Innovation in bloodcare technology

User Manual

Sterile Tube Welder STW6810-RFID

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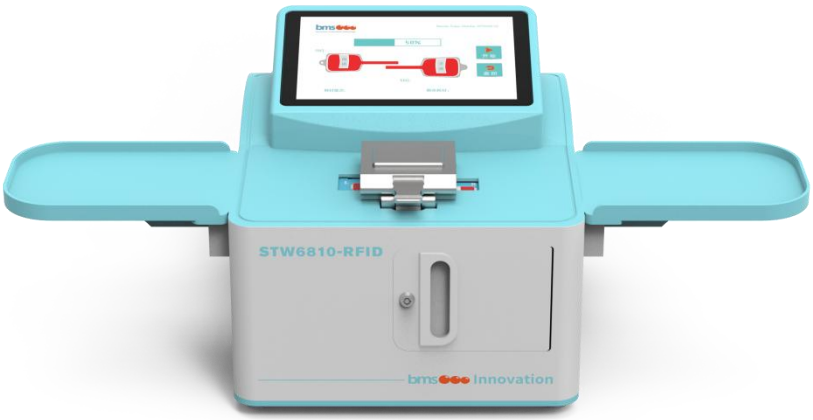
Sterile Tube Welder
STW6810-RFID

User Manual



Please read this User Manual carefully before using the Device

and use the Device as instructed in this User Manual!

CONTENTS

INTRODUCTION

Sterile Tube Welder STW6810-RFID is used for welding treatment of blood product. Please refer to this Manual for the welding range of blood bag tube. In case of use beyond the capacity range specified herein, the application effectiveness and suitability of this Device should be confirmed first; otherwise, the manufacturer will not guarantee the effect of the application, and shall perform no obligation or responsibility. The user is obliged to observe all the operation steps described in this Manual.

Contact info


Wuhan bms Medicaltech Co., Ltd.

No. 3 & 4, 5th Floor,B9, Phase I, Block B,Hi-tech Medical Devices Park, 818 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, China (Wuhan Free Trade Zone)

After-sales Service Provider: Wuhan bms Medicaltech Co., Ltd.

Tel: 86-27-65028187

Email: customer@bms-bloodcare.com

MedUnion S.L.

EC REP Carrer de Tapioles,33,2-1,Barcelona,08004,Spain

SRN：ES-AR-000019366

Contraindications, Important Safety Precautions, Tips, Contents and Conventions

Safety Precautions: In this Manual, headings titled note, caution or warning appear to emphasize important and critical instructions.

Warning: notify operators of dangerous or inappropriate practices that may result in personal injury, affect their health or cause device contamination.

Caution: specify all special precautions that operators should take for the safe and efficient use of device.

Note: emphasize important information.

Contraindications:

No contact with water or other liquid is allowed for Sterile Tube Welder to avoid damage.

The Sterile Tube Welder should not be changed, disassembled or adjusted without authorization.

The Sterile Tube Welder and its connecting lines should not be collided with any hard object.

The Sterile Tube Welder should be well ventilated and no sundries should be piled up around.

All maintenance works of the Sterile Tube Welder shall be carried out by trained or authorized professionals.

This Manual should be carefully read and understood before using the Sterile Tube Welder.

This Device can only be connected to a power outlet with protective grounding. Do Not use the power outlet if the grounding wire is not well connected.

Do Not place the device on a position where it is difficult to disconnect the power.

If you need to clean, move or put aside the device for a long time, please turn off the device first and remove the power cord from the socket.

Wear protective device, clothing and gloves when handling any sample.

If the device is not used with the operation methods specified in this Manual, protection provided by the device may be damaged.

Any re-testing as per EN 60601-1 may damage the device and impair the protection against hazards.

not intended for use in oxygen rich environment

Part I: Functions and Technical Specifications

1.1 Functions

Product Name: Sterile Tube Welder

Product Type: STW6810-RFID

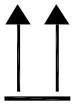
Structure and Composition: this Product is composed of host, AC power cord, blood bag tray, Cassette and operation screen.

Scope of Application: this Product is suitable for aseptically joining 2 PVC blood bag tubes together.

1.2 Technical Specifications

SN	Product Performance and Parameters
1	▲ Machine Performance: 2 PVC blood bag tubes shall be cut, fused, sterilized and integrated into one by using patented metal Cassette.
2	▲ Shell Material: ABS, upper cover: aluminum alloy
3	▲ Rated Voltage: AC input a. c. 200～240V, 50Hz
4	▲ Input Power: 300VA
5	▲ Fuse Spec.: F4AL250V
6	▲ Operation: 10-inch touch screen
7	▲ Pipe Spec.: ID ≥2.7mm, wall thickness ≥0.5mm, OD ≤5.0mm
8	▲ Connection Mode: above-mentioned tubes with the same diameter (dry-dry, dry-wet/wet-wet) can be welded with each other.
9	▲ Connection Strength: the welded part of the tube shall bear a pulling force of not less than 40N for 5 min.
10	▲ Welding Time: ≤22S
11	▲ Bearing Capacity of Tray: ≤1.5kg
12	▲ Weight: 14.5±0.5kg
13	▲ Size: length X width X height (442mm x760mm x290mm)
14	▲ Consumables: metal Cassette
15	▲ Network Interface: RJ45 (one of which is for internal use of the Enterprise, and the Ethernet port can be connected with external device. If necessary, please contact the manufacturer. Connection by any customer or user on their own shall be invalid)
16	▲ USB interface: USB 2.0 (only for internal use of the enterprise)

1.3 Graphical Symbols for the Device

NO.	Location	Symbols and Signs	Description
1	Labels and Instructions		manufacturer
2	Labels and Instructions		Authorised representative in the European community
3	Labels		Date of manufacture
4	Labels		caution
5	Labels		Consult instructions for use
6	Labels		Radio frequency symbol
7	Labels		Disposal of waste product must comply strictly in accordance with the state administrative regulations
8	Cover of device		Caution,hot surface
9	Backside of the device		Protecting earthling
10	Backside of the device		Connect (AC power)
11	Backside of the device		Disconnect (AC power)
12	Backside of the device		USB Interface
13	Backside of the device		Network Interface
14	Packing Case		Keep dry
15	Packing Case		Upward
16	Packing Case		Limit number of stacking layers
17	Packing Case		Do not roll

Part II: Description of External Structure

2.1 Front Panel

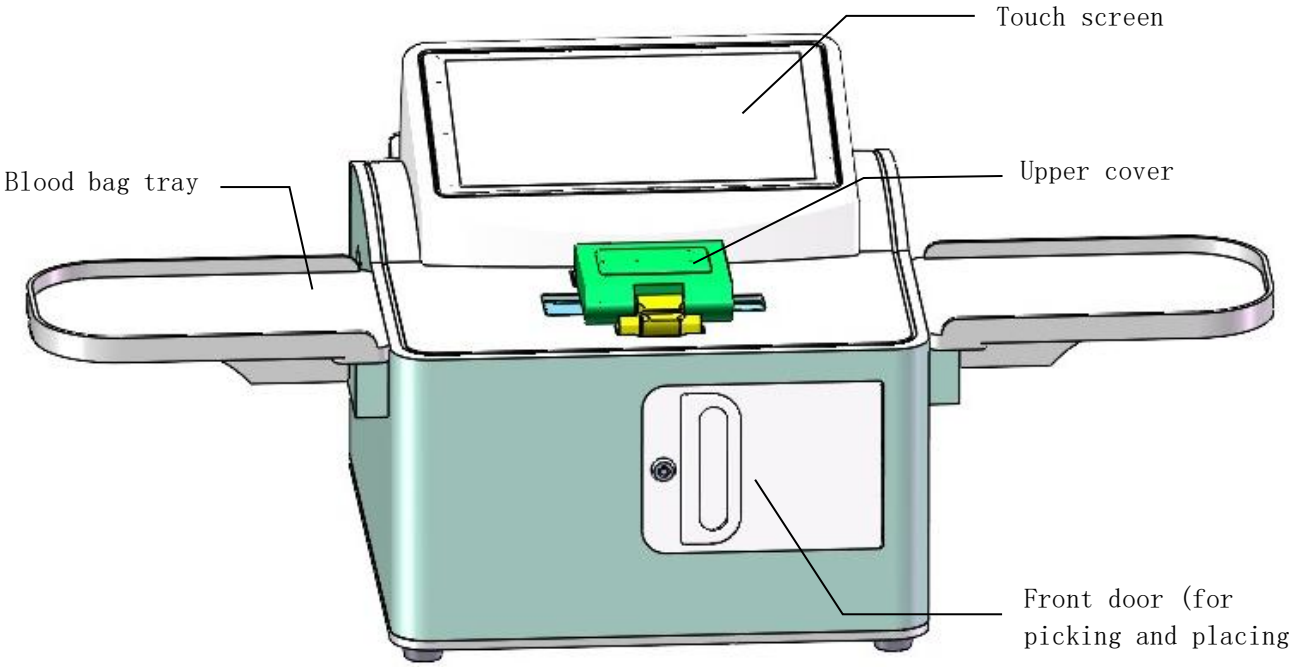


Figure 1

2.2 Rear Panel

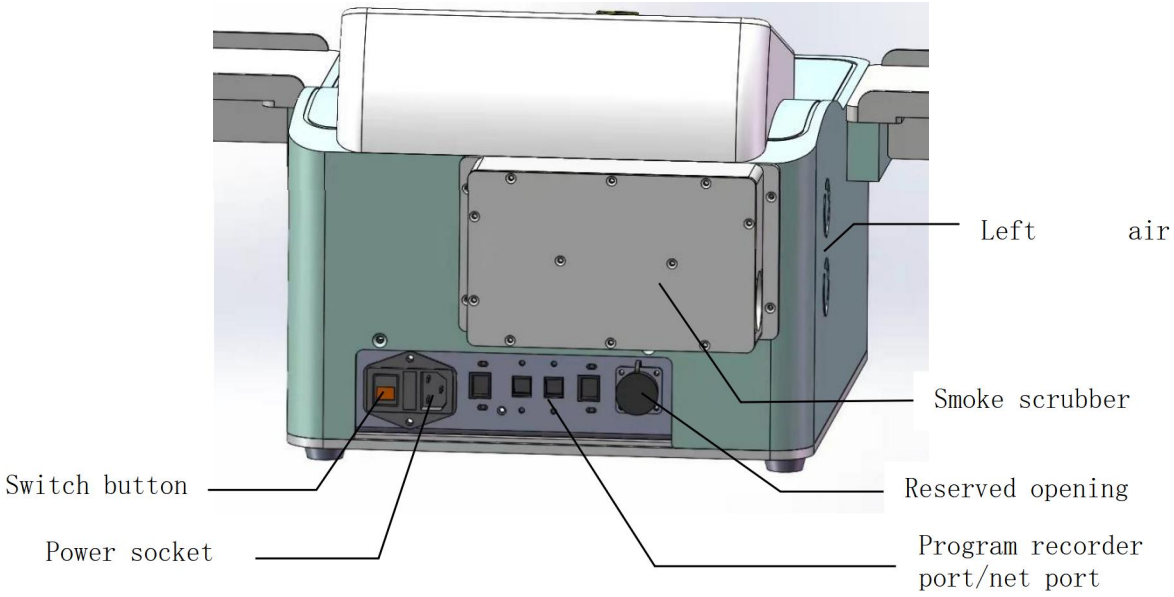


Figure 2

2.3 Tube clamp

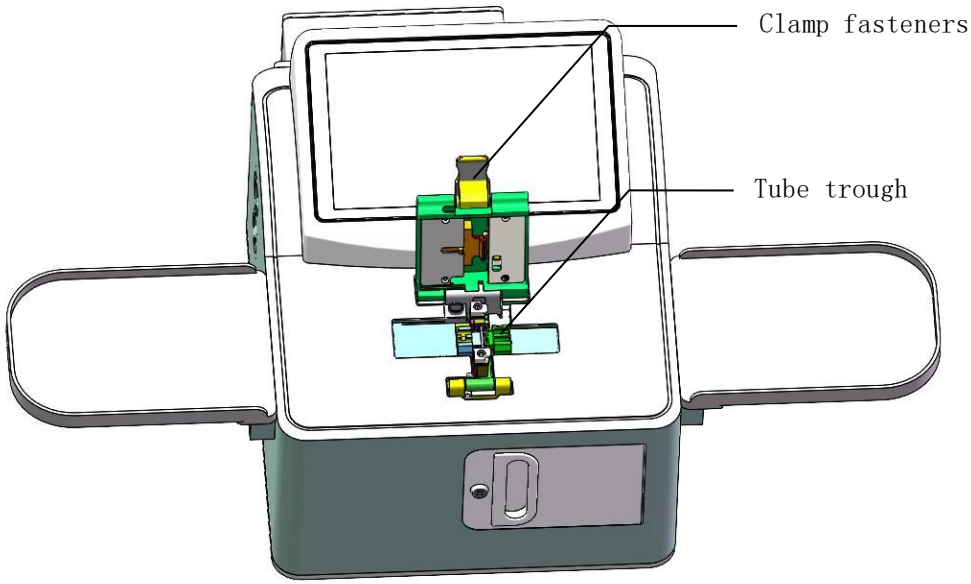


Figure 3

2.4 Cassette

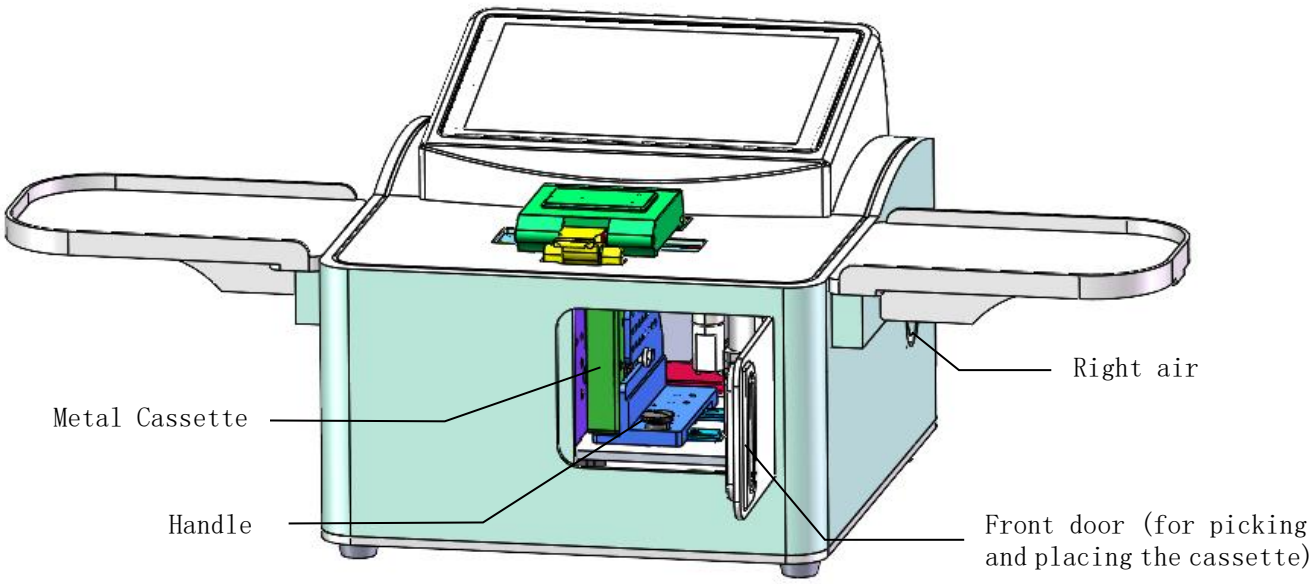
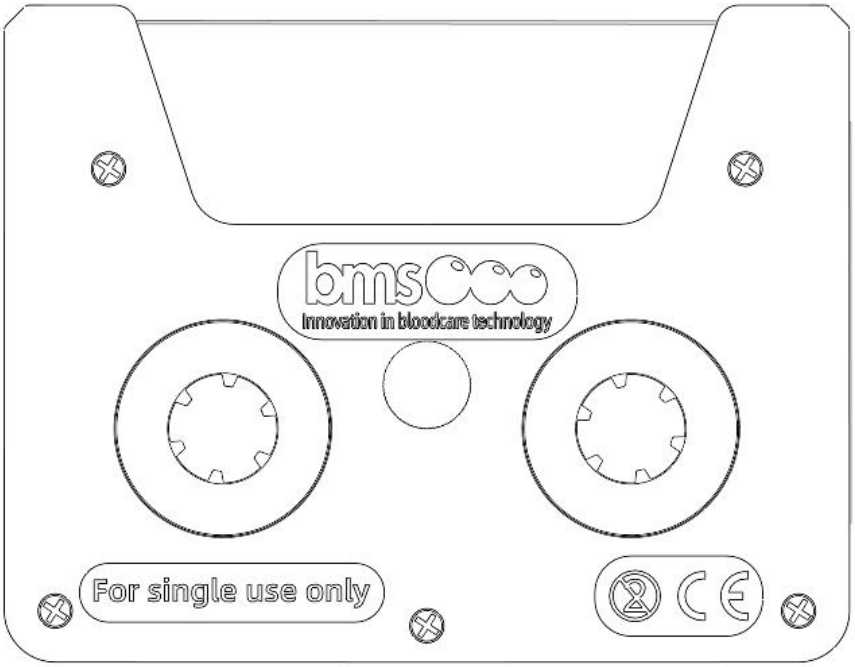


Figure 4

2.5 Description of Cassette

Disposable Consumables: the number of Cassette uses shall be subject to that specified in the Label. It is no need to disinfect and sterilize if used at normal temperature after unsealing. Please make replacement immediately after use, instead of reusing, otherwise, it will cause leak of welding interface.



bms
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金属丝线盒使用说明
CAUTIONS

序号 NO.	技术参数 Specification
1	本金属丝线盒专机专用，配套本公司无菌接管机系列产品使用。 This cassette is specially designed for the series of Sterile Tube Welders of our company.
2	单个金属丝线盒的使用次数以标签规定使用次数为准，且不可重复使用。 The number of uses of each single cassette shall be subject to that specified in the label, and no cassette could be reused.
3	金属丝线盒外尺寸为：L116mm*W90mm*H21mm External dimension of wire cassette: L116mm*W90mm*H21mm
4	金属丝材质满足接驳的要求，且接驳过程中发热段金属温度均匀，不会使接驳端碳化或生成粒子及化学残留物。 The texture of wire meets the requirements of tube welding, and the metal temperature of heating section is uniform during the tube welding, which will not cause carbonization of the welding end or generate particles/ chemical residues.
5	使用完毕按照医疗废弃物作相应处理。 It should be disposed in accordance with medical waste treatment after being used.

Figure 5

2.6 Packing List of Standard Accessories

No.	Name	Quantity	Remarks
1	Sterile Tube Welder STW6810-RFID	1	
2	Certificate of Compliance	1	
3	Warranty Card	1	
4	User Manual	1	
5	Metal Cassette	--	Sell consumables separately and configure them according to customers' purchase demand
6	Blood bag tray	2	
7	AC power cord	1	
8	Key to front hatch	2	

Part III: Operating Principle

The key process of Tube welding is as follows:

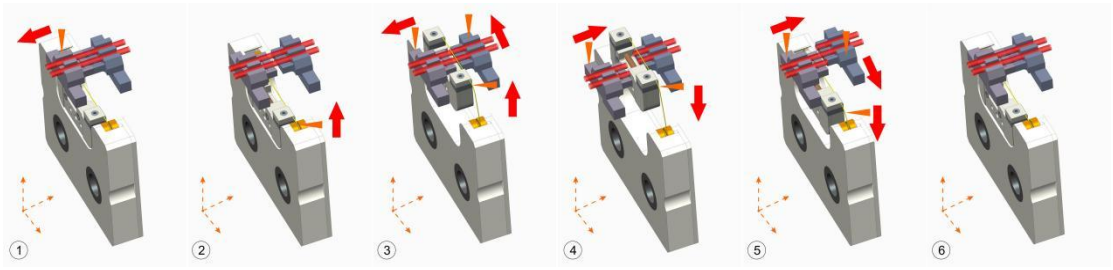

Figure 6

1. After the welded Tube is fastened by clamps, the left part of the clamp shall be moved to the left to stretch the tube.

2. At this time, wire in the Cassette shall be heated to cut off the tube.

3. The system heat source can heat the welded pipe in a non-contact manner.

4. After the pipe is cut off, the clamp shall start to move and align with the tube to be welded.

5. When the heating element leaves the heating position quickly, the clamp will quickly press the pipe sections together.

6. Then open the clamp, take out the tube, welding completed.

Part IV: Warnings and Contraindications

4.1 Warnings

4.1.1 Product Users

Trained and qualified personnel shall be assigned to use this Sterile Tube Welder.

4.1.2 Potential Safety Hazards and Use Restrictions:

1) This Device can ensure its function and safety under the following conditions:

A) Only required parts and components provided by us or agents.

B) Only specially trained personnel can operate the device with the methods specified in the product instruction manual.

2) The device or system should not be used in close proximity or stacked up with other device; if having to use it in close proximity or stack up, be sure to observe and verify that it can operate normally under the configuration in which it is used.

3) The operator must treat the treated blood as a potential source of infection.

4)If the user failed to operate the device with the method specified in the product instruction manual, the device might be damaged and invalidated.

4.1.3 Emergency and Corrective Measures

Sterile Tube Welder STW6810-RFID has a stable and reliable design, but it may also have electrical or mechanical failures causing leakage of pipe welding. In case of failure in the process of use, please handle it according to the tips on the device operation. If you could not shoot the trouble by yourself, please contact our customer service in time, and we will arrange professionals to check and maintain the device.

4.1.4 Monitoring, Evaluation and Control

Failure to comply with all operating instructions or repeated use of Cassettees can lead to leakage or non-sterile state of welding joint, so please carefully check each joint. For whatever reason, interface leakage, if occurred, means that the aseptic assurance of the system used may have declined and may lead to contamination. Please contact the manufacturer or technical personnel with maintenance qualification.

4.1.5 This Device can complete the function of connection alone, with no need for

work together with other device.

4.1.6 This device is designed and tested according to Category A Standard in CISPR 11. For the electromagnetic compatibility requirements, please refer to "9.2 Electromagnetic Compatibility (EMC)" in "Part IX: Safety and Electromagnetic Compatibility Requirements". It is forbidden to use this device beside strong radiation sources (such as unshielded RF sources), which may interfere with the normal operation of this device.

4.1.7 The product itself contains no harmful substance, nor produce harmful substance to operators.

4.1.8 The metal Cassette is used as consumables of Sterile Tube Welder STW6810-RFID. The discarded Cassette replaced after use cannot be thrown away directly. The user should clean the Cassette before treating it as medical waste (cleaning method: wipe the exposed wire with medical cotton swab dipped in medicinal alcohol).

Before the Sterile Tube Welder is scrapped, the user shall clean and dispose of the device in accordance with the relevant regulations of the country or region where the customer is located on the disposal of medical device waste.

4.1.9 Other Precautions

1) Proper installation of Cassette is essential for the device tube welding (see 5.2 for detailed procedures).

2) Please take care not to spill any liquid into the device; liquid spilled into the device may cause abnormal operation or incomplete welding interface.

3) As consumables, the Cassette need no sterilization once opened at normal temperature. However, the number of uses shall be subject to that specified in the label, and the Cassette cannot be reused, otherwise, it will lead to tube welding leakage or non-sterile state in the tube.

4) It is required to ensure the working ambient temperature and warm up the machine before each use.

5) In the process of the device operating or cleaning, once liquid (blood, detergent, etc.) has entered into the device, it should be shut down immediately and the technical service personnel should be notified.

6) When the device is working, it is forbidden for operators to contact the upper cover of the device to prevent scald burn risk generated inside the device in

operation.

7) When welding is completed, the clamp will be automatically reset, and attention should be paid to avoid possible injuries to operators caused by the clamp displacement during reset.

8) Liquid is prohibited to splash on the device and no hard object is allowed to invade the device so as to prevent damage.

9) If the blood bag tube is welded, the integrity of welded portion should be checked.

4.2 Contraindications

There is no contraindication and the Sterile Tube Welder shall not be directly used on patients.

Part V: Operations

5.1 The Device Operation

5.1.1 Boot up and enter the boot screen.

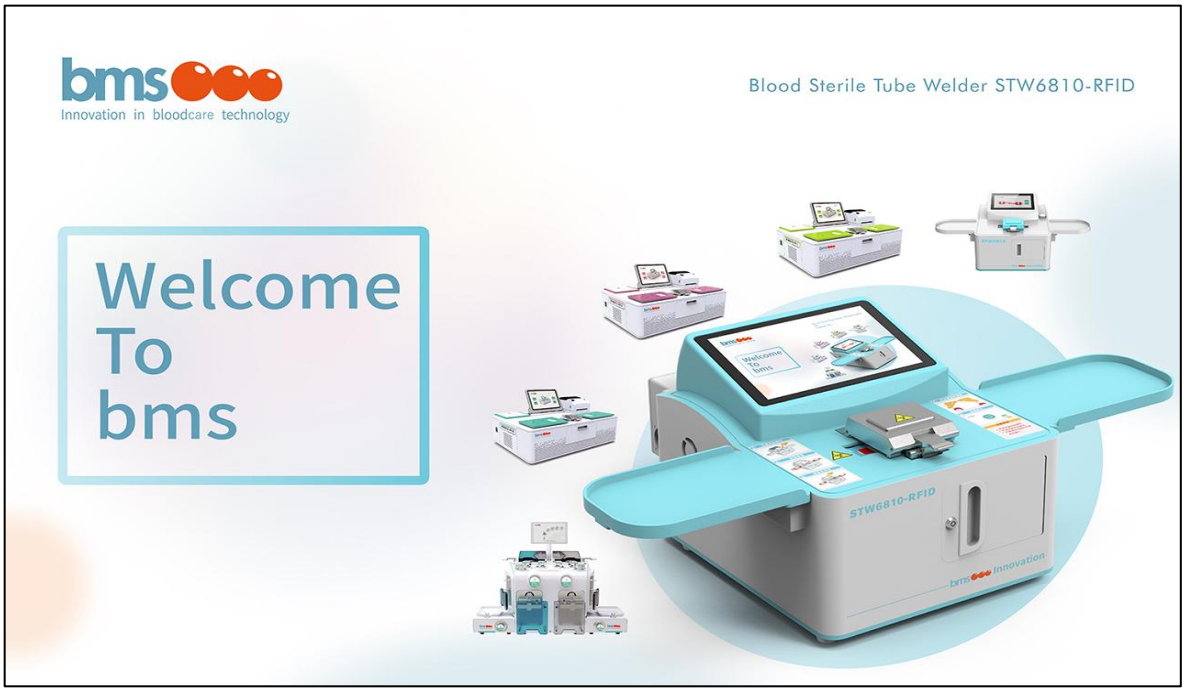

Figure 7

5.1.2 Wait for the device to finish preheating and enter the main interface.

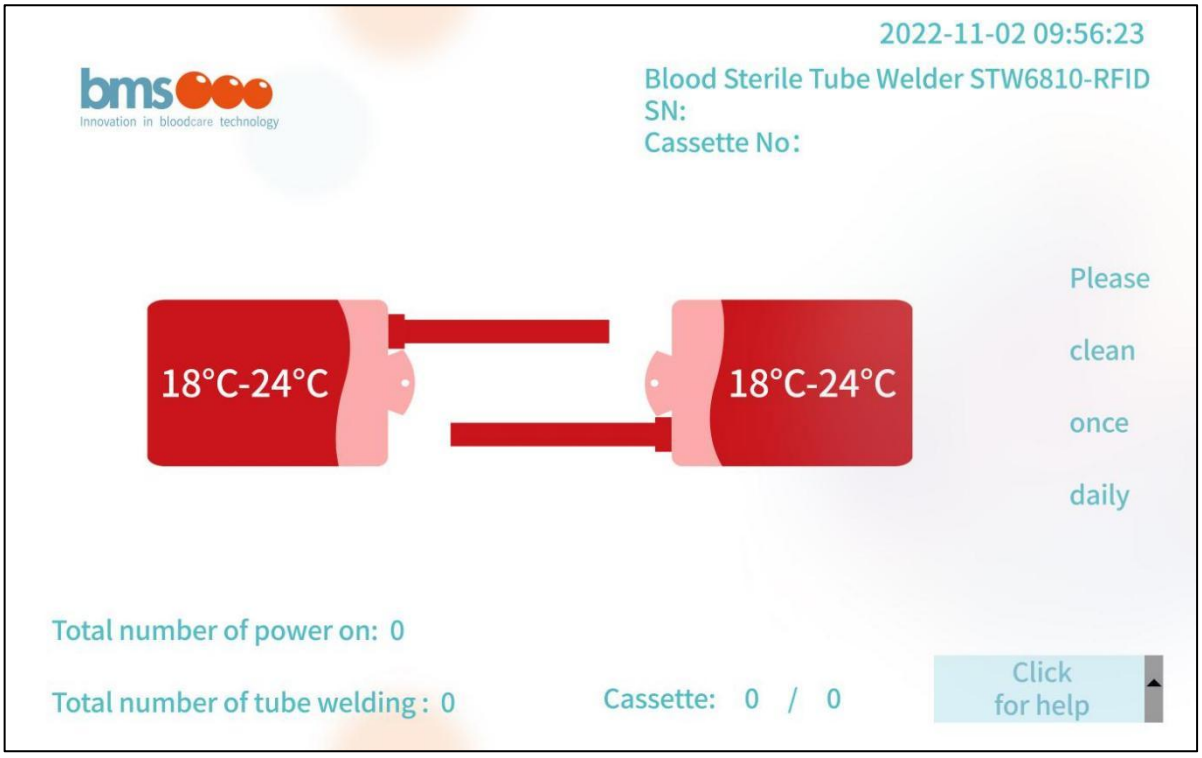

Figure 8

5.1.3 Once the device is warmed up, the tube to be welded shall be well placed, the metal upper cover shall be closed and then the Tube will be automatically welded.

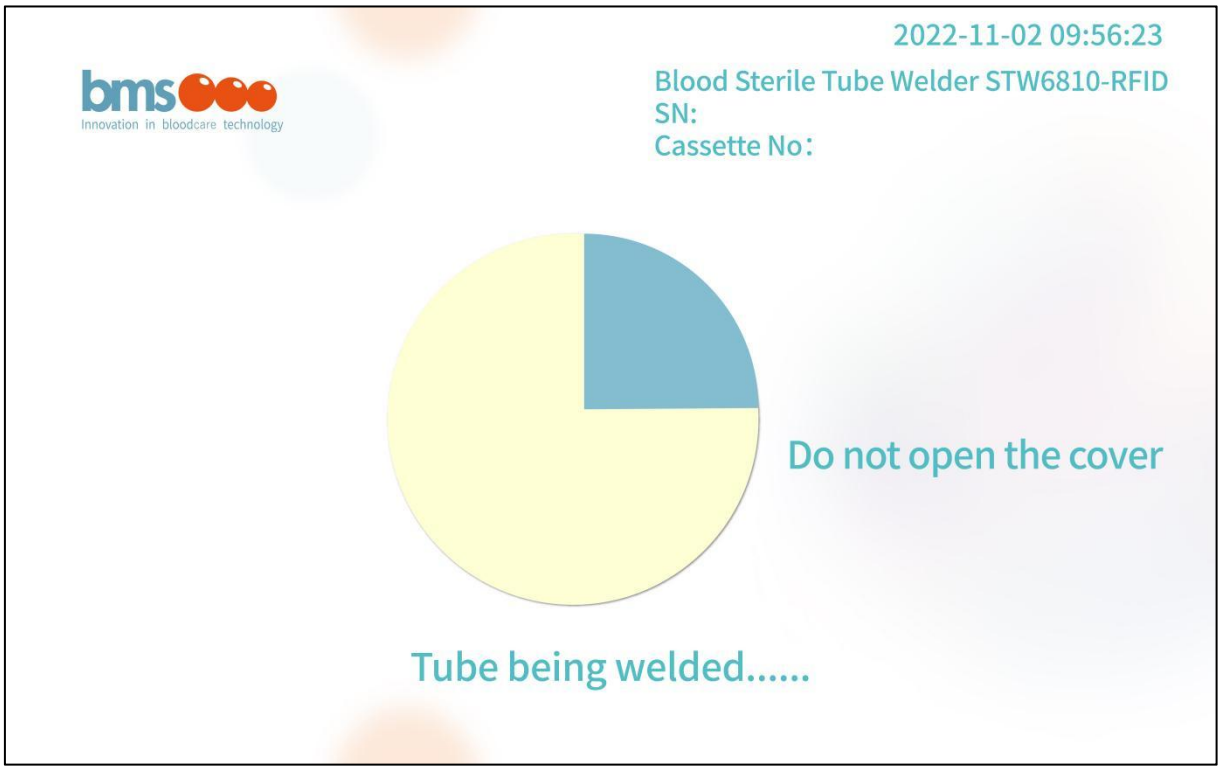

Figure 9

5.1.4 Do Not open the metal upper cover or touch the cover lock in the process of welding.

5.1.5 The tube, once welded, is closed and non-conductive, and the welded portion shall be pinched after the tube is taken out.

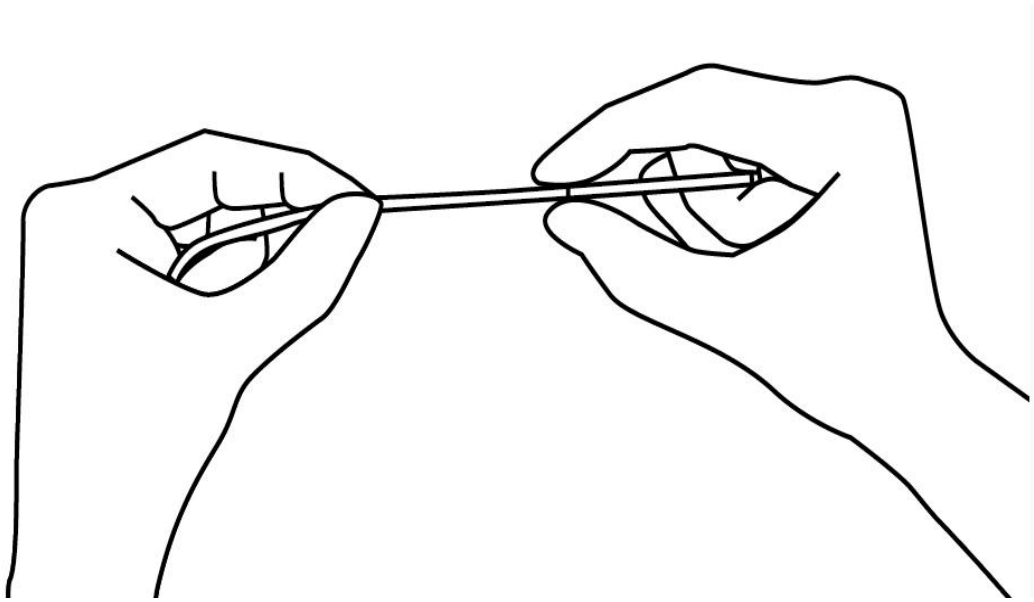

Figure 10

5.1.6 Once the metal upper cover is opened, the left and right clamps will automatically reset within the specified time, and the next welding can be started at any time.

Figure 11

5.1.7 When there is no Cassette in the device or the Cassette is taken out, the following warning will appear.

Figure 12

5.1.8 If the Cassette is exhausted, the following reminder will appear. If appeared, please refer to "5.2 Cassette Replacement" for operation.

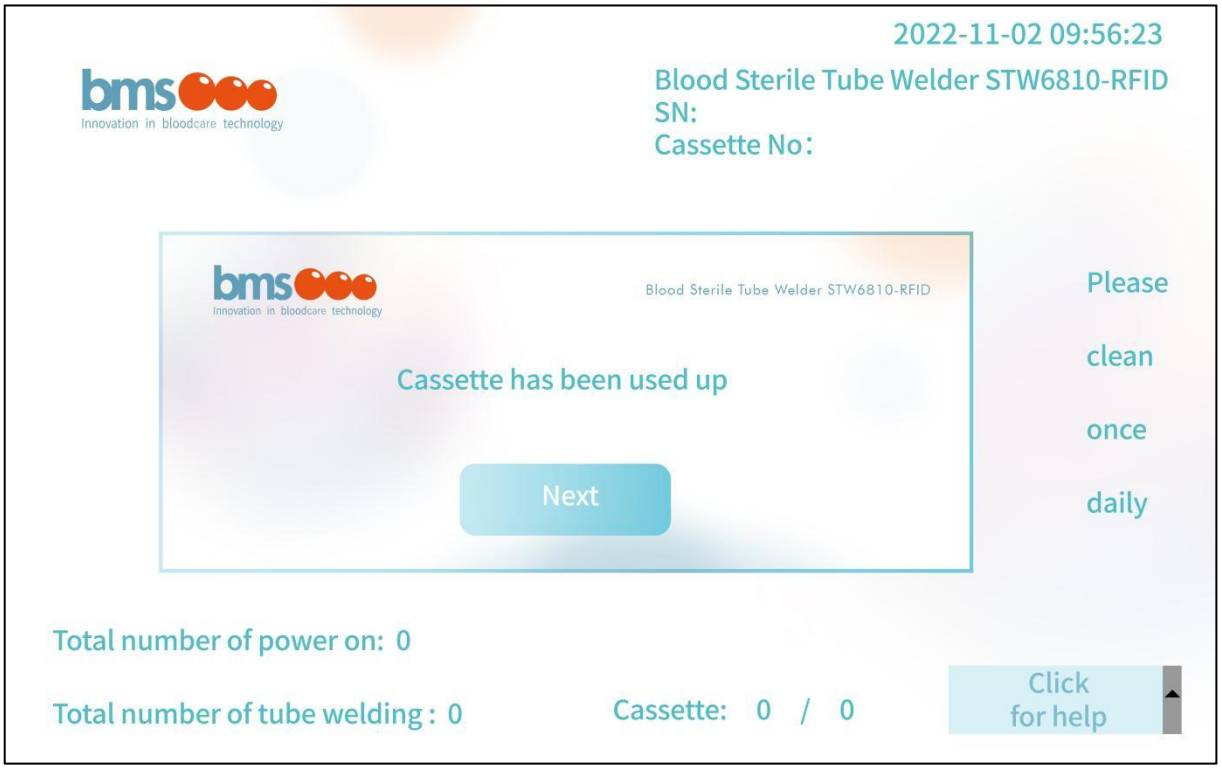

Figure 13

5.2 Cassette Replacement

The Cassette shall be taken as consumables of Sterile Tube Welder STW6810-RFID, the number of uses of single Cassette shall subject to that specified in the label, and it shall be replaced in time in the end of use. The operation methods and steps are detailed as follows:

5.2.1 When the prompt of replacing the Cassette appears in the device interface, open the upper cover and take out the welded pipe, and click "Next".

5.2.2 Open the door (Figure 14-1), lift the fastener up (Figure 14-2), move the Cassette to rightward and take it out (Figure 14-3 and Figure 14-4), and click "Next".

5.2.3 Open a package of new Cassette and install screws. Keep the screw direction rightward, put the Cassette along the card slot and move leftward to the extreme end (Figure 14-5 and Figure 14-6).

5.2.4 Close the door and click "Next".

5.2.5 Please make sure that the wire is clamped into the slot and tightened. Click "Finish" after confirmation. (If the wire is not correctly clamped into the slot, you can push it into the slot with one end of the cotton swab; if the wire is not tightened, you can click on the screen "Tight" for fastening).

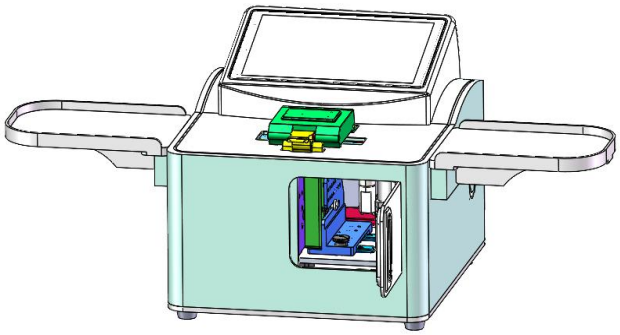

Figure 14-1

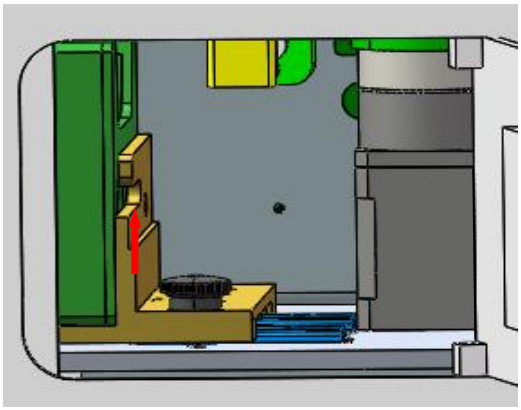

Figure 14-2

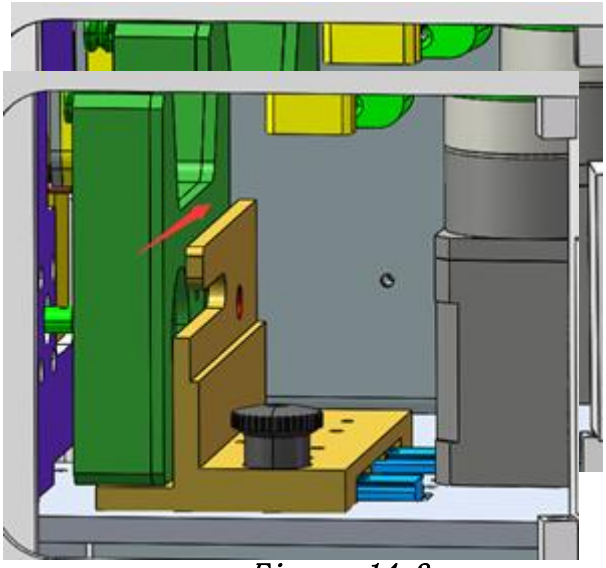

Figure 14-3

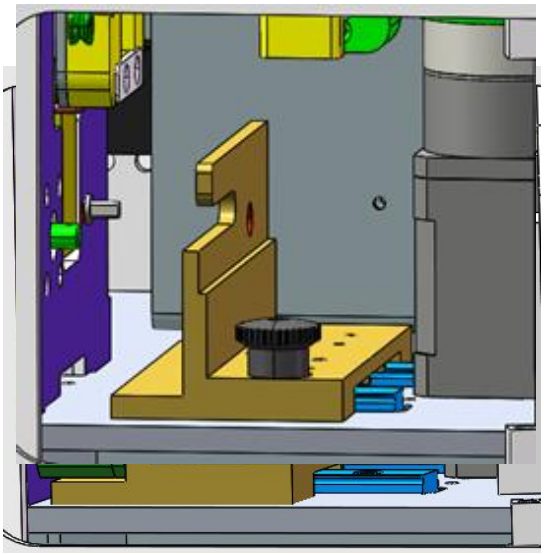

Figure 14-4

Figure 14-5

Figure 14-6

Part VI: Troubleshooting and Routine Maintenance

6.1 Troubleshooting

6.1.1 If the device made no response to clicking due to improper operation or for any other reason, please take out the tube first and then try to restart the device.

6.1.2 To replace the metal wire cassette, you must follow the on-screen instructions step by step.

6.1.3 When replacing the metal wire Cassette, make sure that the metal wire Cassette is closely attached to the internal side wall of the device.

6.1.4 After replacing the metal wire Cassette, please check that the wire in the metal wire Cassette is in a tight state and in the correct position.

6.1.5 After replacing the metal wire Cassette, please check and make sure that the fastener is in the correct position.

6.2 Routine Maintenance

6.2.1 Cleaning and Disinfection:

1) When cleaning and disinfecting the machine surface, turn off the machine and disconnect the power cord from the device.

2) In the process of cleaning, make sure that no liquid flow into the device. If any liquid (blood, blood component or detergent) entered into the device, notify the technical service personnel in time.

3) Clean the surface of the device with wet cloth and neutral cleaner. Do Not use any abrasive and corrosive cleaner, and Do Not use any cleaner or lubricant dissolving plastic; wipe the metal clamp and heating element with medical cotton swab wet by 70%~80% (volume fraction) medical alcohol dips for 2 times for 3min. Do Not use any other strong acidic or strong alkaline detergent.

4) Be cautious of burning danger. Do Not clean the heating element in operation.

5) Before use, check whether the surface of the heating element and the upper and lower clamps are clean. If there is any dirt, use medical alcohol dips to wet medical cotton swab for cleaning; if any dirt is found in the working process, turn off the machine and wipe the heating element and upper and lower clamps after the metal resistance wire and heating element are cooled down.

6) It is recommended to clean once a week and protective gloves should be used for cleaning.

6.2.2 Inspection and Maintenance:

1) bms requires routine inspection and maintenance once every year to ensure safe and trouble-free operation of the device.

2) If the Sterile Tube Welder STW6810-RFID falls, it is highly recommended to maintain and repair even though no surface damage is found.

3) For any maintenance service, please contact Wuhan bms Medicaltech Co., Ltd.

4) Scope of Inspection and Maintenance:

A) Check the safety of electricity consumption in accordance with relevant state regulations.

B) Carefully check the component loss.

C) The device surface cleaning and heating element and clamp surface cleaning.

Part VII: Technical Support

If the user finds any system failure, please contact Wuhan bms Medicaltech Co., Ltd. for inspection and maintenance, and only our company or dealer can provide the parts and components required for maintenance. Please see the after-sale service commitment letter (or warranty card) for the free warranty period. Please describe the problem and provide the serial number of the product if any repair is required, so that the problem can be solved quickly. Follow the procedures below to find the contact information of bms:

1) Click "Help" in the welding interface, you can find our contact information and view the software version of the device (The content is only an example, subject to the actual product interface display).

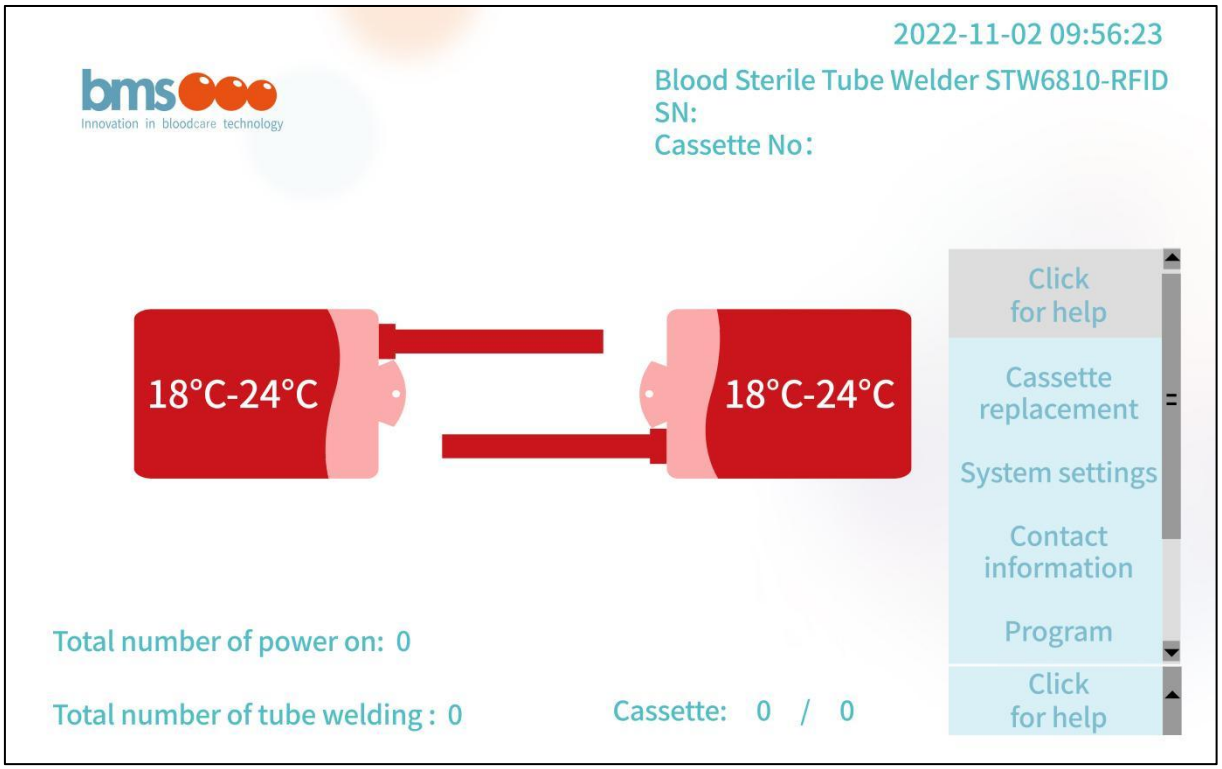

Figure 15

Figure 16

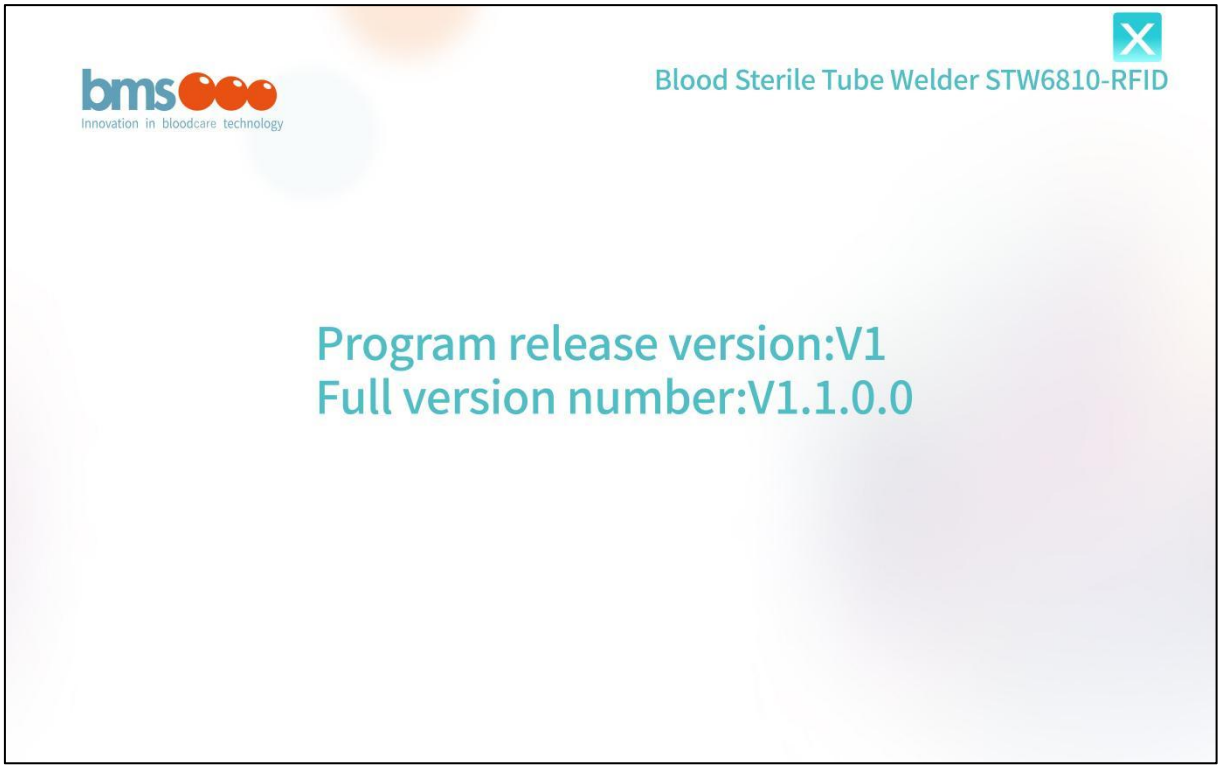

Figure 17

2) Click "System Setting" on the welding interface, you can select the device language and adjust the brightness and sound of screen.

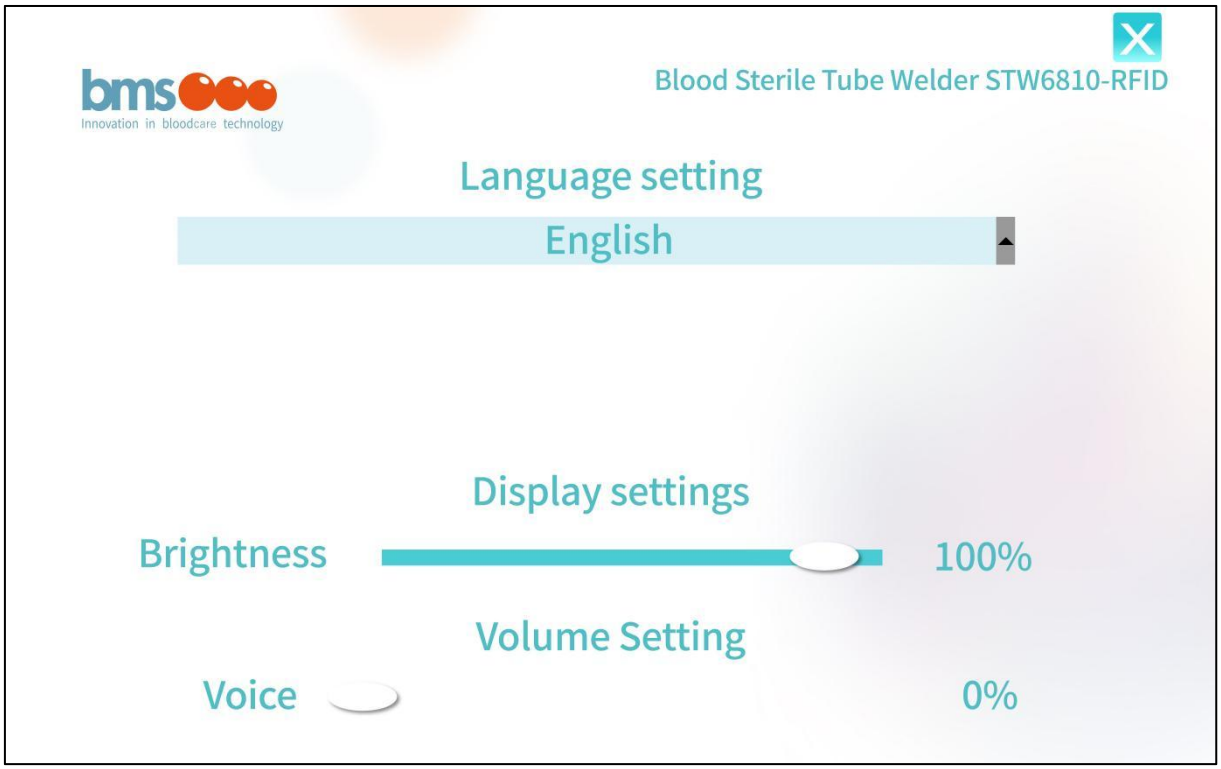

Figure 18

3) Click "Select Program" on the welding interface, you can switch the welding type of the device.

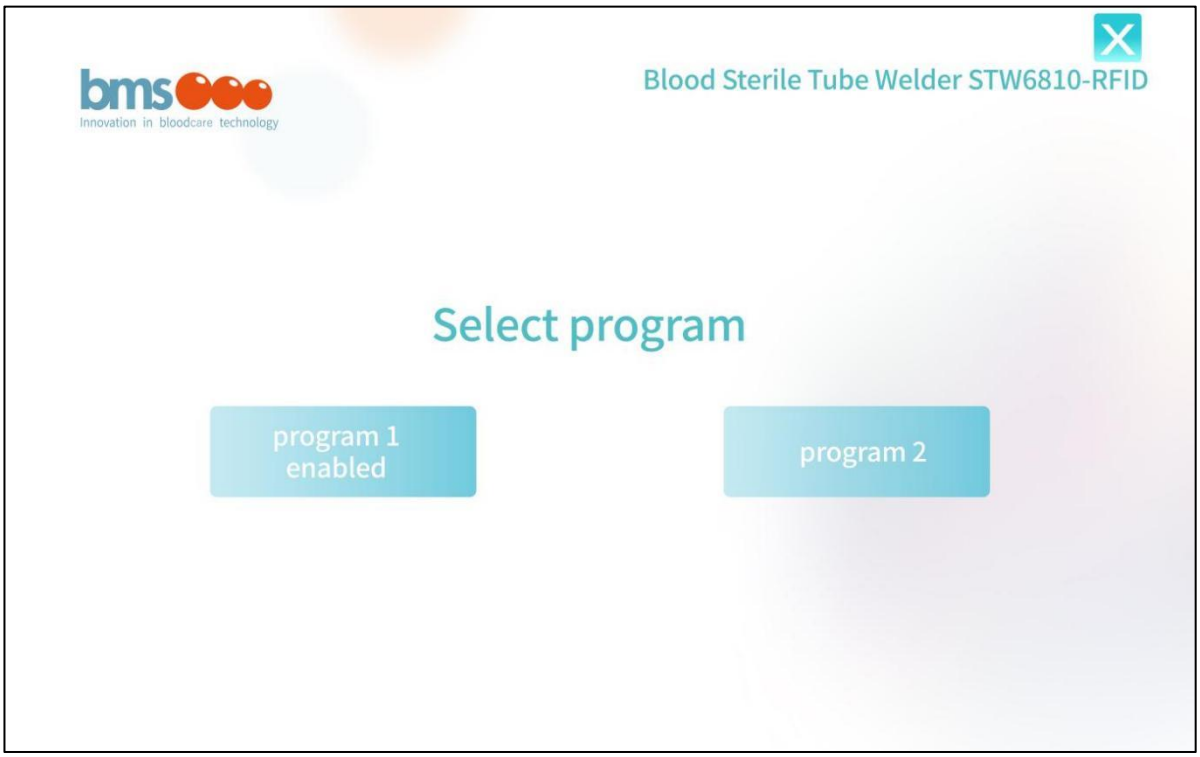

Figure 19

4) For access to the device control background, please contact the manufacturer to obtain the login account and password.


2022-11-02 09:56:23
Blood Sterile Tube Welder STW6810-RFID
SN:
Blood Sterile Tube Welder STW6810-RFID
Please sign in administrator account
Sign in
Cancel
Total number of power on: 0
Total number of tube welding : 0
Cassette: 0 / 0
Click for help

Figure 20

Part VIII: Storage, Transportation, Installation and Disposal

8.1 Storage and Transportation

8.1.1 Storage

- Environmental Conditions: Temperature: -20℃~55℃ and Humidity: 10%~93% (HR); Atmospheric Pressure: 70kPa~106kPa.
- The device should be kept in a well-ventilated room.
- Avoid excessive temperature or humidity during storage and Do Not store in any vibrating place or any place with excessive dust to prevent dust from falling into the device.
- Do Not store in flammable, explosive or highly-corrosive environment.
- Do Not store under ultraviolet radiation for a long time, which will cause fading of the device shell.

8.1.2 Transportation

The device must be transported in the original packing Cassette or packing accessories provided by the manufacturer.

Note

- The device shall be transported in cartons and all packaging materials can be split and reused.
- Packing material in cartons: pearl wool.
- Please check whether each component of the device is damaged and the delivery list is complete or not. If there is any damaged or missing part or component, please call the manufacturer and the supplier.
- Do Not hold the Sterile Tube Welder STW6810-RFID upside down or sideways (no tilt should exceed 60° horizontally).
- Number of stacking layers: no more than 3.

8.2 Installation

- The device is non-mobile and should be placed in the space and worktable meeting the requirement of the working environment; Do Not place the device in any position where it is difficult to operate the disconnector.
- The left and right of the device should be kept at least 10cm away from any other object.

- Try to keep the device well-ventilated; please Do Not block the inlet and outlet vents of the device.
- Before the device is used, the self-contained tray must be inserted into the corresponding vacancies on both sides of the device.

8.3 Working Environment

- Relative Humidity: 10%~70% (no condensation).
- Ambient Temperature: 10℃~30℃.
- Atmospheric Pressure: 70kPa~106kPa.
- Avoid direct sunshining.
- It is recommended to use the device at 18℃~28℃.
- The countertop should be smooth and should not be made of hard material (such as glass and metal).
- The temperature of the metal cover is less than 70℃ during the process of taking over(heating) the device to prevent scalding.

The followings are prohibited from being placed in this device:

- It is forbidden to place any inflammable, explosive and toxic substance around the device.
- If in use, it is forbidden to put any things other than blood bags in the device tray.

8.4 Power Connection

The device contains a detachable AC power cord that is plugged into the power grid. To avoid the risk of electric shock, the device must be connected only to a protected grounded power grid.

Note

- Carefully check the wire and plug before connecting.
- Ensure the power voltage up to specification.
- Insert the plug into the corresponding hole on the power panel.

8.5 Power On/Off

When the external power plug is connected, the device can be turned on/off by the "on/off" switch on the back of the device.

Please disconnect the external power plug of the device once shut down.

8.6 Disposal

When the device's service life is expired, the user shall dispose of it in accordance with relevant local laws and regulations.

Part IX: Safety and Electromagnetic Compatibility Requirements

9.1 Safety Requirements

Safety standards that this device shall meet:

EN 60601-1:2006+A1:2013+A11:2011+A12:2014(IEC 60601-1:2005+2012) *Medical electrical device Part1: General requirements for basic safety and essential performance*

Safety Category: I

Enclosure Protection Class: IPX0

9.2 Electromagnetic Compatibility (EMC)

The Sterile Tube Welder shall comply with the emission and immunity requirements specified in EN 60601-1-2:2015(IEC 60601-1-2:2014) *Medical electrical device – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.*

This device is designed and tested as Category A Device in CISPR 11; in the home environment, this device may cause radio interference, so protective measures shall be taken; it is recommended to evaluate the electromagnetic environment before the device is used.

- It is forbidden to use this device beside strong radiation sources, which may interfere with the normal operation of this device.
- In all cases marked with this symbol, the product instruction manual must be consulted.

As the manufacturer of Sterile Tube Welder, Wuhan bms Medicaltech Co., Ltd. has the responsibility to provide customers and users with the electromagnetic compatibility information of the device in Tables 1 and 2 below.

Users shall ensure the electromagnetic compatibility environment of the device according to the electromagnetic compatibility information provided in the product instruction manual, so that the device can work normally.

Table 1 Information Sheet of Electromagnetic Immunity of this Product

Guidances and manufacturer's statement - electromagnetic immunity			
The Sterile Tube Welder is expected to be used in the following electromagnetic environment, and the purchaser or user shall ensure to use the Sterile Tube Welder in such electromagnetic environment.			
Port	Test Item	EMC Basic Standard	Test Value
Enclosure	ELECTROSTATIC DISCHARGE	IEC 61000-4-2	air: 2kV, 4kV, 8kV, 15kV Contact: 8kV,
	Radiated RF EM fields[a)]	IEC 61000-4-3	3V/m[f)], 80MHz-2.7GHz[b)], 80%AM at 1kHz[c)]
	Rated power frequency magnetic fields[d)e)]	IEC 61000-1-8	3A/m[g)], 50/60Hz
AC power supply	Electrical fast transients/bursts	IEC 61000-4-4	±2kV 100kHz repetition frequency
	Surges Line-to-line	IEC 61000-4-5	±0.5kV, ±1kV
	Surges Line-to-ground	IEC 61000-4-5	±0.5kV, ±1kV, ±2kV
	Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz-80MHz 6V in ISM bands between 0.15 MHz and 80MHz 80% AM at 1kHz
	Voltage dips	IEC 61000-4-11	0% *U*T;1cycle and 70% *U*T;25/30 cycles Single phase:at0°

Table 2 Electromagnetic Emission Information Sheet of this Product

Guidances and manufacturer's statement - electromagnetic emission		
The Sterile Tube Welder is expected to be used in the following electromagnetic environment, and the purchaser or user shall ensure to use the Sterile Tube Welder in such electromagnetic environment.		
RF Emission CISPR 11	Conformity	Electromagnetic Environment -Guidance
RF Emission CISPR 11	Group I	The Sterile Tube Welder will use RF energy only for its internal functions, so its RF emission is very low and there is less possibility of interference to any nearby electronic device.
Harmonic Emission IEC 61000-3-2	Category A	The Sterile Tube Welder is a device used for non-domestic purpose and not directly connected to residential low-voltage power supply network facilities.
Voltage Fluctuation/Flicker Emission IEC 61000-3-3	N.A.	
RF Emission CISPR 11	N.A.	

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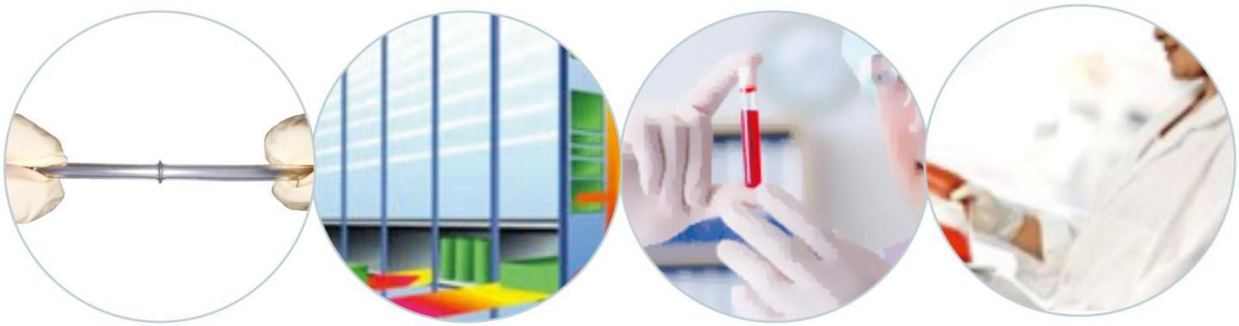

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China

Wuhan bms Medicaltech Co., Ltd

Service Hotline : 86-27-65028187
E-mail : info@bms-bloodcare.com
Add : No. 3 & 4, 5th Floor,B9, Phase I, Block B,Hi-techMedical Devices Park, 818 Gaoxin Avenue , East Lake High-tech Development Zone, Wuhan, China (Wuhan Free Trade Zone)

Germany

bms Medical Technologies GmbH

Add: Medical Valley Center Forchheim, Nürnberger Strasse 62, D-91301 Forchheim, Germany
Email: info@bms-bloodcare.com

Sales partner