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GLOBAL ENVIRONMENT FACILITY
INVESTING IN OUR PLANET

GLOBAL HEALTHCARE WASTE PROJECT

MODULE 21: Non-Mercury Alternatives



Module Overview

- List mercury-containing products in healthcare and their alternatives
- Describe different types of non-mercury thermometers and non-mercury sphygmomanometers
- Present standards and specifications for non-mercury devices
- Present methods of validation and/or calibration of non-mercury devices
- Provide additional resources

Learning Objectives

- Identify mercury-containing products in healthcare and their alternatives
- Be aware of the range of alternatives for mercury thermometers and sphygmomanometers
- Know the key specifications for non-mercury devices
- Understand the procedure for validation and/or calibration of non-mercury devices


WHO Policy Paper on Mercury (August 2005)

- Short-term: **Develop mercury clean-up, waste handling and storage procedures**
- Medium-term: **Discourage mercury use in health-care settings**
- Long-term: **Ban use of mercury-containing devices and promote use of mercury-free alternatives**

Examples of Mercury-Containing Products in Health Care

- **Thermometers**
 - Body temperature thermometers, incubator and other equipment thermometers, refrigeration thermometer
- **Sphygmomanometers**
- **Gastrointestinal tubes**
 - Cantor tubes, esophagael dilators, feeding tubes, Miller Abbott tubes
- **Dental amalgam**
- **Lamps**
 - UV germicidal, fluorescent, high-intensity mercury vapor lamps
- **Laboratory chemicals**
 - B5 and Zenkers fixatives, immunoelectrophoresis reagents, stains, thimerosal, some test kits
- **Pharmaceuticals**
 - Solutions with thimerosal or phenylmercuric nitrate, Merbromin, diuretics w/ Hg salts
- **Batteries**
 - In alarms, defibrillators, meters, monitors, etc.
- **Electrical equipment**
 - Tilt mercury switches, float controls, reed relays, old thermostats, analyzers

Some Alternatives to Mercury- Containing Products in Health Care

- | • Product |  | • Alternatives |
|----------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| – Mercury thermometers | | – Digital thermometers, alcohol, galinstan, etc. |
| – Hg-based blood pressure monitoring devices | | – Aneroid, electronic, oscillometric |
| – Esophageal devices, Cantor & Miller-Abbott tubes | | – Tungsten-filled dilators, products w/ tungsten tubing, Anderson AN-20 |
| – Hg dental amalgams | | – Composite resin, porcelain |
| – Hg batteries | | – Lithium, zinc air, alkaline |
| – Lamps & lighting devices | | – LEDs, non-Hg lamps |
| – Hg switches | | – Electronic switches |

About Mercury-Free Alternatives

- Studies show that alternatives can be as accurate as mercury devices
- Mercury-free alternatives must meet existing standards
- Alternatives of unknown quality should be validated before use
- Like mercury sphygmomanometers, aneroid blood pressure devices should be periodically maintained and calibrated

Types of Non-Mercury Thermometers

- Thermistor-based digital thermometers (most common)



- Phase-change (dot matrix) thermometers



- Tympanic infrared thermometers



- Temporal artery infrared thermometers



Types of Non-Mercury Thermometers

- Galinstan-in-glass thermometers (look just like mercury thermometers)
- Alcohol-dye thermometers (used in refrigerators or for weather)
- Thermochromic (cholesteric) liquid crystal thermometers
- Thermocouple and platinum resistance thermometers (can be extremely accurate; used for calibration)



Key Specifications for Non-Mercury Digital Thermometers

1. Accuracy

Maximum Error	Measuring T Range
0.1°C	35.5°C – 42.0°C
0.2°C	Outside T range
Ambient temperature range: 18°C to 28°C	

Maximum Error	Measuring T Range
±0.3°C	<35.8°C
±0.2°C	35.8°C to <37°C
±0.1°C	37°C to 39°C
±0.2°C	>39°C to 41°C
±0.3°C	>41°C
Ambient temperature operating range: 16°C to 40°C at a relative humidity of 15-95% (non-condensing)	

Key Specifications for Non-Mercury Digital Thermometers

Other important specifications:

- Meets accuracy requirement after storage at different temperatures, exposure to a range of humidities, and some degree of mechanical shock
- Readability
- Electrical safety
- Availability of instructions

Key Specifications for Non-Mercury Digital Thermometers

All of the presented specifications and more are defined by two international standards:

EN 12470-3:2000+A1:2009

ASTM E1112-00

The digital thermometer must meet one or both standards.

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p align="right"> Formular für die Erteilung einer
 Zulassung
 (Antrag auf Zulassung eines
 Arzneimittels)
 (Antrag auf Zulassung eines
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 (Antrag auf Zulassung eines
 Arzneimittels) </p> |
| <h2 align="center">Declaration of Conformity</h2> | |
| <p>Manufacturer: Boehringer Ingelheim Technologies GmbH
 Address: Boehringer Ingelheim Pharma KG, Bismarckstr. 11/118, Mannheim, (Germany, Europe)</p> | |
| <p>Product Description: Strongid (Trimethoprim) Oral Suspension (Trimethoprim) Oral Suspension
 Product Name: Strongid (Trimethoprim) Oral Suspension (Trimethoprim) Oral Suspension</p> | |
| <p>Product: Strongid (Trimethoprim) Oral Suspension (Trimethoprim) Oral Suspension</p> | <p>Type of Product: Trimethoprim (Trimethoprim) Oral Suspension (Trimethoprim) Oral Suspension</p> |
| <p>Classification: in UNMOG/WHO, WHO Code: A01AD06 (Trimethoprim) Oral Suspension (Trimethoprim) Oral Suspension</p> | |
| <p>Declaration: I hereby declare that the above information provided is true and correct and that the product is in compliance with the requirements of the EU Directive 609/1986 (EU Directive 609/1986) for medicinal products. All supporting documentation is required under the provisions of the declaration. This declaration is valid under the sole responsibility of the manufacturer.</p> | |
| <p>Signature: Legal Representative of the manufacturer
 Signature: Legal Representative of the manufacturer</p> | |

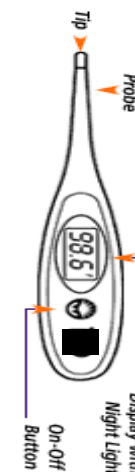
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Key Specifications for Non-Mercury Digital Thermometers

- *Certification* of conformity to international standards IEC/EN 60601 or UL 60601; EN 1041 and EN 980; ATSM E1104
- Optional: ISO 9001 certification of the manufacturing facility; ISO 14000 certification of the manufacturer
- ISO 13485 or ISO 13488 certification of manufacturer
- Approval by the competent regulatory authority of the country if applicable

Optional Specifications for Digital Thermometers

- Rapid response time: 10 seconds or less
- Extra large display
- Audible alarm when peak temperature is reached
- Display of self-check results during start-up
- Automatic shut-off
- Memory functions
- Mercury-free or “no added mercury” battery
- Easily replaceable battery or rechargeable battery
- Long battery life: e.g., 4000 temperature readings
- If solar-powered, up to 72 hours per solar charge



Optional Specifications for Non-Mercury Digital Thermometers

- Flexible probe tip
- Dual scale (both °C and °F)
- Disposable sterile probe covers or sheaths
- Removal of probe covers: manual or eject button
- Customized colors
- At least one year warranty
- Resistant to specific disinfectants and cleaners
- Minimum packaging waste
- Ergonomic design



Key Specifications for Non-Mercury Phase-Change Thermometers

- Compliance with the Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature

ASTM E825-98 (2009) – disposable

ASTM E1299-96 (2010) - reusable

EN 12470-2:2000



Key Specifications for Non-Mercury IR Tympanic Thermometers

- Standard Specification for Infrared Ear Thermometers

EN 12470-5:2003

ASTM E1965-98 (2009)



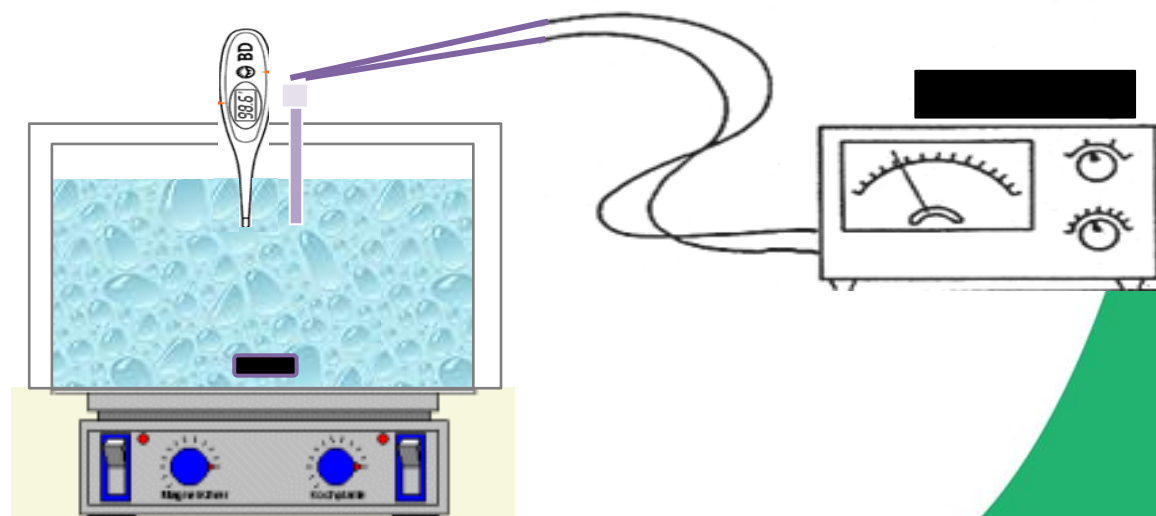
Available Resources

- Examples
 - If the non-mercury thermometer is sold in the UK: Medicines and Healthcare Products Regulatory Agency (UK) report MHRA 04144 (Thermometer Review), January 2005
 - If the non-mercury thermometer is sold in the US: Request the 510(k) number from the manufacturer and confirm their clearance by checking the database of the US Food and Drug Administration (FDA) of devices given 510(k) clearance and approval

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/default.htm>

Validation Testing of Thermometer Accuracy

- Constant temperature bath with reference thermometer
 - Large glass flask (>100 times the volume of the thermometer) with insulation (5-7 cm), top cover, and continuous magnetic stirring
 - Distilled water with reference and test thermometers near each other
 - Measure two or more points between the working range
 - Conduct test three times to check repeatability



Validation Testing of Thermometer Accuracy

- What reference thermometer to use?
 - Reference thermometer traceable through an unbroken chain of comparisons to a national or international standard body
 - Common reference used:
Platinum resistance thermometer
- Results of Leick-Rude & Bloom study:
25% of the mercury thermometers tested were off by $>0.2^{\circ}\text{C}$



Source: MK Leick-Rude and Bloom LF, *Neonatal Network*; Volume 17 No. 5, 21-37 (1998)

Types of Non-Mercury Sphygmomanometers

- Mechanical dial aneroid sphygmomanometer (most common)
- Digital display aneroid sphygmomanometer (common)
- Electronic oscillometric sphygmomanometer
- Doppler-based plethysmographic blood pressure monitor
- Photocell-based blood pressure monitor
- Strain gauge-based blood pressure monitor



Key Specifications for Aneroid Sphygmomanometers

1. Accuracy, range, air leakage, deflation rate, rapid exhaust

Maximum error of the cuff pressure measurement	± 0.4 kPa for the T range of 15°- 25°C, relative humidity of 15% to 85% and decreasing pressure
	± 0.4 kPa or 2 % whichever is greater, for the T range of 10°-40°C, relative humidity range of 15% to 85% and decreasing pressure
Nominal range and measuring range	0 kPa to at least 35 kPa (260 mmHg)
Air leakage	No pressure drop exceeding 0.5 kPa/min
Pressure reduction (deflation) rate	Adjustable to a rate of 0.3 to 0.4 kPa/s
Rapid exhaust	Not exceeding 10 seconds from 35 to 2 kPa (260 mmHg to 15 mmHg)

Key Specifications for Aneroid Sphygmomanometers

2. Proper markings
3. Mechanical strength: Should function properly after falling 25 cm (or 1 m for “shock resistant” devices)
4. Parts in contact with the patient should be capable of being disinfected
5. Instructions for use; cleaning and disinfection; routine maintenance, inspection and preventive maintenance should be provided

Key Specifications for Aneroid Sphygmomanometers

All of the presented specifications and more are defined by:

ANSI/AAMI/ISO 81060-1:2007

The aneroid sphygmomanometer should meet the above standard.



Key Recommended Practices for Aneroid Sphygmomanometers

British Hypertension Society (BHS):

The protocol for *both* mercury and non-mercury devices include:

- ✓ proper maintenance, calibration, and validation;
- ✓ using a cuff of the appropriate size;
- ✓ reading blood pressure to the nearest 2 mmHg, taking the mean of at least two readings.



Validating Aneroid Sphygmomanometers

British Hypertension Society (BHS) Grading Criteria:

Grade	Absolute difference between standard and test device		
	$\leq 5\%$	$\leq 10\%$	$\leq 5\%$
A	60	85	95
B	50	75	90
C	40	65	85
D	worse than C		

Lists of Validated Non-Mercury Sphygmomanometers

Available lists of recommended aneroids, automated blood pressure devices for clinical use in hospitals, oscillatory automated blood pressure devices, etc. that have been validated using the AAMI and BHS protocols:

“Blood pressure measuring devices: recommendations of the European Society of Hypertension,” E. O’Brien et al., BMJ, 322, 531-536 (2001).

Lists of Evaluated Non-Hg Sphygmomanometers

- “Mercury-free blood pressure measurement equipment- Experience in the Swedish health sector,” PM Nr 7/05, Swedish Chemicals Inspectorate, Sundbyberg, November 2005
- BHS Approved Non-Mercury Sphygmomanometers – in the Health Care Without Harm website
- Recommended Non-Mercury Sphygmomanometers based on BHS and AAMI protocols: **dabl[®]Educational Trust** website

Validation of Sphygmomanometers

- The European Society of Hypertension has developed an international protocol for validating blood pressure measuring devices in adults
- The 2010 revision of the International Protocol can be found in:

E. O'Brien et al., *Blood Pressure Monitoring*, 15: 23-38 (2010)

Is the Mercury Sphygmomanometer the “Gold Standard”?

- Knight et al. study (2001): Out of 356 mercury sphygmomanometers studied
 - 69% had no service records, NONE met all the relevant quality standards, 4% met less than half the standards, and only 2/3rd were accurate at all pressure levels
- Study by Markandu et al. (2000) of 469 mercury sphygmomanometers
 - 38% had dirty mercury columns, 21% had columns at the wrong angle, 1% had leaking mercury, 38% had tubing problems, 26% had dirty or damaged cuffs, and most staff were not aware of the need for regular maintenance

Calibration of Aneroid Sphygmomanometers



Typical Accuracy of
Mercury Standard:
 ± 3 mmHg



Typical Accuracies of Electronic
Pressure Standards:
 ± 0.1 to ± 1 mmHg

Examples of Sphygmomanometer Calibration Set-Ups



NOTE: Follow
manufacturer's
instructions for calibration
set-up.

Typical Calibration Procedures for Non-Hg Sphygmomanometers

1. Check to make sure the pointer of the aneroid dial is pointed to zero or that the digital display shows zero when no pressure is applied. If the pointer or display is not at zero, follow the manufacturer's instructions to set the zero point. (Some aneroid units have an adjustment screw to set zero. Digital units may have a button to set zero.)
2. Connect a bulb to the bottom of a Y tubing.
3. Connect one side arm of the Y tubing to the aneroid dial or to the digital meter of the sphygmomanometer being calibrated.
4. Connect the other side arm of the Y tubing to a reference manometer. (Note: For some aneroid units, it may be necessary to also attach a 500 cc volume.)

Typical Calibration Procedures for Non-Hg Sphygmomanometers

5. Squeeze the bulb to pressurize the gauge or digital meter to about 280 mmHg and close the valve. Observe if the pressure is stable (± 2 mmHg). If not, check the calibration set-up for air leaks.
6. If the pressure is stable, increase the pressure to slightly above 300 mmHg and bleed down the pressure no faster than 10 mmHg per second.
7. Stop at 300, 250, 200, 150, 100, 60, and 0 mmHg based on readings of the reference manometer. Record the readings of the sphygmomanometer being tested and of the reference manometer at each pressure.
8. Calculate the difference between the two readings. Add the error of the reference manometer to the error of the sphygmomanometer being tested to determine the accuracy of the sphygmomanometer.

Typical Calibration Procedures for Non-Hg Sphygmomanometers

9. If the errors are $\leq \pm 3$ mmHg, the sphygmomanometer is within the required accuracy.
10. If the errors are $> \pm 3$ mmHg, determine if the errors are linear (readings deviate by about the same amount) or non-linear (readings deviate by different amounts).

Idealized example of linear error

Sphygmomanometer reading	Reference pressure	Difference
295	300	-5
245	250	-5
195	200	-5
145	150	-5
95	100	-5
55	60	-5

Idealized example of non-linear error

Sphygmomanometer reading	Reference pressure	Difference
290	300	-10
245	250	-5
200	200	0
155	150	+5
110	100	+10
80	60	+20

Typical Calibration Procedures for Non-Hg Sphygmomanometers

11. Follow the manufacturer's instructions to re-calibrate the instrument.
 - For aneroid dials, this may entail the following: removing the retaining ring and glass from the gauge; carefully removing the needle and dial face to reveal the bellows; locating the concave triangle with a pin at its center; and moving the pin toward the sides of the triangle, right or left, to fix a linear error; or moving the pin linearly within the triangle, up or down, to fix a non-linear error (very small adjustments have to be made); and replacing the dial face, needle, glass and retaining ring,
 - For digital units, re-calibration may entail adjusting pressure readings by moving plungers or rotating screws according to manufacturer's instructions.
12. Repeat the test above to ensure that the accuracy is at or within ± 3 mmHg. If not, repeat the re-calibration adjustments until the required accuracy is achieved.

Typical Maintenance of Aneroid Sphygmomanometers

- Aneroid gauges should be tested and calibrated at least every 6 months or more frequently if the device is dropped (some manufacturers suggest every 2 years but a more frequent calibration test is recommended)
- Check for any leaks in the cuff, tubing or inflation bulb
- Check that the gauge reading returns to zero when deflated; if not, adjust zero following the manufacturer's instructions
- Clean and disinfect the device at least every 6 months following the manufacturer's instructions
- Make sure the device is fully deflated and stored in its case when not in use

Summary

- For digital thermometers: specify compliance with **EN 12470-3:2000+A1:2009** and/or **ASTM E1112-00**
- For color-changing dot matrix thermometers, specify compliance with **ASTM E825-98 (2009)**, **ASTM E1299-96** and **EN 12470-2**
- For infrared ear thermometers, specify compliance with **EN 12470-5** and **ASTM E1965-98**
- Confirm compliance by checking databases of MHRA, FDA, and other government regulatory agencies. If necessary, validate with a reference thermometer (e.g., platinum resistance thermometer)
- For aneroid sphygmomanometers, specify compliance with **ANSI/AAMI/ISO 81060-1:2007**
- Refer to validation test results and recommendations by BHS, Swedish Inspectorate, dabl Trust, etc.

UNDP GEF Guidance Document

- GUIDANCE ON TECHNICAL SPECIFICATIONS FOR NON-MERCURY MEDICAL DEVICES

Available from: www.gefmedwaste.org

Discussion

- What mercury-containing materials can be found in your facility?
- Are non-mercury alternatives available?
- How would you incorporate the international standards in the procurement specifications? What are the barriers to eliminating mercury –containing materials? How can we overcome these barriers?
- How would you set up a system for validation and periodic calibration in your facility?