**Product Technical Requirements for Medical Device**

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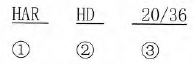
**Harmonic HD 1000i Ultrasonic Surgical Devices**

1. **Product model/specification and classification description:**
   1. **Product models/specifications:**

|  |  |  |  |
| --- | --- | --- | --- |
| Model | Shaft diameter | Shaft length | Sterilization method |
| HARHD20 | 5.46mm | 20cm | Ethylene oxide |
| HARHD36 | 5.46mm | 36cm | Ethylene oxide |

* 1. **Classification description on product models/specifications:**

Classification description on product models (only applicable to HARHD20/HARHD36):



① HAR refers to Harmonic

② HD refers to trade name

③ 20/36 refers to shaft length, in cm

* 1. **Version and naming rules of software of generator used in coordination with the product:**

Software released version: 2016-1

Naming rules of software (full version):



X: Major enhanced update (e.g. software algorithm changes due to learning data adjustment in advanced hemostasis mode);

Y: Minor enhanced update;

Z: Corrective update;

1. **Performance indicators**
   1. Safety properties
      1. The general requirements for safety of equipment shall comply with the requirements of GB 9706.1-2007
      2. The electromagnetic compatibility requirement of equipment shall comply with the requirements of YY 0505-2012.
   2. Appearance

Surface: Uniform color, smooth; clear and firm characters and icons; free from deformation, disbonding, scratch or bubble.

* 1. Sterility
     1. The shear sterilized by ethylene oxide shall be sterile
     2. The shear sterilized by ethylene oxide shall have residual EO not greater than 4mg/device
  2. General performance of shear
     1. The error of the outer diameter of the operating shaft shall not exceed the labeled value ± 0.05mm.
     2. The jaws of the shear shall be sufficient in grasping force to prevent the grasped object from dropping.
     3. The hardness of the metal part of the shear shall be not less than 120 HV0.2.
     4. Outer diameter of the maximum inserted part of shear shall be no greater than 5.588 mm.
  3. Working performance of shear
     1. Connect the Harmonic HD 1000i Ultrasonic Surgical Devices with the Ultrasonic Surgical & Electrosurgical Generator and enable the Harmonic Mode; they shall function properly.
     2. Displacement of shear: 71 μm ± 5μm
     3. Working frequency of shear:

HARHD20: 50 kHz ± 500 Hz

HARHD36: 49.2 kHz ± 500 Hz

* + 1. Working power of shear: ≤ 10 W (no loading)
    2. Maximum clamping force: no less than 21 N
    3. Maximum grasping force: no less than 10 N
    4. Primary tip vibration excursion and its error:

HARHD36: 70.8 μm ± 2.2 μm

HARHD20: 71.0 μm ±3.1 μm

* + 1. Upper limit of secondary tip vibration excursion

HARHD36: Hook: 25.6 μm; tab: 71.3 μm;

HARHD20: Hook: 29.5 μm; tab: 58.9 μm;

* + 1. Tip vibration frequency and its error

HARHD36：49122 Hz ± 183Hz

HARHD20：50034 Hz ± 146Hz

* + 1. Quiescent electrical power and its error

HARHD36：2.6 W ± 0.7 W

HARHD20：2.5 W ± 0.7 W

* + 1. Maximum electrical power: No more than 60W

1. **Test methods**
   1. Safety properties
      1. The general requirements for safety of equipment shall be tested according to the methods specified in GB 9706.1-2007.
      2. The electromagnetic compatibility requirements of equipment shall be tested according to the methods specified in YY 0505-2012.
   2. Appearance

Perform visual inspection and hand feeling test; the result shall comply with the requirements of 2.2.

* 1. Sterility
     1. Conduct the test according to the methods specified in the Chinese Pharmacopeia (Edition 2015); the result shall comply with the requirements of 2.3.1.
     2. EO residues: Conduct the test according to the methods specified in GB/T 16886.7-2001; the result shall comply with the requirements of 2.3.2.
  2. General performance of shear
     1. The shear shall be measured by using a general measuring tool; the result shall comply with the requirements of 2.4.1.
     2. Simulate actual operations: Clamp a 10 cm × 10 cm paper sample with a thickness of 3 mm; the result shall comply with the requirements of 2.4.2.
     3. Hardness test: Contact the test according to the methods specified in GB 4340.1-2009; the result shall comply with the requirements of 2.4.3.
     4. The shear shall be measured by using a general measuring tool; the result shall comply with the requirements of 2.4.4.
  3. Working performance of shear:
     1. Operate according to the IFU; the result shall comply with the requirements of 2.5.1.
     2. Maximum displacement test of shear: The equipment shall be set at the power level of 5 in order to carry out the load curve test of the displacement. In the laboratory environment, the system acquires the electricity from the standard electricity output and is connected with the typical handle and the foot pedal. Use the laser vibration meter to test and record the longitudinal displacement of the distal head end of the shear, and draw the load function curve of the displacement on the PC. The result shall comply with the requirement of 2.5.2.
     3. Shear working frequency test: The equipment shall be set at the power level of 5 in order to carry out the load curve test of the working frequency. In the laboratory environment, the system acquires the electricity from the standard electricity output and is connected with the typical handle and the foot pedal. Use the laser vibration meter to test and record the longitudinal displacement of the distal head end of the shear, and draw the load function curve of the working frequency on the PC. The result shall comply with the requirement of 2.5.3.
     4. Shear working power test: The equipment shall be set at the power level of 5 in order to carry out the load curve test of the working power. In the laboratory environment, the system acquires the electricity from the standard electricity output and is connected with the typical handle and the foot pedal. Use the laser vibration meter to test and record the longitudinal displacement of the distal head end of the shear, and draw the load function curve of the working power on the PC. The result shall comply with the requirement of 2.5.4.
     5. Maximum clamping force

The clamping force of the jaw is to clamp a coil (one or more loops) of Class II 1# suture complying with YY 1116-2010 at 1/2 site of the head end of clamp; after the weight of 21 N is lifted at the other end of the clamp, lift the weight along the vertical direction of a piece of shears containing gasket in the closed state of the clamp jaw and maintain the clamping state for 3s; then the ultrasonic knife shall not be damaged or deformed.

* + 1. Maximum grasping force

The grasping force of clamp jaw is to clamp the monolayer suede material on the innermost part of the clamp by holding tight the handle. For the other end, use a tension meter to pull the suede in parallel direction. Under the premise that the jaw has no deformation, the maximum grasping force obtained shall comply with the requirements of 2.5.6.

* + 1. Primary tip vibration excursion and its error:

The tip displacement of the shears is measured by laser vibrometer at the specified measuring angle. In view of the main longitudinal shears amplitude and the design curvature of shears, the laser should be set at 28° angle to the longitudinal axis of the device, aiming at the circular tip area of the shears. When the jaw is open, the device is activated at power level 5 and once stability is achieved (transient behavior stops), the vibration amplitude of the tip can be captured (Record the data within 2 s after excitation only). Sometimes the tip coating of blade is removed to achieve good laser locking on the vibrating surface. Use fine-grained sandpaper to remove the tip coating of shears. The result shall comply with the requirements of 2.5.7.

* + 1. Upper limit of secondary tip vibration excursion

The upper limit of secondary vibration excursion of other two components of the tip, i.e. hook and tag, can also be measured with a laser vibrometer at the specified measuring angle. In view of the main longitudinal shears amplitude and the design curvature of shears, the laser should be set at 90° angle to the longitudinal axis of the device, aiming at the circular tip area of the shears. When the jaw is open, the device is activated at power level 5 and once stability is achieved (transient behavior stops), the vibration amplitude of the tip can be captured (Record the data within 2 s after excitation only). Sometimes the tip coating of shears is removed to achieve good laser locking on the vibrating surface. Use fine-grained sandpaper to remove the tip coating of shears. The test result shall comply with the requirements of 2.5.8.

* + 1. Tip vibration frequency and its error

Use a laser vibrometer to measure the tip vibration frequency; the result shall comply with the requirements of 2.5.9.

* + 1. Quiescent electrical power and its error

Set the primary tip vibration excursion to its maximum value and then use the phase-corrected wattmeter used for ultrasonic design to directly measure the electrical power of the shears within 3 s when excited at power level 5; the result shall comply with the requirements of 2.5.10.

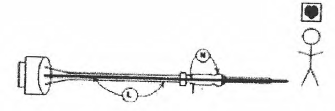
* + 1. Maximum electrical power:

After the primary tip vibration excursion is set to the maximum value, two layers of Ultrasuede material (thickness: 3 mm ± 1 mm) are placed at the front 2/3 site of the clamp and the maximum electrical power of the shears is measured with the phase-corrected wattmeter used for ultrasonic design after the shears are excited at the power level 5. The result shall comply with the requirements of 2.5.11.

**Annex A**

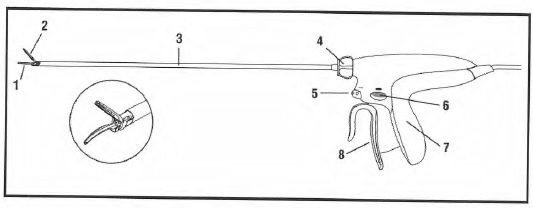
Safety

1. Product classification and safety characteristics
2. Classification according to the type of protection against electric shock: Not applicable
3. Classification according to the degree of protection against electric shock: Type CF applied part
4. Classification according to the degree of protection against liquid ingress: Not applicable
5. Classification according to the safety degree of product used in the flammable anesthesia gas mixed with air, oxygen or nitrous oxide: Not applicable
6. Classification according to the operation mode: Not applicable
7. Rated voltage and frequency of equipment: Not applicable
8. Input power of equipment: Not applicable
9. Whether the equipment has defibrillation-proof applied part: Not applicable
10. Whether the equipment has a signal input or output part: No
11. Permanently installed equipment or non-permanently installed equipment: Non-permanently installed equipment
12. Electrical insulation diagram



|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Area | Insulation type: Operation insulation/basic insulation/supplementary insulation/double insulation/reinforced insulation | Reference voltage (~V) | Test voltage (~V) | Creepage distance (mm) | Air clearance (mm) |
| L | DI/BI | 425/240 | 4700 | 16.0 | 9.0 |
| N | DI/BI | 300/240 | 4200 | 12.0 | 7.0 |

Annex B Schematic diagram and structural composition of product



|  |  |
| --- | --- |
| 1. Coated shear | 1. Energy button |
| 1. Clamp arm and tissue pad | 1. Advanced hemostasis energy button |
| 1. Shaft | 1. Handle |
| 1. Rotation knob | 1. Closing handle |