CE 0123

Ultrasonic Osteotomy Surgical System

Instructions For Use

Model XD880A

V1.9

TABLE OF CONTENTS

1. GENERAL SAFETY STATEMENTS

1.1. Operator Instructions

Please read this manual carefully, and be noticed any operation that doesn't follow this manual may lead to serious consequences. Operators are recommended to read the entire manual and operate the instrument only in accordance with all the instructions contained herein.

This operator's manual aims to provide contents about the installation, debugging, operation, use, maintenance of Ultrasonic Osteotomy Surgical System-Model XD880A (hereinafter referred as "XD880A" or "the Product"); it shall not be used as reference material for surgical techniques.

Warning 1-1: Please read this manual carefully before using XD880A. It should only be operated by staffs that are familiar with orthopedics surgical techniques and are trained about the Product.

Warning 1-2: Operator should read and understand the working principle and follow the operational methods of XD880A, in order to avoid injury to operator or patient or damaging the Product or any other medical instrument during the surgery.

Warning 1-3: It is recommended to prepare a standby device to perform the surgery in O.R. in case any malfunction that might place the patient in hazard occurs to the Product.

Warning 1-4: Equipment is intended for use within a professional healthcare facility and not intended for field or transport use.

1.2. Indications

XD880A product is indicated for surgeon use to cut and reshape bone tissues as used in spine surgery, neurosurgery (bone only), orthopedics surgery and bone surgery.

1.3. Contra Indications

XD880A is contra indicated for soft tissues (blood vessel, muscle, fascia and etc) cuttings and stops of bleeding.

1.4. Environmental Statement

The Product consists of materials that may be recycled if disassembled by a specialized company. Please follow the relevant government rules and regulations.

1.5. EMC Statement

XD880A is designed and tested to comply with IEC 60601-1-2:2014 guidelines for EMC.

Warning 1-5: Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

Warning 1-6: 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.

Warning 1-7: Use of accessories, transducers 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.

Warning 1-8: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the XD880A, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note 1-1: This device is considered medical electrical equipment. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.

Note 1-2: 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.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity (in accordance with EN/IEC 60601-1-2:2014)

Table 1 Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The XD880A is intended for use in the electromagnetic environment specified below. The customer or the user of the XD880A should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The XD880A 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 A	The XD880A is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and manufacturer's declaration - electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity			
The XD880A is intended for use in the electromagnetic environment specified below. The customer or the user of the XD880A 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 ±15 kV air	±8 kV contact ±15 kV air	Floors 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 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 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; 250/300 cycle	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; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mians voltage prior to application of the test level.			

Table 3 Guidance and manufacturer's declaration - electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity				
The XD880A is intended for use in the electromagnetic environment specified below. The customer or the user of the XD880A should assure that it is used in such an environment				
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**	
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the XD880A, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$; $d=1.2\sqrt{P}$	
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz	3 V/m 80 MHz – 2,7 GHz	80MHz to 800MHz: $d=1.2\sqrt{P}$ 800MHz to 2.7GHz: $d=2.3\sqrt{P}$	Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, 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 the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				
[a] 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 the XD880A is used exceeds the applicable RF compliance level above, the XD880A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the XD880A. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.				

Table 4 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the XD880A			
The XD880A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the XD880A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the XD880A as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d=3.5\sqrt{p}$	**80MHz to 800MHz** $d=1.2\sqrt{p}$	**800MHz to 2.7GHz** $d=2.3\sqrt{p}$
0,01	/	0.12	0.23
0,1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 5 Guidance and manufacturer's declaration - electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity							
The XD880A is intended for use in the electromagnetic environment specified below. The customer or the user of the XD880A should assure that it is used in such an environment							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band a)** (MHz)	**Service a)**	**Modulation b)**	**Modulation b)** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
	385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 – 390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5240						
	5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, 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 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E=\frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

1.6. Summary of Warning and Notice

1.6.1. List of Warnings

- **Warning 1-1:** Please read this manual carefully before using XD880A. It should only be operated by staffs that are familiar with orthopedics surgical techniques and are trained about the Product.

- **Warning 1-2:** Operator should read and understand the working principle and follow the operational methods of XD880A, in order to avoid injury to operator or patient or damaging the Product or any other medical instrument during the surgery.

- **Warning 1-3:** It is recommended to prepare a standby device to perform the surgery in O.R. in case any malfunction that might place the patient in hazard occurs to the Product.

- **Warning 1-4:** Equipment is intended for use within a professional healthcare facility and not intended for field or transport use.

- **Warning 1-5:** Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

- **Warning 1-6:** 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.

- **Warning 1-7:** Use of accessories, transducers 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."

- **Warning 1-8:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the XD880A, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- **Warning 2-1:** Use of accessories that are not manufactured by SMTP Technology Co., Ltd., mismatched or incompatible, outdated or damaged may lead to serious surgical consequences

and may injure operator or patient.

- **Warning 4-1:** The voltage of external power supply should be the same as required by XD880A, otherwise the instrument may be damaged and there may be risk of electric shock or fire hazard.

- **Warning 4-2:** To avoid the risk of electric shock, the Product must only be connected to a mains power supply with protective earth.

- **Warning 4-3:** Do not position the equipment so that it is difficult to operate the disconnection device.

- **Warning 4-4:** Make sure the peristaltic pump stops working when replacing liquid-flow tube to avoid hurting operator.

- **Warning 4-5:** Turn the Mains Power OFF and disconnect the power cord to replace fuses. Fuse-to-replace must be the same rated current as stipulated in this operator's manual. Otherwise, the Product may be damaged, and there maybe risk of electric shock or fire hazard.

- **Warning 5-1:** XD880A should be operated in the required environment (refer to Chapter 3 SPECIFICATION).

- **Warning 5-2:** XD880A is not suitable for use in places where there is mixture of flammable anesthetic and air or oxygen, because the spark produced by the collision between the Product and other metal instruments may light those gases and injure the operator or patient.

- **Warning 5-3:** XD880A cannot be used together with MRI equipment.

- **Warning 5-4:** Confirm the peristaltic pump functions properly, no damage of the liquid-flow tube, and confirm there is sufficient irrigant in the tubing before applying XD880A in surgery.

- **Warning 5-5:** Accessories intended for use in sterile field must be disinfected and sterilized before clinical use.

- **Warning 5-6:** Make sure no inversion use of ultrasonic application part whenever there is ultrasound output, otherwise the operator may be injured and handpiece may be damaged by the backflow infiltration.

- **Warning 5-7:** During self-test procedure, make sure cutting tip doesn't contact with patient, operator and other instruments or other objects to ensure self-test process going well and prevent hurting operator or patient.

- **Warning 5-8:** The automatic identification feature of the Product reduces the power of ultrasound output when there is no contact between tip and bone tissue, thus to protect soft tissue from being injured in some cases. Whereas the identification is qualitative identification, there might be identification error due to individual patient's differences and different operational methods of operators, therefore in order to protect soft tissue, operator should follow regular surgical techniques to safely and cautiously perform the surgery other than rely on the automatic identification function.

- **Warning 5-9:** Make sure sufficient irrigant discharges when outputs ultrasound, so as to prevent cutting tip from damaging by overheating or injuring tissue. The flow grade setting is recommended to set at 4 or higher.

- **Warning 5-10:** Without the operator's permission, anyone else should not modify the setting parameters of XD880A console during surgery.

- **Warning 5-11:** Do not to restart the instrument until 20s after XD880A shutting down to avoid shortening the Product lifetime.

- **Warning 6-1:** Under conditions of correct device operation by operator and normal irrigant output, the local temperature of the operational location is no more than 41℃, whereas, the friction between cutting tip and bone tissue in bone cutting operation when there is no irrigant output will lead to high temperature, to as high as 80℃ at the contacting location. Operator shall follow the warnings and notes for clinical use specified in this chapter (Chapter 6 ATTENTIONS DURING CLINICAL USE), to prevent patient injuries resulting from local overheating at the operational site.

- **Warning 6-2:** The by-products during the surgery (smog and aerosol) might present cancerigenic and infectious hazards, therefore proper measures (protective glass and filter-type respirator) should be taken to protect O.R. staff.

- **Warning 6-3:** A continuous motion of the cutting tip is needed for bone removal in order to minimize contact duration and minimize temperature increase, thus to avoid thermal damage.

- **Warning 6-4:** During clinical use, do not cut in too deep at one cutting. A lateral sweeping layer-by-layer cutting motion is recommended for bone removal. When the surgical site is too deep, it is recommended to repeat the cutting motions, and make sure adequate cooling and lubrication to prevent thermal damage.

- **Warning 6-5:** Do not squeeze the important soft tissues (e.g. dura mater and nerve) during the surgical procedure.

- **Warning 6-6:** During surgical procedures, once found dura mater damaged, make sure cutting tip with ultrasound output do not contact with the dura mater lesion position.

- **Warning 6-7:** In order to protect operator, do not hold the tip during surgery, and the correct hand position is to hold the handpiece housing.

- **Warning 6-8:** Do not use cutting tips exceeding lifetime during clinical use. Tips showing signs of deformation, cracking or damage should be replaced immediately to prevent cutting tip broken and causing malpractice.

- **Warning 6-9:** Under excessive use (or beyond cutting tip lifetime) or wrong operational method, cutting tip could break into two or more fragments. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that no more broken piece is left in the surgical cavity.

- **Warning 6-10:** Breakage of cutting tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Cutting tips showing signs of deformation, cracking or damage should be replaced immediately.

- **Warning 6-11:** There might be bone chips formed during the bone cutting procedure, therefore operator should check and clean the surgical cavity after surgery to ensure that no more bone pieces are left in the surgical cavity.

- **Warning 6-12:** The patient leakage current may increase if XD880A is used together with the endoscope device.

- **Warning 6-13:** If XD880A is used with the endoscope device, the applicability of the endoscope passage must be checked before use, mismatched passage may cause injury to the

endoscope or the patient.

- **Warning 6-14:** If XD880A is used with the endoscope device, the tip must be checked before use, irregular tip shape, rough tip surface and sharp edge and protrusion of the tip may cause injury to the patient.

- **Warning 6-15:** XD880A Ultrasonic Osteotomy Surgical System is not applicable for endoscope of type CF applied parts.

- **Warning 6-16:** Make sure there is no contact or friction between cutting tip and metal devices or other objects to avoid shortening the lifetime of cutting tip.

- **Warning 7-1:** Do not open the case of console without authorization in order to avoid damage to the instrument or electric shock hazard. Open the case of console without producer's permission will void any applicable warranty.

- **Warning 7-2:** Immediately suspend operation if error appears on display and/or an audible indicator sounds. Remove cutting tip from surgical site, and do not touch the cutting tip or any metallic parts of the console. In case error cannot be recovered, turn the Mains Power off and contact the after sales service.

- **Warning 8-1:** Turn off the Mains Power and follow hospital regulations to clean the console.

- **Warning 8-2:** When cleaning the console, avoid liquid spraying or penetrating into the console to avoid damage to the internal electronic components, which may affect the service life of the console or cause risk of electric shock or fire in the subsequent use.

- **Warning 8-3:** The following reprocessing methods are in accordance with ISO17664-1. Please follow the instructions to ensure safe and intended use next time.

- **Warning 8-4:** Do not use alcohol to clean the power connector of the Handpiece.

- **Warning 8-5:** Avoid overloading the washer/disinfector as this may compromise cleaning effectiveness.

1.6.2. List of Notes

- **Note 1-1:** This device is considered medical electrical equipment. Medical electrical equipment

needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.

- **Note 1-2:** 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.

- **Note 2-1:** Foot switch consists of yellow (left) pedal and blue (right) pedal. Depress the blue pedal, only the peristaltic pump is activated and the irrigation function is only available; depress the yellow pedal, both the peristaltic pump and handpiece ultrasound output are activated to be ready for bone cutting. The function of single key foot switch is the same as the yellow(left) pedal of the double key foot switch.

- **Note 2-2:** The recommended operations of cutting tips listed in Table 2-1 are only for references. In actual clinical use, under the precondition of safety, operator shall adopt the reasonable operational methods according to indications, pathologies, anatomies and operator's techniques.

- **Note 2-3:** The expected lifetime of "Handpiece" given in Table 2-2 take into account only the lifetime according to normal operations. Abnormal operations or accidental damages in actual uses will affect the expected lifetime of such accessories.

- **Note 2-4:** Shipping and storage should be carried out according to the "Shipping and storage conditions" stipulated in Chapter 3 SPECIFICATION, otherwise the expected lifetime of accessories will be shortened.

- **Note 2-5:** All accessories should be inspected strictly prior to each use, and replace immediately once found damage.

- **Note 4-1**: Prior to applying XD880A in surgery, ensure the vent of console is not blocked in operation, and ventilation fan works well to prevent system overheating and thereby affect the working condition of system.

- **Note 4-2:** When connecting foot switch to console, make sure the connector is clean and dry,

and keep the red dot on the connector in line with the red dot on top of the receptacle. Otherwise the foot switch cannot be connected, and forced incorrect connection may cause damages to connector or receptacle.

- **Note 4-3:** When connecting handpiece to console, make sure the connector is clean and dry, and keep the red dot on the connector in line with the red dot on top of the receptacle. Otherwise the handpiece cannot be connected, and forced incorrect connection may cause damages to connector or receptacle.

- **Note 4-4:** Do not apply excessive physical force to mount and remove cutting tip or handpiece to avoid damages.

- **Note 4-5:** Liquid-flow tube should be placed fully on the roller of peristaltic pump and clamped. Inclined or place too deep may cause peristaltic pump fail to work properly, and tube not clamped may cause irrigant flow by gravity to the operating table and lead to adverse consequences.

- **Note 5-1:** When connecting the console power cord, confirm the Mains Power is OFF.

- **Note 5-2:** After steam sterilization, handpiece needs to be cooled to room temperature before usage, otherwise operator may get burnt.

- **Note 5-3:** Pay close attention to the direction of tube when installing to peristaltic pump, make it consistent with the direction indicator and do not install in reverse.

- **Note 5-4:** Confirm the connected part between infusion bag and infusion set is sterile, and such sterile environment isn't destroyed by the connecting process.

- **Note 5-5:** Confirm the connected part between infusion set and liquid-flow tube is sterile, and such sterile environment isn't destroyed by the connecting process.

- **Note 5-6:** In order to ensure there is sufficient irrigant discharges, depress blue pedal before surgery to activate peristaltic pump and make the liquid-flow tube full of irrigant and make the irrigant reach to the tip.

- **Note 5-7:** Flow setting only controls the irrigant output by depressing the yellow foot pedal. In "Ready" state , whenever depress the blue pedal, the irrigant output is of the highest.

- **Note 5-8:** When the system sound volume is set too low and operator cannot hear the corresponding sound indicator of operation, the operator may make incorrect judgment of the current ultrasound output condition.

- **Note 6-1:** When mounting cutting tip to handpiece, always use specialized wrench to tighten the cutting tip.

- **Note 6-2:** Try to avoid collision between cutting tip and other instruments, so as not to affect the lifetime of the cutting tip

- **Note 6-3:** During surgery, confirm there is no ultrasound output when replacing cutting tip or handpiece thus to protect operator.

- **Note 6-4:** When waiting for use in surgery, handpiece should be kept from contacting with other instruments, patient or flammable objects, and confirm the console is at “Standby” or power off state, to avoid harming operator or patient due to accidental start up.

- **Note 8-1:** Remove all accessories and clean them individually as required.

- **Note 8-2:** Place the instruments in the washer/disinfector so that dead zones do not arise and the water can properly drain. Also, make sure that the handpiece and the metal front cone are properly held in place in the washing tray and cannot move during the washing process, as shocks could damage them.

- **Note 8-3:** The automatic disinfection was not experimentally tested. According to ISO 15883-1, the thermo-disinfection at a temperature of 90 °C for 5 minutes determines an A0 value of 3000.

- **Note 8-4:** Do not use the ultrasonic cleaner to clean handpiece.

- **Note 9-1:** After moist heat sterilization, The handpiece should be cooled down to normal temperature, and then take to use.

- **Note 9-2:** Do not stack trays during sterilization.

- **Note 10-1:** Make sure XD880A is upright and no violent vibration when being moved, handled, installed, and when it is working.

2. SYSTEM OVERVIEW

2.1. System Contents

The XD880A system consists of a console, foot switch and accessories. The accessories include handpiece, cutting tip, tip wrench, liquid-flow sleeve, liquid-flow tube.

2.1.1. Console and foot switch

- **Console**

Model: XD880A

The console consists of peristaltic pump, user interface, foot switch receptacle and handpiece receptacle.

Figure 2-1 Console

- **Foot switch**

Foot switch is a foot controlled device which controls the start/stop of ultrasound and irrigant output. Two kinds of foot switches are applied to the console: double key foot switch and single key foot switch.

(a) Double key foot switch

Model: XDF05802

(b) Single key foot switch

Model: XDF05801

Figure 2-2 Foot switch

Note 2-1: Foot switch consists of yellow (left) pedal and blue (right) pedal. Depress the blue pedal, only the peristaltic pump is activated and the irrigation function is only available; depress the yellow pedal, both the peristaltic pump and handpiece ultrasound output are activated to be ready for bone cutting. The function of single key foot switch is the same as the yellow(left) pedal of the double key foot switch.

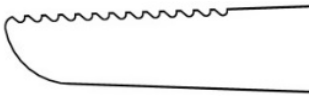
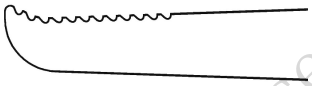
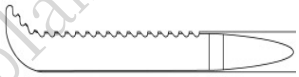
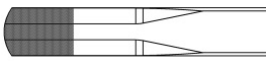
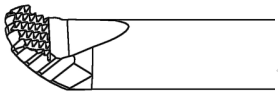
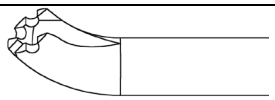
Figure 2-3 Foot switch connector

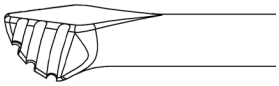
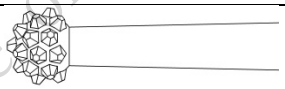
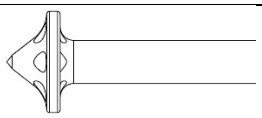
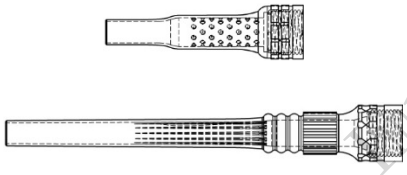
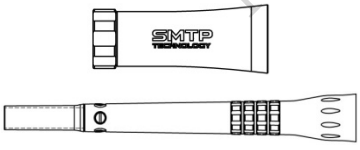
2.1.2. Accessories

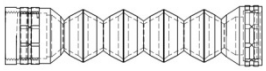
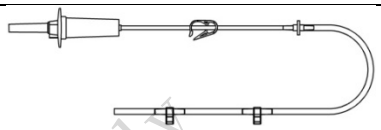
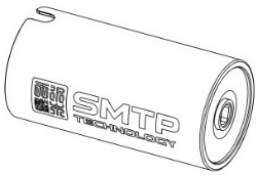
Accessories of XD880A include special: handpiece, tips, wrench, liquid-flow sleeve and liquid-flow tube.

Table 2-1 Accessories

Name	Model	Accessory piture	Specification

Name	Model	Accessory piture	Specification
Handpiece	XDF01838		Used for cutting bone tissue and bone tissue approximation, applied to multiple open orthopedics operations.
Bilateral scalpel with serrations	XDF02801521		Used for cutting directly, includes transverse and longitudinal curved tip and many length specifications.
Unilateral scalpel with serrations	XDF02801528		Used for cutting transversely, includes many length specifications.
Unilateral hook-shaped scalpel with serrations	XDF02801529		Used for cutting from inner to outter, includes many length specifications.
Round scalpel with serration	XDF02801537		Used for cutting directly, includes many length specifications.
Hook-shaped scalpel with serrations	XDF02806518		Used for cutting from inner to outter and the hook can get into smaller gaps, includes many length specifications.
Grinding and cutting scalpel	XDF02801522		Used for both grinding and cutting by different side.
Curette with teeth	XDF02806510C		Used for cutting from inner to outter and grinding, includes many length specifications.
Small head slope side file scalpel	XDF02806552		Used for cutting from inner to outter and fine grinding.
File burr	XDF02806517		Used for cutting from inner to outter and fine grinding.

Name	Model	Accessory piture	Specification
V-shaped scalpel	XDF02806525		Used for cutting out a V-shaped slot.
Rake shaped scalpel	XDF02812565		Used for cutting from inner to outter and grinding, includes many length specifications.
Spherical scalpel	XDF02806523		Used for grinding operation.
Needle tip	XDF02806513		Used for drilling operation.
Spiral shaped scalpel	XDF02812532		Used for drilling and grinding operation, includes many length specifications.
Trephine	XDF02812533		Used for drilling and grinding operation, includes many length specifications.
Curved spade scalpel	XDF02812560		Used for bone cement cutting, includes many length specifications.
Open hole umbrella scalpel	XDF02812563		Used for bone cement cutting and squeeze the bone cement out of the cavum medullare, includes many length specifications.
Liquid-flow sleeve （soft）	XDF09801		Used to guide the irrigant and protect the surgeon, includes many length specifications that applied to the corresponding tips.
Liquid-flow sleeve （hard）	XDF0980115		Used to guide the irrigant and protect the surgeon, includes many length specifications that applied to the corresponding tips.

Name	Model	Accessory piture	Specification
Protection sleeve	XDF09820		Used to protect the surgeon in MIS,
Liquid-flow tube	XDF03801		Single channel liquid-flow tube, used for irrigant.
Tip wrench	XDF07801		Normal wrench
	XDF07801N		Torque wrench
Sterilization box	XDF06801		Sterilization box for reusable accessories.

Note 2-2: The recommended operations of cutting tips listed in Table 2-1 are only for references. In actual clinical use, under the precondition of safety, operator shall adopt the reasonable operational methods according to indications, pathologies, anatomies and operator's techniques.

Accessories of XD880A may change over time, please check with SMTP Technology Co., Ltd. or its authorized distributors for the latest configuration before purchase.

Warning 2-1: Use of accessories that are not manufactured by SMTP Technology Co., Ltd., mismatched or incompatible, outdated or damaged may lead to serious surgical consequences and may injure operator or patient.

2.2. Principle of Operation

The Product is designed to cut bone by using ultrasonic energy, the following Figure 2-6 shows the working principle of XD880A.

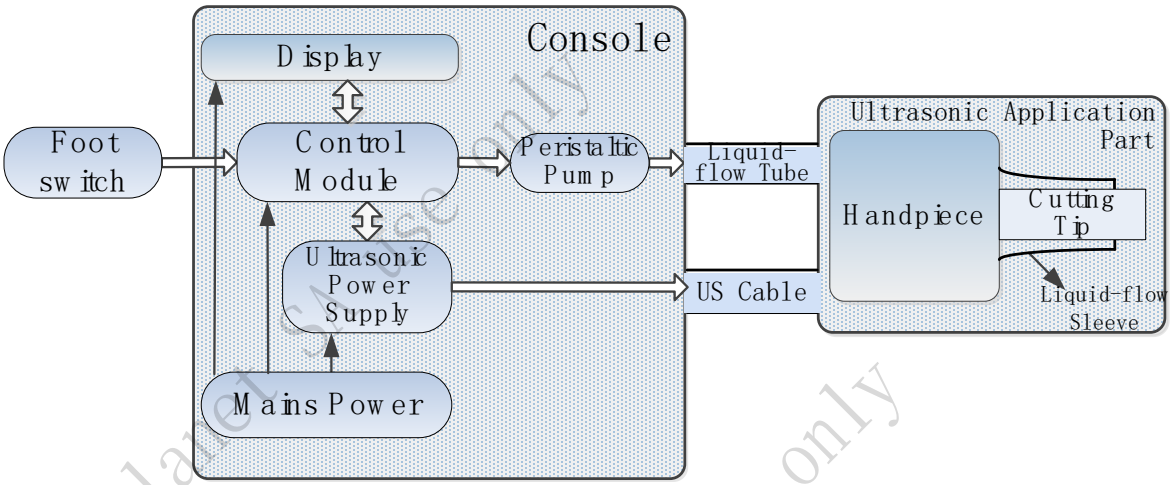


Figure 2-6 XD880A working principle

- **Display screen:** displays interface information and responds to user actions.
- **Ultrasonic application part:** converts the electrical energy into ultrasonic energy to cut bone tissue.
- **Control module:** controls the entire surgical procedure, including the controls over foot switch, ultrasonic application part and ultrasonic power.
- **Ultrasonic power supply:** converts the Mains Power into desired electricity and outputs the desired electric power to ultrasonic application part.
- **Mains Power:** supplies electricity to each part of the system.
- **Foot switch:** controls the start/stop of ultrasound and irrigant output.

2.3. Expected Lifetime

As frequency and time of use increases, accessories (consumables) may be aging or damaged that they cannot be used any longer, then these accessories need to be replaced in time. The following

Table 2-2 lists the expected lifetime of accessories.

Table 2-2 Expected lifetime of system accessories

Accessory Item	Expected Lifetime
Handpiece	No more than 100 sterilization cycles (recommended)
Cutting tip	Disposable
Liquid-flow sleeve	Disposable
Liquid-flow tube	Disposable
Wrench	Worn or damaged

Note 2-3: The expected lifetime of "Handpiece" given in Table 2-2 take into account only the lifetime according to normal operations. Abnormal operations or accidental damages in actual uses will affect the expected lifetime of such accessories.

Note 2-4: Shipping and storage should be carried out according to the "Shipping and storage conditions" stipulated in Chapter 3 SPECIFICATION, otherwise the expected lifetime of accessories will be shortened.

Note 2-5: All accessories should be inspected strictly prior to each use, and replace immediately once found damage.

3. SPECIFICATION

The specification of XD880A is listed in Table 3-1.

Table 3-1 XD880A specification

Product model code	XD880A
Classification of protection against electric shock	Class I
Degree of protection against electric shock	Type BF applied part
Operation mode	Continuous
Safety Standard	IEC60601-1:2005+A1:2012
Degree of water-proof	Console: IPX0 Foot switch: IPX8
Drive frequency of console	39 kHz±4KHz
Primary tip vibration excursion	≤120μm
Main acoustic output area of the tip's cutting edge	≤ 20 mm^2
Exported output acoustic power at the tip's cutting edge	≤1500mW at Grade 5
Power reserve index	≥ 2
Maximum flow	120ml/min±20%
Ultrasound output mode	Continuous or pulsed mode
Handpiece cable length	About 4m
Foot switch cable length	About 5m
Power cord length	About 3m
Rated voltage and frequency	AC 100V~ 240V, 50/60Hz

Input power	160VA
Fuse	2×T3.15AH 250V
Operating environment conditions	Environment Temperature:10℃~30℃
	Relative Humidity: 30%~75%, no condensation
	Atmospheric pressure: 700hPa~1060hPa
Shipping and storage conditions	Environment Temperature: -30℃~50℃
	Relative Humidity: ≤ 90%, no condensation
	Atmospheric pressure: 700hPa~1060hPa
Dimension (LWH)	39.3 cm×31 cm×17.4cm
Weight（net weight）	6.9kg

4. SYSTEM SET-UP

4.1. Unpacking

Upon the receipt of XD880A, please:

1. Perform visual inspection of the shipment packing for obvious damage.
2. Verify the quantity and model of accessories in the package with the packing list.

Contact the supplier of any damage of packages or difference in quantities and models found mismatching with that on the packing list.

4.2. Console Appearance and Buttons Descriptions

4.2.1. Front view of XD880A console

Front view of XD880A console as in Figure 4-1 :

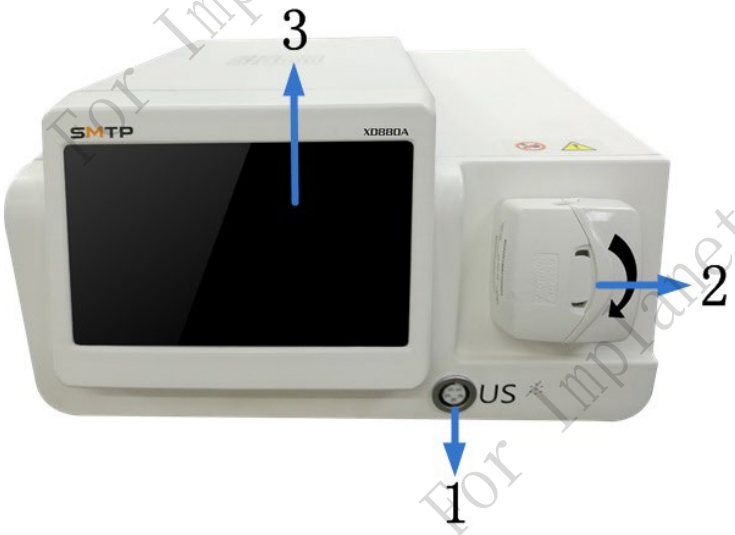


Figure 4-1 Front view of XD880A console

1. **Handpiece receptacle**

It is ultrasonic energy output interface, and it's for handpiece cable

connection.

2. Peristaltic pump

Refer to 4.2.3 Peristaltic pump.

3. Display screen

Displays user operation interface and responds to user actions.

4.2.2. Rear view of XD880A console

Rear view of XD880A console as in Figure 4-2:

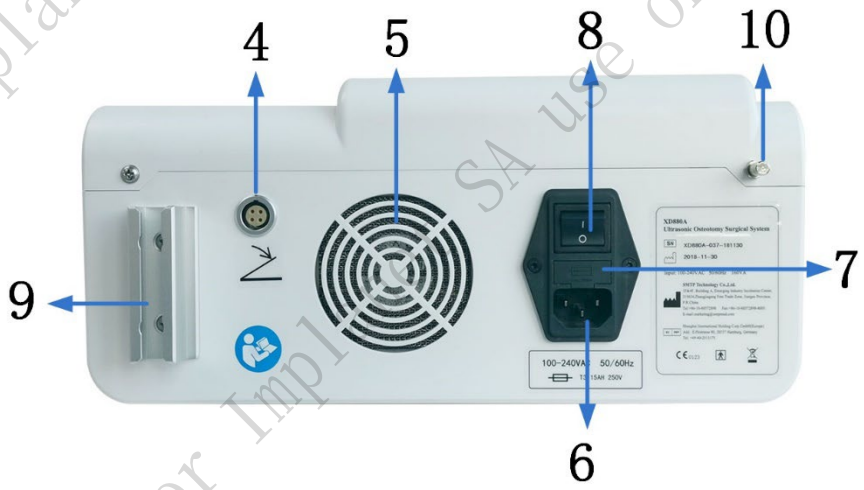


Figure 4-2 Rear view of console

4. Foot switch receptacle

Connect the foot switch cable connector to the receptacle.

5. Vent

Vent and ventilation fans within are for console ventilation.

Note 4-1: Prior to applying XD880A in surgery, ensure the vent of console is not blocked in operation, and ventilation fan works well to prevent system overheating and thereby affect the working condition of system.

6. Mains Power receptacle

It's for connection with the output connector of power cord to provide power supply for the whole instrument.

Warning 4-1:	The voltage of external power supply should be the same as required by XD880A, otherwise the instrument may be damaged and there may be risk of electric shock or fire hazard.
Warning 4-2:	To avoid the risk of electric shock, the Product must only be connected to a mains power supply with protective earth.
Warning 4-3:	Do not position the equipment so that it is difficult to operate the disconnection device.

7. Fuse holder

There are two fuses in the holder, refer to Chapter 3 SPECIFICATION for fuse specification.

8. Mains Power switch

It is the main switch of the Product, turn Mains Power switch ON to start device; turn the switch OFF to stop device, and it's in a state of no power.

In emergency situation, turn off the Mains Power can cut off power completely.

9. Hook base

It is used to assemble the hook, which can be used to hang the infusion bag. The **maximum** safe load of the hook is 750g.

10. equipotentiality terminal

Terminal for connecting the product to equipotential system. After connecting the terminal to the equipotential system with potential equalization wires that meet the requirements, the potential of the metal part connected to the equipotential terminals in the product is

close to or equal to the potential of the equipotential system.

4.2.3. Peristaltic pump

The peristaltic pump is covered by pump cover, as shown in Figure 4-3:

Figure 4-3 Peristaltic pump

1. **Pump cover**

   Open or close the peristaltic pump when assembling and replacing the liquid-flow tube.

2. **Peristaltic pump body**

   Fixed at the housing of console, rotor within actuates irrigant flow.

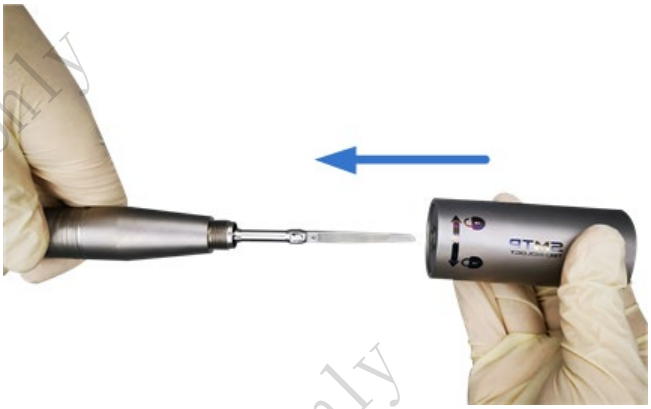
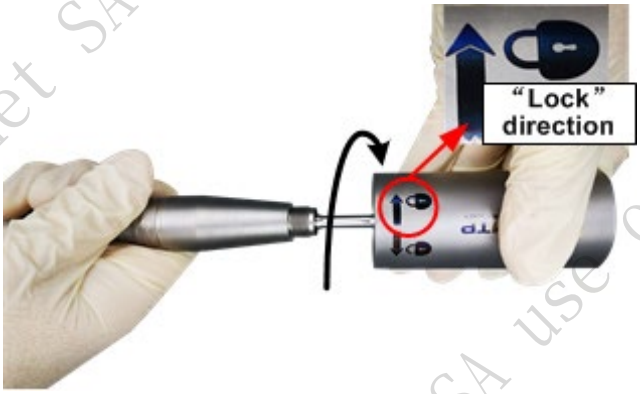
3. **Rotation direction indicator**

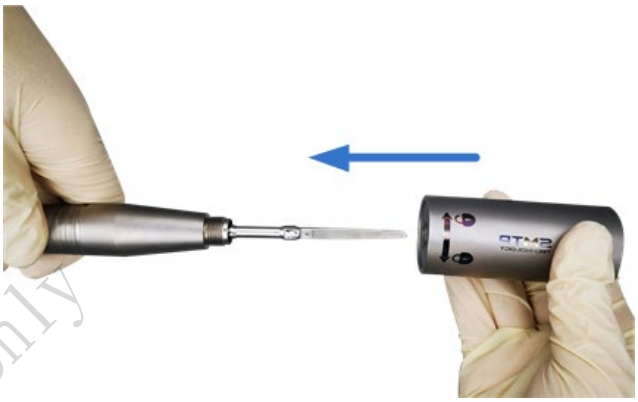
   It indicates the rotation direction of peristaltic pump rotor and direction of irrigant. Always follow the direction indicator to place liquid-flow tube, with the end connected with handpiece placing at the left side of peristaltic pump, and the end connected with irrigant at the right side.

4.3. How to use the torque wrench

Torque wrench is used to tighten or loosen the tips, as shown in the following:

Table 4-1 How to use the torque wrench

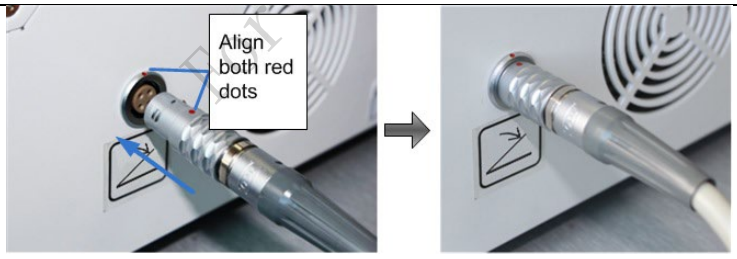
Tighten the tip	 When the tip needs to be tightened after connected to the handpiece, put on the torque wrench according to the direction shown in the figure above.  Then turn the torque wrench to tighten the tip according to the "Lock" direction marked on the torque wrench until "click" sound is heard.

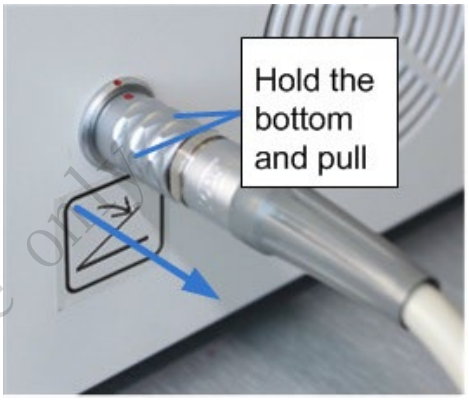
Loosen the tip	
	When the tip needs to be loosened, firstly put on the torque wrench the same as the tighten step.
	
	Turn the torque wrench to loosen the tip according to the "Unlock" direction marked on the torque wrench.

4.4. Assemble and Disassemble Accessories

4.4.1. Foot switch

Table 4-2 Assemble and disassemble of foot switch

Assemble	
	Align the red dot at foot switch connector with the red

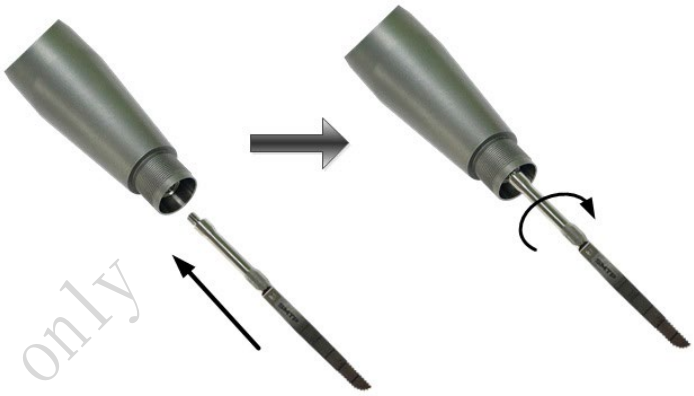
	dot on top of foot switch receptacle on the rear of console, and insert fully into receptacle.
Disassemble	
	Pull out the foot switch connector gently.

Note 4-2: When connecting foot switch to console, make sure the connector is clean and dry, and keep the red dot on the connector in line with the red dot on top of the receptacle. Otherwise the foot switch cannot be connected, and forced incorrect connection may cause damages to connector or receptacle.

4.4.2. Handpiece

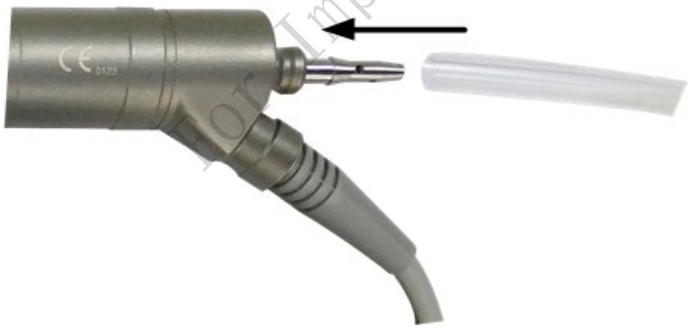
Table 4-3 Assemble and disassemble of handpiece

Assemble	
	Align the red dot at handpiece connector with the red dot on top of the handpiece receptacle on the front of console, and insert fully into receptacle.



Insert cutting tip into tip connector at handpiece. Turn the cutting tip clockwise to mount until the cutting tip cannot rotate in anymore. Then use specialized wrench to turn clockwise to tighten the cutting tip.

Hold the bottom of liquid-flow sleeve and gently rotate up to mount the sleeve.

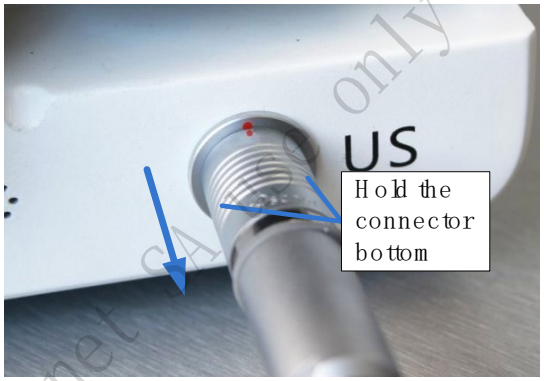


Connect one side of the liquid-flow tube to the

liquid-flow tube connector at the end of the handpiece, place the liquid-flow tube on the roller in the peristaltic pump (refer to section 4.4.3), and then connect the other side of the liquid-flow tube to the infusion set.

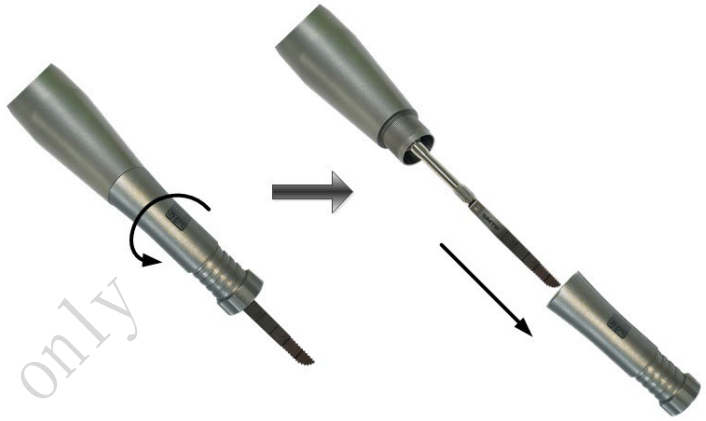
Handpiece assembly completed shown as follows:

Disassemble



Pull out handpiece connector from the receptacle gently.

Pull out the liquid-flow tube from the liquid-flow tube connector of the handpiece.



Hold the bottom of liquid-flow sleeve and gently rotate out to remove the sleeve.

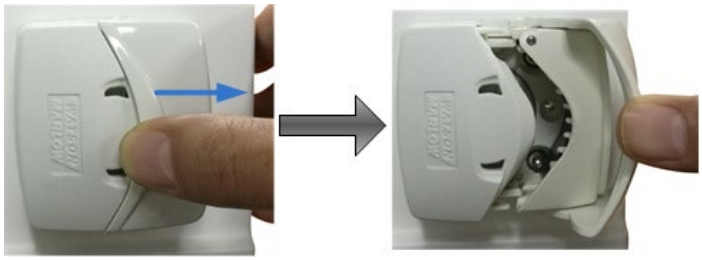
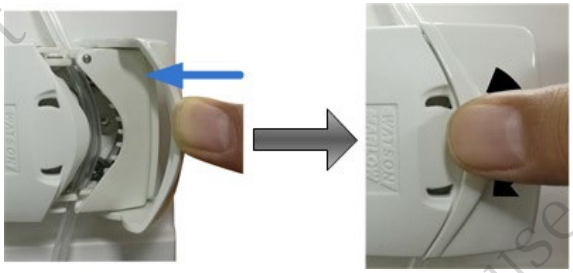
Use specilized wrench to turn counter-clockwise to un-tighten the tip. Then turn counter-clockwise to remove the tip till it's completely separated.

Note 4-3: When connecting handpiece to console, make sure the connector is clean and dry, and keep the red dot on the connector in line with the red dot on top of the receptacle. Otherwise the handpiece cannot be connected, and forced incorrect connection may cause damages to connector or receptacle.

Note 4-4: Do not apply excessive physical force to mount and remove cutting tip or handpiece to avoid damages.

4.4.3. Liquid-flow tube

Table 4-4 Assemble liquid-flow tube

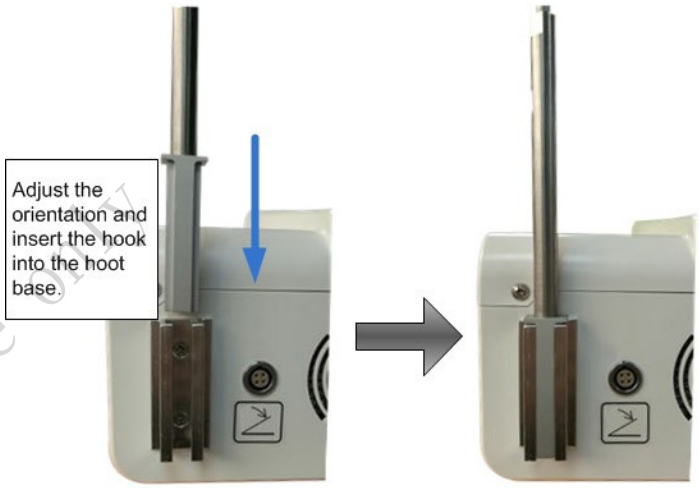
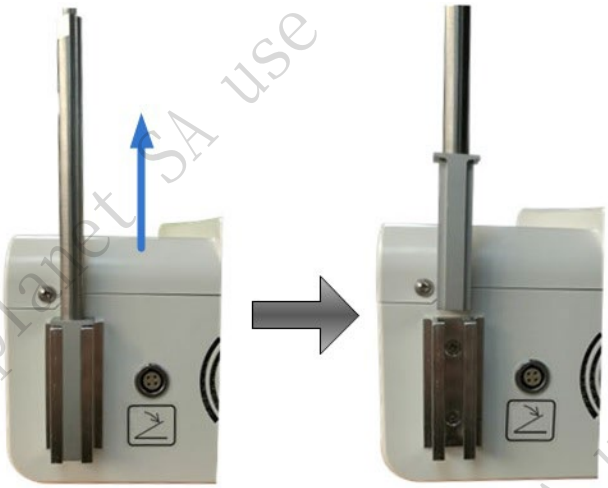
Open peristaltic pump	 Lift open the pump cover.
Place liquid-flow tube	 Place liquid-flow tube on the roller in the peristaltic pump; make sure the tube is fully placed at pump slot.
Close peristaltic pump	 Push down to close the cover and press liquid-flow tube.

Warning 4-4: Make sure the peristaltic pump stops working when replacing liquid-flow tube to avoid hurting operator.

Note 4-5: Liquid-flow tube should be placed fully on the roller of peristaltic pump and clamped. Inclined or place too deep may cause peristaltic pump fail to work properly, and tube not clamped may cause irrigant flow by gravity to the operating table and lead to adverse consequences.

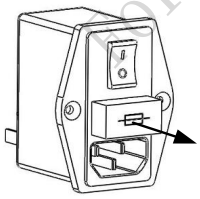
4.4.4. Hook

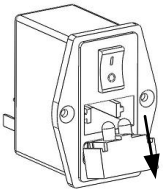
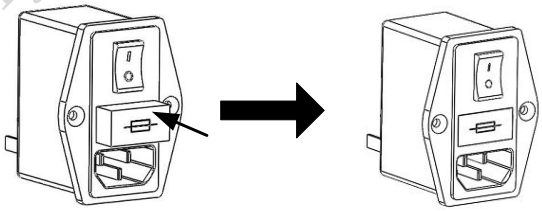
Table 4-5 Assemble and disassemble of hook

Assemble	 Adjust the orientation and insert the hook into the hook base.
Disassemble	 Lift the hook up and out from the hook base.

4.4.5. Fuse

Table 4-6 Mount and replace fuse

Open fuse holder	 Pull out fuse holder.

Install fuse	 Install fuse in the holder.
Close fuse holder	 Push back fuse holder gently.

Warning 4-5: Turn the Mains Power OFF and disconnect the power cord to replace fuses. Fuse-to-replace must be the same rated current as stipulated in this operator's manual. Otherwise, the Product may be damaged, and there maybe risk of electric shock or fire hazard.

5. SYSTEM OPERATION

5.1. System Start

Note 5-1: When connecting the console power cord, confirm the Mains Power is OFF.

Warning 5-1: XD880A should be operated in the required environment (refer to Chapter 3 SPECIFICATION).

Warning 5-2: XD880A is not suitable for use in places where there is mixture of flammable anesthetic and air or oxygen, because the spark produced by the collision between the Product and other metal instruments may light those gases and injure the operator or patient.

Warning 5-3: XD880A cannot be used together with MRI equipment.

Warning 5-4: Confirm the peristaltic pump functions properly, no damage of the liquid-flow tube, and confirm there is sufficient irrigant in the tubing before applying XD880A in surgery.

Warning 5-5: Accessories intended for use in sterile field must be disinfected and sterilized before clinical use.

Warning 4-1: The voltage of external power supply should be the same as required by XD880A, otherwise the instrument may be damaged and there may be risk of electric shock or fire hazard.

Warning 4-2: To avoid the risk of electric shock, the Product must only be connected to a mains power supply with protective earth.

1. Connect output end of power cord to Mains Power receptacle on the rear of console, and connect the input end of power cord to a proper grounding mains electricity supply output port (hospital grade).

2. Connect foot switch to console (refer to 4.4.1 Foot switch).

3. Connect handpiece to console (refer to 4.4.2 Handpiece).

Note 5-2: After steam sterilization, handpiece needs to be cooled to room temperature before usage, otherwise operator may get burnt.

4. Place liquid-flow tube in the peristaltic pump (refer to 4.4.3 Liquid-flow tube). Connect infusion set to irrigant container, and then connect the infusion set to the connector at liquid-flow tube.

Note 5-3: Pay close attention to the direction of tube when installing to peristaltic pump, make it consistent with the direction indicator and do not install in reverse.

Note 5-4: Confirm the connected part between infusion bag and infusion set is sterile, and such sterile environment isn't destroyed by the connecting process.

Note 5-5: Confirm the connected part between infusion set and liquid-flow tube is sterile, and such sterile environment isn't destroyed by the connecting process.

5. To assemble handpiece, user should mount cutting tip into handpiece with the wrench provided by the manufacturer, tighten liquid-flow sleeve to cutting tip and connect the handpiece connector at liquid-flow tube with handpiece (refer to 4.4.2 Handpiece).

Handpiece assembly should be performed by specially trained staff only in the sterile environment.

If desired, use suitable disinfected vessel clamp, sterile cable clips or sterile adhesive tape strips to attach liquid-flow tube and handpiece cable to operating table.

6. Turn on Mains Power and wait for system finish starting.

Note 5-6: In order to ensure there is sufficient irrigant discharge, depress blue pedal before surgery to activate peristaltic pump and make the liquid-flow tube full of irrigant and make the irrigant reach to the tip.

5.2. System Running

Warning 5-6: Make sure no inversion use of ultrasonic application part whenever there is ultrasound output, otherwise the operator may be injured and handpiece may be damaged by the backflow infiltration.

System startup screen as showed below:

Figure 5-1 System startup screen

The main screen of XD880A is as the figure showed below:

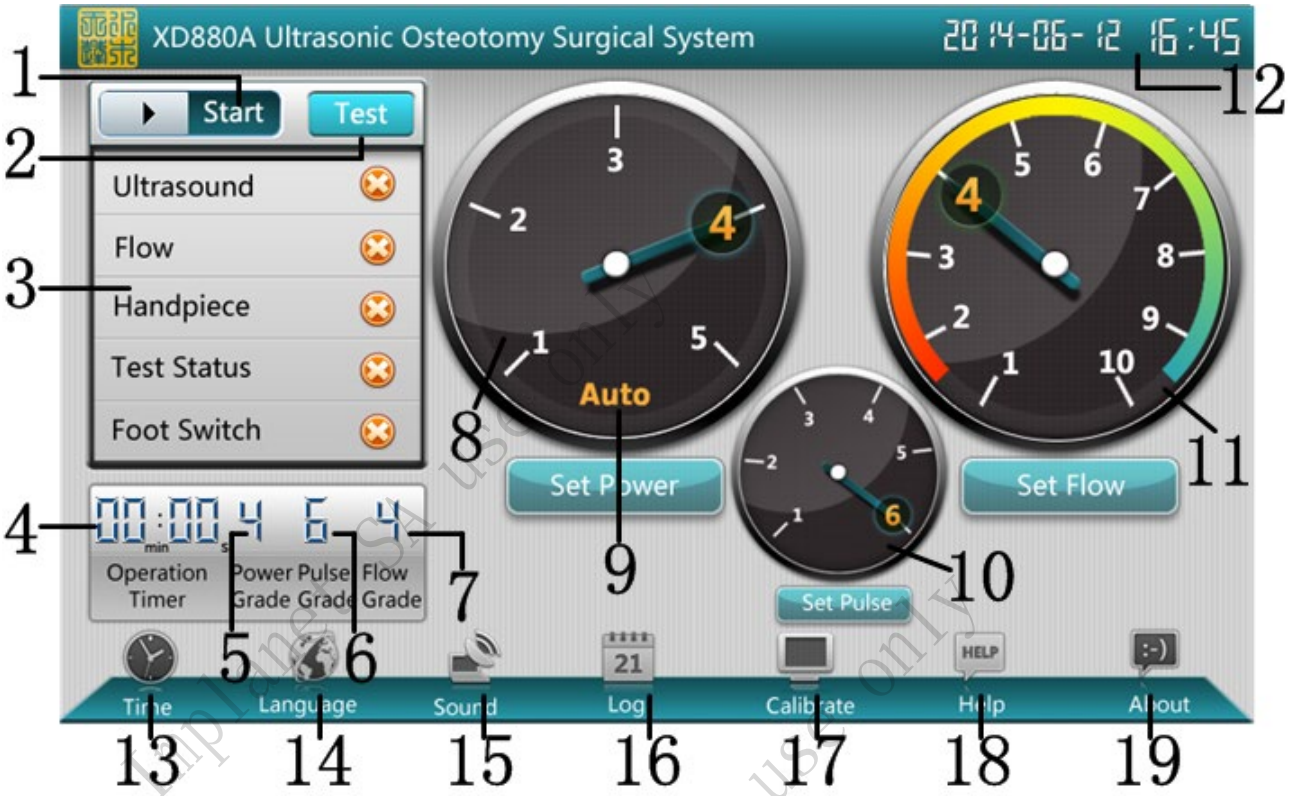


Figure 5-2 Main screen

- **Start key**

Press the touch key “Start”, system enters “Ready” state (the “Stop” key displays on the screen), depress foot switch there is irrigant output or ultrasound output. Press the “Stop” key, system returned to “Standby” state, the machine stops working, and there is no ultrasound or irrigant output.

- **Self-test**

Press the touch key “Test” to start system self-test, after self-test XD880A works at its best working condition. Please run self-test for the first time use, and after cutting tip or handpiece replacement. Once the self-test passes, the status indication of self-test item turns into “✓” from “✗”.

Warning 5-7:	During self-test procedure, make sure cutting tip doesn’t contact with patient, operator and other instruments or other objects to ensure self-test process going well and prevent hurting operator or

patient.

- **Working status**

Indicate the current working status by icons as detailed in the following table:

Table 5-1 Working status

Status	Description
Flow and ultrasound	Depress the yellow (left) pedal of foot switch, there is irrigant and ultrasound output, and irrigant and ultrasound status indication shows "✓"; release the yellow (left) pedal, the indication shows "✗".
Flow	Depress the blue (right) pedal of foot switch, there is irrigant output, and the flow status indication shows "✓"; release the blue (right) pedal, the indication shows "✗".
Handpiece	If system detects ultrasonic handpiece properly connected to the console, the status indication shows "✓"; if detects wrongly connected or disconnected, the indication shows "✗".
Test	Press the self-test key to start system self-test. The self-test status indication shows "✓" when passes, and the indication shows "✗" when fails.
Foot switch	If system detects foot switch properly connected to the console, the foot switch status indication shows "✓"; if detects wrongly connected or disconnected, the indication shows "✗".

- **Operating timer**

It records the ultrasound output time. When system condition changes to "Standby" from "Ready", the timer resets.

- **Power grade**

It indicates the current power grade.

- **Pulse grade**

It indicates the current pulse grade.

- **Flow grade**

It indicates the current flow grade.

- **Power setting dashboard**

The power can be set by clicking the digit from 1 to 5 on the dashboard. 1 is the lowest and 5 is the highest. At grade 5, the ultrasound output is very high and makes the cutting tip move very fast, therefore the grade 5 should be used very carefully and surgeon needs to be very skilled at surgical techniques.

- **Auto button**

The Auto button starts/stops the automatic tissue identification function. Press [Auto] button, system switches between Auto and Auto status, specified as follows in Table 5-2:

Table 5-2 Auto button description

Status	Description
Auto	The automatic tissue identification function is activated, and ultrasound output is automatic selective to different tissues during the cutting operation. It's normal ultrasound output for hard tissue, and limited ultrasound output for soft tissue or when the tip is placed in the air.
Auto	The automatic identification function is deactivated, and ultrasound output is at normal power grade settings.

Warning 5-8: The automatic identification feature of the Product reduces the power of ultrasound output when there

	is no contact between tip and bone tissue, thus to protect soft tissue from being injured in some cases. Whereas the identification is qualitative identification, there might be identification error due to individual patient's differences and different operational methods of operators, therefore in order to protect soft tissue, operator should follow regular surgical techniques to safely and cautiously perform the surgery other than rely on the automatic identification function.

- **Pulse setting dashboard**

The pulse grade can be set by clicking the digit from 1 to 6 on the dashboard.

Each grade is detailed in table 5-3:

Grade	Description
6	6 is continuous mode, refers to 100% ultrasound output or zero resting period. 6 is the default setting of the system.
1~5	1-5 is pulsed mode based on duration of active period and resting period of ultrasound output. **1** 50% ultrasound output period, 50% resting period. **2** 60% ultrasound output period, 40% resting period. **3** 70% ultrasound output period, 30% resting period. **4** 80% ultrasound output period, 20% resting period. **5** 90% ultrasound output period, 10% resting

	period.

- **Flow setting dashboard**

The flow grade can be set by clicking the digit from 1 to 10 on the dashboard. 1 is the lowest and 10 is the highest.

Note 5-7: Flow setting only controls the irrigant output by depressing the yellow foot pedal. In "Ready" state , whenever depress the blue pedal, the irrigant output is of the highest.

Warning 5-9: Make sure sufficient irrigant discharges when outputs ultrasound, so as to prevent cutting tip from damaging by overheating or injuring tissue. The flow grade setting is recommended to set at 4 or higher.

Warning 5-10: Without the operator's permission, anyone else should not modify the setting parameters of XD880A console during surgery.

- **Date and time**

It displays the current date and time.

- **Time setting**

Click to enter time setting interface, as shown in Figure 5-3**:**

Figure 5-3 Time setting

Click “+” or “-“ to adjust date and time, and click OK to save the adjustment or click to cancel.

- **Language selection**

Click to enter the Language Setting interface, as shown in Figure 5-4:

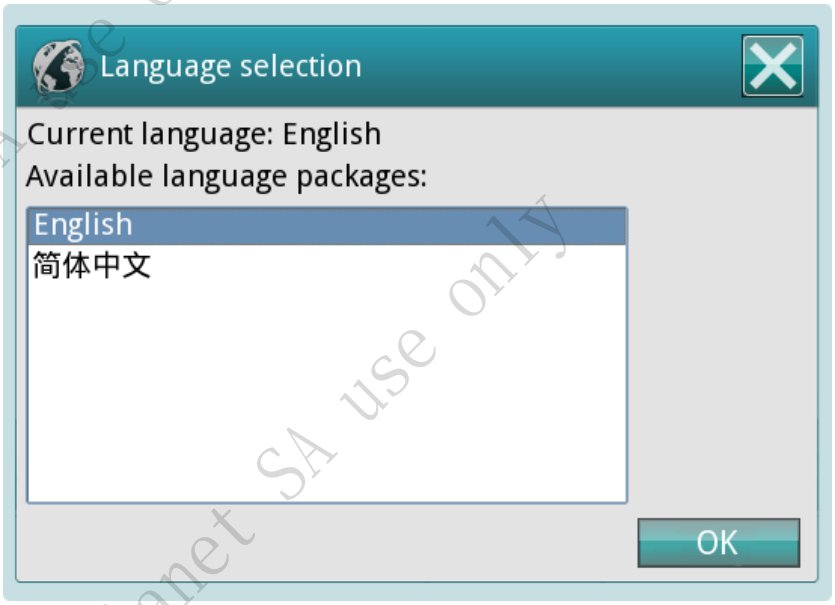


Figure 5-4 Language selection

Select desired language for interface, and click OK to save selection or click to cancel selection

- **Volume control**

Click to enter volume control interface, as shown in Figure 5-5:

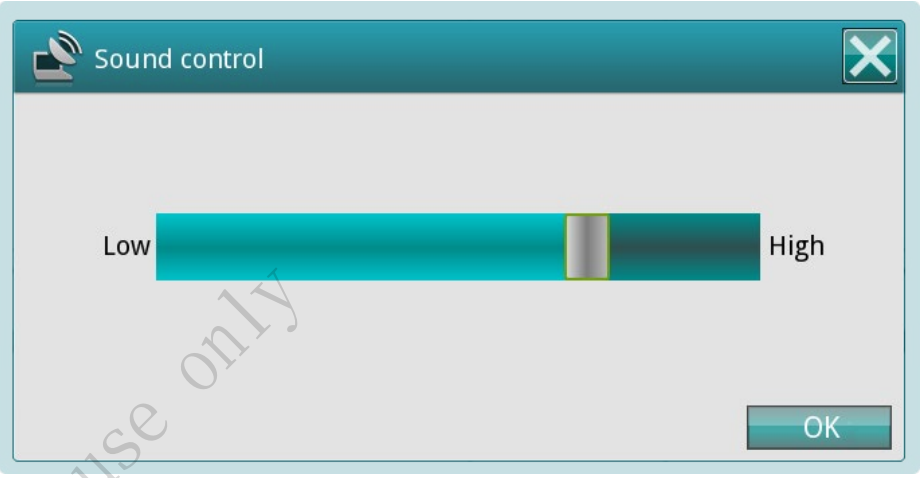


Figure 5-5 Volume control

Slide the slider to control system volume.

Note 5-8: When the system sound volume is set too low and operator cannot hear the corresponding sound indicator of operation, the operator may make incorrect judgment of the current ultrasound output condition.

- **Log**

Click to enter System Log interface, as shown in Figure 5-6**:**

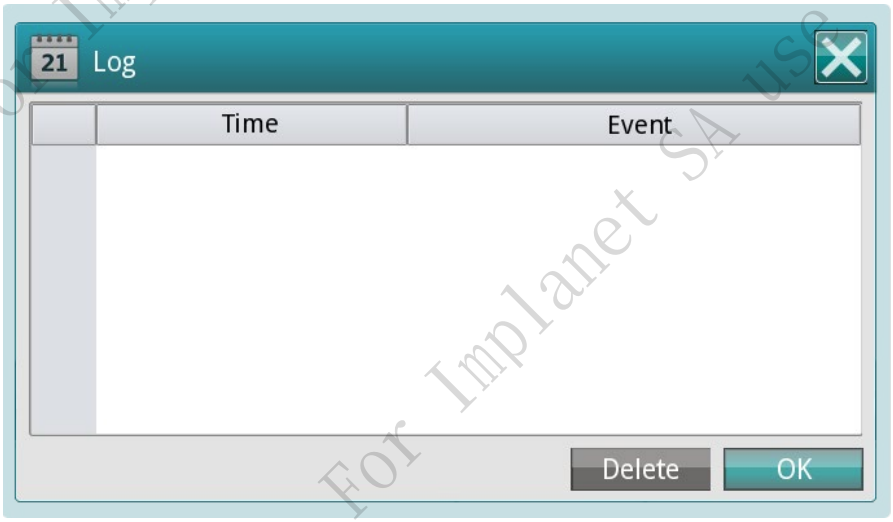


Figure 5-6 System log

System log interface shows the important events and their occurrence time, and click Delete to clean logs.

- **Touch screen calibration**

Click to enter the Touch Screen Calibration interface, this is now only available to technical support staff.

- **Help**

Click to enter the Help interface, as shown in Figure 5-8:

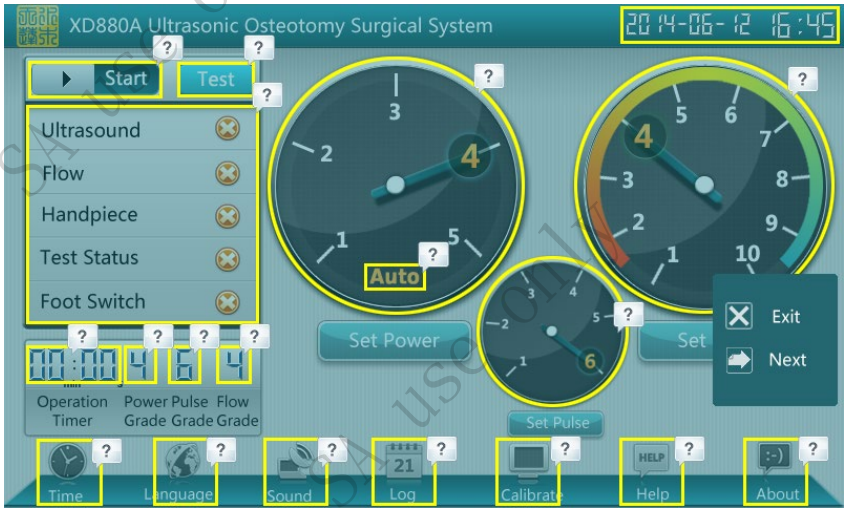
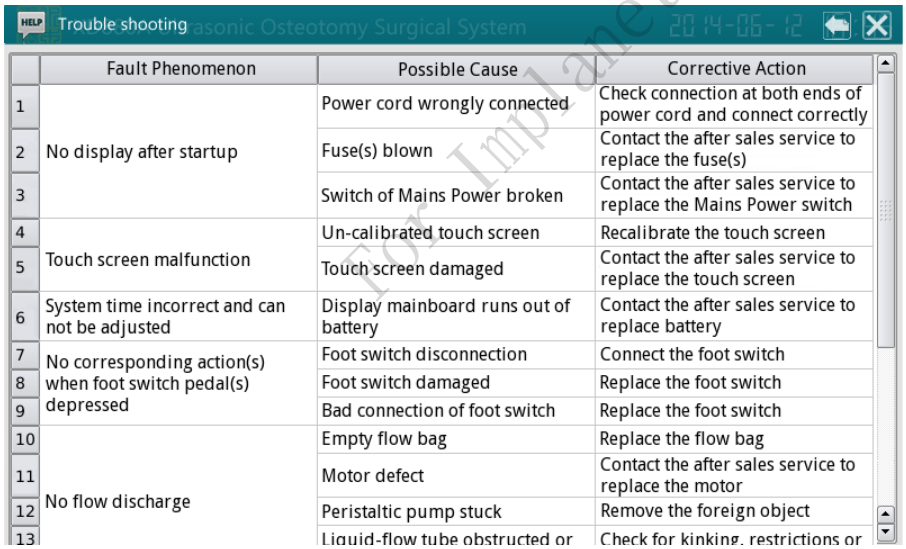


Figure 5-8 Help interface

The Help Screen provides access to quick guides for system operation and troubleshooting. Click each "?", corresponding information box pop-up showing the help information to help better use of XD880A instrument. Click "X" at the right dark box to exit this help screen. Click " ⇨ " to move to the Troubleshooting screen, as shown in Figure 5-9:



	Fault Phenomenon	Possible Cause	Corrective Action
1	No display after startup	Power cord wrongly connected	Check connection at both ends of power cord and connect correctly
2		Fuse(s) blown	Contact the after sales service to replace the fuse(s)
3		Switch of Mains Power broken	Contact the after sales service to replace the Mains Power switch
4	Touch screen malfunction	Un-calibrated touch screen	Recalibrate the touch screen
5		Touch screen damaged	Contact the after sales service to replace the touch screen
6	System time incorrect and can not be adjusted	Display mainboard runs out of battery	Contact the after sales service to replace battery
7	No corresponding action(s) when foot switch pedal(s) depressed	Foot switch disconnection	Connect the foot switch
8		Foot switch damaged	Replace the foot switch
9		Bad connection of foot switch	Replace the foot switch
10	No flow discharge	Empty flow bag	Replace the flow bag
11		Motor defect	Contact the after sales service to replace the motor
12		Peristaltic pump stuck	Remove the foreign object
13		Liquid-flow tube obstructed or	Check for kinking, restrictions or

Figure 5-9 Troubleshooting screen

The Troubleshooting screen provides possible faults, and their possible causes and corrective actions. Click the "⇦ " on the upper right corner to return to the Help screen. Click "X" on the upper right corner to exit the entire Help screen.

- **About**

Click to enter the About screen, where users may find version and copyright information about XD880A.

5.3. System Inspection

Follow hospital regulations to perform regularly system inspection towards its functionality and safety, details in Table 5-4.

Table 5-4 System safety inspection

Accessories	Inspection Method
Cutting Tip	Inspect the blade surface, replace at once if any crack, broken or deformation found.
Handpiece	Inspect handpiece surface, connector and cable, repair or replace at once if any crack, broken or deformation found.
Foot switch	Inspect foot switch, connector and cable, repair or replace at once if any crack or broken found.
Peristaltic pump	Inspect the cover and replace at once if any crack or broken found. Inspect the pump shaft and repair or replace at once if any loosens found.

Perform system function inspection after system assembly completed and startups according to 5.1 System Start. Perform system function inspection before each surgery operation to make sure to minimize the risk in case malfunction occurs. The following are system function inspection steps:

1. Click "Start" key to "Ready" status.
2. Place the cutting tip in the air and keep from contacting with patient, other instruments or

objects. Click “Self-test” key on display to run self test, and status indicator turns from  to  once self test completed.

3. Depress the blue pedal of foot switch, peristaltic pump runs and irrigant discharges from cutting tip, and the “Flow” status indication shows  .

4. Release the blue pedal of foot switch, peristaltic pump stops, and the “Flow” status indication shows  .

5. Depress the yellow pedal of foot switch, peristaltic pump runs and flow discharges from cutting tip, “Flow and Ultrasound” status indicator shows  ; meanwhile, system sounds out ultrasound output indication tone, and ultrasound timer on the screen starts timing.

6. Release the yellow pedal of foot switch, peristaltic pump stops, and “Flow and Ultrasound” status indicator shows  ; meanwhile, ultrasound output stops, and timer stops timing.

7. Click “Stop” key system returns to “Standby” status, ultrasound timer clears, and the system function inspection completes.

If any equipment error occurs during the system function inspection, please refer to Chapter 7 TROUBLESHOOTING.

5.4. System Shutoff

System shutoff shall follow the following steps:

a. Turn the Mains Power OFF, and disconnect power cord from the rear receptacle of the console.

b. Pull out handpiece and disconnect foot switch.

c. Clean and disinfect the system accessories following hospital regulations and Chapter 8 MAINTENANCE, CLEAN AND DISINFECTION of this operator’s manual.

Warning 5-11: Do not to restart the instrument until 20s after XD880A shutting down to avoid shortening the Product lifetime.

6. ATTENTIONS DURING CLINICAL USE

XD880A is an ultrasonic bone cutting tool, besides of its own security measures correct operations of this tool by operators during clinical uses are very important to ensure safety surgical procedures. In operations, operators should pay extra attentions to the following warnings**:**

Warning 6-1: Under conditions of correct device operation by operator and normal irrigant output, the local temperature of the operational location is no more than 41℃, whereas, the friction between cutting tip and bone tissue in bone cutting operation when there is no irrigant output will lead to high temperature, to as high as 80℃ at the contacting location. Operator shall follow the warnings and notes for clinical use specified in this chapter (Chapter 6 ATTENTIONS DURING CLINICAL USE), to prevent patient injuries resulting from local overheating at the operational site.

Warning 6-2: The by-products during the surgery (smog and aerosol) might present cancerigenic and infectious hazards, therefore proper measures (protective glass and filter-type respirator) should be taken to protect O.R. staff.

Warning 6-3: A continuous motion of the cutting tip is needed for bone removal in order to minimize contact duration and minimize temperature increase, thus to avoid thermal damage.

Warning 6-4: During clinical use, do not cut in too deep at one cutting. A lateral sweeping layer-by-layer cutting motion is recommended for bone removal. When the surgical site is too deep, it is recommended to repeat the cutting motions, and make sure adequate cooling and lubrication to prevent thermal damage.

Warning 6-5: Do not squeeze the important soft tissues (e.g. dura mater and nerve) during the surgical procedure.

Warning 6-6: During surgical procedures, once found dura mater damaged, make sure cutting tip with ultrasound output do not contact with the dura mater lesion position.

Warning 6-7: In order to protect operator, do not hold cutting tip during surgery, and the correct

hand position is to hold the handpiece housing.

Figure 6-1 Correct holding

Figure 6-2 Incorrect holding

Warning 6-8: Do not use cutting tips exceeding lifetime during clinical use. Tips showing signs of deformation, cracking or damage should be replaced immediately to prevent cutting tip broken and causing malpractice.

Warning 6-9: Under excessive use (or beyond cutting tip lifetime) or wrong operational method, cutting tip could break into two or more fragments. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that no more broken piece is left in the surgical cavity.

Warning 6-10: Breakage of cutting tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Cutting tips showing signs of deformation, cracking or damage should be replaced immediately.

Warning 6-11: There might be bone chips formed during the bone cutting procedure, therefore operator should check and clean the surgical cavity after surgery to ensure that no more bone pieces are left in the surgical cavity.

Warning 6-12: The patient leakage current may increase if XD880A is used together with the endoscope device.

Warning 6-13: If XD880A is used with the endoscope device, the applicability of the endoscope passage must be checked before use, mismatched passage may cause injury to

the endoscope or the patient.

Warning 6-14: If XD880A is used with the endoscope device, the tip must be checked before use, irregular tip shape, rough tip surface and sharp edge and protrusion of the tip may cause injury to the patient.

Warning 6-15: XD880A Ultrasonic Osteotomy Surgical System is not applicable for endoscope of type CF applied parts.

Warning 5-9: Make sure sufficient irrigant discharges when outputs ultrasound, so as to prevent cutting tip from damaging by overheating or injuring tissue. The flow grade setting is recommended to set at 4 or higher.

Warning 5-10: Without the operator's permission, anyone else should not modify the setting parameters of XD880A console during surgery.

In addition to the above warnings, operators should also mind several other warnings**:**

Warning 6-16: Make sure there is no contact or friction between cutting tip and metal devices or other objects to avoid shortening the lifetime of cutting tip.

Warning 5-6: Make sure no inversion use of ultrasonic application part whenever there is ultrasound output, otherwise the operator may be injured and handpiece may be damaged by the backflow infiltration.

In the mean time, the following notes should be noticed**:**

Note 6-1: When mounting cutting tip to handpiece, always use specialized wrench to tighten the cutting tip.

Note 6-2: Try to avoid collision between cutting tip and other instruments, so as not to affect the lifetime of the cutting tip.

Note 6-3: During surgery, confirm there is no ultrasound output when replacing cutting tip or handpiece thus to protect operator.

Note 6-4: When waiting for use in surgery, handpiece should be kept from contacting with other instruments, patient or flammable objects, and confirm the console is at "Standby"

or power off state, to avoid harming operator or patient due to accidental start up.

Note 2-1: Foot switch consists of yellow (left) pedal and blue (right) pedal. Depress the blue pedal, only the peristaltic pump is activated and the irrigation function is only available; depress the yellow pedal, both the peristaltic pump and handpiece ultrasound output are activated to be ready for bone cutting. The function of single key foot switch is the same as the yellow(left) pedal of the double key foot switch.

Note 5-3: Pay close attention to the direction of tube when installing to peristaltic pump, make it consistent with the direction indicator and do not install in reverse.

Note 5-4: Confirm the connected part between infusion bag and infusion set is sterile, and such sterile environment isn't destroyed by the connecting process.

Note 5-5: Confirm the connected part between infusion set and liquid-flow tube is sterile, and such sterile environment isn't destroyed by the connecting process.

Note 5-6: In order to ensure there is sufficient irrigant discharges, depress blue pedal before surgery to activate peristaltic pump and make the liquid-flow tube full of irrigant and make the irrigant reach to the tip.

7. TROUBLESHOOTING

The possible faults, causes, and the corrective actions of XD880A are listed in Table 7-1. If there are faults that cannot be corrected or other faults, please contact authorized after sales service.

Warning 7-1: Do not open the case of console without authorization in order to avoid damage to the instrument or electric shock hazard. Open the case of console without producer's permission will void any applicable warranty.

Table 7-1 Possible faults, causes and corrective actions

Fault Phenomenon	Possible Cause	Corrective Action
No display after startup	Power cord wrongly connected.	Check connection at both ends of power cord and connect correctly.
	Fuse(s) blown.	Contact the after sales service to replace the fuse(s).
	Switch of Mains Power broken.	Contact the after sales service to replace the Mains Power switch.
Touch screen malfunction	Un-calibrated touch screen.	Recalibrate the touch screen.
	Touch screen damaged.	Contact the after sales service to replace the touch screen.
System time incorrect and cannot be adjusted	Display mainboard runs out of battery.	Contact the after sales service to replace battery.
No corresponding action(s) when foot switch pedal(s)	Foot switch disconnection.	Connect the foot switch.
	Foot switch damaged.	Replace the foot switch.

depressed	Bad connection of foot switch.	Replace the foot switch.
No irrigant discharge	Empty irrigant bag.	Replace the irrigant bag.
	Motor defect.	Contact the after sales service to replace the motor.
	Peristaltic pump stuck.	Remove the foreign object.
	Liquid-flow tube obstructed or defective.	Check for kinking, restrictions or leaks. Replace the tube if necessary.
	Liquid-flow tube damaged.	Replace the liquid-flow tube.
No or small amount ultrasound output	Self-test failed.	Run self-test.
	Insufficient power.	Increase the output power of system.
	Cutting tip loose.	Tighten the cutting tip.
	Cutting tip overheating.	Increase flow or wait until the cutting tip cooled.
	Cutting tip damaged (cracking or breakage).	Replace the cutting tip.
	Backflow to handpiece.	Replace the handpiece.
	Handpiece damaged.	Replace the handpiece.
Fatal error alert	Fatal error occurred on hardware or software.	Operate following the system guidance information. Contact after sales service if error still exists.

An alert is displayed together with a continuous audible indicator when error occurs. The screen cannot be operated anymore, and ultrasound and flow are force to suspend.

Warning 7-2: Immediately suspend operation if error appears on display and/or an audible indicator sounds. Remove cutting tip from surgical site, and do not touch the cutting tip or any metallic parts of the console. In case error cannot be recovered, turn the Mains Power off and contact the after sales service.

8. CLEANING

The following items are considered reusable and should be cleaned as recommended:

- Console
- Foot switch
- Handpiece
- Wrench & Torque Wrench
- Sterilization box

The following items are considered single use and must not be reused:

- Cutting Tip
- Liquid-flow Sleeve
- Liquid-flow Tube

8.1 Instrument Cleaning—Console and Foot switch

Warning 8-1: Turn off the Mains Power and follow hospital regulations to clean the console.

Warning 8-2: When cleaning the console, avoid liquid spraying or penetrating into the console to avoid damage to the internal electronic components, which may affect the service life of the console or cause risk of electric shock or fire in the subsequent use.

Note 8-1: Remove all accessories and clean them individually as required.

8.1.1 Console

The console is an power generator and is not intended to contact the patient. The steps of cleaning of the console should be followed:

1. Prepare neutral enzymatic detergent solution, such as 3M 70508, according to detergent manufacturer's instructions.
2. Use a clean soft cloth and neutral detergent solution to wipe the surface

of console manually. Visually inspect the surface of the console to ensure that all the visible debris has been removed.

3. Use a clean soft cloth and tap water(cold) to wipe the detergent solution manually.
4. Use a dry soft cloth to wipe the surface dry manually.
5. Visual inspect the console for cleanliness and damage following cleaning, repeat the cleaning steps if debris remains and mark the damaged parts clearly to prevent future use.

8.1.2 Footswitch

The foot switch is used by the operator's foot to control the output of the ultrasound. It is not intended to contact the patient. The steps of cleaning of the foot switch should be followed:

1. Prepare neutral enzymatic detergent solution, such as 3M 70508, according to detergent manufacturer's instructions.
2. Submerse foot switch and cable in the detergent solution for 2 minutes, and make sure the foot switch connector is not submersed.
3. Use a clean soft brush to manually clean foot switch and cable when submersing. Visually inspect the surface of the foot switch to ensure that all the visible debris has been removed.
4. Take out foot switch and cable, and rinse with running tap water(cold) for at least 1 minute.
5. Use a dry soft cloth to wipe foot switch and cable dry manually.
6. Visual inspect the foot switch for cleanliness and damage following cleaning, repeat the cleaning steps if debris remains and mark the damaged parts clearly to prevent future use.

8.2 Accessories Cleaning: Handpiece, Wrench, Torque Wrench and Sterilization box

The reusable parts, including Handpiece, Wrench, Torque Wrench and Sterilization Box, should be sterilized by moist heat method before use, and should be cleaned before sterilization.

Before cleaning, the following accessories need to be ready: clean soft cloth, standard soft

bristle, low-linting wipes, purified water1) and neutral enzymatic detergent solution (such as 3M 70508).

> **Warning 8-3:** The following reprocessing methods are in accordance with ISO17664-1. Please follow the instructions to ensure safe and intended use next time.

8.2.1 Manual Cleaning

- **Handpiece**

Handpiece is held by the operator and is used to complete the bone cutting associated with the cutting tip. The handpiece should be thoroughly cleaned after use and the following cleaning steps should be followed:

a. Disassemble

If there is cutting tip, liquid-flow sleeve or liquid-flow tube connected to the handpiece, the cutting tip, liquid-flow sleeve and liquid-flow tube should be disassembled from the handpiece(refer to section 4.4.2) firstly before thorough cleaning.

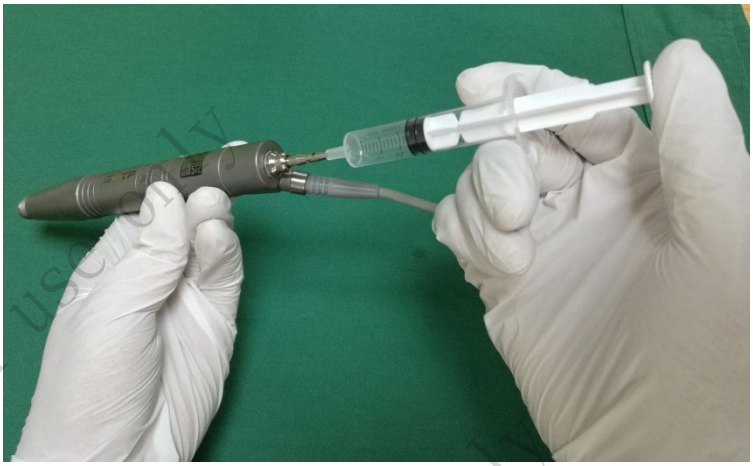
b. Point-of-Use Processing

Wipe the handpiece to remove all visible blood and soils immediately after use. If transport to the decontamination processing area is delayed, cover the handpiece with a damp cloth to keep it moist in order to facilitate later thorough cleaning process.

c. Thorough cleaning

1. Prepare neutral enzymatic detergent solution, such as 3M 70508, according to detergent manufacturer's instructions.
2. Use a clean soft cloth dipped with a little tap water(cold) to manually wipe the surface of handpiece, cable and connector to remove the easily removed soils.
3. Use a brush with detergent solution to brush all the visible debris or soils manually.
4. Use a clean soft cloth to wipe the detergent solution and soils clear under running tap water(cold).

5. Use a single-use syringe (20 ml) to inject the enzymatic detergent solution into the internal channel at the end of the handpiece three times in order to effectively remove the residues from the internal channel surfaces.



6. Use the syringe to inject purified water[1)] into the internal channel at the end of the handpiece four times in order to remove the detergent residues.
7. Rinse the handpiece under running purified water[1)] for at least 1 minute.
8. Use a dry soft cloth to dry handpiece and handpiece cable.

d. Inspect

Visual inspect handpiece and cable for signs of damage such as crack, broken, deformation, etc. Mark damaged parts clearly to prevent future use.

e. Post-cleaning

Visual inspect all parts for cleanliness and damage following cleaning and prior to terminal sterilization. The inner surface can be inspected with the use of magnifying glass under adequate lighting. Repeat the cleaning steps if debris remains.

Low-linting wipes is recommended to dry the Handpiece. After cleaning, please tidy up the Handpiece cable and the Handpiece does not need to reconnect with the tips.

- **Wrench and Torque Wrench**

The wrench and torque wrench are used to assemble/disassemble the tip to/from the handpiece. The following cleaning steps should be followed:

a. Point-of-Use Processing

Wipe the wrench or torque wrench to remove all visible blood and soils

immediately after use. If transport to the decontamination processing area is delayed, cover the wrench or torque wrench with a damp cloth to keep it moist in order to facilitate later thorough cleaning process.

b. Thorough cleaning

1. Prepare neutral enzymatic detergent solution, such as 3M 70508, according to detergent manufacturer's instructions, and submerse the wrench for at least 2 minutes.
2. Use a clean soft brush with detergent solution to manually brush all the visible soils when submersing, and make sure no soils left on the surface.
3. Rinse the wrench with purified water[1)] for at least 1 minute.
4. Use a dry clean soft cloth to wipe the wrench dry.

c. Inspect

Visual inspect the wrench for signs of damage such as crack, broken, deformation, etc. Mark damaged parts clearly to prevent future use.

d. Post-cleaning

Visual inspect all parts for cleanliness and damage following cleaning and prior to terminal sterilization. Repeat the cleaning steps if debris remains.

- **Sterilization box**

The following cleaning steps should be followed when cleaning the sterilization box:

a. Point-of-Use Processing

Wipe the sterilization box to remove all visible blood and soils immediately after use.

b. Thorough cleaning

1. Prepare neutral enzymatic detergent solution, such as 3M 70508, according to detergent manufacturer's instructions, and submerse the sterilization box for at least 2 minutes.
2. Use a clean soft brush with detergent solution to manually brush all the visible soils when submersing, and make sure no soils left on the surface.
3. Rinse the sterilization box with purified water[1)] for at least 1 minute.

4. Use a dry clean soft cloth to wipe the sterilization box dry.

c. Inspect

Visual inspect the sterilization box for signs of damage such as crack, broken, deformation, etc. Mark damaged parts clearly to prevent future use.

d. Post-cleaning

Visual inspect all parts for cleanliness and damage following cleaning and prior to terminal sterilization. Repeat the cleaning steps if debris remains.

Warning 8-4: Do not use alcohol to clean the power connector of the Handpiece.

8.2.2 Automated Cleaning

The following steps should be performed when using automated cleaning:

a. Disassemble

If there is cutting tip, liquid-flow sleeve or liquid-flow tube connected to the handpiece, the cutting tip, liquid-flow sleeve and liquid-flow tube should be disassembled from the handpiece(refer to section 4.4.2) firstly before thorough cleaning.

The wrench and torque wrench can't be disassembled.

b. Point-of-Use Processing

Wipe the accessories to remove all visible blood and soils immediately after use. If transport to the decontamination processing area is delayed, cover the accessories with a damp cloth to keep it moist in order to facilitate later thorough cleaning process.

c. Pre-cleaning

1. Prepare neutral enzymatic detergent solution, such as 3M 70508, according to detergent manufacturer's instructions.
2. Use a clean soft brush with detergent solution to manually brush all the visible soils on the surface of the accessories.
3. Use a single-use syringe (20 ml) to inject the enzymatic detergent solution into the internal channel at the end of the handpiece three times in order

to effectively remove the residues from the internal channel surfaces.

4. Use the syringe to inject purified water[1)] into the internal channel at the end of the handpiece four times in order to remove the detergent residues.

5. Rinse the accessories under running purified water[1)] for at least 1 minute.

6. Visually inspect the surfaces of all accessories until all visible debris and soils are removed. The inner surface can be inspected with the use of magnifying glass under adequate lighting. Repeat the above steps as required until all visible debris and soils are removed.

d. Automated cleaning

1. Lay all the accessories: handpiece, wrench and torque wrench in a metallic tray. Arrange the material in a washer/disinfector into which the detergent solution liquid and neutralising solution have been previously loaded, in accordance with the manufacturer's instructions.

Note 8-2: Place the instruments in the washer/disinfector so that dead zones do not arise and the water can properly drain. Also, make sure that the handpiece and the metal front cone are properly held in place in the washing tray and cannot move during the washing process, as shocks could damage them.

Warning 8-5: Avoid overloading the washer/disinfector as this may compromise cleaning effectiveness.

2. Sequence and parameters applicable to the cycle:

Phase	Time	Parameters
Pre-wash 1	1 min	Cold tap or purified water
Washing 1	5min	with neutral enzymatic detergent solution at ≥ 65.5°C(150℉)
Rinse 1	1 min	Rinsing with purified water[1)]

Disinfection	5 min	Thermo-disinfection at 90°C(194℉) with demineralized water
Drying	6 min	≥98.8°C (210℉)

Note 8-3: The automatic disinfection was not experimentally tested. According to ISO 15883-1, the thermo-disinfection at a temperature of 90 °C for 5 minutes determines an A0 value of 3000.

Note 8-4: Do not use the ultrasonic cleaner to clean handpiece.

e. Post-cleaning

Inspect all parts for cleanliness and damage following cleaning and prior to terminal sterilization.

1) Purified water: The final rinse purified water should meet the requirements of the Critical Water in AAMI TIR34 Water for the reprocessing of medical devices.

9. STERILIZATION

Prior to surgery, handpiece and wrench (and torque wrench) need to be sterilized by moist heat sterilization. The sterilization parameters are shown as follows:

ITEM	PARAMETER 1	PARAMETER 2
Configuration	Items wrapped, without sterilization box*	Items wrapped, without sterilization box*
Cycle	Gravity	Prevacuum
Temperature	121 ℃(250℉)	134 ℃(273.2℉)
Exposure Time	30min	4min
Minimum Dry Time	15-30minutes	20-30minutes

*No sterilization box, wrapped in sterilization wrap.

ITEM	PARAMETER 1	PARAMETER 2
Configuration	Items in SMTP sterilization box (XDF06801)*	Items in SMTP sterilization box (XDF06801)*
Cycle	Gravity	Prevacuum
Temperature	121 ℃(250℉)	134 ℃(273.2℉)
Exposure Time	30min	4min
Minimum Dry Time	15-30minutes	20-30minutes

*Sterilization box wrapped in sterilization wrap.

Note 9-1: After moist heat sterilization, The handpiece should be cooled down to normal temperature, and then take to use.

Note 9-2: Do not stack trays during sterilization.

10. MAINTENANCE

10.1 Console

1. Handle the console gently and avoid bumping.
2. Turn off the Mains Power after use, and disassemble the accessories and place in required environment conditions.
3. If it is not going to be used for a long time, the console needs to be cleaned and stored.

Note 10-1: Make sure XD880A is upright and no violent vibration when being moved, handled, installed, and when it is working.

10.2 Handpiece

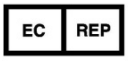
1. Handle the handpiece gently, avoid knocking and dropping.
2. After usage, wipe clean and dry the handpiece, avoid storing with other hard objects.

10.3 Wrench

1. Wrench shall only be used in tip mounting and removing.
2. After use, clean the wrench and store.

11. EXPLANATION OF SYMBOLS

Table 11-1 Explanation of XD880A related symbols

Symbol	Description	Symbol	Description
	Protective earth ground		Caution: Consult accompanying documents
	Warning: Dangerous voltage		Type BF equipment
	Foot switch		Rotation direction of peristaltic pump
	Authorized EC representative		Production date
	Manufacturer		Non-sterile
	Batch Code		Use by Date
	Do not reuse		Sterilized using Ethylene Oxide
	Do not use if package is damaged		SMTP CE number
	Caution: Pinch hazard		AC

I	Mains Power ON	O	Mains Power OFF
	No soaking for handpiece	US	Ultrasound Output
	Fuse		This Side Up
	Keep away from rain		Stack limit
	Storage temperature		Fragile
	Keep away from heat		
	The disposal of the waste of electric and electronic equipments is to be compliant with EN 50419 (WEEE directive). This kind of waste must be sent to separate collection facilities for recovery and recycling after decontaminated following decontamination instructions.		

12. SERVICE

12.1. Service

All requests for repairs and parts replacements should be directed to SMTP Technology Co., Ltd. or its authorized representative. Always provide models of malfunctioning parts and product serial number.

The warranty parts and the warranty periods are listed in Table 12-1, unless otherwise specified in contract or regulated by local laws and regulations, and the warranty period starts from the date of receipt.

Parts need to be repaired or replaced shall be returned to SMTP Technology Co., Ltd. or its authorized distributors within the following warranty periods, and would be repaired or replaced after verification of failures by SMTP Technology Co., Ltd.

Table 12-1 Warranty items and periods

Item	Warranty Period
Console	1 Year
Foot switch	1 Year
Handpiece and handpiece cable	6 Months

Conditions that will void any applicable warranty**:**

1. Use of parts furnished by other sources;
2. Use of parts sold by other sales agents unauthorized by SMTP Technology Co., Ltd.;
3. Repaired at other repair centers unauthorized by SMTP Technology Co., Ltd.;
4. Operator doesn’t comply with the operator’s manual;
5. Broken by misuse or neglect.

12.2. Important Notice

Customers shall only return any Product or any part of the Product after permitted by SMTP Technology Co., Ltd. or its authorized distributor.

By returning any material to SMTP the customer must certify that any and all parts returned are or have been rendered free of any hazardous or noxious matter or radioactive contamination and are safe for handling under normal repair center conditions.

12.3. Contact Method

Manufacture: SMTP Technology Co., Ltd.

Address: 1F&4F, Building A, Emerging Industry Incubation Center, Zhangjiagang Free Trade Zone, Jiangsu, P.R.China

Website: www.smtpmed.com

Email: marketing@smtpmed.com

Tel: +86-512-82508100

Fax: +86-512-82508100

Service Tel: +86-512-82508100

SMTP Technology Co., Ltd.
1F&4F, Building A, Emerging Industry Incubation Center,
Zhangjiagang Free Trade Zone, Jiangsu, 215600, P.R.China

EC REP

Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Dimdi No.: DE/0000040627

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