Technical specifications

- Mercury free medical devices -

Technical Specification: HCW Equipment

HGF-01-01 Mercury free aneroid sphygmomanometer

Item:		Photo / Drawing / Graphic
Non-automated non-invasive sphygmomanometers using an aneroid manometer *Code: HGF-01-01*		
Technical Data:	**(Main)**	
Specification	Anaeroid	
Unit of measurement	mmHg or kPa	
Nominal range and measuring range	0 mmHg (0 kPa) to at least 260 mmHg (35 kPa)	
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)	
Dynamic response	<1.5 seconds in cuff pressure indication for a specified drop in pressure; see compliance test	
Cleaning, sterilization, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned, and disinfected or sterilized	
Application:		
To measure patient blood pressure, for clinical use		

Further relevant information:

DESCRIPTION OF REQUIREMENTS

- Should meet the requirements of ANSI/AAMI/ISO 81060 1:2007 or comparable
- Markings should be clearly legible and sufficiently durable to remain clearly legible during the expected service life;
- Marking should include the name or trademark and address of manufacturer, model, serial or batch number if appropriate, proper disposal, etc.;
- Should have an indication when the reading error due to parallax exceeds ±2 mmHg (0.3 kPa)
- Cuff marking should indicate the correct positioning and appropriate limb circumference
- 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
- 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

General requirements

- Electrical safety: Compliance with IEC 60601-1 if electricity is used
- Mechanical safety: should avoid rough surfaces, sharp corners and edges that could cause injury or damage
- Mechanical strength: should function properly after falling 25 cm (or 1 m for “shock-resistant” sphygmomanometers), except for stationary devices;
- Should function properly after shock and vibration;
- Maximum error for the cuff pressure measurement over the nominal range:
    - ≤ ±3 mmHg (±0.4 kPa) for the following conditions: temperature range of 15–25 °C, relative humidity range of 15–85% (non-condensing) and decreasing pressure;
    - ≤ ±3 mmHg (±0.4 kPa) or 2%, whichever is greater, for the following conditions: temperature range of 10–40 °C, relative humidity range of 15–85% (non-condensing) and decreasing pressure;
- Nominal range and measuring range: 0 mmHg (0 kPa) to at least 260 mmHg (35 kPa)
- Air leakage: should not cause a pressure drop that exceeds 4 mmHg/min (0.5 kPa/min);
- 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)
- Rapid exhaust: Should not exceed 10 seconds from 260 mmHg (35 kPa) to 15 mmHg (2 kPa);
- Dimensions of cuff: Dimensions based on the limb circumference at the midpoint of the intended range of the cuff
- Cuff, bladder and tubing connectors: Should be able to withstand the maximum pressure; should have a means to prevent accidental disconnection;
- Tamper proofing or unauthorized access: Should prevent tampering with, or unauthorized access to, adjustments and functions that affect accuracy

Additional requirements

- Scale mark and zero: Requirements for a tolerance zone and movement of the elastic sensing element
- Hysteresis error <4 mmHg (0.5 kPa) throughout the pressure range;
- Construction and materials: Not more than 3 mmHg (0.4 kPa) difference in pressure indication after 10 000 full-scale cycles;
- Information supplied by the manufacturer; Should include identification; instructions for use; instructions for cleaning, and sterilization or disinfection; instructions for routine maintenance, as well as inspection and preventive maintenance by service personnel; instructions for end-of-life disposal; and technical description

HGF-01-02 Mercury free automatic spygmomanometer

Item:		Photo / Drawing / Graphic
Automated non-invasive (medical electrical) sphygmomanometer *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

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) *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: ACadapter(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

HGF-01-10 Small Blood Pressure Monitor Cuff

Item:		Photo / Drawing / Graphic
Blood Pressure Cuff, Small (Child cuff) *Code: HGF-01-10*		
Technical Data:	**(Main)**	
Connection	Must fit with HGF-01-02	
Material	Latex free	
Cleaning, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected	
Application:		
To monitor blood pressure and pulse at child, for clinical use, validated		

Further relevant information:

For paediatric users (Child cuff)
Easily connects to blood pressure monitor HGF-01-02
Made from nylon
Fit for 18 to 26 CM Arm Circumference

HGF-01-11 Extra Large Blood Pressure Monitor Cuff

Item:		Photo / Drawing / Graphic
Blood Pressure Cuff, X-Large Adult *Code: HGF-01-11*		
Technical Data:	**(Main)**	
Connection	Must fit with HGF-01-02	
Material	Latex free	
Cleaning, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected	
Application:		
To monitor blood pressure and pulse at patients with large arms, for clinical use, validated		

Further relevant information:

For Bariatric users, arm sizes up to 17" in diameter
Easily connects to blood pressure monitor HGF-01-02
Made from comfortable nylon
Must fit an arm size (circumference) of up to 50 cm

HGF-01-12 Dual Head Stethoscope

Item:		Photo / Drawing / Graphic
Dual Head Stethoscope *Code: HGF-01-12*		
Technical Data:	**(Main)**	
Material	Latex free, lightweight material	
Weight	<500g	
Cleaning, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected	
Application:		
For auscultation, or listening to the internal sounds of an animal or human body.		

Further relevant information:

- Soft eartips
- Aluminum chest piece
- Non-chill bell and diaphragm ring
- Diaphragm side detects high frequency sound
- Bell side detects low frequency sound
- Snap on diaphragm ring
- Latex-free tube

HGF-01-20 Battery Charger

Item:		Photo / Drawing / Graphic
Ni-MH AA & AAA Battery Charger With USB Port *Code: HGF-01-03*		
Technical Data:	**(Main)**	
Charing time	4h	
Battery size	AA / AAA	
Cleaning, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected	
Application:		
To charge batteries used for medical devices such as digital blood pressure devices		

Further relevant information:

4-hour Ni-MH battery charger with USB charge port
Recharges 2 or 4 AA / AAA Ni-MH batteries at a time
Protects against wrong polarity charging and over charging
Comes equipped with a USB port

HGF-01-21 Rechargeable Batteries AA

Item:		Photo / Drawing / Graphic
Rechargeable Batteries AA *Code: HGF-01-21*		
Technical Data:	**(Main)**	
Number of batteries in pack	8	
Capacity	>2000 mAh	
Size	AA	
Cleaning, disinfection	Reusable parts that come in contact with the patient should be capable of being cleaned and disinfected	
Application:		
To be used as power supply for portable medical devices		

Further relevant information:

Pack of 8 1.2V AA batteries with a capacity of >2000mAh
Ni-MH rechargeable batteries
Long-life, energy saving, recyclable rechargeable battery
Maintain 80% capacity after 3 years non-use
Can be charged for >1000 times when fully or partially drained

HGF-02-01 Mercury free digital thermometer

Item:		Photo / Drawing / Graphic
Digital Clinical Thermometer *Code: HGF-01-03*		
Technical Data:	**(Main)**	
Temp. Range: Resolution: Accuracy: Battery Life: Ambient Temperature	<35.0 - >41.0 °C 0.1 °C or less +/- 0.1°C >200 hours 10-35°C	
Application:		
Medical device, for the measurement of patient temperature, for clinical use 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