



Leaders in Hypertension Diagnosis & Treatment: Defeating The Silent Killer

Biobeat Blood Pressure Monitoring
For Diagnosis and Management of Hypertension



ACC AHA Hypertension Guidelines 2017*

4.2. Out-of-Office and Self-Monitoring of BP

Recommendation for Out-of-Office and Self-Monitoring of BP

References that support the recommendation are summarized in Online Data Supplement 3 and Systematic Review Report.

COR	LOE	Recommendation
I	A ^{SR}	1. Out-of-office BP measurements are recommended to confirm the diagnosis of hypertension (Table 11) and for titration of BP-lowering medication, in conjunction with telehealth counseling or clinical interventions. ^{S4.2-1–S4.2-4}

Recommendation-Specific Supportive Text

1. **ABPM** is used to obtain out-of-office BP readings at set intervals, usually over a period of 24 hours. **HBPM** is used to obtain a record of out-of-office BP readings taken by a patient. Both **ABPM** and **HBPM** typically provide BP estimates that are based on multiple measurements. A systematic review conducted by the US Preventive Services Task Force reported that **ABPM** provided a better method to predict long-term CVD outcomes than did office BPs. It incorporates new information from studies of **HBPM**, **ABPM**, the relationship of overall CVD risk to the effectiveness of blood pressure lowering, clinical outcomes related to different blood pressure goals, strategies to improve blood pressure control and various other areas. A small body of evidence suggested, but did not confirm, that **HBPM** could serve as a similar predictor of outcomes.^{S4.2-4} Meta-analyses of

4.3. Ambulatory BP Monitoring

All of the major RCTs have been based on use of clinic BP readings. However, **ABPM** is often used to supplement BP readings obtained in office settings.^{S4.3-1} The monitors are usually programmed to obtain readings every 15 to 30 minutes throughout the day and every 15 minutes to 1 hour during the night. **ABPM** is conducted while individuals go about their normal daily activities. **ABPM** can a) provide estimates of mean BP over the entire monitoring period and separately during nighttime and daytime, b) determine the daytime-to-nighttime BP ratio to identify the extent of nocturnal “dipping,” c) identify the early-morning BP surge pattern, d) estimate BP variability, and e) allow for recognition of symptomatic hypotension. The US Centers for

as a guide but should be interpreted with caution. Higher daytime SBP measurements from **ABPM** can be associated with an increased risk of CVD and all-cause death independent of clinic-measured BP.^{S4.3-14} A meta-analysis of observational studies that included 13 844 individuals suggested nighttime BP is a stronger risk factor for CHD and stroke than either clinic or daytime BP.^{S4.3-15}

Recommendations for Masked and White Coat Hypertension

References that support recommendations are summarized in Online Data Supplements 4, 5, and 6.

COR	LOE	Recommendations
Ia	B-NR	1. In adults with an untreated SBP greater than 130 mm Hg but less than 160 mm Hg or DBP greater than 80 mm Hg but less than 100 mm Hg, it is reasonable to screen for the presence of white coat hypertension by using either daytime ABPM or HBPM before diagnosis of hypertension. ^{S4.4-1–S4.4-3}
Ia	C-LD	2. In adults with white coat hypertension, periodic monitoring with either ABPM or HBPM is reasonable to detect transition to sustained hypertension (S4.4-2,S4.4-5,S4.4-7).
Ia	C-LD	3. In adults being treated for hypertension with office BP readings not at goal and HBPM readings suggestive of a significant white coat effect, confirmation by ABPM can be useful (S4.4-9,S4.4-10).
Ia	B-NR	4. In adults with untreated office BPs that are consistently between 120 mm Hg and 129 mm Hg for SBP or between 75 mm Hg and 79 mm Hg for DBP, screening for masked hypertension with HBPM (or ABPM) is reasonable (S4.4-3,S4.4-4,S4.4-6,S4.4-8,S4.4-11).
Iib	C-LD	5. In adults on multiple-drug therapies for hypertension and office BPs within 10 mm Hg above goal, it may be reasonable to screen for white coat effect with HBPM (or ABPM) (S4.4-3,S4.4-7,S4.4-12).
Iib	C-EO	6. It may be reasonable to screen for masked uncontrolled hypertension with HBPM in adults being treated for hypertension and office readings at goal, in the presence of target organ damage or increased overall CVD risk.
Iib	C-EO	7. In adults being treated for hypertension with elevated HBPM readings suggestive of masked uncontrolled hypertension, confirmation of the diagnosis by ABPM might be reasonable before intensification of antihypertensive drug treatment.

Significant Potential to Save Lives by Expanding the Use of ABPM

With Biobeat's Next-generation BPM

- Current standard of care is cumbersome and has low compliance, wherefore its utilization in the USA is very low
- A recent European study has demonstrated:

THE LANCET

Relationship between clinic and ambulatory blood pressure and mortality:
an observational cohort study in 59 124 patients

Natalie Staplin, Alejandro de la Sierra*, Luis M ruilope, Jonathan R Emberson, Ernest Vinyoles, Manuel Gorostidi, Gema Ruiz-Hurtado, Julian Segura, Colin Baigent, Bryan Williams*

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ABPM is far more informative about the risk of all-cause death and cardiovascular death than clinic BP

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“

Night-time ABPM is six times more informative for death than clinic systolic blood pressure

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“

Day-time ABPM is nearly twice as informative for death as daytime ambulatory systolic blood pressure

”

“

Masked hypertension is concerning as these patients usually remain undetected with screening using clinic blood pressure alone

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Disrupting Cuffless Blood Pressure Monitoring

ABPM Currently Uses a Cumbersome Device that Carries Low Compliance



Monday morning
Go to clinic



Nurse attaches device



Wear device for 24 hours, cuff will inflate every 15 minutes



Tuesday morning
Return to clinic



Data is manually downloaded to computer



Device is washed for next patient

In the USA

120M

People have hypertension

47%

Adult Hypertension

35%

Of the patients are misdiagnosed

20%

False Positive "White Coat"

15%

False Negative "Masked"

Disrupting Cuffless Blood Pressure Monitoring

With Biobeat's Cuffless BP system

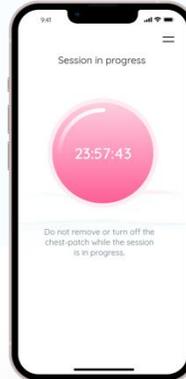
Beat Hypertension, Save Lives : Precision Monitoring for Hypertension Control



Chest-monitor delivered to patient



Patient connects device to chest



Device is connected to mobile app for 24h



Report is automatically generated and sent to care provider



Chest-monitor is discarded

Platform for diagnosis HTN



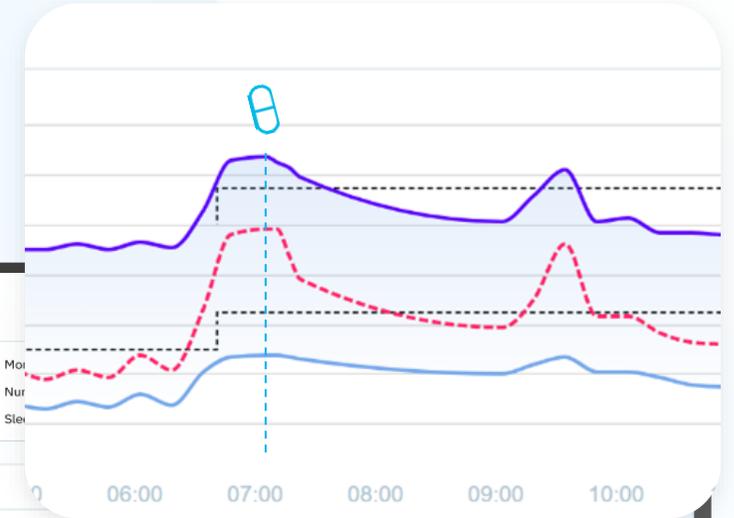
Report automatically generated and analyzed



Data is accessed from any web platform



Data is interactively displayed in graphical form including trend analysis



Traditional ABPM Comparison VS Biobeat BPM



SPACE LABS
HEALTHCARE



Cuff Blood Pressure

Heart Rate

Inflation of cuff every 30 minutes for 24 hours

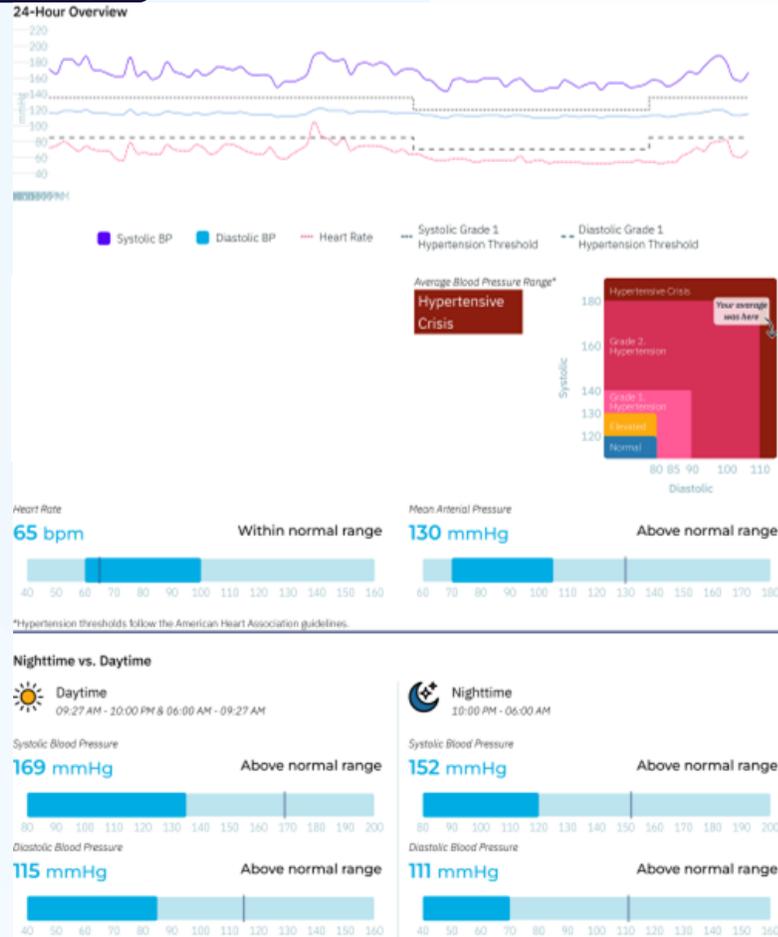


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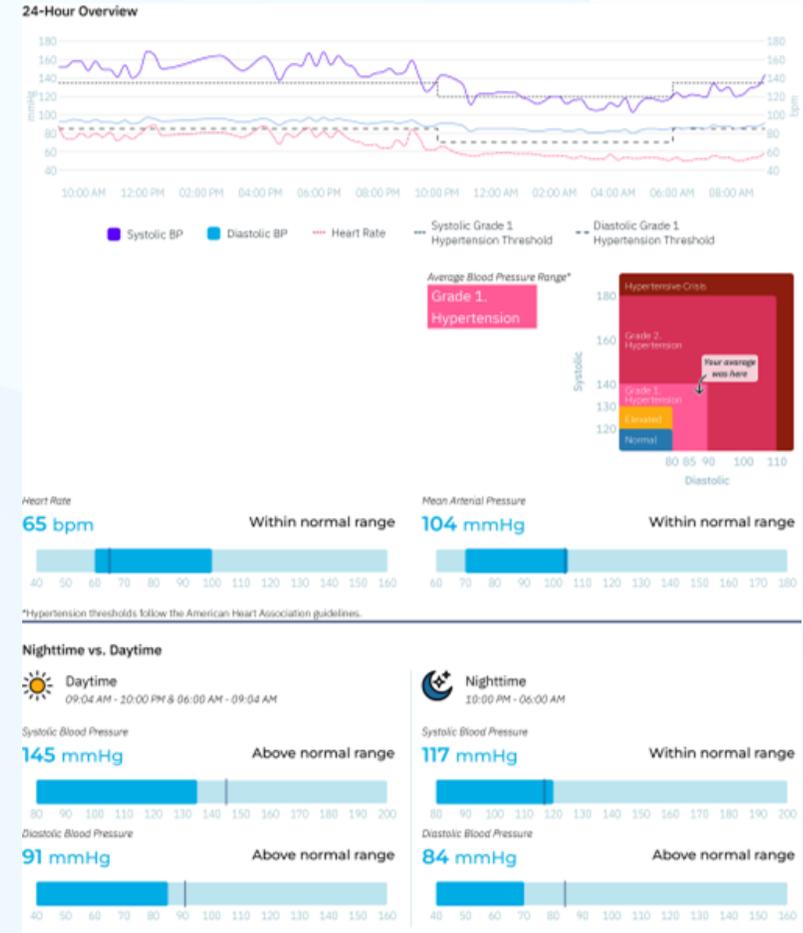


Balancing Blood Pressure with Biobeat's Platform

Pre-treatment



Two weeks after treatment



Reimbursement

Device/report

93784, 93786, 93788, 93790

\$120

Total CMS reimbursement

\$261

COMMON ABPM INDICATIONS AND INSURANCE COVERAGES		
Indication (ICD-10)	Covered by Medicare/Medicaid	Covered by commercial insurers
White coat hypertension (R03.0)	Yes	Usually
Masked hypertension (ICD-10 code pending)	Planned	Usually
Resistant or labile hypertension (I10)	No	Usually
Nocturnal hypertension (no specific ICD-10 code)	No	Usually
Post-prandial or orthostatic hypotension or syncope (I95.1 or R55)	No	Usually

CMS coverage indications for ABPM*	
For diagnosis of suspected white coat hypertension	Elevated average office BP (per new American Heart Association guideline) on two separate visits with at least two separate measurements made at each visit and with at least two BP measurements outside the office < 130/80 mm Hg
For diagnosis of suspected masked hypertension	Average office systolic BP 120-129 mm Hg or diastolic BP 75-79 mm Hg on two separate office visits with at least two separate measurements made at each visit and with at least two BP measurements outside the office ≥ 130/80 mm Hg

*Patient is covered for one test per year

SAMPLE REIMBURSEMENTS

Shown below are ABPM reimbursements at a university-affiliated clinic in 2019. Actual amounts vary by insurer, location, etc.

Primary Insurance	CPT code 93784 reimbursement (USD)
Commercial 1	\$248.09
Commercial 2	\$172.16
Commercial 3	\$163.93
Commercial 4	\$124.44
Medicaid	\$63.29
Medicare	\$60.00

CPT code	Procedure
93784	Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation, and report.
93786	Recording only (reported on the date monitoring is completed)
93788	Scanning analysis with report
93790	Review with interpretation and report



Clinical Publication



Description of the study		where published	Link
Assessing workflow, satisfaction, and potential cost reduction when using a cuffless ambulatory blood pressure monitor	ABPM	Journal of Family Medicine & Community Health	https://www.jscimedcentral.com/public/assets/articles/familymedicine-9-1189.pdf
Comparing blood pressure measurements between a photoplethysmography-based and a standard cuff-based manometry device	Blood pressure	Scientific Reports (Nature Research)	https://www.nature.com/articles/s41598-020-73172-3
A Pilot Study of Blood Pressure Monitoring After Cardiac Surgery Using a Wearable, Non-invasive Sensor	Blood pressure	Frontiers in Medicine	https://www.frontiersin.org/articles/10.3389/fmed.2021.693926/full
Twenty-Four-Hour Ambulatory Blood Pressure Measurement Using a Novel Noninvasive, Cuffless, Wireless Device	Blood pressure	American Journal of Hypertension	https://academic.oup.com/ajh/article/34/11/1171/6304850?login=false
Influence of Sex, BMI, and Skin Color on the Accuracy of Non-Invasive Cuffless Photoplethysmography-Based Blood Pressure Measurements	Blood pressure	Frontiers in Physiology	https://www.frontiersin.org/articles/10.3389/fphys.2022.911544/full
Continuous monitoring of advanced hemodynamic parameters during hemodialysis demonstrated early variations in patients experiencing intradialytic hypotension	Dialysis	Dialysis	https://www.mdpi.com/2227-9059/12/6/1177
Wireless, non-invasive, wearable device for continuous remote monitoring of hemodynamic parameters in a swine model of controlled hemorrhagic shock	Hemorrhage	Scientific Reports (Nature Research)	https://www.nature.com/articles/s41598-020-74686-6



Thank you!

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