MD-480A

PHACO EMULSIFIER

USER'S MANUAL

Version 1.0

CONTENTS

PRECAUTIONS

- The instrument should be operated by trained doctors.
- Please read the manual carefully before installation and operation
- Please refer to §5. Cleaning, Disinfection and Sterilization to avoid cross-infection while using.
- Unplug power supply before cleaning.
- Please refer to §6. Maintenance, Attentions and Simple Defects Treatment for maintenance, attentions and simple defects treatment.

WARNINGS

- The customer is fully responsible for maintenance and management of the instrument after purchasing.
- Do not make any modification to the software and hardware of the Device without authorization.
- The manufacturer won't be responsible for any damage or injury caused by any failure to follow the instructions in the **User's Manual**.
- The manufacturer reserves the right to modify equipment characteristics without previous notice under ***FDA Laws*** and ***MDD (93/42/EEC)*** Regulation.
- The quality guarantee of MD-480A will be invalid if it is opened (even partially), modified or repaired in any way by anyone who is not authorized by the manufacturer.
- According to FDA laws, MD-480A is a prescription device and is to be used by or under the supervision of a licensed physician.
- Disconnect AC power before cleaning the housing.
- Do not drop the handpieces.
- Although appropriate shielding measures have been taken to the instrument, the 40kHz (in U/S mode）and 1MHz (in Cautery mode) electromagnetic radiation generated by the instrument is still possible to interfere with other electronic devices. Therefore, patient with pacemaker should use it cautiously. If other medical electronic devices will be applied with MD-480A at the same time, it is recommended to test the mutual interference before clinical application.
- It is only allowed to use the Handpieces, Cautery Forceps and all Tubing sets supplied along with the instrument.
- Do not touch the activated U/S Tip; otherwise, it may cause injury.
- Do not adjust the U/S Handpiece when it is close to patient's eye in order to avoid injury to patient.
- The irrigation solution’s hanging height should be controlled according to the requirement of §4.2.1 Phaco Emulsification. If the height is too low, it can not guarantee the necessary flow rate; while if the height is too high, it may lead to the risk of excessive static press.

- The height of the instrument placed should be controlled according to the requirement of §4.2.1 Phaco Emulsification, in order to ensure the exit of irrigation solution is higher than the level of patient's eye.
- Make sure the liquid in the Drain Container shall not exceed the maximum capacity. Otherwise, it may cause injury to patient.
- MD-480A has the program of “TEST”. Please perform this program when the system is started up and before each surgery to make sure the system is working in normal state.
- Keep the original package properly. All detachable accessories should be put into the original package before moving.
- Warnings of predicable potential hazards are contained in the **User’s Manual**. Please maintain vigilance at any time to those unpredictable hazards. The manufacturer won’t be responsible for damages and losses caused by negligence or ignorance of the preventive measures in the **User’s Manual**.
- The assembly, expanding, readjustment, improvement and repair should be operated by personnel authorized by the manufacturer. Do not open the housing for repair without permission. The manufacturer won’t be responsible for the consequences of safety and effectiveness caused by unauthorized repair.

For any question, please contact the Manufacturer or your Local Distributor

CAUTION

HOW TO PREVENT CROSS-INFECTION

- Between uses on different patients all parts mentioned in Chapter 5 must be cleaned, disinfected and sterilized to prevent cross-infection.
- Manufacturer advocates a preventive action and a cleaning procedure in Chapter 5. Cleaning, Disinfection and Sterilization.

TISSUE EXPOSURE TO ULTRASOUND ENERGY

- The MD-480A is designed for use in ophthalmology only.
- The system controls limit of the high-frequency cautery output energy within the parameters specified for its intended purpose. Please refer to **Annex A** of the **User's Manual**.
- No control of ultrasound energy is available to the users other than the duration of exposure, considering the current concern for possible unknown hazards, and despite the extremely low output intensities used in this ultrasound system.

Labels and Indicators

Front Panel

	Application Part of BF Mode
	Symbol of "Type B"
CAUTERY	Bipolar Cautery Forceps Socket
U/S	Phaco Emulsifier Handpiece Socket
VIT	Vitrector Socket

Rear Panel

INPUT	Power Input Socket
~220V 50Hz	Power Rating
Power Switch	Power Switch Button
|	Power On
○	Power Off
Footswitch	Footswitch Socket
Fuse	Fuse Socket
5S 3A/250V	Fuse Specification
IPX8	The degree of protection against ingress of liquids

User's Manual

	Attention — Important prompt information during operation.
	Note! Important information that operator must read carefully.

Chapter1. Introduction

1.1 General Description

MD-480A Ultrasonic Phaco Emulsifier is a medical device designed for surgery of cataract extraction. It utilizes ultrasound energy to crash the cataract lens, emulsifies it and pumps it out. In order to cope with cases often occurred in the process of surgery, MD-480A is designed with anterior segment vitrectomy, bipolar cautery. Vitrectomy is for cutting the lens, and cautery is used to burn the blood vessels to stop bleeding.

1.2 Intended Use

MD-480A Ultrasonic Phaco Emulsifier is used for surgery of cataract extraction.

1.3 Contraindications

Patients with severe eye infection or trauma are prohibited to use the device.

1.4 Software Version

MD-480A V1.0

Chapter2. Specifications

2.1 Working Conditions

1) Power supply: AC220V±10%，50Hz±2%
2) Temperature: 10°C-30°C
3) Relative Humidity: ≤70%

2.2 Main Specifications

2.2.1 Phaco Emulsification

1) Phaco Emulsification Frequency: 40KHz±20%
2) U/S Handpiece Top End Vibration Accuracy: Max. 120μm±20%
3) Stimulating Power Range: 0~100%, soft keyboard input or adjustable stepping, Step: 1%
4) Pulse Frequency:1Hz~99Hz, soft keyboard input or adjustable stepping, Step:1Hz; effective emulsification time:1%~99% (≥5ms)
5) Soft Keyboard Input or Adjustable Stepping: Step:1%; display accuracy: ≤±10%
6) Burst Time: 5ms~100ms, soft keyboard input or adjustable stepping; Step:1ms; display accuracy: ≤±10%
7) Max. Vacuum:66.7kPa (500mmHg); display accuracy: ≤±15%
8) Max. Flow Rate: 40 ml/min; display accuracy: ≤±20%

⚠ ***Note: 1 mmHg = 0.133 kPa, the common values are shown in Table 2.1.***

Table 2.1 Comparison Table for Conversion between mmHg and kPa

mmHg	kPa
100	13.3
200	26.7
300	40.0
400	53.3
500	66.7

2.2.2 High-Frequency Cautery

1) Rating Frequency:1MHz±20%
2) Max. Output Power: 10W±20% (200Ω Load)
3) Output Adjustable Range: 0~100%, soft keyboard input or adjustable stepping, Step: 1%; display accuracy: ≤±20%

2.2.3 Vitrectomy

1) Cutting Frequency: single mode or (20~600) times/min, soft keyboard input or adjustable stepping, step of 5 times/min, display accuracy: ≤ ±15%

2) Max. Vacuum: 66.7kPa (500mmHg), display accuracy: ⩽ ±15%

3) Max. Flow Rate: 40 ml/min, display accuracy: ⩽ ±20%

2.2.4 Irrigation/Aspiration

1) Vacuum Range: 1mmHg~500mmHg

2) Flow Rate: 1 ml /min~40 ml /min

3) Max. Vacuum: 66.7kPa (500mmHg), display accuracy: ⩽ ±15%

4) Max. Flow Rate: 40 ml/min, display accuracy: ⩽ ±20%

5) Reflux Rate: 20 ml/min±20%

2.3 Safety

In accordance to IEC 60601-1:1988+A1+A2.

2.4 Storage and Transportation

1) Storage Condition:

The instrument should be stored in a well-ventilated room with no corrosive gas.

Temperature: -10℃-45℃;

Relative humidity: ≤80%.

2) Transportation Condition:

The accessories should be packed in to original package before transportation. Severe impact and crash, rain and snow shall be avoided.

2.5 Classification

1) As per the type of protection against electric shock: Class I;

2) As per the degree of protection against electric shock:
   ——U/S Handpiece, Vitrector, I/A handpiece: Type B;
   ——Bipolar Cautery Forceps: Type BF;

3) As per the degree of protection against ingress of liquids:
   ——Main Unit: IPX0;
   ——Footswitch: IPX8;

4) As per the safety degree under flammable anesthetic gas mixed with air or under flammable anesthetic gas mixed with oxygen or nitrous oxide: not belong to AP and APG equipment;

5) As per the mode of operation: Intermittent load continuous operation; continuous load for 30 minutes, interval for 20 minutes.

6) MD-480A has no application part for protection of defibrillator discharge effect

7) MD-480A has no signal-in/signal-out part;

8) MD-480A is not permanently-installed device.

Chapter3. Installation and Connection

3.1 Structure

MD-480A consists of the Main Unit, U/S (Phaco Emulsification) Handpiece, Bipolar Cautery Forceps, Vitrector, I/A (Irrigation/Aspiration) Handpiece, Footswitch and accessories (including U/S Tip, U/S and/or I/A Sleeves, U/S and/or I/A Test Chamber and Vitrectomy Irrigation Sleeve). The structure is shown in Fig 3-1.

Fig 3-1a: Front Panel

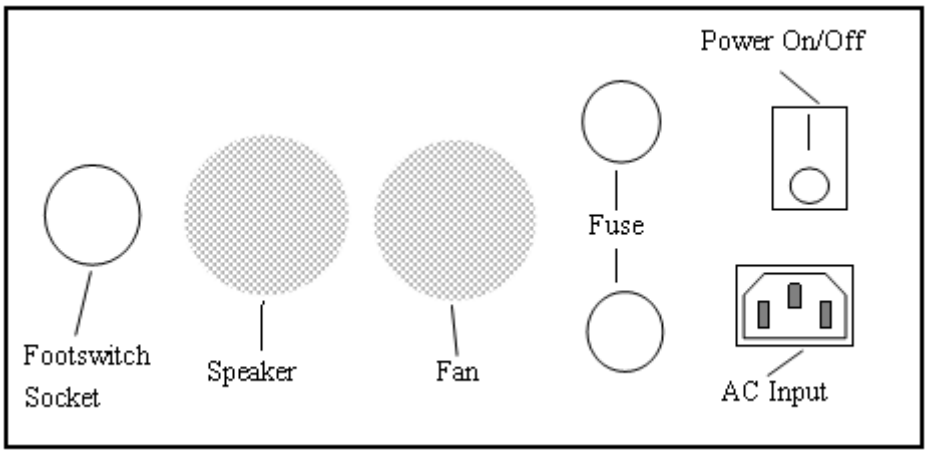


Fig 3-1b: Rear Panel

1) Power Input Socket

   For connection with power supply cable. Please refer to § 3.3.1 Power Cable Connection.

2) Power Switch

   Press the switch " | " side to start MD-480A, and the power LED lights up.

   While MD-480A is running, press the switch to "○" side to shut it down and the Power LED turns out.

3) Color Touch LCD

Use the soft keys on touch screen to operate MD-480A. Please refer to § 4. Operation for details.

4) LED Power Indicator

The LED Power Indicator is lit green when MD-480A is started up.

The LED Power Indicator is off when MD-480A is shut down.

5) U/S Handpiece Socket

For connection with U/S Handpiece. Please refer to § 3.3.4 U/S Handpiece Connection / Disconnection.

6) Bipolar Cautery Forceps Socket

For connection with the Cautery Forceps. Please refer to § 3.3.6 Bipolar Cautery Forceps Connection/Disconnection.

7) Vitrectomy Socket

For connection with the Vitrector. Please refer to § 3.3.7 Vitrector Connection/Disconnection.

8) Peristaltic Pump

Under the mode of U/S, Vitrectomy or I/A, press the Footswitch to Detent 2, the Peristaltic Pump will start working to produce a vacuum. Refer to § 4.14 Operation of Footswitch.

9) Vacuum Sense Port

Detect the vacuum inside the tubing real-timely and the vacuum value displays on the screen. See Fig 4-2⑤.

10) Irrigation Pinch Valve

Under the mode of U/S, Vitrectomy or I/A, press the Footswitch to 1st detent, the irrigation pinch is open. Refer to § 4.14 Operation of Footswitch.

11) Footswitch Socket

For connection with Footswitch. Refer to § 3.3.2 Footswitch Connection/Disconnection.

12) Fuse

Two fuses are used to protect MD-480A from excessive current.

13) Fan

Heat dissipation of MD-480A.

14) Speaker

Speaker of MD-480A.

15) Footswitch

There are three pedals, separately: treadle, cautery switch (left) and reflux switch (top), as shown in Fig 3-2.

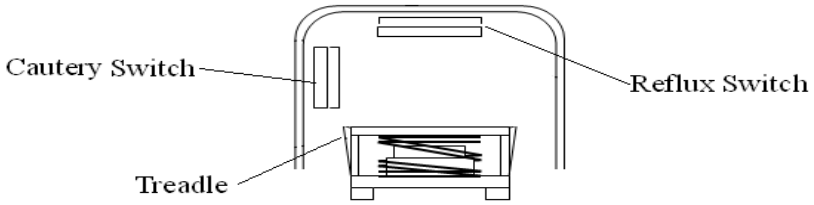


Fig 3-2 Schematic Diagram of Footswitch

3.2 Environment Requirements

MD-480A is required to be working in the environment with temperature of 10℃-30℃, and relative humidity no more than 70%. In order to assure MD-480A is running well, please use it in the air-conditioned room.

Proper grounded single-phase three-pole power socket should be used. Improper connection of protective earth may cause not only interference, but also the risk of current leakage.

MD-480A requires AC power of 220V±10%, please use AC voltage stabilizer if the local AC power cannot meet the requirement.

Do not use the equipment in locations subject to intense electric or magnetic fields. Avoid high electromagnetic devices (e.g. Microwave, RF generator) and direct sunlight.

MD-480A should be placed on a stable worktable whose height should ensure the bottom of the instrument shall not be lower than patient's eye.

3.3 Accessories Connection

⚠ ***Note: It is prohibited to connect or disconnect power cable and footswitch when the instrument is power on!***

3.3.1 Power Cable Connection

Insert one end of the power cable into the "**AC Input**" on the rear panel of the main unit and the other end into a proper grounded single-phase three-pole power socket on the wall or the AC voltage stabilizer.

⚠ ***Note: Please check if the single-phase three-pole AC power socket or the AC voltage stabilizer is well grounded.***

3.3.2 Footswitch Connection/Disconnection

Connect the footswitch connector with the footswitch socket, being sure the pit in the footswitch connector aligns with the bulge in the socket. Then fasten the ring of the connector clockwise to complete the connection of the footswitch.

To disconnect the footswitch, please first loosen the ring of the connector anticlockwise and then pull the footswitch connector horizontally to disconnect it.

3.3.3 Tubing Connection

1) Irrigation Tubing Connection

The Irrigation Bottle of balanced salt solution may be put on the perfusion support.

Touch the Irrigation key **IRR.** to open the Irrigation Pinch Valve and insert the Irrigation Tubing into Irrigation Pinch Valve. See Fig 3-3. Touch **IRR.** again to close the Irrigation Pinch Valve.

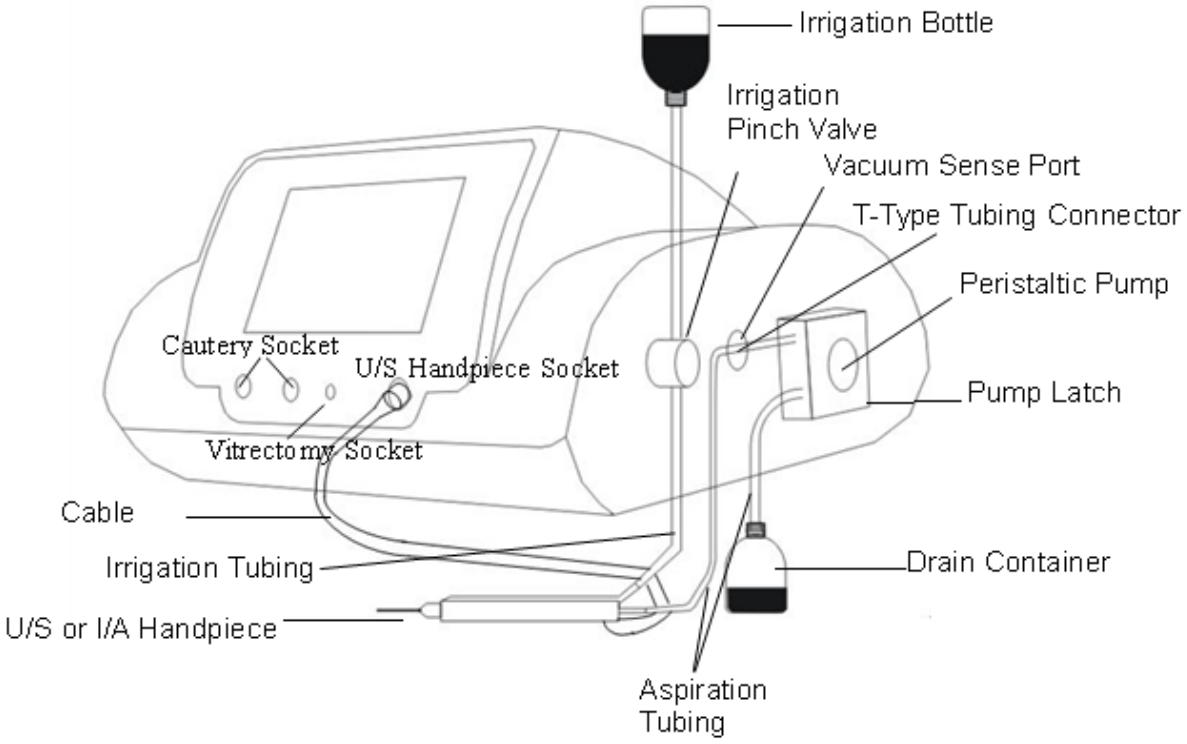


Fig 3-3: Tubing Connection

The irrigation pressure varies with the relative height from Vacuum Sense Port to Irrigation Bottle, and their corresponding values are shown in Table 3-1.

Table 3-1

Relative Height（cm）	20	40	60	80	90
Irrigation Pressure（mmHg）	14.5±2.5	30.5±2.5	45.5±2.5	58.5±1.5	66.5±1.5

⚠ ***Notes:***

① The silicon rubber tubing used shall meet related standards, and be registered for product certificates through medical device listing approval. Please refer to §7.2.1 Accessories for detailed specification.

② Make sure there is sufficient balanced salt solution in the Irrigation Bottle and the height of the Irrigation Bottle should make the vertical distance between the solution level and the Vacuum Sense Port to be 80cm ~90cm.

2) Aspiration Tubing Connection

Connect one end of the T-pipe connector onto the Vacuum Sense Port. See Fig 3-3.

Follow the instruction of Fig 3-4(a) to open the Peristaltic Pump clip, and wind the silicon rubber tubing onto the Peristaltic Pump as shown in Fig 3-4(b). Close the pump clip as Fig 3-4(b), and put the outlet pipe into the Drain Container, see Fig 3-3.

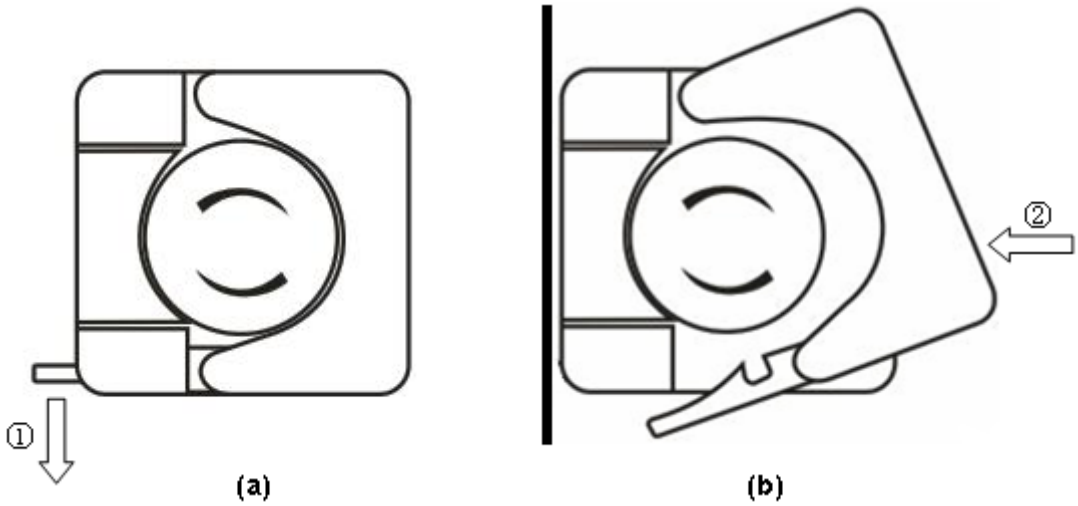


Fig 3-4: Peristaltic Pump

3.3.4 U/S Handpiece Connection/Disconnection

Place the red mark on the U/S Handpiece connector aligning with the red mark on U/S Socket, and then insert the connector into the socket horizontally to finish the connection. For disconnecting the U/S Handpiece, hold the connector of U/S Handpiece and pull it out horizontally.

Screw the U/S Tip onto the U/S Handpiece and fasten it with Tip Wrench; then screw on the Irrigation Sleeve, see Fig 3-5.

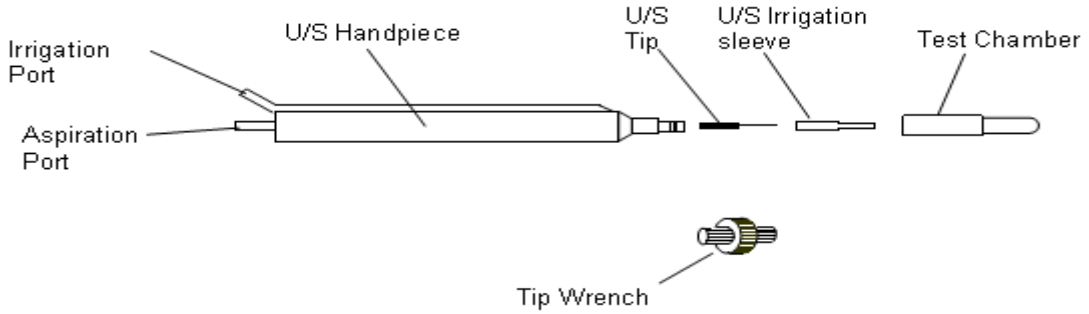


Fig 3-5 Installation of U/S Handpiece

Connect the Irrigation Tubing with the Irrigation Port of U/S Handpiece; and connect Aspiration Tubing with the Aspiration Port of U/S Handpiece. See Fig 3-3.

3.3.5 I/A Handpiece Connection/Disconnection

The installation of I/A Handpiece and I/A Tip is shown in Fig 3-6.

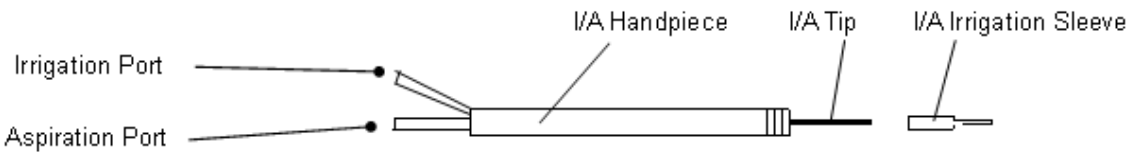


Fig 3-6 Installation of I/A Handpiece

Connect the Irrigation Tubing with the Irrigation Port of I/A Handpiece; and connect Aspiration Tubing with the Aspiration Port of I/A Handpiece.

3.3.6 Bipolar Cautery Forceps Connection/Disconnection

Align the connector of Bipolar Cautery Forceps with the Cautery Socket, and then insert the connector into the socket horizontally to finish the connection. For disconnecting the Bipolar Cautery Forceps, hold the connector of Bipolar Cautery Forceps and pull it out horizontally.

3.3.7 Vitrector Connection/Disconnection

Align the Vitrector connector with Vitrectomy Socket and screw the connector clockwise to finish the connection. For disconnecting the Vitrector, hold the connector of the Vitrector and screw it out anticlockwise.

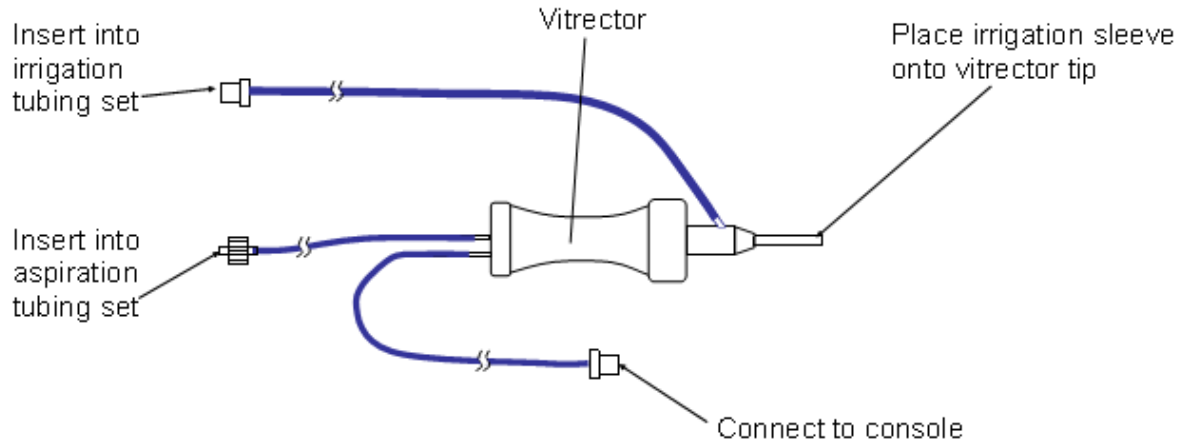


Fig 3-7 Vitrector Connection

Insert the Irrigation Connector into Irrigation Tubing; and insert the Aspiration Connector into Aspiration Tubing.

3.3.8 Fuse Replacement

The specification of fuse is: 5S 3A/250V Slow Fuse, φ5×20.

The replacement of fuse will be completed with a tool of "—" screw driver. As shown in Fig 3-8, put the screw driver into the slot of the fuse socket along direction ① and press it. Rotate the screw driver anti-clockwise as per direction ② and the fuse socket will pop out automatically. Hold the fuse socket to pull it out and then take out the fuse from the fuse socket.

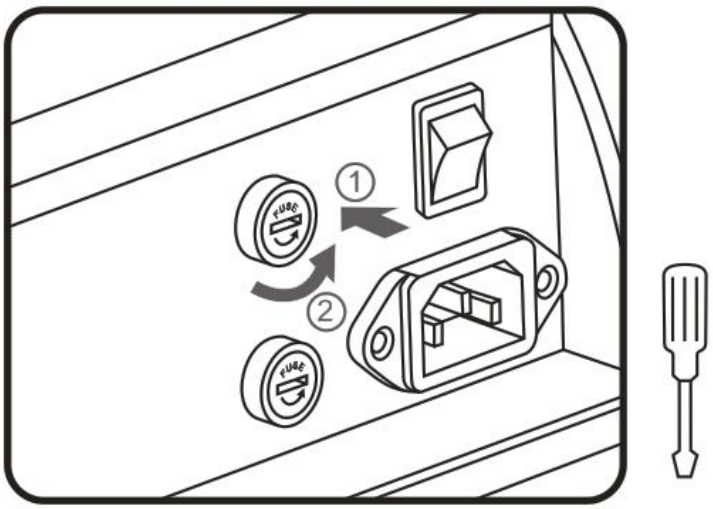


Fig 3-8: Disassembly of Fuse

⚠ ***Note: New fuses must be same as specified in the User's Manual.***

As shown in Fig 3-9, put the new fuse in the fuse socket, and place the fuse socket into the fuse socket hole along direction ①. Put the screw driver into the slot of the fuse socket along direction ① and press it. Rotate the screw driver clockwise as per direction ② to complete the fuse replacement.

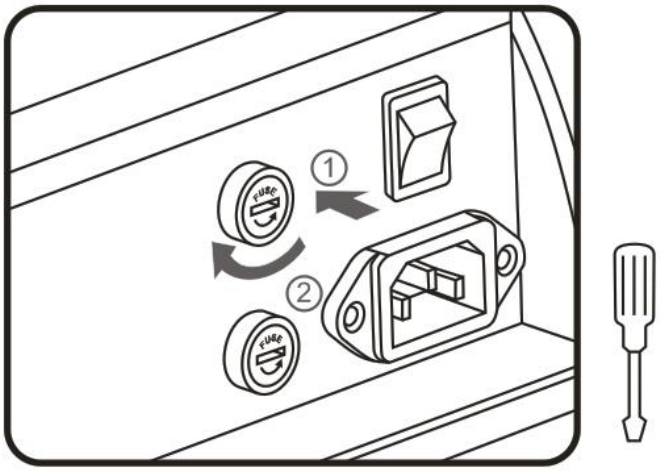


Fig 3-9: Installation of Fuse

Chapter4. Operation

4.1 Start-Up and Shut-Down

4.1.1 Check-Ups before Start-Up

1) Check the ambient environment:
   - If there is any device around which may cause interference to MD-480A;
   - If MD-480A is working in a dry room.
2) Check the appearance of MD-480A:
   - If there are cracks on the housing and LCD screen.
3) Check if U/S Handpiece, Vitrector and Cautery Forceps are well-connected:
   - If the connector looses and there are cracks on the applied part;
   - If the cables wind up with other cables;
   - If the surfaces and cables of U/S Handpiece, Vitrector and Forceps are with cracks or bad insulation.
4) Check if the Footswitch is well connected:
   - If the connector is loose;
   - If the Footswitch cable winds up with others;
   - If the Footswitch is working rightly.
5) Above check-ups must be done and passed before starting MD-480A.

4.1.2 Start-Up

Press the power switch on the rear panel to the position of " | ", MD-480A starts and the power indicator lights up and turns to green. The screen displays the startup interface and then enter the U/S (Phaco emulsification) interface after self-check.

4.1.3 Check-Ups before Uses

Please make following routine checks before uses:

1) If the Power LED indicator lights up as green;
2) If the touch screen works rightly;
3) If the footswitch works rightly;
4) Check the system settings according to §4.12 Parameter Setup;
5) Connect tubing according to §3.3.3 Tubing Connection;
6) Test tubing according to §4.11 Test;
7) For disinfection and sterilization of U/S Handpiece, Vitrector and Bipolar Cautery Forceps, please refer to §5. Cleaning, Disinfection and Sterilization.

4.1.4 Shut-Down

Press the power switch on the rear panel to the position of "O", MD-480A shuts down.

⚠ ***Note: Please unplug the power cable and disconnect it from the main power supply.***

4.2 Operation

4.2.1 Phaco Emulsification

1) Connect power cables, Footswitch and U/S Handpiece etc. Refer to §3.3 Accessories Connection;
2) Turn on the power switch to start MD-480A (Make sure the Vacuum Sense Port is opened before turning on the power switch);
3) Connect the U/S Handpiece and U/S Tubing. Please refer to § 3.3.4 U/S Handpiece Connection/Disconnection;
4) Take up the handpiece and infuse 3/4 of solution into the Test Chamber; install the Test Chamber onto the Handpiece;
5) Touch **TEST** key in the main interface to start ***Auto Test***, please refer to §4.11 Test;
6) Observe the testing process and wait till it is finished;
7) If the ***Auto Test*** passes, please switch to step 9;
8) If there is Tubing Block, Tubing Leakage or Handpiece Failure, please check if the tubing kit is inclosed, intertwined, knotted and blocked. Return to step 4 to restart the test after the problem solved.
9) Take off the Test Chamber from the Handpiece.
10) Click **SET** --- **TUNE** keys to finish tuning when the **TUNE** key returned to blue from highlighted.
11) To set the parameters or load a set of saved parameters. Please refer to § 4.12 Parameter Setup and § 4.13 Save and Load of Working Parameters.
12) Use the Footswitch to perform surgical operation. Please refer to § 4.14 Operation of Footswitch.

⚠ ***Notes:***

(1) After each replacement of Handpiece, it is necessary to operate TUNE to confirm. Please refer to §4.12.3 TUNE.

(2) It is necessary to test the system before each clinical application!

(3) The main unit should be placed at the height to ensure the Vacuum Sense Port is as the same level of as patient's eye.

(4) The height from Vacuum Sense Port to irrigation solution level should be between 80cm ~90 cm. Please do test again when the Irrigation Bottle is lowered during operation.

(5) Only the recommended tubing kit can be used with the instrument. Please refer to §7.2.1 Accessories.

(6) Please check the cables of Handpiece and others. Stop using and contact us if there is any broken.

(7) It is prohibited to make any modification (bend, cut or carve etc.) to U/S Handpiece and U/S

Tip. Otherwise it may cause malfunction or injury to patient.

(8) Do not touch the activated U/S Tip; otherwise, it may cause injury.

(9) Do not adjust U/S Handpiece when it is close to patient's eye, in order to avoid injury to patient.

(10) Make sure the liquid in the Drain Container shall not exceed the maximum capacity. Otherwise, it may cause injury to patient.

(11) Please clean the Handpiece immediately after use to avoid block of tubing.

(12) Handpiece cannot be cleaned with metal brush.

(13) Handpiece must be disinfected before uses.

(14) Handpiece must be cleaned before high-temperature disinfection.

(15) It is prohibited to output ultrasound power without water. Otherwise the handpiece may be destroyed.

4.2.2 Auto Clean of the U/S Handpiece

1) Connect Handpiece and its tubing. Please refer to §3.3.4 U/S Handpiece Connection / Disconnection;
2) Fill the Irrigation Bottle with distilled water;
3) Install the Test Chamber;
4) Touch the **CLEAN** key in Main Interface to start **Auto Clean**. Please refer to §4.10 Cleaning. Distilled water should be used to clean the tubing and handpiece.
5) Touch **CLEAN** key again to exit and return to Main Interface.
6) Take off the Irrigation Tubing and Aspiration Tubing.
7) Take off the Test Chamber, Irrigation Sleeve and U/S Tip in sequence.
8) Connect the injector to Irrigation Port and Aspiration Port of the Handpiece with silicone tube. And push the injector several times to blow dry the Handpiece.

4.2.3 Irrigation/Aspiration

Please refer to §4.2.1 Phaco Emulsification and §4.2.2 Auto Clean of the Handpiece for test, clean and attentions.

4.2.4 Vitrectomy

For vitrectomy and its tubing connection, please refer to §3.3.7 Vitrector Connection/Disconnection.

☞ ***Attention: Other installation and attentions are same with the operation of Phaco Emulsification.***

4.2.5 Cautery

1) Please refer to §3.3.6 Bipolar Cautery Forceps Connection/Disconnection for connection of Bipolar Cautery Forceps.
2) Touch **CAUTERY** key in the Main Interface to enter Cautery interface and set the working

parameters of Cautery.

3) Clip blood vessel with the Forceps, manipulate footswitch and release it soon. Please refer to §4.14.2 Cautery Switch for details.

☞ ***Attention: The Cautery Switch on the Footswitch also works under other mode besides the Cautery mode, which means the Cautery can be also started under other modes. To press the Cautery switch under U/S and Vitrectomy mode will start Cautery. So, please set the parameters before use the Cautery function.***

⚠ ***Notes:***

① High-frequency Cautery may cause unexpected influence on other medical devices nearby.

② Patient should be kept away from metal material of grounding or with considerable capacitance to ground (such as operating table bracket). The anti-static separating board is suggested.

③ The cables of Cautery should be kept away from patient and other cables; the temporary-unused Cautery Forceps should be isolated from patients.

④ Flammable anesthetic and oxidizing gases such as nitrous oxide (N2O) and oxygen are prohibited in operation, unless they have been sucked away before the operation.

⑤ It may cause risks to patients with pacemaker or other active implanted medical devices, because high-frequency surgical instruments may cause interference to pacemakers or even damage it. Please consult heart doctor.

⑥ Check the insulation of Cautery cables before each use. And stop using it if any damage is found.

⑦ For output data of high-frequency Cautery, please refer to Annex A.

⑧ Caution: malfunction of high-frequency device may cause unexpected increase of the output power.

4.3 Starting Interface

Switch on MD-480A and Starting interface appears on the screen. After 5 seconds it enters the U/S mode.

Fig 4-1 Starting Interface

4.4 Main Interface

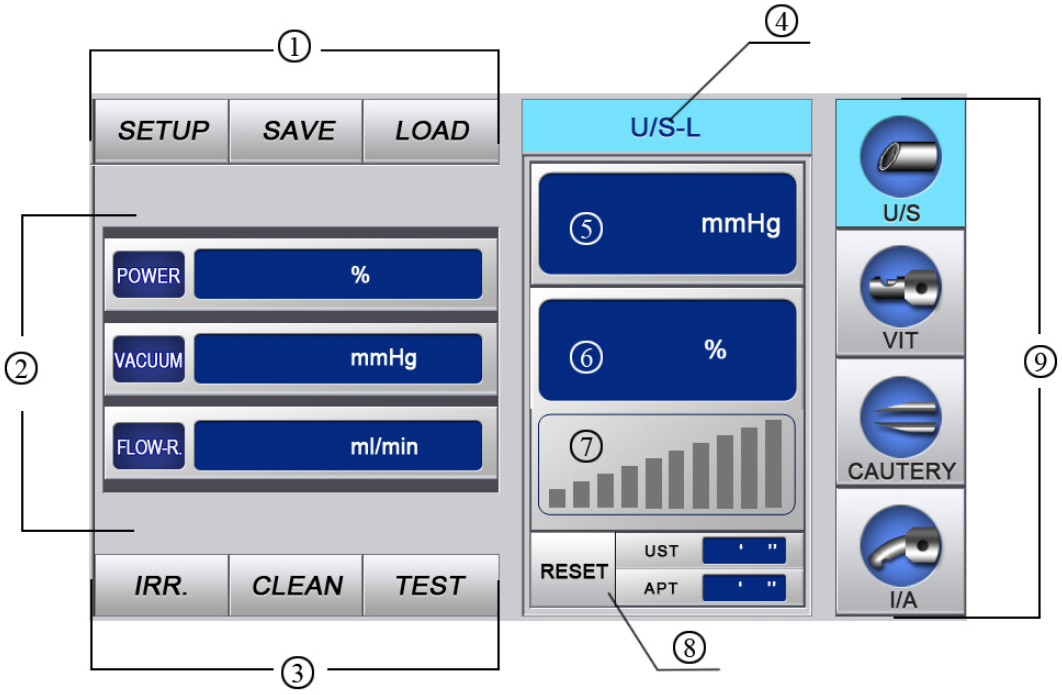


Fig 4-2 Main Interface

① **Parameters Setup Area**

SETUP To enter system setup interface and set parameters including U/S mode, volume, Tune and Advanced Settings. Please Refer to §4.12 Parameter Setup for details.

SAVE To enter Save Interface and save up to 10 groups of working parameters for each working mode. Please refer to §4.13.1 SAVE for details.

LOAD To load pre-saved working parameters. Please refer to §4.13.2 LOAD for details.

② **Working Parameters Area**

Different working mode has different working parameters to be set. See Table 4.1.

Table 4.1 Parameters for Each Working Mode

Working Mode		Changeable Parameters
U/S	Continuous	Power, Vacuum, Flow Rate
	Linear	Power, Vacuum, Flow Rate
	Pulse	Power, Vacuum, Flow Rate, Frequency, Duty
	Burst	Power, Vacuum, Flow Rate, Pulse Width
Vitrectomy		Rate, Vacuum, Flow Rate
Cautery		Power
I/A		Vacuum, Flow Rate.

Fig 4-3: Working Parameters Area

Touch the Parameter Name area or the Parameter Value area (See Fig 4-3) to call out the numeric keypad under edit mode (see Fig 4-4). Use the numeric keys or ▲ ▼ keys to change the value and then touch **ENTER** to save it or touch **CANCEL** to exit without saving.

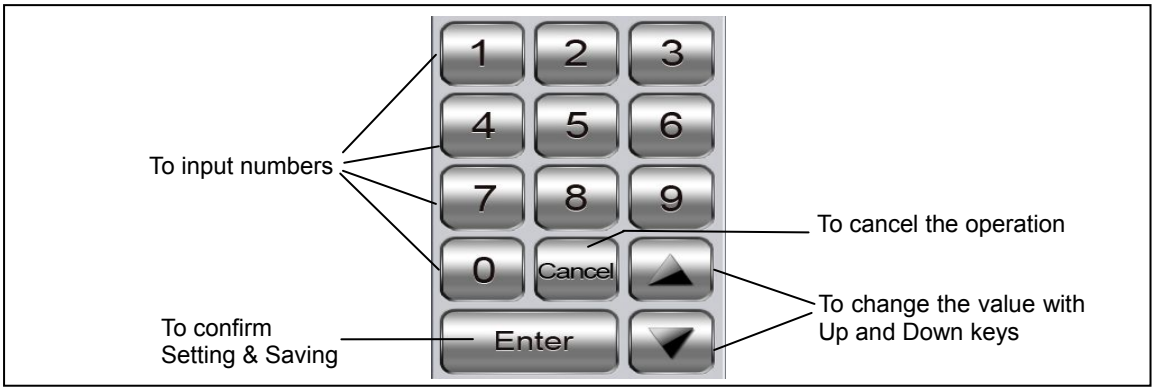


Fig 4-4 Numeric Keypad

③ Auxiliary Function Keys

IRR. To start Irrigation function. Refer to § 4.9 Irrigation.

CLEAN To start Cleaning function. Refer to § 4.10 Cleaning.

TEST To start a Test. Refer to § 4.11 Test.

④ Working Mode Display Area

This area displays the current working mode.

⑤ Real-time Vacuum Display Area

This area displays the real-time vacuum.

⑥ Real-time Ultrasound Power Display Area

This area displays the current output ultrasound power.

☞ ***Attention: There is no info in this area if no ultrasound output.***

⑦ Real-time Histogram Area

The real-time histogram displays as a notification when the footswitch is pressed to detent 3. It indicates the power under the mode of U/S—Continuous, U/S—Linear, U/S—Pulse, the more the green column on the histogram, the greater the real-time power, on the contrary, the less the green column, the smaller the real-time power. But under U/S—Burst mode, it indicates the time interval of power output and is separated into 10 degrees, the smaller level, the longer the interval, and the greater the level, the shorter the time interval.

⑧ **Ultrasound Output Time Display Area**

Ultrasound Output Time can be separated into absolute time (UST) and relative time (APT). UST refers to the accumulated time of power output and APT refers to the real power output time. When the Footswitch is pressed to Detent 3 under U/S mode and there is ultrasound output, the Time Display Area displays xx' xx", which means xx mins xx secs. The value will be reset to 0 by restarting or touch **RESET**.

Attention: APT = UST × Average Ultrasound Power Percentage

⑨ **Working Modes Area**

U/S To enter interface of Phaco Emulsification, please refer to §4.5 Phaco Emulsification.

VIT To enter interface of Vitrectomy, please refer to §4.6 Vitrectomy.

Cautery To enter interface of Cautery, please refer to §4.7 Cautery.

I/A To enter interface of I/A, please refer to §4.8 Irrigation/Aspiration.

4.5 Phaco Emulsification (U/S)

Touch **U/S** to enter the interface of Phaco Emulsification, see Fig 4-5. There are 4 modes of U/S that are Continuous, Linear, Pulse, and Burst. They can be pre-set in the System settings, please refer to §4.12.1 U/S Setup. The default mode is U/S-Linear.

Fig 4-5 U/S—Linear Mode

4.5.1 U/S—Continuous

Under U/S—Continuous mode, the U/S power is controlled by treadle of the footswitch and output continuously according to the pre-set power. The working parameters are shown in Table 4.2.

Table 4.2 Parameters Setting (U/S-Continuous)

Parameter	Description	Range	Default Value
Power	Output Power of Ultrasound	0%~100%	50%
Vacuum	Max. Vacuum Allowed	1 mmHg～500mmHg	80mmHg
Flow Rate	Rate of Peristaltic Pump to aspirate balance solution	1ml/min～40 ml/min	25ml/min

4.5.2 U/S－Linear

Under U/S-Linear mode, the treadle of footswitch controls the U/S power output and its maximum value is the pre-set value. The working parameters are shown in Table 4.3.

Table 4.3 Parameter Setting (U/S-Linear)

Parameter	Description	Range	Default Value
Power	Output Power of Ultrasound	0%~100%	50%
Vacuum	Max. Vacuum Allowed	1 mmHg～500mmHg	80mmHg
Flow Rate	Rate of Peristaltic Pump to aspirate balance solution	1ml/min～40 ml/min	25ml/min

4.5.3 U/S-Pulse

Under U/S-Pulse mode, the Treadle of Footswitch controls the U/S power output and its maximum value is the pre-set value; the power output type depends on the preset frequency and duty (effective stimulating time percentage) and is output intermittently. The working parameters are shown in Table 4.4.

Table 4.4 Parameter Setting (U/S-Pulse)

Parameter	Description	Range	Default Value
Power	Output Power of Ultrasound	0%~100%	70%
Vacuum	Max. Vacuum Allowed	1 mmHg～500mmHg	80mmHg
Flow Rate	Rate of Peristaltic Pump to aspirate balance solution	1ml/min～40 ml/min	25ml/min
Frequency	Pulse rates: Pulses per second	1 Hz～99Hz	10Hz
Duty	Duty cycle	1%~99%	50%

4.5.4 U/S-Burst

Under U/S-Burst mode, the ultrasound power is output according to the preset value. The single burst time is determined by set pulse width and the intermittent time of power output is controlled by the treadle of footswitch, as shown in Table 4.5. The maximum frequency is output continuously. The working parameters are shown in Table 4.6. The Detent 3 Grading of burst is provided by the real-time histogram, please refer to §4.4 Main Interface for details.

Table 4.5 Detent 3 Grading—Burst Stop Time

Detent 3 Grading	1	2	3	4	5	6	7	8	9	10
Intermittent Time of Burst (s)	1.5	1	0.7	0.45	0.3	0.2	0.13	0.09	0.06	0

Table 4.6 Parameter Setting (U/S-Burst)

Parameter	Description	Range	Default Value
Power	Output Power of Ultrasound	0%~100%	70%
Vacuum	Max. Vacuum Allowed for Anterior Chamber	1 mmHg～500mmHg	80mmHg
Flow Rate	Rate of Peristaltic Pump to aspirate balance solution	1ml/min～40 ml/min	25ml/min
Pulse Width	Ultrasound Pulse Width	5ms~100ms	30ms

4.6 Vitrectomy

Touch **VIT** to enter the interface of Vitrectomy, see Fig 4-6.

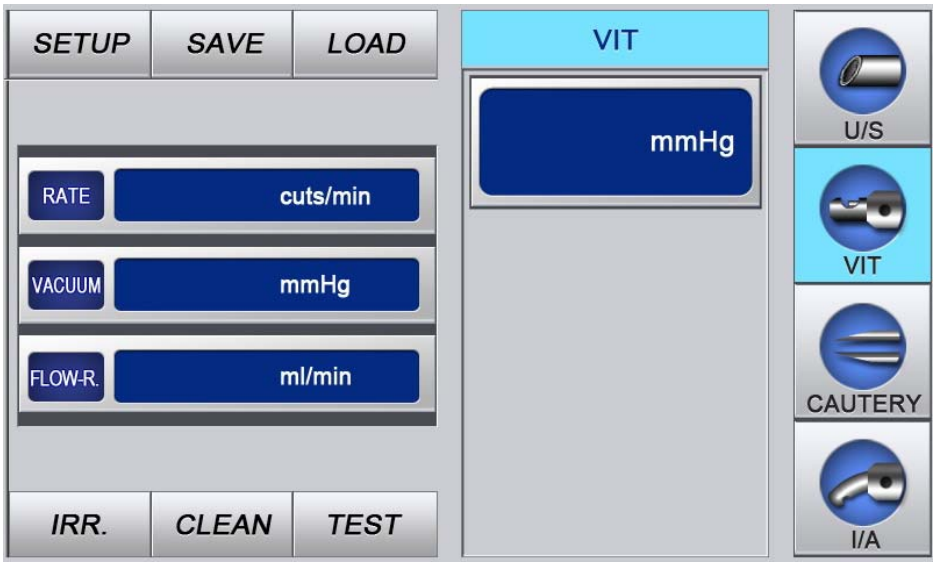
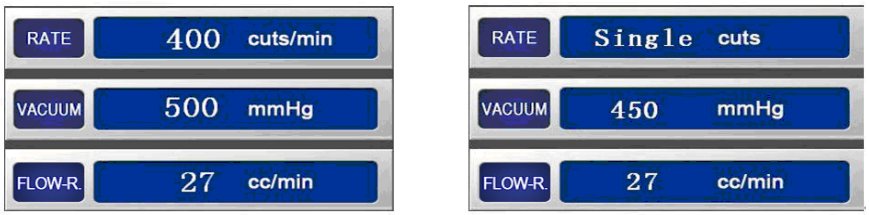


Fig 4-6 Vitrectomy Interface

Under VIT mode, the treadle of footswitch controls surgical operation of vitrectomy according to the set parameters.

There are Multiple Mode and Singe Mode as shown in Fig 4-7.



(a) Multiple Mode **(b) Single Mode**

Fig 4-7 Multiple Mode and Single Mode

Single Mode means cut once by pressing the treadle once. When the vitrectomy rate is set as 1~19, it indicates Single Mode; when the vitrectomy rate is set from 20~600, it indicates 20～600 cuts/min. The working parameters are shown in Table 4.7.

Table 4.7 Parameter Setting (Vitrectomy)

Parameter	Description	Range	Default Value
Rate	Rate of Vitrectomy	Single Mode: 1cut/min~19cuts/min； Multiple Mode: 20cuts/min~600cuts/min	400cuts/min
Vacuum	Max. Vacuum Allowed for Anterior Chamber	1 mmHg～500mmHg	350mmHg
Flow Rate	Rate of Peristaltic Pump to aspirate balance solution	1ml/min～40 ml/min	25ml/min

4.7 Cautery

Touch **Cautery** to enter the interface of Cautery, see Fig 4-8.

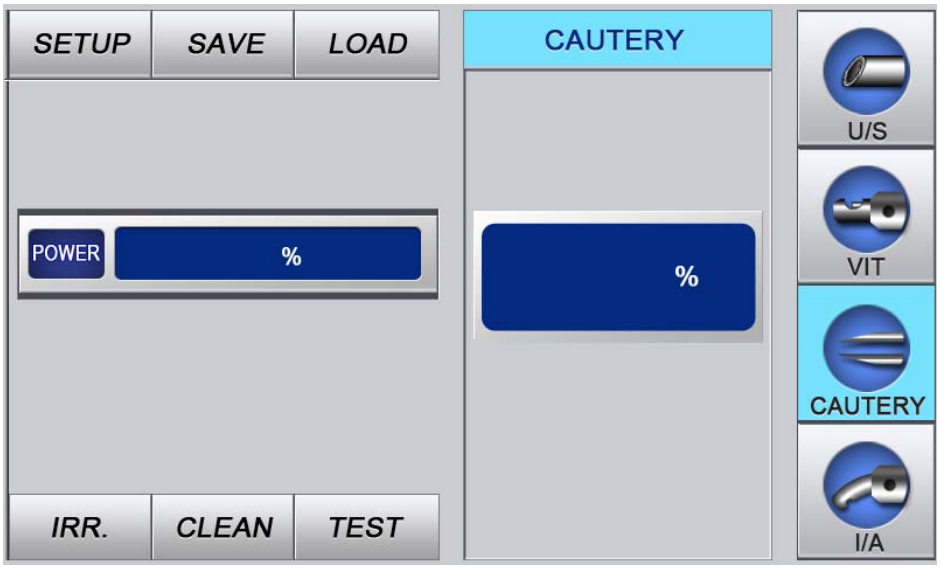


Fig 4-8 Cautery Interface

The Cautery Switch of footswitch controls the power output. It can be turned on directly under the state of U/S, VIT, Cautery and I/A for power output. Release the Cautery Switch to return to the state before Cautery operation. There is no output when the power is 0. The working parameters are shown in Table 4.8.

Table 4.8 Parameter Setting (Cautery)

Parameter	Description	Range	Default Value
Power	Power Output under Cautery Mode	0%~100%	30%

4.8 Irrigation/Aspiration

Touch **I/A** to enter the interface of Irrigation/Aspiration, see Fig 4-9.

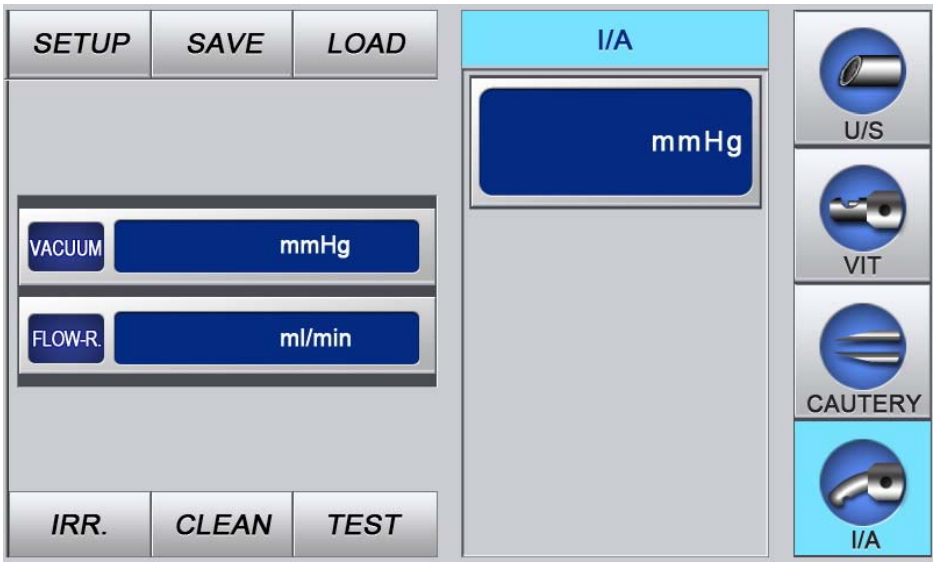


Fig 4-9 I/A Interface

The treadle of Footswitch controls the I/A operation and suck out crushed fragments of cataract according to the set vacuum. The working parameters are shown in Table 4.9.

Table 4.9 Parameter Setting (I/A)

Parameter	Description	Range	Default Value
Vacuum	Max. Vacuum Allowed for Anterior Chamber	1 mmHg～500mmHg	450mmHg
Flow Rate	Rate of Peristaltic Pump to aspirate balance solution	1ml/min～40 ml/min	25ml/min

4.9 Irrigation

Touch **IRR.** to open Irrigation Pinch Valve and the Irrigation Interface appears at the same time, see Fig 4-10. Touch **IRR.** again to stop irrigating water and the Irrigation Interface disappears.

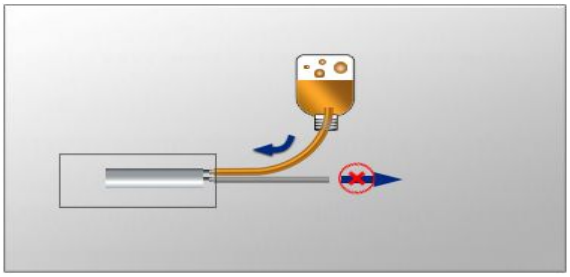


Fig 4-10 Irrigation Interface

☞ ***Attention: Touch other functional keys directly or press the footswitch will stop irrigation and switch to other operations.***

4.10 Cleaning

Touch **CLEAN** to open Irrigation Pinch Valve and Peristaltic Pump, and perform cleaning of the tubing and Handpiece. Wash tubing and Handpiece with distilled water in the Irrigation Bottle, the Interface of Cleaning and Vacuum Value appears at the same time, see Fig 4-11. Touch **CLEAN** again after cleaning to close the Irrigation Pinch Valve and Peristaltic Pump. The picture of Clean disappears.

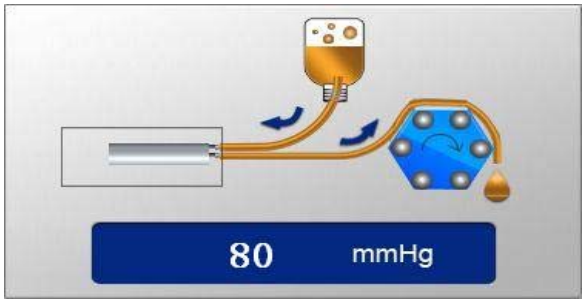


Fig 4-11 Interface of Cleaning

☞ ***Attention: Touch other functional keys directly or press the footswitch will stop irrigation and switch to other operations.***

4.11 Test

⚠ ***Note: Test must be performed before a surgery!***

Touch **TEST** to enter the Interface of Test and start automatic test, see Fig 4-12. This operation simulates the whole process of U/S to test the tubing and ensure the normal working of the system.

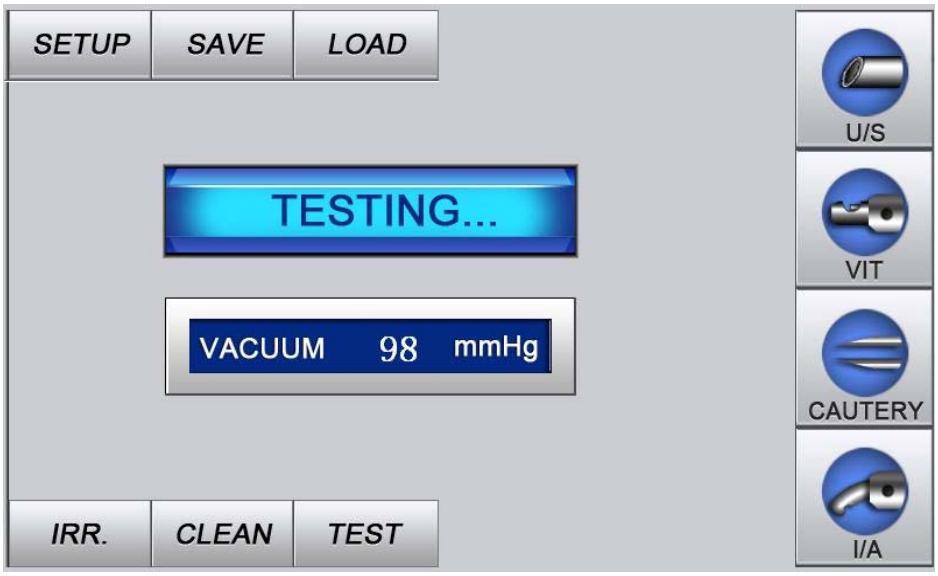


Fig 4-12 Interface of Test

The test includes: tubing block test, tubing leakage test, handpiece matching test. If one of the above errors appears, check or replace the tubing and handpiece immediately. Touch **TEST** again to repeat the test and Fig 4-16 appears after testing. If the volume is on, there will be prompt sound. Then touch working mode key to enter U/S, VIT, Cautery or I/A directly.

1) Tubing Block Test

If the tubing is blocked, the prompt picture will appear on the screen as shown in Fig 4-13. And there will be prompt sound if the volume is on.

Fig 4-13 Interface of Tubing Block

2) Tubing Leakage Test

If the tubing is broken, the prompt picture will appear on the screen as shown in Fig 4-14. And there will be prompt sound if the volume is on.

Fig 4-14 Interface of Tubing Leakage

3) Handpiece Matching Test

If the handpiece does not match, the prompt picture will appear on the screen as shown in Fig 4-15. And there will be prompt sound if the volume is on.

Fig 4-15 Interface of Handpiece Failure

4) Test Passed

Fig 4-16 Test Passed

4.12 Parameter Setup

Touch **SETUP** to enter the Interface of Parameter Setup, see Fig 4-17. Mode of U/S, Volume of Speaker, Tune, Chinese/English selection and advanced settings can be set under the interface.

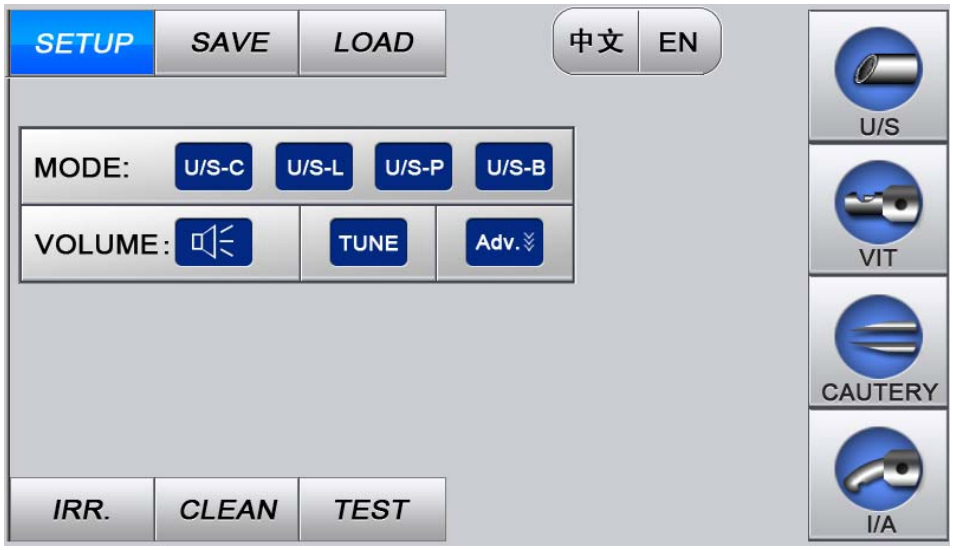


Fig 4-17 Interface of Parameter Setup

4.12.1 U/S Setup

Touch **US-C**, **US-L**, **US-P** or **US-B** to select the mode of U/S. The selected mode will be high-lighted and saved until reset.

☞ ***Attention: If U/S-Linear is selected, U/S-L is highlighted in the Parameter Setup Interface.***

4.12.2 Speaker Setup

There are three selections for the volume of speaker, "loud"  , "small"  , and "close"  . Touch the corresponding key to make selection. When the volume is set at "loud" and "small", there will be prompt sound during the operation of Test, Cleaning, Irrigation, U/S, Vitrectomy, Cautery, I/A and Footswitch.

4.12.3 TUNE

When the Handpiece is connected, touch **TUNE** to start the function of tune and look for resonance frequency, the **TUNE** key is highlighted then. If the Handpiece is matched, the resonance frequency will be stored automatically; otherwise, the interface as shown in Fig 4-15 will appear on the screen.

⚠ ***Note: When the Handpiece is replaced, it is required to operate TUNE, and make U/S surgical operation after the test is passed.***

4.12.4 Chinese/English Setup

Touch 中文 to switch to Chinese mode; and touch **EN** to switch to English mode.

4.12.5 Advanced Settings

Touch **Adv.** to open the advanced settings menu, see Fig 4-18.

Fig 4-18 Advanced Settings Menu

1) Sensitivity

Set protective sensitivity of anterior chamber within the range of 1-9. The sensitivity indicates the vacuum variation level to start the function of anterior chamber protection. The smaller the value, the higher the sensitivity.

☞ ***Attention: If the set value is beyond the range of parameter or meaningless, the set value is invalid! The following settings are similar.***

2) Gear Calibration

Gear of Footswitch: Detent 1(grade 5～19), Detent 2 (grade 45～59), Detent 3(grade 90～160). It is used to calibrate the mechanical error of the Footswitch and is not necessary to adjust normally.

3) Default

Touch **Default** key, the dialogue box will pop up as shown in Fig 4-19. Touch **Yes** key, the value of SENS and GEAR will return to the default setting; touch **No** will save the current setting.

Fig 4-19 Dialogue Box to Confirm Default

⚠ ***Note: The sensitivity and gear have been set to proper value before delivery; adjustment should be done prudently under the guidance of engineer. After GEAR and SENS setting, touch Adv. again to exit from advanced setting and the set value will only be valid then.***

4.13 Save and Load of Working Parameters

4.13.1 SAVE

Touch **SAVE** under the interface of working mode (U/S, VIT, CAUTERY, I/A), the numeric keypad pops up on the screen. Click any key from 0～9 to save the current working parameters to the corresponding position of the memory. 10 groups of working parameters can be saved for each working mode.

☞ ***Attention: The SAVE key is only valid under each working mode where the parameters are not set. It is invalid under the interface of SETUP.***

4.13.2 LOAD

Touch **LOAD** key under the interface of working mode (U/S, VIT, CAUTERY, I/A), the numeric keypad pops up on the screen. Click any key from 0～9 to load the saved parameters as the current working parameters. Since 10 groups of parameters can be saved for each working mode, 10 groups of working parameters can be called out. Touch **Cancel** key to give up loading and exit from the keypad.

☞ ***Attentions：***

① MD-480A loads parameters from position "0" of each working mode after it is switched on. Therefore, you may save the frequently-used parameters to position "0".

② The LOAD key is only valid under each working mode where the parameters are not set. It is invalid under the interface of SETUP. The position of loaded parameters must be where parameters have been saved once, otherwise, the loaded parameters are invalid. For example if you load parameters from position "0", parameters must be saved in position "0" beforehand. 10 groups of working parameters for each working mode are pre-saved before delivery. Please make amendment accordingly before use.

4.14 Operation of Footswitch

4.14.1 Reflux Switch

It is valid under the working mode of U/S, Vitrectomy and I/A.

Reflux is to release the tissue sucked mistakenly. Press the Reflux Switch will suck the liquid from the tubing backwards. The maximum reflux time is 1 second. Uplift or press the Reflux Switch until 1 second will stop sucking. The Reflux Switch is only able to be pressed when the treadle uplifted. When the Reflux Switch is pressed and liquid sucked backwards, the following picture appears on the screen, as shown in Fig 4-20; there will be prompt sound when the volume is on. Uplifting or pressing Reflux Switch for 1 second will return to the previous state.

Fig 4-20 Picture of Reflux

4.14.2 Cautery Switch

It is used to control the power output of Cautery.

Press Cautery Switch under the working mode of U/S, VIT, I/A, will output the power according to the preset power and the actual output power and Cautery sign will display as shown in Fig 4-21(a); meanwhile, there will be continuous prompt sound with higher-frequency. Release the Cautery Switch, there will be no power output and the output power and Cautery sign disappear; the system will return the previous state. Under Cautery mode, the state of Cautery is shown in Fig 4-21(b).

(a) Cautery State under Non-Cautery Mode (b) Cautery State under Cautery Mode

Fig 4-21 State of Cautery

4.14.3 Treadle

There are three detents for the Treadle, as shown in Fig 4-22. Press the treadle to Detent 1 for Irrigation, Detent 2 for starting Peristaltic Pump and Detent 3 to perform corresponding operations according to the working mode. The Treadle is invalid under Cautery Mode.

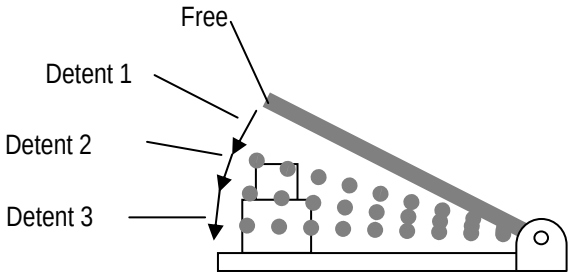


Fig 4-22 Schematic Diagram of Treadle

Under U/S mode, press the Treadle to Detent 3 for power output. Under U/S-C, the ultrasound power output continuously according to the preset value; for U/S-L, the output power is controlled by the Treadle, the lower it is pressed, the higher the power; for U/S-P, the ultrasound power output intermittently according to the preset frequency and duty, it is controlled by the treadle; for U/S-B, the ultrasound power output according to the preset value, the single burst time is the pulse width setting value, the intermittent time of burst is controlled by the treadle linearly.

Under VIT Mode, press Treadle to Detent 3 to start the Vitrector and cut according the preset rate.

Under U/S Mode, when the Treadle is pressed to Detent 3, the real-time output power and time

parameters are also displayed on the screen.

If the volume is on, there will be different prompt sound according to different mode and detents of Treadle. For example, in Detent 2 of aspiration, there will be low-frequency prompt sound, and when the vacuum reaches set value, there will be high-frequency short prompt sound. Under U/S Mode, the prompt sound of Detent 3 changes according to the power output. The lower the frequency, the lower the sound; and vise versa. However, under I/A Mode, the prompt sound of Detent 3 changes according to the vacuum. The lower the vacuum, the lower the sound; and vise versa.

Chapter5. Cleaning, Disinfection and Sterilization

The U/S Handpiece, U/S tip, Vitrector, Bipolar Cautery Forceps, Silicon Tubing and all parts must be cleaned after operation. Disinfection and Sterilization must be done after cleaning.

The U/S Handpiece can be cleaned automatically or manually. Please refer to §4.10 Cleaning for the automatic cleaning of U/S Handpiece.

5.1 Manual Cleaning of U/S Handpiece

1) Remove the Irrigation Tubing and Aspiration Tubing;
2) Remove the Test Chamber，U/S Irrigation Sleeve and U/S Tip successively;
3) Fill the syringe with distilled water;
4) Connect the syringe to the Irrigation Port of the Handpiece;
5) Press the syringe hardly to inject distilled water into the Handpiece and wash from the Irrigation Port;
6) Press the syringe several times to push air into the Handpiece for the purpose to blow the Handpiece dry.

5.2 Disinfection and Sterilization

High temperature and high pressure disinfection (natural cooling after sterilization) is allowed for U/S Handpiece, Vitrector, I/A Handpiece and its accessories (containing U/S Tip, U/S and I/A Sleeves, U/S and I/A Test Chambers), as well as Bipolar Cautery Forceps (containing cable), including the medical silicone tubing recommended by the manufacturer. Disinfectant, fumigation and other routine disinfection methods for surgical instruments can also be used.

On the premise that the disinfection and sterilization methods under the **User's Manual** is followed up, the U/S and I/A Sleeves, U/S and I/A Test Chambers, VIT Irrigation Sleeve and other accessories with silicon material as well as cable of Bipolar Cautery Forceps, including the medical silicone tubing recommended by the manufacturer, are allowed to be reused no more than 20 times.

Chapter6. Maintenance, Attentions and Simple Defects Treatment

6.1 Maintenance and Attentions to the Instrument

1) The power voltage of MD-480A is AC220V±10%. If your power supply can not meet the requirement, an AC stabilized power supply for more than 500W is recommended to be used in order to ensure the proper work of the instrument.

⚠ ***Note: Single-phase three-pole grounding power outlet should be used to ensure the safety.***

2) Do not use the instrument in locations with flammable anesthetic to avoid explosion.
3) Switch off the instrument promptly and contact the manufacturer in case of failure. Do not open the housing without authorization.
4) The instrument should be installed and used in locations away from strong electromagnetic sources (intense electric and/or magnetic fields). Large X-Ray equipment, high-frequency electric knife and etc may all influence the normal working of the instrument.
5) Avoid interference of high-frequency devices (such as wireless telephone, cordless telephone), which may cause malfunction of the instrument.
6) Although appropriate shielding measures have been taken to the instrument, the 40kHz (in U/S mode） and 1MHz (in Cautery mode) electromagnetic radiation generated by the instrument is still possible to interfere with other electronic devices. Therefore, patient with pacemaker should use cautiously. If other medical electronic devices need to be used with MD-480A at the same time, it is recommended to test the mutual interference before clinical usage.
7) The instrument must be operated by trained doctors only. The training of application and operation will be provided by the manufacturer (or distributor authorized by the manufacturer). The user is recommended to receive clinical application training in local hospitals with enough experience.
8) The operation and application of the instrument must be done according to the requirement of the **User's Manual**.
9) Check-ups must be done before uses, please refer to §4.1.3 Check-Ups before Uses for details.
10) Cleaning, disinfection and sterilization must be done after uses, please refer to §5. Cleaning, Disinfection and Sterilization for details.
11) The U/S Handpiece must be working under water-cooled condition. Pay attention to keep appropriate amount of solution inside the Irrigation Bottle and the tubing unblocked. It is prohibited to output ultrasound power without water.
12) The U/S Handpiece, Vitrector and other hand parts should be handled carefully. Check the function of the parts carefully in case of dropping and if there is abnormal, contact the manufacturer for repair.
13) It is only allowed to use accessories provided by the manufacturer. Please contact the Manufacturer for purchasing.
14) Replace the U/S Tip when it becomes blunt and influences the effect of working. Replace the tubing

and connecting parts in case of breakage, leakage, seepage and so on. Disposal of waste parts should conform to the local environment protection provision.

15) When the instrument is abandoned, the disposal should conform to the local environment protection provision; the same measures with the disposal of electronic devices (computer and etc.) can be taken.
16) Avoid frequent startup and shutdown to the instrument. If restart is required after shutdown, please wait for more than 2 minutes.
17) Do not use the instrument if the fan is broken, in order to prevent unpredictable consequences.
18) If the instrument is not used for a long time, it should be powered on twice a week for more than 2 hours each time.
19) Keep the instrument clean. Use soft cloth or dry brush to remove dust on the surface of the instrument. Mild detergent with soft cloth is allowed to wipe off the dirt on the surface. Do not use detergent containing organic solvents and abrasive materials.
20) The routine inspection and maintenance must be carried out only when the power of complete instrument is shut off.

6.2 Maintenance of LCD Screen

1) Clean the LCD screen with glasses cloth, lens tissue or other soft material.
2) The LCD Screen should be applied in relative dry conditions to avoid humidity entering into the interior of screen. Prevent splashing of liquid onto the screen.
3) Do not open the LCD monitor if it is not working. High voltage may cause serious injury to people.
4) Do not touch the LCD screen with hard object, which will cause irreparable damage to the screen.
5) Avoid strong shock and vibration during transportation
6) Perform the touch-screen operation with finger belly.

6.3 Trouble Shooting

If following troubles are found, please check and operate as per the following procedures:

Trouble Appearance	Treatment
Power Indicator is not light.	1. Check if the power supply plug and socket are well connected. 2. Pull off the plug and check if the fuse is burnt out. Always use same standard 3A fuse if replacement is required. 3. Replace the fuse according to §3.3.8 Fuse Replacement for details.

- If above operations are not effective, please don't open the housing without authorization. Contact the supplier immediately. Explain the problems in detail for proper and in time support.
- The instrument is a high-tech product designed elaborately. Only qualified trained engineers are authorized to repair the instrument.
- The Manufacturer is not responsible for problems caused by any kind of unauthorized repair.
- If required, the Manufacturer can provide the complete maintenance and repair manual to the authorized qualified engineers.

Chapter7. Service and Support Information

7.1 Warranty

1) On the premise of using in accordance with the **User's Manual**, MD-480A Phaco Emulsifier has a warranty of one year and the U/S Handpiece has a warranty of six months from the date of purchasing. U/S Tip, Tip Wrench, Test Chamber and Irrigation Sleeve have no warranty.
2) If the device does not work properly, please contact your local distributor or the Manufacturer immediately.
3) Following repairs will be charged within warranty period:

- Problems caused by man-made damages;
- Damages caused by unauthorized disassembly and/or repair;
- Damages caused by inappropriate operation.

4) The Manufacturer provides continuous maintenance and repair after warranty period with certain charges.

7.2 Accessories and Materials

7.2.1 Accessories

#	Accessories	Manufacturer	Specification
1	U/S and/or I/A Sleeve	MEDA Co., Ltd.	19Ga
2	U/S and/or I/A Test Chamber		C61001 Silicone test chamber
3	VIT Irrigation Sleeve		4422CE
4	Silicon Tubing for medical uses		(ID X OD), Length (2×4) mm, L1.8m, (4×6) mm, L1.8m

7.2.2 Detachable Accessories

#	Item	Manufacturer	Specification
1	U/S Handpiece	MEDA Co., Ltd.	01-899145B
2	U/S Tip		LT 30 (19G/30^0)
3	Vitrector		4420CE
4	I/A Handpiece		607006 0.3mm/straight
5	Bipolar Cautery Forceps/Cable		10-3002/L-105000

7.2.3 Material

Housing Material	Specification
Flameproof ABS Engineering Plastic（≥FV-2）	MCN-480A

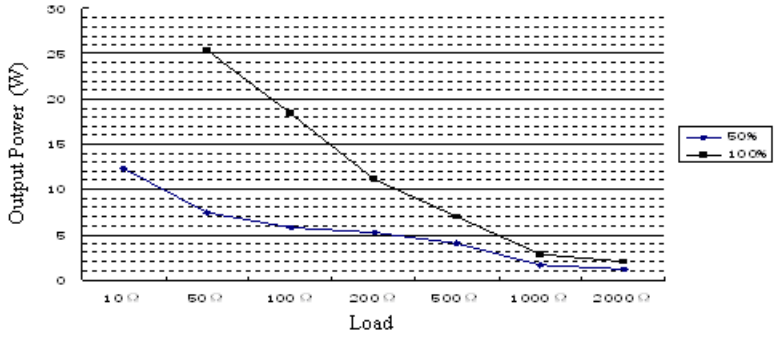
⚠ ***Notes:***

① ***Only the accessories specified by the Manufacturer can be used to MD-480A.***

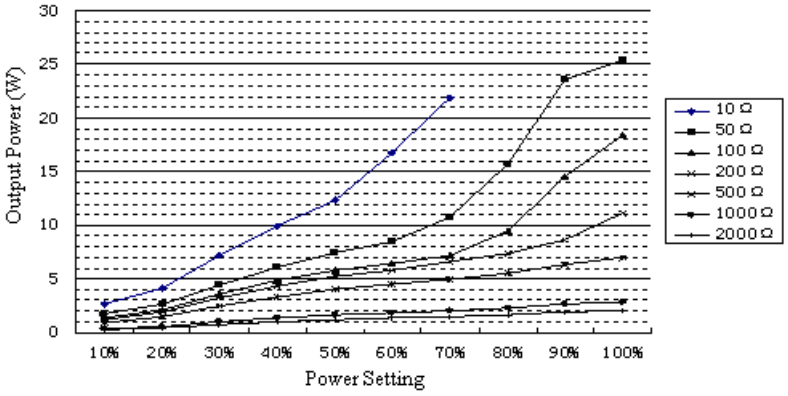
② ***Silicon tubing kits should meet applicable standards and obtain registration certificate for medical device marketing.***

Annex A. High-Frequency Cautery Output Information

A.1 The Power Output Curve of Output Controller on 50% and 100% Setting



A.2 Relation Curve between Output Power and Output Controller



A.3 Relation Curve between Max. Output Voltage and Cautery Power Setting