Pre read 1. Next-Generation Blood Pressure (BP) Technology: Opportunities and Challenges

Cuffless blood pressure (BP) monitoring technologies, such as optical systems (which will be the focus of this document), offer the potential for continuous, non-invasive BP measurement with minimal burden to the patient, often requiring only a watch, bracelet, or ring. These innovations hold promise for hypertension screening, diagnosis, and management through ongoing monitoring of treatment response.

Cuffless BP technologies (most using optical PPG) promise continuous, low-burden monitoring via a watch, bracelet, ring, or phone camera. Potential use cases span screening**,** diagnosis (as an alternative to conventional 24-hour cuff-based ambulatory blood pressure monitoring), and treatment response tracking. Two persistent concerns are **accuracy** (validation vs clinical standards) and **accessibility** (cost, connectivity, literacy).

Screening

Most hypertension screening currently occurs in healthcare settings using conventional cuff-based monitors. However, many modern smartwatches now include optical photoplethysmography (PPG) sensors capable of estimating BP, offering an opportunity for broader, earlier detection. While some of these devices are not classified as medical devices, they often include features that alert users to potential high BP readings and recommend follow-up with a validated BP monitor. Additionally, smartphone cameras can, in principle, be used for BP estimation, potentially providing a low-cost, widely accessible tool for community-level hypertension screening.

Therefore, modern wearables can surface risk of hypertension at scale. Some devices (not all medical-grade) issue risk alerts prompting follow-up with a validated cuff. Smartphone camera apps may extend reach in community or resource-limited settings.

User-engagement levers (screening):

- **Step-by-step journey:** You see a high blood pressure alert on your device → tap *“What next?”* → easily book a follow-up blood pressure check within 7 days (via app, text, or phone).
- **Helpful reminders:** Short daily updates over a week to keep you on track (e.g. “You’re on day 3 of 7 – nearly there!”).
- **Trusted sources:** Messages come from familiar NHS or GP channels, not just the device company.
- **Easy access:** QR codes in pharmacies, loaner blood pressure cuffs from local health centres, and simple guides in different languages help people take the next step quickly.

Equity & access guardrails (screening):

- **Cost offset:** loaner device / deposit model; community hubs for measurements.
- **Language & literacy:** plain-English + translated easy-read; video explainers; iconography.
- **Skin tone & physiology:** ensure subgroup performance is communicated (limits + mitigation).

Making it fair and affordable:

- **Keeping costs low:** People can borrow blood pressure cuffs using a small deposit, or visit local community hubs to get their readings done.
- **Clear communication:** Use simple, plain English and provide easy-read versions, translations, short videos, and clear symbols so everyone can understand.
- **Fair for everyone:** Make sure devices work well for people of all skin tones and body types, and be open about any limits and how these are being addressed.

Diagnosis

The current gold standard for diagnosing hypertension is 24-hour ambulatory blood pressure monitoring (ABPM) using cuff-based devices. Although accurate, this approach is resource-intensive and inconvenient. Patients must attend a healthcare facility to have the monitor fitted, wear it for 24 hours with intermittent cuff inflation, and then return it for data processing. Healthcare providers, in turn, must purchase and maintain the devices, fit and remove monitors, process data, and schedule follow-up consultations.

These logistical burdens create barriers to efficient diagnosis that cuffless BP technology could potentially eliminate by enabling continuous, comfortable, and remote monitoring.

User-engagement levers (diagnosis):

- **One-tap set-up** after a single calibration; automatic day/night logging; no diaries unless needed.
- **Clarity on next steps:** “If your 24-h average is high, we’ll contact you within X days.”
- **Confidence cues:** show validation badge (BIHS-recognised), firmware version, and last calibration date**.**

Equity & access guardrails (diagnosis):

- **Device access:** clinic loan pool; postal kits; practice pickup/return.
- **Connectivity fallback:** store-and-forward syncing at pharmacy/clinic if home internet is unavailable.
- **Noise-aware design:** cushions for manual work/shift patterns; sleep-friendly prompts.

Monitoring Treatment Response

Home BP monitoring with cuff-based devices also imposes burdens: patients must purchase the equipment, set aside time for measurements, and communicate results to healthcare professionals. Consequently, most BP monitoring and management still occur during in-person visits.

Cuffless, wearable technology could transform this model by allowing continuous BP monitoring without patient effort, reducing both clinic visits and patient inconvenience while improving long-term hypertension management.

User-engagement levers (treatment):

- **Tiny goals:** "We will notify you if something changes".
- **Meaningful feedback:** trend arrows, not raw volatility; explain variability.
- **Shared plan:** show agreed target (e.g., 7-day average) and when the team will review.

Equity & access guardrails (treatment):

- **Quiet defaults:** minimal alerts; do-not-disturb windows; caregiver proxy access where appropriate.
- **Accessibility:** adjustable font/contrast; voice prompts; vibrations for users with hearing loss.

Current State of the Art

Currently, most cuffless BP devices that are classified as medical devices (see Table) require calibration using a conventional cuff-based monitor. Their primary applications therefore lie in diagnosis and treatment monitoring rather than initial screening.

- Most medical-grade cuffless devices still require calibration with a conventional cuff.
- Primary current strengths: trending and convenience; primary risks: accuracy drift**,** population bias**,** overclaiming**.**
- Adoption must pair proportionate claims with confirmatory pathways (e.g., 7-day cuff).

Despite growing adoption, two major concerns remain:

1. **Accuracy:** Whether these devices can achieve validation standards comparable to traditional BP monitors (see briefing on validation).
2. **Accessibility:** Whether their cost and technological requirements could worsen the digital divide in existing inequalities in hypertension detection and management.

Accessibility Considerations

Key accessibility challenges include the relatively high cost of current cuffless monitors, dependence on digital connectivity (e.g., Bluetooth, internet), and varying levels of digital literacy.

Barriers we must actively design out:

- Cost (device + cuff), connectivity, digital skills, work schedules, language, disability, skin-tone-related optical variance.

However, optical BP sensing technology itself is intrinsically low-cost, and with appropriate public–private partnerships, large-scale community screening could be made feasible. Integration with health systems could also ensure that users benefit without requiring advanced digital skills.

Cuffless Blood Pressure Monitoring Devices — AI generated* Technical & Regulatory Summary (Oct 2025)

Device / Company	Requires Cuff Calibration?	Form Factor & Core Technology	Continuous / 24 h Monitoring	Regulatory Status (Oct 2025)	Peer-Reviewed Validation Evidence	Consumer Availability / Use Notes
Aktiia (Hilo / G0)	✅ Yes	Wrist optical PPG sensor + proprietary pulse-wave AI analysis	✅ Continuous (trend)	CE Class IIa; FDA 510(k) (2025 — first OTC cuffless BP clearance)	Multiple peer-reviewed studies (2021–24) vs oscillometric and ABPM methods	EU + US availability 2025; requires initial and periodic cuff calibration
Biobeat (BB-613 Patch / Watch)	✅ Yes	PPG + Pulse-Wave Transit Time (PWTT) from multi-site optical sensors	✅ Continuous	FDA 510(k) (2019–24); CE-marked	Validation in 510(k); limited independent peer review	Used for remote trend monitoring (RPM); not diagnostic replacement
Samsung Galaxy Watch (+ Health Monitor)	✅ Yes (re-calibration ≈ every 4 weeks)	Wrist PPG + AI pulse-wave analysis	⚠️ Limited (spot / trend)	MFDS (Korea); CE (EU); not FDA-cleared for BP in US	Independent studies show acceptable accuracy post-calibration but bias at extremes	Consumer wellness tool; regional availability; not for diagnosis
Biospectal OptiBP (App)	⚠️ Optional (calibration improves accuracy)	Smartphone camera records fingertip PPG → AI BP estimation (software-only)	⚠️ Spot only	CE MDR Class IIa (2023); FDA pending	WHO/HRP multi-country studies (2021–24)	Software-only; lighting/skin tone affect accuracy; not FDA-cleared
Sky Labs CART BP (Ring)	✅ Yes	Finger ring using PPG + deep-learning algorithms	✅ Continuous / 24 h (incl. sleep)	MFDS (Korea) approved; CE / FDA pending	Korean Circ J 2024 (33 pts) vs ABPM; also A-line & auscultatory comparisons	Sold in Korea (2025); CE/FDA under review; classified as medical device (KR)
Huawei Watch D	❌ No (built-in micro-air cuff)	Hybrid wrist device with mini pneumatic cuff (oscillometric method)	⚠️ Short-period only	CE, CFDA (China)	ISO 81060-2 validated; semi-cuff approach	Available Asia/EU; technically not 'cuffless'
Other Research Prototypes	✅ Usually Yes (prototype-dependent)	ECG + PPG (PWTT), camera PPG, ballistocardiography etc.	⚠️ Variable	Typically research / wellness-only	Lab studies; small samples	Await ISO 81060-3 standard adoption

✅ = required / validated ⚠️ = optional or partial ❌ = not needed (built-in pressure mechanism)

- All optical cuffless devices (Aktiia, Biobeat, Samsung, Sky Labs) rely on initial oscillometric calibration.
- Aktiia and Biobeat are currently the only FDA-cleared cuffless BP systems.
- Sky Labs has MFDS approval in Korea and is undergoing CE/FDA reviews.