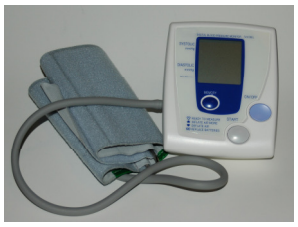

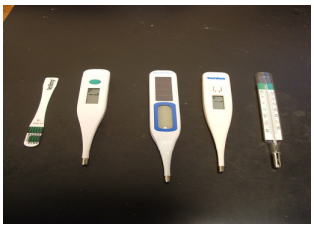

MERCURY REPLACEMENT IN HEALTHCARE

Thermometers and Sphygmomanometers

Technical Guidance

World Health Organization

DISCLAIMER

The cover photographs are:

Cover designed by

Production and design by:

TABLE OF CONTENTS

Foreword

Elemental mercury has been used for decades in thermometers and sphygmomanometers in the healthcare 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 methyl mercury. Methyl mercury 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 healthcare setting, elemental mercury may be released as a result of spillage from broken thermometers or leaking equipment. Inhalation of these mercury vapors may cause damage to the lungs, kidneys and central nervous system. Symptoms of mercury poisoning may include shortness of breath, dyspnea and irritability, depression and tremors upon chronic exposure.

The potential environmental damage, human toxicity and disposal costs of mercury have led to a growing demand for non-mercury containing devices in healthcare. 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, USA
Jorge Emmanuel, UNDP - GEF, USA
Peter Orris, University of Illinois, USA
Yves Chartier, World Health Organization, Switzerland

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 Center in Occupational and Environmental Health

In conjunction with:
The United Nations Development Programme's Global Environment Facility funded Global Healthcare Waste Project 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, USA
Shanthi Mendos, Wold Health Organization, Switzerland
Susan Wilbrun, World Health Organization, Switzerland

I. 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 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 -39ºC and a boiling point of 357ºC 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 the burning of coal and the 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 in other industrial processes and are contained in many consumer and industrial products[1].

b. Exposure

Whenever people intentionally produce and use mercury, much of that mercury will eventually volatize 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[2]. 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[3].

After mercury vapor 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 still further by migratory fish.

In healthcare settings the common breakage or 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 over 40,000 thermometers were lost per year, most to breakage, in their 33 public hospitals and 38 clinics, while in Mexico a national pediatric teaching hospital broke on average 385 thermometers a month[4]. In 1996, prior to the closing of a significant number of hospital-based incinerators, the US Environmental Protection Agency had designated the burning of medical waste as the fourth largest mercury emission source in the US[5].

c. Human Toxicity

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[6]. Target organs of elemental mercury vapor inhalation include the lung, kidney and central nervous system. Symptoms of mercury poisoning include shortness of breath, dyspnea, and cough with acute exposure while chronic lower dose exposure generally leads to irritability, depression, tremors, and slurred speech[6].

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 prior to birth and in infancy. In 2000 the National Research Council of the US National Academies 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[7].

d. Costs

In 2005, Transande et al., using blood mercury data from the US Centers for Disease Control and Prevention estimated that the loss of productivity based on the predicted neurotoxicity of mercury amounted to between 2.2 and 43.8 billion dollars annually for the US from coal burning power plants alone[8].

e. WHO Policy

The health care sector's contribution to this problem has come in large part from mercury thermometers and sphygmomanometers. In a 2005 Policy Paper, the World Health Organization noted that "of all mercury instruments used in health care, the largest amount of mercury is used in mercury sphygmomanometers (80 to 100g/unit), and their widespread use, collectively make them one of the largest mercury reservoirs in the healthcare setting." In calling for a phase-out of mercury devices from health care it explained that "by choosing a mercury-free alternative a healthcare 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" [9]

WHO recognizes that one of the major causes for 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 BP measuring devices for clinical use [10] More recently WHO provided technical support to develop and validate an accurate and affordable solar powered semiautomatic blood pressure measurement device for resource constrained settings.[11]

f. 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 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 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.[12] 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.[13]

II. 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 the Fahrenheit scale (32ºF – 212ºF) was established. Because of mercury's high coefficient of expansion the results were highly reproducible. 18 years later, Anders Celsius proposed a scale of zero (melting point of water) to 100 degrees (boiling point) as more practical but 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 century. He practiced in Liverpool form 1780 to 1805 publishing his findings and theories and corresponding 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 which has a scale to measure the temperature change. As the temperature changes the mercury moves up or down the tube and the change can be 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 is dependent of 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, etc.

The American Society of Testing and Materials has established voluntary performance standards for thermometers (summarized below) and thermometers used in healthcare are typically tested against these standards. According to the performance standards mercury thermometers must be accurate to ±0.2ºF between 98.0ºF and 102.0ºF and ±0.4ºF at the extremes of <96.4ºF and >106ºF[16]. Adjusting for

human error a properly validated, calibrated and maintained mercury thermometer meeting the ASTM standard will be accurate within the limits set above[12].

d. Mercury Free Thermometers

The 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 guidance 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 devices.

Digital thermometers, so called because they display the temperature in digital format, are equipped with either an electronic sensor requiring body contact or 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 color, usually black with the temperature indicated by the last dot to change color.

Tympanic infrared (IR) 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 IR 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 methods of temperature measuring devices, mercury-in-glass thermometer, digital oral thermometer, liquid crystal forehead thermometer and a digital infrared tympanic thermometer. All four measurements were conducted simultaneously for 207 patients. The mean and standard deviation for the four methods were reported as follows: mercury in glass 36.795ºC, standard deviation = 0.695; oral digital 36.845ºC, standard deviation = 0.632; liquid crystal forehead 36.718ºC, standard deviation = 0.723; and digital infrared tympanic 36.78ºC, standard deviation = 0.717. While all three alternatives were comparable to the mercury thermometer, the authors favored the digital thermometer for general use, the tympanic model for uncooperative patients and the liquid crystal forehead method for home use[13].

f. Cost Considerations

There are several factors which need to be considered in addition to the price of the device. The rate of use of consumable items such as alcohol wipes, batteries, cuffs, other parts, 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 the staff on the proper operation of the units.

In 2005 Crawford et al.[19] modeled comparable costs in a large teaching hospital of 2205 beds in the UK over a 10 year period and estimated that the mercury thermometer was the cheapest thermometer alternative as there were no batteries, covers, repairs or calibration required. This calculation was based upon 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, referenced 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 of one digital 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 programs entail participatory stakeholder involvement, conducting an inventory to identify the amounts and uses of mercury-containing devices and materials in the healthcare 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, procurement, safe removal or disposal of mercury devices, preparations including staff education, periodic maintenance and calibration as needed, and monitoring the use of the non-mercury alternatives to ensure the effectiveness of the replacement program. 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.[20]

Step 4 Determine which thermometer is right for your application.

Many aspects have to be considered when selecting the types of non-mercury thermometers. Many scientific papers compare the accuracy and suitability of different types of thermometers and the conclusions are sometimes contradictory[21]. Consultations with health care providers as to which types of

non-mercury thermometer are appropriate to accommodate the age of the patients, their medical conditions, institutional setting, portability, sterilization process, ease of use, safety, and patient comfort are important. Costs, time spent for temperature measurement, storage requirements, and uniformity are important system or institutional considerations as well.

Digital clinical thermometers should meet the requirements of either EN 12470-3:2000+A1:2009[22] or ASTM E1112-00[23]. Phase change (or so-called 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 IR thermometers in ASTM E1965-98 (2009)[27]. In general, digital thermometers, tympanic IR thermometers, and temporal artery IR thermometers should conform to EN 60601-1, the basic safety standard for medical electrical devices[28].

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℃	Measuring temperature range:35.5℃ – 42.0℃ Ambient temperature range: 18℃ to 28℃	Method in 7.3 of EN 12470-3:2000
	0.2℃	Outside the above measuring range or ambient temperature range	
Minimum measuring range	35.5℃ – 40.0℃		Method in 7.2 of EN 12470-3:2000
Resolution (digital increment)	0.1℃ or less		Visual inspection
Ambient temperature operating range	10℃ – 35℃		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 requirements above).

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℃	Measuring temperature range: <35.8℃ Ambient temperature range: See below	Method in 5.4 of ASTM E1112-00
	±0.2℃	Measuring temperature range: 35.8℃ to <37℃ Ambient temperature range: See below	
	±0.1℃	Measuring temperature range: 37℃ to 39℃ Ambient temperature range: See below	
	±0.2℃	Measuring temperature range: >39℃ to 41℃ Ambient temperature range: See below	

	±0.3℃ Measuring temperature range:>41℃ Ambient temperature range: See below	
Parameter	Summary of the Specification	Test Procedure
Precision and bias	Test results should have an expanded uncertainty (k=3) not exceeding 0.045℃	See 5.6 in ASTM E1112-00
Measuring range	35.5℃-41.0℃	(Digital display)
Resolution (digital increment)	0.1℃ or less	(Digital display)
Ambient temperature operating range	16℃ to 40℃ at a relative humidity of 15-95% (non-condensing)	Method in 5.5.1 of ASTM E1112-00

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 to 50℃ and a relative humidity of 15 to 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℃ 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, 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 and 55℃ 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℃ and a relative humidity of 85% for 48 hours [see sections 6.3.4 and	The device should meet the ASTM accuracy requirement after being exposed to at least four test conditions involving two temperatures

	7.10]	and four relative humidities [see section 5.5.1]
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 meter [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 by more than 0.01℃ [see sections 6.2.5 and 7.5]	n/a

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[29] [see section 6.5]	The device and its accessories (such as battery chargers) should meet general electrical safety requirements found in UL 544[30] [see section 4.6.1]
Electromagnetic compatibility	The device should conform to EN 60601-1-2[31] [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	n/a

	patient [see section 6.6]	

Parameter	Summary of the specification in EN 12470-3:2000	Summary of the specification in ASTM E1112-00
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

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[32]; 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 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[33] [see 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, compared to 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[34]. ASTM International has an additional standard specification, ATSM E1104 – 98[35], 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 which may be added according to the needs and desires of the healthcare facility. Some of these optional features may entail additional costs.

- 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[36]
- Long battery life, for example, 4000 temperature readings or 300 hours
- Easily replaceable battery 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
- Available Features of Digital Thermometers (continued)
- Customized colors to distinguish between oral, rectal, and axillary use
- Resistant to specific disinfectants and cleaners used in the healthcare facility
- Minimum 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.

Requirements for Phase Change Thermometers

Summary of requirements in ASTM E825-98[37]:

Parameter	Summary of the Specification		Section
Maximum error over the specified temperature range	±0.3℃	< 35.8℃	5.3 (see test method in 6.2.1)
	±0.2℃	35.8℃ – 36.9℃	
	±0.1℃	37.0℃ – 39.0℃	
	±0.2℃	39.1℃ – 41.0℃	
	±0.3℃	> 41.0℃	
Minimum measuring range	35 to 40.4℃ unless otherwise labeled		5.2
Measurement retention	≥ 1 minute		5.4 (see test method in 6.2.4)
Resolution (graduation)	≤ 0.1℃		5.6
Operating environment	The device should meet the ASTM accuracy requirement in the range of 18 to 33℃ 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 year, 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 to 38℃ and relative humidities from 15 to 90%, and for 1 month at temperatures from 15.5 to 32℃ and relative humidities from 30 to 75%		5.9 (see test method in 6.4)
Marking and labeling	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℃		6.6
Identification	“Conforms to ASTM E825 (name and address of producer or distributor)” – [see section 7 for the full statement of identification]		7

Requirements for Tympanic Infrared Thermometers

Key parameters in European standard EN 12470-5:2003[38]:

Parameter	Summary of the Specification		Test Procedure
Maximum permissible error over the specified temperature range	±0.2℃	Measuring temperature range: 35.5℃ – 42.0℃ Ambient temperature range: 18℃ to 28℃	Method in 7.4 and 7.5 of EN 12470-5:2003
	±0.3℃	Outside the above measuring range or ambient temperature range	
Minimum measuring range	35.5℃ – 40.0℃		Method in 7.3 of EN 12470-5:2003
Maximum permissible clinical repeatability	±0.3℃ 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℃ or less		Visual inspection
Ambient temperature operating range	16℃ – 35℃		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 manufacturer's specifications.)

Key requirements in ASTM E1865-98 (reapproved 2009)[39]:

Parameter	Summary of the Specification		Section
Maximum permissible laboratory error for given blackbody temperature range	0.3℃	< 36℃	5.3 (see test method in 6.1.4)
	0.2℃	36℃ – 39℃	
	0.3℃	> 39℃	
Minimum measuring range	34.4 to 42.2℃ unless otherwise labeled		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℃		5.8.1
Operating temperature	The device should meet the laboratory error requirement operating in the range of 16 to 40℃ unless otherwise marked		5.6.1.1
Operating humidity	Up to 95% for the specified operating		5.7

range	temperature range	

Requirements for Temporal Artery Infrared Thermometers

Key requirements in ASTM E1865-98 (reapproved 2009)[40]:

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

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*

In January 2005 Medicines and Healthcare products Regulatory Agency (UK) report MHRA 04144 (Thermometer Review) contains 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=54173A

A partial listing of products available in the Philippines are contained in a Guide to Alternatives for Healthcare Professionals, Health Care Without Harm, South East Asia, published in 2007 which can be found at: 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

* These product listings are examples. Other listings are also available.

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 program.

Step 7 Develop a budget for the replacement program 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 the purchase of any consumables needed on an ongoing basis.

Step 8 Develop a bid specification for the purchase of the replacement units to 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 vendor's aid in planning for the education and continuing education if necessary.

Step 10 Prepare the interim storage site for phased-out mercury 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 the removal and transfer of the mercury-containing units.

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

Step 12 Perform any initial tests or calibration as per 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.

III. SPHYGMOMANOMETERS

a. History

The sphygmograph, a device attached to the forearm that 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. S.R. 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 and independently in 1897 Hill and Barnard introduced a similar device with an aneroid manometer[41].

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[28].

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 pressures. 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 and 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[42]. Despite major progress in medical devices over the past century most of this methodology is still the same as it was in the early twentieth century.

c. Accuracy of Mercury Sphygmomanometers

While 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, as well, 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 finally the patients level of anxiety.

Proper maintenance includes a visible inspection of the unit and regular calibration of a validated unit. A study by Markandu et al.[43] 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 turned hindering readings of the mercury meniscus (18%), incorrect orientation of the mercury column in portable units (20%), and three units with observed mercury leaks. 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[30].

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 is 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 [44]

In addition there are monitors which are Doppler-based plethysmographic, photocell-based, and strain gauge-based. 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 the 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.[45] A semi-automated device that has been designed for the purpose of measuring blood pressure in resource constrained settings that satisfy the criteria drawn up by the WHO and is reasonably priced has undergone technical and field validation in collaboration with WHO .[46]

f. Calibration

Calibration is a comparison between a measurement of known value with the device being tested. As part of its guidelines on the management of hypertension[47] the British Hypertension Society (BHS) has published guidelines on the proper use of non-invasive, semi-automated

sphygmomanometers. The protocol for *both* mercury and non-mercury devices include proper maintenance, calibration, and validation.

The American Heart Association (AHA), in its recommendations,[48] 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.

Though not included in these recommendations, it should be noted that utilizing an electronic pressure generating device for comparison provides an accuracy of an order of magnitude better that of a mercury column due to the variability related to mercury manometry.[49].

Calibration procedures assure 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 British Hypertension Society are the most widely accepted, though the European Society of Hypertension Working Group on Blood Pressure Monitoring has developed an International Protocol that is easier to perform[50]. 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, 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 British Hypertension Society's device grading criteria (see table below) is 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.[51] The grade is linked to the percentages of readings falling within 5 mm Hg, 10 mm Hg, and 15 mm Hg of the mercury standard. All three percentages must be greater than or equal to the values shown 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.

Validation protocols are completed by the manufacturer or 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.

BRITISH HYPERTENSION SOCIETY GRADING CRITERIA

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

Wan et al.[52] conducted a review of published studies of automatic digital devices. This review included 113 studies from 22 different countries. The devices had been validated against at least one recognized protocol (British Hypertension Society Protocol (BHS), 1993, Association for the Advancement of Medical Instrumentation (AAMI), 2002, or the European Society of Hypertension International (EHS-IP), 2002. Of those validated by the BHS protocol, 25/31 (81%) satisfactorily passed the protocol, 37/41 (90%) devices validated by the AAMI protocol passed the protocol and 34/35 (97%) devices validated by the EHS-IP protocol passed.

It should be noted that the EHS-IP protocol requires 33 test subjects while the BHS and AAMI protocols require 85 subjects[34]. In addition to passing the validation protocol, regular calibration and maintenance are necessary to assure the accuracy of the sphygmomanometer.

h. Cost Considerations

The cost of mercury and aneroid sphygmomanometers are essentially equal with both devices often being manufactured by the same company. Osciloscopic, automatic devices, are more expensive[53].

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.

Requirements for Aneroid Sphygmomanometers

Non-automated non-invasive sphygmomanometers using an aneroid manometer should meet the requirements of ANSI/AAMI/ISO 81060-1:2007[54].

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/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
GENEREAL REQUIREMENTS		
Test requirements	(type tests, samples, environnemental 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
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℃ to 25℃, relative humidity range of 15% to 85% (non-condensing), and decreasing pressure; see compliance test	7.1.1
	≤ ± 3 mmHg (± 0.4 kPa) or 2 % whichever is greater, for the following conditions: temperature range of 10℃ to 40℃, relative humidity range of 15% to 85% (non-condensing), and decreasing pressure; see	

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

Requirements for Automated Sphygmomanometers

Automated non-invasive (medical electrical) sphygmomanometers should meet the requirements of ANSI/AAMI/ISO 81060-2:2009[55] and ANSI/AAMI/EC 80601-2-30:2009[56].

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	201.12.1.103 (see compliance test)
	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	
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 s; 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 a risk management, expected service life, equipment safety, etc. as detailed in section 4 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005[57]	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
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

Parameter	Summary of the Specification	Section
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 in 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 in 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[58]; 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

Summary of requirements in ANSI/AAMI/ISO 81060-2:2009[59]

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[60]; 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

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 the ease of use, requirements for calibration and maintenance of the unit and the time estimates needed to install, calibrate, 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 has cataloged validation reports and provided the results for various models in tabular form.

The British Hypertension Society maintains a web page with devices that have passed their validation tests with prices and other information at 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, of 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 program for both clinical users and maintenance personal. Both the procedures and educational program should be developed in conjunction with personnel who will be using the new devices for maximum effectiveness.

Step 5. Develop a budget for the replacement program 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 the purchase of any supplies needed for maintenance on an ongoing basis.

Step 6. Develop a bid specification for the purchase of the replacement units. Include in the bid specification 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 vendor's aid in planning for the education and continuing education if necessary.

Step 8. Prepare the interim storage site for phased-out mercury 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 the removal and transfer of the mercury-containing units.

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

Step 10. Perform any initial tests or calibration as per 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.

IV. Conclusion

Alternatives to mercury-containing thermometers and sphygmomanometers are available, accurate, and practical in clinical settings. These alternatives should be considered when replacing or phasing out mercury units in healthcare settings. The elimination of mercury, a potent neurotoxin, from these devices protects healthcare 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 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. With these understandings and if phased in as suggested in this document, these devices will provide equivalent accuracy and comparable clinical utility.

References

[1] U.S. Environmental Protection Agency http://www.epa.gov/mercury/about.htm, Accessed 12/2010

[2] U.S. Environmental Protection Agency, http://www.epa.gov/mercury/control_emissions/global.htm. Accessed 12/2010

[3] Health Canada, http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q1-q6_e.html. Accessed 12/2010

[4] Karliner, J. et al. (2008) Mercury Free Health Care, World Medical Journal, 54, No 2, 39-45.

[5] "Treatment Technologies for Mercury in Soil, Waste, and Water," U.S. EPA Office of Superfund Remediation and Technology Innovation, 2007, http://www.epa.gov/tio/download/remed/542r07003.pdf.

[6] Agency for Toxic Substances and Disease Registry web accessed on October 6, 2010 at www.atsdr.cdc.gov/toxprofiles/tp46-c2.pdf

[7] Toxicological Effects of Methylmercury," US National Research Council, 2000, p.4, http://www.nap.edu/catalog.php?record_id=9899#toc

[8] Transande, L. Landrigan,P. Schechter C, Public Health and Economic Consequences of Methyl Mercury Toxicity to the Developing Brain Environ Health Perspect 113:590–596 (2005).

[9] http://www.who.int/water_sanitation_health/medicalwaste/mercury/en/ Accessed 12/2010

[10] Parati G, et al Recommendations for blood pressure measuring devices for office/clinic use in low resource setting. Blood Press Monit. 2005; 10: 3-10.

[11](Parati G etal l A new solar-powered blood pressure measuring device for low-resource settings. Hypertension. 2010 Dec;56(6):1047-53.

[12] 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 UNDP GEF Global Health Care Waste Project, June 2, 2010. http://www.mercuryfreehealthcare.org//Toward_the_Tipping_Point.pdf

[13] The global initiative, a collaboration with Health Care Without Harm is a component of the UNEP Mercury Products Partnership, led by the U.S. Environmental Protection Agendy. See www.mercuryfreehealthcare.org .

[14] World Encyclopedia web www.neworldencyclopedia.org/entry/Thermometer, Accessed 10/2010

[15] Halliday, S, Dr James Currie (1756–1805): Liverpool physician, campaigner, hydrotherapist and man of letters, J Med Biogr, 2006, 14 (1), p. 36.

[16] Sustainable Hospitals Project web accessed on October 14, 2010 at http://www.sustainablehospitals.org/HTMLSrc/IP_Merc_FTNonmerc.html.

[17] Emmanuel, J. "Guidance on Technical Specifications for Non-Mercury Medical Devices," GEF Project on Global Healthcare Waste, United Nations Development Programme, July 2010.

[18]Fadzil, F. M., Choon, D., & Arumugam, K. (2010). A comparative study on the accuracy of noninvasive thermometers. *Australian Family Physician, 39*(4), 237-239.

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

[20] See for example: "Guidance on the Cleanup, Temporary or Intermediate Storage, and Transport of Mercury Waste From Healthcare Facilities," United Nations Development Program, GEF Global Healthcare Waste Project, 2010.

[21]See for example: J.C. Lowe, Thyroid Sci 4(3), CLS1-9 (2009); V. Giantin et al., J Clin Nurs, 17(11), 1518-25 (2008); M.J. Moya Villaescusa, A. Sánchez Pérez and A. Bermejo Fenoll, Med Oral Patol Oral Cir Bucal, 13(6), E385-9 (2008); O.P.

Spitzer, Dimens Crit Care Nurs, 27(1), 24-9 (2008); J.L. Moran et al., Crit Care Med., 35(1), 312-3 (2007); D. C. Crawford, B. Hicks, and M. J. Thompson, J Med Eng & Tech, 30(4) , 199-211 (2006); S.R. Dodd, J Clin Epidemiol, 59(4), 354-7 (2006); H.M. Rosenthal and A. Leslie, J Neonatal Nurs, 12(4), 125-129 (2006); D. Crawford, N. Greene and S. Wentworth, "Thermometer Review: UK Survey 2005," MHRA 04144, Medicines and Healthcare products Regulatory Agency, Department of Health, UK (January 2005); S. Farnell et al., J Clin Nurs, 14(5), 632-9 (2005); L. Khorshid et al., J Clin Nurs, 14(4), 496-500 (2005); I. Sermet-Gaudelus, I. Chadelat and G Lenoir, Arch Pediatr, 12(8), 1292-300 (2005); N. McKenzie, Pediatr Nurs, 29(2), 117-25 (2003); F. Qureshi et al., Pak J Med Sci, 19(2), 111-113 (2003); L.S. Smith, BMC Nurs, 2, 1 (2003); D. Dowding, Prof Nurse, 18(3), 166-8 (2002); S. Macqueen, Br J Nurs, 10(1), 55-8 (2001); B.N. Jensen et al., Acta chirurgica, 166(11), 848-51 (2000); A. Sganga et al., Am J Mat Child Nurs, 25(2), 76-9 (2000); P.C. Valle, O. Kildahl-Andersen, and K. Steinvoll, Tidsskr Nor Laegeforen, 120(1), 15-7 (2000); Y. Amoateng-Adjepong, J. Del Mundo and C.A. Manthous, Chest, 115, 1002-1005 (1999); D. Prentice and J. Moreland, Geriatr Nurs, 20(6):314-7 (1999); M.K. Leick-Rude and L.F. Bloom, Neonatal Netw, 17(5), 21-37 (1998); T. Matsukawa et al., Can J Anaesth, 43(12), 1224-8 (1996); S.T. Zengeya and I. Blumenthal, Euro J Ped, 155(12), 1005-8 (1997); R. Mackenzie and A.J. Ashbury, Brit Journal Anaesth, 72(2), 246-249 (1994); S.P. Davies et al., J Adv Nurs, 11(5), 535 – 543 (1986).

[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, 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] "Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature, ASTM E1965 – 98 (Reapproved 2009).

[28] "Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: Electromagnetic compatibility – Requirements and tests," EN 60601-1.

[29] "Medical Electrical Equipment-Part 1: General Requirements for Safety," European Norm IEC/EN 60601-1.

[30] "Standards for Safety, Medical and Dental Equipment, UL 544, Underwriters Laboratories, Northbrook, IL; Note: 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.

[31] "Medical Electrical Equipment-Part 1: General Requirements for Safety 2, Collateral Standard: Electromagnetic Compatibility-Requirements and Tests," European Norm IEC/EN 60601-1-2.

[32] "Information supplied by the manufacturer of medical devices," European Norm EN 1041, August 2008.

[33] "Symbols for use in the labelling of medical devices," European Norm EN 980, 2008.

[34] "Sampling procedures for inspection by attributes -- Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection," ISO 2859-2:1985.

[35] "Standard Specification for Clinical Thermometer Probe Covers and Sheaths," E1104 – 98 (Reapproved 2009).

[36] 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: "An Investigation of Alternatives to Miniature Batteries Containing

Mercury," C. Galligan and G. Morose, report by the Lowell Center for Sustainable Production for the Maine Department of Environmental Protection, December 17, 2004.]

[37] "Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature, E825 – 98 (Reapproved 2009).

[38] "Clinical thermometers – Part 5: Performance of infra-red ear thermometers (with maximum device)," European Norm EN 12470-5:2003.

[39] "Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature," ASTM E1965 – 98 (Reapproved 2009).

[40] "Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature," *ibid*.

[41] Naqvi, NH and Blaufox, MD Blood Pressure Measurement: An Illustrated History, Parthenon Publishing, New York 1998, P. 5-6 ff.

[42] www.answers.com web accessed on October 6, 2010.

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

[44] Affordable technology: blood pressure measuring devices for low-resource settings. Geneva, World Health Organization, 2005.

[45]"Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives," Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR, 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

[46] Parati G etal l A new solar-powered blood pressure measuring device for low-resource settings. Hypertension. 2010 Dec;56(6):1047-53

[47]"Guidelines for management of hypertension: report of the fourth working party of the British Hypertension Society, 2004—BHS IV," B. Williams et al., Journal of Human Hypertension, 18, 139–185 (2004).

[48] "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," T.G. Pickering et al., AHA Scientific Statement, Hypertension, 45, 142 (2005).

[49] Coleman AJS, Stephen D.; Ashworth, Mark; Vowler, Sarah L.; Shennan, Andrew. Accuracy of the pressure scale of sphygmomanometers in clinical use within primary care. *Blood Press Monit.* 2005; 10(4):181-188.

[50] "Blood pressure measuring devices: recommendations of the European Society of Hypertension," E. O'Brien et al., BMJ, 322, 531-536 (2001).

[51] O'Brien, E. et al. (2002). 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, 7*, 3-17; O'Brien, E. (1993). The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *Journal of Hypertension 11* (suppl. 2): S43-S62.

[52]Wan, Y., Heneghan, C., Stevens, R., McManus, R.J., Ward, A., Perera, R., Thompson, M. (2010). Determining which automatic digital blood pressure device performs adequately: a systematic review. J. of Human Hypertension 24:431-438.

[53] Galligan, C et al (2003) An Investigation of alternative to mercury containing products. Lowell Center for Sustainable Production, University of Massachusetts at Lowell, P. 21.

[54] "Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type," ANSI/AAMI/ISO 81060-1:2007.

[55] "Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type," ANSI/AAMI/ISO 81060-2:2009.

[56] "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.

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

[58] "Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –

Collateral standard: Electromagnetic compatibility – Requirements and tests, IEC 60601-1-2.

[59] "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.

[60] "Clinical investigation of medical devices for human subjects -- Part 1: General requirements," ISO 14155-1:2003.