FREQUENTLY ASKED QUESTIONS (FAQ)

RFP-PE005-SECURE — Blood Pressure Measuring Devices for Home-Based Monitoring in Pregnancy

This document answers common questions about RFP-PE005-SECURE and the SUPREME-SECURE programme. It is published alongside the RFP and updated on a rolling basis throughout the submission period; all questions received are compiled here so that every interested party has equal access to the same information. This FAQ does not replace the RFP; where there is any inconsistency, the RFP and its annexes prevail.

1. How many manufacturers could be selected through this RFP?

We currently expect to identify one or two suppliers. The final number may depend on the quality of proposals received, product readiness, fit with the target product requirements, and overall programme needs.

2. What type of product is this RFP looking for?

This RFP is for design-locked or near design-locked automated or semi-automated upper arm cuff blood pressure (BP) measuring devices, intended for measurement of blood pressure at or near the home by a community health worker (CHW) or by the woman herself with CHW support, as an adjunct to facility-based antenatal care measurement in pregnant and postpartum women.

3. Who can respond to this RFP?

This RFP is open to **device manufacturers only** — the Legal Manufacturer of an eligible device (the entity ultimately responsible for the design, manufacturing, labelling, intended use, quality, safety, regulatory compliance and lifecycle management of the product). In line with Unitaid guidance and CHAI alignment, distributors, agents, resellers and other third parties that are not the Legal Manufacturer are not eligible to apply. This is because the successful bidder must be able to make labelling and intended-use changes to the product, which is essential to delivering the objectives of this RFP.

4. What is the service delivery model this RFP is designed around, and why this one?

Self-monitoring of blood pressure can be delivered in many ways, and SUPREME-SECURE recognises the value of the full range of models. Following a scenario analysis and country consultation, the consortium concluded that a **CHW-supported, shared-device model** is the most mature and implementation-ready of these options, and it is therefore the priority for this RFP — the aim is to select products that fit this scenario. In this model, a clinician recommends at an antenatal visit that a woman monitors her BP between visits; she is linked with a CHW who makes home visits carrying a shared, health-system-owned device; she measures her own BP with the CHW supporting device use and interpretation; and the CHW records the reading, shares it with the facility, and supports referral where needed. Prioritising this model now does not preclude other self-monitoring approaches in future work.

5. Are automated and semi-automated devices both eligible?

Yes. Both fully automated and semi-automated (manual-inflation) upper arm cuff devices are eligible. Devices with an integrated interpretation aid (for example a classification or alert indicator against clinical thresholds) are considered advantageous for lay and CHW use; the specific format of the interpretation aid is not prescribed.

6. Which technologies are out of scope?

Cuffless devices (including smartphone applications that estimate BP optically and cuffless wearables), wrist- and finger-cuff devices, and manual auscultatory (mercury/aneroid) devices are **not eligible** under this RFP. Proposals featuring out-of-scope technologies will not be evaluated. Wrist- and finger-cuff devices, although cuffed, are outside the scope of this round, which is limited to upper arm cuff devices.

7. Why are cuffless devices excluded?

There is currently no settled consensus standard for the clinical evaluation of cuffless BP devices. ISO 81060-2:2018 is scoped to cuffed devices and is not appropriate to the underlying technology of cuffless devices; emerging

frameworks (including draft FDA guidance issued in January 2026) are not yet settled. WHO and European Society of Hypertension guidance does not recommend cuffless devices for clinical use, and per-user calibration is incompatible with a shared-device model. This exclusion applies to the current RFP round and is not a permanent position of the consortium.

8. Does the product need to be fully design locked at submission?

Preference will be given to products with documented design lock. Products with a credible, time-bound plan to achieve design lock by 15 September 2026 may also be considered.

9. What does "design lock" mean in this context?

Design lock means that the device design, components, firmware/software, cuff specification, labelling, and manufacturing process have been finalised and can be documented by the supplier.

10. Are products still in early R&D eligible?

Products in early R&D are unlikely to be a good fit for this RFP. The RFP is intended for products that are design locked or close to design lock and have completed the analytical/technical performance characterisation, including validation to ISO 81060-2:2018 in a general population.

11. Does my device need to be validated in a pregnant population to apply?

No — prior pregnancy validation is not required to apply. The eligibility gate is validation to ISO 81060-2:2018 in a general population for the exact model offered. Bidders should disclose whether the model has also been validated in a pregnant population (including women with gestational hypertension and pre-eclampsia), and confirm willingness to support such validation and adopt the resulting labelling. Where the model has not been validated in pregnancy, generating that evidence is a core purpose of the programme (see Question 13 and the RFP support section).

12. My device is approved only for professional use. Can I still apply?

Yes. Most pregnancy-relevant cuffed devices currently registered in project countries carry a professional-use claim, and few manufacturers hold a single product with a combined professional and lay/community intended-use claim. **This requirement is not intended to limit the pool:** a professional-use device is eligible, and extending the intended-use claim to lay/community use in pregnancy — with the corresponding human factors evidence and labelling — is a central objective of this workstream and a commitment expected of successful bidders, where the applicable regulatory framework permits. The manufacturer must be able to make the necessary labelling and intended-use changes to the product. Manufacturers may propose the same model for both uses or a variant model; both are acceptable, provided the exact model offered is identified.

13. What performance data should be submitted?

Bidders should submit all available analytical/technical and clinical performance data for the exact model offered, including ISO 81060-2:2018 general-population validation, any pregnancy special-population validation, independent listings (e.g. STRIDE BP), and conformity to applicable IEC/ISO standards (including ISO 14971). Supporting reports should be submitted as separate attachments.

14. What standards and specifications inform the target product characteristics?

The target product characteristics in the RFP were informed by the WHO Technical Specifications for Automated Non-Invasive Blood Pressure Measuring Devices with Cuff (2020), together with WHO self-care and self-monitoring of blood pressure guidance, and reference the applicable performance standards (ISO 81060-2:2018 and IEC 80601-2-30). The target product profile extends beyond WHO's procurement-focused specifications to address monitoring in pregnancy and the CHW-supported, shared-device model. Because the device is shared across a caseload, the RFP also asks about cleaning and disinfection and about reliable access to consumables and replacement parts (cuffs, batteries and spares).

15. Who will conduct the evaluations planned under SUPREME-SECURE?

SUPREME-SECURE expects to fund and conduct a single evidence-generation study in Ghana and Kenya, encompassing both clinical validation in pregnant and pre-eclamptic populations and an operational assessment of the CHW-supported model. The successful supplier will be expected to participate, provide required study materials, and give technical support. Analytical calibration checks against reference equipment remain the manufacturer's responsibility.

16. What study materials will selected suppliers need to provide?

Selected suppliers should be able to provide sufficient quantities of devices, cuffs, spare parts, consumables and relevant technical documentation, free of charge, for the planned study, together with replacement units and technical support. This free-of-charge supply is limited to the quantities needed for the study and is not an open-ended or commercial-scale supply obligation.

17. Is WHO Prequalification required?

There is currently no WHO Prequalification pathway or other streamlined global pathway for blood pressure measuring devices, so WHO PQ is not an eligibility requirement. Suppliers should be willing to pursue WHO Prequalification if and when WHO establishes a pathway covering BP measuring devices.

18. What regulatory approval is used as the benchmark?

Suppliers should have, be actively pursuing, or be willing to pursue — with a credible, time-bound plan — approval for the exact model offered from a Stringent Regulatory Authority (SRA) or the regulatory authority of an IMDRF founding member (for example the US FDA, the European Commission/CE, Health Canada, Australia's TGA, or Japan's PMDA). There is no WHO-Listed Authority (WLA) pathway for non-IVD medical devices such as BP monitors, so WLA is not used as a benchmark for this RFP.

19. Is ISO 13485 certification required?

All applicable manufacturing sites should operate under ISO 13485:2016 certification or have a documented, time-bound plan to obtain certification (noting that, where ISO 13485 is not yet held, achieving it can add significant time to the project). Valid certificates should be provided upon request. Devices should also conform (or have a plan to conform) to the applicable IEC 60601 series, IEC 80601-2-30, ISO 81060 and ISO 14971 standards.

20. Which countries are in scope for registration and market entry?

The SUPREME-SECURE implementation countries listed for this RFP are Ghana, Kenya, Malawi, Senegal and Tanzania. Evidence generation is planned in Ghana and Kenya. Final registration commitments will be agreed during workplan discussions.

21. Is the supplier expected to register in all implementation countries?

No. Selected suppliers are expected to undertake product registration in at least two SUPREME-SECURE implementation countries, including Ghana and Kenya (the two evidence-generation countries), with any additional countries and the final list agreed during workplan discussions.

22. What type of support may be available to selected suppliers?

SUPREME-SECURE may provide an independent performance evaluation (the funded study above), technical assistance (documentation, validation and study protocols, human factors, labelling and intended-use extension, regulatory strategy and dossier preparation, quality management), commercial advisory and product launch support, and targeted financial incentives to offset regulatory filing costs — subject to a product support justification process and approval by the Independent Review Panel (IRP) and Unitaid. **Financial support is not guaranteed.** The commitments expected of a supplier are primarily contributions of product, documentation, technical input and staff time; the study is funded and conducted by SUPREME-SECURE, not by the manufacturer.

23. Will access pricing be required?

Yes. Selected suppliers will be expected to supply the product to eligible procurement entities at or below an agreed transparent and affordable access price, under terms to be defined in the programme support contract. Access pricing is intended to cover such elements as the device, cuffs and spare parts, training, service, calibration and required maintenance — the precise scope to be agreed during contract negotiation.

24. How will proposals be evaluated?

Eligible proposals will be assessed on technical and financial criteria, including device performance and validation status, fit to the CHW-supported use case, manufacturing capability and capacity, regulatory strategy, prior experience and quality track record, proposed timelines, and access price (device, cuffs and spare parts) with associated supply conditions and total cost of ownership. Eligibility is a separate pass/fail screen; scoring is applied only to eligible proposals. The process is overseen by the IRP, and final selection is aligned with Unitaid.

25. Are gender and climate considerations part of the evaluation?

Yes, but as secondary considerations. Environmental and climate-smart manufacturing practices and gender-related organisational policies may be considered where proposals are otherwise comparable. Inclusive cuff sizing for the target population is treated as a product requirement rather than a secondary consideration.

26. What documents must be submitted?

Bidders must submit the signed declaration (Form A), quality audit agreement (Form B), financial forensics audit agreement (Form C), and the completed RFP Excel questionnaire (Annex IV). As only device manufacturers (the Legal Manufacturer) may apply, no Letter of Authorisation is required. Supporting documents should be submitted as separate attachments.

27. Can supporting documents be embedded in the Excel questionnaire?

No. Supporting documents such as certificates, validation reports, instructions for use and audit reports should be submitted as separate file attachments and not embedded in the Excel questionnaire.

28. Will individual answers be provided to bidder questions?

No. Questions received by the deadline will be compiled into this single Q&A document and shared with all registered interested parties to ensure equal access to information. After the informational session, this FAQ is the sole mechanism for responding to queries.

29. What is the timeline?

The indicative timeline is below. All times are Coordinated Universal Time (UTC). Dates are subject to change; any changes are notified via this FAQ and the RFP webpage. **Please note that the proposal submission deadline has been extended from 15 September 2026 to 21 September 2026, 23:59 UTC. The extension applies to all bidders, and all other milestones are unchanged at this stage.**

Milestone	Indicative date
RFP posted publicly	18 August 2026
Informational session for potential Bidders	25 August 2026
Deadline for Bidder questions (email only)	1 September 2026, 23:59 UTC
Consolidated Q&A published	8 September 2026
Proposal submission deadline	~~15 September 2026, 23:59 UTC~~ **EXTENDED to 21 September 2026, 23:59 UTC**
Shortlisted manufacturers notified	7 October 2026
One-to-one manufacturer meetings	12–23 October 2026 (meetings 13–21 Oct)
Revised RFP responses submitted	4 November 2026, 23:59 UTC
Contract signature (indicative)	~21 January 2027

Dates are indicative and subject to change.

30. Where should proposals and questions be submitted?

All questions and proposals should be submitted by email to secure.rfp@auruminstitute.org. The submission subject line should include: **RFP-PE005-SECURE – [Bidder Organization Name]**. Telephone enquiries will not be accepted. Neither Unitaid nor consortium members other than the Aurum Institute will respond to RFP enquiries.

31. What is the commercial arrangement for selected manufacturers? Does the programme purchase the devices, are devices supplied free of charge, and is there any budget or remuneration for participating manufacturers?

- The programme supports market entry and evidence generation rather than acting as a direct bulk purchaser; a supported partnership leads to an agreed access price for procurement entities.
- Devices for the evaluation are supplied by the manufacturer free of charge, limited to the quantities needed for the study — not an open-ended or commercial-scale obligation.
- The study is funded and conducted by SUPREME-SECURE, not the manufacturer. Technical assistance and targeted filing-cost incentives may be available, subject to IRP and Unitaid approval; there is no general remuneration.

32. What quantity of devices is anticipated?

- Evaluation quantities and any procurement volumes are confirmed during contracting and are demand-driven.

Bidders should state in the questionnaire the quantity they can supply free of charge for the evaluations (Section I.5), together with manufacturing capacity and scale-up plans (Section F.1c) and ex-works pricing at annual volumes of 1,000, 10,000 and 100,000 units (Section I.3).

This FAQ was Last updated: 15 September 2026