



The Future of 24-Hour Blood Pressure Monitoring

Biobeat demonstrates high accuracy in a validation study performed by the **Mayo Clinic**, showing excellent agreement with continuous invasive arterial-line measurements in ICU patients.



EXECUTIVE SUMMARY

Hypertension (HTN) is the most common modifiable cardiovascular risk factor worldwide, affecting 48% of the adult population in the United States according to the Centers for Disease Control data from 2021–2023.

Despite its ubiquity, hypertension remains challenging to diagnose accurately.

Blood pressure is a simple measurement but a highly complex and variable physiologic parameter. It is inherently circadian, continuously adapting to multiple physiologic inputs including physical activity, medication timing, emotional state, meals, autonomic tone and sleep. These natural fluctuations highlight the limitations of current BP measurement strategies, which often fail to reflect true blood pressure behavior across the full 24-hour cycle.

This is why the American College of Cardiology/American Heart Association 2017 Hypertension Guidelines recognize ambulatory blood pressure monitoring (ABPM) as a Class 1A recommendation for confirming hypertension. Subsequent AHA guidance and updates through 2025 continue to reinforce the central role of out-of-office BP monitoring, including ABPM, for accurate diagnosis and management of hypertension.

However, ABPM remains underutilized in routine clinical practice. Fewer than 0.5% of commercially insured patients with newly treated or treatment-resistant hypertension had ABPM claims submitted to their insurance, according to a study in the International Journal of Cardiology.

Accurate blood pressure assessment requires that the act of measurement itself doesn't alter the physiologic value. However, traditional cuff-based techniques can influence BP, particularly during inflation, which may trigger sympathetic activation, discomfort or anticipatory stress.

48%

of U.S. adults are affected by hypertension

A classic study published in The Lancet in 1990 demonstrated that cuff inflation can raise measured systolic BP by up to 20 mmHg. This highlights a fundamental limitation of intermittent cuff-based methods and reinforces the need for measurement strategies that do not interfere with the parameter they aim to capture.

A prospective validation study from Mayo Clinic published in the Journal of Human Hypertension by Hellou et al., evaluated Biobeat's cuffless chest patch against invasive intra-arterial pressure (IAP) monitoring in post-cardiac surgery patients. The study demonstrated strong correlation, minimal bias, no measurement drift, and consistent performance across skin tones and across different patient positions.

The findings suggest that cuffless continuous blood pressure monitoring may represent a clinically viable and scalable evolution of 24-hour blood pressure assessment.



KEY CLINICAL TAKEAWAY

“

Continuous cuffless monitoring may represent the next evolution of 24-hour blood pressure assessment.

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CLINICAL PROBLEM

Measuring a dynamic parameter with a spotty measurement tool

PHYSIOLOGIC FACTORS AFFECTING BLOOD PRESSURE

- Circadian day-night variation
- Physical activity and periods of rest
- Medication timing and pharmacologic effects
- Emotional state, mood and stress
- Food intake and postprandial hemodynamics
- Autonomic balance and sympathetic activation
- Sleep quality and sleep stages

Because of these natural fluctuations, spot measurements from traditional BP tools capture only a snapshot in time and often fail to represent true 24-hour blood pressure behavior. Only continuous or 24-hour monitoring accurately characterizes a patient's average blood pressure and circadian pattern. Nevertheless, most BP measurements still occur in the office, providing isolated values that do not reflect real-world physiology, even in patients already diagnosed with or at risk for hypertension.

PATTERNS OFTEN MISSED BY SPOT MEASUREMENTS

- Nocturnal dipping or reverse-dipping patterns
- Masked hypertension
- White coat hypertension
- Morning blood pressure surge

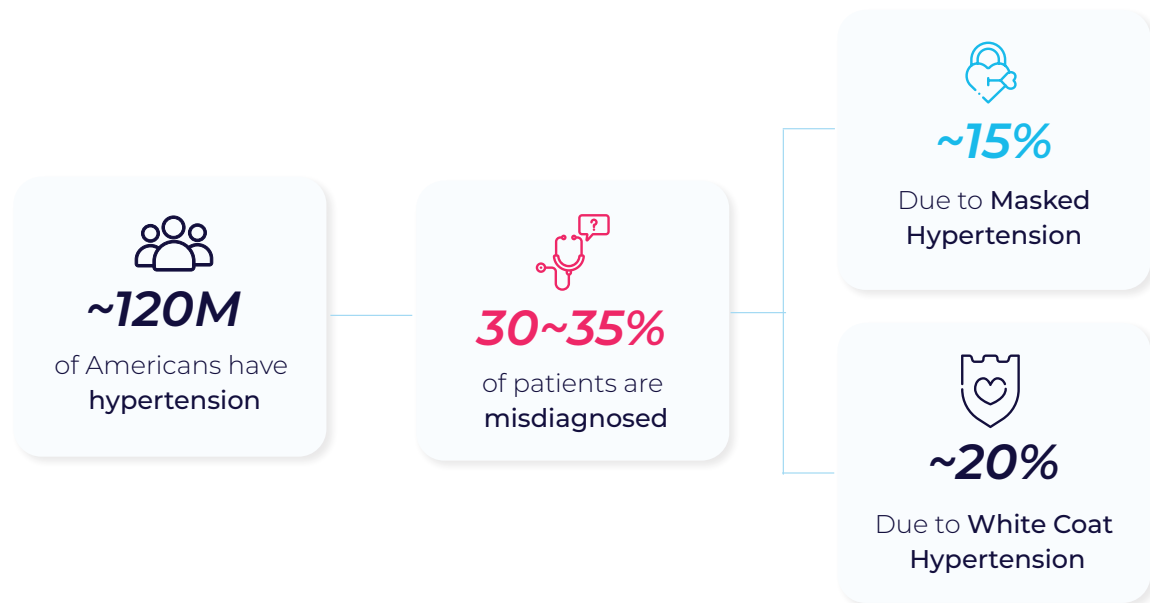
WHEN THESE PATTERNS ARE MISSED, THE RESULT IS

CLINICAL CONSEQUENCES »

- Frequent misclassification of blood pressure status
- Underdiagnosis of true hypertension
- Overtreatment of patients with white coat responses
- Persistent uncontrolled hypertension

MISDIAGNOSIS IN HYPERTENSION MANAGEMENT

Despite the availability of effective antihypertensive therapies, one in four patients remains uncontrolled largely because their true 24-hour blood pressure profile is never captured.



Misdiagnosis is a major clinical challenge in hypertension management. Up to 30-35% of patients are incorrectly classified, largely due to masked or white coat hypertension:

WHITE COAT SYNDROME

Approximately 20% of individuals experience white coat hypertension, where anxiety, stress or the discomfort of cuff inflation artificially elevates blood pressure value

(Source: <https://pmc.ncbi.nlm.nih.gov/articles/PMC4262763/>).

MASKED HYPERTENSION

Conversely, masked hypertension affects about 15% of adults, occurring when in-office readings fail to capture elevated pressures seen during daily life due to work-related stress, physical activity, early morning surge, or nocturnal hypertension.

(Source: <https://pmc.ncbi.nlm.nih.gov/articles/PMC3652723/#T5>).

These patterns contribute significantly to the overall burden of misdiagnosis and highlight the need for accurate, continuous, and real-world blood pressure assessment.



It's particularly important to capture nocturnal averages when diagnosing and treating hypertension. Multiple studies demonstrate that nighttime blood pressure is more strongly associated with cardiovascular outcomes than daytime measurements alone. Nocturnal blood pressure is up to six times more predictive of mortality than systolic blood pressure spot readings obtained in the clinic. (Source: 2023 study in The Lancet)

WHY ABPM REMAINS OPERATIONALLY CHALLENGING

Despite being the gold standard for HTN diagnosis, traditional cuff-based ABPM presents significant practical barriers, leaving many patients at risk of undiagnosed and uncontrolled hypertension.

Most physician offices have limited ABPMs — too few for a condition that affects nearly half the U.S. adult population. The devices themselves are uncomfortable and even cumbersome for patients:



Device inflation
every 15–30 minutes



Sleep disturbance



Pain and discomfort



Behavioral modification
during measurement, such as
pausing or bracing for discomfort



Multiple office visits



It's especially common for patients to fail to complete nighttime measurements, skewing the 24-hour average.

Besides the patient burden, ABPM requires office staff to spend significant time setting up patients with the device, entering data and sterilizing devices after use.

As a result, ABPM remains underutilized, often reserved for a small subset of patients rather than a routine diagnostic tool.

CLINICAL SOLUTION

A scalable cuffless device for accurate, continuous blood pressure measurement

CLINICAL VALIDATION AGAINST INVASIVE ARTERIAL PRESSURE MONITORING

To address the foundational question of Biobeat's accuracy, researchers evaluated the photoplethysmography (PPG)-based cuffless chest patch against invasive radial intra-arterial monitoring in 92 patients recovering from cardiac surgery at Sheba Medical Center. The results are published in a prospective validation study in the Journal of Human Hypertension.

STUDY DESIGN

In the single-center validation, researchers monitored blood pressure in 92 adult patients following coronary artery bypass or valve surgery simultaneously with Biobeat's cuffless chest-worn PPG device and the standard invasive arterial catheter. The mean monitoring duration was 25.6 ± 17.2 hours.

This setting allowed direct comparison with the clinical gold standard for continuous blood pressure measurement.

Mean monitoring duration

**25.6
± 17.2
hours**

TOTAL PAIRED MEASUREMENTS:

78,659

Systolic

78,818

Diastolic

92,544

Heart Rate Readings

PATIENT POPULATION

The study reflects a medically complex, real-world cardiovascular population in terms of smoking, age, obesity, diabetes, congestive heart failure, hypertension, ischemic heart disease and valvular disease.

96 patients were recruited for the study

88 patients were included in the final analysis

Mean age: **63.2** years

33% women

HIGH CARDIOVASCULAR RISK BURDEN:

- **62.5%** hypertension
- **41.7%** ischemic heart disease
- **32.3%** diabetes

ACTIVE CARDIOVASCULAR MEDICATION:

- Statins
- Anti-PLT
- Insulin
- CCB

STUDY RESULTS

Accuracy & correlation

Across the entire range of blood pressure in approximately 80,000 data sets, the correlation coefficients between the cuffless device and invasive arterial monitoring were excellent, with minimal bias and high agreement in BP and HR measurements between the Biobeat cuffless PPG-based device and IAP. This indicates strong linear agreement across tens of thousands of paired measurements.

CORRELATION COEFFICIENTS

Systolic blood pressure (SBP): $r = 0.96$

Diastolic blood pressure (DBP): $r = 0.97$

Mean Arterial Pressure (MAP): $r = 0.97$

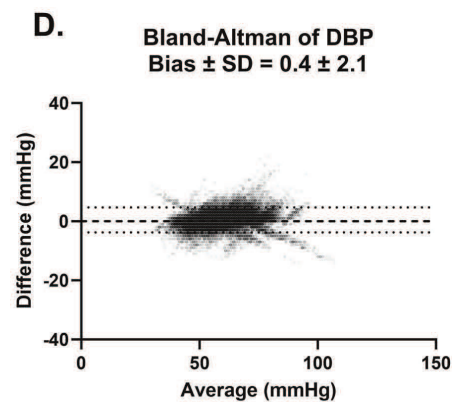
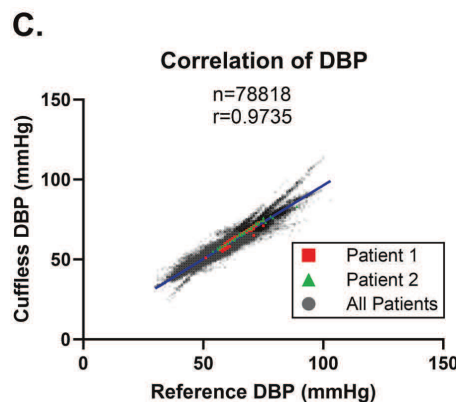
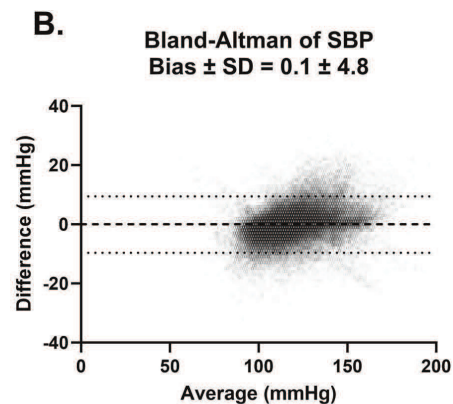
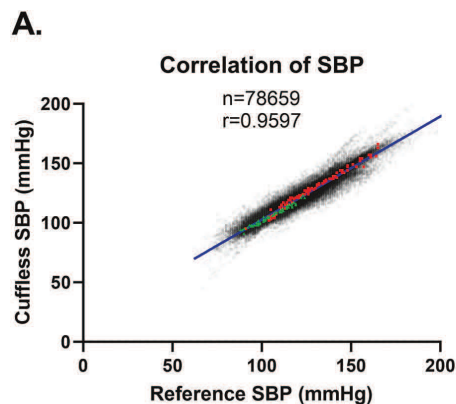
Heart rate (HR): $r = 0.96$

BLAND-ALTMAN ANALYSIS DEMONSTRATED:

SBP bias: 0.1 ± 4.8 mmHg

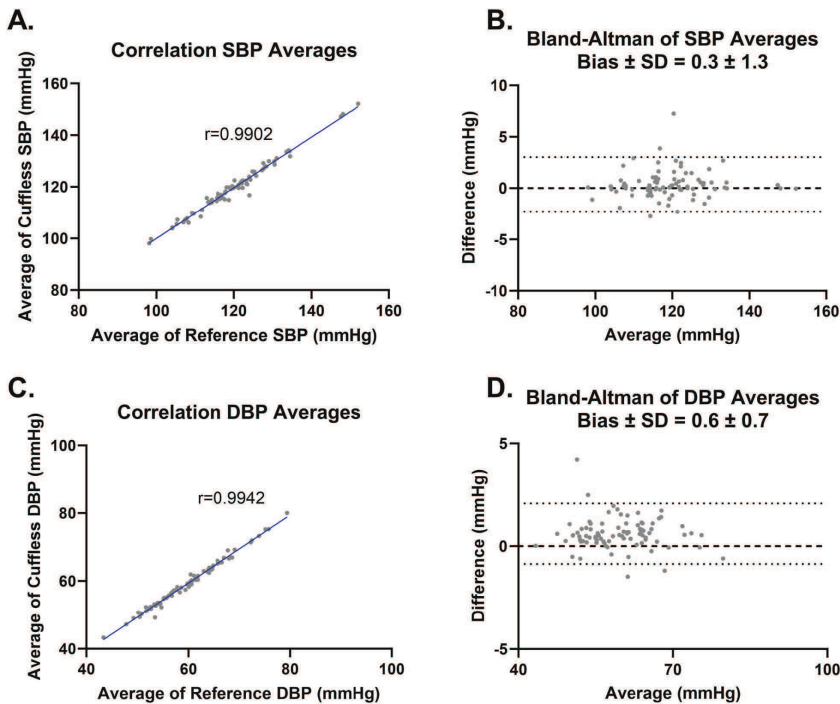
DBP bias: 0.4 ± 2.1 mmHg

MAP bias: 0.26 ± 2.6 mmHg



When comparing each patient's average values rather than the point-by-point data, the agreement between the cuffless device and the invasive reference remained superb.

AGREEMENT USING PATIENT-LEVEL AVERAGES



Mean bias in averages

**0.3
mmHg**

giving physicians strong confidence that the average mean is true.

ISO ACCURACY CRITERIA

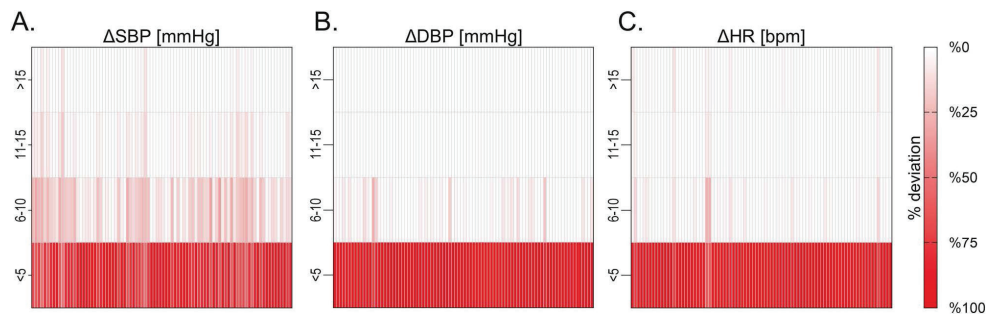
Absolute mean difference ≤ 6 mmHg
Standard deviation ≤ 10 mmHg

Biobeat's measurement variability is well within international accuracy standards.

DISTRIBUTION OF AGREEMENT

- **95%** of SBP readings were within 10 mmHg of the reference
- **99.9%** of DBP readings were within 10 mmHg

The heat map shows the distribution of measurement bias per participant across four ranges (0–5, 6–10, 11–15, and >15 mmHg), with darker red indicating a higher proportion of readings in that range.



95%

Systolic accuracy

<10 mmHg

99.9%

Diastolic accuracy

<10 mmHg

95.4%

Heart rate accuracy

<10 bpm

PERFORMANCE ACROSS SKIN TONES



Represents the highly diverse population of of the USA



The study stratified results according to the Fitzpatrick skin tone scale (I–VI).

Biobeat’s device maintained a strong correlation and minimal bias across all categories.

This is clinically meaningful given ongoing concerns about optical sensor performance across varying pigmentation levels.

- Excellent correlation across all tones
- r range: 0.95 – 0.97
- No clinically meaningful bias differences
- Demonstrated performance in diverse skin pigmentation
- Supports applicability across populations

Skin tone (Fitzpatrick scale)	Number (%) N = 96	Number of pairs	Pearson r	p-value	Bias ± SD	95% Limits of Agreement
I	17 (17.7%)	15,718	0.970	<0.0001	0.04 ± 4.56	-8.891 to +8.963
II	16 (16.7%)	11,282	0.950	<0.0001	-0.16 ± 4.48	-8.933 to +8.621
III	22 (22.9%)	14,861	0.958	<0.0001	-0.09 ± 5.24	-10.36 to +10.17
IV	15 (15.6%)	12,533	0.952	<0.0001	-0.07 ± 4.79	-9.454 to +9.317
V	14 (14.6%)	13,335	0.953	<0.0001	-0.01 ± 4.92	-9.656 to +9.634
VI	10 (10.4%)	8007	0.958	<0.0001	-0.04 ± 5.24	-10.31 to +10.24
NA	2 (2.1%)					

DYNAMIC TRACKING

Across all patients in the study, the device demonstrated preserved physiologic trend tracking over time, including clear day-night variation. Researchers observed no significant measurement drift.

The device not only provided accurate spot measurements but also reliably tracked dynamic changes in blood pressure in parallel with invasive arterial monitoring.

POSTURE-INDEPENDENT ACCURACY

Researchers recorded patient posture in the A-line study, ensuring that Biobeat was validated across various positions and demonstrated good accuracy.

Position	Number (%)	Pearson r	p-value	Bias ± SD	95% Limits of Agreement
Lying on back	30,981 (37.6%)	0.96	<0.0001	-0.17 ± 4.69	-9.37 to +9.03
Lying on left side	2085 (2.5%)	0.98	<0.0001	0.39 ± 4.58	-8.6 to +9.37
Lying on right side	3355 (4.1%)	0.96	<0.0001	0.62 ± 4.73	-8.66 to +9.89
Sitting in bed	1226 (1.5%)	0.97	<0.0001	1.99 ± 5.09	-7.98 to +11.95
Sitting in chair	8854 (10.8%)	0.96	<0.0001	0.33 ± 4.85	-9.17 to +9.83
Position unknown	35,808 (43.5%)	0.95	<0.0001	-0.17 ± 5.05	-10.06 to +9.73



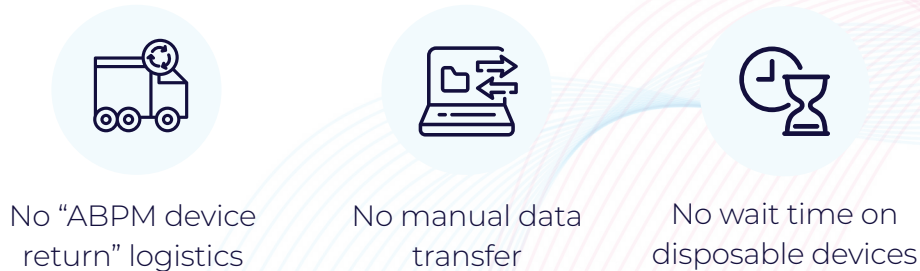
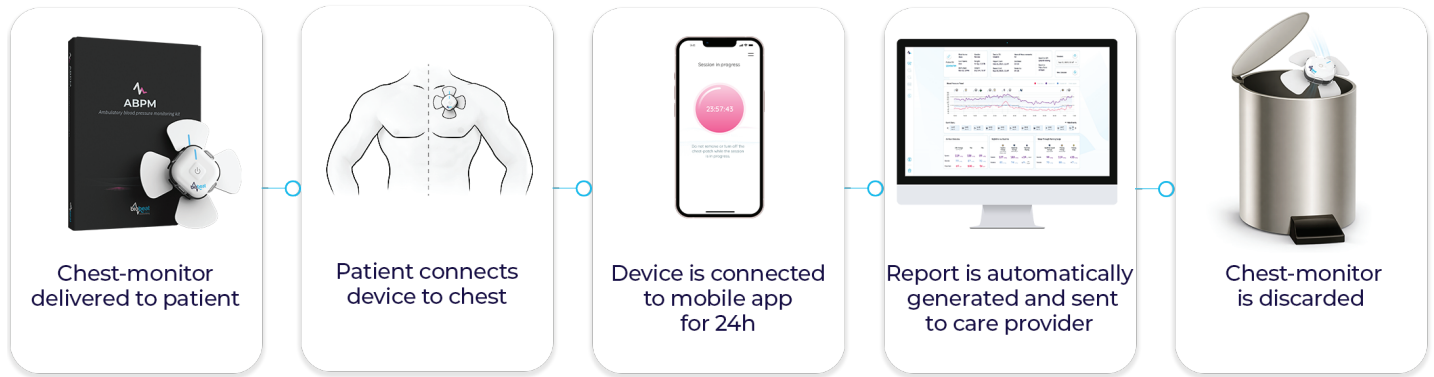
Further multicenter studies in ambulatory populations and formal validation under updated ISO standards are warranted. Longitudinal outcomes data will be critical to demonstrate the impact on cardiovascular endpoints.

CLINICAL IMPLICATIONS

Scaling access to 24-hour monitoring

The cuffless, single-use, chest-worn system that's FDA cleared and clinically validated represents the future of ABPM at scale.

Beat Hypertension, Save Lives : Precision Monitoring for Hypertension Control



With an accessible device like Biobeat, physicians can prescribe a cuffless ABPM screening to every patient who needs it. The device communicates wirelessly with a cloud-based processing center, and results are automatically sent to the physician and can even be integrated into EPIC. It may be eligible for reimbursement under the same CPT codes as ABPM screening.

Patients are more likely to adhere to the full 24-hour screening regimen, ensuring that physicians have continuous, automated data capture.

This includes:

- Accurate daytime and nighttime averages
- Dipping pattern assessment
- Morning surge evaluation
- Real-world activity correlation



CLOSING THE HYPERTENSION GAP

WITH BETTER DIAGNOSTIC AND MANAGEMENT TECHNOLOGY

In a prospective comparison against invasive arterial pressure monitoring, Biobeat's cuffless PPG-based chest patch demonstrated strong correlation, minimal bias and consistent performance across patient subgroups.

Reducing the rate of adults with uncontrolled hypertension in the U.S. requires new technology to improve diagnosis and ongoing condition management. With 24-hour data from a device that's well-tolerated by patients and clinically validated, Biobeat has the potential to redefine how clinicians diagnose and manage HTN.

The future of hypertension can't be controlled solely by more medications. It has to be driven by better measurement as well.

CONTACT TO SET A DEMO:

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the research:

