

Validation and Method Comparison for a Zero-Touch Monitoring Device

Introduction

Monitoring vital signs is an objective way to assess essential physiological functions used to evaluate patient health. Historically, vital signs are collected through manual measurement and include temperature, pulse, and respiration (TPR). Digital monitoring devices that use contact sensors or leads allow for more continuous monitoring, which provides an advantage over periodic manual measurements. However, contact sensors can cause stress for both the animal and the health-care provider, as they require the attachment of electrodes to the patient's body and often use wires to transmit signals. Causes of stress may include attached sensors aggravating the animal's skin, wires tangling around the animal, animals chewing through wires or leads, and health-care providers being scratched or bitten during attachment or removal of sensors. Therefore, a contactless monitoring device that does not require attaching sensors to the patient's body while providing more continuous monitoring than manual measurements would improve patient care.

VetGuardian® is a Zero-Touch device that monitors key vital signs. The device reports temperature, pulse, and respiration, and provides a live camera feed as well. Vital signs are primarily acquired using Doppler radar and thermal imagery, without the need for contact sensors attached to the patient. Patient data can be accessed remotely, and alerts can be sent via text when vital signs fall outside pre-set limits.

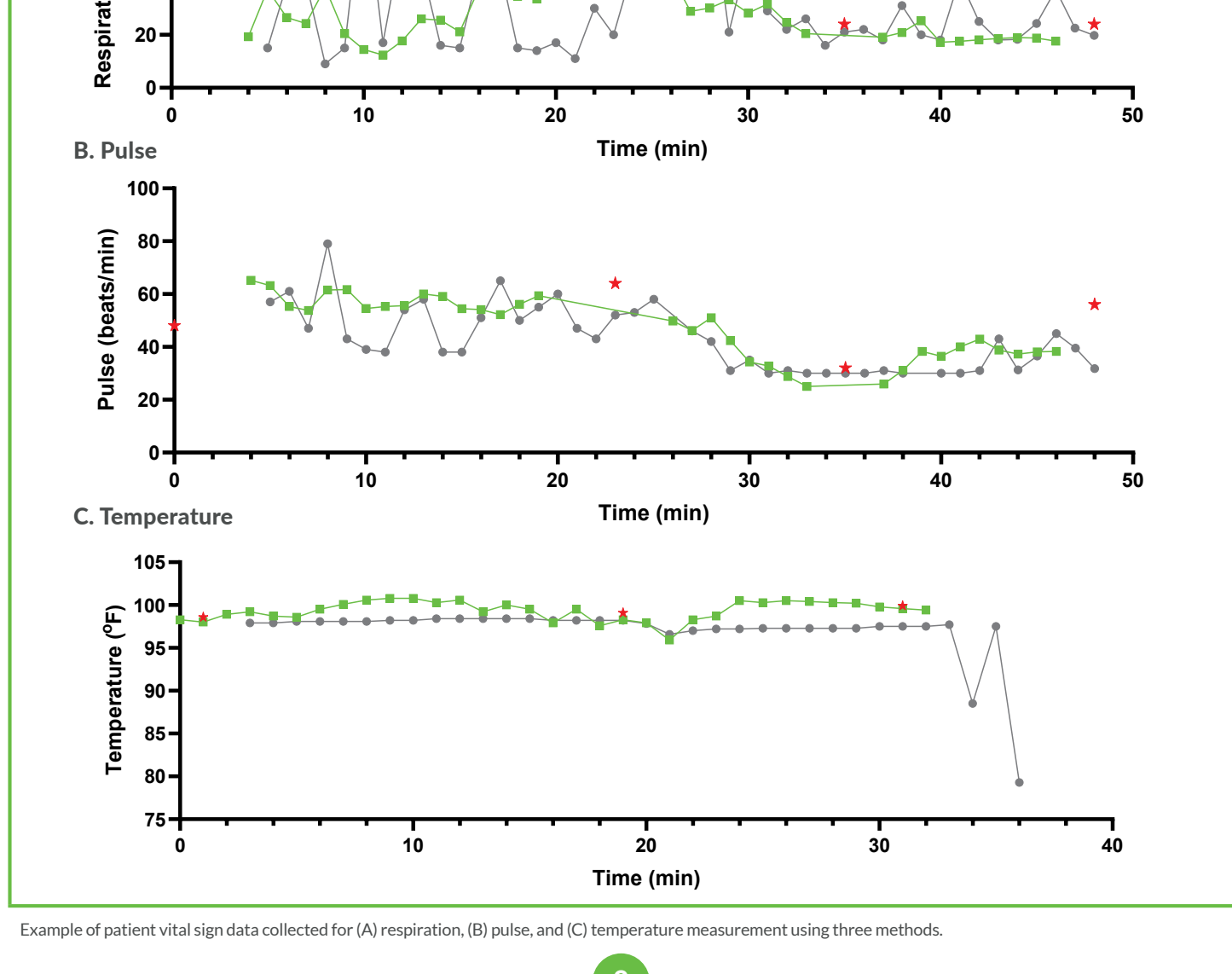
This study aims to evaluate the accuracy of vital sign monitoring using the VetGuardian Zero-Touch monitoring device compared to a contact device. Manual measurements were used as the gold standard.

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Methods

Data Collection

Ten dogs were enrolled and monitored using three methods of post-surgical vital sign monitoring in a real-world environment. All animals were scheduled for routine surgery and anesthesia at a small animal clinic in Zachary, Louisiana, and no animals were anesthetized for the sole purpose of this study. Animals were monitored post-surgery, in a recovery kennel, until they recovered from anesthesia and began moving.



Example of patient vital sign data collected for (A) respiration, (B) pulse, and (C) temperature measurement using three methods.

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Temperature, pulse, and respiration rate were measured using manual measurements, a contact monitor, and a Zero-Touch monitor. For manual measurements, standard TPR methods were used. Breaths were counted by sight or touch, heart beats were counted using a stethoscope, and temperature was collected by rectal probe. Manual measurements were taken at roughly 15-minute intervals throughout the course of the run. A contact device with three leads was used for contact monitoring and a VetGuardian device (Zero-Touch device) was used for contactless monitoring. Both the Contact and Zero-Touch devices were used throughout the course of the run. An example of temperature, pulse, and respiration readings across the three methods is shown in Figure 1.

The Zero-Touch device was placed 3 feet from the recovery cage and positioned at a downward 45-degree angle towards the animal. This placement ensures the most accurate vital sign readings by minimizing interference from surrounding motion and cage reflection. Accurate measurement of temperature using thermal imaging requires calibration to account for variability in the environment and distance from the thermal camera to the subject. Temperature readings from the Zero-Touch device were calibrated using a manual measurement taken with a rectal probe before the run was initiated.

Data Analysis

Readings from the Contact and Zero-Touch devices were compared to manual readings to determine accuracy. The process of taking manual measurements can disrupt readings from the Contact and Zero-Touch devices. Therefore, readings from the Contact and Zero-Touch devices are not available at the exact manual time point and readings within plus or minus 1.5 minutes of a manual measurement were used for comparison. All readings from the Contact or Zero-Touch devices within this 3-minute window around a manual measurement were averaged to determine a vital sign reading at a given time point. Only time points with at least one reading for both the Contact and Zero-Touch devices within the 3-minute window were used for the analysis.

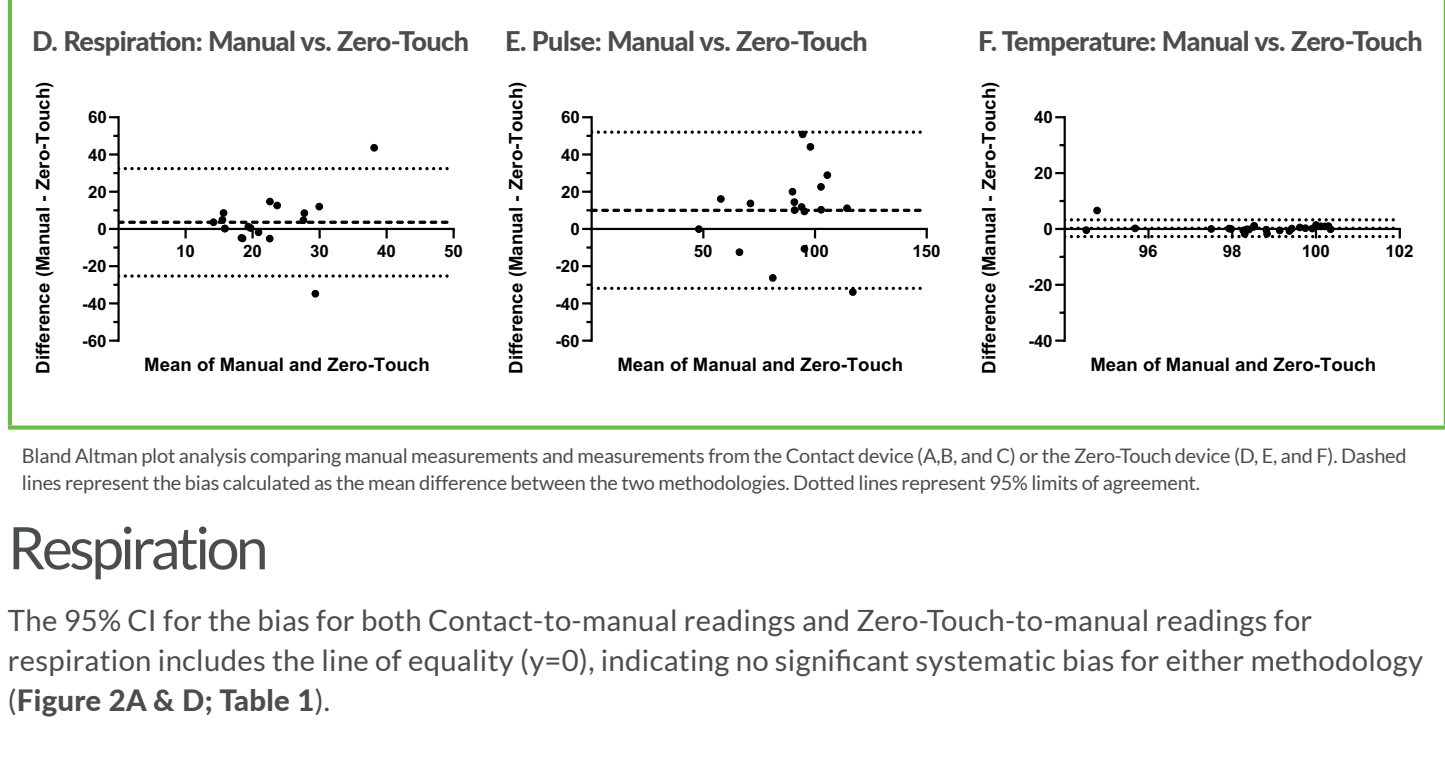
Bland-Altman analysis, calculated as the mean difference, was performed to evaluate bias and determine the 95% limits of agreement between the Contact device and manual measurement, as well as the Zero-Touch device and manual measurement. Additionally, mean percent differences were calculated as the mean of the absolute value of the difference divided by the average of the values at each time point. A paired Student's t-Test was used to determine statistical significance.

Results

Animals were monitored post-surgery until they recovered from anesthesia. Runs lasted from 29.5 to 48 minutes (median, 34.5 minutes). Eighteen manual time points had both Contact and Zero-Touch readings within a plus or minus 1.5-minute window for respiration and pulse, and these timepoints were used in the analysis. Twenty-five manual time points had both Contact and Zero-Touch readings within a plus or minus 1.5-minute window for temperature, and these timepoints were used in the analysis.

Bland-Altman bias plot analysis evaluates agreement between two methodologies (Figure 2). For all three

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Bland Altman plot analysis comparing manual measurements and measurements from the Contact device (A, B, and C) or the Zero-Touch device (D, E, and F). Dashed lines represent the bias calculated as the mean difference between the two methodologies. Dotted lines represent 95% limits of agreement.

Respiration

The 95% CI for the bias for both Contact-to-manual readings and Zero-Touch-to-manual readings for respiration includes the line of equality (y=0), indicating no significant systematic bias for either methodology (Figure 2A & D; Table 1).

The 95% limits of agreement for the two method comparisons showed very similar ranges, though the Contact-to-manual reading range was slightly wider, indicating more variation in the difference in measurements (Figure 2A & D; Table 1).

The mean percent difference was higher from the Contact-to-manual readings than the Zero-Touch-to-manual readings, suggesting that the Zero-Touch readings may be closer than the Contact readings to the manual readings (Table 1). However, this difference was not statistically significant (P > 0.05), suggesting that Contact and Zero-Touch respiration readings have similar accuracy when compared to a manual reading.

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Pulse

Both the Contact-to-manual readings and Zero-Touch-to-manual readings showed a bias for pulse, where the manual readings are overall higher than the Contact or Zero-Touch readings. The magnitude of this bias was very similar for the two method comparisons. However, only the Zero-Touch comparison had a 95% CI for bias that did not include the line of equality, suggesting that the Zero-Touch device reports a slightly lower pulse than manual readings on average (Figure 2B & E; Table 1).

The 95% limits of agreement for the two method comparisons were very similar sizes, indicating a similar range of differences in measurements (Figure 2B & E; Table 1).

The mean percent differences for the Contact-to-manual readings and the Zero-Touch-to-manual readings were very similar and not statistically different (P > 0.05) (Table 1). This suggests that Contact and Zero-Touch pulse readings have similar accuracy when compared to a manual reading.

Temperature

The magnitude of the bias for temperature was larger for the Contact-to-manual read comparison than the Zero-Touch-to-manual read comparison, though not statistically different (P > 0.05). Only the Contact-to-manual comparison had a 95% CI for bias that did not include the line of equality, suggesting that the Contact device on average reports a slightly lower temperature than manual readings (Figure 2C & F; Table 1).

The 95% limits of agreement were larger for the Contact-to-manual temperature readings than the Zero-Touch-to-manual temperature readings, indicating more variation in the difference in measurements for Contact readings compared to manual readings than Zero-Touch readings compared to manual readings (Figure 2C & F; Table 1).

The mean percent difference was higher from the Contact-to-manual temperature readings than the Zero-Touch-to-manual temperature readings, suggesting that the Zero-Touch readings may be closer than the Contact readings to the manual reading (Table 1). However, this difference was not statistically significant (P > 0.05), suggesting that Contact and Zero-Touch temperature readings have similar accuracy when compared to a manual reading.

	Respiration (breaths/min.)		Pulse (beats/min.)		Temperature (°F)	
	Manual vs. Contact	Manual vs. Zero-Touch	Manual vs. Contact	Manual vs. Zero-Touch	Manual vs. Contact	Manual vs. Zero-Touch
Bias (95% CI)	-2.3 (-9.2-4.6)*	3.6 (-3.0-10.2)*	9.4 (-0.5-19.3)*	10.0 (0.4-19.7)*	5.4 (1.3-9.4)*	0.3 (-0.4-1.1)*
95% Limits of Agreement	-32.6 to 27.9	-25.3 to 32.5	-33.9 to 52.6	-31.9 to 52.0	-15.2 to 25.9	-2.7 to 3.3
Mean Percent Difference	41.0%*	36.1%*	22.4%*	21.0%*	6.5%*	0.9%*

*Manual to Contact comparison is not significantly different than Manual to Zero-Touch comparison (Paired t-Test, P > 0.05)% limits of agreement.

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Conclusions

The VetGuardian Zero-Touch monitoring device showed similar accuracies to a Contact monitoring device when compared to manual measurements. The level of agreement to manual measurements was consistent for both the Contact and Zero-Touch monitoring devices for respiration, pulse, and temperature readings in dogs post-surgery. Further studies are recommended to increase the sample size and to evaluate the ability of the Zero-Touch device to accurately detect changes in vital signs over time. Together, the results of this study provide confidence in the accuracy of the vital sign readings obtained from the VetGuardian monitoring device in a real-world environment, when used as directed.

Acknowledgements

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Abbreviations and acronyms

TPR	Temperature, Pulse, and Respiration
CI	Confidence Interval

