Draft Guidance for FDA Staff and Industry

Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers) - Accuracy (CPG 7124.23)

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Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy

Preface

Public Comment:

Interested persons may submit written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. For questions regarding the use or interpretation of this guidance, contact Jeffrey Governale at 240-632-6851.

Additional Copies:

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Compliance Policy Guide

Draft Guidance

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Sub Chapter 310
Cardiovascular

Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers) - Accuracy (CPG 7124.23)

BACKGROUND:

In 1980, the Food and Drug Administration's (FDA's) standing policy for the level of accuracy of blood pressure measurement devices (sphygmomanometers) was based on the 1960 Federal purchasing specification GG-S-618D, pending the development of voluntary standards for sphygmomanometers by the Association for the Advancement of Medical Instrumentation (AAMI).

In 1987, AAMI completed the development of the "ANSI/AAMI SP9-1985 American National Standard for Non-Automated Sphygmomanometers" and the "ANSI/AAMI SP10-1987 American National Standard for Electronic or Automated Sphygmomanometers" that were approved by the American National Standards Institute (ANSI).

In 1992 and 1994, these standards were revised and issued by AAMI as "ANSI/AAMI SP9-1994 American National Standard Non-Automated Sphygmomanometers" and "ANSI/AAMI SP10-1992 American National Standard Electronic or Automated Sphygmomanometers."

As amended by the FDA Modernization Act of 1997, Section 514(c) of the Federal Food, Drug, and Cosmetic Act allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements. The FDA now completely recognizes the standards ANSI/AAMI SP9-1994 and ANSI/AAMI SP10-1992 for the purpose of premarket clearance. To be consistent with current industry practice, the FDA intends to use the accuracy and exhaust rate criteria identified in these recognized consensus standards as guidance for testing, surveillance, and compliance purposes, as well as for premarket clearance. Therefore, this revised guidance reflects the accuracy and exhaust rate criteria in the currently recognized revisions of these voluntary standards.

FDA has utilized the accuracy and exhaust rate criteria of these voluntary standards as a basis for determining the accuracy of blood pressure measurement devices regulated as Class II and identified as blood pressure computer (21 CFR 870.1110), blood pressure cuff (21 CFR 870.1120), and non-invasive blood pressure measurement system (21 CFR 870.1130).

POLICY:

Those blood pressure measurement devices, identified above, which do not meet the accuracy and exhaust rate criteria in the ANSI/AAMI voluntary standards for non-automated, electronic, and automated sphygmomanometers may, after an evaluation of all relevant facts, be recommended for legal action.

When determining whether to pursue enforcement action for these blood pressure measurement devices, the Agency should consider all information relevant to possible charges of adulteration and misbranding. This information is not limited to the accuracy and exhaust rate criteria listed in the tables below but includes all compelling reasons for either pursuing or not pursuing the action.

REGULATORY ACTION GUIDANCE:

The following tables represent the accuracy and exhaust rate criteria, which should be used as a factor in considering whether to recommend seizure and/or other legal action to the Center for Devices and Radiological Health's Office of Compliance (HFZ-306):

ANSI/AAMI SP9-1994 AMERICAN NATIONAL STANDARD FOR NON-AUTOMATED SPHYGMOMANOMETERS

ACCURACY (Sections 4.4.1.3 & 4.4.2.3)	RANGE	TEMPERATURE
+/- 6 mm Hg	0 to 260 mm Hg	0^0C to 17^0C
+/- 3 mm Hg	0 to 260 mm Hg	18^0C to 33^0C
+/- 6 mm Hg	0 to 260 mm Hg	34^0C to 46^0C

The above applies to both aneroid manometers and mercury gravity manometers.

Valve/Cuff Exhaust Rate: A maximum (bleed rate) of 6 mm Hg/second to a minimum of 2 mm Hg/second throughout the 250 to 50 mm Hg range for the self-bleeding pressure control valve. (See Section 4.5.3.1.) For the manually adjustable valve, the valve should be adjustable so as to control the pressure drop in a volume of no more than 80 cc at a rate of 20 mm Hg in 10 seconds at initial differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg. (See Section 4.5.2.2.)

It should be noted that aneroid manometers should not have a needle restraint at 0 mm Hg. (See Section 4.4.1.6.)

ANSI/AAMI SP10-1992 AMERICAN NATIONAL STANDARD FOR ELECTRONIC OR AUTOMATED SPHYGMOMANOMETERS

ACCURACY (Section 4.4.1)	RANGE
+/- 3 mm Hg or +/- 2% of reading (whichever is greater)	20 to 250 mm Hg
Indicated pressure should be less than 23 mm Hg.	input pressure greater than 0 but less than 20 mm Hg
Indicated pressure should be 0 +/- 3 mm Hg	input pressure less than or equal to 0 mm Hg
Indicated pressure should be greater than 245 mm Hg or an overrange as indicated	input pressure greater than 250 mm Hg

The American Heart Association has recommended that the cuff deflation rate be 2 to 3 mm Hg per second (Section A4.5.2). To ensure this rate, the maximum valve leakage should not exceed 1 mm Hg per second.

Note: The above accuracy and exhaust rate specifications cover electronic, and automated sphygmomanometers.

Note: If a zero or range control is provided, proper instructions for operation and verification should be attached to the device as a readily visible label. If the zeroing function is performed automatically, then the device should automatically reset to zero when required and meet the accuracy criteria without operator intervention.

Some systems do not indicate or display pressure under dynamic measurement conditions. For these systems, manufacturers should verify performance using appropriate auxiliary equipment (Section 4.4.1)

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