en: User Manual

SA10 Portable Controller

For use with Software Version V1

en: User Manual

REF SA10, Portable Controller

Preface

Before use SA10 Portable Controller, please read, understand, and follow the accompanying instructions. And please keep them properly for future reference and equipment maintenance.

This manual is designed to provide instructions for use of SA10 Portable Controller. It is not a reference to surgical techniques. Please visit www.snssurgical.com.cn/en/support for the latest version of this manual.

To understand and complete tasks in a safe and thorough manner throughout this manual, please pay attention to those instructions provided in the form of a Warning, a Precaution, or a Note statement.

Warning

- A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in serious adverse reaction, potential safety hazards, personal injury or even loss of life.

Precaution

- A Precaution statement indicates an operating or maintenance procedure, practice, or condition that should be exercised with any special care in order to use safely and effectively, and, if not strictly observed, could result in damage to or destruction of the equipment, and/or harm to environment.

Note

- A Note statement indicates an operating or maintenance procedure, practice, or condition that is necessary to accomplish a task efficiently.

Customer Service

The service of the Portable Controller shall be conducted by the service engineers/technicians on behalf of or authorized by Shanghai Saints Sages Surgical Co., Ltd. Refer to Section 8 for the details of service and warranty.

Electric Shock

- To avoid the risk of electric shock, the Portable Controller must only be connected to a supply main with protective earth.
- Untrained service engineer and technician are not allowed to open the Controller chassis.
- Connect the Controller power cord to a properly grounded power receptacle. Do not use power plug adapters.
- Do not connect wet instruments to the Controller. Ensure that all instruments and adapters are connected correctly and that no metal is exposed at any connection points.
- Connect and disconnect adapters and accessories to the Controller only when the energy is off. Failure to do so may result in injury or electric shock to the patient or operating room personnel.
- Use only CO_2 extinguisher in case of a fire on the Controller. Spraying with water or other liquid extinguisher can induce the serious personal injury. Power off the Controller before extinguishing to avoid electric shock.

The Controller and accessories must not be disposed in trash at the end of life with other waste. They may contain hazardous substances that can cause serious environment pollution. Dispose of this product according to local regulation.

Rx ONLY Precaution: Federal (USA) law restricts this device to sale by or on the order of a physician.

This user manual is for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using SA10 Portable Controller.

Equipment covered in this manual

REF SA10, Portable Controller

Compatible devices for use with SA10 Portable Controller

REF SASD45, SanAgile™ Advanced Dissector, 5.5mm, 45cm, Curved

SASD36, SanAgile™ Advanced Dissector, 5.5mm, 36cm, Curved

SASD23, SanAgile™ Advanced Dissector, 5.5mm, 23cm, Curved

SASD14, SanAgile™ Advanced Dissector, 5.5mm, 14cm, Curved

SAS45, SanAgile™ Dissector, 5.5mm, 45cm, Curved

SAS36, SanAgile™ Dissector, 5.5mm, 36cm, Curved

SAS23, SanAgile™ Dissector, 5.5mm, 23cm, Curved

SAS14, SanAgile™ Dissector, 5.5mm, 14cm, Curved

Please refer to the Instruction for Use of SanAgile™ Advanced Dissector and SanAgile™ Dissector for the details on the compatibility.

Table of Content

1 Overview

1.1 Product Characteristics

SA10 Portable Controller is a compact portable generator and provides power to drive SanAgile™ dissectors for dissection, coagulation, and cutting tissues in open or laparoscopic procedures.

SA10 Portable Controller is designed to cut and coagulate the tissue through activating two setting from the compatible dissector. The MAX setting is designed for dissection and the MIN setting is for coagulation. The clinical intended use is achieved by the surgeon when pressure is applied to tissue placed between the Clamp Jaw and the exposed portion of the Tissue Blade while ultrasonic energy is activated through the use of two output power settings.

The Controller transforms the electrical energy into a high frequency of approximately 55.5 kHz, which is converted into an ultrasonic wave pulse via a transducer core within the Advanced Dissector. This pulse vibrates the tissue blade and produces heat in the tissue.

When coagulating the vessel, the jaw clamping force grasps the tube walls on both sides of the vessel, and the thermal effect caused by dissector friction denatures the collagen in the tube walls on both sides, forming irreversible cross-linking, hence occludes the blood vessels for a permanent fusion.

When cutting the tissue, the cavitation effect caused by high-frequency vibration accelerates the vaporization of heated water in the tissue cells in contact with the dissector, breaks the protein hydrogen bonds and disintegrates the cells, so that the tissue is divided.

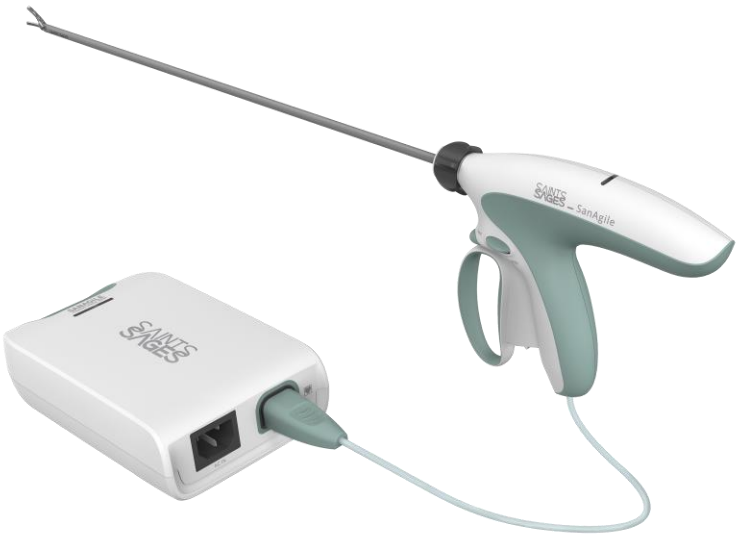


Figure 1：SA10 Portable Controller with SanAgile™ Advanced Dissector

1.2 Devices and Components

SA10 Portable Controller can use with a series of SanAgile™ Advanced Dissector. The equipment covered in this manual refers to SA10 Portable Controller.

Please refer to the Instructions for Use of SanAgile™ Advanced Dissector for the details on the compatible dissector.

1.3 How Supplied

Only the User Manual, Quick Reference Guide and power cord will accompany the Controller in a shipping package. Service manual is provided on website, the paper verison of which is available upon request.The compatible SanAgile™ Advanced Dissector is supplied separately and must be purchased before the surgery. Please ensure to purchase the compatible dissectors listed in the Preface of this User Manual for the clinical use.

Note:

- The Controller supports only the compatible SanAgile™ Advanced Dissectors. The use of any incompatible dissectors and accessories may not result in the desired clinical effect of SanAgile™ portfolio. Please do not use the incompatible dissectors and/or accessories

with this Controller.

1.4 Intended Purpose

SA10 Portable Controller is intended to seal and cut vessels and/or to dissect, coagulate and cut soft tissue via ultrasonic oscillation.

1.5 Indications for Use

SA10 Portable Controller is intended to provide power to drive SanAgile™ Ultrasonic Surgery Advanced Dissectors that are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired.

1.6 Contraindications

- SA10 Portable Controller is not indicated for incising bone.
- SA10 Portable Controller is not intended for contraceptive tubal occlusion.

1.7 General Warning

- Do not use in patients who have electronic implants such as cardia pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- Do not use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen or in close proximity to volatile solvents such as ether or alcohol, as explosion may occur.
- Do not place SA10 Portable Controller near or in contact with flammable materials such as gauze or surgical drapes. Instruments that are activated or hot from use may cause a fire.
- Portable and mobile RF communications equipment in the proximity may affect the performance of the equipment. Refer to the EMC information provided in Section 6 of this manual.
- Visually inspect SA10 Portable Controller, components and the compatible accessories for breaks, cracks, nicks, or other damage. Do not use damaged components. Use of damaged components may result in injury to the patient or operator.
- After the Controller is powered on, contacting the Clamp Jaw or Tissue Blade of the dissector is prohibited.

- Avoid accidental activation when attaching dissector to the Controller. Accidental activation of the dissector can cause serious injury to the patient or surgical team.
- Do not activate the dissector when not in contact with target tissue, as this may cause injuries.
- As with all energy sources (Electrosurgery, Lasers, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- When not using SA10 Portable Controller, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

Infection hazard:

- Non-sterile Controller will contaminate the sterile field and place the patient at risk for infection.
- Controller is provided non-sterile and must be cleaned and disinfected prior to first use and each re-use. Refer to Section 4 for the parameters in reprocessing the Cleaning and Disinfection.

1.8 General Precaution

- Use only SanAgile™ Advanced dissectors with SA10 Portable Controller. Devices and components from other manufacturers are not compatible with SA10 Portable Controller and may cause injury to the patient and user.
- Do not activate the Controller while cleaning and disinfection. Injury to operating room personnel may result.
- No modification of the instruments is allowed.
- Modification or opening of the Controller invalidates the warranty and could create hazardous conditions.

2 Operation Instruction

2.1 SA10 Portable Controller

Figure 2: SA10 Portable Controller

1	Power Cord Receptacle (AC IN Port)	Receptacle used to attach the power cord to the Controller.
2	Instrument Receptacle (Dissector Port)	Used to attach the instrument to the Controller.
3	Controller Status LED	Displays the Controller status.

2.2 Setup

2.2.1 Overview

2.2.1.1 The Controller can be activated by the dissector.

2.2.1.2 The MAX setting is designed for dissection and can be activated from MAX button of the dissector. The MIN setting is designed for coagulation and can be

activated from MIN button of the dissector.

2.2.1.3 The Controller provides the Controller Status LED to indicate the Controller status.

2.2.2 Controller Status LED

The Controller Status LED color indicates the operational status of the SA10 Portable Controller.

Green Light	Red Light
When plug in the Controller, the Controller runs the self-check. Once it succeeds, the Controller Status LED illuminates green with breathing (Controller Status LED repeats from off to green), and ready for use.	When the Controller fails in running a self-check, or detects an error, the Controller Status LED illuminates red without flashing. Please plug in the power cord again to the Controller.

Note
When the Controller Status LED keeps off after plug in, please check the power cord. After plug in the power cord again, if the LED is still off, please replace a new power cord, or contact Saints Sages for the technical support. See the contact details in Section 8 **Service and Warranty**.

Figure 3: Indicator Status

2.3 Connecting dissector to Controller

Precaution

- The dissector jaws may remain open when in the package. Do not try to close the jaws during the assembly.

2.3.1 Examine the Controller and Advanced Dissector for damage. Do not use the damaged devices. If the package of dissector is damaged or unintentionally opened, please replace with a new dissector.

2.3.2 Secure the Controller on a cart, if available, or any other suitable fixture in the appropriate position. The Controller can also be hung to cantilever support of boom system or cart with strap or hook.

2.3.3 Hold the Controller in one hand, connect the power cord to the Power Cord Receptacle (AC IN Port) on the Controller and to a grounded electrical outlet. The power requirements for the Controller are listed in Section 5 **Technical Specification** of this manual.

2.3.4 After the power cord is connected to the Controller, the Controller runs the self-test. The Controller Status LED illuminates green with breathing when the self-test succeeds.

2.3.5 Hold the Controller in one hand, connect the Dissector Plug (1) into Instrument Receptacle (Dissector Port) (2) on the Controller.

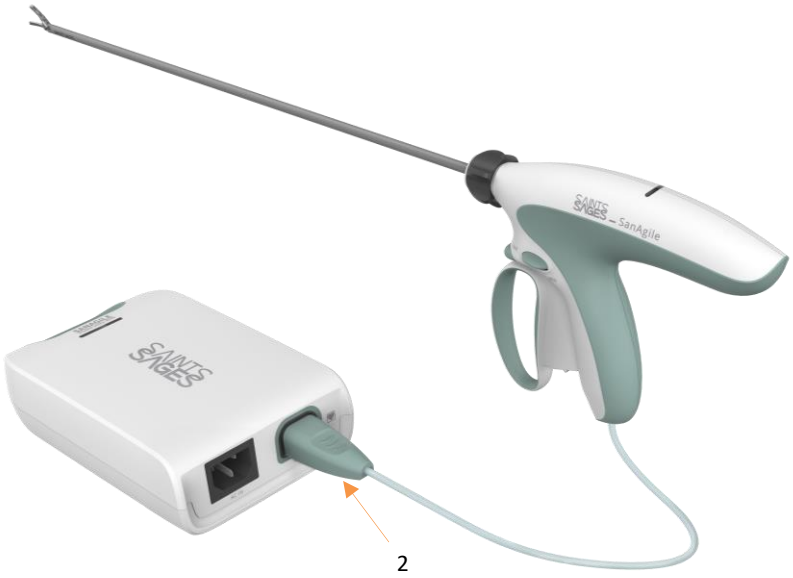


Figure 4: Connecting dissector to Controller

2.4 Operation

Precaution

- Verify that the Controller is secured to a cart or any other suitable fixture or hung to cantilever support of boom system or cart with strap or hook before powering up.
- Verify the connection between the Controller and Advanced Dissectors are secured and ready for use.

2.4.1 Prior to the surgery, keep the jaws open, press MAX and MIN Buttons of the dissector respectively to check the audio feedback and Dissector Status LED works. Refer to the Instructions for Use of the Advanced Dissector for the illustration of Dissector Status LED.

2.4.2 Close the jaws by pressing the Clamp Jaw Lever if the jaws remain open and push the dissector shaft into a trocar of the diameter > 5 mm or incision.

2.4.3 Open the jaws until the dissector shaft is fully inserted.

2.4.4 The dissector shaft can be rotated 360° using the Rotation Wheel to facilitate visualization and access to the target tissue.

Warning

- Avoid contact with any or all metal or other hard objects when the Controller is activated. Contact with staples, clips, or other instruments while the Controller is activated and energy is delivered may result in scratches on the blade, cracked or broken

blades and premature blade failure.

Note

- Through the study, SA10 Portable Controller has been verified for a quick soft tissue dissection using the MAX setting, and the coagulation of isolated vessels up to and including 7mm in diameter using the MIN setting when connecting to SanAgile™ Ultrasonic Surgery Advanced Dissector. The study data is available within Saints Sages.

2.5 Disconnecting dissector from Controller

2.5.1 Close the jaws by pressing Clamp Jaw Lever and remove the shaft from trocar.

2.5.2 Unplug the Dissector Plug and the power cord from the Controller.

2.5.3 Discard the dissector in an appropriate container and dispose it according to the applicable local regulation.

3 Patient and Operation Room Safety

3.1 Before a Procedure

Precaution

- Use only SanAgile™ Advanced Dissector with SA10 Portable Controller. Devices from other manufactures are not compatible with SA10 Portable Controller and may cause injury to the patient and the operator.

3.1.1 Visually inspect the Controller and Advanced Dissector for breaks, cracks, nicks, or other damage. Do not use damaged components. Use of damaged components may result in injury to the patient or user.

3.1.2 Visually check the assembly and connection are secured, ensure both the Controller self-test and Advanced Dissector self-test are completed before the procedure.

3.1.3 Controller is provided non-sterile and must be cleaned and disinfected prior to first use and each re-use. Refer to Section 4 **Cleaning and Disinfection** for the details.

3.1.4 Controller must be separated from other equipment. Do not put any articles on the top of the Controller.

3.1.5 Ensure the availability of backup dissector and Controller in case of the failure.

3.2 During a Procedure

3.2.1 Tissue Pad damage may occur if the dissector is activated without tissue in the closed jaws. Activation without tissue between the jaws will cause tissue pad

degradation.

3.2.2 Avoid contact with the dissector jaws when the Controller is activated. Do not contact with any or all metal or other hard objects, or bone during the activation.

3.2.3 Place the vessel or tissue in the center of the jaws when using SanAgile™ Ultrasonic Surgery Advanced Dissector to assure optimal hemostatic effect. Do not place issue in the jaw hinge. Do not drag the tissue.

3.2.4 Stop the activation immediately after vessel sealing and cutting are complete.

3.3 After a Procedure

3.3.1 Clean and disinfect the Controller according to the instructions provided in Section 4 **Cleaning and Disinfection** in this manual.

3.3.2 When not using the Controller, place it in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in injury.

4 Cleaning and Disinfection

SA10 Portable Controller is designed for multiple patient multiple use, hence requires cleaning and disinfection prior to each use. Before cleaning, power off the SA10 Portable Controller, unplug the power cord from the grounded electrical outlet, and then thoroughly inspect the SA10 Portable Controller for any signs of damage, cracks, or improper mechanical function. Do not use the SA10 Portable Controller if there are signs of damage. Discard it or send it to an authorized service facility for replacement where appropriate if damage or degradation is present.

Warning

- The Portable Controller is not waterproof. Make sure the Controller is kept away from other liquids to prevent splashing.
- Spilling or spraying fluids on or into the Controller or immersing the Controller may result in damage to the device and create a risk of electric shock or fire.

Precaution

- Do not activate the energy while cleaning and disinfection. Injury to operating room personnel may result from the malfunction of the Controller.

Note

- The operator must qualify cleaning effectiveness when deviating from the instructions in this manual.
- Do not clean the Controller with abrasive cleaning or disinfectant compounds, solvents or other materials that could scratch the panels or damage the Controller.
- Do not open or remove the enclosure of SA10 Portable Controller. Opening or removing the enclosure voids the warranty and will damage to the Controller.
- The hospital is responsible for ensuring the Controller has an electrical safety check performed by the qualified service engineer once a year.

4.1 Cleaning

Proceed with cleaning as follows:

- Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions. The following detergent is approved for use with the Controller:

  CIDEZYME® XTRA, dispense 8 ml per liter of water as required.
- Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
- Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
- Dry with a soft, clean cloth.

4.2 Disinfecting

- If the Controller becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectant is approved for use with the Controller:

  Cidex OPA.
- Wipe the surfaces. Make sure the surfaces are treated uniformly.
- Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.
- Clean surfaces contaminated with blood before using the disinfectant. Otherwise, it may be less effective.

- Within the applied decontamination process, ensure that the detergent or disinfectant residuals are completely removed after wiping down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

5 Technical Specification

Protection Against Electric Shock	Class I, CF	
Ingress Protection Rating	IP20	
Main Input	100-240V~，50/60Hz, 100VA	
Output	Drive Frequency	55.5kHz ± 2% (Both Max and Min)
	Max. Electrical Power (Pmax)	35W ± 10%
	Power Reserve Index (Pi)	>4
Operation Conditions	Ambient Temperature	10℃～40℃；
	Relative Humidity	30%-75%, no condensing
	Atmosphere Pressure	700hPa～1060hPa
Transport and Storage Conditions	Ambient Temperature	-20℃～55℃
	Relative Humidity	20%～80%, no condensing
	Atmosphere Pressure	700hPa～1060hPa
Dimension (L×W×H)	Controller	19.0cm×12.0cm×5.2cm
Weight	Controller	<1Kg
Power Cord	3m	
Duty Cycle (Mode of Operation)	Intermittent 20s	

Under maximum power settings and rated load conditions, the assembled Controller is capable of operating at a duty cycle of 50% in any mode throughout the operation.

6 Electromagnetic Compatibility (IEC 60601-1-2)

6.1 Important information

SA10 Portable Controller conforms to IEC 60601-1-2:2014+A1:2020 standard for both immunity and emission. It requires special warnings and precautions regarding electromagnetic compatibility (EMC) and put into service according to the EMC information provided in this manual.

The equipment is intended for use in the electromagnetic environments specified below. Nevertheless, special warnings and precautions need to be observed.

The equipment with following ESSENTIAL PERFORMANCE is intended to be used in professional healthcare facility environment except for the RF shielded room of a medical device system for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

ESSENTIAL PERFORMANCE:

EP1	Energy outputs when the activation buttons are triggered and stops when released.
EP2	The LED indicators and audible tones are coupled with energy output.

Warning:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Statement

- The equipment is designed compatible with high frequency surgical equipment. The condition includes working or standby in close proximity to high frequency surgical equipment.

Warning

- The use of accessories other than those specified in the User Manual and the compatible device Instructions for Use may result in increased emissions or decreased immunity of the equipment.

Below cable information is provided for EMC reference.

Cable	**Max. cable length, Shielded/unshielded**		**Number**	**Cable Classification**
AC Power Cord	3.0m	Unshielded	1 set	AC Power

6.2 Guidance and Manufacturer's Declaration

Table 1 - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic environment - Guidance**
RF Emission CISPR 11	Group 1, Class A	The equipment is suitable for use in a professional healthcare facility environment. **Precaution:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance	

Table 2 – Enclosure Port			
Immunity Test	**Immunity Test Level**	**Compliance Level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	The equipment is suitable for use in a professional healthcare facility environment.
Radiated RF Electromagnetic Field IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to table 3	Refer to table 3	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	

Table 3 – Proximity fields from RF wireless communications equipment			
Test Frequency (MHz)	**Band [a] (MHz)**	**Modulation [b] (Hz)**	**Immunity Test Level (V/m)**
385	380-390	Pulse modulation 18Hz	27
450	430-470	FM [c] ±5kHz deviation, 1kHz sine	28
710	704-787	Pulse modulation 217Hz	9
745			
780			
810	800-960	Pulse modulation 18Hz	28
870			
930			

1720	1700-1990	Pulse modulation 217Hz	28
1845			
1970			
2450	2400-2570	Pulse modulation 217Hz	28
5240	5100-5800	Pulse modulation 217Hz	9
5500			
5785			

Note: If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and SA10 Portable Controller may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some service, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it does not represent actual modulation, it would be worst case.

Table 4 – Input a.c. Power Port

Immunity Test	**Immunity Test Level**	**Compliance Level**	**Electromagnetic environment - Guidance**
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100kHz repetition frequency	± 2 kV 100kHz repetition frequency	The equipment is suitable for use in a professional healthcare facility environment.
Surge Line to line IEC 61000-4-5	± 0.5 kV, ±1 kV	± 0.5 kV, ±1 kV	
Surge Line to ground IEC 61000-4-5	± 0.5 kV, ±1 kV, ±2 kV	± 0.5 kV, ±1 kV, ±2 kV	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%AM at 1kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%AM at 1kHz	

Voltage dips IEC 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycles	0% UT; 250/300 cycles	

Table 5 – Signal Input/Output Port			
Immunity Test	**Immunity Test Level**	**Compliance Level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	The equipment is suitable for use in a professional healthcare facility environment.
Electrical fast transient/burst IEC 61000-4-4	± 1 kV 100kHz repetition frequency	± 1 kV 100kHz repetition frequency	
Surge Line(s) to Ground: IEC 61000-4-5	± 1 kV	± 1 kV	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%AM 100kHz repetition frequency	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%AM 100kHz repetition frequency	

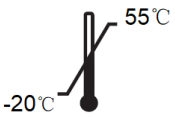
Table 6 – Patient Coupling Port			
Immunity Test	**Immunity Test Level**	**Compliance Level**	**Electromagnetic**

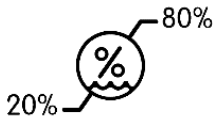
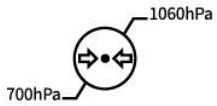
			environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	The equipment is suitable for use in a professional healthcare facility environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%AM 100kHz repetition frequency	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%AM 100kHz repetition frequency	

Table 7 – Proximity Magnetic Fields		
Test Frequency	**Modulation**	**Immunity Test Level (A/m)**
134.2 kHz	Pulse Modulation [b)] 2,1 kHz	65 [c)]
13.56 MHz	Pulse Modulation [b)] 50 kHz	7.5 [c)]
b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s, before modulation is applied.		

7 Symbols

No.	Symbols	Meaning
1		Type CF Applied Part
2		Non-ionizing Electromagnetic Radiation
3		Explosion Risk if Used with Flammable Anesthetics

No.	Symbols	Meaning
4		Electric Shock. Do Not Remove the Cover
5		Alternating Current
6		Refer to Instruction Manual / Booklet
7		Manufacturer
8		Authorized Representative in the European Community/European Union
9		Importer
10		Consult the User Manual or Instructions for Use
11		Serial Number
12		Country of Manufacture /Date of Manufacture
13		Medical Device
14		Temperature Limitation: -20℃～55℃

No.	Symbols	Meaning
15		Humidity Limitation: 20%～80%
16		Atmospheric Pressure Limitation: 700hPa ~ 1060hPa
17	REF	Catalogue Number
18	UDI	Unique Device Identifier
19	Rx ONLY	For Prescription Use Only
20	CE 0297	CE Mark with Notified Body Number
21		Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU.
22	IP20	Ingress Protection Rating
23		Quantity: 1
24		Environmental Protection Use Period

No.	Symbols	Meaning
25		This way up
26		Fragile, handle with care
27		Keep dry
28		NRTL Mark with SGS Contract Number
29		INMETRO Seal with OCP number

8 Service and Warranty

Periodic calibration is not required for SA10 Portable Controller. If the Controller is not used for over half a year, plug the power cord to the Controller for at least 30 mins before the procedure.

Saints Sage warrants each device listed below to be free from defects in material or manufacture for normal use and service for the period set forth below. Saints Sages' obligation under this warranty is limited to the replacement, at its sole option, of any product, or part thereof, which has been returned to it (or its authorized distributor) within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to the satisfaction of Saints Sages, that the product is defective.

- Controller and power cord: one year

Notwithstanding any other provision herein or in any other document or communication, Saints Sages' liability with respect to this limited warranty and the products sold hereunder shall be limited to the aggregate purchase price for the products sold to the customer. This limited warranty is nontransferable and runs only to the original purchaser of the covered product(s). There are no warranties which extend beyond the terms hereof. The device will be replacement at the cost of the original purchaser beyond the warranty period. Saints Sages serves the right to make changes to products built and/or sold by it (or its authorized distributor) at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

Incident Reporting

Any serious incident that has occurred in relation to this device should be reported to Saints Sages and the competent authority of the European Union member state in which the user and/or patient is established.

Technical Support

For additional information about the use of the devices hereof, consult Service Manual or contact Saints Sages at one of the following.

Service Hotline: +86-4006196507

Email: service@snssurgical.com.cn

www.snssurgical.com.cn

9 Environmental Safety

9.1 EU 2011/65/EU (RoHS)

The Controller and accessories have been assessed and/or tested in a typical configuration as described in this user manual in accordance with the Directive and standards listed below:

- EU Directive 2011/65/EU and amendments
- EN IEC 63000:2018

9.2 REACH

The EU REACH Regulation 1907/2006 requires to provide chemical content information for Substances of Very High Concern (SVHC), if they are present in the relevant article above a concentration of 0.1% weight by weight. Information on substances, contained in the Controller and accessories, can be found on the website: www.snssurgical.com.cn/en/support.

9.3 Disposing of SA10 Portable Controller

SA10 Portable Controller and accessories must not be disposed in trash at the end of life with other waste. They may contain hazardous substances that can cause serious environment pollution. To recycle waste equipment, obtain instructions from Saints Sages Service Hotline (+86-4006196507), contact your local sales representative or dispose of this product according to local regulation.

9.4 China RoHS Compliance (applies to China only)

Hazardous Substances Table

部件名称 (Component)	**有毒有害物质或元素 (Toxic and Hazardous Substances or Elements)**					
	铅 (Pb)	**汞 (Hg)**	**镉 (Cd)**	**六价铬 (Cr(VI))**	**多溴联苯 (PBB)**	**多溴二苯醚 (PBDE)**
印刷电路板包含定制器件 (Main PCBA including customized components)	O	O	O	O	O	O
LED 显示 (LED Display)	O	O	O	O	O	O
电源模块 (PSU)	×	O	O	O	O	O
金属部件(含散热片) (Metal Parts including cooling fin)	O	O	O	O	O	O

部件名称 (Component)	有毒有害物质或元素 (Toxic and Hazardous Substances or Elements)					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr(VI))	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
电源线 (Power Cord)	O	O	O	O	O	O
塑料部件 (Plastic Parts)	O	O	O	O	O	O
硅橡胶部件 (Rubber Parts)	O	O	O	O	O	O
线缆组件 含连接器 (Cable Assembly including Connectors)	×	O	O	O	O	O
紧固件 (Fasteners)	O	O	O	O	O	O

O：表示该有毒有害物质在该部件所有均质材料中的含量，按照组成单元EEP-A，EEP-B，EEP-C的分类，均在GB/T 26572规定的限量要求以下。

O: indicates that the content of the toxic and hazardous substance in all the Homogenous Materials of the part, according to EEP-A, EEP-B, EEP-C, is below the concentration limit requirement as described in GB/T 26572.

X：表示该有毒有害物质至少在该部件的某一均质材料中的含量，按照组成单元EEP-A, EEP-B，EEP-C的分类，超出GB/T 26572规定的限量要求。

X: indicates that the content of the toxic and hazardous substance in at least one Homogenous Material of the part, according to EEP-A, EEP-B, EEP-C, exceeds the concentration limit requirement as described in GB/T 26572.

重要事项/Importance:

产品标签上的环保使用期限/ Environmental Protection Use Period, EPUP

本标识表示在此期间内，在正常工作条件下，产品中所含有毒或危险物质或成分不会发生泄露和变异。因而此类产品的使用不会导致任何严重的环境污染、任何人身伤害或财产损失。不应将此期间视为保修期或保证有效期。标签上带有污染控制标志的产品是可回收的。请根据当地法规要求进行处理。

This symbol indicates that within the specified EPUP, any toxic and hazardous substances or elements contained within the device will not be disclosed and varied under the normal operation condition; hence the use of this device will not lead to serious environmental pollution, personal injury or property damage. It shall not be regarded as a warranty term or guarantee period. Any device label containing this symbol indicates the device can be recyclable. Please dispose the device according to local rules and regulations.

Rx ONLY

www.snssurgical.com.cn

MD

CE

Shanghai Saints Sages Surgical Co., Ltd.
No.19, Lane 388, Shengrong Road, Pilot Free Trade Zone,
201210 Shanghai, People's Republic of China

EC REP

Emergo Europe B.V.,
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.

Part Number: IFU-SASD-003SG

Rev. March/2025

www.snssurgical.com.cn