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Draft – Not for Implementation

Cuffless Non-invasive Blood Pressure Measuring Devices – Clinical Performance Testing and Evaluation

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Document issued on January 23, 2026.

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For questions about this document, contact OHT2: Office of Cardiovascular Devices/DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices at (240) 402-6540.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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Cuffless Non-Invasive Blood Pressure Measuring Devices – Clinical Performance Testing and Evaluation

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance provides recommendations for clinical performance testing and evaluation to support premarket submissions for cuffless non-invasive blood pressure measuring devices. A cuffless blood pressure measuring device generally is a non-invasive blood pressure measurement system that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through sensors. This guidance does not include the totality of information that should be included in a premarket submission.

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database. If submitting a Declaration of Conformity to a recognized standard, we recommend you include the appropriate supporting documentation. For more information regarding use of consensus standards in regulatory submissions, refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope/Device Description

The scope of this document includes non-invasive blood pressure measuring systems that are cuffless. Generally, these devices have been classified as class II devices and regulated under 21 CFR 870.1130 with the product code listed in Table 1:

Table 1. Device Type within the Scope of This Guidance

Regulation Name	Regulation	Product Code
Noninvasive blood pressure measurement system	21 CFR 870.1130	DXN

Cuff-based devices under product code DXN and Neonatal ICU Continuous Non-Invasive Blood Pressure Monitors under product code QYF are outside the scope of this draft guidance.

Although the product code listed above is current as of the date of issuance of this guidance, new product codes or classification regulations may be created and could fall within the scope of this guidance. We recommend that you reference the product code database or contact OHT2: Office of Cardiovascular Devices if you are uncertain whether this guidance applies to your device and the product code for your device is not already identified in this guidance.

As part of a premarket submission, you should clearly describe the device's intended use, device technology, and principles of operation. For cuffless devices with a new intended use or new technological characteristics that introduce different questions of safety and effectiveness, as compared to previously cleared cuffless non-invasive blood pressure measuring devices, a De Novo request or premarket approval application (PMA) may be required.

Indications for Use/Intended Use:
Cuffless non-invasive blood pressure measuring devices are intended to measure an individual's blood pressure. For more specific cleared indications for use for currently marketed cuffless non-invasive blood pressure measuring devices, see FDA's 510(k) Premarket Notification Database.

To ensure a clear understanding of your device and the appropriate regulatory pathway, the premarket submission should clearly describe, for example, if the device is intended to provide:

- intermittent/spot-checking measurements or provides continuous measurements;
- autonomous initiation of measurement acquisition or only on-demand initiation of measurements;
- measurements only under resting conditions or other conditions (e.g., ambulation, exercise);
- measurements when the user is at one or more specific body positions and what positions those are or provides measurements regardless of body position; and/or
- measurements during sleep.

We recommend you also include details about the following, some of which may be required under the applicable premarket submission requirements:

- the intended environment;
- patient population;
- context of use;
- how the output(s) of the device are intended to be used (e.g., general blood pressure monitoring, diagnosis of conditions such as hypertension, perioperative monitoring, high intensity care monitoring, production of alarms); and
- how the user is intended to interpret and use the device's output(s).

Device Technological Characteristics:

In the device description of a premarket submission, we recommend that you identify and describe:

- location/types of the sensor(s) (e.g., photoplethysmogram, electrocardiogram) and how the user interacts with them;
- any parameters derived from the sensor(s) (e.g., pulse arrival time ("PAT"), pulse wave transit time ("PWTT"));
- how the signal(s) or parameter(s) are used to compute the device measurement(s);
- if the device requires initialization or otherwise requires memory of a previous state in order to calculate its output(s) (e.g., a device which uses a cuff-based sphygmomanometer to provide a known blood pressure measurement at initialization and, if so, how often re-initialization should be performed);
- if the device requires input of personal information (e.g., age, weight, height) to calibrate its output(s);
- how the device is able to identify conditions (e.g., body position, motion) in order to determine when measurement(s) are acquired, if applicable;
- the overall algorithm including:
    - the scientific principles underlying how the device achieves its intended use;
    - a description of how the input(s) are used to calculate the output(s);
    - if the device incorporates signal quality checks to remove or correct poor quality signal, an explanation of how this is achieved (e.g., identify filtering thresholds, down sampling if applicable); and
- the training/tuning methodologies and dataset(s) used in model development, including artificial intelligence/machine learning techniques and evaluations or any techniques and evaluations that rely on training/tuning the model to match one or more datasets, if applicable.

This guidance does not include the totality of information that should be included in a premarket submission. You should refer to and use other available resources to prepare your premarket submission.[1,2]

III. Clinical Performance Testing

The recommendations for clinical performance testing to support a premarket submission depend in part on the technological characteristics of the cuffless blood pressure measuring device. FDA recommends that the clinical performance testing should represent the intended use of the device including, for example, device calibration.

A. Clinical Validation Study Protocol

We recommend that you conduct clinical study(ies) to evaluate the performance of the cuffless non-invasive blood pressure measuring device. Clinical validation study recommendations are based on current FDA-recognized consensus standards and the specific intended use and technological characteristics of the device. This section contains examples of device attributes that may affect these considerations, which should be addressed in the protocol and/or report that is submitted in a premarket submission. Note FDA generally considers these studies to be considered Nonsignificant Risk Device Studies.[3]

Due to the breadth of devices covered by this guidance, the considerations described herein should not be considered exhaustive. To assist in determining the appropriate performance evaluation for your device, we strongly recommend early engagement with the Agency through the Q-Submission Program[4] where detailed feedback specific to your device can be obtained prior to initiating studies. For example, there may be additional clinical performance evaluation considerations for devices incorporating artificial intelligence/machine learning techniques, or if the intended use of the device includes measurement(s) in the presence of multiple or non-standard body positions (e.g., ambulation, sleep, vehicular transport, etc.), or if the device is capable of autonomously initiating measurement(s). In general, given the novelty and variety of this device technology, FDA recommends utilizing the Q-Submission Program to obtain feedback for all new devices of this type.

We recommend that you include adequate description of the design characteristics and intended use in these early engagements (i.e., Q-Submissions) since FDA feedback represents our best

[1] For more information on 510(k) submissions, refer to 21 CFR 807.87 and FDA's guidance "Electronic Submission Template for Medical Device 510(k) Submissions." For more information on the De Novo classification pathway, refer to 21 CFR 860.220 and FDA's guidance "De Novo Classification Process (Evaluation of Automatic Class III Designation)."

[2] FDA also issued a guidance document "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring," that contains information about certain modified devices, including devices under product code DXN, that are used for remote monitoring.

[3] See also, the FDA guidance "Significant Risk and Nonsignificant Risk Medical Device Studies: Guidance For IRBs, Clinical Investigators, and Sponsors."

[4] For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

advice based on the information provided in the Q-Submission and other information known at that point in time.

Sample size considerations

- We recommend that at least 85 participants between the ages 21 years and 50 years old be tested if the device is intended for use in adults between the ages 21 years and 50 years old.[5] This should include at least 30% females and 30% males.[6]
- There may be additional sample size considerations for devices incorporating Artificial Intelligence/Machine Learning techniques.

Special patient populations and/or Confounding factors

Special patient populations and/or confounding factors should be identified based on the device's technological characteristics and intended use. We recommend these be evaluated to understand their impact on the accuracy of the device. We typically recommend that performance evaluation should be conducted using at least 85 additional participants of each special population based on the intended use population.[7] An increased sample size may be needed to determine confounding factors do not affect the performance. We recommend adequate sampling across the applicable populations. For example, for intended populations including adults over 50 years, we recommend that you enroll at least 85 subjects over 50 years and at least 20% of this sub-population in the upper most decade.

Example list of special populations:

- > 50 years of age
- any pediatric sub-population
- individuals with arrhythmias
- individuals undergoing vasoactive drug therapy
- pregnant women[8]

Patient demographics

We recommend that you identify patient demographics consistent with the device's technological characteristics and intended use. Increased sample size may be needed to demonstrate patient demographics and/or sub-populations do not affect the performance. We recommend adequate sampling across the intended use patient populations to support the performance of the device. Adequate sampling may involve stratifying subgroups to ensure sufficient enrollment across the full spectrum of each attribute. For example, we recommend that the study enrolls at least 25% in each Monk Skin Tone scale 1-4, 5-7, and 8-10 (or equivalent scale).

Example list of relevant and/or potentially confounding patient demographics:

[5] See current FDA-recognized IEEE Std 1708 *Standard for Wearable, Cuffless Blood Pressure Measuring Devices*.
[6] See current FDA-recognized ISO 81060-2 *Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type*.
[7] See current FDA-recognized IEEE Std 1708.
[8] See current FDA-recognized IEEE Std 1708 and the Supplemental Information Sheet (SIS) for IEEE Std 1708 for information on extent of recognition.

- age
- BMI
- pulse/heart rate
- sex
- height
- weight
- skin pigmentation
- other patient demographics that are used to calibrate the device

We recommend that you refer to the currently FDA-recognized consensus standards and the applicable Supplemental Information Sheets (SISs) for details about test methods.[9]

- IEEE Std 1708 *Standard for Wearable, Cuffless Blood Pressure Measuring Devices*
- ISO 81060-2 *Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type*
- ISO 81060-3 *Non-invasive sphygmomanometers – Part 3: Clinical investigation of continuous automated measurement type*

B. Performance Evaluation Considerations

FDA's recommendations for clinical performance testing to be submitted in a premarket submission depend on the technological characteristics and intended use of the cuffless non-invasive blood pressure measuring device.

Typically, for cuffless non-invasive blood pressure measuring devices, FDA recommends that you submit clinical performance data from Static, Stability, and Change tests, when applicable, to support device accuracy consistent with the intended use of the device for users in a seated, resting position, as described in ISO 81060-2, unless otherwise stated. We recommend that each study population identified based on the device's intended use remain consistent throughout all the following applicable tests. Additionally, the Agency recommends that these tests be evaluated independently (i.e., no pooling). We generally recommend that devices with intermittent measurements be evaluated against manual auscultation through the method described in ISO 81060-2. We recommend that devices with continuous measurements be evaluated against arterial line measurements as described in ISO 81060-3. Table 2 provides information on the importance of each performance test and testing considerations.

[9] See FDA Recognized Consensus Standards Database. FDA considers IEEE Std 1708 relevant to all cuffless non-invasive blood pressure measuring devices. Due to the partial recognition of IEEE Std 1708, FDA also recommends use of ISO 81060-3 for devices that provide continuous blood pressure measurements. As stated in the respective SISs for IEEE Std 1708 and ISO 81060-3, some clauses of these standards are not recognized due to conflicts with ISO 81060-2. Therefore, where appropriate, we recommend reference to ISO 81060-2 as well for designing your clinical validation study protocol. Specifically, FDA does not believe that the methodology described in Clause 4.2.2 of IEEE Std 1708-2014 provides valid measurements; therefore, FDA recommends that you instead use Clause 5.2 of ISO 81060-2 Third edition 2018-11 [Including Amendment 1 (2020) and Amendment 2 (2024)] for conducting your clinical investigation. FDA also does not believe that Clause 4.5.3.2 of IEEE 1708-2014 provides statistical justification for the acceptance criteria; therefore, FDA recommends that you instead use the acceptance criteria described by ISO 81060-2 for evaluating the performance of your device.

215 **Table 2. Clinical Performance Testing Description and Considerations**

Test	Description and Considerations
Static Test	Intended to demonstrate that the device can provide accurate measurements for users following device setup. We recommend that you conduct a static test for all cuffless devices that measure one or more absolute blood pressure parameters. For devices that require initialization or otherwise rely on memory of a previous state to operate, this testing should be performed shortly after initialization of the device.
Stability Test	Intended to demonstrate that the device can provide accurate measurements for users throughout the duration of the labeled window of accuracy. We recommend that you conduct a stability test for all devices that rely on initialization with a known blood pressure measurement or otherwise use memory of a previous device state. We recommend that a finite time window be included in the device labeling, and the stability test should cover the duration of this window. For example, if a device is initialized with a known cuff-based blood pressure measurement and is labeled to be accurate for 28 days, we recommend that a static test be performed on Day 1 and that a stability test be performed first around Day 14 (i.e., approximately midpoint) and again on Day 28. Where possible, we recommend that the time of day that subjects are tested be varied so as to introduce circadian variation.
Change Test	Intended to demonstrate that the device can provide accurate measurements for users following a change in blood pressure. We recommend that you conduct an induced change test for all devices that rely on initialization with a known blood pressure measurement, otherwise use memory of a previous device state, or rely on calibration using personal input parameters. We recommend that testing demonstrate maintained accuracy at blood pressure values both above the point of initialization and below the point of initialization. We recommend that large changes are defined for systolic blood pressure values at least 15 mmHg above or below the initialization point and for diastolic blood pressure values at least 10 mmHg above or below the initialization point. To ensure a sufficient number of changes is obtained, we recommend that at least 30% of all measurements for systolic and diastolic blood pressure included in the induced change test be large increases and that at least 30% of all measurements be large decreases. Natural changes can often be more representative of the intended use of the device but may be less predictably obtained in clinical studies. We recommend that you consider how you intend to evaluate natural changes and that you discuss planned assessments with FDA.[10]
Additional Considerations	There may be additional testing considerations if the intended use of the device includes other body positions, autonomous measurements, ambulation, exercise, sleep, transport, etc.

216

[10] For details on the Q-Submission Program, refer to FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

C. Recommended Acceptance Criteria

FDA recommends the following acceptance criteria for each test – Static, Stability, and Change, and each intended patient population. We recommend that the performance demonstrated by the device be consistent with criteria below. The acceptance criteria for the Change test should be evaluated only on the subset of subjects that achieve the necessary change in blood pressure.

- Criterion #1: A mean error less than or equal ±5.0 mmHg and a standard deviation less than 8.0 mmHg.[11]
- Criterion #2: Is determined by the interaction of mean error and standard deviation – i.e., the maximum allowable standard deviation is a function of the measured mean error.[12]

[11] See Clause 5.2.4.1.2 a) of the current FDA-recognized ISO 81060-2 Third edition 2018-11 [Including AMD1:2020 and AMD2:2024].

[12] See Table 1 in Clause 5.2.4.1.2 b) of the current FDA-recognized ISO 81060-2 Third edition 2018-11 [Including AMD1:2020 and AMD2:2024].

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Guidance History	Date	Description
Level 1 Draft Guidance	January 2026	See Notice of Availability for more information.**

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