

		NTLD-EC-02
PRODUCT INFORMATION		Version:2.0

1. Product brand, name and model:

Product name : Aneroid Sphygmomanometer

Product model : HS-GF-303

Classification rule and class:

According to MDD, Annex IX Rule 1: I WITH MEASURING FUNCTION

Conforming assessment route:

MDD 93/42/EEC Annex V, Article 3

2. Producing location and address:

Name: HONSUN (NANTONG) Co., Ltd

Address: No.8 Tongxing Road, Economic & Technical Development Area, Nantong City, Jiangsu, P.R. China.

Fax: +86 0513 80580022

Tel: +86 0513 85986706

3. Notified body and address:

Notified body: TÜV SÜD Product Service GmbH

Address: Ridlerstr, 65, 80339 München, German

4. Introduction of product and compare list

a. Elements

Membrane box gauze. According to the rule, when the pressure is placed on the inner wall of membrane box, cyclic and corrugated membrane will be deformed, which maximum elasticity will cause displacement along axis to push pointer forward moving around scale panel for measurement reading through gear transmission. The blood pressure unit: mmHg (kPa)

b. Intended Use

Aneroid Sphygmomanometer is a non-automated, mechanical blood-pressure monitor that used for the indirect measurement (noninvasive) and display of arterial blood pressure.

c. The Side effect of the Aneroid Sphygmomanometer

The Aneroid Sphygmomanometer has no side effect

d. Main technical parameter:

Accuracy: Pressure \pm 3mmHg (0.5kPa)

Leak air velocity \leq 4 mmHg/min.

The service life of the blood pressure form is 10000 times above.

Measuring range: 0 to 300 mmHg

Measuring resolution: 2 mmHg

Pressure reduction rate: 2-3sec

e. Annex:

Accessories:

1 cuff (nylon/Cotton/Shining Nylon/PVC)with PVC/Latex/TPU bladder

Mode	Size(cm)
newborn.	7~12
infant	13~19
child	18.4~26.7
adult	25.4~40.6
Fat man	33~51
thigh	40.6~66

2 bulb and valve

3 stethoscopes (optional)

4 soft bag

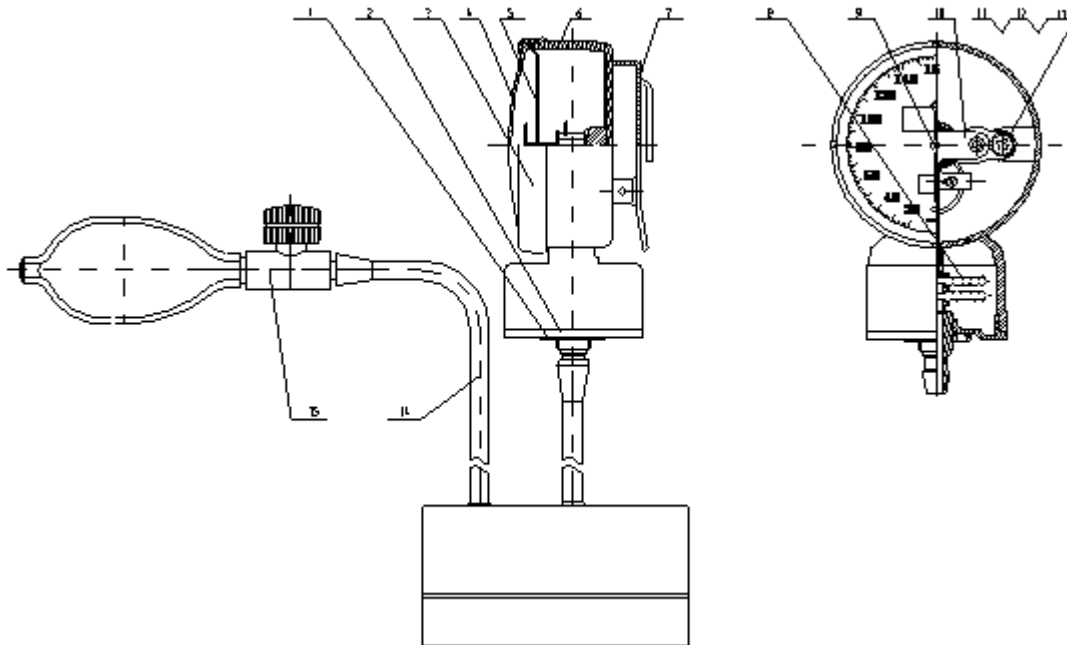
cuff placed on the upper arm, by materials, they can be divided into nylon/Cotton/Shining Nylon/PVC altogether 4 materials. By size, they can be divided into adult, child and newborn.

Instruction including: the aneroid sphygmomanometer’s measurement, attention and maintenance. It’s the manual for operation.



6、Layout

Aneroid sphygmomanometer:



- | | |
|-------------------------|----------------------|
| 1. SCREW CAP | 2. BASE BOARD |
| 3. MOMANOMETER RING | 4. MOMANOMETER GLASS |
| 5. DIAL | 6. GAUZE CASE |
| 7. MOMANOMETER CLIP | 8. MEMBRANCE WELDING |
| 9. POINTER ASSEMBLING | 10. MECHANISM |
| 11. CROSS-SCREW | 12. ELASTIC WASHER |
| 13. FLAT WASHER | 14. CUFF |
| 15. VALVE AND LATEX BUL | |

7、maintance:

- 7.1 Avoid cuff, bladder and bulb to be touched by sharp instrument and erosional chemicals.
- 7.2 Dispatching and assembling gauges without technician are prohibited.
- 7.3 Avoid strong mechanic shaking and dumping.
- 7.4 Use the device under the required temperature.
- 7.5 Avoid long time scorching and raining.

8、 Cleaning

- 8.1 Use neutral scour to wash cuff.
- 8.2 Use wet cloth to wipe tube and bulb.
- 8.3 Use soft and dry cloth to wipe gauge.
- 8.4 Using erosion scour is prohibited.

9、Reserve

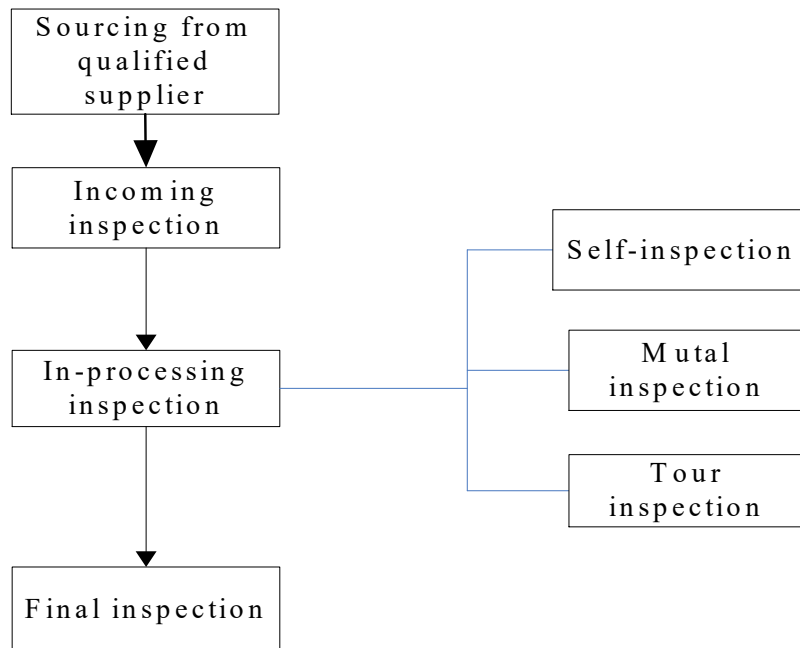
9.1 Release air in bladder before reserving。

9.2 Temperature: -20℃~+70℃

9.3 Humidity: 20~85%

9.4 Use the accessory bag。

Flow of quality inspection



- ✧ Material Sourcing: Supplier Evaluation, Choosing qualified Supplier, Sourcing material

Establishing raw-material inspection standard. Testing and inspecting raw-material. If not acceptable, carrying out non-conformity control procedure.

- ✧ Training on the worker for the key procedure. Testing facility is calibrated..
Operator strictly follows the working instruction and self-inspection and mutual inspection. Inspectors make the tour inspection and sampled test.
- ✧ Finished products inspection standard is formulated according to the factory standard. Finishing good testing is conducted following the standard..

1. Special process description

No

2. The key control point

The quality requirement for finished products:

In accordance with EN1060-1&EN1060-2