High-Frequency Surgical System

Operation Technical Instruction

Name of registrant/manufacturer: 233(HENAN) TRADING CO.,LTD

Product Standard No.：YZB Country /1512-2014 High-frequency Surgical System

I. Overview

Before installing and using the product, please read the Technical Instruction Manual.

This manual combines "Instruction Manual" and "Technical Instruction Manual" for easy reading.

The performance parameters and safety indicators of the high-fr equency surgical system (hereinafter referred to as high-frequency s urgical system) are in accordance with GB9706.1-2007 《Medical Elec trical Equipment Part I: General Requirements for Safety 》、 GB9706. 4-2009《 Medical Electrical Equipment Part II: Special safety requirem ents for high-frequency surgical equipment》, YY0505-2012 《Medica l Electrical equipment Part 1-2: General safety requirements and par allel standards: Electromagnetic compatibility requirements and tests.

It is suitable for vascular closure (diameter less than 7mm) / rapid coagulation and dissection of tissue bundles in electrosurgery.

II. Product performance and composition

1. According to the classification of electric shock protection, the high-frequency surgical system belongs to class Ⅰ CF type, which is a high-frequency electronic equipment with protection against defibrillation discharge effect. Foot switch is anti-immersion type (IPX8) with internal electrical sealing.

2. structure

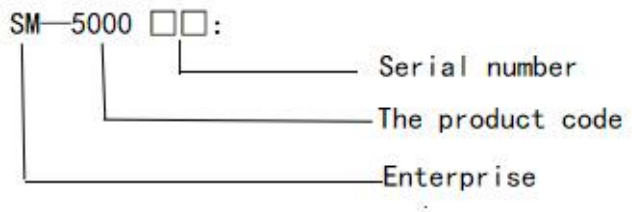
Components: Main machine of high-frequency operation system, single foot switch/double foot switch, accessory connection wire, power cord.

Type: table top.

Geometric dimensions: 420mm (L) ×420mm (W) ×150mm (H).

Weight: 9Kg.

3. The high-frequency surgical system is SM-5000 series.



4. Working Time

Intermittent loading runs continuously with the operation/interval of 10s/30s.

5. Normal working conditions

Ambient temperature: +10 ° C to +40 ° C.

Relative humidity: 30%-75%.

Atmospheric pressure: 700hPa ~ 1060hPa.

Power supply: ~ 220V±22V; 50 hz + 1 hz.

III.Panel Introduction

1. The front panel:

The following (1) is the front panel of SM-5000 and SM-5000B,

(2) is the front panel of SM-5000BT and SM-5000DT.

(1) The front view of front panel 1 is shown in Figure 1 below.

1-- Seal energy indicator 2 -- Seal work indicator 3 -- Cut energy indicator

4 -- Cut work indicator 5-- Seal energy up button 6-- Seal energy down button

7-- Cut energy up button 8-- Cut energy down button 9-- volume up/down button

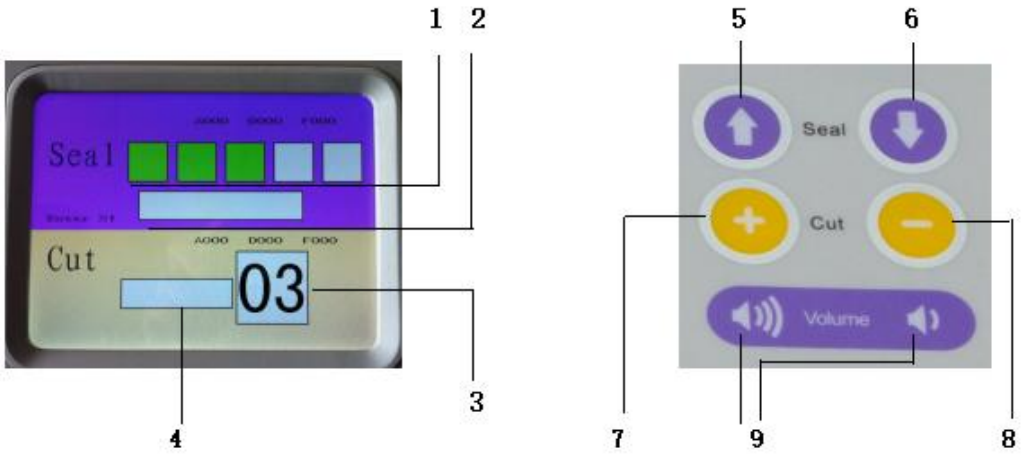


Figure 1 Front view of front panel 1

(2) The front view of front panel 2 is shown in Figure 2 below.

1*-- Cut energy indicator 2*-- Seal energy indicator 3*-- Seal energy up button

4*-- Energy down button 5*-- Cut energy indicator 6*-- Seal energy indicator

7*-- Volume up button 8*-- Volume down button

9*-- Electrodes identification

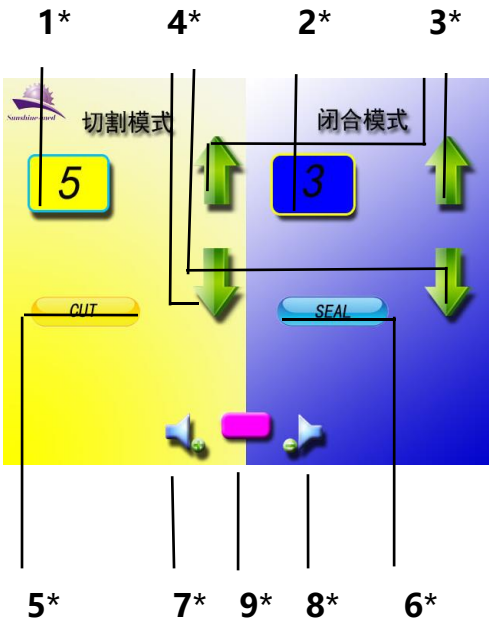


Figure 2 Front view of front panel 2

2. The output panel

The front view of the output panel is shown in Figure 3.

10, 11-- display/touch screen 12, 13-- output socket 14-- power switch

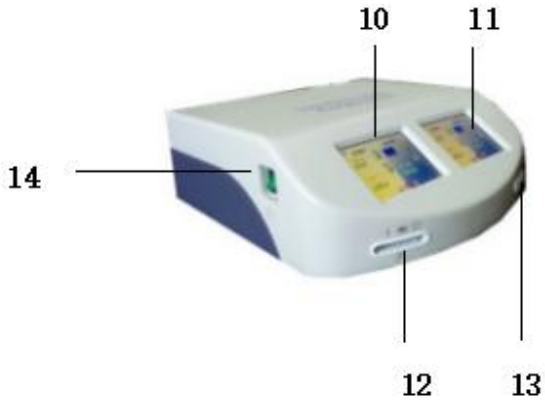


Figure 3. Front view of output panel

3. The rear panel

The front view of the rear panel is shown in Figure 4.

15, 16- foot switch socket 17- Product nameplate 18- power socket

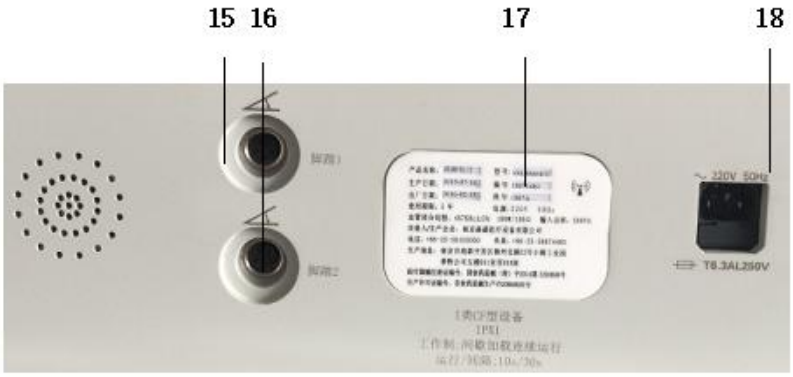


Figure 4. Front view of rear panel

IV. Contraindications

1）Severe cardiopulmonary insufficiency.

2）Blood coagulation disorder.

3）Acute diffuse peritonitis.

4）Extensive intraperitoneal adhesions.

5）Vessels larger than 7mm in diameter.

6）Tubal ligation or tubal condensation during sterilization.

V.Maintenance

1. Maintenance

(1) Avoid violent vibration, corrosion of harmful gases and liquid inflow.(2) Keep the surface clean.

(3) When cleaning bipolar surgical accessories, do not scrape or rub with hard objects, nor soak with liquid medicine and other liquids. Disinfection should be carried out through ethylene oxide(EtO), gas plasma (Sterrad).

(4) Before using tools to open the housing, you must unplug the power cable.

VI. Transportation and storage conditions

Temperature: -40℃ to +70℃.

Relative humidity: 10%-100%.

Atmospheric pressure: 500hPa ~ 1060hPa.