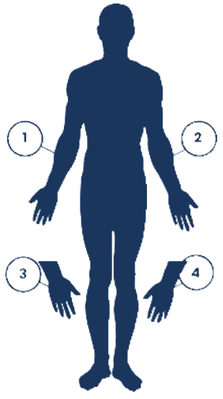
Age (neonate to 17 years)

Weight (> 2.5 kg)

Skin Pigmentation (Light, Medium, Dark)

IV THERAPY

Pediatric patients who required continuous IV therapy were monitored in this study and received the appropriate IV therapy and dosage as determined by the medical protocols required to treat their specific conditions.



HAND
75 Subjects

FOREARM
71 Subjects

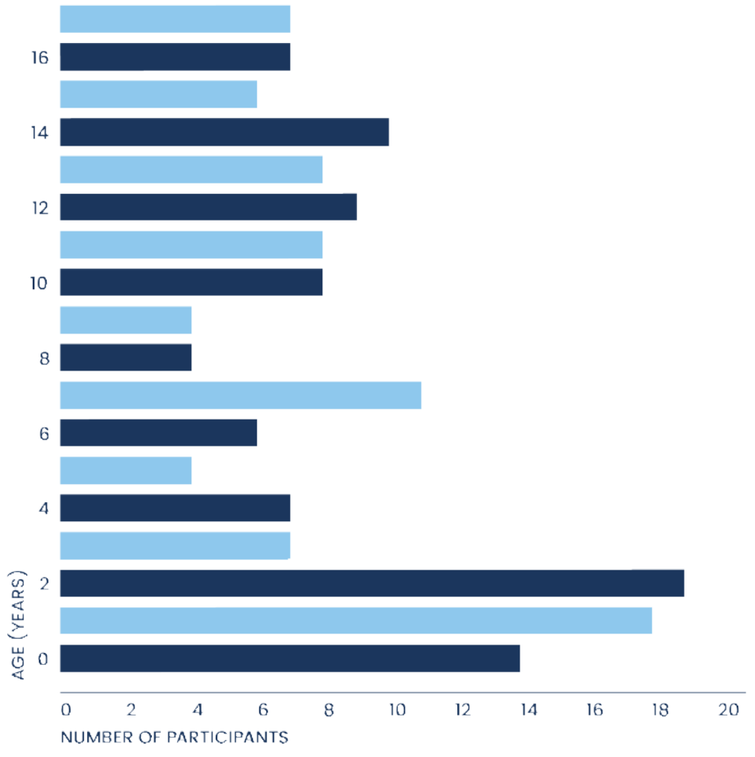
FOOT
9 Subjects

AC
1 Subject

SENSOR LOCATION

Each subject received an IV based on nurse assessment of the best location for IV therapy. The ivWatch sensor was placed on the skin or over the dressing adjacent to the catheter and within 1 inch from the catheter hub.

DEMOGRAPHICS



GENDER

73 Male
83 Female

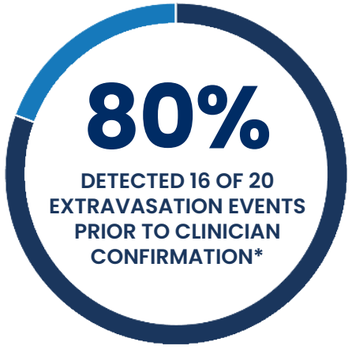
SKIN PIGMENTATION

122 Light skin
17 Medium skin
17 Dark skin

INFILTRATION RATE

A total of 23 clinician-confirmed extravasations occurred in 156 patients, corresponding to an infiltration rate of 14.7% for the non-alarming group study population.

EXTRAVASATION NOTIFICATIONS: NON-ALARMING



15.2 HOURS

Median time between red Check IV notifications and clinician confirmation of extravasation.

DEVICE/CLINICIAN DETECTION TIME DIFFERENCE

In order to evaluate the data against study objectives, the yellow and red Check IV notification data was collected, but not analyzed until after a clinician-confirmed extravasation event.

32 HOURS
BEFORE CLINICIAN CONFIRMATION

A yellow Check IV notification occurred an average time of 32.3 hours before clinician detection.

32.3 hours | 95% Confidence Interval: 17.3 to 47.3 hours

29 HOURS
BEFORE CLINICIAN CONFIRMATION

A red Check IV notification occurred an average time of 29.8 hours before clinician detection.

29.8 hours | 95% Confidence Interval: 14.8 to 44.8 hours

Note: Since larger time differences influence "average time" calculations, the median time between ivWatch detection and clinical detection may be a more appropriate description. The median time between device detection and clinical detection was 15.2 and 22.8 hours for red and yellow notifications, respectively.

*For the non-alarming study, 16 out of the 20 notifications were detected prior to clinician confirmation when the IV was located in the hand or forearm. For all IV sites, 18 out of 23 infiltration cases were detected by the device prior to clinician confirmation.

NON-ALARMING PHASE CONCLUSIONS

The results from this study demonstrate a higher level of reliability using the ivWatch Model 400 continuous monitoring device. Data indicates that the ivWatch Patient Monitor detects infiltrations prior to clinician confirmation 80 percent of the time, while alerting clinicians of infiltrations 15.2 hours (median time) before it was visible during standard nursing practices or other IV assessment techniques. Results show that the ivWatch Patient Monitor can aid clinicians in identifying infiltrated tissue, decreasing patient harm, and improving patient safety.

DATE OF PHASE

August 2015 - February 2016

SPONSOR

ivWatch, LLC

INVESTIGATORS

Principal Investigator:
Darcy Doellman
MSN, RN, CRNI, VA-BC

Investigators:
Sylvia Rineair
MSHA, BSN, RN, VA-BC

Candice Fletcher Overly
MSN, RN, VA-BC

Neil Johnson, M.D.

STUDY LOCATION

Cincinnati Children's Hospital Medical Center (CCHMC)
3333 Burnet Avenue
Cincinnati, OH 45229

INTERNAL PROTOCOL ID

IVW400CS-09

CCHMC IRB

2015-0896

Alarming Phase

BACKGROUND

In the alarming group, 57 children—from neonate (two weeks) to 17 years who required continuous IV therapy—received a subcutaneous infusion in various locations (forearm or dorsal aspect of the hand). The rate, dosage, and solution of each IV therapy was determined by the medical protocols required to treat each child's specific condition. Each site was continuously monitored during IV therapy, and the visible/audible Check IV notifications were enabled on each ivWatch Patient Monitor.

STUDY OBJECTIVES

1. Measure the performance of the ivWatch Model 400 for detecting extravasations.
2. Determine the notification rate by measuring how often the ivWatch Patient Monitor issues extravasation notifications.

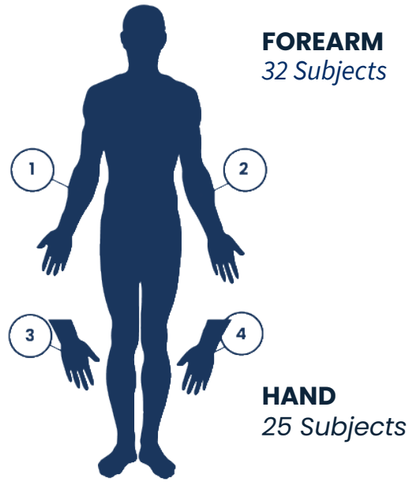
PARTICIPANTS

57

MONTHS

MEASURED ATTRIBUTES FROM EACH RESEARCH SUBJECT

Age (neonate to 17 years)
Weight (> 2.5 kg)
Skin Pigmentation (Light, Medium, Dark)



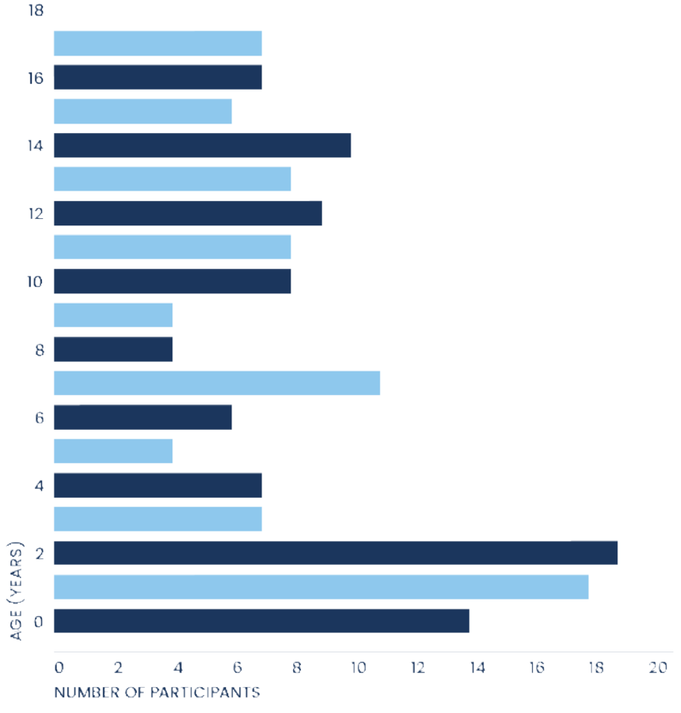
FOREARM
32 Subjects

HAND
25 Subjects

SENSOR LOCATION

Each subject received an IV based on nurse assessment of best location for IV therapy. The ivWatch sensor was placed on the skin or over the dressing, adjacent to the catheter and within 1-inch from the catheter hub.

DEMOGRAPHICS



GENDER

26 Male
31 Female

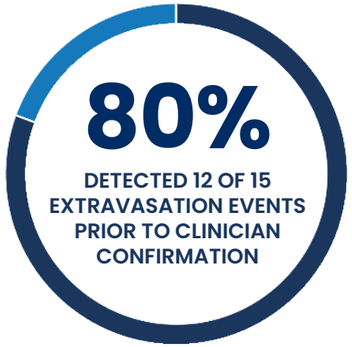
SKIN PIGMENTATION

44 Light skin
3 Medium skin
10 Dark skin

INFILTRATION RATE

A total of 15 clinician-confirmed infiltrations occurred in 57 patients, corresponding to an infiltration rate of 26.3% for the alarming group study population.

EXTRAVASATION NOTIFICATIONS: ALARMING



A yellow and red Check IV notification occurred in 12 out of 15 clinician-confirmed infiltrations.

80% | 95% Confidence Interval: 51.9 to 95.7%

2.1 HOURS

Median time between red Check IV notification and clinician confirmation of extravasation.

DEVICE PERFORMANCE

The ivWatch Patient Monitor issued a yellow and red notification in 12 of the 15 clinician-confirmed extravasations for the alarming group. The false positive notification rate (yellow and red notifications) of the ivWatch Patient Monitor was also estimated* and results corresponded to approximately one notification every four days.

1 IN 4 DAYS

A false yellow notification was issued at a rate of 0.27 notifications per day, or about one notification every four days.

0.27 | 95% Confidence Interval: 0.119 to 0.631 alarms/day

1 IN 4 DAYS

A false red notification was issued at a rate of 0.28 notifications per day, or about one notification every four days.

0.28 | 95% Confidence Interval: 0.156 to 0.500 alarms/day

**False notifications can often have real causes that prompt for clinically relevant assessments of the IV site. For example, pressure on the sensor could possibly cause a notification, but pressure on the IV site could be a clinically relevant event that would need a clinician assessment in order to maintain the integrity of the IV.*

ALARMING PHASE CONCLUSIONS

The results from this study demonstrate that the ivWatch Patient Monitor can aid clinicians in identifying extravasations, decreasing patient harm, and improving patient safety. Clinical study data indicates that the ivWatch Patient Monitor detected extravasations prior to confirmation by clinicians 80% of the time, with the median time of 2.1 hours between red Check IV notification and clinician confirmation.

DATE OF PHASE

August 2015 - February 2016

SPONSOR

ivWatch, LLC

INVESTIGATORS

Principal Investigator:
Darcy Doellman
MSN, RN, CRNI, VA-BC

Investigators:
Sylvia Rineair
MSHA, BSN, RN, VA-BC

Candice Fletcher Overly
MSN, RN, VA-BC

Neil Johnson, M.D.

STUDY LOCATION

Cincinnati Children's Hospital Medical Center (CCHMC)
3333 Burnet Avenue
Cincinnati, OH 45229

INTERNAL PROTOCOL ID

IVW400CS-09

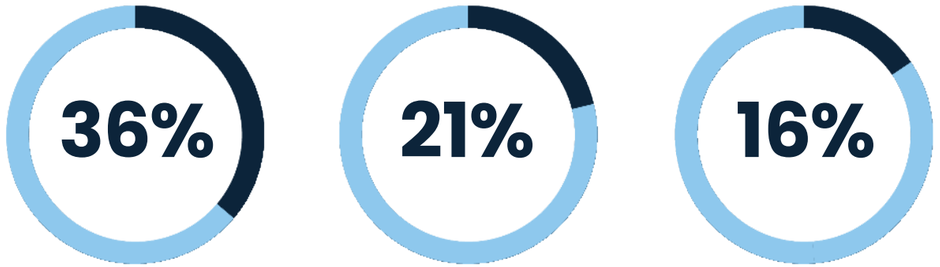
CCHMC IRB

2015-0896

ADDITIONAL CLINICAL STUDY DATA ANALYSIS OF VOLUME OF INFILTRATIONS

Although the exact volume of infiltrated fluid is unknown in this study, the swelling percent recorded by CCHMC can be used as a relative measurement of volume, using this formula:

Swelling Percentage Metric =
Length of swelling at its longest point/length of arm



Median Swelling for Non-alarming Study

Median Swelling for Alarming Study

Median Swelling for Cases when IV Terminated within 1 Hour of Red Check IV Notification

The swelling percent was recorded for most of the clinician-confirmed extravasations in this study. The median swelling percent for the non-alarming and alarming groups were 36% and 21%, respectively. In five of the 12 detected infiltrations in the alarming group, the clinician terminated the IV within one hour of the red Check IV notification. The median swelling percent was 16% for these five cases. In the other seven detected cases in the alarming group, the clinician restarted monitoring with the ivWatch device after a red Check IV notification, and the infiltration was eventually found and confirmed by a clinician. In these seven cases, the swelling percent recorded reflects the extravasation at the time when the clinician was able to confirm the infiltration. It can be estimated that there was almost no (0 %) visible swelling at the IV site when the ivWatch device issued a notification.

Results from this pediatric study have shown the benefits of using the ivWatch technology for early detection of infiltration. The ivWatch device issued notifications for extravasation events and alerted clinicians of infiltrations hours before they were detected by a clinician. This device can aid clinicians in identifying extravasations early in order to decrease patient harm and improve patient safety.

References

1. Helm, R. E., Klausner, J. D., Klemperer, J. D., Flint, L. M., & Huang, E. (2015). Accepted but unacceptable. Journal of Infusion Nursing, 38(3), 189–203. https://doi.org/10.1097/nan.0000000000000100

2. Gorski, L. A., Hadaway, L., Hagle, M. E., Broadhurst, D., Clare, S., Kleidon, T., Meyer, B. M., Nickel, B., Rowley, S., Sharpe, E., & Alexander, M. (2021). Infusion therapy standards of practice, 8th edition. Journal of Infusion Nursing, 44(1S). https://doi.org/10.1097/nan.0000000000000396

3. Alexander, M., Corrigan, Avv., Gorski, L., Hankins, J., & Perucca, R. (2010). Infusion nursing: An evidence-based approach (3rd ed.). Saunders Elsevier.

4. Chemical Burn: Baby in Intensive Care Unit. Patrick Malone & Associates Law. (2019, March 12). Retrieved January 31, 2022, from https://www.patrickmalonelaw.com/track-record/verdicts-settlements/

5. Naramore, W. J., Brown, S., Schears, G. J, & Cole, M. A. (2019). ivWatch SmartTouch Sensor: Device Validation for Infiltrated Tissues. ClinicalTrials.gov Identifier: NCT04064229. Retrieved February 11, 2022, from https://clinicaltrials.gov/ct2/show/NCT04064229?ter=ivwatch&draw=2&rank=2

6. Jämsä, J. O., Uutela, K. H., Tapper, A. M., & Lehtonen, L. (2021). Clinical alarms and alarm fatigue in a university hospital emergency department—a retrospective data analysis. Acta Anaesthesiologica Scandinavica, 65(7), 979–985. https://doi.org/10.1111/aas.13824

ivWatch.com