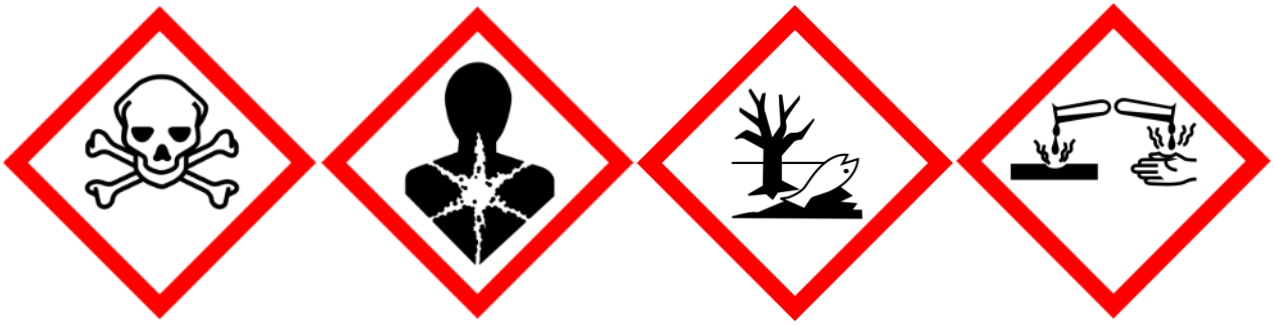

# Recommendations on the replacement of mercury containing medical devices

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## List of Abbreviations

| | |
|---|---|
| BAT | Best Available Technology |
| BREF | Best Available Technology Reference |
| ESM | Environmentally Sound Management |
| HCW | Healthcare Waste |
| HCWM | Healthcare Waste Management |
| IPPC | Integrated Pollution Prevention and Control |
| MoH | Ministry of Health |
| IEC | Information, Education, Communication |
| NGO | Non-Governmental Organization |
| PPE | Personal Protection Equipment |
| WHO | World Health Organization |
| WI | Waste Incineration |

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# 1 Scope

The purpose of this recommendation is to provide guidance on the replacement of mercury containing medical devices with mercury-free once according to WHO technical specification and the recommendations by the Basel Convention. The protection of human health is at the core of the Minamata Convention, whose objective (Article 1) “is to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds”.

Actions addressed in this program specifically relate to health sector obligations under Article 4 of the Convention which addresses mercury added products. Mercury containing measuring devices, including thermometers and sphygmomanometers, are among the list of items whose manufacture, import and export must cease by 2020.

To support the introduction of mercury free thermometers and sphygmomanometers, a product replacement program for mercury containing medical devices will be carried out at the model hospitals, and extended to include other health facilities in selected regions. For the procurement technical specification which were developed by WHO[1] and are based on the EN 12470-3:2000 (Clinical thermometers) and other standards will be used for the selection and purchasing of durable non-mercury thermometers and sphygmomanometers. The management and the disposal of the outdated mercury thermometers and sphygmomanometers will be carried out in accordance with the technical guidance provided by the Basel Convention on wastes containing mercury[2].

[1] Replacement of mercury thermometers and sphygmomanometers in health care. Technical guidance, WHO, 2011.
[2] Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and wastes containing or contaminated with mercury. Revised final version (31 October 2011), UNEP

# 2 Legal Background

Relevant international conventions for the replacement of mercury containing thermometers include especially the Minamata Convention, the Basel Convention and the Rotterdam Convention.

Table 1: Status of ratification of international Conventions

| Name of Convention | Status of ratification of countries |
|---|---|
| Basel Convention: Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and wastes containing or contaminated with mercury (UNEP 2011) | http://www.basel.int/Countries/StatusofRatifications/PartiesSignatories/tabid/1290/Default.aspx |
| Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade | http://www.pic.int/Countries/Statusofratifications/tabid/1072/language/en-US/Default.aspx |
| Minamata Convention on mercury (UNEP 2013) | http://www.mercuryconvention.org/Countries/tabid/3428/Default.aspx |

For the replacement of mercury containing medical devices in accordance with ***the Minamata Convention*** the applicable requirements would be:

*Article 3: Mercury supply sources and trade*

6. Each Party shall not allow the export of mercury except:
   a) To a Party that has provided the exporting Party with its written consent, and only for the purpose of:
      (i) A use allowed to the importing Party under this Convention; or
      (ii) Environmentally sound interim storage as set out in Article 10; or
   b) To a non-Party that has provided the exporting Party with its written consent, including certification demonstrating that:
      (i) The non-Party has measures in place to ensure the protection of human health and the environment and to ensure its compliance with the provisions of Articles 10 and 11; and
      (ii) Such mercury will be used only for a use allowed to a Party under this Convention or for environmentally sound interim storage as set out in Article 10.

*Article 4: Mercury-added products*

Mercury-containing measuring devices, including thermometers and sphygmomanometers, are among the items listed whose manufacture, import and export must cease by 2020, except where exemptions apply. (see Annex A)

**Article 11: Mercury wastes**

1. The relevant definitions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal shall apply to wastes covered under this Convention for Parties to the Basel Convention. Parties to this Convention that are not Parties to the Basel Convention shall use those definitions as guidance as applied to wastes covered under this Convention.

2. For the purposes of this Convention, mercury wastes means substances or objects:

   (a) Consisting of mercury or mercury compounds;
   (b) Containing mercury or mercury compounds; or
   (c) Contaminated with mercury or mercury compounds,

in a quantity above the relevant thresholds defined by the Conference of the Parties, in collaboration with the relevant bodies of the Basel Convention in a harmonized manner, that are disposed of or are intended to be disposed of or are required to be disposed of by the provisions of national law or this Convention. This definition excludes overburden, waste rock and tailings from mining, except from primary mercury mining, unless they contain mercury or mercury compounds above thresholds defined by the Conference of the Parties.

3. Each Party shall take appropriate measures so that mercury waste is:

(a) Managed in an environmentally sound manner, taking into account the guidelines developed under the Basel Convention and in accordance with requirements that the Conference of the Parties shall adopt in an additional annex in accordance with Article 27. In developing requirements, the Conference of the Parties shall take into account Parties' waste management regulations and programmes;
(b) Only recovered, recycled, reclaimed or directly re-used for a use allowed to a Party under this Convention or for environmentally sound disposal pursuant to paragraph 3 (a);
(c) For Parties to the Basel Convention, not transported across international boundaries except for the purpose of environmentally sound disposal in conformity with this Article and with that Convention. In circumstances where the Basel Convention does not apply to transport across international boundaries, a Party shall allow such transport only after taking into account relevant international rules, standards, and guidelines.

4. The Conference of the Parties shall seek to cooperate closely with the relevant bodies of the Basel Convention in the review and update, as appropriate, of the guidelines referred to in paragraph 3 (a).

5. Parties are encouraged to cooperate with each other and with relevant intergovernmental organizations and other entities, as appropriate, to develop and maintain global, regional and national capacity for the management of mercury wastes in an environmentally sound manner.

In relation to health, the Convention includes an article dedicated to health aspects (Article 16), which specifically calls for the development and implementation of strategies and programmes to protect populations at risks from exposure to mercury and mercury compounds, including through the establishment of national guidelines and through health promotion and health education activities. This article also calls for the provision of preventive and curative services for persons affected by mercury exposure and for the strengthening of health sector capacities for addressing mercury related health issues.

***The Basel Convention***

requires rom each party in paragraph 2 (b) of Article 4 to take the appropriate measures to "ensure the availability of adequate disposal facilities for the environmentally sound management of hazardous or other wastes, that shall be located, to the extent possible, within it, whatever the place of their disposal", In paragraph 8 of Article 4, the Convention requires that "hazardous wastes or other wastes, to be exported, are managed in an environmentally sound manner in the State of import or elsewhere.

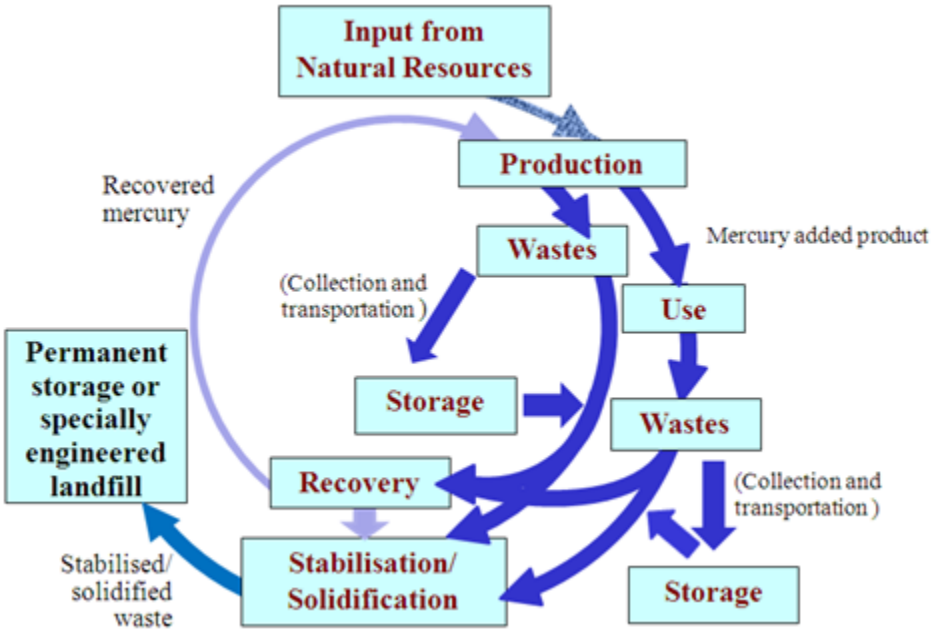
The Basel Convention listed mercury in the Annex I as hazardous waste

| Entries with direct reference to mercury | |
|---|---|
| Y29 | Wastes having as constituents:<br>***Mercury***; ***mercury compounds*** |

The general requirements from the "Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and wastes containing or contaminated

with mercury (UNEP 2011)" – Minamata Convention, Article 11, § 3a – are to Minimize mercury release at each stage. The following graphic display the general principles:

Figure 1: Basic concept of mercury management (UNEP, TG Mercury, 2011)



# 3 Strategy development - phase-out mercury containing medical devices

For the carrying out of the phasing out of the mercury containing devices, a seven step strategy was developed in line with the requirements of the Minamata convention and the Basel Convention.

Figure 2: 7 steps for the mercury elimination program


**Step 1: Stakeholder engagement strategy**

Prior the start of the procurement process for non-mercury containing medical devices, the stakeholders will be informed by a participatory process about the planned activities. During the process the relevant details about each stakeholder group's respective roles, interests and potential influence over the process will be identified. Also the details about which kinds of participatory instruments and processes will be used at which point in the process to facilitate and ensure adequate stakeholder involvement will be clarified.

**Step 2: Situation assessment and inventory**

For the project, a pre assessment on mercury thermometers was already carried out. The numbers of medical devices that require replacement are identified and by this the volume of waste material to be collected, stored and disposed can be defined.

**Step 3: Strategy and program development**

To allow the safe replacement of the mercury containing devices, a clear strategy is developed which includes specific intervention packages and supporting activities which are defined and agreed by all partners/stakeholders. The roles and responsibilities for the delivery of the above is articulated and agreed, time-bound targets and measurable indicators will be fixed. This will include a monitoring framework to facilitate reporting on delivery of interventions and any unforeseen or unexpected issues.

**Step 4: Collection, transportation, storage**

For the replacement of mercury containing medical devices an exchange system is foreseen. Existing mercury containing medical devices will be exchanged against digital once. The collected mercury containing medical devices may be stored for a short period of time, before transport to centralized facilities or directly to treatment facilities, at the hospitals. It is suggested to undertake such storage in a secure outdoor location, if possible, to prevent exposures to mercury that may be released from mercury devices that are broken during handling.

The collected mercury thermometers will be packed and transported to central storage places or treatment plants pending disposal. For the transportation of the mercury waste the local transport requirements or the requirements as mentioned in the UN Model Regulations on the Transport of Dangerous Goods (orange book) will be obtained. Criteria for siting and design of storage facilities include, among others:

- Not built in sensitive locations (floodplains, earthquake zones etc.), unless technical and legal conditions are sufficient to ensure the ESM of facilities in the area in question
- Floors covered with mercury-resistant material
- Constant, low temperature
- Storage area clearly marked with warning signs
- Not to store mercury waste in inappropriate containers (e.g. made from aluminium)

For final disposal, export of the treated waste might be required. For transboundary movement and transport of hazardous wastes, the following documents will be consulted to determine specific requirements:

(a) Basel Convention: Manual for the Implementation of the Basel Convention (SBC 1995a);
(b) UN Model Regulations: UN Recommendations on the Transport of Dangerous Goods - Model Regulations
(c) International Civil Aviation Organization (ICAO): Technical Instructions for the Transport of Dangerous Goods by Air;
(d) International Air Transport Association (IATA): Dangerous Goods Regulations Manual

**Step 5: Recovery / Recycling**

Mercury containing medical devices are considered as Elemental Mercury-containing wastes. Recommended treatment is extraction (physical-chemical treatment) to extract and purify the mercury contained in the waste for re-use or disposal operations and to decontaminate the remaining waste to recover the components (glass) or to make it eligible for disposal operations. The recovered mercury will only be used for the purposes allowed under the Minamata Convention and national law.

The mercury containing medical devices will be collected without any breakage. After collection of the elemental mercury-containing wastes, elemental mercury in the products will be extracted, and the extracted elemental mercury is distilled for purification under reduced pressure.

For the extraction vacuum thermal processing will be used. The process includes the following stages:

(a) Heating the input material in a special kiln or in a charging operation to evaporate the mercury contained in the waste at temperatures of between 340°C and 650°C and pressures of a few millibars;
(b) Collecting and cooling of mercury containing vapour;

(c) Distillation to generate pure liquid mercury.

**Step 6: Disposal operations**

As the recovered mercury from the mercury containing medical devices cannot be destroyed, alternative solutions will be used. Disposal operations, i.e. those operations which do not lead to the possibility of resource recovery, recycling, reclamation, direct re-use of alternative uses, available for mercury wastes include physico-chemical treatment, disposal in specially engineered landfills and permanent storage in underground facilities.

**Sulphur stabilization of elemental mercury**

Sulphur and elemental mercury are mixed under heat in a vacuum mixer, thus reacting to form mercury sulphide.

Reported characteristics of the final product:

- Product is a powder with no detectable releases of mercury vapour
- Complies with applicable leaching standard
- Weight increases by approximately 16%, volume approximately 6-fold

Photo 1: Commercial stabilization plant (*courtesy: NQR Nordische Quecksilber Rückgewinnung GmbH*)

**Step 7: Monitoring and reporting**

Throughout the logistics chain a monitoring system will be applied to ensure the traceability of mercury wastes. This will help to ensure that they are not diverted for illegitimate uses or inadequately disposed.

Traceability will consist out of a set of actions, measures and procedures to identify and record every activity of hazardous waste management during the program from generation to disposal. The generated mercury wastes will be traceable throughout the lifecycle, including after disposal. Traceability will apply to all relevant actors upstream (e.g. waste generators) and downstream (e.g. transporters, recyclers, disposers). All information on the characteristics and quantity of the mercury and mercury waste in question as well as the risks associated with its management will be available to the relevant authorities at all times. Detailed reports and tracking records from dealers, transporters, recyclers, disposers and others involved will be requested.

| At the entrance, for each delivery | At the exist, for each shipment departure |
|---|---|
| Identification of the shipment (including notification identification (ID) in case of export) | Identification of the shipment (including notification ID in case of export) |
| Date of delivery | Date of departure |
| Person in charge of the transport | Person in charge of the transport |
| Person in charge of the transfer (import/export) | Person in charge of the transfer (import/export) |
| Previous holder and origin | Next holder and description of the destination/purpose |
| Description of waste (with relevant identification code, if applicable)/quality of commodity mercury | Description of waste (with relevant identification code, if applicable)/quality of commodity mercury |
| Quantity of the mercury waste/commodity mercury | Quantity of the mercury waste/commodity mercury |
| Quantity of mercury in the waste | Quantity of mercury in the waste |
| Location of the storage in the facility | List of the ID of all the flasks for commodity mercury |
| | Estimated date of arrival at the destination |

In case of transboundary movements of mercury waste, where appropriate, the Basel Convention requirements shall apply for the Parties to the Basel Convention.

# 4 Annex

## 4.1 Annex 1: Recommended technical specifications for non-mercury containing medical devices

### 4.1.1 HGF-01-02 Mercury free automatic spygmomanometer

| Item: | | Photo / Drawing / Graphic |
|---|---|---|
| Automated non-invasive (medical electrical) sphygmomanometer<br>*Code: HGF-01-02* | |  |
| **Technical Data:** | **(Main)** | |
| Unit of measurement | mmHg | |
| Maximum error | ≤ ±3 mmHg (±0.4 kPa) or 2% of the reading, whichever is greater | |
| Cleaning, disinfection | Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected | |
| **Application:** | | |
| To measure patient blood pressure, for clinical use | | |

**Further relevant information:**
Should meet the requirements of ANSI/AAMI/ISO 81060-2:2009 and ANSI/AAMI/EC 80601-2-30:2009.

**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
- Nominal blood pressure indication range:
  - Diastolic blood pressure: at least 20 mmHg (2.7 kPa) to 60 mmHg (8.0 kPa) in neonatal mode and 40 mmHg (5.3 kPa) to 130 mmHg (17.3 kPa) otherwise
  - Systolic blood pressure: at least 40 mmHg (5.3 kPa) to 110 mmHg (14.7 kPa) in neonatal mode and 60 mmHg (8.0 kPa) to 230 mmHg (30.7 kPa) otherwise
- Maximum pressure in normal condition: <150 mmHg (20 kPa) in neonatal mode and <300 mmHg (40 kPa) otherwise
- Maximum pressure in single fault condition: Should not exceed +10 % of the maximum rated pressure for more than 3 seconds
- Manometer test mode: The device should have a test mode that can be used to verify calibration
- Laboratory limits of the change in error of the blood pressure determination: Less than 3 mmHg (0.4 kPa);
- Warranty period: 12 months from the date of putting into operation

- Operation manual must be available in English and French language
- ISO 9001 is required

**Various other requirements**

- General requirements : Requirements include performing risk management, expected service life, equipment safety, etc., as detailed in section 4 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005
- 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
- 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
- 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
- Protection from hazards and fault conditions: Requirements to protect against electrical and mechanical hazards of the device, excessive temperatures, interruption of power supply, etc., as detailed in sections 201.8 to 201.11, section 201.13, and sections 8 to 11 and 13 of IEC 60601- 1:2005 or ANSI/AAMI ES60601-1:2005
- Programmable devices: Requirements related to programmable electrical devices, as detailed in section 14 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005
- Construction: Requirements related to serviceability, mechanical strength, shock and vibration, etc., including compliance tests, as detailed in section 201.15 and section 15 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005
- 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
- Electromagnetic compatibility: Requirements involve a risk management process, detailed in section 17 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005; should conform to IEC 60601-1-2 (27); test method in section 202
- Cuff, tubing, cuff connectors: Requirements involving construction and pressurization
- Unauthorized access: Should prevent tampering with, or unauthorized access to, controls that affect accuracy
- Maximum inflating time: Requirements related to a pressure-relief protection device
- Automatic cycling modes: Requirements related to a protection device for long-term and short-term automatic mode, if applicable

**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
- Validation with an auscultatory reference sphygmomanometer: Minimum of 85 subjects with three valid blood pressure determinations for each
- Validation with reference invasive blood pressure monitoring equipment: clinical validation studies should comply with ISO 14155 (49); validation with reference invasive blood pressure monitoring equipment should not be used for patients or subjects solely for the purpose of validating sphygmomanometer performance
- Validation for pregnant patients: A sphygmomanometer for use in pregnant, including pre-eclamptic, patients should be clinically evaluated in that patient population

### 4.1.2 HGF-01-03 Mercury Free Digital Blood Pressure Monitor

| Item: | | Photo / Drawing / Graphic |
|---|---|---|
| Mercury Free Digital Blood Pressure Monitor (automated non-invasive blood pressure -NIBP)<br>*Code: HGF-01-03* | |  |
| **Technical Data:** | **(Main)** | |
| Unit of measurement | mmHg | |
| Maximum error | ≤ ±3 mmHg (±0.4 kPa) or 2% of the reading, whichever is greater | |
| Pulse rate | ≤ ±5% of reading | |
| Cleaning, disinfection | Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected | |
| **Application:** | | |
| To monitor patient blood pressure and pulse, for clinical use, validated | | |

**Further relevant information:**
Should meet the requirements of ANSI/AAMI/ISO 81060-2:2009 and ANSI/AAMI/EC 80601-2-30:2009.

Must include: Blood Pressure Monitor, Cuffs (different size), BladderSet, >1m Air Tube, AC Adapter, Battery Pack

Display: Digital display
Measurement: Oscillometric method
Measurement Range:

- Pressure: 0 to 299 mmHg
- Pulse rate: 30 to199 beats/min

Inflation: Automatic inflation with pumping
Deflation: Automatic deflation by electromagnetic control valve
Air Release: Automatic rapid air release by electromagnetic control valve
Pressure Detection: Electrostatic capacity semi-conductor pressure sensor
Power supply: AC adapter(120VAC,60Hz,13VA)or (120VAC,50/60Hz,0.2A)Batterypack(4.8VDC,6W)
Electric Shock Protection Method: Class IIB type
Operating Temperature: 10 to 40°C
Humidity: 30 to 85% RH

**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
- Nominal blood pressure indication range:
    - Diastolic blood pressure: at least 20 mmHg (2.7 kPa) to 60 mmHg (8.0 kPa) in neonatal mode and 40 mmHg (5.3 kPa) to 130 mmHg (17.3 kPa) otherwise
    - Systolic blood pressure: at least 40 mmHg (5.3 kPa) to 110 mmHg (14.7 kPa) in neonatal mode and 60 mmHg (8.0 kPa) to 230 mmHg (30.7 kPa) otherwise
- Maximum pressure in normal condition: <150 mmHg (20 kPa) in neonatal mode and <300 mmHg (40 kPa) otherwise
- Maximum pressure in single fault condition: Should not exceed +10 % of the maximum rated pressure for more than 3 seconds
- Manometer test mode: The device should have a test mode that can be used to verify calibration
- Laboratory limits of the change in error of the blood pressure determination: Less than 3 mmHg (0.4 kPa);
- Warranty period: 12 months from the date of putting into operation
- Operation manual must be available in English and French language
- ISO 9001 is required

**Various other requirements**

- General requirements : Requirements include performing risk management, expected service life, equipment safety, etc., as detailed in section 4 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005
- 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
- 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
- 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
- Protection from hazards and fault conditions: Requirements to protect against electrical and mechanical hazards of the device, excessive temperatures, interruption of power supply, etc., as detailed in sections 201.8 to 201.11, section 201.13, and sections 8 to 11 and 13 of IEC 60601- 1:2005 or ANSI/AAMI ES60601-1:2005
- Programmable devices: Requirements related to programmable electrical devices, as detailed in section 14 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005
- Construction: Requirements related to serviceability, mechanical strength, shock and vibration, etc., including compliance tests, as detailed in section 201.15 and section 15 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005
- 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
- Electromagnetic compatibility: Requirements involve a risk management process, detailed in section 17 of IEC 60601-1:2005 or ANSI/AAMI ES60601-1:2005; should conform to IEC 60601-1-2 (27); test method in section 202
- Cuff, tubing, cuff connectors: Requirements involving construction and pressurization
- Unauthorized access: Should prevent tampering with, or unauthorized access to, controls that affect accuracy
- Maximum inflating time: Requirements related to a pressure-relief protection device

- Automatic cycling modes: Requirements related to a protection device for long-term and short-term automatic mode, if applicable

**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
- Validation with an auscultatory reference sphygmomanometer: Minimum of 85 subjects with three valid blood pressure determinations for each
- Validation with reference invasive blood pressure monitoring equipment: clinical validation studies should comply with ISO 14155 (49); validation with reference invasive blood pressure monitoring equipment should not be used for patients or subjects solely for the purpose of validating sphygmomanometer performance
- Validation for pregnant patients: A sphygmomanometer for use in pregnant, including pre-eclamptic, patients should be clinically evaluated in that patient population

### 4.1.3 HGF-02-01 Mercury free digital thermometer

| Item: | | Photo / Drawing / Graphic |
|---|---|---|
| Digital Clinical Thermometer<br>*Code: HGF-01-03* | |  |
| **Technical Data:** | **(Main)** | |
| Temp. Range:<br>Resolution:<br>Accuracy:<br>Battery Life:<br>Ambient Temperature | <35.0 - >41.0 ˚C<br>0.1 ˚C or less<br>+/- 0.1˚C<br>>200 hours<br>10-35˚C | |
| **Application:** | | |
| Medical device, for the measurement of patient temperature, for clinical use<br><br>Fulfils the requirements of the EN 12470. Device should be tested in accordance of the method described in the EN 12470-3:2000 | | |

**Further Relevant information:**

**A DESCRIPTION OF REQUIREMENTS**

1 The maximum permissible error over the specified temperature range measuring temperature range must be not more than 0.1˚C in the temperature range 35.5–42.0 ˚C at an ambient temperature range of 18–28 ˚C and not more than 0.2 ˚C outside the measuring range or ambient temperature range

2 The minimum measuring range must be 35.5–40.0 ˚C, preferred range will be <35.0 - >41.0 ˚C

3 The resolution (digital increment) shall be 0.1 ˚C or less

4 The ambient temperature operating range shall be 10–35 ˚C

5 The device should give a visual or auditory warning when the measured temperature is not within the specified measuring range

6 The time respond should be not more than 60 seconds under the conditions as mentioned in the EN 12470

7 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

8 The device should meet the EN accuracy requirement after exposure to either 55 ˚C or 80 ˚C for a specified number of days as mentioned in the EN 12470.

9 Numerals should appear at least 4 mm high

10 The device should meet the EN accuracy requirement after being exposed to five cycles of 0 ˚C and 55 ˚C for an hour each

11 The device should meet the EN accuracy requirement after being exposed to a temperature of 45 ˚C and a relative humidity of 85% for 48 hours

12 The device should meet the EN accuracy requirement after being dropped onto a hard surface from a height of 1 metre

13 The device should meet the EN accuracy requirement after being immersed in water for 30 minutes

14 The energy dissipated by the probe should not cause a temperature rise in the indicated temperature of more than 0.01 ˚C

**15** For electrical safety the device should comply with EN 60601-1
**16** For electromagnetic compatibility the device should conform to EN 60601-1-2
**17** The device should provide a visual or auditory warning when the supply voltage is not within specified limits
**18** For mechanical safety the device should not have sharp ends or angles, and the probe should be smoothly rounded to prevent injuries to the user or patient
**19** The device should be free from biological hazards
**20** The device should have a self testing routine
**21** Information from the manufacturer should comply with EN 1041
**22** 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.
**25** Warranty period: 12 months from the date of putting into operation
**26** Operation manual must be available in English and French language
**27** ISO 9001 is required

# 5 HGF-02-02 Professional Infrared Non-Contact Thermometer

| Item: | | Photo / Drawing / Graphic |
|---|---|---|
| Infrared Non-Contact Thermometer<br>*Code: HGF-02-02* | |  |
| **Technical Data:** | **(Main)** | |
| Temp. Range:<br>Resolution:<br>Accuracy:<br>Battery Life:<br>Ambient Temperature | <35.0 - >41.0 ˚C<br>0.1 ˚C or less<br>+/ 0.2˚C<br>>200 hours<br>10-35˚C | |
| **Application:** | | |
| Medical device, for the measurement of patient temperature, for clinical use<br><br>Must be CE marked or FDA approved.<br><br>Clinically calibrated to convert the forehead temperature reading (external surface) into internal body temperature | | |

**Further Relevant information:**

**A DESCRIPTION OF REQUIREMENTS**

**1** The maximum permissible error over the specified temperature range measuring temperature range must be not more than 0.2˚C in the temperature range 35.5–42.0 ˚C at an ambient temperature range of 18–28 ˚C and not more than 0.3 ˚C outside the measuring range or ambient temperature range

**2** The minimum measuring range must be 35.5–40.0 ˚C, preferred range will be <35.0 - >41.0 ˚C

**3** The resolution (digital increment) shall be 0.1 ˚C or less

**4** The ambient temperature operating range shall be 10–35 ˚C

**5** The device should give a visual or auditory warning when the measured temperature is not within the specified measuring range

**6** The time respond should be not more than 60 seconds

**9** Numerals should appear at least 4 mm high

**10** The device should meet the accuracy requirement after being exposed to five cycles of 0 ˚C and 55 ˚C for an hour each

**11** The device should meet the accuracy requirement after being exposed to a temperature of 45 ˚C and a relative humidity of 85% for 48 hours

**12** The device should meet the accuracy requirement after being dropped onto a hard surface from a height of 1 metre

**14** The energy dissipated by the probe should not cause a temperature rise in the indicated temperature of more than 0.01 ˚C

**15** For electrical safety the device should comply with EN 60601-1

**16** For electromagnetic compatibility the device should conform to EN 60601-1-2

**17** The device should provide a visual or auditory warning when the supply voltage is not within specified limits

**18** For mechanical safety the device should not have sharp ends or angles, and the probe

should be smoothly rounded to prevent injuries to the user or patient

**19** The device should be free from biological hazards

**20** The device should have a self testing routine

**21** Information from the manufacturer should comply with EN 1041

**22** 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.

**25** Warranty period: 12 months from the date of putting into operation

**26** Operation manual must be available in English and French language

**27** ISO 9001 is required

## 5.1 Annex 2: References


- Global Environment Facility (2013): Initial Guidelines for Enabling Activities for the Minamata Convention on Mercury. Washington D.C.: Global Environment Facility.
- Health Care without Harm. (2010). Toward the Tipping Point: WHO-HCWH Global Initiative to Substitute Mercury-Based Medical Devices in Health Care, A two-year progress report. Washington D.C.: Health Care Without Harm.
- UNEP/ISWA (2015): Practical Sourcebook on Mercury Waste Storage and Disposal. . Practical Sourcebook on Mercury Storage. Geneva: UNEP.
- World Health Organization. (2011). Replacement of mercury thermometers and sphygmomanometers in health care: technical guidance. (J. M. Shimek, J. Emmanuel, P. Orris, & I. Chartier, Eds.) Geneva: WHO.
- UN Model Regulations (Rev. 19 (2015): UN Recommendations on the Transport of Dangerous Goods - Model Regulations Nineteenth revised edition: UNECE

## 5.2 Annex 3: Further reading & Resources

- Developing national strategies for Phasing out Mercury-containing thermometers and sphygmomanometers in health care, including in the context of the Minamata Convention on Mercury (WHO, 2015)
    - http://www.who.int/ipcs/assessment/public_health/WHOGuidanceReportonMercury2015.pdf?ua=1&ua=1

- Safe Management of wastes from health-care activities: Second Edition (WHO, 2014)
    - http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/

- Guidance on Maintaining and Calibrating Non-Mercury Clinical Thermometers and Sphygmomanometers (UNDP, 2013)
    - http://noharm.org/lib/downloads/mercury/Guidance_Hg_2013.pdf

- Replacement of Mercury Thermometers and Sphygmomanometers in Health Care. Technical Guidance. (WHO, 2011)
    - http://www.who.int/water_sanitation_health/publications/2011/mercury_thermometers/en/index.html

- Mercury Elimination Guide for Hospitals (Health Care without Harm, 2011)
    - http://www.mercuryfreehealthcare.org/HCWH_Mercury_Guide.html

- Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and waste containing or contaminated with mercury (UNEP, 2011)
    - http://www.basel.int/Portals/4/Basel%20Convention/docs/techmatters/mercury/guidelines/UNEP-CHW-10-6-Add_2_rev_1.pdf

- Good practices for the management of mercury releases from waste (UNEP, 2010)
    - http://www.unep.org/chemicalsandwaste/Portals/9/Mercury/Documents/INC2/Good_practices_Oct2010.pdf

- Mercury in Health Care (WHO, 2005)
    - http://www.who.int/water_sanitation_health/medicalwaste/mercury/en/

- Clean-up, storage and Transport of Mercury Waste from Health Care Facilities (UNDP, 2010)
    - http://www.undp.org/content/undp/en/home/librarypage/environment-energy/chemicals_management/cleanup-storage-and-transport-of-mercury-waste-from-healthcare-facilities/