Validation of the CardioWatch 287-2 Non-Invasive Blood Pressure Algorithm

1. Introduction

The CardioWatch 287-2 is a state-of-the-art wearable device engineered to intermittently monitor non-inasive blood pressure (NIBP) with high accuracy. Accurate NIBP monitoring is essential for managing various health conditions, including hypertension and cardiovascular diseases, and provides critical data during perioperative care. Wearable technology such as the CardioWatch 287-2 offers a convenient and non-invasive method for continuous monitoring, significantly enhancing patient outcomes and providing invaluable data for healthcare providers.

Blood pressure (BP) is a vital indicator of cardiovascular health, and its frequent and accurate monitoring can facilitate early detection of hypertensive disorders, guide therapeutic interventions, and prevent complications associated with cardiovascular diseases. Traditional BP measurement methods, such as the use of manual cuffs and arterial lines, while accurate, are often cumbersome, invasive, and impractical for continuous use. The CardioWatch 287-2 addresses these limitations by offering a seamless, non-invasive solution that can be integrated into daily life without discomfort or disruption.

To validate its NIBP algorithm, several clinical studies were conducted across diverse populations, comparing its performance against established reference devices such as arterial line recordings, automated cuff measurements, ambulatory blood pressure monitoring (ABPM), and manual auscultation. These studies aimed to assess the device's accuracy, reliability, and consistency across various conditions, including resting and active states, different body positions, demographics, and health conditions. The validation process involved rigorous testing under controlled clinical settings and real-world scenarios to ensure the device's performance is both reliable and robust.

The following sections summarize the findings from these extensive validation studies.

2. Study Summaries

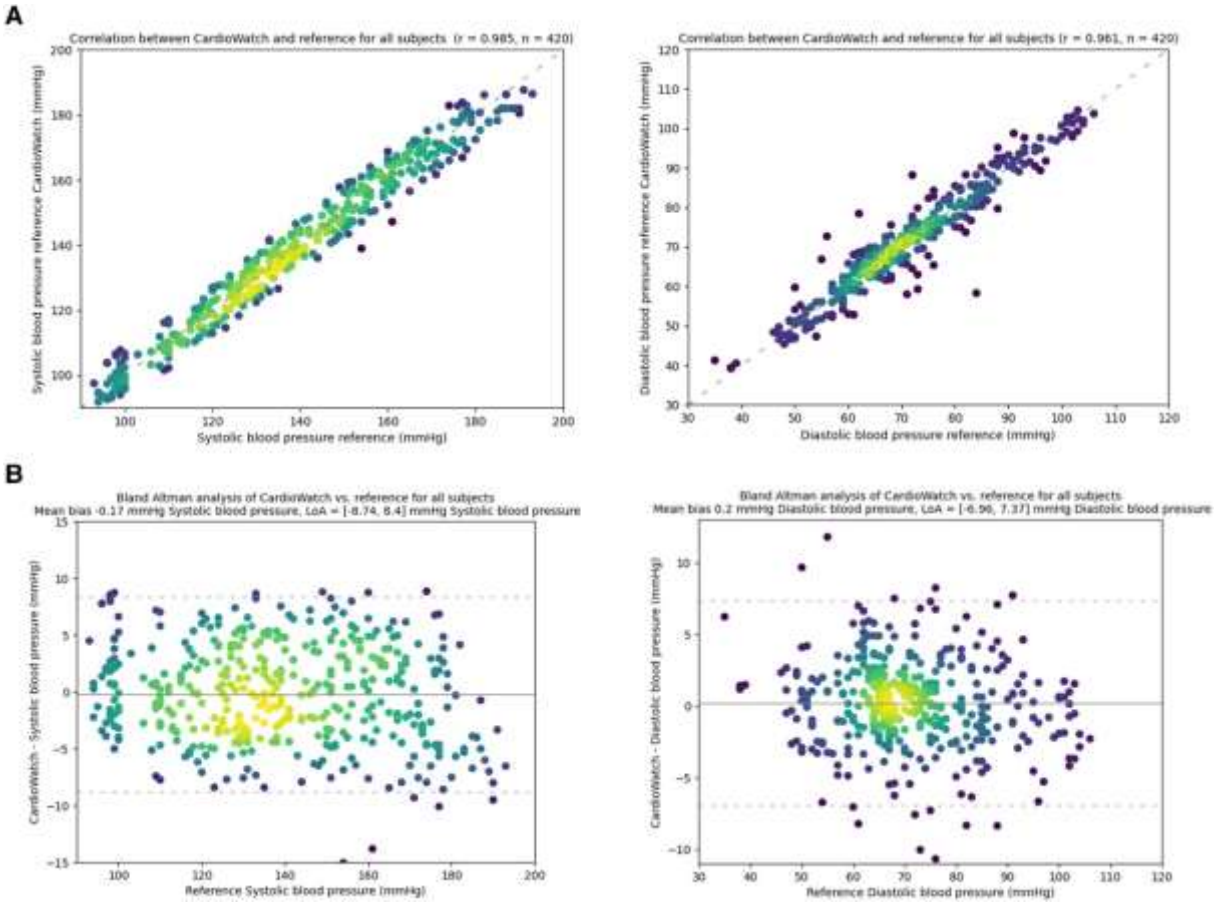
2.1 MULTI-VITAL-study

Study Centre: Reinier de Graaf Gasthuis, Delft, the Netherlands
Study Period: October 2022 – February 2023
Publication: DOI: https://doi.org/10.1093/ehjdh/ztae006
Study Population: 97 patients at rest undergoing awake cardiac catheterization
Reference Device: Arterial line
Population Characteristics:

- Age: 67 ± 11 years
- Female: 33 (33%)
- BMI: 27.4 ± 4.5 kg/m²
- Skin type: I-VI
- Clinical BP (systolic / diastolic): 144.2 ± 21.2 mmHg / 81.6 ± 13.0 mmHg

Measurement Pairs: 420 epochs (30 seconds)
Results:

- Systolic: ≤100 mmH in 48 samples (11%) and ≥160 mmHg in 106 samples (25%);
- Diastolic: ≤70 mmHg in 222 samples (53%) and ≥85 mmHg in 99 samples (24%);
- Mean error (systolic / diastolic): ±3.7 (SD ± 4.4) mmHg / ±2.5 (SD ± 3.7) mmHg
- Correlation (systolic / diastolic): R = 0.985 / R = 0.961
- Bias (systolic / diastolic): -0.17 mmHg / 0.2 mmHg
- 95% LoA (systolic / diastolic): -8.74 to 8.4 mmHg / -6.96 to 7.37 mmHg



2.2 RECAMO study

Study Centre: Reinier de Graaf Gasthuis, Delft, the Netherlands
Study Period: June 2023 – December 2023
Publication: under review
Study Population:

- Long-term study-arm: 150 patients receiving 24-hour holter monitoring
- 24-hour ABPM study-arm: daily automated BP measurements; 40 patients receiving 24-hour ABPM monitoring

Reference Device:

- Long term study-arm: manual auscultation day 1 and 28. 28 day daily automated BP cuff, 40 patients;
- 24-hour ABPM study-arm: manual auscultation day 1 and 2. 24-hour ABPM device with BP readings every 30 minute.

2.3 HIIT-study

Study Centre: The Hague Tech, The Hague, the Netherlands
Study Period: January-March 2024
Publication: under review
Study Population: 35 healthy volunteers during cycling high-intensity interval training (HIIT)
Reference Device: automated BP cuff

2.3 BP-Treat

Study Centre: Reinier de Graaf Gasthuis, Delft, the Netherlands
Study Period: June 2024 – Present
Publication: study ongoing
Study Population: 80 patients receiving (changes) in BP-lowering medication followed for 1 month
Reference Device: automated BP cuff measurements every 7 days.

3. Conclusion

The comprehensive validation studies conducted on the CardioWatch 287-2 confirm that its NIBP algorithm delivers highly accurate and reliable intermittent NIBP measurements across diverse populations and conditions. The results consistently demonstrate low mean errors and standard deviations, indicating strong agreement with reference measures such as arterial line recordings, automated BP cuffs, ABPM devices, and manual auscultation.

The MULTI-VITAL study, performed at Reinier de Graaf Gasthuis, validated the device's accuracy in a clinical setting during cardiac catheterization, This underscores the device's precision in high-stakes medical environments, making it suitable for monitoring patients with critical health conditions.

These findings collectively demonstrate the CardioWatch 287-2's robust performance across various BP levels. The mean error and standard deviation remain consistently below 4 mmHg and 5 mmHg, respectively, validating the device's capability to provide precise and consistent NIBP readings. Additionally, the CardioWatch 287-2's accuracy across different demographic groups, including both genders and various skin types, reinforces its versatility.

The CardioWatch 287-2's ability to provide real-time, accurate NIBP data can aid in the early detection and monitoring of hypertension, guide clinical decision-making, and optimize patient monitoring. Its ease of use and non-invasive nature make it an accessible tool for a wide range of users, promoting better health outcomes through enhanced monitoring and timely interventions.

In conclusion, the validation studies strongly support the CardioWatch 287-2 as a reliable and precise tool for intermittent NIBP monitoring. Its consistent performance across various conditions and populations underscores its potential for improving health outcomes through better monitoring and early intervention.

Summary – Validation of the Corsano CardioWatch 287-2 Non-invasive Blood Pressure Algorithm

Study acronym	Study centre	Study period	Study population	Reference device	Population characteristics	Measurement pairs	Results
MULTI-VITAL-study (DOI)	Reinier de Graaf Gasthuis, Delft, the Netherlands	October 2022 – February 2023	97 patients in rest undergoing awake cardiac catheterization	Arterial line	Age: 67±11 years Female: 33 (33%) BMI: 27.4±4.5 kg/m2 Skin type: I-VI Clinical BP (systolic/diastolic): 144.2 ± 21.2 mmHg / 81.6 ± 13.0 mmHg	420 epochs (30 seconds)	- Mean error (systolic / diastolic): ±3.7 (SD ± 4.4) mmHg / ±2.5 (SD ± 3.7) mmHg - Correlation (systolic / diastolic): R = 0.985 / R = 0.961 - Bias (systolic / diastolic): -0.17 mmHg / 0.2 mmHg - 95% LoA (systolic / diastolic): -8.74 to 8.4 mmHg / -6.96 to 7.37 mmHg
RECAMO-long-term study-arm	Reinier de Graaf Gasthuis, Delft, the Netherlands	June 2023 – December 2023	150 patients receiving 24-hour holter monitoring	Manual auscultation on day 1&28, 28 days, daily Automated cuff measurements	Under review	Under review	Under review
RECAMO-24h-ABPM study-arm	Reinier de Graaf Gasthuis, Delft, the Netherlands	June 2023 – December 2023	40 patients receiving 24-hour ABPM monitoring	Manual auscultation on day 1 and 2, and 24-hour ABPM, BP reading every half hour	Under review	Under review	Under review
HIIT-study	The Hague Tech, The Hague, the Netherlands	Jan-March 2024	35 healthy volunteers during a cycling HIIT	Automated BP cuff	Under review	Under review	Under review
BP-Treat	Reinier de Graaf Gasthuis,	June 2024 - Present	80 patients receiving in BP-	Automated BP cuff every 7 days up to 1 month	Ongoing	Ongoing	Ongoing

	Delft, the Netherlands		lowering medication				

Abbreviations: SD: standard deviation; BP: blood pressure; ABPM: ambulatory blood pressure monitoring; R = pearson correlation coefficient; LoA: limits of agreement; BMI: body mass index; HIIT: high intensity interval training