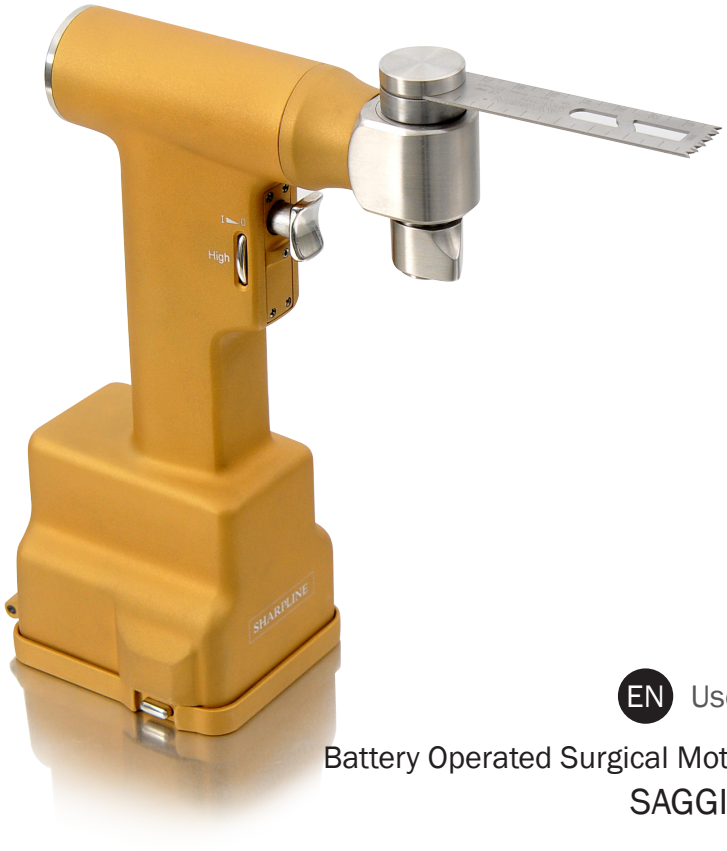
SHARPX

Surgical Motor Systems

Battery Operated



EN User Manual

Battery Operated Surgical Motor System
SAGGITAL SAW

SHARPLINE

Digitally signed by Jighili Tatiana
Date: 2021.06.25 17:29:38 EEST
Reason: MoldSign Signature
Location: Moldova

SHARPLINE.

Contents

1. GENERAL INFORMATION

Sharpline SharpX motor system is designed for orthopedic, cardiovascular and trauma-related surgical operations and is a both battery-powered surgical motor system.

SharpX motor system is designed to be used in professional surgical operations. Any surgeon or operator using the equipment is responsible for learning how to use such equipment and the most suitable method of use. It should be noted that improper use may lead to serious accidents.

WARNING LABELS AND SYMBOLS AVAILABLE IN THIS MANUAL

The following table explains the warning labels and informative symbols available in this user's manual. Failure to comply with these warnings may lead to injuries to parties involved.

Indicates a possible serious danger.
If not avoided, it may lead to death or serious injuries.

Indicates a possible danger.
If not avoided, it may lead to serious injuries.

Indicates a possible danger.
If not taken heed of, it may lead to material damage or injuries which may require outpatient care.

Indicates a reminder.
Explains usage and maintenance recommendations and tips and tricks. If not taken heed of, it may lead to inefficient operation, shortened life of the product or material damages.

1.2 SYMBOLS FOUND ON THE DEVICE

Symbols are means of communicating important information. This symbol, when found on the device, means that related documents have important contents.

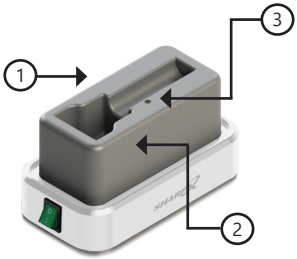
This symbol indicates that the tool should not be dipped in water.

This symbol indicates that the device is designed in compliance with type BF offering protection against electric shock and residual current. It further indicates that the device can be used on patients in compliance with IEC 60601-1 standard.

This symbol indicates that relevant documents offer recommendations on operation and maintenance, and that if not taken heed of, it may lead to shortened life of product or material damages.

Any electronic components (electronic card, fuse, pic controller, etc.), motor, batteries, etc. shall not be disposed of with urban waste. See Article 6.

2. DEVICE DESCRIPTION, USAGE AND FEATURES



S-226 SharpX Charging Unit
1) Charging Unit Body
2) Device Connection Pins
3) Device Display LED

S-210 SharpX Power Box
4) Handpiece Connection Slot
5) Display Screen
6) Capacity Control Button
7) Handle

S-210 SharpX Power Box is attached to S-226 SharpX Charging Unit as shown below.

Charging time is maxiumum 60-90 minutes depending on the battery capacity.

When S-226 SharpX Charging Unit is active the display LED is (3) green.

In order to charge the battery S-210 SharpX Power Box, the battery level must be below 95%. Otherwise, charging shall not start.

When S-210 SharpX Power Box is mounted on S-226 SharpX Charging Unit, Power Box Display Screen (5) is activated and displays the capacity of Power Box.

Once the S-226 SharpX Charging Unit starts charging, the LED display (3) turns red and a warning sound is heard.

When S-210 Power Box is charging, display screen (5) “Battery Charging” indicates that the battery placed in the Power Box is charging.

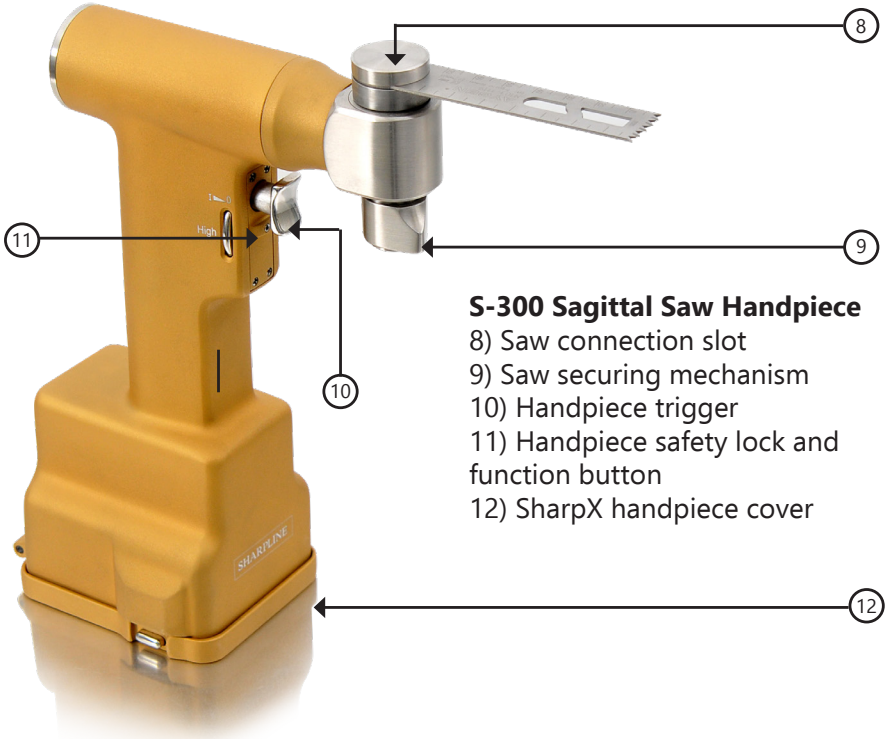
When the battery located in the S-210 Power Box is fully charged, and battery level has reached up to 100%, “Battery is Full” phrase is displayed on display screen (5) and a warning sound is heard.

If the battery level goes down to 0% as S-210 Power Box is used, the device shuts down and a warning sound is heard. The motor may stop working under excessive loads when battery level is above 0%."

S-210 Power Box is not suitable for sterilization in autoclave and must not be placed in it.

The working temperatures of motor and electronic components of S-210 Power Box is constantly measured. When the components heat up above the recommended temperature, a visual warning is displayed on device display and a warning sound is heard which indicates the device is shutting down.

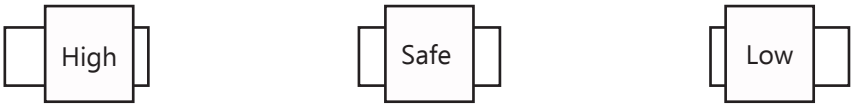
S-210 Power Box must be fully charged before each use. It is not recommended to use it
When the battery level is lower than 25%



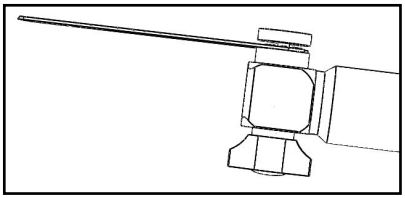
S-300 Sagittal Saw Handpiece
8) Saw connection slot
9) Saw securing mechanism
10) Handpiece trigger
11) Handpiece safety lock and function button
12) SharpX handpiece cover

2.1 Preparing Before Usage

Before attaching an attachment or power box to S-300 SharpX Sternum Handpiece ensure that handpiece's safety lock (11) is located in the middle, in the safe mode and that triggers are locked mechanically.

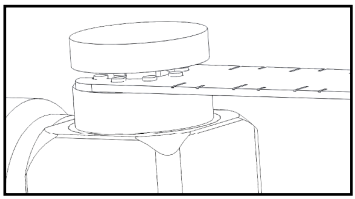


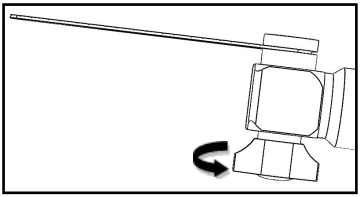
The life span of SharpX product varies depending on the method and number of use and usage during operation. Considering and implementing the warnings in the user manual extends the life of the product and ensures safe operation.
The life span of SharpX Handpiece is 7 years, cannulated drill accessories is 7 years, the battery is 2 years and others are 10 years.



Press on S-300 SharpX saw securing mechanism (9) and have the upper cover released. You will see that there are eight different pins on the connection slot (8) where the saw blade is to be mounted on.

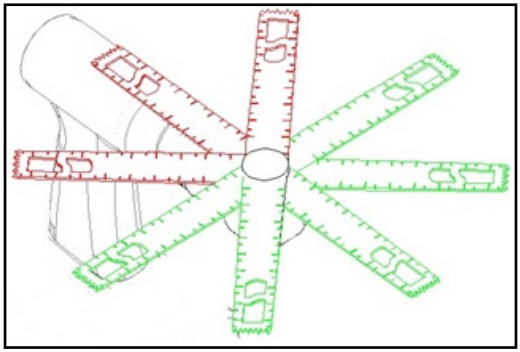
Place the grooves on the blade according to the pins on the connection slot properly and ensure proper assembly of the blade.





Ensure that the blade is secured, having rotated the securing mechanism (9) in the direction of the arrow as shown in the image to secure the cover.

Ensure that Sharpline saw blade is secured properly and that the pins are placed properly on the slots available on the blade.



Saw blade can be mounted on S-300 SharpX saw handpiece in eight different (360°) directions. However, number of recommended directions is limited to five for proper use. In the figure above, the blade assemblages indicated with green are suitable for use, while the ones indicated with red are not suitable for use.

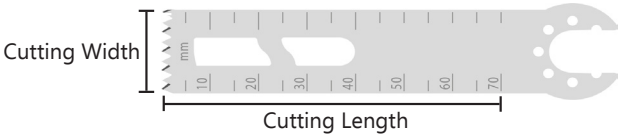
Before use, saw blade must be mounted on S-300 SharpX saw handpiece as shown in the figure above as indicated with green. Otherwise, improper assembly and use may cause harm to the user.

Suitable Use of Product

Sharpline's S-300 SharpX saw handpiece and saw blades must be inspected by the authorized personnel before usage and it must be confirmed that the products ordered are suitable for the operation and sufficient for the proper working of the system.

Compatibility of the saw blade model to be used in the operation must be inspected and confirmed by the operator depending on the length of blade, cutting length and width.

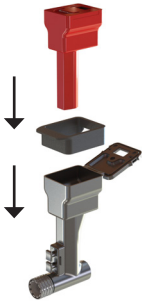
Sharpline Surgical Instruments Co. Inc. cannot be held liable for any problems which may arise due to wrong saw blade selection.



The space between each line of the ruler available on Sharpline's saw blade is 5 mm.

A successful surgery is only possible with tools capable of cutting properly. Therefore, cutting tools must be observed for wear and failure after each use.

S-210 SharpX Power Box is attached into S-300 Sagittal Handpiece as shown below

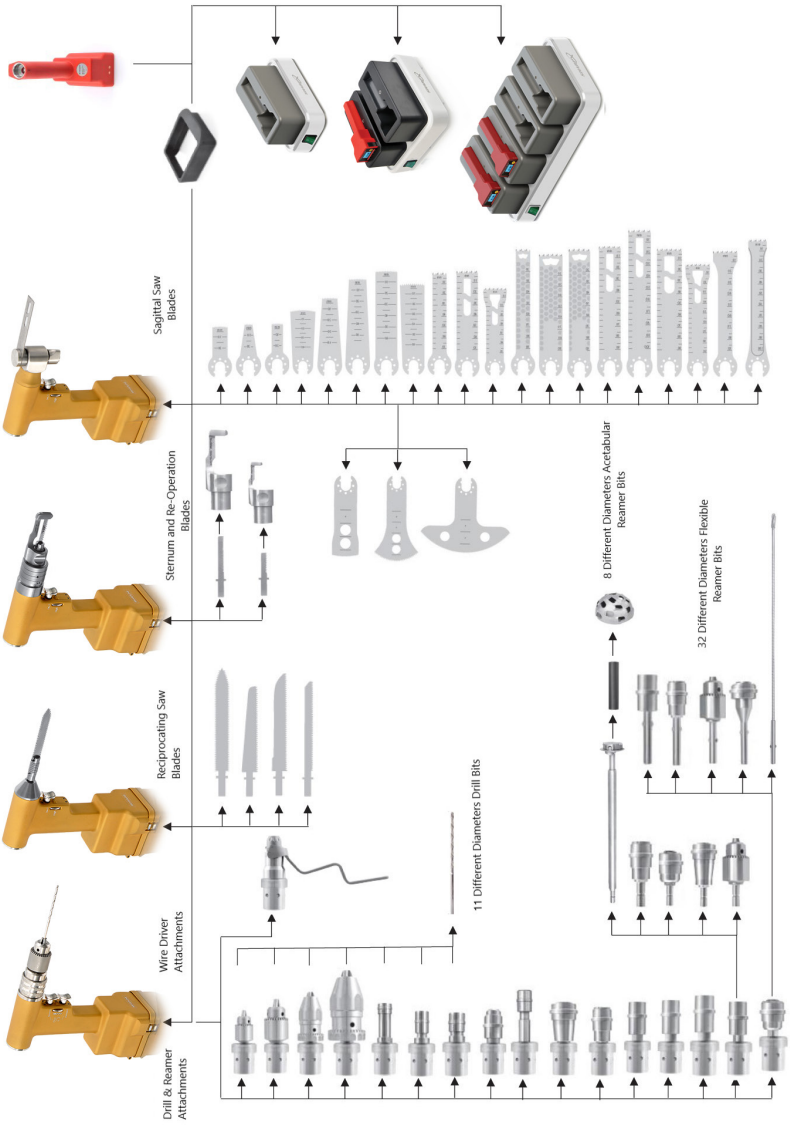


S-300 Handpiece Cover (12) must be closed properly after placing S-210 Power Box in order to have the device ready for use.

Ensure that S-300 Handpiece Cover (12) is closed and locked properly. Otherwise, the device does not work before the cover is secured.

SHARPLINE.

A DIAGRAM OF THE POSSIBLE ACCESSORIES OF THE PRODUCT



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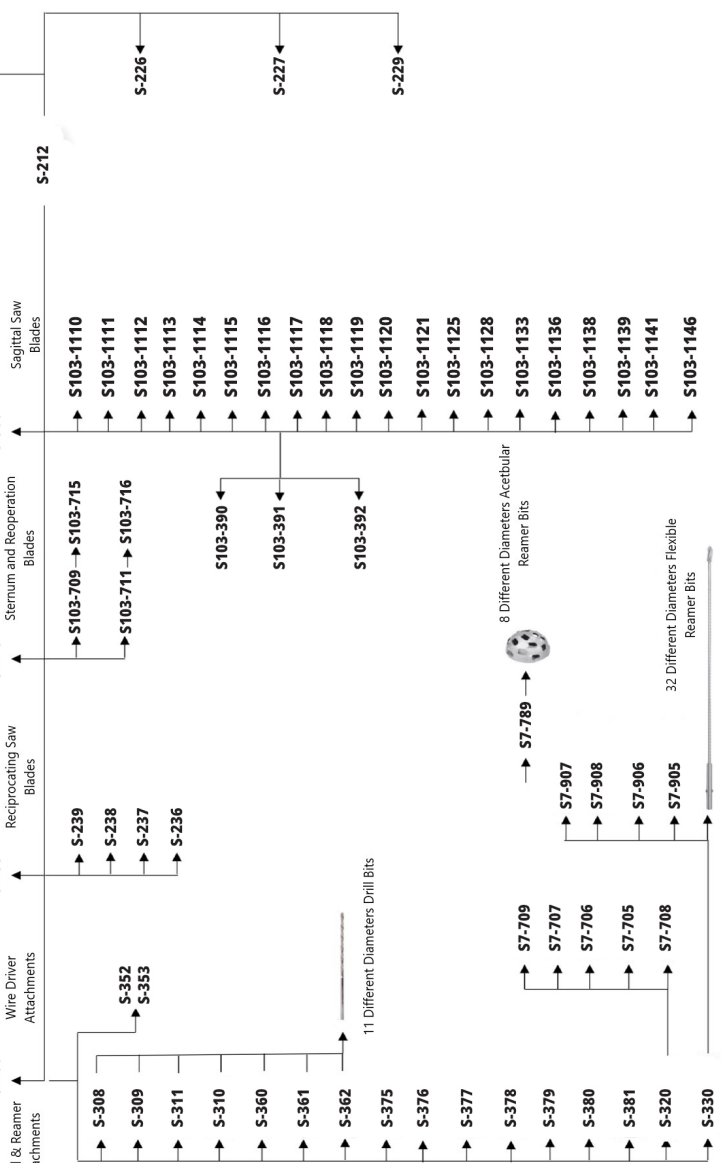
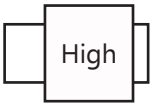


2.2 HIGH SPEED MODE

After completing the assembly of S-300 SharpX properly, having selected the suitable blade, Handpiece safety lock (11) is pushed to the left on S-300 Handpiece as shown in the label.

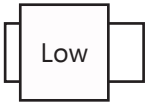


Ensure that handpiece safety lock (11) is in safe mode when replacing S-300 SharpX Handpiece Attachments or cutting or drilling bits. Do not operate the product before ensuring that all the components are mounted properly.

When high speed mode is on and S-300 SharpX Handpiece trigger (10) is engaged, the system operates at 12.000 cpm high speed.

2.3 LOW SPEED MODE

After completing the assembly of S-300 SharpX properly, having selected the suitable blade, Handpiece safety lock (11) is pushed to the right on S-300 Handpiece as shown in the label. When low speed mode is on and S-300 SharpX Handpiece trigger (10) is engaged, the system operates at 10.000 cpm high speed.



3 TECHNICAL SPECIFICATIONS

S-210	SharpX Power Box
Type of Battery	Li-Ion
Maximum Speed (cpm)	15000
Operating Voltage (V)	14.8
Power (Watt)	350
Battery Capacity (mAh)	2500
Dimensions	75x61x160 mm
Weight (g)	465
Arch Protection Class	IEC 60601-1-2, 60601-1

S-300	SharpX Sagittal Saw Handpiece
Dimensions	77x153x218 mm
Maximum Speed (cpm)	10.000 - 12.000 cpm
Weight (g)	850

3.1 Environmental Conditions Which Influence Use

Do not store or use in explosive environments.
The following table shows the factors influencing use due to environmental conditions.

	Operation	Transportation and Storage
Temperature	10 – 27 °C	-20 - 40°C
Relative Humidity	30 - 75 %	10 - 75 %
Atmospheric Pressure	70 - 106 kPa	50 - 106 kPa

4. CLEANING, DISINFECTION, LUBRICATION and STERILIZATION

SharpX made of high quality stainless steel, aluminium and several other materials. None of the components of the system is made of latex.
The system does not require regular maintenance while necessary maintenance and control actions must be taken before and after each use. Proper performance of practices -lubrication, disinfection, cleaning, and sterilization- in each phase of product life is of almost importance for the proper working of the system, its life and the health of patient and operator. Therefore, each step must be taken with care.
You need to do this step below after each usage;
1. Cleaning
2. Disinfection
3. Lubrication
4. Sterilization
5. Storage in Proper Conditions

4.1. Cleaning, Disinfection

All apparatus of the system must be cleaned after each usage.

1. First step of cleaning is removing of the battery (Page 6.).
2. Disassembly to the attachments.
3.Pre-wash all the components expect power unit and the battery, 1 min under cold tap water.
4. During pre-wash, clean the recesses found on the surface with soft lint-free cloth and soft-bristled brush to assist.
5. Organic impurities (blood and tissues) include large amounts of proteins. When processed under temperatures over 93°C, proteins go through reaction and they start to stick to the surface. For the reason, clean the wastes with your hand via hot water and soup before disinfection and sterilization.
Recommended water for cleaning is shown on Table 1.
Steps, time and conditions of cleaning is specified on Table 2.


You can soak S-300 SharpX Handpiece without S-210 SharpX Power Unit.


Do not immerse to charger and the battery in liqid. Clean with dry cloth to the battery and charger

Water Use Condition	Unit	Tap Water	Critical Water
Hardness (mg/L = ppm CaCO3)	mg /L	<150	< 1
pH	n/a	6-9	5-7
Chlorides	mg /L	<250	<1
Silicas	mg /L	<150	<1

Tablo 1: Recommended Water for Cleaning

Process Sequence	Time (min)/ Temperatures	Water Quality	Detergent Features
Pre-wash/Rinsing	1 / (Max. 95°C)	Tap Water*	N/A
Washing 1 (Manual)	2 / Soğuk	Tap Water*	Neutral Enzymatic Detergent (pH 7-10)
Washing 2 (Mechanical)	5 / (40°C)	Tap Water*	pH 7-10
Final Rinsing	2 / (40°C)	Critical Water*	N/A
Drying	40 min / 90°C	N/A	N/A

*See Table 1

Tablo-2: Parameters of Mechanical Washing Process

Temperature of the water used in pre-washing should be 93°C and it shuld be awaited 1 min. [according to EN ISO 15883]

The device certainly cannot be cleaned with corrosive materials such as Sodium Hypochlorite (NaOCl), Sodium Hydroxide (NaOH), Formic Acid (HCOOH) or Caustic Soda.

Asidic solutions cannot be used as a disinfectant.

If cleaning inside washing machines, in this case the product must be placed and fixed to silicone fixation found in the basket. Depending on hospital sterilization units specified conditions, the baskets need to has not any the sharp edge and burr. The product placing base of the basket is need to be proper straight structure for placing the silicon fixations.

If transfer is not possible right after usage, then the motor must be wrapped in humid pad and must be placed in a plastic bag. Moreover, it is possible to place a clean pad soaked with enzymatic gel or spray foam on the motor. The motor shall never be cured in salt water or any other liquid and its contact with salt water shall be avoided.

This product is resistant to alkaline washing solutions. You can use alkaline solutions regardless of brand. It is recommended to use detergents with between 7 and 10 pH levels.

It is necessary to select a detergent specifically designed for each application. For example;

•Type of impurity,
•Type of mechanical device,
•Manual cleaning,
•Material used in the product,
•Hardness of water, etc.

Medical motor must be decontaminated using customized soft plastic brushes, soft and lint-free cleaning cloth, sponge, detergent-disinfectant/enzymatic solution, or compressed air gun.
Medical motor never be processed using hard decontamination equipment. As the use of such equipment will form rough surfaces which will harbor microorganisms, abrasive material shall never be used.

In the disinfection of one-tools, the cutting inserts, which may be stainless steel, tungsten carbide or gold-plated, may be ultrasonically washed. Wastes such as dust, crust, etc. , especially in hart-tripped areas of cutting inserts should be cleaned with compressed air or with a plastic brush.

Medical motor must be decontaminated using customized soft plastic brushes, soft and lint-free cleaning cloth, sponge, detergent-disinfectant/enzymatic solution, or compressed air gun.
This is important as some microorganisms may form biofilms which will be harder to clean using classic methods.

Drying can be performed using compressed air; in the absence of a compressed air gun, a lavage injector may be used instead.
Medical motor, after going through pre-cleaning-decontamination-disinfection-rinsing-drying processes, is packed and sterilized having selected the barrier in accordance with the sterilization method used.

The measures recommended above comply with hygiene demands and job safety directives. Proper preparation of the devices for reuse is assessed within the coverage of laws and regulations in effect with respect to medical tools.

4.2. Lubrication

Lubricate moving parts before each sterilization.

For lubrication, Sharpline S8-510 coded spray oil is recommended. We also recommend that Pana Spray Plus or Lubricare or Dr. Weigert as an alternative.

4.3. Sterilization

Battery certainly cannot be sterilized !!

Product Not Be Sterilized
S-210 SharpX Power Box
S-226 SharpX Battery Charger w/1
S-227 SharpX Battery Charger w/2
S-229 SharpX Battery Charger w/4

All products and accessories mentioned above are suitable for the sterilization and cleaning methods described below.

Products and accessories must be kept sterile and clean then not in use.

As carcinogenic, toxic, and allergic substances such as ethylene oxide may partially be absorbed by the parts of the system during sterilization,they may pose danger for the patient and the operator. Such sterilization material shall never be used.

Sterilization Method	Temperature	Duration	Standard
Pressurized Steam	121 C °	20 mins	DIN 58946/DIN 285
	134 C °	3.5 mins - 5 dk mins	DIN 58946/DIN 285

Care must also be taken to avoid any immediate changes in the temperature during disinfection, cleaning, sterilization and storage of the products.

Please ship your products for maintenance, repair or technical support to Sharpline's authorized service only after cleaning and sterilizing these products following the cleaning instructions.

5. Guidance And Manufacturer's Declaration

5.1 Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment w- Guidance
RF Emissions CISSPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker Emissions IEC 61000-3-3	Comply	

5.2 Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air Horizantal Coupling Plane: ±8 kV Vertical Coupling Plane: ±8 kV	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air Horizantal Coupling Plane: ±8 kV Vertical Coupling Plane: ±8 kV	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least %30.
Electrical fast transient / burst IEC 6100-4-4	±2 kV for power supply lines	±2 kV for power supply lines	The power quality of electric network should be as in a commercial or hospital environment.
Surge IEC 61000-4-5	±0,5 kV line(s) to line(s) ±1 kV line(s) to line(s) ±2 kV line(s) to line(s)	±0,5 kV line(s) to line(s) ±1 kV line(s) to line(s) ±2 kV line(s) to line(s)	The power quality of electric network should be as in a commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	%0 Voltage Reduction 0,5 Period %0 Voltage Reduction 1 Period %70 Voltage Reduction 25 Period %0 Voltage Reduction 250 Period	%0 Voltage Reduction 0,5 Period %0 Voltage Reduction 1 Period %70 Voltage Reduction 25 Period %0 Voltage Reduction 250 Period	The power quality of electric network should be as in a commercial or hospital environment.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields IEC 61000-4-6	0,15 MHz to 80 MHz	0,15 MHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Dermatome, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 Mhz to 800 MHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey," should be less than the compliance level in each frequency range."
Interference may occur in the vicinity of equipment marked with following symbol:

⚠ At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

6. DISPOSAL

WEEE waste may contain hazardous substances which may cause harm to the environment and may have undesirable effects.
Therefore, WEEE is a large source of raw materials. It is unacceptable to allow this potential resource to be wasted with increasing world demand and reduced raw material volume for the new product. If the equipment is collected separately, it can be recycled. Thus, 80-90% of equipment can be used as recycled raw material and the energy used for remanufacturing is saved.For these reasons, Sharpline asks the end user to take any electrical and electronic equipment to the nearest disposal facility.

7. TROUBLESHOOTING TABLE

Failure	Reason	Solution
Motor of the Electricity-powered surgical motor does not run or runs slower than it is supposed to.	System is poorly assembled and motor is locked.	Dismount the system into its components and reassemble. Ensure that the components are correctly located.
	Parts of S-300 which need to be lubricated before sterilization are not lubricated.	Lubricate the parts which need to be lubricated before sterilization. (see Article 8)
S-300 motor does not stop.	Failure of speed control unit functions.	System failure. Contact your Sharpline representative.
One of S-300 Motor components is broken or deactivated.	Motor is deactivated. Subjected to physical shock or improper assembly	System failure. Contact your Sharpline representative.
S-300 makes abnormal noises or is very loud when being operated.	Insufficient lubrication. System is not lubricated or poorly lubricated.	Check the assembly and lubrication of the system. If the problem persists even after second lubrication, contact your Sharpline representative.
	One of S-300 moving parts is eroded or broken. One of S-300 moving parts is worn.	Contact your Sharpline representative for the repair of the part or the whole motor system having first checked the failed part.
	Motor components are improperly assembled. No assemblage	Ensure that the motor components are properly located.
Excessive corrosion at visible parts of S-300.	Improper sterilization or cleaning.	Contact your Sharpline representative.
	Cleaned using chlorine or other corrosive agents.	Contact your Sharpline representative.
	Insufficient lubrication System is not lubricated or poorly lubricated.	Ensure the system is properly assembled and lubricated.

8. MANUFACTURER INFORMATİON

Contact Sharpline head office or its dealers in case you have questions or problems.

SHARPLINE.

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sharpline.de

SHARPLINE®

SHARPX

Surgical Motor Systems

Battery Operated

SAGGITAL SAW

EN User Manual

ISO 13485:2012 CERTIFIED

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ISO 9001:2008 CERTIFIED