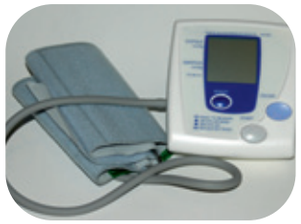
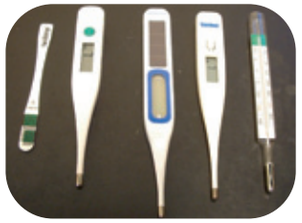
This short guide is designed to provide step-by-step instructions for the safe substitution of non-mercury thermometers and sphygmomanometers in health-care settings. It identifies the resources available to provide confidence that the substituted products will provide equivalent accuracy and comparable clinical utility, while protecting health-care workers and the environment. It is designed for professionals responsible for institutions or ministries desiring to switch to safer non-polluting technologies in health care.

This guide is also an output of a global mercury-free health-care initiative in which the World Health Organization is engaged. This global initiative aims to promote the substitution of mercury-based medical devices with safe, affordable, accurate alternatives around the world. The global mercury-free health-care initiative has documented mercury substitution in dozens of countries. It has also produced a series of additional resources for health professionals, health system managers and government officials that can be useful in developing and implementing policy and strategies for mercury substitution in the health sector.

9 789241 548182





Replacement of mercury thermometers and sphygmomanometers in health care

Technical guidance

Edited by: Jo Anna M Shimek, Jorge Emmanuel, Peter Orris and Yves Chartier

World Health Organization

Replacement of mercury thermometers and sphygmomanometers in health care

Technical guidance

Edited by: Jo Anna M Shimek, Jorge Emmanuel, Peter Orris and Yves Chartier

WHO Library Cataloguing-in-Publication Data

Replacement of mercury thermometers and sphygmomanometers in health care: technical guidance / edited by Jo Anna M Shimek ... [et al].

1. Sphygmomanometers — standards. 2. Thermometers — standards. 3. Mercury — adverse effects. 4. Monitoring, Physiologic — instrumentation. 5. Environmental exposure. 6. Manuals. I. Shimek, Jo Anna M II. Emmanuel, Jorge III. Orris, Peter IV. Chartier, Yves V. World Health Organization.

ISBN 978 92 4 154818 2 (NLM classification: QV 293)

Printed in France

Cover photographs (top to bottom): Solar BPMB—World Health Organization; Health Care Without Harm (photos 2–5); Peter Orris.

Cover designed by: Design One, Canberra, Australia

Production and design by: Biotext, Canberra, Australia

Contents

Tables

Foreword

Elemental mercury has been used for decades in thermometers and sphygmomanometers in the health-care setting. Mercury, naturally occurring in the earth's crust, is released during volcanic eruptions and as a by-product of human activities such as the burning of coal, or mining and refining of metals.

Once released, mercury may travel great distances before depositing on land and water, where it reacts with organic materials to form methylmercury. Methylmercury bioaccumulates and becomes part of the aquatic food chain. This organic mercury is a potent neurotoxin, especially for developing fetal and children's brains.

In addition, in the health-care setting, elemental mercury may be released as a result of spillage from broken thermometers or leaking equipment. Inhalation of these mercury vapours may cause damage to the lungs, kidneys and central nervous system. Symptoms of mercury poisoning from chronic exposure may include shortness of breath, dyspnoea and irritability, depression and tremors.

The potential environmental damage, human toxicity and disposal costs of mercury have led to a growing demand for non-mercury-containing devices in health care. This guide will describe available alternative non-mercury-containing devices for thermometers and sphygmomanometers, and provide guidance on the selection of alternative devices.

Acknowledgements

This publication was written by:

Jo Anna M Shimek, University of Illinois, United States of America

Jorge Emmanuel, United Nations Development Programme—Global Environment Facility, Global Healthcare Waste Project, United States of America

Peter Orris, University of Illinois, United States of America

Yves Chartier, World Health Organization, Switzerland

It was prepared by:

The Great Lakes Centers for Occupational and Environmental Safety and Health of the University of Illinois at Chicago's School of Public Health: A WHO Collaborating Centre in Occupational and Environmental Health

In conjunction with:

The Global Healthcare Waste Project, funded by the United Nations Development Programme's Global Environment Facility, in cooperation with the World Health Organization and Health Care Without Harm

The authors wish to thank the following experts for their reviews and helpful comments:

Bjorn Fahlgren, World Health Organization, Switzerland

Carolyn Vickers, World Health Organization, Switzerland

Josh Karliner, Health Care Without Harm, United States of America

Shanthi Mendis, World Health Organization, Switzerland

Susan Wilburn, World Health Organization, Switzerland

I. WHO policy

The health-care sector's contribution to the global environmental releases of mercury and their associated health impacts has come, in large part, from mercury thermometers and sphygmomanometers. In a 2005 policy paper, the World Health Organization (WHO) noted that "of all mercury instruments used in health care, the largest amount of mercury is used in mercury sphygmomanometers (80 to 100 g/unit), and their widespread use collectively make them one of the largest mercury reservoirs in the health-care setting". In calling for a phase-out of mercury measuring devices from health care, it explained that "by choosing a mercury-free alternative, a health-care institution can make a tremendous impact in reducing the potential for mercury exposure to patients, staff and the environment. It is important to recognize that no matter what type of blood pressure measurement device is used, both aneroid and mercury sphygmomanometers must be checked regularly in order to avoid errors" (*1*).

WHO recognizes that one of the major causes of poor blood pressure control in low-resource settings is the unavailability of reliable, easily obtainable and affordable devices for blood pressure measurement. WHO has drawn up technical specifications for mercury-free, accurate and affordable blood pressure measuring devices for clinical use (*2*). More recently, WHO provided technical support to develop and validate an accurate and affordable solar-powered semi-automatic blood pressure measurement device for resource-constrained settings (*3*).

II. Purpose of this guide

This short guide is designed to provide step-by-step instructions for the safe substitution of non-mercury thermometers and sphygmomanometers in health-care settings. It identifies available resources that support the equivalent accuracy and comparable clinical utility of the substituted products , while protecting health-care workers and the environment. It is designed for professionals responsible for institutions or ministries desiring to switch to safer non-polluting technologies in health care.

This guide is also an output of a global mercury-free health-care initiative in which WHO is engaged. This global initiative aims to promote the substitution of mercury-based medical devices with safe, affordable, accurate alternatives around the world. The global mercury-free health-care initiative has documented mercury substitution in dozens of countries (*4*). It has also produced a series of additional resources for health professionals, health-system managers and government officials that can be useful in developing and implementing policy and strategies for mercury substitution in the health sector (*5*).

III. Background

a. Chemistry

Temperature and blood pressure are two key components in the evaluation of the health of a patient. The mercury thermometer and the mercury sphygmomanometer have been used to provide this information for more than 100 years. Mercury is a naturally occurring element with its greatest stores within the earth's crust. It is a unique metal that is a liquid at room temperature. Mercury has a freezing point of –39 °C, a boiling point of 357 °C and does not burn, making it a useful material for a wide range of applications.

Mercury is released by volcanic eruptions, often in the form of mercury salts such as mercury sulfide, and as a by-product in many human activities such as burning coal, and mining and refining of metals such as copper, gold, lead and zinc. The largest present intentional use of mercury is by artisanal and small-scale gold miners. Mercury compounds are used in chemical manufacturing, the production of cement and other industrial processes, and are contained in many consumer and industrial products (*6*).

b. Exposure

Whenever people intentionally produce and use mercury, much of that mercury will eventually volatilize into the atmosphere. It is estimated that approximately one-third of the mercury circulating in the global environment is naturally occurring, and approximately two-thirds is a result of industrial and other human activities (*7*). The amount of mercury that is circulating in the world's atmosphere, soils, lakes, streams and oceans has increased by a factor of between two and four since the start of the industrial era (*8*).

After mercury vapour is released, depending upon air currents, it may travel short or long distances before falling back to earth. A portion of the mercury that falls into the ocean or onto the land will again volatilize and travel still further. The residual mercury that falls on land will likely bind to organic material in the soil. This eventually drains into streams and rivers, and then to lakes and oceans. In the aquatic environment, much of the elemental mercury becomes bound to sediment and the rest is carried by the currents. In these aquatic environments, microorganisms metabolize mercury into methylmercury, an organometallic compound. Methylmercury

becomes part of the aquatic food chain; it bioaccumulates and biomagnifies, and—on occasion—is transported even further by migratory fish.

In health-care settings, the common breakage of mercury-containing devices, spilling of mercury and incineration of mercury-containing medical waste contribute to both indoor and outdoor emissions. In 2007, a survey in Buenos Aires noted that more than 40 000 thermometers were lost per year, most to breakage, in their 33 public hospitals and 38 clinics, and in Mexico a national paediatric teaching hospital broke an average of 385 thermometers per month (*9*). In 1996, before a significant number of hospital-based incinerators were closed, the United States Environmental Protection Agency designated the burning of medical waste as the fourth-largest mercury emission source in the United States (*10*).

c. Human exposure

Due to its high surface tension and volatility, elemental mercury forms small drops when spilled and vaporizes rapidly into the air. Indoors, mercury spills become an inhalation hazard (*11*). Target organs of elemental mercury vapour inhalation include the lung, kidney and central nervous system. Symptoms of mercury poisoning include shortness of breath, dyspnoea and cough with acute exposure; chronic exposure to lower doses generally leads to irritability, depression, tremors and slurred speech (*11*).

The general population is exposed to the mercury released into the environment through a diet containing fish. This exposure is of most concern with respect to children before birth and in infancy. In 2000, the National Research Council of the United States National Academy of Sciences found that the population at highest risk for methylmercury exposure is the children of women who consumed large amounts of fish and seafood during or immediately prior to pregnancy. It found that the risk to this population is likely to be sufficient to result in an increase in the number of children who must struggle to keep up in school and who might require remedial classes or special education (*12*).

d. Costs

In 2005, Transande et al., using blood mercury data from the United States Centers for Disease Control and Prevention, estimated that the loss of productivity based on the predicted neurotoxicity of mercury amounted to between US$2.2 and US$43.8 billion annually for the United States from coal-burning power plants alone (*13*). See specific cost considerations in the chapters on thermometers and sphygmomanometers.

IV. Thermometers

a. History

In 1654, Ferdinando II de' Medici crafted the first modern thermometer by designing a sealed tube partially filled with alcohol and a reservoir bulb, thereby eliminating the interference of barometric pressure common in previous models (*14*).

Daniel Gabriel Fahrenheit produced a thermometer using mercury in 1724 and established the Fahrenheit scale (32–212 °F). Because of mercury's high coefficient of expansion, the results were highly reproducible. Eighteen years later, Anders Celsius proposed that a scale of zero degrees (melting point of water) to 100 degrees (boiling point) was more practical. Both scales are still used today, as is the original mercury sealed-glass thermometer (*10*).

Dr James Currie popularized the use of these glass thermometers for the measurement of patient temperatures towards the end of the 18th century. He practised in Liverpool from 1780 to 1805, published his findings and theories, and corresponded with the leading scientists of the day (*15*).

b. Operation of mercury thermometers

Mercury-in-glass thermometers have two components: a reservoir of mercury, or a bulb, attached to a glass tube that has a scale to measure the temperature change. As the temperature changes, the mercury moves up or down the tube, and the change is recorded. Thermometers used in health care are designed to record the maximum temperature obtained during the recording period by use of a constriction in the neck of the thermometer that prevents the mercury from falling back into the reservoir. Once the temperature is recorded, the thermometer must be "shaken" to return the mercury to the reservoir. The thermometer is then ready to take another reading (*10*).

c. Accuracy of mercury thermometers

The accuracy of the mercury thermometer depends on several factors, including proper placement, length of time kept at site, technique used by the clinician, patient's activities before and during the measurement, clothing, ambient temperature and humidity.

The American Society of Testing and Materials (ASTM) has established voluntary performance standards for thermometers, and thermometers used in health care are typically tested against these standards. According to the performance standards, mercury thermometers must be accurate to ±0.2 °F between 98.0 °F and 102.0 °F, and to ±0.4 °F at the extremes of <96.4 °F and >106 °F (*16*). Adjusting for human error, a properly validated, calibrated and maintained mercury thermometer meeting the ASTM standard will be accurate within the above limits (*12*).

d. Mercury-free thermometers

Commercially available alternatives to mercury thermometers include thermistor-based digital thermometers, galinstan-in-glass thermometers, alcohol-dye thermometers, tympanic infrared thermometers, temporal artery infrared thermometers, thermocouple-based thermometers, phase-change (dot-matrix) thermometers and thermochromic (cholesteric) liquid crystal thermometers (*17*). This guide focuses primarily on digital, phase-change, tympanic infrared and temporal artery infrared thermometers, although some of the specifications may apply to other types of non-mercury measuring devices.

Digital thermometers, so called because they display the temperature in digital format, are equipped with either an electronic sensor (requiring body contact) or an infrared sensor (for remote sensing) to ascertain the body temperature.

Phase-change thermometers use a grid of dots attached to a thin plastic disposable stick to indicate the temperature. The dots are made up of a non-toxic compound, and each row of dots represents temperature increments. The stick may be placed under the tongue and, as the temperature increases, the dots will change colour (usually to black), with the temperature indicated by the last dot to change colour.

Tympanic infrared thermometers, or ear thermometers, are typically battery-operated units resembling an otoscope probe. The probe, with

a disposable plastic cover, is inserted into the outer part of the ear canal to measure the thermal radiation of the tympanic membrane. The signal from the infrared sensor is converted to a digital temperature display.

A temporal artery infrared thermometer, sometimes called a forehead thermometer, takes the body temperature as the user slides the probe sensor across the patient's forehead, crossing over the temporal artery. In doing so, the sensor measures the thermal radiation of the skin surface over the temporal artery and computes the body temperature. Temporal artery thermometers are generally portable, battery-operated electronic devices with a digital display screen.

e. Accuracy of mercury-free thermometers

Fadzil et al. (*18*) conducted a study at the University of Malaya Medical Centre comparing four different temperature-measuring devices: mercury-in-glass thermometer, digital oral thermometer, liquid crystal forehead thermometer and digital tympanic infrared thermometer. All four measurements were conducted simultaneously for 207 patients. The means and standard deviations for the four methods were reported as follows: mercury-in-glass, mean 36.795 °C, standard deviation 0.695; digital oral, mean 36.845 °C, standard deviation 0.632; liquid crystal forehead, mean 36.718 °C, standard deviation 0.723; and digital tympanic infrared, mean 36.78 °C, standard deviation 0.717. Although all three alternates were comparable to the mercury thermometer, the authors favoured the digital thermometer for general use, the tympanic model for uncooperative patients and the liquid crystal forehead method for home use (*13*). Many other scientific papers compare the accuracy and suitability of different types of thermometers, and the conclusions are sometimes contradictory (*19*).

f. Cost considerations

The purchase price of devices, which varies from country to country, remains a key point to be considered. Other factors in addition to purchase price need to be considered such as, the rate of use of consumable items like alcohol wipes, batteries, cuffs and other parts, and repair and calibration costs all need to be considered. Two factors often overlooked are the costs of disposal of the mercury-containing units and the education of staff on the proper operation of the units.

In 2005, Crawford et al. (*20*) modelled comparable costs in a large teaching hospital of 2205 beds in the United Kingdom over a 10-year period. They estimated that the mercury thermometer was the

cheapest thermometer alternative as no batteries, covers, repairs or calibration were required. This calculation was based on the assumption of a 10% breakage per year of these glass devices and replacing all with the compact digital units. In reality, as discussed above, the rate of breakage is much higher. If the thermometer breakage rate for the Mexican pediatric hospital (see above) with 212 beds is extrapolated to this 2205-bed setting, the rate would be closer to 200%.

Further, a one-for-one replacement is not necessary given the versatility and greater durability of the digital device. At a luxuriant replacement ratio of one digital device for every two glass devices, a breakage rate of only 33% or above would make the contact, compact electronic devices cheaper, even if all other pricing assumptions (5:1 differential) remained the same. Certainly, exact costs will vary with location, model and number of units purchased. However, hospitals that have substituted mercury thermometers in a number of countries—including Argentina, Mexico and the Philippines—report cost savings with the digital devices.

g. Mercury thermometer replacement

In general, successful mercury replacement programmes entail:

- involving participatory stakeholders;
- conducting an inventory to identify the numbers and uses of mercury-containing devices and materials in the health-care facility;
- evaluating the feasibility and acceptability of non-mercury alternatives;
- identifying vendors; planning the phase-out of mercury and the phase-in of non-mercury alternatives;
- developing a budget and procurement process;
- safely removing or disposing mercury-measuring devices;
- preparing programs such as staff education;
- periodically maintaining and calibrating the equipment, as needed;
- monitoring the use of the non-mercury alternatives to ensure the effectiveness of the replacement programme.

An example of this approach is outlined in the steps below.

Step 1 Involve stakeholders in the facility—such as the medical and nursing staff, heads of departments where mercury thermometers are commonly used, and the departments involved in budgeting and purchasing—in the planning and implementation of the phase-out of mercury. Promulgate institutional policies regarding the phase-out of mercury, as appropriate.

Step 2 Conduct an inventory to determine the types, locations, uses and quantities of mercury-containing devices in the facility, as well as disposal practices.

Step 3 Implement proper clean-up and storage procedures for mercury-containing devices and mercury waste. Ensure that mercury waste is placed in sealed primary and secondary containers, and that the storage area is secure, properly marked and vented to the outside (*21*).

Step 4 Determine which thermometer is right for your application.

Many aspects have to be considered when selecting the type of non-mercury thermometers. Consultation with health-care providers about which types of non-mercury thermometer are appropriate to accommodate the age of the patients and their medical conditions, the institutional setting, portability, the sterilization process, ease of use, safety and patient comfort is important. Costs, time spent for temperature measurement, storage requirements and uniformity are also important system or institutional considerations.

Digital clinical thermometers should meet the requirements of either European Norm EN 12470-3:2000+A1:2009 (*22*) or ASTM E1112-00 (*23*). Phase-change (dot-matrix) thermometers should meet the requirements of ASTM E825-98 (*24*). Tympanic infrared (ear) thermometers should meet the requirements of EN 12470-5:2003 (*25*) or ASTM E1965-98 (2009) (*26*). Temporal artery infrared thermometers should meet the requirements specific to skin infrared thermometers in ASTM E1965-98 (2009) (*26*). In general, digital thermometers, tympanic infrared thermometers and temporal artery infrared thermometers should conform to EN 60601-1, the basic safety standard for medical electrical devices (*27*). See Annex 1 for more information.

Step 5 Identify vendors that can provide the chosen thermometer type. If desired, ask the vendor(s) for several trial units and evaluate them in the areas where they will be used. After receiving feedback from the users of the units, identify the desired type for purchase.

Mercury-free product listings[1]

In January 2005, the report *MHRA 04144 Thermometer review: UK market survey 2005* of the Medicines and Healthcare products Regulatory Agency was released and contained a listing of products available at that time on the market in the United Kingdom:
http://www.wales.nhs.uk/sites3/docmetadata.cfm?orgid=443&id=54173

A partial listing of products available in the Philippines is contained in *Guide to alternatives for healthcare personnel*, Health Care Without Harm, Southeast Asia, published in 2007:
http://www.noharm.org/lib/downloads/mercury/Mercury-Free_Guide_to_Alternatives.pdf

For products sold in the United States, the Food and Drug Administration (FDA) maintains a listing of all approved medical devices including thermometers. These can be searched by manufacturer's name, product name or 510k number (FDA application code). The search form is found at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

Step 6 Determine the phase-in schedule for the new units. Consideration should be given to the time needed to install or replace the units, calibration of the units (if needed) and a staff educational programme.

Step 7 Develop a budget for the replacement programme, including the purchase of the units and accessories (such as probe covers or sheaths), installation as needed, staff education on the use of the new devices, calibration and maintenance schedules, removal and storage of the mercury-containing units and purchase of any consumables needed on an ongoing basis.

[1] These product listings are examples. Other listings are also available.

Step 8 Develop a bid specification for the purchase of the replacement units and include the number of units that will be required. Specify conformity with the appropriate standard, warranty requirements, desired optional features and any other local considerations. Follow the standard procedures for competitive bidding or other procurement method. Compare the vendor packages for compliance with the appropriate standard and other specifications. Require certification or proof of compliance with the standard, especially from new vendors or vendors not listed in national or international certified product listings. Consider the ability of the vendor to provide the required number of units in a timely fashion so as to fit the phase-in schedule. Select the vendor for the project.

Step 9 Review the selected vendor's requirements for calibration and maintenance of the thermometer, and obtain any needed equipment. Determine who will be assigned the task of conducting the required calibration and maintenance, and on what schedule. Solicit the vendor's aid in planning for education and continuing education, if necessary.

Step 10 Prepare the interim storage site for phased-out mercury measuring devices. If approved mercury-disposal facilities are available in the country, identify the waste vendor that will be responsible for disposal of the mercury-containing units and develop procedures that will be followed for their removal and transfer.

Step 11 Purchase the units according to the phase-in schedule.

Step 12 Perform any initial tests or calibration as per the manufacturer's specifications.

Step 13 Conduct the planned staff educational activity related to the operation and maintenance of the new devices.

Step 14 Distribute or install new devices in exchange for old mercury thermometers. Remove and transfer the mercury-containing units to a designated storage area. If the country has approved mercury-disposal facilities, transport and dispose of the mercury-containing units at an approved disposal site according to local hazardous waste regulations.

Step 15 Monitor and ensure that the non-mercury thermometers are properly used and maintained, and that any waste, including end-of-life waste, is managed in an environmentally sound manner.

V. Sphygmomanometers

a. History

The sphygmograph, a device that was attached to the forearm and recorded arterial pulsations on an external graph, was developed in 1855 by Karl Vierordt. A host of other sphygmometers, devices that externally measured arterial pressure by directly compressing the radial artery, followed through the end of the century and beyond. SR von Basch introduced the rubber, hollow ball filled with water or mercury to obstruct the artery, and combined this with an aneroid manometer in 1880. The mercury sphygmomanometer, a sphygmometer with a separate compression device for the arm, was introduced by Scipione Riva-Rocci in 1896. Independently, in 1897, Hill and Barnard introduced a similar device with an aneroid manometer (*35*).

In 1905, Nikoli Korotkoff was the first to suggest listening to artery sounds while using a stethoscope, which by then was nearly a century old. This auscultatory method was more reliable than palpation in identifying the diastolic pressure (*27*).

b. Operation of a manual sphygmomanometer

A manual sphygmomanometer's basic components include an inflatable cuff to place pressure on the artery, a pressure-measuring scale and an inflation bulb to inflate the cuff. Sphygmomanometers are used with a stethoscope to measure the systolic and diastolic blood pressure. To measure blood pressure, the inflatable cuff is placed around the upper arm and inflated to a point where the blood flow is cut off. As the cuff is inflated, the needle on the aneroid scale or mercury in the manometer rises through the column, and the resulting pressure is displayed on the scale. The stethoscope is placed over the brachial artery at the elbow. The pressure is slowly relieved by deflating the cuff and, as the blood starts flowing again, a pounding sound will be heard through the stethoscope. This number displayed on the scale at this point is the systolic blood pressure, which represents the maximum output pressure of the heart. As the pressure continues to be reduced, a point is reached where there is no sound indicating that the heart is at rest. This number as displayed on the scale is known as the diastolic pressure. Despite major progress in medical devices over the past century, most of this methodology is still the same as in the early 20th century.

c. Accuracy of mercury sphygmomanometers

Although the mercury thermometer is a relatively simple device, the manual mercury sphygmomanometer is a more complicated piece of equipment. However, if properly validated, calibrated and maintained, it will provide accurate blood pressure readings. Accuracy is dependent on several human factors, such as proper cuff size, proper placement of the cuff on the arm, recognition of emergence and disappearance of the arterial sounds, accurate recording of the systolic and diastolic end points, and the patient's level of anxiety.

Proper maintenance includes a visual inspection of the unit and regular calibration of a validated unit. A study by Markandu et al. (*36*) at a large teaching hospital in London tested 469 mercury sphygmomanometers, observed medical professionals taking blood pressure readings and reviewed results of a questionnaire completed by the medical staff. Twenty-five units were excluded from examination as they had missing components. The physical inspection of the units found obscure mercury columns due to dirt or mercury oxidation (38%); scales that had faded or columns that had turned, hindering readings of the mercury meniscus (18%); incorrect orientation of the mercury column in portable units (20%); and very few with observed mercury leaks (0.7%). Cuffs and tubing had also deteriorated in many units. Validation records were not reviewed and maintenance records were available for only 23 of 444 units (*29*).

d. Mercury-free sphygmomanometers

There are two common alternatives to the mercury sphygmomanometer: aneroid and oscillometric devices. Aneroid devices are liquid-free devices that use mechanical parts to relay the blood pressure to the gauge. This device uses the normal blood pressure cuff and stethoscope to determine the systolic and diastolic pressures.

The oscillometric devices are operated automatically once the cuff is placed on the upper arm. Inflation and deflation of the cuff are obtained by electronic means. Pressure-wave changes are transmitted to the oscillating device and an algorithm, often proprietary, is used to calculate the systolic and diastolic pressures, which are displayed on a digital readout. Given the inaccuracy of the auscultatory technique, validated and affordable electronic devices that have the option to select manual readings are preferred options for low-resource settings (*37*).

In addition, there are Doppler-based plethysmographic monitors, photocell-based monitors and strain-gauge-based monitors. These devices are for specialty purposes and are not in general use. They will not be covered in this document, but the same general approaches apply to their introduction as to the aneroid and oscillometric devices.

e. Accuracy of mercury-free sphygmomanometers

Properly maintained, calibrated and validated mercury-free sphygmomanometers will provide comparable accuracy to devices containing mercury. The accuracy of these alternative sphygmomanometers can be measured by the ability of the device to satisfactorily complete the validation protocol. Properly calibrated and maintained devices operated according to manufacturer specifications should be able meet the requirements (*38*). A semi-automated device that has been designed to measure blood pressure in resource-constrained settings, satisfies the criteria drawn up by the World Health Organization (WHO) and is reasonably priced has undergone technical and field validation in collaboration with WHO (*11*).

f. Calibration

Calibration is a comparison between the reference value and the value from the device being tested. As part of its guidelines on the management of hypertension (*39*), the British Hypertension Society (BHS) has published guidelines on the proper use of non-invasive, semi-automated sphygmomanometers. The protocols for *both* mercury and non-mercury measuring devices include proper maintenance, calibration and validation.

The American Heart Association, in its recommendations (*40*), notes that all manual devices—mercury and aneroid sphygmomanometers—should be checked for accuracy of the pressure registration mechanism on a regular basis.

The aneroid devices should be checked by connecting the manometer to a mercury column or an electronic testing device with a Y-tube. The needle should rest at the zero point before the cuff is inflated and should register a reading that is within 4 mmHg of the mercury column when the cuff is inflated to pressures of 100 and 200 mmHg. The needle should return to zero after deflation.

Although not included in these recommendations, it should be noted that using an electronic pressure-generating device for comparison provides an accuracy that is an order of magnitude better than that of a

mercury column due to the variability related to mercury manometry (*41*).

Calibration procedures ensure that the unit is performing according to the manufacturer's specifications.

g. Validation

Validation is a process to determine whether a measurement technology is able to produce an accurate value when tested on a human population. For sphygmomanometers, the protocols of the Association for the Advancement of Medical Instrumentation (AAMI) and the BHS are the most widely accepted, although the European Society of Hypertension Working Group on Blood Pressure Monitoring has developed an international protocol that is easier to perform (*42*). Devices that pass the criteria of these protocols are judged to be state of the art with respect to accuracy in a clinical setting. Devices having passed these protocols include mercury, aneroid and automated blood pressure devices for clinical use in hospitals; oscillatory automated blood pressure devices; oscillatory automated blood pressure devices for self-measurement at the upper arm and at the wrist; and ambulatory blood pressure monitoring devices.

The BHS's device-grading criteria (see Table 5.1) are based on a comparison of blood pressure measured by the device being tested with measurements made by trained observers using a mercury sphygmomanometer and stethoscope (*43*). The grade is linked to the percentages of readings falling within 5 mmHg, 10 mmHg and 15 mmHg of the mercury standard. All three percentages must be greater than or equal to the values shown in the table for a specific grade to be awarded. Devices that achieve Grade A or B for both systolic and diastolic blood pressure are considered acceptable for clinical use.

Table 5.1 British Hypertension Society grading criteria

	Absolute difference between standard and test device		
Grade	**≤5 mmHg**	**≤10 mmHg**	**≤15 mmHg**
A	60%	85%	95%
B	50%	75%	90%
C	40%	65%	85%
D	worse than C		

Validation protocols are completed by the manufacturer or an independent agency to demonstrate compliance with the performance standards. As long as the unit is properly calibrated according to the manufacturer's operating instructions and the unit has demonstrated compliance with the performance standards, the unit will produce reliable results. Results of the executed validation protocol should be made available to the purchaser and any calibration procedures should be provided by the manufacturer.

Wan et al. (*44*) conducted a review of published studies of automatic digital devices. The review included 113 studies from 22 different countries. The devices had been validated against at least one recognized protocol: BHS protocol, 1993; AAMI protocol, 2002; or the European Society of Hypertension International Protocol (EHS-IP), 2002. When the BHS protocol was used for validation, 25 of 31 devices (81%) passed satisfactorily; when the AAMI protocol was used, 37 of 41 devices (90%) passed; and when the EHS-IP protocol was used, 34 of 35 devices (97%) passed.

It should be noted that the EHS-IP protocol requires 33 test subjects, whereas the BHS and AAMI protocols require 85 subjects (*32*). In addition to passing the validation protocol, regular calibration and maintenance are necessary to ensure the accuracy of the sphygmomanometer.

h. Cost considerations

The costs of mercury and aneroid sphygmomanometers are essentially equal, with both devices often being manufactured by the same company. Oscilloscopic, automatic devices are more expensive (*45*).

i. Replacement of mercury-containing sphygmomanometers

Step 1 Follow steps 1 to 3 in the section on mercury thermometer replacement.

Step 2 Based on the information provided above, determine which type of sphygmomanometer will meet the needs of your facilities (see Annex 2).

Step 3 Identify the vendors that are able to provide the sphygmomanometer of choice. As part of the unit selection process, it may be desirable to run a trial in the facility where the units will be evaluated to determine ease of use,

requirements for calibration and maintenance of the unit, and the time estimates needed to install, calibrate and maintain the units and educate the staff. After receiving feedback from the users of the unit, identify the desired type and model of the unit.

Mercury-free product listings

Many validation protocols have been completed for existing products, with the results published in the scientific literature. Several independent groups have catalogued validation reports and provided the results for various models in tabular form.

The BHS maintains a web page listing devices that have passed their validation tests, with prices and other information:
http://www.bhsoc.org/blood_pressure_list.stm.

The dabl Educational Trust has a web site that lists products and the results, or lack of results, for all three validation protocols:
http://www.dableducational.org/sphygmomanometers.html

Step 4 Determine the phase-in schedule for the new units. Consideration should be given to the time needed to install or replace the units, and calibration of the units, if needed. Develop standard operating procedures for the new units and an educational programme for both clinical users and maintenance personnel. For maximum effectiveness, both the procedures and the educational programme should be developed in conjunction with personnel who will be using the new devices.

Step 5 Develop a budget for the replacement programme, including the purchase of the units, installation as needed, staff education on the use of the new devices, calibration and maintenance schedules, removal and storage of the mercury-containing units, and purchase of any supplies needed for maintenance on an ongoing basis.

Step 6 Develop a bid specification for the purchase of the replacement units and include the number of units that will be required. Specify conformity with the appropriate standard, warranty requirements and any other local considerations. Follow the standard procedures for competitive bidding or other procurement method. Compare the vendor packages for compliance with the appropriate standard and other specifications. Require

certification or proof of compliance with the standard, especially from new vendors or vendors not listed in national or international certified product listings. Consider the ability of the vendor to provide the required number of units in a timely fashion so as to fit the phase-in schedule. Select the vendor for the project.

Step 7 Review the selected vendor's requirements for calibration and maintenance of the sphygmomanometer, and obtain any needed equipment. Determine who will be assigned the task of conducting the required calibration and maintenance, and on what schedule. Solicit the vendor's aid in planning for education and continuing education, if necessary.

Step 8 Prepare the interim storage site for phased-out mercury measuring devices. If approved mercury-disposal facilities are available in the country, identify the waste vendor who will be responsible for disposal of the mercury-containing units and develop procedures that will be followed for their removal and transfer.

Step 9 Purchase the units according to the phase-in schedule.

Step 10 Perform any initial tests or calibration as per the manufacturer's specifications. An electronic pressure gauge should be available for calibration purposes.

Step 11 Conduct the planned staff educational activity related to the operation and maintenance of the new devices. Request vendor assistance and participation in this process.

Step 12 Distribute or install new devices in exchange for old mercury sphygmomanometers. Remove and transfer the mercury-containing units to a designated storage area. If the country has approved mercury-disposal facilities, transport and dispose of the mercury-containing units at an approved disposal site according to local hazardous waste regulations.

Step 13 Monitor and ensure that the non-mercury sphygmomanometers are properly used and maintained, and that any waste, including end-of-life waste, is managed in an environmentally sound manner.

VI. Conclusion

Alternatives to mercury-containing thermometers and sphygmomanometers are available, and are accurate and practical in clinical settings. These alternatives should be considered when replacing or phasing out mercury units in health-care settings. The elimination of mercury, a potent neurotoxin, from these devices protects health-care providers and their communities. In this way, it promotes good health for patients as well. This guide provides a step-by-step approach to phasing out mercury thermometers and sphygmomanometers. It emphasizes the availability and cost considerations of alternative equipment, and their conformity with existing international or national standards with the understanding that they must be properly validated by the manufacturer and calibrated by the user. If this is kept in mind and if replacement equipment is phased-in as suggested in this document, the new devices will provide equivalent accuracy and comparable clinical utility.

Annex 1

Table A1.1 Requirements for digital thermometers

Key parameters in European standard EN 12470-3:2000+A1:2009:

Parameter	Summary of the specification		Test procedure
Maximum permissible error over the specified temperature range	0.1 °C	Measuring temperature range: 35.5–42.0 °C Ambient temperature range: 18–28 °C	Method in 7.3 of EN 12470-3:2000
	0.2 °C	Outside the above measuring range or ambient temperature range	
Minimum measuring range	35.5–40.0 °C		Method in 7.2 of EN 12470-3:2000
Resolution (digital increment)	0.1 °C or less		Visual inspection
Ambient temperature operating range	10–35 °C		Method in 7.7 of EN 12470-3:2000

Note: If the digital thermometer uses a single-use protective probe cover, the thermometer together with the probe cover must meet the above requirements.

Table A1.1 Requirements for digital thermometers *continued*

Key parameters in ASTM E1112-00 (reapproved 2006):

Parameter	Summary of the specification		Test procedure
Maximum permissible error over the specified temperature range	±0.3 °C	Measuring temperature range: <35.8 °C Ambient temperature range: see below	Method in 5.4 of ASTM E1112-00
	±0.2 °C	Measuring temperature range: 35.8–<37 °C Ambient temperature range: see below	
	±0.1 °C	Measuring temperature range: 37–39 °C Ambient temperature range: see below	
	±0.2 °C	Measuring temperature range: >39–41 °C Ambient temperature range: see below	
	±0.3 °C	Measuring temperature range: >41 °C Ambient temperature range: see below	
Precision and bias	Test results should have an expanded uncertainty (k = 3) not exceeding 0.045 °C		See 5.6 in ASTM E1112-00
Measuring range	35.5–41.0 °C		(Digital display)
Resolution (digital increment)	≤0.1 °C		(Digital display)
Ambient temperature operating range	16–40 °C at a relative humidity of 15–95% (non-condensing)		Method in 5.5.1 of ASTM E1112-00

Table A1.1 Requirements for digital thermometers *continued*

Other important general parameters in the EN and ASTM standards; relevant sections in the respective standards are referenced in brackets [ ]:

Parameter	Summary of the specification in EN 12470-3:2000	Summary of the specification in ASTM E1112-00
Warning when out of range	The device should give a visual or auditory warning when the measured temperature is not within the specified measuring range [see sections 6.2.1 and 7.2]	n/a
Time response	60 seconds under specified conditions [see sections 6.2.4 and 7.4]	n/a
Effect of storage	The device should meet the EN accuracy requirement after being stored in its unopened primary package at five different temperatures for 24 hours each in sequence [see sections 6.3.2 and 7.8]	The device should meet the ASTM accuracy requirement after being stored and/or transported in an environment of –20 °C to 50 °C and a relative humidity of 15–95% non-condensing for one month [see test method in section 5.5.2]
Long-term stability	The device should meet the EN accuracy requirement after exposure to either 55 °C or 80 °C for a specified number of days [see section 6.2.6]	n/a
Readability	Numerals should appear at least 4 mm high [see section 6.4.1.2]	Numerals should appear at least 2.5 mm high and 1.5 mm wide, with at least 0.7 mm in between [see section 4.4.2.2]
Ability to withstand thermal shock	The device should meet the EN accuracy requirement after being exposed to five cycles of 0 °C and 55 °C for an hour each [see sections 6.3.3 and 7.9]	n/a
Effect of humidity	The device should meet the EN accuracy requirement after being exposed to a temperature of 45 °C and a relative humidity of 85% for 48 hours [see sections 6.3.4 and 7.10]	The device should meet the ASTM accuracy requirement after being exposed to at least four test conditions involving two temperatures and four relative humidities [see section 5.5.1]

Table A1.1 Requirements for digital thermometers *continued*

Parameter	Summary of the specification in EN 12470-3:2000	Summary of the specification in ASTM E1112-00
Resistance to mechanical shock	The device should meet the EN accuracy requirement after being dropped onto a hard surface from a height of 1 metre [see sections 6.3.6 and 7.11]	The instruction manual should inform the user if the performance is degraded by mechanical shock such as from a drop test; the device should withstand dropping without presenting an electrical hazard [see sections 4.3.3.3 and 4.6.2.1]
Water resistance	The device should meet the EN accuracy requirement after being immersed in water for 30 minutes [see sections 6.3.7 and 7.12]	n/a
Maximum energy dissipation	The energy dissipated by the probe should not cause a temperature rise in the indicated temperature of more than 0.01 °C [see sections 6.2.5 and 7.5]	n/a

n/a, not available,
Note: See the list of available features of digital thermometers, below.

Table A1.1 Requirements for digital thermometers *continued*

Important parameters related to safety in the EN or ASTM standards; relevant sections in the respective standards are referenced in brackets [ ]:

Parameter	Summary of the specification in EN 12470-3:2000	Summary of the specification in ASTM E1112-00
Electrical safety	The device should comply with EN 60601-1 (*28*) [see section 6.5]	The device and its accessories (such as battery chargers) should meet general electrical safety requirements found in UL 544 (*29*) [see section 4.6.1]
Electromagnetic compatibility	The device should conform to EN 60601-1-2 (*27*) [see section 6.3.5]	n/a
Voltage limit indication	The device should provide a visual or auditory warning when the supply voltage is not within specified limits [see section 6.4.1.1]	n/a
Battery condition	n/a	The accuracy and condition of the device should not be affected by the battery condition unless a continuous automatic indication of unreliable condition is provided [see section 4.5]
Mechanical safety	The device should not have sharp ends or angles, and the probe should be smoothly rounded to prevent injuries to the user or patient [see section 6.6]	n/a
Material of construction	The device should be free from biological hazards [see section 6.4.2]	The case and any non-disposable accessories should withstand biological and physical cleaning without degrading performance; the parts of the device intended for contact with the patient should be non-toxic [see section 4.6.2 and test methods in sections 5.2 and 5.3]
Functional safe test	The device should have a self-testing routine [see section 4.4.1.3]	n/a

n/a, not available.
Note: See the list of available features of digital thermometers, below.

Table A1.1 Requirements for digital thermometers *continued*

Parameters related to marking and documentation in the EN or ASTM standards; relevant sections in the respective standards are referenced in brackets [ ]:

Parameter	Summary of the specification in EN 12470-3:2000	Summary of the specification in ASTM E1112-00
Marking	Information from the manufacturer should comply with EN 1041 (*30*); marking should include the symbol "C" adjacent to the numerals, the body site (if applicable), etc. [see sections 8.1 and 8.2]	Identification markings should not deteriorate when the device is cleaned [see cleaning test in section 5.2]; markings should include model, serial or lot number, temperature scale, etc. [see section 4.7]
Instructions for use	The information in the instructions should include environmental conditions of use, storage and transport; cleaning and disinfection; selection, replacement and disposal of batteries, if applicable; probe cover use, if applicable; measuring time; maintenance and calibration; etc. [see section 8.3]	Instructions should include operation, care and use, biological and physical cleaning, service and repair if permitted, determination of accuracy, recalibration, detailed specifications, etc. [see sections 4.3.3, 4.7 and 4.8]
Identification	Compliance with EN 1041 and EN 980 (*31*) [see section 8.1]	"Conforms to ASTM E1112 (name and address of producer or distributor)" [see section 4.7.6.1 for the full statement of identification]

Note that the above specifications do not apply to specialized temperature-measuring devices, such as pulmonary artery catheters and temperature probes for hypothermic patients. Basal temperature thermometers require higher accuracy, typically 0.05 °C, than the standard fever thermometer.

EN 12470-3:2000 requires that each individual lot shall be subjected to individual or statistical testing, as explained in section 7.1.1 and in ISO 2859-2:1985 (*32*). ASTM International has an additional standard specification, ASTM E1104-98 (*33*), for clinical thermometer probe covers and sheaths.

Available features of digital thermometers

The following specifications, not required by the European Norm nor by the ASTM standard, pertain to features available from different suppliers that may be added according to the needs and desires of the health-care facility. Some of these optional features may entail additional costs. They are:

- rapid response time (e.g. 10 seconds or less);
- extra-large display or display with magnifying lens;
- audible alarm when the peak temperature is reached;
- display of self-check results during start-up;
- memory function that stores the last temperature reading or many temperature readings;
- automatic shut-off;
- mercury-free or "no added mercury" battery (*34*);
- long battery life; for example, 4000 temperature readings or 300 hours;
- easily replaceable or rechargeable battery;
- if solar powered, up to 72 hours per solar charge;
- flexible probe tip;
- dual scale (both °C and °F);
- standard disposable sterile probe covers;
- method of removal of probe covers: manual or eject button;
- customized colours to distinguish between oral, rectal and axillary use;
- resistance to specific disinfectants and cleaners used in the health-care facility;
- minimal packaging waste;
- at least one year warranty;

- proof of certification of conformity to international standards, including EN 12470-3:2000 or ASTM E1112; IEC/EN 60601 or UL 60601; EN 1041 and EN 980; ATSM E1104, if applicable;
- ISO 9001 (quality management) certification of the manufacturing facility;
- ISO 13485 or ISO 13488 (medical device quality management) certification of the medical device manufacturer;
- ISO 14000 (environmental management) certification of the manufacture.

Table A1.2 Requirements for phase-change thermometers

Summary of requirements in ASTM E825-98 (*24*):

Parameter	Summary of the specification		Section
Maximum error over the specified temperature range	±0.3 °C	<35.8 °C	5.3 (see test method in 6.2.1)
	±0.2 °C	35.8–36.9 °C	
	±0.1 °C	37.0–39.0 °C	
	±0.2 °C	39.1–41.0 °C	
	±0.3 °C	>41.0 °C	
Minimum measuring range	35–40.4 °C unless otherwise labelled		5.2
Measurement retention	≥1 minute		5.4 (see test method in 6.2.4)
Resolution (graduation)	≤0.1 °C		5.6
Operating environment	The device should meet the ASTM accuracy requirement in the range of 18–33 °C unless otherwise marked		5.5 (see test method in 6.3)
Workmanship	No constructional defects to prevent meeting the ASTM accuracy requirement		5.7
Stability	All requirements should be met over the shelf life; if the shelf life is less than 5 years, the expiration date should be displayed		5.8
Storage environment	The device should meet the ASTM accuracy requirement after storage for 1 day at temperatures from –18 °C to 38 °C and relative humidities from 15% to 90%, and for 1 month at temperatures from 15.5 °C to 32 °C and relative humidities from 30% to 75%		5.9 (see test method in 6.4)
Marking and labelling	Markings should include the name and/or trademark of the manufacturer or distributor, serial number or code to indicate manufacturing lot, etc.; operating instructions should be provided		5.10
Toxicity	Parts intended for contact and chemicals should be non-toxic		5.11 (see test method in 6.5)
Precision and bias	Test results should have an expanded uncertainty (k = 3) not exceeding 0.045 °C		6.6
Identification	"Conforms to ASTM E825 (name and address of producer or distributor)"—see section 7 for the full statement of identification		7

Table A1.3 Requirements for tympanic infrared thermometers

Key parameters in European standard EN 12470-5:2003 (*25*):

Parameter	Summary of the specification		Test procedure
Maximum permissible error over the specified temperature range	±0.2 °C	Measuring temperature range: 35.5–42.0 °C Ambient temperature range: 18–28 °C	Method in 7.4 and 7.5 of EN 12470-5:2003
	±0.3 °C	Outside the above measuring range or ambient temperature range	
Minimum measuring range	35.5–40.0 °C		Method in 7.3 of EN 12470-5:2003
Maximum permissible clinical repeatability	±0.3 °C for every patient age group (newborn, children, adults) for which the infrared ear thermometer is intended for use		Method in 7.7 of EN 12470-5:2003
Resolution (digital increment)	0.1 °C or less		Visual inspection
Ambient temperature operating range	16–35 °C		Method in 7.4 of EN 12470-5:2003

Note: If the infrared ear thermometer uses a protective probe cover, the thermometer together with the probe cover must meet the requirements above. If the probe cover is intended for multiple use, the above requirements must be met after the probe cover has been cleaned, disinfected and/or sterilized according to the manufacturer's specifications.

Table A1.3 Requirements for tympanic infrared thermometers *continued*

Key requirements in ASTM E1865-98 (reapproved 2009) (*26*):

Parameter	Summary of the specification		Section
Maximum permissible laboratory error for given black-body temperature range	0.3 °C	<36 °C	5.3 (see test method in 6.1.4)
	0.2 °C	36–39 °C	
	0.3 °C	>39 °C	
Minimum measuring range	34.4–42.2 °C unless otherwise labelled		5.2
Clinical accuracy	To be determined and disclosed upon request for each device model, adjustable display mode and age group intended for use		5.5.1 (see also 6.2)
Display resolution	0.1 °C		5.8.1
Operating temperature	The device should meet the laboratory error requirement operating in the range of 16–40°C unless otherwise marked		5.6.1.1
Operating humidity range	Up to 95% for the specified operating temperature range		5.7

Table A1.4 Requirements for temporal artery infrared thermometers

Key requirements in ASTM E1865-98 (reapproved 2009) (*26*):

Parameter	Summary of the specification	Section
Maximum permissible laboratory error for given black-body temperature range	0.3 °C	5.4 (see test method in 6.1.5)
Minimum measuring range	22–40.0 °C	5.2
Display resolution	0.1 °C	5.8.1
Operating temperature	The device should meet the laboratory error requirement operating in the range of 16–40 °C unless otherwise marked	5.6.1.1
Operating humidity range	Up to 95% for the specified operating temperature range	5.7

Annex 2

Table A2.1 Requirements for aneroid sphygmomanometers

Non-automated non-invasive sphygmomanometers using an aneroid manometer should meet the requirements of ANSI/AAMI/ISO 81060-1:2007 (*47*).

Parameter	Summary of the specification	Section
Identification and marking		
Unit of measurement	mmHg or kPa	4.1
Legibility of markings	Should be clearly legible; see compliance test	4.2
Durability of markings	Should be sufficiently durable to remain clearly legible during the expected service life; see compliance test	4.3
Marking	Should include the name or trademark and address of manufacturer, model, serial or batch number if appropriate, proper disposal, etc.	4.4
Usability of reading	Should have an indication when the reading error due to parallax exceeds ±2 mmHg (0.3 kPa)	4.5
Cuff marking	Should indicate the correct positioning and appropriate limb circumference	4.6
Marking on the packaging	Should include contents; special storage or handling, if any; intended use of the cuff; and appropriate symbols or label for equipment or components that are sterile, have an expiration date, or are for single use	4.7
General requirements		
Test requirements	(Type tests, samples, environmental conditions, etc.)	5
Electrical safety	Compliance with IEC 60601-1 if electricity is used	6.2
Mechanical safety	Should avoid rough surfaces, sharp corners and edges that could cause injury or damage	6.3
Mechanical strength	Should function properly after falling 25 cm (or 1 m for "shock-resistant" sphygmomanometers), except for stationary devices; see compliance test	6.4.1
	Should function properly after shock and vibration; see compliance tests	6.4.2

Table A2.1 Requirements for aneroid sphygmomanometers *continued*

Parameter	Summary of the specification	Section
	Accuracy and other key requirements	
Maximum error for the cuff pressure measurement over the nominal range	≤ ±3 mmHg (±0.4 kPa) for the following conditions: temperature range of 15–25 °C, relative humidity range of 15–85% (non-condensing) and decreasing pressure; see compliance test ≤ ±3 mmHg (±0.4 kPa) or 2%, whichever is greater, for the following conditions: temperature range of 10–40 °C, relative humidity range of 15–85% (non-condensing) and decreasing pressure; see compliance test	7.1.1
Nominal range and measuring range	0 mmHg (0 kPa) to at least 260 mmHg (35 kPa)	7.1.2
Air leakage	Should not cause a pressure drop that exceeds 4 mmHg/min (0.5 kPa/min); see compliance test	7.2.1
Pressure reduction rate	Should be adjustable to a deflation rate of 2 mmHg/s (0.3 kPa/s) to 3 mmHg/s (0.4 kPa/s); see compliance test	7.2.2
Rapid exhaust	Should not exceed 10 seconds from 260 mmHg (35 kPa) to 15 mmHg (2 kPa); see compliance test	7.2.3
Dimensions of cuff	Dimensions based on the limb circumference at the midpoint of the intended range of the cuff	7.2.4
Cuff, bladder and tubing connectors	Should be able to withstand the maximum pressure; should have a means to prevent accidental disconnection; see compliance tests	7.2.5 and 7.2.6
Tamper proofing or unauthorized access	Should prevent tampering with, or unauthorized access to, adjustments and functions that affect accuracy	7.3
Dynamic response	<1.5 seconds in cuff pressure indication for a specified drop in pressure; see compliance test	7.4
	Additional requirements	
Scale mark and zero	Requirements for a tolerance zone and movement of the elastic sensing element	9.1 and 9.2
Hysteresis error	<4 mmHg (0.5 kPa) throughout the pressure range; see compliance test	9.3
Construction and materials	Not more than 3 mmHg (0.4 kPa) difference in pressure indication after 10 000 full-scale cycles; see compliance test	9.4
Cleaning, sterilization, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned, and disinfected or sterilized	10

Table A2.1 Requirements for aneroid sphygmomanometers *continued*

Parameter	Summary of the specification	Section
	Additional requirements *continued*	
Information supplied by the manufacturer	Should include identification; instructions for use; instructions for cleaning, and sterilization or disinfection; instructions for routine maintenance, as well as inspection and preventive maintenance by service personnel; instructions for end-of-life disposal; and technical description	12

Table A2.2 Requirements for automated sphygmomanometers

Automated non-invasive (medical electrical) sphygmomanometers should meet the requirements of ANSI/AAMI/ISO 81060-2:2009 (*47*) and ANSI/AAMI/EC 80601-2-30:2009 (*48*).

Parameter	Summary of the specification	Section
Essential requirements		
Maximum error for the measurement of the cuff pressure over the nominal measurement range	≤ ±3 mmHg (±0.4 kPa) or 2% of the reading, whichever is greater	201.12.1.102
Nominal blood pressure indication range	Diastolic blood pressure: at least 20 mmHg (2.7 kPa) to 60 mmHg (8.0 kPa) in neonatal mode and 40 mmHg (5.3 kPa) to 130 mmHg (17.3 kPa) otherwise Systolic blood pressure: at least 40 mmHg (5.3 kPa) to 110 mmHg (14.7 kPa) in neonatal mode and 60 mmHg (8.0 kPa) to 230 mmHg (30.7 kPa) otherwise	201.12.1.103 (see compliance test)
Maximum pressure in normal condition	<150 mmHg (20 kPa) in neonatal mode and <300 mmHg (40 kPa) otherwise	201.12.1.104
Maximum pressure in single fault condition	Should not exceed +10 % of the maximum rated pressure for more than 3 seconds; see 201.12.1.105 for the requirements of the protection device to prevent this	201.12.1.105
Manometer test mode	The device should have a test mode that can be used to verify calibration	201.12.1.106
Laboratory limits of the change in error of the blood pressure determination	Less than 3 mmHg (0.4 kPa); see compliance test	201.12.1.107
Alarm systems	See 201.12.3.101	201.12.3
Various other requirements		
General requirements	Requirements include performing risk management, expected service life, equipment safety, etc., as detailed in section 4 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005 (*28*)	201.4
Requirements for testing	Requirements for type testing, sampling, environmental and other conditions, test sequence, etc., as detailed in section 5 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.5

Table A2.2 Requirements for automated sphygmomanometers *continued*

Parameter	Summary of the specification	Section
Various other requirements *continued*		
Classification	Requirements pertain to protection against electric shock, protection against entry of water or dust, etc., as detailed in section 6 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.6
Identification and markings	Requirements involve legibility and durability of markings, markings on the outside and inside of the equipment or parts, abbreviations, marking of controls, markings for different uses (e.g. neonatal), warning and safety notices, etc., as detailed in section 201 and section 7 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.7
Protection from hazards and fault conditions	Requirements to protect against electrical and mechanical hazards of the device, excessive temperatures, interruption of power supply, etc., as detailed in sections 201.8 to 201.11, section 201.13, and sections 8 to 11 and 13 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.8, 201.9, 201.10, 201.11
Programmable devices	Requirements related to programmable electrical devices, as detailed in section 14 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.14
Construction	Requirements related to serviceability, mechanical strength, shock and vibration, etc., including compliance tests, as detailed in section 201.15 and section 15 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.15
Requirements for electrical systems	Various other requirements dealing with power supply, enclosure, leakage current, etc., as detailed in section 16 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005	201.16
Electromagnetic compatibility	Requirements involve a risk management process, detailed in section 17 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005; should conform to IEC 60601-1-2 (*27*); test method in section 202	201.17, 202, and IEC 60601-1-2
Cuff, tubing, cuff connectors	Requirements involving construction and pressurization	201.101 and 201.102
Unauthorized access	Should prevent tampering with, or unauthorized access to, controls that affect accuracy	201.103
Maximum inflating time	Requirements related to a pressure-relief protection device	201.104
Automatic cycling modes	Requirements related to a protection device for long-term and short-term automatic mode, if applicable	201.105

Table A2.3 Summary of requirements in ANSI/AAMI/ISO 81060-2:2009 (*47*)

Parameter	Summary of the specification	Section
Validation studies		
General requirements	Automated sphygmomanometers should be clinically validated using either a non-invasive (auscultatory) reference sphygmomanometer or a reference invasive blood pressure monitoring equipment in each mode of operation	4
Validation with an auscultatory reference sphygmomanometer	Minimum of 85 subjects with three valid blood pressure determinations for each (see details about the study procedure and data analysis in section 5)	5
Validation with reference invasive blood pressure monitoring equipment	See study procedure and data analysis in section 6; clinical validation studies should comply with ISO 14155 (49); validation with reference invasive blood pressure monitoring equipment should not be used for patients or subjects solely for the purpose of validating sphygmomanometer performance	6
Validation for pregnant patients	A sphygmomanometer for use in pregnant, including pre-eclamptic, patients should be clinically evaluated in that patient population	7

References

1. *Mercury in health care: policy paper*. Geneva, World Health Organization (http://www.who.int/water_sanitation_health/medicalwaste/mercury/en/, accessed December 2010).
2. Parati G et al. Recommendations for blood pressure measuring devices for office/clinic use in low resource setting. *Blood Pressure Monitoring*, 2005, 10:3–10.
3. Parati G et al. A new solar-powered blood pressure measuring device for low-resource settings. *Hypertension*, 2010, 56(6):1047–1053.
4. Karliner J. *Toward the tipping point: WHO–HCWH global initiative to substitute mercury-based medical devices in health care, a two-year progress report*. World Health Organization and Health Care Without Harm, in association with the United Nations Development Programme Global Environment Facility Global Health Care Waste Project, 2010 (http://www.mercuryfreehealthcare.org//Toward_the_Tipping_Point.pdf).
5. The global initiative, a collaboration with Health Care Without Harm, is a component of the United Nations Environment Programme Mercury Products Partnership, led by the United States Environmental Protection Agency (http://www.mercuryfreehealthcare.org).
6. *Mercury—basic information*. United States Environmental Protection Agency (http://www.epa.gov/mercury/about.htm, accessed December 2010).
7. *Mercury emissions—the global context*. United States Environmental Protection Agency (http://www.epa.gov/mercury/control_emissions/global.htm, accessed December 2010).
8. *Mercury—your health and the environment*. Health Canada (http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q1-q6_e.html, accessed December 2010).
9. Karliner J et al. Mercury free health care. *World Medical Journal*, 2008, 54(2):39–45.
10. *Treatment technologies for mercury in soil, waste, and water*. Washington DC, United States Environmental Protection Agency Office of Superfund Remediation and Technology Innovation, 2007 (http://www.epa.gov/tio/download/remed/542r07003.pdf).

11. Agency for Toxic Substances and Disease Registry (http://www.atsdr.cdc.gov/toxprofiles/tp46-c2.pdf, accessed 6 October 2010).

12. United States National Research Council. *Toxicological effects of methylmercury*, Washington DC, National Academy Press, 2000:4 (http://www.nap.edu/catalog.php?record_id=9899#toc).

13. Transande L, Landrigan P, Schechter C. Public health and economic consequences of methyl mercury toxicity to the developing brain. *Environmental Health Perspectives*, 2005, 113:590–596.

14. World Encyclopedia (http://www.neworldencyclopedia.org/entry/Thermometer, accessed October 2010).

15. Halliday S. Dr James Currie (1756–1805): Liverpool physician, campaigner, hydrotherapist and man of letters. *Journal of Medical Biography*, 2006, 14(1):36.

16. *Selecting non-mercury thermometers*. Sustainable Hospitals Project (http://www.sustainablehospitals.org/HTMLSrc/IP_Merc_FTNonmerc.html, accessed 14 October 2010).

17. Emmanuel J. *Guidance on technical specifications for non-mercury medical devices*. Global Environment Facility Project on Global Healthcare Waste, United Nations Development Programme, 2010.

18. Fadzil FM, Choon D, Arumugam K. A comparative study on the accuracy of noninvasive thermometers. *Australian Family Physician*, 2010, 39(4):237–239.

19. See, for example: Lowe JC. *Thyroid Science*, 2009, 4(3):CLS1-9; Giantin V et al. *Journal of Clinical Nursing*, 2008, 17(11):1518–1525; Moya Villaescusa MJ, Sánchez Pérez A, Bermejo Fenoll A. *Medicina Oral, Patología Oral y Cirugía Bucal*, 2008, 13(6):E385–389; Spitzer OP. *Dimensions of Critical Care Nursing*, 2008, 27(1):24–29; Moran JL et al. *Critical Care Medicine*, 2007, 35(1):312–313; Crawford DC, Hicks B, Thompson MJ. *Journal of Medical Engineering & Technology*, 2006, 30(4):199–211; Dodd SR. *Journal of Clinical Epidemiology*, 2006, 59(4):354–357; Rosenthal HM, Leslie A. *Journal of Neonatal Nursing*, 2006, 12(4): 125–129; Crawford D, Greene N, Wentworth S. *Thermometer review: UK survey 2005*. MHRA 04144, Medicines and Healthcare products Regulatory Agency, Department of Health, United Kingdom, January 2005; Farnell S et al. *Journal of Clinical Nursing*, 2005, 14(5):632–639; Khorshid L et al. *Journal of Clinical Nursing*, 2005, 14(4):496–500; Sermet-Gaudelus I, Chadelat I, Lenoir G. *Archives of Pediatrics and Adolescent Medicine*, 2005, 12(8):1292–1300; McKenzie N. *Pediatric Nursing*, 2003, 29(2):117–125; Qureshi F et al. *Pakistan Journal of Medical Sciences*, 2003, 19(2):111–113; Smith LS. *BMC Nursing*, 2003, 2:1; Dowding D, *Professional Nurse*, 2002, 18(3):166–168; Macqueen S. *British Journal of Nursing*, 2001, 10(1):55–58; Jensen BN et al. *Acta chirurgica*, 2000, 166(11):848–851; Sganga A et al. *American Journal of Maternal and Child Nursing*, 2000, 25(2):76–79; Valle PC, Kildahl-Andersen O, Steinvoll K. *Tidsskr Nor Laegeforen*, 2000, 120(1):15–17; Amoateng-Adjepong Y, Del Mundo J, Manthous CA. *Chest*, 1999, 115:1002–1005; Prentice D, Moreland J. *Geriatric Nursing*, 1999, 20(6):314–317; Leick-Rude MK, Bloom LF. *Neonatal Network*, 1998, 17(5):21–37; Matsukawa T et al. *Canadian Journal of Anaesthesia*, 1996, 43(12):1224–1228; Zengeya ST, Blumenthal I. *European Journal of Pediatrics*, 1997, 155(12):1005–1008; Mackenzie R, Ashbury AJ. *British Journal of Anaesthesia*, 1994, 72(2):246–249; Davies SP et al. *Journal of Advanced Nursing*, 1986, 11(5):535–543.

20. Crawford D, Hicks B, Thompson M. Which thermometer? Factors influencing best choice for intermittent clinical temperature assessment. *Journal of Medical Engineering & Technology*, 2006, 30(4):199–211.

21. See, for example, *Guidance on the cleanup, temporary or intermediate storage, and transport of mercury waste from healthcare facilities*. United Nations Development Programme, Global Environment Facility Global Healthcare Waste Project, 2010.

22. *Clinical thermometers—Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device*. European Standard EN 12470-3:2000+A1, June 2009.

23. *Standard specification for electronic thermometer for intermittent determination of patient temperature*. ASTM E1112-00, reapproved 2006. See also ASTM E1104 related to clinical thermometer probe covers and sheaths.

24. *Standard specification for phase change-type disposable fever thermometer for intermittent determination of human temperature*. ASTM E825-98 (reapproved 2009).

25. *Clinical thermometers—Part 5: Performance of infra-red ear thermometers (with maximum device)*. European Norm EN 12470-5:2003.

26. *Standard specification for infrared thermometers for intermittent determination of patient temperature*. ASTM E1965-98 (reapproved 2009).

27. *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance; Collateral standard: Electromagnetic compatibility—requirements and tests*. European Norm EN 60601-1.

28. *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*. ANSI/AAMI ES60601-1:2005, 2006; or IEC 60601-1:2005.

29. *Standards for safety, medical and dental equipment*, UL 544. Northbrook, IL, Underwriters Laboratories. This UL standard has since been superseded by *Medical electrical equipment—Part 1: General requirements for safety*, UL 60601-1, and its subsequent revisions, Underwriters Laboratories, 25 April 2003.

30. *Information supplied by the manufacturer of medical devices*. European Norm EN 1041, August 2008.

31. *Symbols for use in the labelling of medical devices*. European Norm EN 980, 2008.

32. *Sampling procedures for inspection by attributes—Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*. ISO 2859-2:1985.

33. *Standard specification for clinical thermometer probe covers and sheaths*. ASTM E1104-98 (reapproved 2009).

34. Many digital thermometers use miniature (button, coin-shaped and button-stacked) batteries. Lithium miniature batteries have no added mercury. Silver oxide, zinc air and alkaline manganese dioxide miniature batteries have an average of 2.5, 8.5 and 10.8 mg of mercury per battery, respectively. Mercury-free versions of all of these miniature batteries have been developed. Non-miniature cylindrical alkaline batteries (AA, AAA, AAAA and N sizes; or R6, R03 and R1 sizes) do not have added mercury. (Reference: Galligan C, Morose G. *An investigation of alternatives to miniature batteries containing mercury*. Report by the Lowell Center for Sustainable Production for the Maine Department of Environmental Protection, December 17, 2004.)

35. Naqvi NH, Blaufox MD. *Blood pressure measurement: an illustrated history*, pp. 5–6 ff. New York, Parthenon Publishing, 1998.

36. Markandu N, Whitcher F, Arnold A, Carney C. The mercury sphygmomanometer should be abandoned before it is proscribed. *Journal of Human Hypertension*, 2000, 14(1):31–36.

37. *Affordable technology: blood pressure measuring devices for low-resource settings*. Geneva, World Health Organization, 2005.

38. *Mercury sphygmomanometers in healthcare and the feasibility of alternatives*. Scientific Committee on Emerging and Newly Identified Health Risks, Directorate General for Health and Consumers, European Commission, 23 September, 2009 (http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_025.pdf).

39. Williams B et al. Guidelines for management of hypertension: report of the fourth working party of the British Hypertension Society, 2004—BHS IV. *Journal of Human Hypertension*, 2004, 18:139–185.

40. Pickering TG et al. Recommendations for blood pressure measurement in humans and experimental animals, part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research, AHA Scientific Statement. *Hypertension*, 2005, 45:142.

41. Coleman AJS, Stephen D, Ashworth M, Vowler SL, Shennan A. Accuracy of the pressure scale of sphygmomanometers in clinical use within primary care. *Blood Pressure Monitoring*, 2005, 10(4):181–188.

42. O'Brien E et al. Blood pressure measuring devices: recommendations of the European Society of Hypertension. *British Medical Journal*, 2001, 322:531–536.

43. O'Brien E et al. Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Pressure Monitoring*, 2002, 7:3–17; O'Brien E. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *Journal of Hypertension*, 1993, 11(Suppl. 2):S43–S62.

44. Wan Y, Heneghan C, Stevens R, McManus RJ, Ward A, Perera R, Thompson M. Determining which automatic digital blood pressure device performs adequately: a systematic review. *Journal of Human Hypertension*, 2010, 24:431–438.

45. Galligan C et al. *An investigation of alternative to mercury containing products*, Lowell Center for Sustainable Production, University of Massachusetts at Lowell, 2003:21.

46. *Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type*. ANSI/AAMI/ISO 81060-1:2007.

47. *Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type*. ANSI/AAMI/ISO 81060-2:2009 (revision of SP10:2002 and Amendment 1:2003 and Amendment 2:2006), 2009.

48. *Medical electrical equipment—Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*. NSI/AAMI/EC 80601-2-30:2009.

49. *Clinical investigation of medical devices for human subjects—Part 1: General requirements*. ISO 14155-1:2003.