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IV catheter placement remains the most common invasive hospital procedure performed worldwide. More than 300 million peripheral IV catheters are sold each year in the United States alone, and 60 to 90 percent of hospitalized patients require an IV during their hospital stay, providing direct administration of fluids and medications into the bloodstream. Although PIV catheter insertion is the most common invasive hospital procedure performed worldwide, 50 percent of IVs will fail, with 23 percent of those failures due to infiltrations.¹

The patient harm caused by an IV infiltration can range from pain and redness to tissue and nerve damage to limb amputation. An IV infiltration of simple saline solution can lead to compartment syndrome resulting in nerve, tissue and joint damage. In addition to the possible localized physical damage, every IV infiltration represents a drug delivery error that can impact the effectiveness of treatments for patients requiring time-sensitive and life-saving drugs. Until now, no product has been available to provide continuous monitoring for early detection of IV infiltration.

This whitepaper summarizes the clinical research for the ivWatch Model 400—the first and only FDA-cleared device capable of providing continuous monitoring of peripheral IVs for the early detection of infiltration events.²

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² For the purposes of this white paper, the terms “infiltration” and “extravasation” are used interchangeably to describe any occurrence of leakage from an IV site into surrounding tissue regardless of IV contents.
ivWatch
PATIENT MONITOR

Monitoring
The ivWatch® Model 400 is the first and only device capable of providing continuous, noninvasive surveillance monitoring of peripheral IVs to aid clinicians in the early detection of IV infiltration and extravasation events. The patented technology represents years of research and development in close partnership with leading hospitals and clinicians in the vascular access space.

The ivWatch Model 400 consists of a patient monitor, an optical sensor cable, and a sterile, disposable receptacle for attaching the sensor to the patient’s skin, near the IV site. Once the device is connected to the patient, the ivWatch Model 400 uses light to continuously monitor a patient’s subcutaneous tissue and measures the changes in the optical properties of the tissue. The sensor cable delivers the light signals from the ivWatch patient monitor to the patient’s skin through the sensor head. The sensor head transmits the reflected light from the tissue back to the patient monitor through the sensor cable.

During an infiltration, fluid accumulates in subcutaneous tissue, causing a significant change in the light scattering. The ivWatch Model 400 recognizes these changes in the reflected light, first providing a YELLOW CHECK IV notification indicating the possibility of an infiltration. If the infusion continues and the signal continues to drop further below the threshold, a RED CHECK IV notification will appear on the monitor, indicating a probable infiltration. The signal processing algorithm used to issue the YELLOW and RED CHECK IV notifications is designed to maximize sensitivity and specificity for infiltration events, while minimizing the number of false alarms from other events such as patient motion.
Monitor processes sensor data and notifies the user of required actions.

Sensor receptacle maintains sensor position on patient.

Sensor cable transmits data.
Early Stage Detection
/ Of Peripheral IV Infiltrations

BACKGROUND
An IRB-approved clinical study 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
1. Determine sensitivity of the ivWatch patient monitor for detecting early stage infiltrations (<10mL of isotonic saline solution).
2. Demonstrate performance for different skin pigmentations, body types, infiltration rates, and common PIV locations.
3. 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)

METHODS

70
PARTICIPANTS

140
INFILTRATED IV SITES
FIVE ATTRIBUTES WERE MEASURED FROM EACH RESEARCH SUBJECT

ACTUAL WEIGHT  ACTUAL HEIGHT  BLOOD PRESSURE  FOREARM CIRCUMFERENCE  SKIN PIGMENTATION

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

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. All subjects were infused with isotonic saline solution.
ISOTONIC SALINE SOLUTION  
All subjects were infused with 10mL of isotonic saline solution. Infiltration rates were randomly selected between 5mL/hr (KVO) and 150mL/hr.

INfiltration Timing  
The infiltration was started randomly between five and 30 minutes after starting monitoring by the ivWatch monitor.

SENSOR NOTIFICATION  
The ivWatch patient monitor issued notifications if conditions consistent with an infiltration were detected. The infiltrated volume was recorded when the yellow and red notifications were issued.

DEMOGRAPHIC RESULTS  

![Gender Pie Chart](image)
- **42 MALE**
- **28 FEMALE**

![Skin Pigmentation Pie Chart](image)
- **40 LIGHT SKIN**
- **10 MEDIUM SKIN**
- **20 DARK SKIN**

![Body Mass Index Pie Chart](image)
- **1 UNDERWEIGHT**
- **23 NORMAL**
- **23 OVERWEIGHT**
- **23 OBESE**
EFFECT OF INFILTRATION RATE

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

SENSITIVITY

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

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

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

99.3% | 95%
Confidence Interval: 95.5 to 99.96%
Early Stage Detection
Of Peripheral IV Infiltrations - CONCLUSION

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 pigmentation, 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.

REFERENCES


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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 a nine-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.
Detecting Infiltrated IV Sites on Pediatric Patients

/ Non-Alarming

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 fossa (AC). 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
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.

METHODS

156 PARTICIPANTS

7 MONTHS
ATTRIBUTES OF SUBJECTS

Age (neonate to 17 years)
Weight (> 2.5 kg)
Skin Pigmentation (Light, Medium, Dark)
Patient’s Medical Condition Required Continuous IV Therapy

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.

DEMOGRAPHIC RESULTS

GENDER
73 MALE
83 FEMALE

SKIN PIGMENTATION
122 LIGHT SKIN
17 MEDIUM SKIN
17 DARK SKIN

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.

DETECTING INFILTRATED IV SITES
INfiltration rate
A total of 23 clinician confirmed extravasations occurred in 156 patients, corresponding to an infiltration rate of 14.7 percent for the non-alarming group study population.

Extravasation notifications: non-alarming

80% detected 16 of 20 extravasation events prior to clinician confirmation.*

15.2 Hours
Median time between red “Check IV” notifications and clinical 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.

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

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.
Detecting Infiltrated IV Sites on Pediatric Patients
/ Non-Alarming - CONCLUSION

STUDY 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 STUDY
August 2015-February 2016

SPONSOR
ivWatch, LLC
1100 Exploration Way, Suite 209
Hampton, VA 23666

STUDY LOCATION
Cincinnati Children’s Hospital Medical Center (CCHMC)
3333 Burnet Avenue
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INVESTIGATORS
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Investigators:
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Candice Fletcher Overly, MSN, RN, VA-BC
Neil Johnson, MD

INTERNAL PROTOCOL ID
IVW400CS-09

CCHMC IRB
2015-0896

CLEARANCE STATEMENT
This portion of the study was not considered as part of the 510(k) clearance as changes were made to the software to improve detection rates prior to the alarming phase of this study.
Detecting Infiltrated IV Sites on Pediatric Patients

/ Alarming

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” extravasation 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.

METHODS

57 PARTICIPANTS

4 MONTHS
ATTRIBUTES OF SUBJECTS

Age (neonate to 17 years)
Weight (> 2.5 kg)
Skin Pigmentation (Light, Medium, Dark)
Patient’s Medical Condition Required Continuous IV Therapy

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.

DEMOGRAPHIC RESULTS

Gender

- 26 Male
- 31 Female

Skin Pigmentation

- 44 Light Skin
- 3 Medium Skin
- 10 Dark Skin

AGE (YEARS)

- 18
- 16
- 14
- 12
- 10
- 8
- 6
- 4
- 2
- 0

Number of Participants

- 10
- 9
- 8
- 7

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.

SITE

- Forearm 32 Subjects
- Hand 25 Subjects

Detecting Infiltrated IV Sites
INfiltration rate
A total of 15 clinician-confirmed infiltrations occurred in 57 patients, corresponding to an infiltration rate of 26.3 percent 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

**The false positive performance cannot be accurately determined without a gold standard available for comparison. As such, the notification rates for all subjects in the alarming group, excluding clinician-confirmed infiltrations, was used to estimate the false positive performance through negative binomial regression.
Detecting Infiltrated IV Sites on Pediatric Patients

STUDY 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 percent of the time, with the median time of 2.1 hours between red “Check IV” notification and clinician confirmation.

DATE OF STUDY
April 2016-July 2016

STUDY LOCATION
Cincinnati Children’s Hospital Medical Center (CCHMC)
3333 Burnet Avenue
Cincinnati, OH 45229

INTERNAL PROTOCOL ID
IVW400CS-09

CCHMC IRB
2015-0896

SPONSOR
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ADDITIONAL CLINICAL STUDY DATA ANALYSIS OF VOLUME OF INFILTRATIONS

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

\[
\text{Swelling Percentage Metric} = \frac{\text{Length of swelling at its longest point}}{\text{length of arm}}
\]

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 percent and 21 percent, 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 percent 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 percent) 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 clinician assessment. This device can aid clinicians in identifying extravasations early, in order to decrease patient harm and improve patient safety.
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 OBJECTIVES
1. Quantify the rates of red notifications and self-correcting yellow notifications.
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.

METHODS

40 PARTICIPANTS

24 HOUR STUDY
FIVE ATTRIBUTES WERE MEASURED FROM EACH RESEARCH SUBJECT

ACTUAL WEIGHT
ACTUAL HEIGHT
BLOOD PRESSURE
FOREARM CIRCUMFERENCE
SKIN PIGMENTATION

SENSOR LOCATION

The ivWatch sensor was randomly placed on either the forearm or dorsal aspect of the hand. A vein viewer 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.

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.
SENSOR NOTIFICATION

The ivWatch patient monitor issued notifications if signals consistent with an infiltration were detected.

DEMOGRAPHIC RESULTS

GENDER

16 MALE
24 FEMALE

SKIN PIGMENTATION

LIGHT
DARK
MEDIUM

40 LIGHT SKIN
10 MEDIUM SKIN
20 DARK SKIN

BODY MASS INDEX

NORMAL
OVERWEIGHT
OBESE

23 NORMAL
23 OVERWEIGHT
23 OBESE

FALSE NOTIFICATIONS

A false yellow notification was issued at a rate of 0.526 notifications per day, or about one notification every two days. 0.526 | 95% Confidence Interval: 0.193 to 1.435.

A false red notification was issued at a rate of 0.255 notifications per day, or less than one notification every four days. 0.255 | 95% Confidence Interval: 0.104 to 0.622

NON-INFILTRATION NOTIFICATION CONDITIONS

In an analysis of the surveillance footage, many of the red and yellow 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.
Minimizing Alarm Fatigue
/ Associated with Infiltration Detection - CONCLUSION

STUDY CONCLUSIONS

1. The red and yellow non-infiltration notification rates of 0.255 and 0.526/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.

REFERENCES


DATE OF STUDY

January 2014

INTERNAL PROTOCOL ID

IVW400CS-05

CHESAPEAKE IRB

Pro00009175

SPONSOR

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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 150mL/hr. The ivWatch Model 400 monitored each site and issued notifications if an infiltration was detected.

STUDY OBJECTIVES
1. Determine how the infiltration rate affects the sensitivity of the ivWatch patient monitor.
2. Determine how the infiltration rate affects the detection volume for the notifications of the ivWatch patient monitor.
3. Examine which patient attributes (skin tone, pigmentation) and infiltration characteristics (infiltration rate, IV site) affect the detected volume.

METHODS

PARTICIPANTS

INFILTRATED IV SITES

EFFECT OF INFILTRATION RATE
FIVE ATTRIBUTES WERE MEASURED FROM EACH RESEARCH SUBJECT

- **Actual Weight**
- **Actual Height**
- **Blood Pressure**
- **Forearm Circumference**
- **Skin Pigmentation**

**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.
ISOTONIC SALINE SOLUTION

All subjects were infused with 10mL 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: 5mL/hr, 50mL/hr, 100mL/hr, 150mL/hr

EFFECT OF INFILTRATION RATE

Red and yellow notifications were issued by ivWatch for all 48 infiltrations in this study prior to 10mL infiltrated volume.
SENSOR NOTIFICATION

The ivWatch patient monitor issued notifications if signals consistent with an infiltration were detected.

DEMOGRAPHIC RESULTS

GENDER

13 MALE
11 FEMALE

SKIN PIGMENTATION

10 LIGHT SKIN
11 MEDIUM SKIN
3 DARK SKIN

BODY MASS INDEX

1 UNDERWEIGHT
8 NORMAL
6 OVERWEIGHT
9 OBESE

AGE (YEARS)

75-80
70-74
65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
18-19

NUMBER OF PARTICIPANTS
Effect of Infiltration Rate
/ On Infiltration Detection - **CONCLUSION**

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**STUDY CONCLUSIONS**

1. The red and yellow notifications were issued by ivWatch for all 48 infiltrations in this study prior to 10mL infiltrated volume.

2. The average volume at the red notification was 1.7mL, 3.0 mL, 3.7mL, and 5.6mL for 5, 50, 100, and 150mL/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.

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**DATE OF STUDY**

October-November 2013

**INTERNAL PROTOCOL ID**

IVW400CS-03

**CHESAPEAKE IRB**

Pro00008941

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For updates and additional information, go to ivwatch.com