Non-Invasive Blood Pressure (NIBP) Monitor Guidance (Text Only)

This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Office of Device Evaluation
Division of Cardiovascular, Respiratory, and Neurological Devices
Circulatory Support and Prosthetic Devices Group

Document issued on: March 10, 1997

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to:

Charles Ho
Food and Drug Administration
10903 New Hampshire Avenue, WO66
Silver Spring, MD 20993

For questions regarding the use or interpretation of this guidance, contact Charles Ho, at 301-796-6320 or by electronic mail at **charles.ho@fda.hhs.gov (mailto:charles.ho@fda.hhs.gov)**.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

Scope

This guidance is 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 §870.1130, Noninvasive Blood Pressure Measurement System
Class: II
Panel: Circulatory System Devices Panel (74)
Product Code: DXN

This guidance applies to non-invasive blood pressure (NIBP) monitors covered by the ANSI/AAMI SP10-1992 standard for electronic or automated sphygmomanometers (SP10 standard). Included in the SP10 standard are automated NIBP monitors which measure blood pressure at the arm, wrist, or finger of the patient using a standard oscillometric measurement method.

This guidance does not apply to NIBP monitors excluded by the SP10 standard, and those which use a non-oscillometric (or non-standard oscillometric) measurement method. Despite this limitation, the information contained in this guidance may be helpful to any NIBP monitor application.

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.

Recommended Information and Testing

1. 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:

- the intended use (an explicit description of all clinical functions performed by the device, e.g., measures systolic and diastolic blood pressures using the oscillometric method, measures heart rate, etc.),
- the contraindications and indications for use (explain when the device is or is not to be clinically used and the intended patient population),
- overall design and assembly drawings with dimensions,
- photographs of the device with all accessories,
- identification of all components and accessories covered by the 510(k),
- a specific identification and description of any collateral devices (other devices which can be connected or used with the NIBP monitor, e.g., personal computers (PCs)),
- material descriptions for all patient or operator contacting materials,
- product specifications with ranges and/or accuracies (e.g., measurement limits, operating limitations, power source specifications, available modes or settings, and any other functional or physical limitation of the device),
- the operational method, which minimally includes a description of:
    - the device's clinical use (e.g., ambulatory use, home use),
    - the inflation and deflation method,

- the initial inflation pressure setting,
- the deflation rate,
- functional charts detailing the operational processes,
- a detailed measurement algorithm which explains how the device:
    1. detects and selects the proper oscillation(s) on which to base its measurements,
    2. manipulates or calculates any reported values,
    3. filters out erroneous readings or values, and
    4. reports the values to the user,
- justification supporting the validity of the selected algorithm,

an explanation of how the device interacts with the patient, which includes:

- identification of the functions which can and cannot be controlled by the patient,
- whether the device can be programmed and to what extent, and
- the knowledge or training required of the operator,

- identification of the legally-marketed predicate device by name, manufacturer, and 510(k) number.

If the 510(k) application is for a modification to an existing device, the manufacturer should provide the specifications for the original device and a detailed and complete description of the similarities and differences between the two versions of the device. Lastly, the manufacturer should provide a table comparing the predicate device to the new device for the items listed above.

2. In-Vitro and Clinical Performance Testing

Substantial equivalence can be demonstrated by showing either 1) sufficient comparison testing with a legally-marketed predicate device, 2) conformance to the SP10 standard, or 3) conformance to any foreign or domestic standard which meets or exceeds the requirements of the SP10 standard.

Comparison Testing

It is strongly recommended that substantial equivalence be demonstrated by showing conformance to the SP10 standard. However, if the manufacturer chooses to provide comparative testing, the provided data should meet the General Requirements (listed below) and account for the following:

- 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 SP10 standard, i.e., a testing issue identified in the SP10 standard is usually (but not always) relevant to the safety and effectiveness of a device. The SP10 standard may not be sufficient, however, for every device;

- 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;
- 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
- 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 SP10 standard; and
- The pass/fail criteria of the SP10 and other standards cannot be used. Rather, the new device should show better or equal performance as compared to the predicate device.

SP10 Standard Testing

To show conformance to the SP10 standard, the manufacturer should list each of the requirements of the standard and describe how the device conforms to each requirement. For every requirement which necessitates clinical or in-vitro testing, the test protocol, test data and results, and analysis should be provided and clearly identified. The necessary detail for each element of a test report is described below in General Requirements. For devices with unique features or intended uses, additional testing beyond the SP10 standard may be necessary.

If the SP10 standard is chosen by the manufacturer, conformance to the entire standard is necessary. Conformance to portions of the standard is 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.

Foreign Standards

If the manufacturer chooses to conform to a standard other than the SP10, it is recommended that they list each requirement of the SP10 standard, compare the foreign standard to the SP10 requirements, and clearly identify where the foreign standard does not meet the requirements of the SP10 standard (if at all). Justification for any differences should be based on valid scientific or statistical analyses and supported by testing if necessary.

Additional Testing

In addition to the testing described above, it is necessary that the manufacturer evaluated the following:

- The intra-device variability between a minimum of three devices; and
- If the device reports a value for mean blood pressure, supportive data demonstrating the accuracy of the device according to one of the above methods is necessary. Since the SP10 standard does not allow for an auscultatory reference standard for mean blood pressure,

comparison to the intra-arterial reference standard will be necessary.

General Requirements

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

- the **test protocol**, which minimally includes:
- the purpose of the test,
- a clear description (with schematics) of the test set-up and any device modifications,
- the identification and precision of the equipment used,
- step-by-step descriptions of the data collection methods and device modes used, and
- 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.
- the **data and results**, which minimally include:
  - clearly labeled data with the appropriate units,
  - the data should be easily associated with the methods described in the protocol,
  - for any graph, a table listing each data point shown on the graph is necessary, and
  - for any calculated values, the calculated values should be obvious and calculated according to formulae presented in the protocol.
- an **analysis**, which minimally includes:
  - an evaluation of the test data according to the pass/fail criteria and purpose defined in the test protocol,
  - identification of the inadequacies and accuracy of the test,
  - evaluation of the need for additional testing, and
  - a clear conclusion which is within the scope of the particular test.

In general, any clinical data necessitates consideration or inclusion of the following:

- the clinical protocol,
- an analysis demonstrating that the study population is representative of the intended patient population (or conformance to the SP10 patient population requirements),
- evaluation of all device capabilities and settings, if appropriate,

- conformance to the investigational device exemption (IDE) regulations, if appropriate, and
- conformance to 21 CFR Part 50, Protection of Human Subjects.

3. In-Vitro Safety Testing

Environmental Testing

The manufacturer should evaluate the ability of the device to function after exposure to the environmental hazards expected when used by an abusive user. Tests for some of these hazards may be found in SP10, IEC 601-1, and IEC 529. These hazards minimally include:

- the hazards identified in the SP10 standard, e.g., temperature and humidity extremes, shock and vibration testing, over inflation,
- controls protection, i.e., the likelihood of inadvertent or unauthorized control changes,
- connector protective incompatibility, i.e., the use of connector designs which prevent insertion into the wrong receptacle or to a power source,
- mechanical safety, i.e., the use of product designs which minimize exposed sharp edges, are mechanically stable, and provide protection to the operator and patient from moving parts,
- fluid spill resistance, i.e., the ability of the device to operate within specifications after fluids have been dripped in the device, and
- strangulation, i.e., the safety considerations which minimize the likelihood of strangulation to adults and children.

Software

To demonstrate the quality of the software used in or with the device, the following is necessary:

- a hazard analysis which:
- accounts for all device hazards associated with its intended use, hardware, and software,
- identifies the specific system and/or components whose failure could cause each hazard,
- identifies the specific software module(s) associated with each hazard, and
- describes the methods used to eliminate or mitigate each hazard,
- a detailed description of the system and software requirements and specifications, which includes measures taken to address the safety hazards identified in the hazard analysis,
- a detailed description of the software verification and validation performed at the system level, an outline of the test strategies/methods and acceptance criteria, and data and analysis evaluating the ability of the software to identify, mitigate, and warn of the failure modes described in the hazard analysis,

- a detailed description of your software revision control procedures, and
- for the version to be distributed commercially, a discussion regarding any software deviations that remain and a description of how these deviations were addressed.

Electrical Safety

Any appropriate standard for electrical safety may be used. If the SP10 standard is used, the manufacturer should conform to the standard's requirements or justify a modification to the standard.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) testing is necessary to demonstrate that the device (1) will not adversely interfere with the performance of other electronic devices (emissions), and (2) will perform as expected in the presence of other electronic devices or other sources of electromagnetic interference (EMI) in the intended environment of use (immunity). To demonstrate EMC for the device, the following information is necessary:

- Identification of every intended environment in which the device will be used, e.g., hospital general ward, hospital ICU/CCU, clinic, vehicle/traffic areas, emergency vehicle (including aircraft), operating room, home. This description should identify the possible sources of EMI which could affect the device.
- Test reports which conform to the General Requirements, identify the selected standard, and justify its use. Testing should be applicable to the intended environments described above and should address the following as appropriate for the device:
  - radiated and conducted electromagnetic and magnetic emissions testing, and
  - EMI testing including radiated and conducted electromagnetic field, magnetic fields, electrostatic discharge (ESD), transient bursts, surges, voltage variations, voltage dips, and short interruptions.

Any omitted tests or deviations from the requirements of the chosen standard require justification. In addition, the manufacturer should provide a list of all known or suspected EMI incidents associated with the device, the results of any related investigations, a description of any corrective action taken, and any device labeling that references EMC or EMI.

Biocompatibility

Identification of all patient and operator contacting materials and conformance to the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," is necessary. 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).

Sterilization

Usually, there are no sterile components to NIBP monitors. If sterile components are identified, refer to the ***510(k) Sterility Review Guidance #K90-1 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm)*** (February 1990) or the most recent sterilization policy or guidance.

Packaging

The manufacturer should describe all packing for the device. This description should include a description of the design, materials, and the sealing method.

For package integrity, any appropriate standard may be used. If the SP10 standard is used, the manufacturer should conform to the standard's requirements or justify any modification.

Shelf Life

Usually a shelf life is not necessary for NIBP monitors. However, if the device contains any sterile or degradable components, shelf life data may be necessary.

4. Labeling

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) 6382041 or at **its internet address (ssLINK/UCM2005299.htm)**.

If the SP10 standard is used, the labeling requirements of the standard should be included or justification provided for any modifications.

5. Regulatory Requirements

Either a Summary of Safety and Effectiveness or a 510(k) Statement is necessary as described in 21 CFR § 807.92 and 21 CFR § 807.93, respectively.

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

An "Indications for Use Statement" is necessary according to Office of Device Evaluation policy. A format for this statement can be provided to the manufacturer by DSMA.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products)

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)