Guidance for Industry

Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1

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Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Sandy F. Stewart, Ph.D., Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-132, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Sandy F. C. Stewart, Ph.D., at 301-827-5610 or by electronic mail at sxs@cdrh.fda.gov.

Additional Copies

World Wide Web CDRH page: http://www.fda.gov/cdrh/ode/blprcuff.pdf, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2239 when prompted for the document shelf number.

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Non-automated Sphygmomanometer (Blood Pressure Cuff) Guidance[1]

1. Scope

This guidance in intended to aid in the preparation or review of premarket notification (510(k)) applications for some of the devices regulated under:

CFR Section:	21 CFR §870.1120, Blood Pressure Cuff
Class:	II
Panel:	Circulatory System Devices Panel (74)
Product Code:	DXQ

This guidance applies to blood pressure cuffs covered by the ANSI/AAMI SP9-1994 standard for non-automated sphygmomanometers (SP9 standard). Included in the SP9 standard are non-automated sphygmomanometers that use (1) an occluding cuff, (2) either an aneroid or mercury gravity sphygmomanometer to measure pressure, and (3) a stethescope or other manual system for detecting Korotkoff sounds.

This guidance does not apply to any automated non-invasive blood pressure monitors, whether using the oscillometric method or any other method, nor does it apply to direct or invasive blood pressure monitoring systems. These devices are classified elsewhere.

This guidance is complementary to the requirements of 21 CFR § 807.87. Other information not identified in this guidance may be required in a 510(k) application. This guidance is subordinate to all other applicable statutes, regulations, and policies.

2. Regulatory Requirements

a. A "Statement of Intended Use," an explicit description of all clinical functions performed by the device, e.g., measures systolic and diastolic blood pressures, etc.;

b. An "Indications for Use Statement," according to Office of Device Evaluation policy. Indications for use should include the intended patient population and contraindications (when the device is or is not to be clinically used);

c. Either a "Summary of Safety and Effectiveness" as described in 21 CFR § 807.92, or a "510(k) Statement" as described in 21 CFR § 807.93;

d. A "Truthful and Accuracy Statement" according to 21 CFR §807.87 (j);

1 This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

e. Identification of the predicate device, including:
   i. The predicate device name;
   ii. The predicate device's manufacturer;
   iii. The predicate device's 510(k) number;

f. If application is for a modification to an existing device then provide:
   i. Specifications for original device;
   ii. Complete description of the similarities and differences between the two versions of the device;
   iii. A table comparing the two versions of the device for the items listed above;

g. Labeling
   i. Conformance to the labeling regulations and policies is necessary. Appropriate labeling guidances are available through the Division of Small Manufacturers Assistance (DSMA) at its toll-free number (800) 638-2041 or at its Internet address:

      http://www.fda.gov/cdrh/dsmamain.html

   ii. If the SP9 standard is used, then the labeling requirements of the standard (Section 4.1) should be included or justification provided for any modifications.

3. Recommended Information and Testing

a. Device Description

The description should include sufficient information to define the design, capabilities, and function of the device, and the scope of the 510(k) submission. Minimal information includes:

i. The overall design;
ii. Photographs of the device with all accessories;
iii. Identification of all components and accessories covered by the 510(k);
iv. Material descriptions for all patient or operator contacting materials;
v. Product specifications with ranges and/or accuracies, including measurement limits, operating limitations, and any other functional or physical limitation of the device;
vi. Packaging, including a description of the design, materials, and the sealing method. For package integrity, any appropriate standard may be used. If the SP9 standard is used, the manufacturer should conform to the standard's requirements (section 4.1) or justify any modification;
vii. If the 510(k) application is for a modification to an existing device, then provide:
   (1) specifications for the original device;
   (2) a complete, detailed description of the similarities and differences between the two versions of the device;
   (3) a table comparing the items listed above for the two versions.

b. In vitro *Performance Testing*

Substantial equivalence can be demonstrated by showing either (1) sufficient comparison testing with a legally-marketed predicate device, (2) conformance to the SP9 standard, or (3) conformance to any foreign or domestic standard which meets or exceeds the requirements of the SP9 standard.

i. Comparison Testing

It is strongly recommended that substantial equivalence be demonstrated by showing conformance to the SP9 standard. However, if the manufacturer chooses to provide comparative testing, the provided data should meet the **Suggested Format for Test Reports** (listed below) and account for the following:

(1) The manufacturer should identify all of the safety and effectiveness issues for their device. These issues can be identified independently or in parallel with the SP9 standard, i.e., a testing issue identified in the SP9 standard is usually (but not always) relevant to the safety and effectiveness of a device. The SP9 standard may not be sufficient, however, for every device;

(2) There should be sufficient comparison testing provided to encompass every safety and effectiveness issue related to the device. Usually, a test will be necessary if it is capable of evaluating a failure mode, functional limitation, or a labeling claim for the device;

(3) All testing should evaluate the device in worst case and normal operating conditions. The worst case scenario should be justified and based on the clinical or actual use of the device;

(4) The comparison testing should be scientifically sound and have a statistically valid sample size. Since this usually results in a large sample size, most manufacturers rely on the smaller sample size required by the SP9 standard;

(5) The pass/fail criteria of the SP9 and other standards cannot be used. Rather, the new device should show better or equal performance as compared to the predicate device.

ii. SP9 Standard Testing

To show conformance to the SP9 standard, the manufacturer should list each of the requirements of the standard and describe how the device conforms to each requirement.2 For *in vitro* testing, the test protocol, test data and results, and analysis should be provided and clearly identified. The appropriate detail for each element of a test report is described below in **Suggested Format for Test Reports**. For devices with unique features or intended uses, additional testing beyond the SP9 standard may be necessary.

2 If SP9 becomes a "Recognized Standard," it will not be necessary to submit the test report. Instead, a "Declaration of Conformity" should be submitted (see the "Guidance on the Recognition and Use of Consensus Standards"). Refer to the CDRH Web page for the most recent list of Recognized Standards.

If the SP9 standard is chosen by the manufacturer, **conformance to the entire standard should be demonstrated**. Conformance to portions of the standard is usually insufficient to permit the standard's use or to allow a labeling claim to that effect. Therefore, if only part of the standard is met, the manufacturer should refer to the **Comparison Testing** section of this guidance.

iii. Foreign Standards

If the manufacturer chooses to conform to a standard other than the SP9, list each requirement of the SP9 standard, compare the foreign standard to the SP9 requirements, and clearly identify where the foreign standard does not meet the requirements of the SP9 standard (if at all). Justification for any differences should be based on valid scientific or statistical analyses and supported by testing if necessary.

c. Additional Testing

In addition to the testing described above, the manufacturer should evaluate the intra-device variability among a minimum of three devices.

d. Suggested Format for Test Reports

In general, any *in vitro* test report should include the following:

i. Test Protocol

The test protocol should include:

(1) the purpose of the test;
(2) a clear description (with schematics) of the test set-up and any device modifications;
(3) identification and precision of equipment used;
(4) step-by-step descriptions of the data collection methods used;
(5) derivation of any formulae used;
(6) justification for the testing parameters (e.g., testing temperature, length of test, the selection of device modes, etc.) and the pass/fail criteria. The testing parameters and pass/fail criteria should be conservative and based on the extreme clinical use of the device, according to the intended use or applicable standard. Depending on the test, it may be appropriate to base the testing parameters on the normal use of the device. However, if an extreme exists, it should be explored.

ii. Test Data and Results

The test data and results should include:

(1) clearly labeled data with appropriate units;
(2) data that is easily associated with the methods described in the protocol;
(3) if graphs are present, a table listing each data point shown on the graph;

(4) if calculated values are present, a section showing how the values were calculated according to formulae presented in the protocol;

iii. Analysis

An **analysis should** include:

(1) an evaluation of the test data according to the pass/fail criteria and purpose defined in the test protocol;
(2) identification of the inadequacies and accuracy of the test;
(3) evaluation of any need for additional testing;
(4) a clear conclusion within the scope of the particular test.

4. *In Vitro* Safety Testing

a. Biocompatibility

The manufacturer should identify all patient and operator contacting materials and conform to the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." For materials that are widely used in the same or similar applications, supportive information demonstrating the material's use in other medical devices or products may be acceptable in establishing biocompatibility. However, any references should be to the same vendor and material, and account for any changes to the material due to subsequent processes or manufacturing (e.g., sterilization, forming, melting).

b. Sterilization

Blood pressure cuffs usually have no sterile components; however, if sterile components are identified, refer to the *510(k) Sterility Review Guidance #K90-1* (February 1990) or the most recent sterilization policy or guidance.

c. Shelf Life

Usually a shelf life is not applicable to blood pressure cuffs. However, if the device contains any sterile or degradable components, shelf life data may be necessary.