

BLOOD PRESSURE DEVICES

Cuffless blood pressure devices in South Korea: evidence behind the new KSH recommendation



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For decades, every major hypertension society has told clinicians the same thing about cuffless blood pressure devices: not yet. So when the 2026 Korean Society of Hypertension (KSH) guidelines,¹ which I had the privilege of helping to develop, assigned a Class IIb, Level of Evidence B recommendation stating that validated cuffless devices "can be considered for out-of-office blood pressure monitoring," I understood it would draw attention — and scrutiny. Here I want to walk through the evidence that led us there, and what I think it means for practice.

Why the rest of the world says "not yet"

The case against cuffless devices is not speculative. Independent validation studies have repeatedly shown that commercially available wearables fail to track real blood pressure change: wrist-worn optical devices have failed to detect nocturnal dipping or treatment-induced reductions, and consumer smartwatches have been shown to largely mirror the cuff value used to calibrate them rather than measure blood pressure independently. In their 2025 review, Mukkamala and colleagues concluded that there is no compelling evidence that pulse-wave or pulse-arrival-time analysis adds meaningful accuracy over the calibrating cuff reading itself.² Against that backdrop, the 2025 AHA/ACC guideline, the accompanying 2026 AHA scientific statement, the 2024 ESC guideline, and the 2026 ESC scientific statement all converge on a Class III

position: cuffless devices should not be used for hypertension diagnosis or management until they demonstrate far greater precision.

What is different in Korea

Our Class IIb recommendation is not a lower evidentiary bar dressed up as innovation — it rests on a specific, reproducible body of Korean validation data for one device, CART BP, a ring-type cuffless monitor. In first-in-human testing, CART BP met ISO 81060-2 static-accuracy criteria against auscultatory reference measurement.³ In a subsequent study, it demonstrated 24-hour ambulatory performance, including the primary awake/asleep comparison, that was concordant with conventional ABPM.⁴ Those two completed protocols — static accuracy and the awake/asleep test — place CART BP further along the ESH's five-step validation pathway than any cuffless device evaluated internationally, though treatment-response and recalibration-stability testing remain outstanding (**Table 1**).⁵

Three additional, distinctly Korean factors shaped our decision. CART BP has cleared the Ministry of Food and Drug Safety and is now reimbursed under the National Health Insurance system for 24-hour monitoring — to my knowledge the first national insurance coverage of its kind anywhere. Korean academic centers have run ESH-aligned validation programs at a scale not matched elsewhere. And the KSH has a track record of

Table 1. Rationale underlying the international Class III position versus the 2026 KSH Class IIb, LOE B recommendation for cuffless blood pressure devices.

Domain	AHA/ACC · ESC · ESH (Class III)	2026 KSH Guidelines (Class IIb, LOE B)
Validation completed	No device has completed the full ESH six-test protocol	CART BP has completed 2 of 5 ESH tests (static, awake/asleep)
BP tracking accuracy	Devices often reflect calibration baseline; failed to track nighttime dip in independent studies	Met ISO 81060-2 static-accuracy limits; passed the ESH awake/asleep test
Treatment response	No commercial device has detected treatment-induced BP reduction	Acknowledged evidence gap; highest-priority pending validation step
Regulatory / insurance	Clearances often rely on substantial equivalence, without full ESH compliance	MFDS-cleared; first device with national health-insurance reimbursement
Outcome / thresholds	No RCT outcome data or cuffless-specific normative thresholds exist	Acknowledged limitation; Class IIb applies to monitoring only, not diagnosis

issuing early, evidence-informed positions on emerging BP technologies, having published the world's first position paper on smartphone- and smartwatch-based cuffless measurement in 2021.⁶

What Class IIb actually means — and does not mean

I want to be explicit about this, because I think the designation is easy to over-read in either direction. Class IIb, LOE B signals that usefulness is "less well established by evidence or opinion," supported by a limited number of studies rather than adequately powered outcome trials. It authorizes conditional, context-specific use; it does not certify that cuffless monitoring performs equivalently to cuff-based methods, and it applies to monitoring, not diagnosis — a cuff-based reference is still required to establish a diagnosis of hypertension.

Despite encouraging milestones, we must balance optimism with unresolved limitations. Calibration dependency remains a central methodological hurdle; apparent accuracy is inseparable from the calibrating cuff reading itself. Furthermore, long-term measurement drift remains inadequately characterized, and current validation cohorts have largely excluded critical populations such as patients with atrial fibrillation, advanced chronic kidney disease, severe obesity, or pregnancy.

Most fundamentally, no cuffless device has yet been evaluated in a trial linking device-guided management to hard cardiovascular outcomes.

Implications for practice

For clinicians in Korea, the practical takeaway is narrow rather than sweeping: a validated, reimbursed device may now reasonably supplement out-of-office monitoring — particularly where repeated, comfortable, near-continuous assessment adds value, such as characterizing nocturnal dipping or blood pressure variability — but it should not replace ABPM or home BP monitoring as the diagnostic reference, and results still warrant clinical judgement. For colleagues elsewhere, I would frame the KSH position less as a recommendation to adopt and more as a signal of what a genuinely validated cuffless device, embedded in the right regulatory and reimbursement infrastructure, can look like. Whether other guideline bodies follow will depend on whether treatment-response validation, recalibration data, and outcome evidence accumulate in the way we hope they will.

Our answer, for now, is a conditional "yes, with caveats." Whether that becomes the international answer will be written in the data still to come.

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