

MTP

Medical
Technical
Products



**MODEL 3000
PHACOEMULSIFICATION SYSTEM**

Operator's Manual

TO OUR VALUED CUSTOMERS:

Thank you for purchasing the Model 3000 Phacoemulsification System (Model 3000) by Medical Technical Products, Inc (MTP). The Model 3000 is intended for use in the disruption and extraction of cataractous lens material from the eye with the use of ultrasonic energy, a process known as “Phacoemulsification”.

The Model 3000 is 510(k) cleared¹. The Model 3000 is the latest example of our commitment to provide products that meet customer expectations of quality, performance, and value.

The operator’s manual is your written guide to the Model 3000. Please read the entire manual carefully. DO NOT attempt to use the system without having an adequate understanding of all of its functions, controls, and limitations.

No information on surgical procedures is given in this manual. MTP claims no responsibility or liability resulting from any technique practiced.



Pay close attention to warnings and cautions throughout this manual.

If you have any questions or require additional information, please contact Medical Technical Products, Inc Customer Service at:

9251 Irvine Boulevard
Irvine, CA 92618 USA

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Monday – Friday 9:00 AM to 5:00 PM (PST)

¹ 510(k) No. K080803, dated 09/22/08

Model 3000 PHACOEMULSIFICATION SYSTEM

Model 3000 PHACO PACKAGE

Qty	Part Number	Description
1	551-0034-001	Console, MTP
1	553-0001-001	Footpedal, Model 3000
1	01-899145	US Handpiece, STT
1	551-7002-001	Travel Case
1	23-9024	US Tip Pack, 19 GA, 30°, LT
1	551-0067-001	Collection Bags, 10 pk
1	551-0050-001	Tubing Cartridge
1	17031-S2-8	Power Cord, 120V (USA)
1	551-7001-001	Vinyl Cover
1	551-6001-001	Operator's Manual
1	430-2215-002	Fuse Set

SYSTEM COMPONENTS SOLD SEPARATELY

Part Number	Description
551-0052-001	Automated IV Pole Cart
553-0001-001	Footpedal, Model 3000
01-899145	US Handpiece, STT
01-899530	US Handpiece, Mini
551-7002-001	Travel Case
430-2215-002	Fuse Set
17031-S2-8	Power Cord, 120V (USA)
551-7001-001	Vinyl Cover
551-6001-001	Operator's Manual

TUBING CARTRIDGE & ACCESSORIES

Part Number	Description
551-0102-004	Tubing Set (4 Tubing Cartridges & 40 Collection Bags)
551-0067-001	Collection Bags (pack of 10)

US PHACO TIPS & ACCESSORIES

Part Number	Description
23-9024	US Tip Pack (Qty 1 ea: US Tip, 30°, 19 GA; US Tip Wrench; Irrigation Sleeve; Test Chamber)
23-9022	US Tip, 30°, 20 GA
23-9023	US Tip, 30°, 19 GA
23-9020	US Tip Wrench
23-9003	19 GA Irrigation Sleeve
23-9021	20 GA Irrigation Sleeve
23-9004	Test Chamber (Pack 5)

IA HANDPIECES & ACCESSORIES

Part Number	Description
23-9000	IA Handpiece, Titanium
23-9001	Aspiration Tip (0.3 mm)
23-9002	Aspiration Tip (0.3 mm, 45°)
23-9003	19 GA Irrigation Sleeve (Pack5)

VITRECTOMY

Part Number	Description
23-9006	Vitrector, Guillotine (includes Irrigation Sleeve)

CAUTERY

Part Number	Description
23-9050	Forceps, Straight (0.4 mm)
23-9051	Cord, Cautery, Reusable 12'

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1.0 

WARNINGS AND PRECAUTIONS

DANGER: Possible risk of fire or explosion! The Model 3000 Phacoemulsification System (Model 3000) should never be used in the presences of flammable anesthetics, oxidizing gases (i.e. nitrous oxide, oxygen), endogenous gases, disinfecting agents, cleaning agents, or aerosol sprays.

WARNING: Inspect condition of all operating equipment prior to beginning surgical procedure.

WARNING: Failure of the system could result in an unintended increase of output power.

WARNING: The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example, operating table supports, etc.).

WARNING: Skin-to-skin contact (e.g. between the arms and body of the patient) should be avoided, e.g. by insertion of dry gauze.

WARNING: Electrical shock hazard exists. DO NOT remove console cover. Call manufacturer for service.

WARNING: Pinch point hazard exists. Keep hands and fingers clear when lowering the display.

WARNING: Console rear panel network and USB connections are for use by trained factory personnel only.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: The console can only be disconnected from the supply mains by means of the power cord. Position the equipment so that the power cord is easily accessible.

WARNING: No modification of this equipment is allowed.

WARNING: The use of accessories other than those listed in this manual has not been evaluated for safety and performance.

WARNING: The following components must be sterilized prior to their use: Ultrasonic Handpiece, Tubing Set, Phaco Tip and Wrench, silicone Tip Sleeve, and Test Chamber. Consult package labels and instructions that accompany these components for reprocessing instructions.

WARNING: Only use ultrasonic handpieces listed in this manual.

WARNING: Do not activate the “prime” and / or “tune” functions while handpiece is in the eye, as this can create a hazardous situation that could result in patient injury.

WARNING: Connected accessories should be rated for at least the minimum peak output voltage of the Model 3000 set at the intended output control setting in the intended operating mode.

WARNING: Avoid HF output settings where maximum output voltage may exceed rated accessory voltage.

WARNING: Surgical waste presents a biological hazard and must be handled and disposed of according to local governing ordinances.

WARNING: Follow local governing ordinances and recycling plans regarding disposal or recycling of device components, accessories and packaging.

WARNING: The ultrasonic handpiece and foot pedal must be disposed of according to local regulations at the end of their useful lives.

WARNING: Use of a damaged U/S tip or one that has been used excessively may adversely affect healthy tissue.

WARNING: Never use a damaged or intentionally modified U/S tip as they could break or malfunction.

WARNING: Do not check function of ultrasonic handpiece by placing hand or finger against tip or unintended damage to healthy tissue may result.

WARNING: Ensure sufficient volume of irrigation solution for the procedure. Level should be monitored during the procedure.

WARNING: Ensure that the maximum capacity of the collection bag is not exceeded as this could cause a hazardous situation to the patient.

WARNING: Do not manually force the pole height because this could cause incorrect indication of bottle height and patient injury.

WARNING: Intraocular pressure of the eye can be affected by the suspension height of the irrigating solution and vacuum level during surgery. Irrigation solution source must be at or above the patient's eye level.

WARNING: Use only tubing set approved for Model 3000.

WARNING: The level of the patient's eye must be between the bottom of the installed tubing cassette and no more than ten (10) centimeters below the bottom of the installed tubing cassette to ensure proper fluid dynamics of the vacuum system.

WARNING: Hazards may exist with patients with cardiac pacemakers or other active implants due to frequency interference with the action of the pacemaker or damage to the pacemaker itself.

WARNING: Ensure that any other monitoring electrode equipment or electromagnetic equipment near the patient will not interfere with the surgical procedure or place the patient at risk with undue contact when used simultaneously with the Model 3000 Phacoemulsification System.

WARNING: Interference produced by operation of the Model 3000 Phacoemulsification System may adversely influence the operation of other electronic equipment.

WARNING: Electrode cables should be positioned in such a way that contact with the patient or other cables is avoided.

WARNING: Temporarily unused active electrodes should be stored in a location that is isolated from the patient.

WARNING: The output power selected should be as low as possible for the intended purpose.

WARNING: To reduce the risk of accidental burns, caution should always be taken when operating high frequency surgical equipment.

CAUTION: Do not activate the ultrasonic handpiece with the tip in air as immediate, irreparable damage may result.

CAUTION: Do not use abrasive cleaners or solvents on the system console, particularly the touchscreen. Non-flammable agents should be used for cleaning and disinfection wherever possible.

CAUTION: Do not spray liquids directly onto the system console or submerge the system console or foot pedal into liquids – see Chapter 9 Cleaning.

CAUTION: Do not activate the US Handpiece continuously at 100% power for more than 1 minute, 50% duty cycle.

WARRANTY

2.0 WARRANTY INFORMATION:

The Model 3000 Phacoemulsification System (Model 3000) is intended for use by medically-trained / qualified ophthalmic / cataract surgeons who bear full responsibility for safe use at all times. Further, to repeat Medical Technical Products Inc (MTP) earlier instruction (*Section 1.0 Warnings and Precautions*), *the operator must read this manual carefully and become familiar with all its warnings.*

MTP makes no medical recommendation. Use of the Model 3000 is a matter of professional medical judgment in all cases.

MTP shall not, in any event, be liable for any actual or anticipated injury, direct, indirect, special, incidental, or consequential damages arising out of the use of this product, even if advised of the possibility of damage. Specifically, MTP is not liable for any costs, such as lost profits or revenue, loss of MTP product use, substitute costs, third party claims, or otherwise. Further, MTP's sole liability is limited to the amount equal to the purchased product price subsequent to any claim. This liability may not be waived or amended without express written consent by MTP.

MTP warrants its products to be free from defects in materials and workmanship for a period of one (1) year from the purchase date. This warranty does not apply to products which have been damaged by accident, abuse, modification, misapplication, and / or resulted from an unsuccessful attempted remedy of any confirmed / unconfirmed nonconformance by a non-MTP trained field service technician/engineer. This warranty applies only to the original purchaser and is not transferrable. Warranty on consumable products is limited to the first use.

MTP's sole warranty obligation under this warranty is limited to repairing / servicing or replacing, at its option, any defective product. This limited warranty is exclusive and shall be in lieu of all other expressed warranties, whether written, verbal, or implied, including any warranty of fitness for a particular purpose or merchantability. The purchaser waives all other warranties, guarantees, or liabilities arising by law or otherwise.

SYSTEM INFORMATION

3.0 PRODUCT INFORMATION

3.1 UNPACKING THE SYSTEM

Your Model 3000 Phacoemulsification System (Model 3000) was thoroughly inspected and tested prior to shipment. Carefully unpack and visually inspect all items for any apparent damage that may have occurred during shipment. If any physical damage is found or any item is missing when received, immediately notify the shipping company and Medical Technical Products, Inc (MTP). All claims for damage should be filed promptly.



NOTE: All packaging material should be saved for repackaging and returning the system if necessary.

3.2 OPERATOR'S MANUAL

The Operator's Manual for the Model 3000 provides the necessary system information for the following areas:

- ◆ System Description
- ◆ System Setup and Preoperational Checks
- ◆ System Operation Overview
- ◆ System Operation
- ◆ System Cleaning and Storage
- ◆ System Service
- ◆ System Troubleshooting
- ◆ System Cleaning and Storage



WARNING: DO NOT attempt to setup and/or operate the Model 3000 until you have read and understood the entire contents of the Operator's Manual. You must have the knowledge and a good understanding of the operational functions, controls, and limitations of the system before its use.



Information on surgical procedures is not provided in this manual. MTP is not responsible nor liable for malpractice resulting from any surgical techniques practiced.

3.3 SYSTEM CONSOLE

The Model 3000 utilizes a versatile, advanced microprocessor for control of all primary functions. It operates with time-saving simplicity and it is extremely easy to operate. The system requires no external air source and accepts a voltage range from 100 to 240 VAC. All operational functions, modes, and program options are independently set by utilizing the system operational menus on the touchscreen of the console.

The tubing cassette loading process is simplified by a latch mechanism on the side of the console which allows the operator to place and lock the cassette with ease.

3.4 SYSTEM HANDPIECE

The Model 3000 features an Ultrasonic (U/S) Handpiece that receives an electrical energy signal from the attached console and transfers it into a mechanical motion. This is accomplished through the use of piezoelectric crystals, which are located inside an environmentally isolated chamber at the interior of the handpiece. The mechanical motion, with a frequency around 40 kHz and amplitude of a few thousandths of an inch, is then transferred to an attached tip. The tip is inserted into the eye by the surgeon and placed in contact with the intraocular lens. The vibrating motion of the tip, enhanced by cavitation energy, emulsifies the lens. The emulsified lens is then aspirated from the eye.

3.5 SYSTEM TUBING CASSETTE

The Tubing Cassette is a reusable component of the Model 3000 that joins the fluid tubing to the system console without direct fluid contact. The cassette provides connections between an irrigating fluid source, such as intravenous administration tubing set, the ultrasonic handpiece, and a waste collection bag. The cassette tubing mates with a pump head in the system console, which provides the driving force to aspirate the emulsified lens and fluid from the surgical site. A valve in the system console controls the gravity flow of the irrigating fluid to the surgical site, maintaining intraocular pressure. The reusable tubing is dual lumen, or two tubes: one to deliver the irrigating fluid, the other to remove the aspirated material.

3.6 SYSTEM FOOT PEDAL

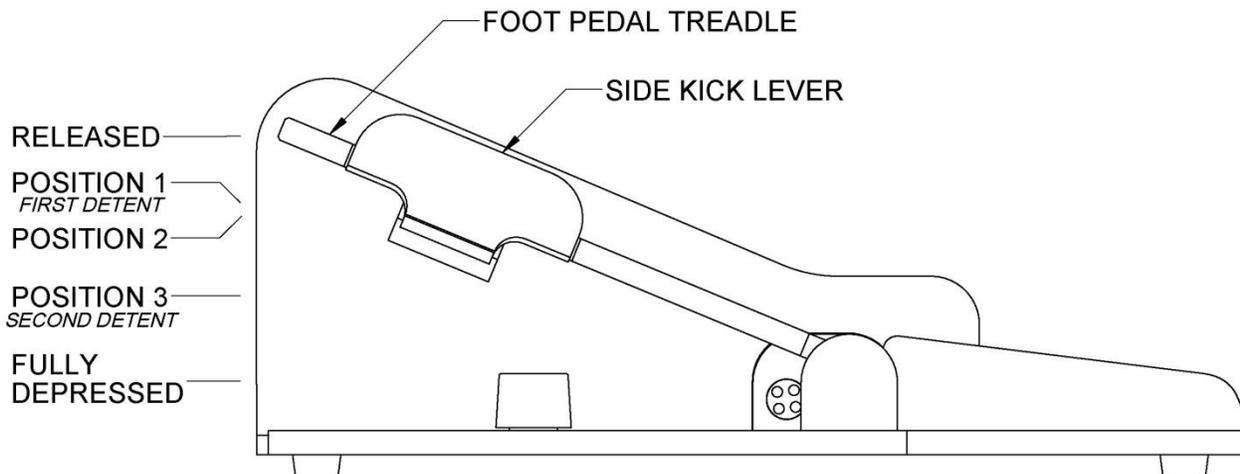
The operation of the Model 3000 is mainly controlled by the Foot Pedal, which is linked to the system by a cable connected to the back panel of the system console.

The main foot pedal has three (3) positions of operation:

- ◆ Position 1: activates Irrigation
- ◆ Position 2: activates Aspiration along with Irrigation
- ◆ Position 3: activates the Ultrasonic Power along with Irrigation and Aspiration



NOTE: Foot pedal positions will vary depending on the Operation Mode selected.



3.7 (OPTIONAL) CART WITH IV POLE

The Model 3000 has an Optional Cart with an Automated IV Pole that can be purchased separately or along with your initial order. The optional cart contains the following features:

- ◆ Locking casters
- ◆ Shelf for holding the system console
- ◆ Hanger for foot pedal storage when not in use
- ◆ Surgical accessories tray
- ◆ Automated IV pole

The automated IV pole has two (2) hangers on the top arms of the pole that can suspend one solution bottle on each hanger. When the cart is connected to the back panel of the console, the height of the IV pole is controlled from the console touchscreen.

All of the system components will be described in full detail in *Section 4.0 System Description* of this manual.

4.0 SYSTEM DESCRIPTION

4.1 SYSTEM OVERVIEW

FIGURES 4-1 through 4-7 refer to all controls, indicators and connections on the Model 3000. Their associated descriptions are as follows:

Item #	Name	Description
1	REAR PANEL LABEL	DISPLAYS SYSTEM RATINGS, SERIAL NUMBER, ALL WARNINGS AND CAUTIONS
2	ON / OFF SWITCH	I (ON) ; O (OFF)
3	RJ 45 CONNECTOR	FACTORY USE
4	USB PORTS 1 & 2	FACTORY USE
5	FOOTPEDAL CONNECTOR	CONNECTION FOR THE SYSTEM FOOT PEDAL
6	IV POLE CONNECTOR	CONNECTION FOR THE OPTIONAL CART WITH AUTOMATED IV POLE
7	AC POWER INPUT	PROVIDES POWER CONNECTION AND OVERLOAD PROTECTION TO THE SYSTEM
8	FUSE HOLDER	CONTAINS TWO SYSTEM FUSES
9	CASSETTE LOCK	LOCKING MECHANISM FOR THE TUBING CASSETTE
10	VENT VALVE	CONTROLS ASPIRATION LINE VENTING
11	IRRIGATION VALVE	CONTROLS FLOW OF IRRIGATION FLUID
12	CASSETTE RELEASE BUTTON	RELEASES THE CASSETTE WHEN PRESSED
13	ULTRASONIC CONNECTOR	PROVIDES POWER TO THE ULTRASONIC HANDPIECE
14	COAGULATION CONNECTOR	PROVIDES POWER TO THE CAUTERY FORCEPS
15	VITRECTOMY PORT	PROVIDES AIR TO THE VITRECTOR
16	PERISTALTIC PUMP HEAD	PROVIDES FLOW FOR SYSTEM ASPIRATION
17	VACUUM SENSOR	SENSOR FOR MEASURING VACUUM
18	TOUCHSCREEN DISPLAY	PROVIDES ACCESS TO USER INTERFACE
19	FRONT PANEL	PROVIDES DISPLAY FOR THE SYSTEM OPERATION
20	SPEAKERS	PROVIDES AUDIBLE VOICE, INDICATORS AND ALERTS

4.1 SYSTEM OVERVIEW (CONTINUED)

FIGURES 4-1 through 4-7 refer to all controls, indicators and connections on the Model 3000. Their associated descriptions are as follows:

Item #	Name	Description
21	CASSETTE ADMINISTRATION TUBE	PROVIDES IRRIGATION INPUT FOR TUBING CASSETE
22	TUBING CASSETTE	PROVIDES SYSTEM CONNECTION FOR IRRIGATION AND ASPIRATION FUNCTIONS
23	COLLECTION TUBE	PROVIDES WASTE OUTPUT TO COLLECTION BAG
24	COLLECTION BAG HANGER	HANGER FOR THE COLLECTION BAG
25	IRRIGATION TUBE	PROVIDES IRRIGATION INPUT FOR ULTRASONIC HANDPIECE
26	ASPIRATION TUBE	PROVIDES ASPIRATION OUTPUT FOR ULTRASONIC HANDPIECE
27	HEEL REST	PROVIDES STABLE SURFACE FOR LEVERAGE ONTO TREADLE
28	MAIN TREADLE	ACTIVATES THE BASIC MODES OF THE SYSTEM, USER INTERFACE FOR CONTROLS
29	LEFT SWITCH (SIDE KICK)	ACTIVATES ASSIGNED FUNCTIONS (DEFAULT: NOT USED)
30	RIGHT SWITCH (SIDE KICK)	ACTIVATES ASSIGNED FUNCTIONS (DEFAULT: REFLUX)
31	ASPIRATION PORT	PROVIDES CONNECTION FOR ASPIRATION OF WASTE
32	IRRIGATION PORT	PROVIDES CONNECTION FOR IRRIGATION FLUID
33	U/S HANDPIECE	SOLID TITANIUM CONSTRUCTION. COMPATIBLE WITH MTP PHACO(S).
34	HANDPIECE ELECTRICAL CONNECTOR	PROVIDES POWER TO THE ULTRASONIC HANDPIECE
35	SOLUTION HANGER	HANGER FOR SUSPENDING SOLUTION BOTTLE
36	HANDLE	HAND GRIP FOR MOVING THE CART
37	SHELF	PROVIDES SECURE MOUNTING LOCATION FOR SYSTEM CONSOLE
38	CABLE MANAGEMENT	STORES THE WRAPPED POWER CORD WHEN NOT IN USE
39	FOOT PEDAL HANGER	STORES THE FOOT PEDAL WHEN NOT IN USE
40	ACCESSORY TRAY	PROVIDES CONVENIENT LOCATION FOR HANDPIECES AND ACCESSORIES

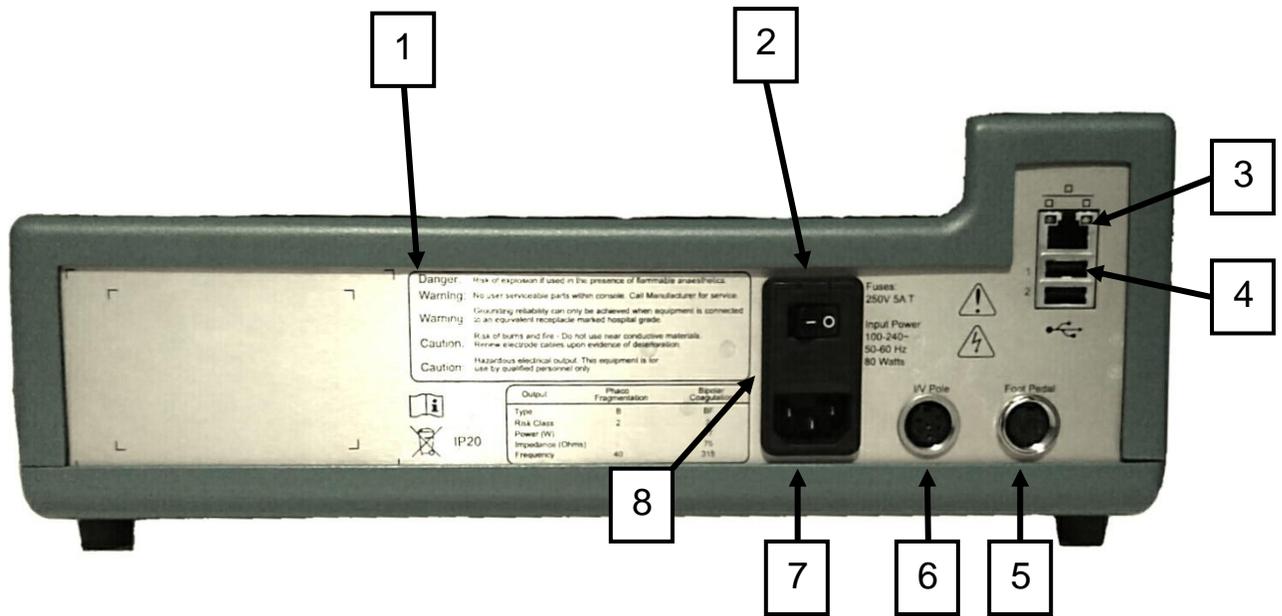


Figure 4-1: Console Back Panel

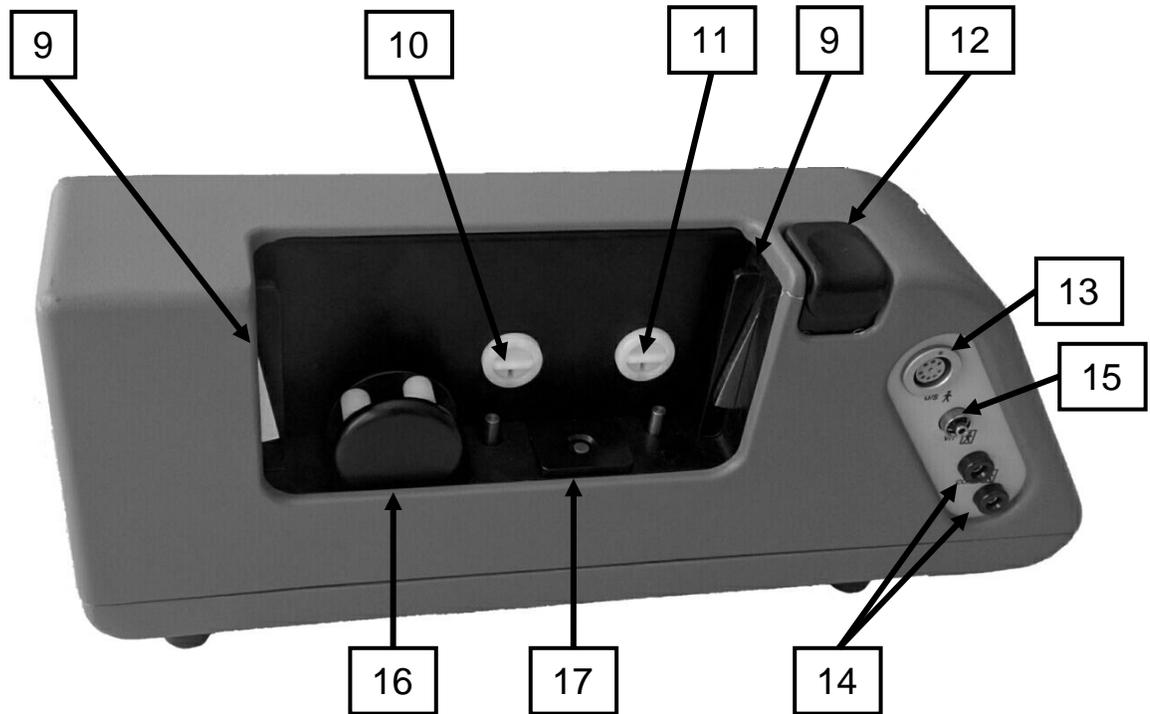


Figure 4-2: Connections Side View

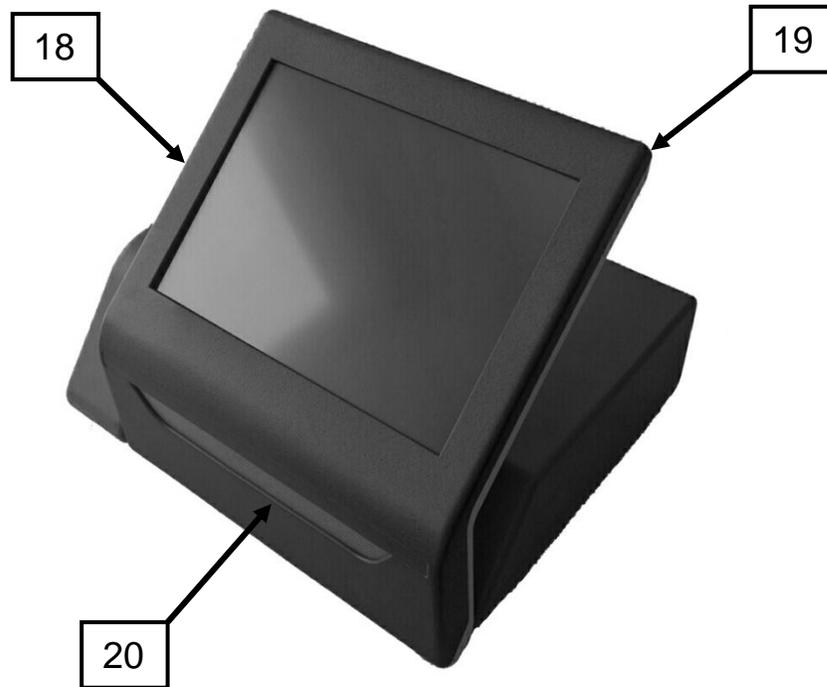


Figure 4-3: Console Front View

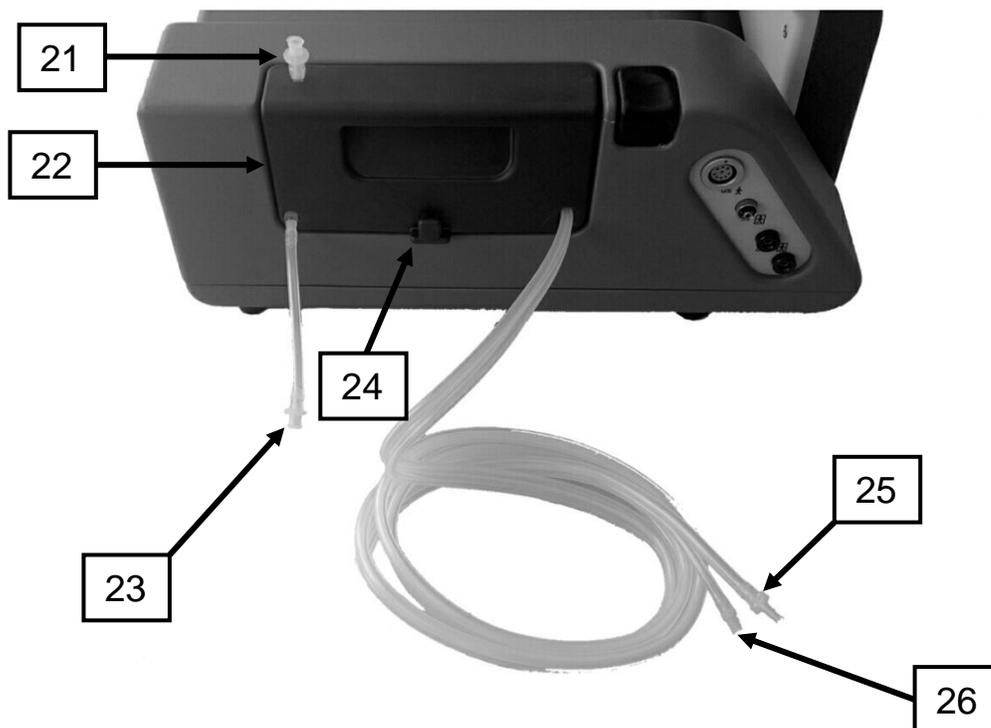


Figure 4-4: Cassette with Tubing Connection Side View

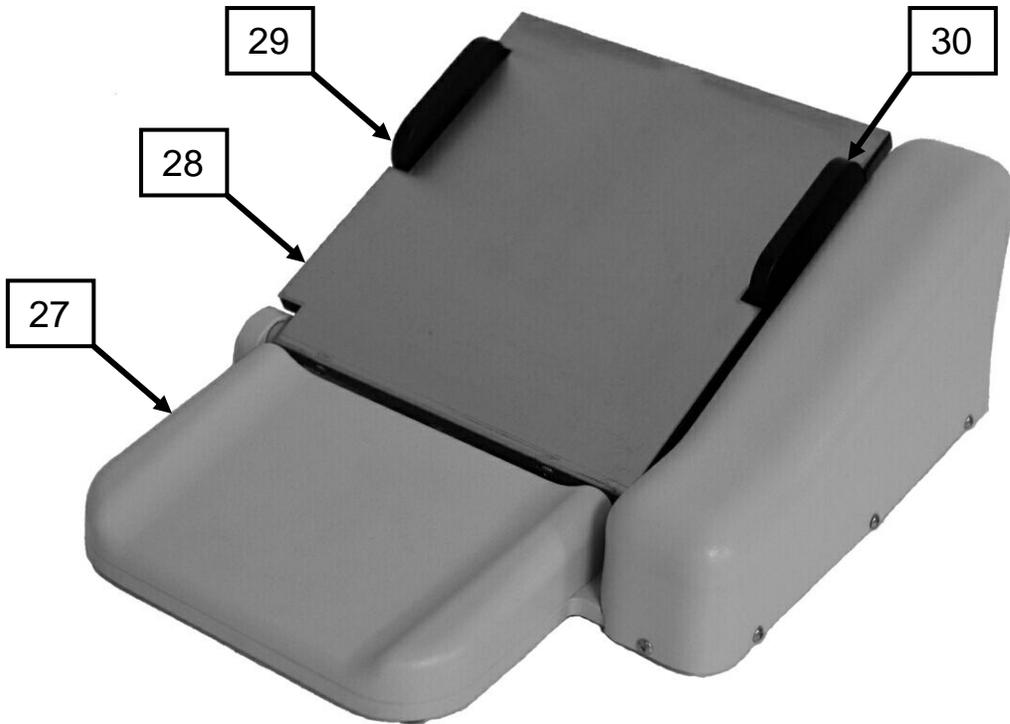


Figure 4-5: Foot Pedal

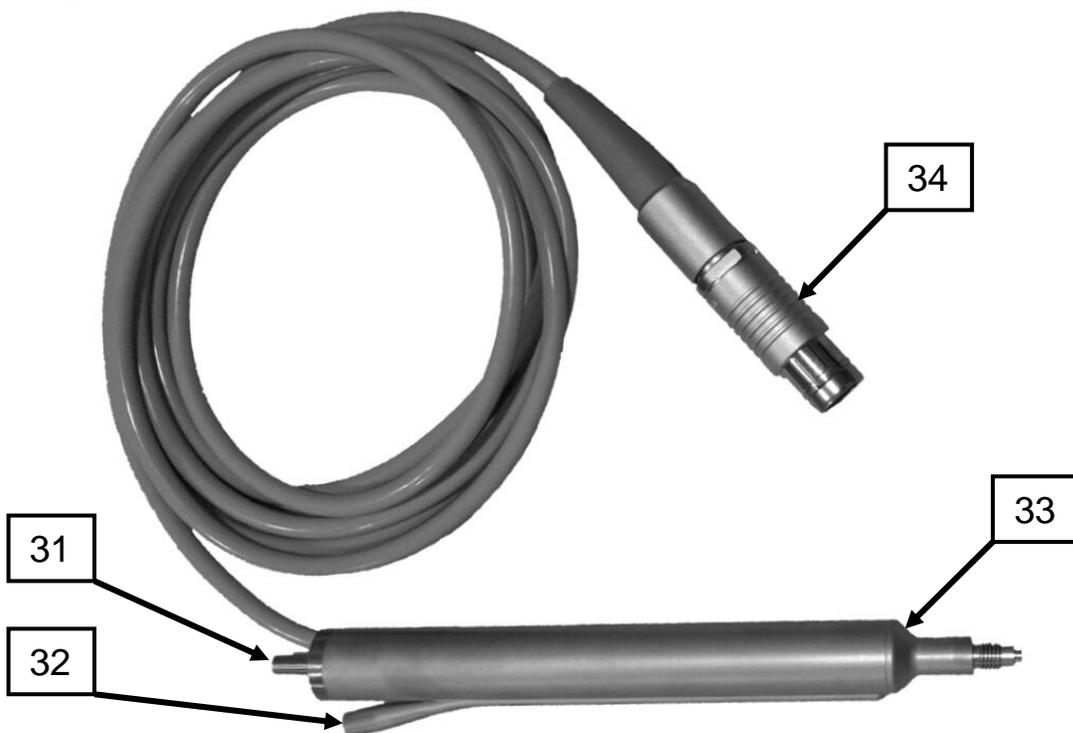


Figure 4-6: Phaco Ultrasonic Handpiece and Cable/Connector

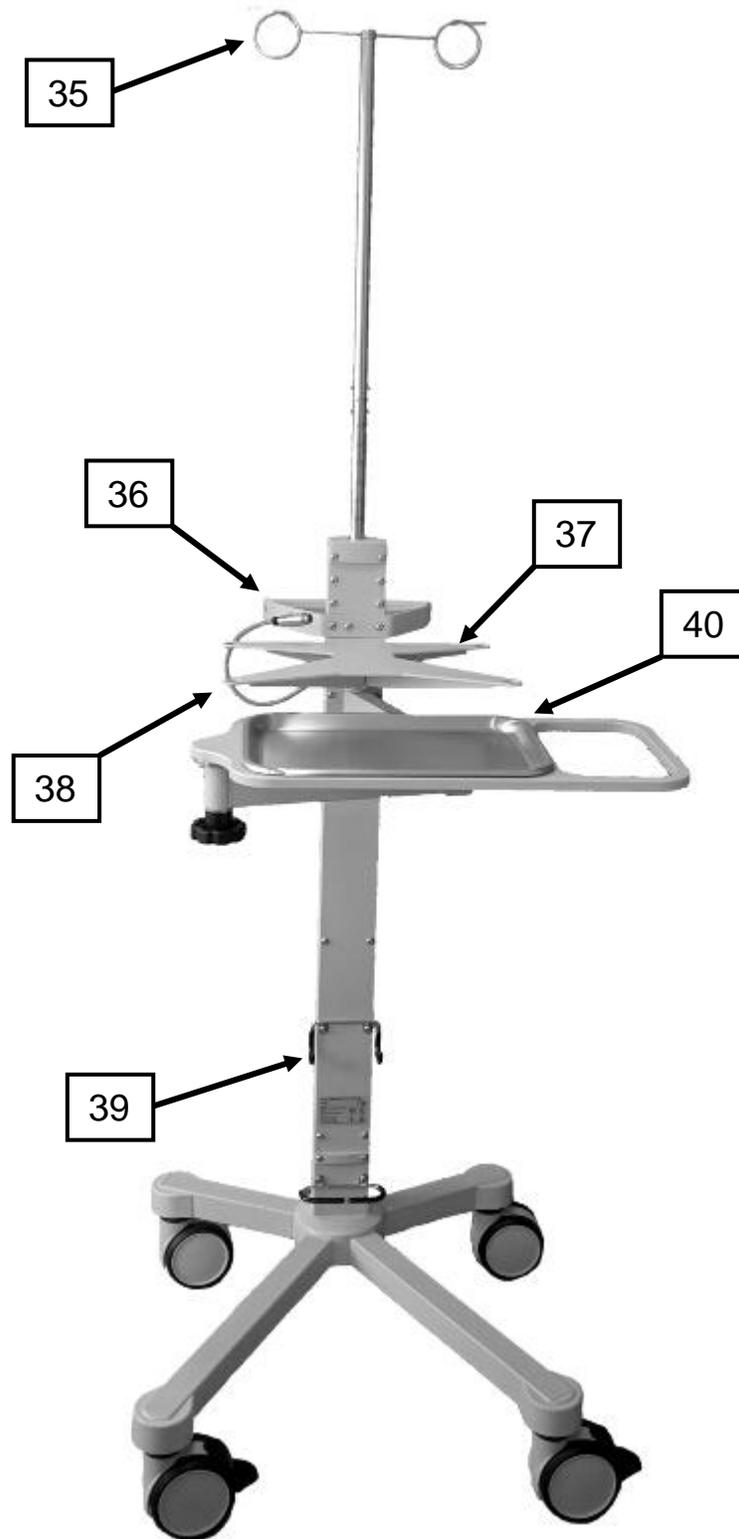
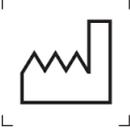
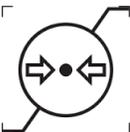
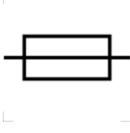


Figure 4-7: Optional Cart with Automated IV Pole

4.2 SYSTEM SIGNS AND SYMBOLS

SIGN / SYMBOL	DESCRIPTION	SIGN / SYMBOL	DESCRIPTION
	Alert: Read all related information. DO NOT bypass.		Humidity Range: Range of humidity in which the device can safely and effectively operate.
	B - Type Equipment: Providing a particular degree of protection against electrical shock, particularly regarding allowable leakage currents and reliability of the protected earth connection (if present).		Manufacture Date: Year the device was manufactured.
	BF - Type Equipment: As type (B) but with isolated or floating (F-type) applied part or parts.		Non-ionizing Radiation: Device emits electromagnetic radiation with insufficient photon energy to ionize matter.
	CE Marking Authorization: Device meets the requirements of applicable European Directives.		Not for General Waste: Component must be properly disposed of.
	Consult Accompanying Documents.		Pressure Range: Range of pressure under which the device can safely and effectively operate.
	Electrical Hazard: Electrical shock may occur when performing necessary tasks associated with electrical environments.		Serial Number: Identification number for the system console.
	European Authorized Representative: A legal entity designated by non- European Union (EU) manufacturers, to represent them in the EU and ensure their compliance with the European Directives.		Temperature Range: Range of temperature in which the device can safely and effectively operate.
	Fuse: Protects the device from excess electrical current.	COAG	Coagulation: Power connection for coagulation handpiece.

4.2 SYSTEM SIGNS AND SYMBOLS (CONTINUED)

SIGN / SYMBOL	DESCRIPTION	SIGN / SYMBOL	DESCRIPTION
I/V POLE	I/V Pole: Connection port for the system (optional) Cart with I/V Pole.	VIT	Vitrectomy: Power connection for vitrectomy handpiece.
FOOTPEDAL	Foot Pedal: Connection port for the system foot pedal.		System Power ON: When system is connected to main power
U/S	Ultrasonic: Power connection for ultrasonic handpiece.		System Power OFF: When system is disconnected from the main power
	Catalog Number: To identify the manufacturer's catalog number. The catalog number shall be placed adjacent to the symbol.		Batch Code: To identify the manufacturer's batch or lot code. The code shall be placed adjacent to the symbol.
	Refer to Operator's Manual: Operator's manual must be read.		

4.3 TECHNICAL SPECIFICATIONS

MANUFACTURER: Medical Technical Products, Inc

MODEL: 3000

CLASSIFICATION: (IEC60601-1) Class I

CONSOLE		
PARAMETER	SPECIFICATION	
DIMENSIONS:		
HEIGHT	6.5 inches	16.5 centimeters
WIDTH	14.5 inches	36.8 centimeters
DEPTH	13.5 inches	34.3 centimeters
WEIGHT	21 lbs.	9.5kilograms
DISPLAY (Color LCD TOUCHSCREEN)	12.1 inches	600 x 800 pixels
ELECTRICAL:		
INPUT VOLTAGE	100 to 240 VAC	@50 to60 Hz
MAXIMUM CURRENT	3A	
LINE FUSES	5A T(Slow Blow)	
MAX. OUTPUT VOLTAGE (Phaco)	530V	
MAX. OUTPUT VOLTAGE (Coag)	30V	
MAX. OUTPUT VOLTAGE (Foot Pedal)	5V	
ULTRASONIC:		
TYPE	Ultrasonic Generator	
MODES	NORMAL, BURST, and MICRO	
FUNCTIONS	Prime, Tune, Fixed, Linear, Reset, and Purge	
PULSE RANGE (Normal Mode)	1 to 10 pulses per second	
PULSE DURATION (Burst Mode)	20 to 100 milliseconds	
PULSE RANGE (Burst Mode)	Single – 1 each time the foot pedal is pressed	
PULSE RANGE(Micro Mode)	5 to 100 milliseconds (ON and OFF)	
DUTY CYCLE	15 seconds ON, 45 seconds OFF	
FREQUENCY	38 kHz to 42 kHz	
(DEFAULT) PHACO POWER	40% Normal Mode, 45% Burst and Micro Mode	
AVAILABLE PHACO POWER	5 to 100%	
(DEFAULT) VACUUM LEVEL	200 mmHg	
VACUUM RANGE	20 to 500 mmHg	

CONSOLE	
PARAMETER	SPECIFICATION
ULTRASONIC (U/S): (continued)	
(DEFAULT) ASPIRATION FLOWRATE	24 cc/min
ASPIRATION FLOW RANGE	2 to 50 cc/min
(DEFAULT) BOTTLE HEIGHT	77 inches (with optional IV Pole Cart)
ULTRASONIC CONTROL	Foot pedal actuation
IRRIGATION / ASPIRATION (I/A):	
ASPIRATION TYPE	Peristaltic pump, low pulsation
FUNCTIONS	Fixed Flow, Linear Flow, Fixed Vacuum, Linear Vacuum
(DEFAULT) VACUUM LEVEL	460 mmHg
VACUUM RANGE	20 to 500 mmHg
(DEFAULT) ASPIRATION FLOWRATE	26 cc/min
ASPIRATION FLOW RANGE	2 to 50 cc/min
(DEFAULT) BOTTLE HEIGHT	84 inches (with optional IV Pole Cart)
I/A CONTROL	Foot pedal actuation
VITRECTOMY (VIT):	
TYPE	Pneumatically-actuated, guillotine action
FUNCTIONS	Fixed Flow, Linear Flow, Fixed Vacuum, Linear Vacuum, Single Cut, Multiple Cut
(DEFAULT) CUT RATE	200 cuts per minute
AVAILABLE CUT RATE	60 to 700 cuts per minute
MAX. OPERATING PRESSURE	20 psi
(DEFAULT) VACUUM LEVEL	120 mmHg
VACUUM RANGE	20 to 500 mmHg
(DEFAULT) ASPIRATION FLOWRATE	26 cc/min
ASPIRATION FLOW RANGE	2 to 50 cc/min
(DEFAULT) BOTTLE HEIGHT	74 inches (with optional IV Pole Cart)
VIT CONTROL	Foot pedal actuation
COAGULATION:	
TYPE	Bipolar generator
MODES	Linear and Fixed
FREQUENCY	315 kHz

CONSOLE		
PARAMETER	SPECIFICATION	

COAGULATION: (continued)		
NOMINAL POWER (100%)	11 Watts	75 Ohm Load
MAX. PEAK VOLTAGE	30V RMS	
(DEFAULT) COAG. POWER	40%	
AVAILABLE COAG. POWER	10 to 100%	
COAG. CONTROL	Foot pedal actuation	

IRRIGATION:		
FLUID DELIVERY	Gravity Fed	
VALVE TYPE	Solenoid-actuated pinch valve	
(DEFAULT) BOTTLE HEIGHT	77 inches (with optional IV Pole Cart)	
IRRIGATION CONTROL	Foot pedal actuation or IRRIGATION soft-key	

FOOT PEDAL		
PARAMETER	SPECIFICATION	

HOUSING	Water-tight (<i>IEC60601-2-2</i>)	
MAIN TREADLE	Control dependent on Mode selected, (3) positions, (2) detents	
(DEFAULT) RIGHT (Side Kick)	Reflux	
(DEFAULT) LEFT (Side Kick)	Not Used	
AVAILABLE FUNCTIONS (Side Kick)	Not Used, Reflux, Mode, Multimode, Irrigation, IV Pole	
FEEDBACK	Vibration motor activated at detents	

HANDPIECE		
PARAMETER	SPECIFICATION	

TYPE	Piezoelectric	
FREQUENCY	38 kHz to 42 kHz	
TIP THREADS	Standard American (#4-40 UNC)	
CONNECTOR	Circular Push-Push, 9-pin	
LENGTH (without Tip)	5.40 inches	13.7 centimeters
WEIGHT (cable included)	3.8 oz.	107.7 grams

CART WITH IV POLE	
PARAMETER	SPECIFICATION
HANGERS	2
HANGER CAPACITY	2 – 500cc glass bottles
POLE TRAVEL	64 to 90 inches (measured from the ground to the bottom of the hanger)
POLE SPEED	2 inches per second
POLE CONTROL	Foot pedal activation or BOTTLE soft-key

4.4 ENVIRONMENTAL REQUIREMENTS

The Model 3000 should be used in a clean environmental that is suitable for surgery. The following environmental LIMITATIONS are as follows:

ENVIRONMENT	OPERATING	STORAGE/TRANSPORT
ALTITUDE	≤6,561 feet (2,000 meters)	≤14,000 feet (4,267 meters)
TEMPERATURE	50°F to 95°F (10°C to 35°C)	41°F to 140°F (5°C to 60°C)
RELATIVE HUMIDITY	30% to 85% RH	30% to 85% RH
ATMOSPHERIC PRESSURE	79 kPa - 102kPa	---

4.5 FACTORY DEFAULT SETTINGS

MODE	FLOW (cc/min)	VACUUM (mmHg)	POWER (%)	PULSE (pulses/s)	FUNCTION	CUT RATE (cuts/min)	BURST (%- ms)	ON/OFF (ms)	IV POLE HEIGHT (in.)
IRR									77
U/S Normal	24	200	40	0	Linear Power				77
U/S Burst	24	200	45		Multi Burst		20		77
U/S Micro	24	200	45		Linear Power			20 / 80	77
I/A	26	460			Linear Flow / Fixed Vac				84
I/A Cap Vac	6	20			Linear Flow / Fixed Vac				84
VIT	20	120			Linear Flow / Fixed Vac / Multi Cut	200			74
COAG			40		Linear Power				

5.0 SYSTEM OPERATION OVERVIEW

This section of the manual contains the information that identifies the operational functionality of the system which includes the following:

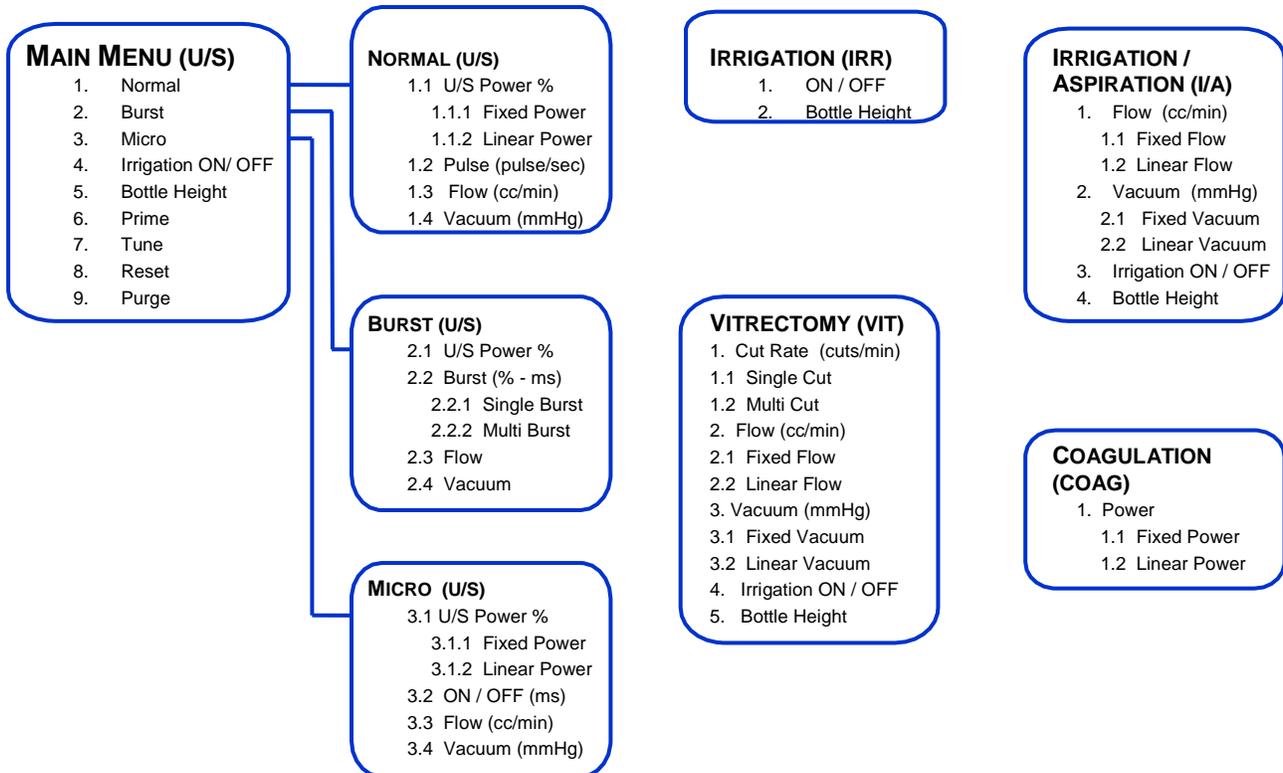
- ◆ Operational Modes
- ◆ Mode Functionality
- ◆ Parameter Settings
- ◆ Optional Commands for additional operation



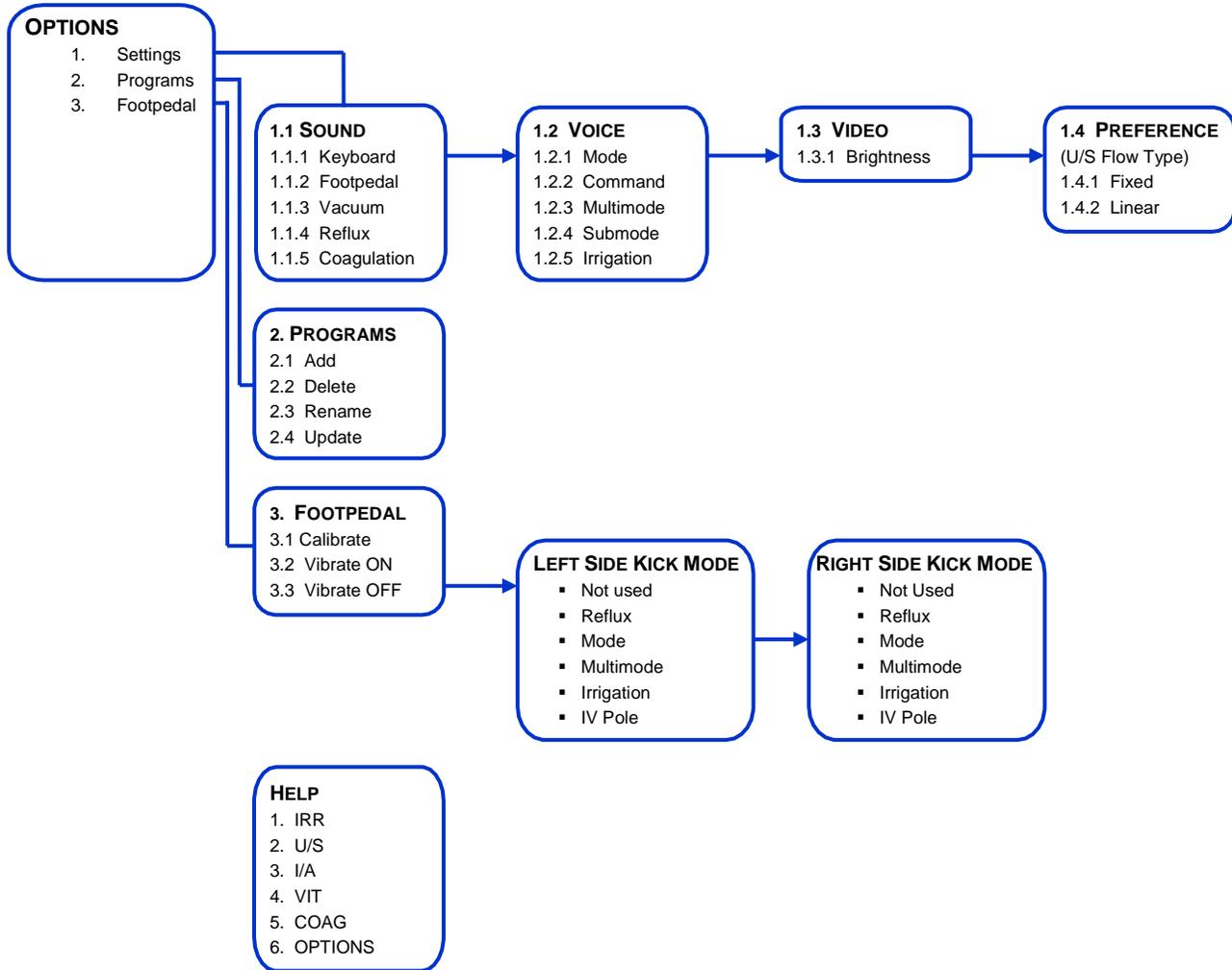
WARNING: This information should be completely read and understood in its entirety before operating the system in order to avoid harm to the system and/or the patient.

5.1 SYSTEM SOFTWARE OVERVIEW

The System Software (*Factory Default Settings*) Overview may be used as a quick reference guide or navigate to the various screens and menus of the system operation.



System Software Overview (continued)



5.2 MAIN MENU

When the console is first turned ON, the initialization screen with the MTP logo is momentarily displayed. The Main Menu (*U/S Phaco Mode*) screen will be displayed after the initialization screen.



The main menu screen is designed for easy navigation between all operational modes and user functions.

The Model 3000 has five (5) basic Modes of operation:

1. Irrigation (**IRR**)
2. Phaco (**U/S**)
3. Irrigation / Aspiration (**I/A**)
4. Vitrectomy (**VIT**)
5. Coagulation (**COAG**)

These five (5) operational Modes are commonly used during anterior surgery procedures. An “Options Mode” is also available with settings and functions that are specific to system operations, user programs, foot pedal settings and software upgrades. Note that the software upgrade function is for factory use only.

The “HELP” soft-key is used to display help information with most screen operational functions. See Section 5.8 Help Mode for additional information on the HELP function.

5.2 MAIN MENU (CONTINUED)



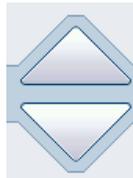
All of the system operational modes are located at the bottom portion of the screen. Press the desired soft-key to activate a mode. The active Mode or function soft-key will be outlined.



The soft-keys along the right-hand side of the screen are used for specific functions while in each Mode. Each Mode will have similar or different functions depending on their operational functionality. Press the desired soft-key to activate the function.

The active function soft-key will be outlined.

Arrow soft-keys are used to make adjustments to a parameter or operation when desired.



Functions of the arrow soft-keys are as follows:

UP Arrow: Increases or raises a parameter or function

DOWN Arrow: Decreases or lowers a parameter or function

The Irrigation soft-key manually turns the Irrigation function ON and OFF in Modes which utilize the irrigation function.



5.3 IRRIGATION (IRR) MODE



Irrigation is a basic operational Mode and is available in all other Modes except Coagulation.

IRR controls the irrigation pinch valve located on the left-hand side of the system where the tubing cassette is placed before system operation.

Control of the irrigation pinch valve is performed by depressing the foot pedal main treadle to the Irrigation position (1). This opens the irrigation pinch valve and allows fluid to flow. Releasing the foot pedal will close the irrigation pinch valve and stop the flow of fluid.

The source of Irrigation flow control is provided by an inverted container of solution, which is suspended above the patient’s eye level in the surgery room. The amount of solution delivered is dependent upon the height of the container. This is known as a “gravity type” system.

Bottle height is measured from the floor to the bottom of the bottle hanger.

5.3 IRRIGATION (IRR) MODE (CONTINUED)

IV Pole: If the optional cart with IV pole is connected to the Model 3000 console, the pole height may be controlled by touching and sliding the bottle on the touch screen to the desired height or by pressing the UP or DOWN arrow keys below the bottle height symbol.

The number displayed on the bottle represents the IV pole height in inches. Each time the UP or DOWN arrow is pressed, the IV pole will rise or lower by one inch.



The arrow keys can also be pressed and held to move the solution container to a desired height, and then pressed to obtain the exact height.

A drip chamber with connecting irrigation tubing is attached to the solution container and routed through the irrigation pinch valve by way of the tubing cassette and then attached to the ultrasonic handpiece irrigation port.

Manual Irrigation may also be performed by pressing the “Irrigation (**IRR**)” soft-key.



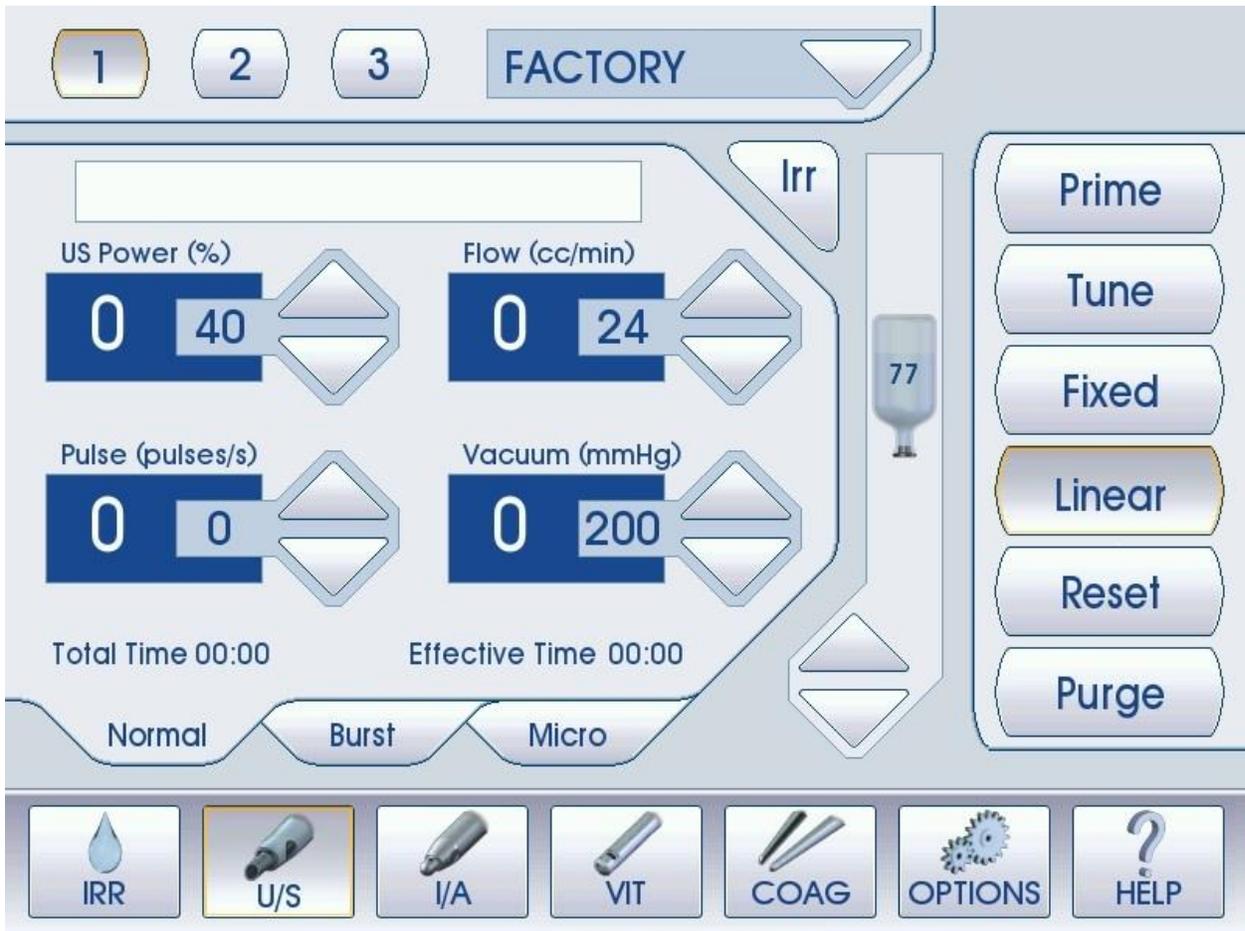
The (**IRR**) soft-key is outlined in red when activated. The (**IRR**) soft-key controls irrigation valve.

Activated (**IRR**) soft-key opens the irrigation valve and allows fluid to flow from solution container. Press the (**IRR**) soft-key a second time to close the irrigation valve and stops the flow of fluid.



IMPORTANT: If the Irrigation (**IRR**) soft-key is pressed on the console and the irrigation function is activated, the foot pedal has no effect on the irrigation pinch valve operation until the (**IRR**) soft-key is deactivated.

5.4 PHACO (U/S) MODE



The Phaco (U/S) Mode is the basic mode used to remove cataracts by the use of ultrasonic energy.

The ultrasonic energy is channeled into a hollow titanium tip attached to an Ultrasonic (Phaco) Handpiece which causes the tip to vibrate at a specified frequency.

This tip vibration creates a jackhammer type effect which emulsifies the cataractous lens and removes the debris through the hollow tip.

5.4.1 PHACO (U/S) MODE FUNCTIONS

Prime: The Prime function is used during system setup to fill the administration tubing, tubing cassette, and the ultrasonic handpiece test chamber with the irrigation solution, as well as to verify that the handpiece is properly tuned.

To activate the Prime function, press the “Prime” soft-key on the console. The “Prime” soft-key will be outlined in red. The aspiration pump will run for approximately 60 seconds, followed by an automatic tuning of the ultrasonic handpiece. The Prime function can be deactivated at any time by pressing the “Prime” soft-key a second time.

Tune: The “Tune” function is used to confirm that the attached ultrasonic handpiece meets the required electrical specifications of voltage, current, phase, and frequency. While the tune function is performed automatically at the end of a Prime cycle, it should be performed whenever a phaco tip is replaced, or the **Check Handpiece!** error message is displayed.

Reset: The Reset function resets the Phaco “Total Time” and “Effective Time” to (00:00).

Purge: The “Purge” function is used to remove fluid from the irrigation and aspiration tubes through the cassette and into the collection bag. To activate a Purge cycle, perform the following steps:

- 5.4.1.1 Disconnect the ultrasonic handpiece and remove the irrigation and aspiration tubes.
- 5.4.1.2 Connect the irrigation and aspiration tubes together to form a closed loop.
- 5.4.1.3 Close the roller clamp on the administration tubing.
- 5.4.1.4 Disconnect the administration tubing from the solution container and the cassette.
- 5.4.1.5 Press the “Purge” soft-key. The Purge soft-key will be outlined in red. The fluid will be purged from the irrigation and aspiration lines.
- 5.4.1.6 Dispose of the administration tubing set and collection bag according to your facility’s waste requirements.

The “Purge” function can be deactivated at any time by pressing the Purge soft-key a second time.

Reflux: The “Reflux” function is normally used to clear lens material from the aspiration line of the ultrasonic handpiece when it becomes occluded. Reflux is also available in all functions.

The foot pedal has the Reflux position on the “Right Side Kick Switch”, by default.

To activate the Reflux function, press and hold the Right Side Kick Switch.

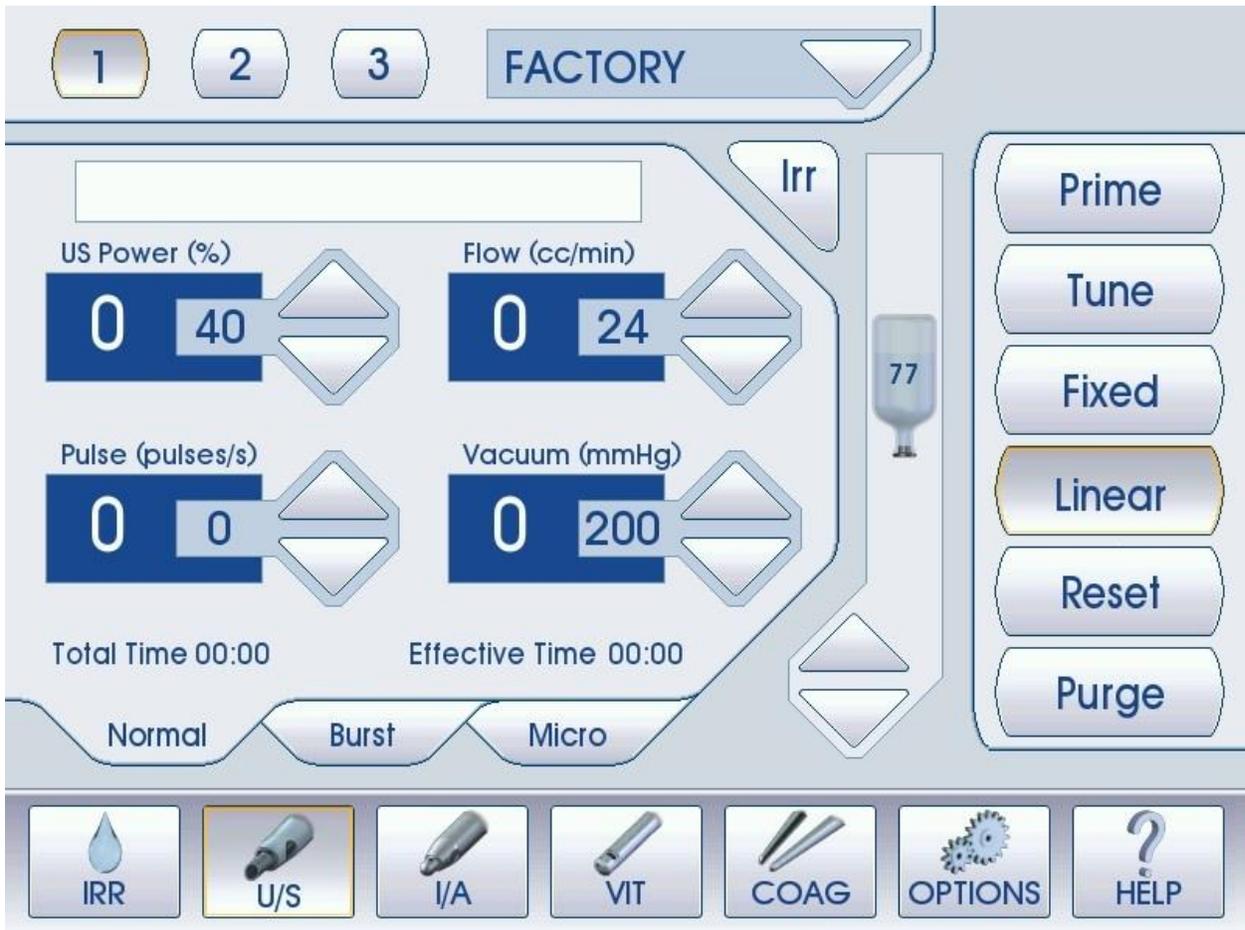
Reflux may have to be performed a few times depending on the occlusion.

Factory Arrow: The factory arrow is used to store user-defined programs. Pressing the arrow will display the “User Programs”. If any of the User Programs are selected, the Mode parameters of the user program will be displayed. If no programs have been saved, the factory list will be empty and all Modes will be set to their “Factory Default” values. (See Section 5.9.1 Programs Mode)

5.4.2 PHACO (U/S) NORMAL MODE

The Normal Mode may be selected for “LINEAR” or “FIXED” U/S Power %.

The U/S Power (%), Flow (cc/min), Vacuum (mmHg), and Pulse (pulses/s) parameters can all be adjusted using the UP and DOWN arrow keys.



Linear: Phaco energy is controlled in a “LINEAR” fashion by the foot pedal from zero to the maximum U/S Power value preset by factory default settings or user-programmed settings.

As discussed earlier in *Section 3.6 System Foot Pedal*, the foot pedal has three (3) positions. Position (3) is Phaco power. When position (3) is reached, the Linear Phaco power starts at zero and, depending on the travel of the foot pedal, can reach the maximum preset U/S Power value with complete depression of the Foot Pedal main treadle. The actual Linear Phaco power will be noted in the US Power (%) display on the console.

Releasing the foot pedal to position (2) or (1) will stop the Phaco power and continue the operation of the current foot pedal position, either Irrigation/Aspiration or Irrigation only, respectively. Releasing the foot pedal completely will cease all operations: Phaco, Aspiration, and Irrigation.

5.4.2 PHACO (U/S) NORMAL MODE (CONTINUED)

Fixed: Phaco energy is controlled in a “FIXED” fashion by the Foot Pedal. When the foot pedal reaches position (3), the U/S Power delivered is the preset value noted to the left of the arrow keys and on the U/S Power (%) display.

Releasing the foot pedal to position (2) or (1) will stop the Phaco power and continue the operation of the current foot pedal position, either Irrigation/Aspiration or Irrigation only, respectively. Releasing the foot pedal completely will cease all operations: Phaco, Aspiration, and Irrigation.

Pulse: When the foot pedal is in position (3), the Pulse function will deliver U/S Phaco power from zero pulses (*Continuous US Power*) to the maximum of ten (10) US Power pulses per second. Pulse also works with Fixed or Linear U/S Phaco power delivery.

5.4.3 PHACO (U/S) BURST MODE

Press the “BURST Tab” while in U/S Phaco Mode. In the Burst Mode, the Pulse (pulses/s) parameter has now changed to “Burst (% - ms)”, percent per milliseconds.

The Burst Mode may be selected for Single or Multi-burst functions at the “FIXED” U/S Power % selected. US Power %, Flow, and Vacuum remain the same as in the Normal Phaco Mode. The Burst %-ms has a pulse width duration range from 20 to 100 milliseconds (ms) in increments of 20 milliseconds (i.e. 20, 40, 60, 80, 100).



Two (2) types of Burst are available for Burst Mode:

1. **SINGLE:** If the Single Burst function is selected and position three (3) on the foot pedal is reached, a single burst of Phaco Power will be delivered at the selected Burst pulse width duration and the selected U/S Power %.
2. **MULTI:** If the Multi-burst function is selected and position three (3) on the foot pedal is reached, the further the foot pedal is depressed in position three (3), the time between bursts decreases until a continuous burst is delivered at the selected pulse width and U/S Power %.



NOTE: “LINEAR” U/S Phaco Power % is NOT available when in Burst Mode.

5.4.4 PHACO (U/S) MICRO MODE

Press the “MICRO Tab” while in U/S Phaco Mode. In the Micro Mode, the Pulse (pulses/s) parameter has now changed to “ON / OFF (ms)”. Micro Mode allows additional control over the ON and OFF times between U/S Phaco Power pulses.

The “ON” UP and DOWN arrow soft-keys are used to select the desired ON time (pulse duration) from 5 to 100 milliseconds (ms) in increments of 5 milliseconds (i.e. 0, 5, 10, 15,20, 25, ... 100).

The “OFF” UP and DOWN arrow soft-keys are used to select the desired OFF time (time between pulses) from 5 to 100 milliseconds (ms) in increments of 5 milliseconds (i.e. 0, 5,10, 15, 20 ...100).



5.4.4 PHACO (U/S) MICRO MODE (CONTINUED)

Linear: : Phaco energy is controlled in a “LINEAR” fashion by the foot pedal from zero to the maximum U/S Power value preset by factory default settings or user-programmed settings.

As discussed earlier in *Section 3.6 System Foot Pedal*, the Foot Pedal has three (3) positions. Position (3) is Phaco power. When position (3) is reached, the Linear Phaco power starts at zero and, depending on the travel of the foot pedal, can reach the maximum preset US Power value with complete depression of the foot pedal main treadle. The actual Linear Phaco power will be noted in the U/S Power (%) display on the console.

Releasing the foot pedal to position (2) or (1) will stop the Phaco power and continue the operation of the current foot pedal position, either Irrigation/Aspiration or Irrigation only respectively. Releasing the foot pedal completely will cease all operations: Phaco, Aspiration, and Irrigation.

5.4.5 MULTIMODE (U/S) SOFT-KEYS 1, 2, 3



The Multimode soft-keys are used as Phaco Mode presets for quick access to user- programmed Phaco Modes. The user can select any of the three (3) multimode soft-keys and edit default Phaco programs by completing the following steps:

- 5.4.5.1 Select any multimode soft-key.
- 5.4.5.2 Select any of the Phaco Tabs: Normal, Burst, or Micro.
- 5.4.5.3 Edit any of the following Phaco parameters for the Phaco Tab selected:

Normal Tab	Burst Tab	Micro Tab
U/S Power (%)	U/S Power (%)	U/S Power (%)
Pulse (pulses/s)	Burst (% - ms)	Burst On / Off (ms)
Flow (cc/min.)	Flow (cc/min.)	Flow (cc/min.)
Vacuum (mmHg)	Vacuum (mmHg)	Vacuum (mmHg)
Fixed	Single	Fixed
Linear	Multi	Linear
Bottle Height	Bottle Height	Bottle Height

- 5.4.5.4 Select another multimode soft-key.
- 5.4.5.5 Select another Phaco Tab and edit any of the Phaco parameters.
- 5.4.5.6 Now select the first multimode soft-key you previously edited. The edited Phaco parameters should be as first edited.



NOTE: The edited Phaco parameters will remain as edited until the system is powered OFF. The Phaco parameters will return to the default factory settings when the system is powered ON.

5.5 IRRIGATION ASPIRATION (I/A) MODE

The Irrigation and Aspiration Mode controls the irrigation pinch valve, venting pinch valve, and the peristaltic pump located on the left side of the system where the cassette and tubing are connected to the system. The Irrigation and Aspiration function is used to remove cortical material, viscoelastic material, and any remaining lens material in the eye.

During Aspiration, Irrigation is required to prevent the collapse of the cornea; the aspirated material is replaced with the irrigation solution. The source of irrigation is provided by an inverted container of irrigation solution which is suspended above patient eye level in the operating room. The amount of the irrigation solution delivered is controlled by the height of the container. A drip chamber with connecting tubing is attached to the irrigation container and routed through the irrigation pinch valve, venting pinch valve, and peristaltic pump to the ultrasonic handpiece from the tubing cassette. The height of the container is measured from the middle of the drip chamber to the level of the patient's eye.



Control of the irrigation pinch valve, venting pinch valve, and peristaltic pump is accomplished by actuation of the foot pedal.

When the foot pedal is depressed to position (1), the irrigation pinch valve will open. No Aspiration will occur within the first 25% of foot pedal travel. The remaining 75% of foot pedal travel will allow control of Aspiration.

5.5.1 I/A MODE FUNCTIONS



Linear Flow: When position (2) is reached, the peristaltic pump speed, or Flow (cc/min), is controlled by the actuation of the foot pedal between zero and the maximum limit set by the user using the UP or DOWN arrow keys or the default setting of the Flow parameter.

The actual Flow Rate display will show the position of the foot pedal from zero to the preset Flow Rate value on the console. The foot pedal has two (2) positions in I/A Mode:

1. Position (1): Irrigation
2. Position (2): Irrigation and Aspiration

Fixed Flow: The Fixed Flow Rate is set by the UP or DOWN arrow keys of the Flow (cc/min.) parameter.

Once the foot pedal reaches position (2), the Flow Rate will be equal to the preset value.

Linear Vac: The user has the ability to hold the Vacuum by holding the foot pedal main treadle in place. After a period in time, this will cause the peristaltic pump to cease, and a message will be displayed on the screen stating that the “Pump has Stopped”. Fully depressing the foot pedal will result in continuous Irrigation and Aspiration. Releasing the foot pedal will cease the Irrigation and Aspiration functions.

Fixed Vac: The Vacuum (mmHg) UP or DOWN arrow soft-keys on the console set the Vacuum value to a user-defined limit or default factory limit. The user cannot stop the Vacuum in Foot Pedal position (2). The Vacuum will increase until the preset value is reached; the peristaltic pump will stop and the “OCCLUSION” alarm will sound.

Reflux: The “Reflux” function is normally used to clear lens material from the aspiration tube of the ultrasonic handpiece when it becomes occluded. Reflux is available in all functions. The foot pedal has the Reflux (default) position on the “Right Side Kick Switch”. To activate the Reflux function, press and hold the Right Side Kick Switch. The Reflux function may have to be performed a few times depending on the occlusion.

5.5.2 MULTIMODE SOFT-KEYS I/A1, I/A2 & CAP VAC



The Multimode soft-keys are used as I/A Mode presets for access to user-programmed I/A Modes. Cap Vac is used to quickly change the Aspiration settings, when the doctor is polishing the posterior capsule and requires very low Flow and Vacuum levels.

The user can select any of the three (3) multimode soft-keys and edit default I/A programs by completing the following steps:

5.5.2.1 Select any multimode soft-key.

5.2.2 Edit any of the following I/A parameters for the multimode soft-key selected:

- ◆ Flow (cc/min)
- ◆ Fixed Flow
- ◆ Linear Flow
- ◆ Vacuum (mmHg)
- ◆ Fixed Vac
- ◆ Linear Vac
- ◆ IV Pole Height

5.5.2.3 Select another multimode soft-key.

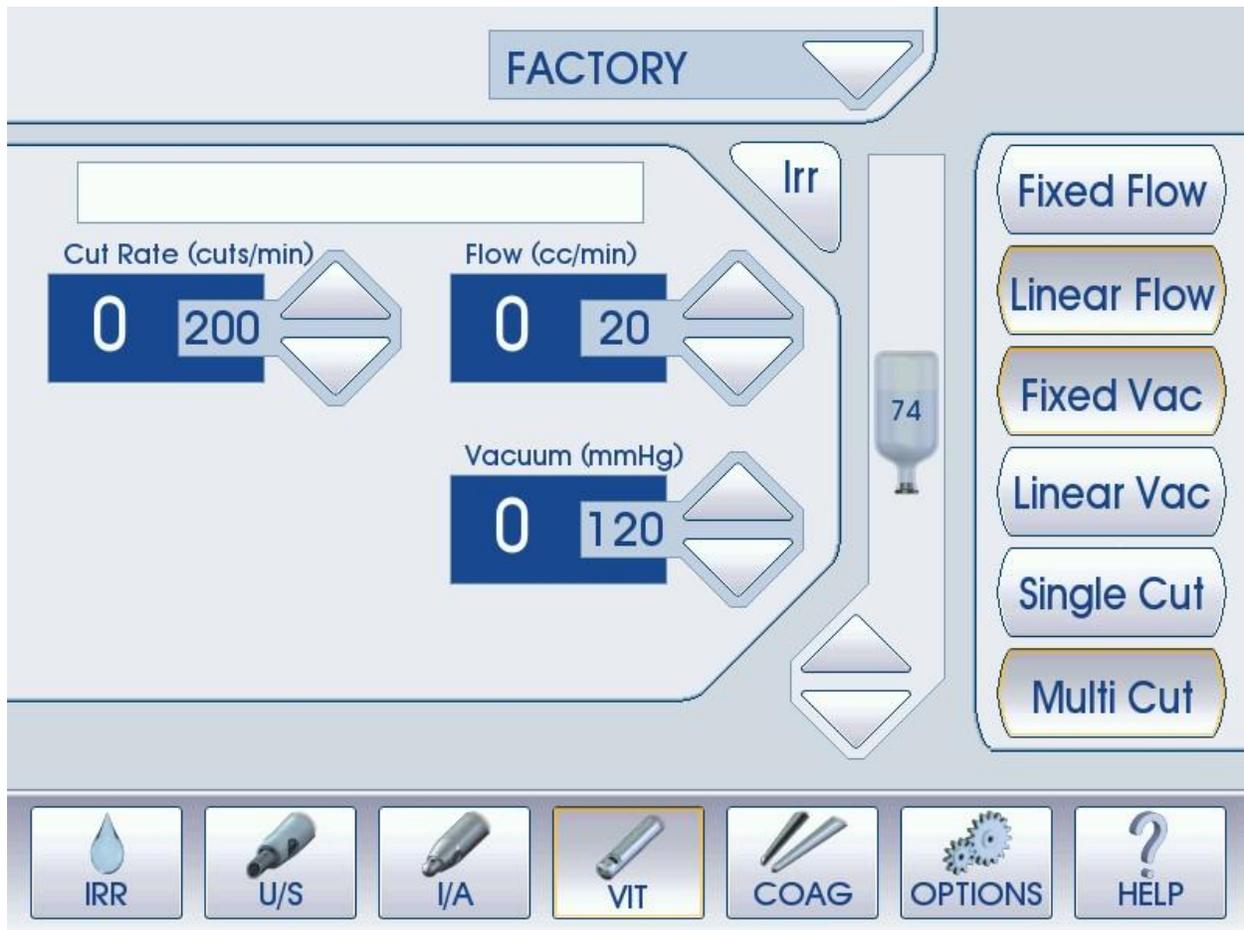
5.5.2.4 Edit any of the I/A parameters listed above in *Section 5.5.2.2* for the multimode soft-key selected:

5.5.2.5 Now select the first multimode soft-key you previously edited. The edited I/A parameters should be as first edited.



NOTE: The edited I/A Mode parameters will remain until the system is powered OFF. I/A Mode parameters will return to default factory settings when the system is powered ON.

5.6 VITRECTOMY (VIT) MODE



Vitrectomy is used to remove the vitreous from the anterior chamber of the eye if the posterior chamber is ruptured. Vitreous loss can occur after a trauma during the primary cataract surgery itself.

The Vitrectomy procedure is performed with a pneumatically-controlled disposable or reusable guillotine cutting needle. The vitreous material is aspirated into the port of the needle and cut by the guillotine cutting action. During the Vitrectomy procedure, Irrigation and Aspiration are required to prevent the collapse of the cornea. The aspirated material is replaced with irrigation solution.

The irrigation source is provided by an inverted container of irrigation solution, which is suspended above patient eye level in the operating room. The delivery amount of the irrigation solution is controlled by the height of the container.

The foot pedal has two (2) positions in the Vitrectomy (VIT) Mode:

1. Position (1): Irrigation
2. Position (2): Irrigation, Aspiration, and Cutting

5.6.1 VIT MODE FUNCTIONS

Linear Flow: When position (2) is reached, the peristaltic pump speed, or Flow (cc/min), is controlled by the actuation of the foot pedal between zero and the maximum limit set by the user using the UP or DOWN arrow keys or the default setting of the Flow parameter. The actual Flow Rate display will show the position of the foot pedal from zero to the preset Flow Rate value on the console.

Fixed Flow: The Fixed Flow Rate is set by the UP or DOWN arrow keys of the Flow (cc/min.) parameter. Once the foot pedal reaches position (2), the Flow Rate will be equal to the preset value.

Linear Vac: The user has the ability to hold the Vacuum by holding the foot pedal main treadle in place. After a period in time, this will cause the peristaltic pump to cease, and a message will be displayed on the screen stating that the “Pump has Stopped”. Fully depressing the foot pedal will result in continuous Irrigation and Aspiration. Releasing the foot pedal will cease the Irrigation and Aspiration functions.

Fixed Vac: The Vacuum (mmHg) UP or DOWN arrow soft-keys on the console set the Vacuum value to a user-defined limit or default factory limit. The user cannot stop the Vacuum in foot pedal position (2). The Vacuum will increase until the preset value is reached; the peristaltic pump will stop and the “OCCLUSION” alarm will sound.

Single Cut: The Vitrectomy Single Cut Mode is activated by depressing the foot pedal to position (2). When the main treadle reaches position (2), Irrigation and Aspiration are both activated along with one (1) cut from the vitrectomy handpiece. Single Cut is normally used when there are just a few Vitreous strands present in the anterior chamber of the eye. The doctor may choose to cut just one strand at a time by depressing the foot pedal once for one (1) single cut.

Multi Cut: The Vitrectomy Multi Cut Mode is activated by depressing the foot pedal to position (2). When the main treadle reaches position (2), Irrigation and Aspiration are both activated along with the number of cuts per minute selected in the Cut Rate (cuts/min) display on the console screen.

The Cut Rate (cuts/min) range is from 60 to 700 cuts per minute in 10 cuts per minute increments (i.e. 60, 70, 80, 90, 100 ...700).

The Cut Rate will remain as selected (Single Cut/ Multi Cut) even with Linear Flow and/or Linear Vac selected.

Reflux: The foot pedal has the Reflux (default) position on the “Right Side Kick Switch”. To activate the Reflux function, press and hold the Right Side Kick Switch. The Reflux function may have to be performed a few times depending on the occlusion.

5.7 COAGULATION (COAG) MODE



The Coagulation mode is mainly used for cauterizing small blood vessels. Most surgeons use the bipolar coagulation for this function. An isolated 315 kHz frequency cautery circuit allows for non-contact tissue coagulation.

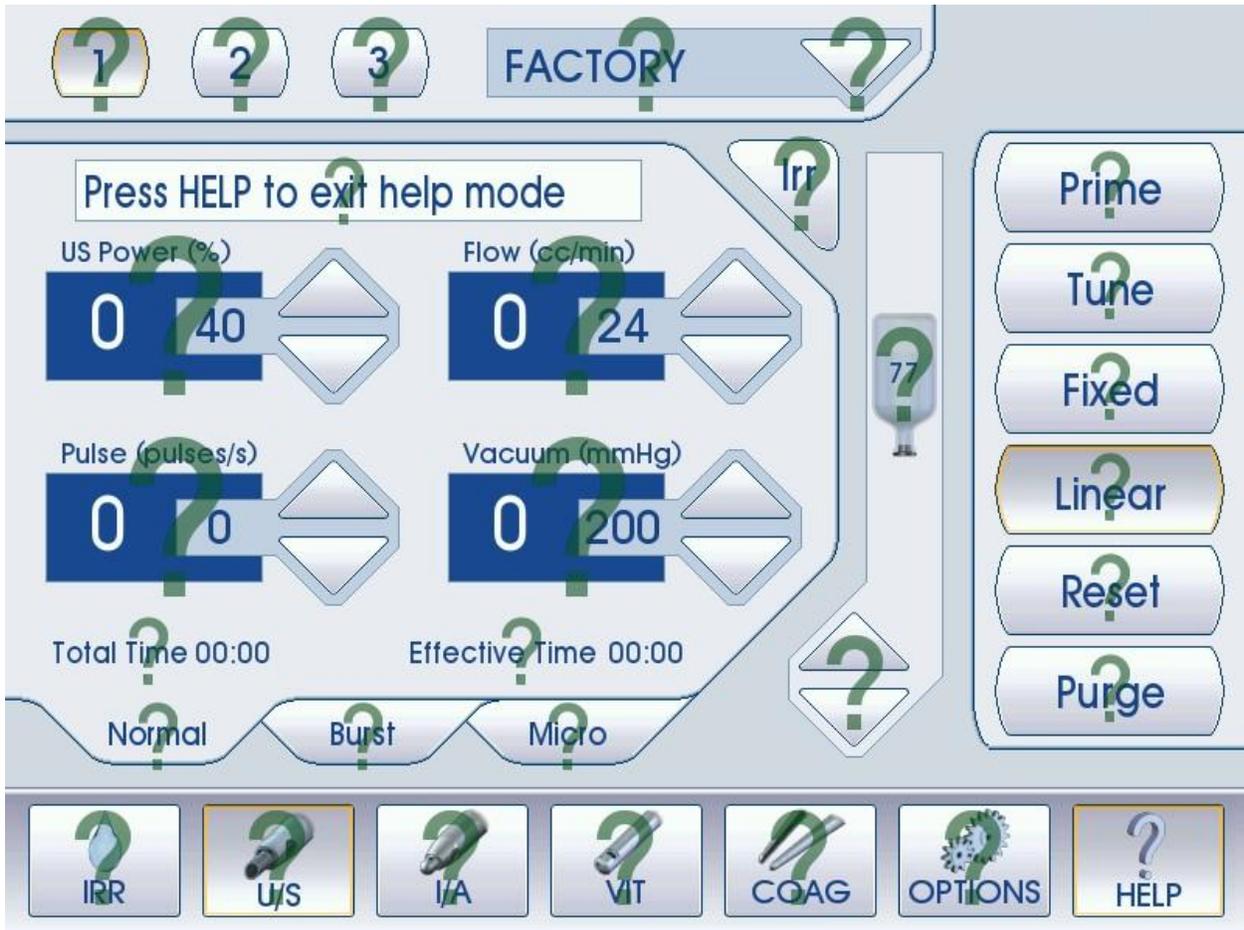
During coagulation, an audible safety tone is emitted from the system alerting the doctor that Coagulation is activated.

The foot pedal has only one (1) position in the COAG Mode. Depressing the Foot Pedal turns ON the COAG power; releasing the Foot Pedal turns OFF the COAG power.

Linear COAG: COAG Power is controlled in a linear fashion by the foot pedal from zero to the maximum limit set by the Power % UP or DOWN soft-keys on the console. The COAG power range is from 0 to 100% power in increments of 10% (i.e. 10, 20, 30, 40 ...100).

Fixed COAG: COAG Power is controlled as a fixed function. Set the desired Power % using the UP or DOWN soft-keys on the console. When the foot pedal is depressed, the Power % will be displayed and equal to the preset value set by the user. Releasing the foot pedal will turn the Power OFF.

5.8 HELP MODE



The HELP Mode allows the user to view the available help for all screens of operation. When in any screen for any mode, press the “HELP” soft-key. A question mark will be displayed over fields and mode functions which have available help information.

Press the question mark on the field or mode function that you require help with and help information will be displayed for your selection.

1. Touch the Help information field to close the information window.
2. Touch the “HELP” soft-key a second time to close the Help field.



5.9 OPTIONS MODE



5.9.1 PROGRAMS MODE

The Programs Tab in the Options menu allows the user to edit and save all parameters in all modes in one easy access location. Twenty-four (24) programs can be created and stored long-term at any given time.

The Programs Mode allows the user to perform the following programming functions:

- ◆ System Overview
- ◆ System Setup
- ◆ System Settings
- ◆ System Operation
- ◆ System Cleaning and Storage
- ◆ System Troubleshooting

An alphanumeric keyboard appears on the Programs Tab of the Options Menu which allows the user to enter a custom program name up to 11 characters including spaces.

 **NOTE:** When the system is powered ON, all programs and parameters will default to their original FACTORY settings until a custom program is chosen from the “PROGRAM” list by pressing the DOWN arrow soft-key at the top of the screen.

5.9.2 CREATE AND SAVE A CUSTOM PROGRAM

- 5.9.2.1 Select and change the desired parameter settings in each mode (IRR, U/S, I/A, VIT, COAG)
- 5.9.2.2 Make a list and write down each Mode and the values of each change for custom program memory verification later in this procedure.
- 5.9.2.3 After all desired parameter settings and Mode functions have been changed, press the “OPTIONS” soft-key.
- 5.9.2.4 Press the “Programs” tab.
- 5.9.2.5 Press the “Add” function soft-key.
- 5.9.2.6 Use the keyboard on the Programs tab to enter the 11 character custom program name.
- 5.9.2.7 Press the “OK” function soft-key or the keyboard ENTER () key to save the custom program, or press “Cancel” to exit and not save the custom program.



NOTE: The remaining steps in this procedure are for creating the first custom program on the system. These steps may also have to be repeated if program memory is questionable.

- 5.9.2.8 After saving the custom program, verify the custom program memory:
 - 5.9.2.8.1 Press the power button to the “OFF” position on the back of the console.
 - 5.9.2.8.2 Wait for 10 seconds and then press the power button to the “ON” position.
 - 5.9.2.8.3 Wait for the system to boot up to the “FACTORY” U/S Phaco mode screen.
 - 5.9.2.8.4 Press the “PROGRAM” DOWN arrow soft- key at the top of the screen, to the right of the word FACTORY.
 - 5.9.2.8.5 Select the custom program name and verify that all the displayed parameter settings and mode functions match the list created earlier in this procedure.

5.9.3 RECALLING A PROGRAM

- 5.9.3.1** Press the “PROGRAM” DOWN arrow soft-key at the top of the screen, to the right of the word FACTORY.
- 5.9.3.2** Scroll down to the desired custom program name.
- 5.9.3.3** Select the custom program name.
- 5.9.3.4** The screen should now display the program name selected and all of the parameter settings and mode functions associated with the program.

5.9.4 RENAMING A SAVED PROGRAM WITHOUT CHANGING PROGRAM SETTINGS

- 5.9.4.1** Press the “PROGRAM” soft-key at the top of the screen, to the right of the word FACTORY.
- 5.9.4.2** Press the “Program Name” you would like to change.
- 5.9.4.3** Press the “OPTIONS” soft-key.
- 5.9.4.4** Press the “Programs” tab.
- 5.9.4.5** Press the “Rename” function soft-key.
- 5.9.4.6** Use the keyboard “Backspace” key () to clear the program name.
- 5.9.4.7** Use the alphanumeric keyboard on the screen to type in the new 11 character program name.
- 5.9.4.8** Press the “OK” function soft-key or the keyboard ENTER () key to save the new program name, or press “Cancel” to exit and not save the new program name.

*: The FACTORY name with its associated Modes and settings cannot be changed.

5.9.5 CHANGE SAVED PROGRAM SETTINGS WITHOUT CHANGING THE PROGRAM NAME

- 5.9.5.1 Press the “PROGRAM” soft-key at the top of the screen, to the right of the word FACTORY.
- 5.9.5.2 Press the “Program Name” you would like to change the settings on.
- 5.9.5.3 Go through each Mode and change the desired parameter settings in each mode (U/S, I/A, VIT, COAG), except the IRRIGATION (IRR) MODE, using the UP and DOWN arrow soft-keys and Mode function keys.
- 5.9.5.4 After all desired parameter settings and Mode functions have been changed, press the “OPTIONS” soft-key.
- 5.9.5.5 Press the “Programs” tab.
- 5.9.5.6 Press the “Update” function soft-key.
- 5.9.5.7 Press the “OK” function soft-key to save the program changes, or press “Cancel” to exit and not save the program changes.
- 5.9.5.8 The Program name remains the same with or without the changes.

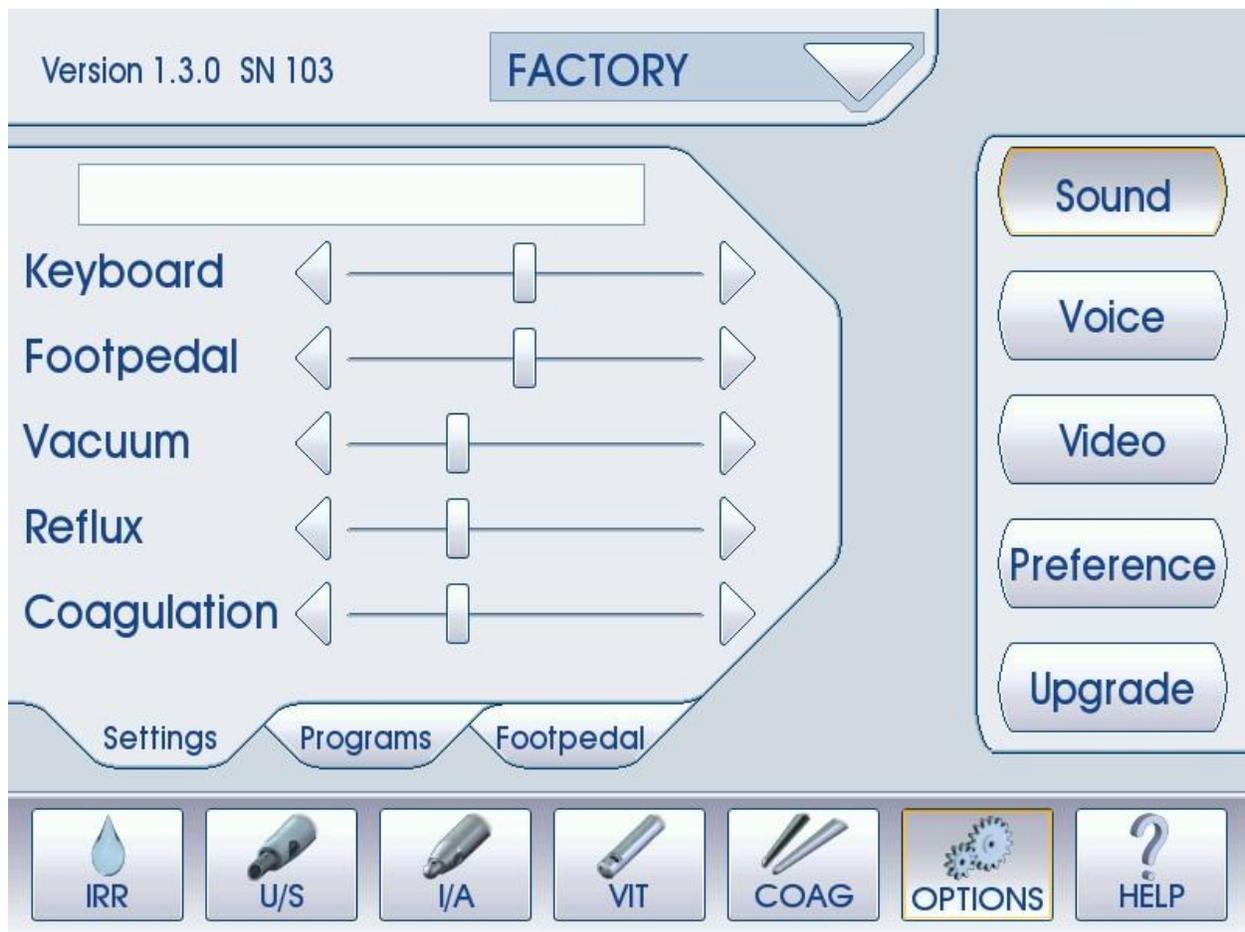
5.9.6 DELETE PROGRAM NAMES

- 5.9.6.1 Press the “PROGRAM” soft-key at the top of the screen, to the right of the word FACTORY.
- 5.9.6.2 Press the “Program Name” you would like to delete.
- 5.9.6.3 Press the “OPTIONS” soft-key.
- 5.9.6.4 Press the “Programs” tab.
- 5.9.6.5 Press the “Delete” function soft-key.
- 5.9.6.6 Press the “OK” function soft-key to delete the program name, or press “Cancel” to exit and not delete the program name.



NOTE: The settings of the deleted program name will remain on the system. Re-save the program per Section 5.9.2 Create and Save a Custom Program or select the FACTORY program to return the system to the Factory default settings.

5.9.7 SETTINGS MODE



The Settings Mode allows the user to edit various system functions for Sound, Voice, Video, Preferences, and system software Upgrades. Note that the software upgrade function is for factory use only.

5.9.8 SOUND

Various tones emitted from the Model 3000 indicate specific functions and/or alerts while the system is powered ON and the Modes are accessible by the user. Some of these tones and alerts include the following:

- ◆ Foot Pedal Position
- ◆ Increase or Decrease in Vacuum
- ◆ Occlusion Alarm
- ◆ Coagulation Operation
- ◆ Pressing Soft-Keys
- ◆ Reflux Activation

5.9.9 CHANGE AN AUDIBLE INDICATOR SETTING

- 5.9.9.1** Press the “OPTIONS” soft-key at the bottom of the screen.
- 5.9.9.2** Press the “Settings” tab.
- 5.9.9.3** Press the “Sound” function soft-key (default).
- 5.9.9.4** Adjust the KEYBOARD, FOOTPEDAL, VACUUM, REFLUX and COAGULATION sound levels by performing the following actions:
 - 5.9.9.4.1** Press the RIGHT arrow to increase the sound.
 - 5.9.9.4.2** Press the LEFT arrow to decrease the sound.
 - 5.9.9.4.3** Or press the Slider soft-key and drag it to the desired sound level.



NOTE: If the KEYBOARD sound is set to the minimum sound level, you will not hear any sound when any of the soft-keys are pressed.
Audible Function Indicators are also saved when saving programmed settings.

5.9.10 VOICE



The Voice Mode allows the user to set their preferences for the audible voice indicators. The Voice indicators are used to state the changes selected to the following areas:

- ◆ Mode: Controls the voice volume for the MODE soft-keys at the bottom of the screen (IRR, U/S, I/A, VIT, COAG, OPTIONS, HELP)
- ◆ Command: Controls the voice volume for all soft-keys on the right side of the screen.
- ◆ Multimode: Controls the voice volume for the soft-keys at the top of the screen. (U/S Phaco Multimodes 1, 2, 3; I/A Multimodes I/A1, I/A2, Cap Vac.)
- ◆ Submode: Controls the voice volume for the “tabs” in the following modes:
(U/S Phaco: Normal, Burst, Micro; OPTIONS: Settings, Programs, Footpedal)
- ◆ Irrigation: Controls the voice volume for the Irrigation (IRR) soft-key just below the PROGRAM soft-key at the top of the screen.
(On all modes except COAG)

5.9.11 CHANGE VOICE INDICATOR SETTING

- 5.9.11.1 Press the “OPTIONS” soft-key at the bottom of the screen.
- 5.9.11.2 Press the “Settings” tab.
- 5.9.11.3 Press the “Voice” function soft-key.
- 5.9.11.4 Adjust the MODE, COMMAND, MULTIMODE, SUBMODE and IRRIGATION Voice sound levels by performing the following actions:
 - 5.9.11.4.1 Press the RIGHT arrow to increase the voice sound
 - 5.9.11.4.2 Press the LEFT arrow to decrease the voice sound
 - 5.9.11.4.3 Or press the Slider soft-key and drag it to the desired voice sound level.

5.9.12 VIDEO



The Video mode allows the user to set their preferences for the LCD display brightness.

5.9.13 CHANGE VIDEO BRIGHTNESS SETTING

- 5.9.13.1** Press the “OPTIONS” soft-key at the bottom of the screen.
- 5.9.13.2** Press the “Settings” tab.
- 5.9.13.3** Press the “Video” function soft-key.
- 5.9.13.4** Adjust the LCD BRIGHTNESS by performing the following actions:
 - 5.9.13.4.1** Press the RIGHT arrow to increase the brightness.
 - 5.9.13.4.2** Press the LEFT arrow to decrease the brightness.
 - 5.9.13.4.3** Or press the Slider soft-key and drag it to the desired brightness.

5.9.14 PREFERENCES



The Preferences mode allows the user to set their preference for the control of the Flow Rate (cc/min) when in the U/S Phaco mode.

Linear Flow: The peristaltic pump speed, or Flow (cc/min), is controlled by the actuation of the foot pedal in position (2) between zero and the maximum limit set by the user using the UP or DOWN arrow keys or the default setting of the Flow parameter. The actual Flow Rate display will show the position of the foot pedal from zero to the preset Flow Rate value on the console. The foot pedal has three (3) positions in the U/S Phaco Mode:

- ◆ Position (1): Irrigation
- ◆ Position (2): Irrigation & Aspiration
- ◆ Position (3): Irrigation, Aspiration & U/S Phaco Power

When the Foot Pedal is in position (3), Flow Rate (cc/min) will remain at the maximum preset value.

Fixed Flow: The Fixed Flow Rate is set by the UP or DOWN arrow keys of the Flow (cc/min.) parameter. Once the Foot Pedal reaches position (2), the Flow Rate will be equal to the preset value.

5.9.15 CHANGE PREFERENCE SETTINGS

- 5.9.15.1** Press the “OPTIONS” soft-key at the bottom of the screen.
- 5.9.15.2** Press the “Settings” tab.
- 5.9.15.3** Press the “Preference” function soft-key.
- 5.9.15.4** Press the desired option: FIXED (default) or LINEAR Flow Rate for U/S Phaco Mode.

5.9.16 FOOT PEDAL MODE



The Foot Pedal Mode allows the user to select a variety of operational functions that are specific to the foot pedal actuation during the operation of the Model 3000. Refer to *Section 3.6*, *Section 4.1*, and *FIGURE 4-5* for foot pedal description.

- Calibrate:** Pressing the Calibrate soft-key will enter into Foot Pedal Calibration (See *Section 5.9.17 Foot Pedal Calibration Procedure*).
- Vibrate ON:** Pressing the Vibration ON soft-key enables tactile feedback on the foot pedal. When depressing the foot pedal between positions 1, 2, and 3, the vibration motor will be activated.
- Vibrate OFF:** Pressing the Vibration OFF soft-key disables the tactile vibration feedback on the foot pedal.

5.9.16 FOOT PEDAL MODE (CONTINUED)

The foot pedal RIGHT and LEFT Side Kick Modes have the same operations as follows:

- ◆ Not Used
- ◆ Reflux
- ◆ Mode
- ◆ Multimode
- ◆ Irrigation
- ◆ IV Pole

As noted in the FACTORY settings:

- ◆ Factory default operation for RIGHT Side Kick Mode is “**REFLUX**”
- ◆ Factory default operation for LEFT Side Kick Mode is “**Not Used**”

The foot pedal RIGHT and LEFT Side Kick Mode settings can be changed to any combination of the six (6) operational functions listed.

Not Used: When this option is selected, the selected side kick has NO function.

Reflux: When this option is selected, the selected side kick function is “Reflux” in any foot pedal main treadle position.

Mode: When this option is selected, and the foot pedal main treadle is not depressed (Side Kicks ONLY), the selected side kick function will switch between main modes of operation: IRR, U/S, I/A, VIT and COAG.

Multimode: When this option is selected, and the foot pedal main treadle is not depressed (Side Kicks ONLY), the selected side kick function will switch between Multimodes 1, 2, and 3 in U/S Phaco Mode, and between Multimodes I/A1, I/A2, and Cap Vac in I/A Mode.

Irrigation: When this option is selected, and the foot pedal main treadle is not depressed (Side Kicks ONLY), the selected side kick function will perform the following:

- ◆ Press the Side Kick – Switch ON the Irrigation function
- ◆ Press the same Side Kick – Switch OFF the Irrigation function

IV Pole: When this option is selected, and the foot pedal main treadle is not depressed (Side Kicks ONLY), the selected side kick function will perform the following functions:

- ◆ Tapping the side kick one (1) time will raise the IV pole one (1) inch each tap.
- ◆ Pressing and holding the side kick will raise the IV pole until the side kick is released
- ◆ Tapping the side kick two (2) times will lower the IV pole (1 inch) each double tap
- ◆ Double tapping and holding the side kick will lower the IV pole until the side kick is released.

5.9.17 FOOT PEDAL CALIBRATION PROCEDURE



The Model 3000 comes pre-calibrated with the foot pedal included in the original system package. However, the foot pedal can be recalibrated at any time to the three (3) foot pedal positions you desire.

! IMPORTANT: The foot pedal should always be recalibrated if there is a problem with the operation of the foot pedal, or if the foot pedal has been repaired or replaced.

For recalibrating the foot pedal, perform the following steps:

- 5.9.17.1 Press the power switch on the back panel to the “ON” position.
- 5.9.17.2 Wait for the system to boot up to the U/S Phaco screen (default).
- 5.9.17.3 Press the “OPTIONS” soft-key at the bottom of the screen.
- 5.9.17.4 Press the “Footpedal” tab.
- 5.9.17.5 Press the “Calibrate” soft-key on the right-hand side of the OPTIONS screen.

! IMPORTANT: The foot pedal calibration procedure must be completed in its entirety once it has been started. If you do not want to carry out the procedure, press the “Cancel” soft-key to exit the procedure.

5.9.17 FOOT PEDAL CALIBRATION PROCEDURE (CONTINUED)

Remember, you have three (3) foot pedal positions. Wherever you choose to press and hold the main treadle for each position is up to you. There is no set standard.

5.9.17.6 Follow the directions on the screen to calibrate the foot pedal.

5.9.17.6.1 Depress and hold the foot pedal at the “first” detent position and press the “OK” soft-key.

5.9.17.6.2 Depress and hold the foot pedal at the “second” detent position and press the “OK” soft-key.

5.9.17.6.3 Completely depress and hold the foot pedal to the “third” detent position and press the “OK” soft-key.

5.9.17.6.4 Release the foot pedal and press the “OK” soft-key.



NOTE: If the Foot Pedal Vibration is “ON”, the vibration will occur between positions (1) and (2) and between positions (2) and (3).

6.0 SYSTEM SETUP AND PREOPERATIONAL CHECKS

This section of the manual contains the recommended instruction for setting up the Model 3000 and performing preoperational checks prior to use. Ensure that all equipment and accessories for performing surgical procedures are present and ready for use, including those for pre-operative site preparation and post-operative care. Read all package labels and instructions that accompany components and materials to ensure proper handling and preparation, including cleaning and sterilization for reusable items. Steps in this section of the manual should be followed while wearing proper gowning and following aseptic technique according to your institution's procedures.

6.1 SYSTEM SETUP



- 6.1.1 Place the console onto the (optional) cart with IV pole, if available.
- 6.1.2 Verify that the power switch on the console back panel is in the “O” OFF position.
- 6.1.3 Connect the power cord to the AC power input connection on the back panel.
- 6.1.4 Connect foot pedal cable to the console back panel connection marked “**FOOT PEDAL**”.
 - 6.1.4.1 Align the notch on the connector with the connection on the back panel.
 - 6.1.4.2 Insert the connector and screw it in by hand until snug.
- 6.1.5 Connect cart cable to the console back panel connection marked “**IV POLE**”, if applicable.
 - 6.1.5.1 Align the notch on the connector with the connection on the back panel.
 - 6.1.5.2 Insert the connector and screw it in by hand until snug.



WARNING: To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.



WARNING: The console can only be disconnected from the supply mains by means of the power cord. Position the equipment so that the power cord is easily accessible.

6.1 SYSTEM SETUP (CONTINUED)

6.1.6 Insert the tubing cassette into the side of the console.

6.1.6.1 Ensure that the tubing in the semi-circular cutout of the cassette mates with the peristaltic pump head.

6.1.6.2 Press the cassette straight down firmly until it locks in place.



6.1.7 Hang the irrigation solution bottle/bag (not included) on the IV pole hanger.

6.1.8 Close the roller clamp on an administration tubing set (not included).

6.1.8.1 Roll the clamp roller until the tubing is collapsed to prevent fluid flow through tubing.

6.1.9 Insert the drip chamber spike into an irrigation solution bottle/bag (not included).

6.1.10 Connect the administration tubing set (male fitting) to the cassette administration tube (female fitting).

6.1.10.1 Prime administration tubing set by squeezing drip chamber.



6.1.11 Hang the collection bag from the hanger located on the bottom center of the cassette.

6.1.12 Connect the collection tube from the cassette to the collection bag.

6.1.13 Power ON the system by pressing the power switch on the back panel to the "I" ON position.

6.1.14 Calibrate Foot Pedal (See Section 5.9.17 Foot Pedal Calibration Procedure)

6.2 ACCESSORY SETUP

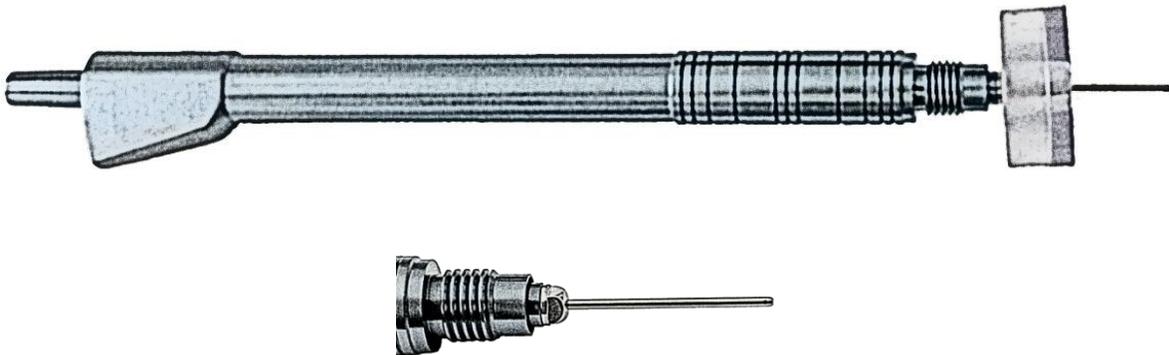
Complete the following instructions prior to using the listed accessories to the Model 3000.



WARNING: The following components must be sterilized prior to their use.

6.2.1 IRRIGATION / ASPIRATION HANDPIECE

- 6.2.1.1** Install the aspiration tip onto the I/A Handpiece using the supplied tip wrench, tighten until fully seated.



CAUTION: DO NOT over-tighten or thread damage to the handpiece may occur.

- 6.2.1.2** Carefully attach threaded irrigation sleeve over I/A tip, exposing desired amount of tip, with the irrigation ports on the tip sleeve in line with the aspiration tip port.



6.2.2 VITRECTROMY HANDPIECE

6.2.2.1 Verify that the irrigation sleeve is installed onto the needle of the Vitrector.



6.2.2.2 Verify that the tubing is in good working condition, free of nicks or cuts.

6.2.3 CAUTERY HANDPIECE



WARNING: Connected accessories should be rated for at least the minimum peak output voltage of the Model 3000 set at the intended output control setting in the intended operating mode.

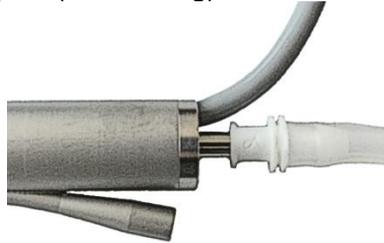
6.2.3.1 Connect the cautery cord to the cautery forceps.



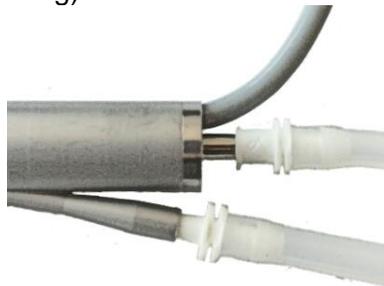
6.2.3.1 Verify that the cord is in good working condition, free of nicks or cuts.

6.2.4 ULTRASONIC HANDPIECE

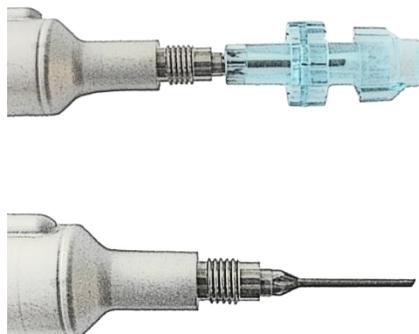
- 6.2.4.1** Connect the aspiration tube from the cassette (female fitting) to the ultrasonic handpiece aspiration port (male fitting).



- 6.2.4.2** Connect the irrigation tube from the cassette (male fitting) to the ultrasonic handpiece irrigation port (female fitting).



- 6.2.4.3** Install the phaco tip onto the U/S handpiece using the supplied tip wrench, tighten until fully seated.



CAUTION: DO NOT over-tighten or thread damage to the handpiece may occur.

- 6.2.4.4** Carefully attach threaded irrigation sleeve over U/S tip, exposing desired amount of tip, with the irrigation ports on the tip sleeve perpendicular to the furthestmost part of the tip bevel.



6.2.4 ULTRASONIC HANDPIECE (CONTINUED)

6.2.4.5 Verify that all tubing is securely connected.

6.2.4.6 Connect the ultrasonic handpiece electrical plug to the left side panel receptacle of the console marked "**U/S**".

6.2.4.6.1 ALWAYS align the red dot on the plug with the red dot on the console receptacle before inserting the connector.

6.2.4.6.2 Fully insert connector.

6.3 SYSTEM PREOPERATIONAL CHECKS

6.3.1 PRIME CYCLE

Perform a Prime cycle to fill the system tubing with irrigation solution and to tune the handpiece.

- 6.3.1.1 Place a test chamber over the phaco tip and sleeve until fully seated.
- 6.3.1.1 Open the roller clamp on the administration tubing set.
- 6.3.1.1 On the screen of the console, select the U/S mode.
- 6.3.1.2 On the console front panel, press the “Prime” soft-key.



NOTE: A successful Prime cycle will be indicated by a “Handpiece Tuned” message. If a different message is displayed, follow the instructions on screen and / or refer to *Section 7.8 System Messages* and *Section 10.0 Troubleshooting*. Refer to *Section 5.4.1 Phaco Mode Functions* for additional information about the priming and tuning functions.

6.3.2 SYSTEM FLUIDICS TEST

- 6.3.2.1 Place and maintain the ultrasonic handpiece at patient eye level.
- 6.3.2.2 In the Normal U/S Mode, depress the foot pedal to “position two (2)” and hold.
- 6.3.2.3 Pinch off the irrigation tube and verify that the test chamber collapses. *This action confirms aspiration.*
- 6.3.2.4 Release the irrigation tube and observe that the test chamber refills with fluid within a few seconds. *This action confirms irrigation.*
- 6.3.2.5 Pinch off the aspiration tube and verify that the Vacuum increases to 200 mmHg, the default preset value. An occlusion message is displayed.
- 6.3.2.6 Release the aspiration tube and confirm that the test chamber does not collapse or dimple. No change in test chamber indicates system is now ready.
- 6.3.2.7 If test chamber collapse occurs, complete the following as required, then repeat test steps 5.3.2.5 through 5.3.2.6 until the test chamber does not collapse or dimple:
 - 6.3.2.7.1 Make sure all connections to the u/s handpiece are secure.
 - 6.3.2.7.2 Avoid severe bends / kinks in all tubing.
 - 6.3.2.7.3 Make sure the u/s handpiece is free of obstructions.
 - 6.3.2.7.4 Increase irrigation solution elevation.
 - 6.3.2.7.5 Decrease maximum Vacuum setting.



NOTE: *Section 6.3.2 Perform a System Fluidics Test & Setup* must be repeated to completion if the U/S Vacuum setting is increased and / or if irrigation solution elevation is decreased.

7.0 SYSTEM OPERATION

Before operating in any mode, verify that all accessories used during operation have been setup per *Section 6.2 Accessory Setup* and verify that all per-operational checks have been performed per *Section 6.3 System Preoperational Checks*.

If you want to use a program, press the program arrow and select your program.

Any necessary adjustments to parameters can be made by pressing the UP or DOWN arrow soft-keys.

Activating the assigned reflux side kick lever will enable the reflux function in any foot pedal position.

7.1 IRR MODE (SECTION 5.3)

7.1.1 Connect Handpiece to Irrigation / Aspiration tubing.

7.1.1.1 Connect the aspiration tube from the cassette (female fitting) to the handpiece aspiration port (male fitting).

7.1.1.2 Connect the irrigation tube from the cassette (male fitting) to the handpiece irrigation port (female fitting).

7.1.1.3 Place a test chamber over the handpiece tip and sleeve until settled firmly.

7.1.1.4 Fully depress foot pedal to remove all air from tubing kit.

7.1.1.5 Remove test chamber from the tip of the handpiece.

7.1.2 On the screen of the console, select IRR mode.

7.1.3 Activate the irrigation function.

7.1.3.1 Depress foot pedal to position 1 to begin irrigation.

7.1.3.2 While in any position on the foot pedal, make any necessary adjustments to the IV pole height as needed by pressing the arrows:

PARAMETER	RANGE	UNITS
IV Pole	64 - 90	INCHES

7.1.3.3 Fully release foot pedal to end irrigation function.

7.2 U/S PHACO MODE (SECTION 5.4)

- 7.2.1 Connect Ultrasonic Handpiece to Irrigation / Aspiration tubing.
 - 7.2.1.1 Connect the aspiration tube from the cassette (female fitting) to the handpiece aspiration port (male fitting).
 - 7.2.1.2 Connect the irrigation tube from the cassette (male fitting) to the handpiece irrigation port (female fitting).
 - 7.2.1.3 Place a test chamber over the handpiece tip and sleeve until fully seated.
 - 7.2.1.4 Depress foot pedal to position 1 to remove all air from tubing kit.
 - 7.2.1.5 On the screen of the console, select Tune.
- 7.2.2 On the screen of the console, select U/S mode.
- 7.2.3 Select Multimode (1, 2, 3).
- 7.2.4 Select Phaco mode.
 - 7.2.4.1 Normal.
 - 7.2.4.1.1 U/S power delivery (Fixed, Linear).
 - 7.2.4.1 Burst.
 - 7.2.4.1.1 U/S power delivery (Single, Multi).
 - 7.2.4.1 Micro.
 - 7.2.4.1.1 U/S power delivery (Fixed, Linear).
- 7.2.5 Activate the ultrasonic function.
 - 7.2.5.1 Depress foot pedal to your desired function of the U/S Phaco mode:
 - ◆ Position (1) for Irrigation only.
 - ◆ Position (2) for Irrigation and Aspiration only.
 - ◆ Position (3) for Irrigation, Aspiration, and U/S Phaco Power
 - 7.2.5.2 While in any position on the foot pedal, make any necessary adjustments to applicable parameters as needed by pressing the UP or DOWN arrows:

PARAMETER	RANGE	UNITS
US Power	0 - 100	%
Flow	2 - 50	cc/min
Vacuum	20 - 500	mmHg
Pulse	0 - 10	pulse/s
Burst	20 - 100	% - ms
ON/OFF	5 - 100	ms

- 7.2.5.3 Fully release foot pedal to end irrigation, aspiration and ultrasonic function.

7.3 I/A MODE (SECTION 5.5)

- 7.3.1 Connect an I/A Handpiece to Irrigation / Aspiration tubing.
 - 7.3.1.1 Connect the aspiration tube from the cassette (female fitting) to the handpiece aspiration port (male fitting).
 - 7.3.1.2 Connect the irrigation tube from the cassette (male fitting) to the handpiece irrigation port (female fitting).
 - 7.3.1.3 Place a test chamber over the handpiece tip and sleeve until fully seated.
 - 7.3.1.4 Depress foot pedal to position 1 to remove all air from tubing kit.
 - 7.3.1.5 Remove test chamber from the tip of the handpiece.
- 7.3.2 On the screen of the console, select I/A mode.
- 7.3.3 Select Multimode (1, 2, Cap Vac).
- 7.3.4 Select Flow (Fixed, Linear).
- 7.3.4 Select Vacuum (Fixed, Linear).
- 7.3.5 Activate the irrigation / aspiration function.
 - 7.3.5.1 Depress foot pedal to your desired function of the Irrigation / Aspiration mode:
 - ◆ Position (1) for Irrigation only.
 - ◆ Position (2) for Irrigation and Aspiration.
 - 7.3.5.2 While in any position on the foot pedal, make any necessary adjustments to applicable parameters as needed by pressing the UP or DOWN arrows:

PARAMETER	RANGE	UNITS
Flow	2 - 50	cc/min
Vacuum	20 - 500	mmHg

- 7.3.5.3 Fully release foot pedal to end irrigation and aspiration function.

7.4 VIT MODE (SECTION 5.6)

- 7.4.1 Install Vitrector to Model 3000 per the included directions for vitrector.
 - 7.4.1.1 Connect the long actuation tubing from the vitrector (female fitting) to the port on the side of the Model 3000 (male fitting).
 - 7.4.1.2 Connect the aspiration tube from the cassette (female fitting) to the vitrector aspiration tubing (male fitting).
 - 7.4.1.3 Connect the irrigation tube from the cassette (male fitting) to the vitrector irrigation tubing (female fitting).
 - 7.4.1.4 Fully immerse aspiration / irrigation ports at the end of the vitrector needle into sterile irrigation solution.
 - 7.4.1.5 Fully depress foot pedal to remove all air from tubing.
- 7.4.2 On the screen of the console, select VIT mode.
- 7.4.3 Select Flow (Fixed, Linear).
- 7.4.4 Select Vacuum (Fixed, Linear).
- 7.4.5 Select Cut (Single, Multi).
- 7.4.6 Activate the vitrectomy function.
 - 7.4.6.1 Depress foot pedal to your desired function of the Vitrectomy mode:
 - ◆ Position (1) for Irrigation only.
 - ◆ Position (2) for Irrigation, Aspiration & Vitrectomy.
 - 7.4.6.2 While in any position on the foot pedal, make any necessary adjustments to applicable parameters as needed by pressing the UP or DOWN arrows:

PARAMETER	RANGE	UNITS
Flow	2 - 50	cc/min
Vacuum	20 - 500	mmHg
Cut Rate	60 - 700	cuts/min

- 7.4.6.3 Fully release foot pedal to end irrigation, aspiration and vitrectomy function.

7.5 COAG MODE (SECTION 5.7)

- 7.4.1 Install Cautery cord to banana jacks on the side of Model 3000.
- 7.4.2 On the screen of the console, select COAG mode.
- 7.4.3 Select Coag power (Fixed, Linear).
- 7.4.6 Activate the coagulation function.
 - 7.4.6.1 Depress foot pedal to your desired function of the Coagulation mode:
 - ◆ Position (1) for Coagulation.
 - 7.4.6.2 While in any position on the foot pedal, make any necessary adjustments to applicable parameters as needed by pressing the UP or DOWN arrows:

PARAMETER	RANGE	UNITS
Power	0 - 100	%

- 7.3.5.3 Fully release foot pedal to end coagulation function.

7.6 REPLACING THE IRRIGATION SOLUTION CONTAINER

Usually replacing the Irrigation Solution Container is performed before or after the phacoemulsification procedure (See *Section 6.3 System Setup and Preoperational Checks*). In some incidences, replacing the irrigation solution container is performed during the procedure.



NOTE: If there is still fluid in the administration tubing drip chamber and there are no air bubbles in the administration tubing, perform the following steps:

- 7.6.1 Obtain the replacement irrigation solution container.
- 7.6.2 Disconnect the drip chamber from the empty solution container and connect it to the replacement container.
- 7.6.3 Place the replacement container on the IV pole hanger and adjust the height as needed.



NOTE: If the administration tubing drip chamber is empty and / or there are air bubbles in the administration tubing, perform the following steps:

- 7.6.4 Obtain the replacement irrigation solution container.
- 7.6.5 Obtain an empty fluid container to prime irrigation solution into.
- 7.6.6 Disconnect the drip chamber from the empty solution container and connect it to the full container.
- 7.6.7 Squeeze the drip chamber to move solution into it.
- 7.6.8 Place the replacement container on the IV pole hanger and adjust the height as needed.
- 7.6.9 Hold the tip of the ultrasonic handpiece over the empty fluid container.
- 7.6.10 Press the “PRIME” soft-key on the right side of the U/S Phaco mode screen.
- 7.6.11 Priming the tubing may need to be performed more than once to remove air bubbles.
- 7.6.12 Once the air bubbles are removed from the tubing, the procedure can be continued.

7.7 REPLACING THE ULTRASONIC U/S HANDPIECE

Usually the ultrasonic handpiece is connected prior to a phacoemulsification procedure, (See *Section 6.3 System Setup and Preoperational Checks*). In some incidences, replacing the ultrasonic handpiece is necessary during the procedure.

7.7.1 Remove the faulty ultrasonic handpiece.

7.7.1.1 Disconnect the cassette aspiration tube (female fitting) from the ultrasonic handpiece aspiration port (male fitting).

7.7.1.2 Disconnect the cassette irrigation tube (male fitting) from the ultrasonic handpiece irrigation port (female fitting).

7.7.2 Refer to *Section 6.2.4 Ultrasonic Handpiece* to install a replacement handpiece and prepare it for necessary preoperational checks.

7.7.3 Refer to *Section 6.3 System Preoperational Checks* to prime the system and perform a system Fluidics Test.

7.8 SYSTEM MESSAGES

These series of messages are typically displayed during the operation of the system.

U/S PRIMING MESSAGES	DESCRIPTION
Priming... Please Wait!	“PRIME” button pressed - will clear when finished priming; automatically goes to tune handpiece.
Vac Test Failed! Prime Again!	Can’t build vacuum when testing during prime - check the tubing set for open connections, leaks.
Fluid Path Blocked! Prime Again!	Vacuum too high during prime - check that the administration tubing set roller clamp is released and irrigation solution is flowing. Check that the tubing set is not pinched or blocked.
OCCLUSION!	Phaco tip occluded, vacuum reached maximum value.
Reflux	Reflux activated on the foot pedal.
Handpiece Tuned	Message appears at the end of a prime cycle or after “Tune” button is pressed.
Check Cassette!	Cassette not seated properly - should click into place when fully seated across the locking mechanism.
Check Handpiece!	Handpiece not plugged in, tip not fully seated onto handpiece and / or handpiece failed tuning.
Check Footpedal!	Check cable of foot pedal for condition, Check foot pedal not plugged in.
Purging... Please Wait!	Purge button pressed - will clear after tubing is purged.

I/A and VIT MESSAGES	DESCRIPTION
OCCLUSION!	Phaco tip occluded, vacuum reached maximum value.
Reflux	Reflux activated on the foot pedal.
Handpiece Tuned	Message appears at the end of a prime cycle or after “Tune” button is pressed.
Check Cassette!	Cassette not seated properly - should click into place when fully seated across lock mechanism.
Check Footpedal!	Check cable of foot pedal for condition, Check foot pedal not plugged in.
Pump stopped	In Linear Vacuum: when the vacuum limit is reached, the peristaltic pump will stop.

7.8 SYSTEM MESSAGES (CONTINUED)

IRR MESSAGES	DESCRIPTION
Check Cassette!	Cassette not seated properly - should click into place when fully seated across lock mechanism.
Check Footpedal!	Check cable of foot pedal for condition, Check foot pedal not plugged in.

PROGRAM MESSAGES	DESCRIPTION
Add Program	Message will be displayed when the “ADD” button is pressed. Enter the program name, and it will appear in the program list box at the top of the screen.
Delete Program	Message will be displayed when the “DELETE” button is pressed. Select the program from the list box to delete and press “OK”
Rename Program	Message will be displayed when the “RENAME” button is pressed. Select the program from the list box to rename, type in the new name, and press “OK”
Save Program	Message will be displayed when the “UPDATE” button is pressed. Select the program from the list box to update and press “OK”

CALIBRATION MESSAGES	DESCRIPTION
Move to First Detent!	Depress the foot pedal until “OK” button is enabled.
Set First Detent!	Set the first detent position; press “OK” button.
Move to Second Detent!	Depress the foot pedal until “OK” button is enabled.
Set Second Detent!	Set the second detent position; press “OK” button.
Depress the Footpedal!	Depress the foot pedal completely.
Set Down Position!	With the foot pedal completely depressed, press the “OK” button.
Release the Footpedal!	Let the foot pedal return to non-depressed position.
Set Released Position!	With the foot pedal in non-depressed position, press the “OK” button.

8.0 SYSTEM CLEANING

This section of the manual contains the instructions for cleaning of the Model 3000 console, foot pedal, cart, and accessories.

For cleaning and sterilization instructions of the following system components, refer to the individual Instruction for Use (IFU) packaged with the item for explicit details on proper care and handling, where applicable:

- ◆ Ultrasonic Handpiece
- ◆ Reusable Tubing Set
- ◆ Phaco Tip (*and Tip Wrench*)
- ◆ Silicone Irrigation Sleeve
- ◆ Test Chamber
- ◆ IV Pole

For cleaning and sterilization instructions of additional accessories included with your system (*optional items NOT MANUFACTURED BY Medical Technical Products, Inc*), the Instructions for Use (IFU) are provided by the accessory manufacturer, where applicable:

- ◆ Cautery
- ◆ Vitrectomy
- ◆ I/A Accessories



WARNING: Sterility assurance is the responsibility of the end user facility. Always follow the facility's requirements for items that need to be cleaned and sterilized.



WARNING: Inadequate cleaning may result in debris exfoliating into the surgical field.



WARNING: Clean console, foot pedal, cart and accessories immediately after every procedure.



CAUTION: Use of cleaning solutions other than the ones listed in this section may damage the surface of the console and void your warranty!

8.1 PURGING THE SYSTEM CONSOLE

- 8.1.1 Close the roller clamp on the administration tubing set.
- 8.1.2 Disconnect tubing kit from handpiece.
- 8.1.3 Connect the aspiration fitting of tubing kit (female fitting) to the irrigation fitting of tubing kit (male fitting).
- 8.1.4 Verify that a collection bag is installed to the collection tube of the tubing kit.
- 8.1.5 On the screen of the console, select U/S mode.
- 8.1.6 On the screen of the console, select Purge.
- 8.1.7 Once the system has completed the purge cycle, on the back panel of the system, press the power switch to the "O" OFF position.

8.2 CLEANING THE SYSTEM CONSOLE

- 8.2.1 On the back panel of the system, press the power switch to the “O” OFF position.
- 8.2.2 Disconnect the Model 3000 from all electrical power.
- 8.2.3 Use a soft cloth dampened with mild soap and water to remove dirt and residue from the touchscreen.
- 8.2.4 Dry the touchscreen with a soft lint-free cloth to prevent water spots.



CAUTION: DO NOT use cleaning solutions on the front panel touchscreen.

- 8.2.5 Clean the surface of the console with either 70% isopropyl alcohol or a mild soap and water solution.
- 8.2.6 Use a small amount of cleaning solution around the electrical and pneumatic connectors on the side and on the back panel of the system.
- 8.2.7 Thoroughly wipe the console with a soft lint-free cloth to remove all cleaning solution or soap and water. DO NOT leave any cleaning solution residue or water spots on the console surface.

8.3 CLEANING THE FOOT PEDAL

- 8.3.1 On the back panel of the system, press the power switch to the “O” OFF position.
- 8.3.2 Disconnect the Model 3000 from all electrical power.
- 8.3.3 Clean the surface of the foot pedal with either 70% isopropyl alcohol or a mild soap and water solution.
- 8.3.4 Thoroughly wipe the foot pedal with a soft lint-free cloth to remove all cleaning solution or soap and water. DO NOT leave any cleaning solution residue or water spots on the foot pedal surfaces.
- 8.3.5 Gently clean the connecting cable at end of each day using either 70% isopropyl alcohol or a mild soap and water solution.
- 8.3.6 After cleaning, examine the foot pedal connecting cable for nicks, tears and wear fractures in the cable sheath.



NOTE: The foot pedal should be wiped clean of any fluids that come in contact with it during the course of the surgery. The surface of the foot pedal could corrode or rust if not thoroughly cleaned.

8.4 CLEANING THE OPTIONAL CART WITH IV POLE

- 8.4.1 On the back panel of the system, press the power switch to the “O” OFF position.
- 8.4.2 Disconnect the Model 3000 from all electrical power.
- 8.4.3 Clean all surfaces of the cart with IV pole with either 70% isopropyl alcohol or a mild soap and water solution.
- 8.4.4 Thoroughly wipe the cart with IV pole with a soft lint-free cloth to remove all cleaning solution or soap and water. DO NOT leave any cleaning solution residue or water spots on the cart with IV pole surfaces.
- 8.4.5 Gently clean the connecting cable at end of each day using either 70% isopropyl alcohol or a mild soap and water solution.
- 8.4.6 After cleaning, examine the cart with IV pole connecting cable for nicks, tears and wear fractures in the cable sheath.



NOTE: The cart with IV pole should be wiped clean of any fluids that come in contact with it during the course of the surgery. Surfaces could corrode or rust if not thoroughly cleaned.

8.5 CLEANING ACCESSORIES

- 8.5.1 Immediately prior to initial and subsequent use, carefully disassemble all items and soak in enzymatic detergent solution.
- 8.5.2 Connect a syringe (not supplied) to the accessory to be washed.
- 8.5.3 Draw enzymatic detergent into the syringe.
- 8.5.4 Disconnect syringe and expel solution. Repeat from 8.5.1 for each fluid pathway.
- 8.5.5 Soak in distilled / deionized water.
- 8.5.6 Connect syringe to the accessory to be flushed.
- 8.5.7 Draw distilled / deionized water into the syringe.
- 8.5.8 Disconnect syringe and expel solution. Repeat from 8.5.5 for each fluid pathway.
- 8.5.9 To rinse the accessory, fill syringe with distilled / deionized water.
- 8.5.10 Expel the distilled / deionized water.
- 8.5.11 Ensure the free flow of distilled / deionized water occurs when expelling. Repeat 2X from 8.5.9 for each fluid pathway.
- 8.5.12 To dry the accessory, expel an empty syringe through the accessory. Repeat for each fluid pathway.

8.6 CLEANING VITRECTOR



NOTE: Follow the cleaning instructions for vitrector provided by the manufacturer.

8.7 STERILIZATION

System components of the Model 3000 may be sterilized by autoclave or Ethylene Oxide (EtO) process.



NOTE: Sterilize per the guidelines provided by ISO 17665-1:2006 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.



NOTE: Sterilize per the guidelines provided by ISO 11135:2014 Sterilization of health care products – Ethylene Oxide –Requirements for the development, validation and routine control of a sterilization process for medical devices.



CAUTION: Do not insert ultrasonic handpiece plug into mating receptacle until completely dry! To avoid electrical arcing damage to plug and / or mating receptacle, allow electromechanical items to air cool after sterilization!



CAUTION: To help prevent damage during sterilization, it is recommended that sterilization be performed in a compartmentalized sterilization case to ensure segregation from other instruments.

9.0 SYSTEM SERVICE

This section of the manual contains the information for Fuse replacement, System Maintenance, System Repairs, and Technical Support.

9.1 FUSE REPLACEMENT

The AC Power input module contains two (2) fuses that protect the unit from excessive power loads and power line fluctuations. The module is located on the back of the back panel of the unit. (Refer to Section 4.1 System Overview and FIGURE 4-1, item #8 for fuse location)

If a power surge occurs, these fuses may need to be replaced. Always replace these fuses with the exact same fuse rating (**5 x 20 mm 250V T 5.0A**) fuses. These fuses are also available from Medical Technical Products, Inc (MTP) part # 430-2215-002.



WARNING: ELECTRICAL HAZARD!

Disconnect the Model 3000 from all electrical power before performing the following steps.

To replace the fuse, perform the following steps:

- 9.1.1 On the back panel of the system, press the power switch to the “O” OFF position.
- 9.1.2 Remove the AC power cord from the system back panel for easy access to the fuse panel.
- 9.1.3 Use a small flat-tipped screwdriver to pull out on the notch on the fuse cover tab above the power switch and pull the cover down. Once the fuse cover is off, the fuse holders can be removed.
- 9.1.4 Push the fuse holder in the opposite direction of the arrow on top of the holders and then pull up on the holders.
- 9.1.5 Remove the old fuses and replace them with the new **5 x 20 mm 250V T 5.0A** fuses.
- 9.1.6 Push the fuse holders back into place towards the arrows on top of the holders.
- 9.1.7 Push the fuse cover back into place until it snaps closed.
- 9.1.8 Connect the AC power cord to the back panel of the system.
- 9.1.9 On the back panel of the system, press the power switch to the “I” ON position.
- 9.1.10 Verify that the Model 3000 powers up and the U/S Phaco screen (default) is displayed.



NOTE: If the Model 3000 does not power up after the fuse replacement check, contact your regional distributor.

9.2 CONTACT TECHNICAL SUPPORT

For Technical support in your country:

- 9.2.1** Contact your regional distributor for technical support.

10.0 SYSTEM TROUBLESHOOTING

AC POWER	
PROBABLE CAUSE	CORRECTIVE ACTION
1. AC Power loose or disconnected	1. Reconnect AC power cord
1. AC line fuse blown	1. Replace fuses

PRIME CYCLE	
PROBABLE CAUSE	CORRECTIVE ACTION
“Check Cassette” Error Message	
1. Priming cycle may have caused cassette to become dislodged	<ol style="list-style-type: none"> 1. Remove and reinstall cassette 2. Run Prime cycle again
“Fluid path blocked, prime again” Error Message	
1. Irrigation tubing may be crimped, blocked or kinked	<ol style="list-style-type: none"> 1. Free the irrigation tubing from occlusion and run a prime cycle 2. Replace administration tubing set and run a prime cycle
“Vac test failed, prime again” Error Message	
1. Peristaltic tubing not properly seated in groove in cassette	<ol style="list-style-type: none"> 1. Remove cassette and align peristaltic tubing in groove 2. Fully seat cassette into locking mechanism and run a prime cycle
2. Ultrasonic handpiece has a leak	<ol style="list-style-type: none"> 1. Remove irrigation and aspiration tubes from the handpiece and connect them together. 2. Run a prime cycle. If prime cycle passes, replace handpiece.
3. Defective tubing cassette	1. Replace tubing cassette and run a prime cycle.
4. Possible defective Model 3000	1. Contact your local distributor or MTP for assistance

IRRIGATION SYSTEM	
PROBABLE CAUSE	CORRECTIVE ACTION
“No Irrigation Flow”	
1. Irrigation valve is closed	<ol style="list-style-type: none"> 1. Depress foot pedal and verify irrigation pinch valve “clicks” 2. If irrigation pinch valve does not “click”, remove and reseat the cassette
2. Irrigation tubing improperly installed	<ol style="list-style-type: none"> 1. Disconnect irrigation tubing and reinstall correctly per <i>Section 6.0 System Setup and Preoperational Checks</i>
3. Kinked or damaged irrigation tube	<ol style="list-style-type: none"> 1. Unkink or replace irrigation tube if needed
4. Closed roller clamp on administration tubing	<ol style="list-style-type: none"> 1. Release roller clamp on administration tubing and verify flow
5. Low bottle height	<ol style="list-style-type: none"> 1. Raise the solution bottle height to the proper level for good fluid flow
6. U/S phaco tip entry site is too large; irrigation solution leaking from wound	<ol style="list-style-type: none"> 1. Reassess U/S Phaco procedure

ASPIRATION SYSTEM	
PROBABLE CAUSE	CORRECTIVE ACTION
“System will not vent”	
1. Venting pinch valve is not operating	<ol style="list-style-type: none"> 1. Verify the venting pinch valve function by activating the Reflux function
2. Defective cassette and / or tubing	<ol style="list-style-type: none"> 1. Verify that the system is in I/A Mode
3. Closed roller clamp on irrigation tubing	<ol style="list-style-type: none"> 1. Verify that the system is in I/A Mode
4. Tubing set is clogged	<ol style="list-style-type: none"> 1. Verify that the system is in I/A Mode

ASPIRATION SYSTEM	
PROBABLE CAUSE	CORRECTIVE ACTION
“No or poor aspiration” vacuum	
1. The system is not in I/A mode	1. Verify that the system is in I/A Mode
2. Vacuum setting is too low	1. Increase the vacuum and rerun mode for NO Error message
3. Tubing Set is incorrectly installed	1. Verify tubing set installation per Section 6.0 System Setup and Preoperational Checks 2. Correct connections and run a prime cycle to verify aspiration with NO Error message
4. Defective tubing set	1. Replace tubing set and run a prime cycle to verify aspiration with No Error message
5. Ultrasonic handpiece is leaking	1. Replace the handpiece and run a prime cycle to verify aspiration with NO Error message
6. Reflux function is being activated	1. Verify that the foot pedal is not activating the Reflux function

U/S PHACO MODE	
PROBABLE CAUSE	CORRECTIVE ACTION
“Ultrasonic (U/S) Handpiece will not Tune”	
1. Loose phaco tip	1. Tighten phaco tip with tip wrench and retune handpiece
2. Damaged phaco tip	1. Replace damaged tip with new phaco tip and retune handpiece
3. Defective ultrasonic handpiece	1. Replace ultrasonic handpiece and retune to system
“Vacuum ERROR Message”	
1. Closed roller clamp on irrigation tubing	1. Release roller clamp on irrigation line and verify flow
2. Vacuum is present in tubing	1. Disconnect and reconnect tubing to relieve vacuum in lines

U/S PHACO MODE	
PROBABLE CAUSE	CORRECTIVE ACTION
“Poor or No Ultrasonic (U/S) Power”	
1. Low U/s Power setting	1. Increase U/S Power setting
2. Foot pedal not fully depressed in Linear Power	1. Depress foot pedal until power is displayed on U/S Phaco screen
3. Defective or loose phaco tip	1. Tighten or replace phaco tip and retune handpiece
4. Defective ultrasonic handpiece	1. Replace the ultrasonic handpiece and retune
5. Reflux is being activated	1. Verify that the foot pedal is not activating the Reflux function

VIT (VITRECTOMY) MODE	
PROBABLE CAUSE	CORRECTIVE ACTION
“Vitrectomy Handpiece will not function”	
1. System is in wrong mode	1. Depress foot pedal until power is displayed on U/S Phaco screen
2. VIT handpiece connected is not properly	1. Depress foot pedal until power is displayed on U/S Phaco screen
3. Defective or loose phaco tip	1. Depress foot pedal until power is displayed on U/S Phaco screen
4. Defective ultrasonic handpiece	1. Depress foot pedal until power is displayed on U/S Phaco screen

COAG (BIPOLAR COAGULATION) MODE	
PROBABLE CAUSE	CORRECTIVE ACTION
“NO Coag Power”	
1. System is in wrong mode	1. Select the COAG Mode and run procedure
2. VIT handpiece connected is not properly	1. Verify the COAG handpiece connections and rerun COAG procedure
3. Defective or loose phaco tip	1. Replace COAG handpiece and rerun COAG procedure
4. Defective ultrasonic handpiece	1. Increase Power setting and rerun COAG procedure
5. Defective cord or COAG accessory	1. Verify accessory connection and / or replace COAG cord

PATIENT ANTERIOR CHAMBER FLUCTUATIONS	
PROBABLE CAUSE	CORRECTIVE ACTION
“IV Bottle to Patient Height”	
1. IV solution bottle is too low	<ol style="list-style-type: none"> 1. Raise the solution bottle until anterior chamber stabilizes 2. Patient’s eye level must be between the bottom of the tubing cassette and 10 centimeters below the bottom of the tubing cassette
2. VIT handpiece connected is not properly	1. Use a high-flow, non-filtered IV administration tubing set
	2. Filtered IV administration tubing sets must be discarded after single use only
	3. DO NOT allow the administration tubing set to sit with fluid in it for an extended period of time (e.g. overnight)
3. Defective or loose phaco tip	1. Decrease the vacuum setting and verify anterior chamber stability
4. Defective ultrasonic handpiece	1. Reassess Phaco operation procedure
5. Defective cord or COAG accessory	1. Check irrigation tubing, administration tubing, ultrasonic handpiece, phaco tip, and silicone tip sleeve. Replace if necessary

11.0 SYSTEM PERFORMANCE

This section of the Operator's Manual will provide ultrasonic tip velocity, bipolar output data and EMC (Electromagnetic Compatibility) data for the Model 3000.

Tip vibration velocity is 9.9 m/s.

Figure 11-1 shows the power output levels for each control setting.

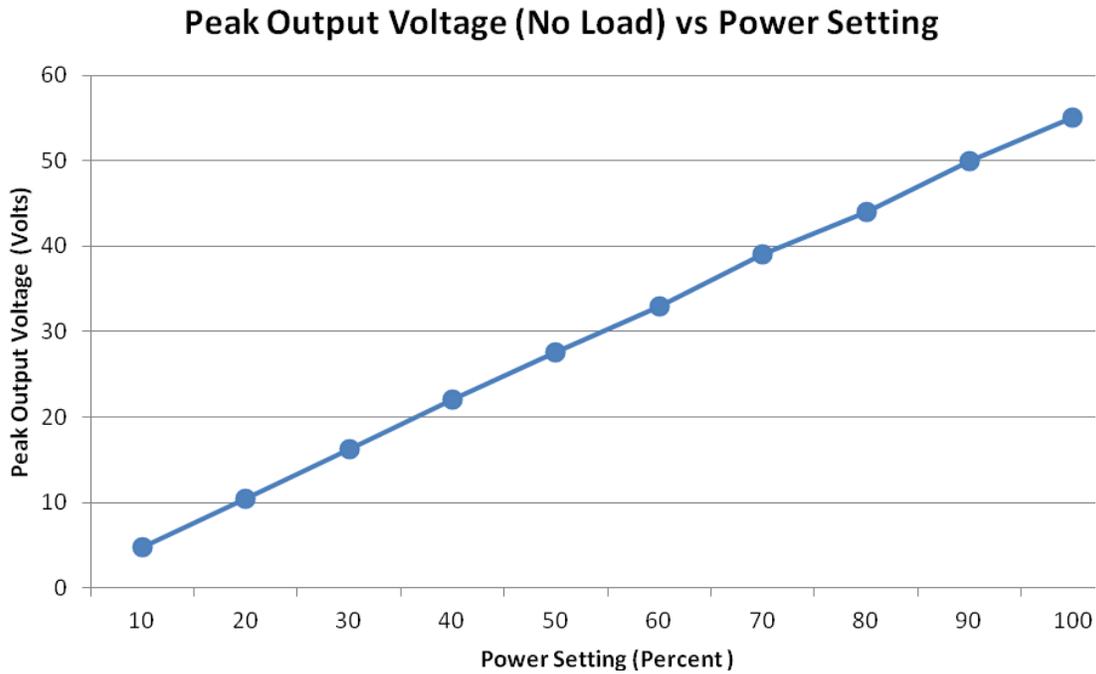
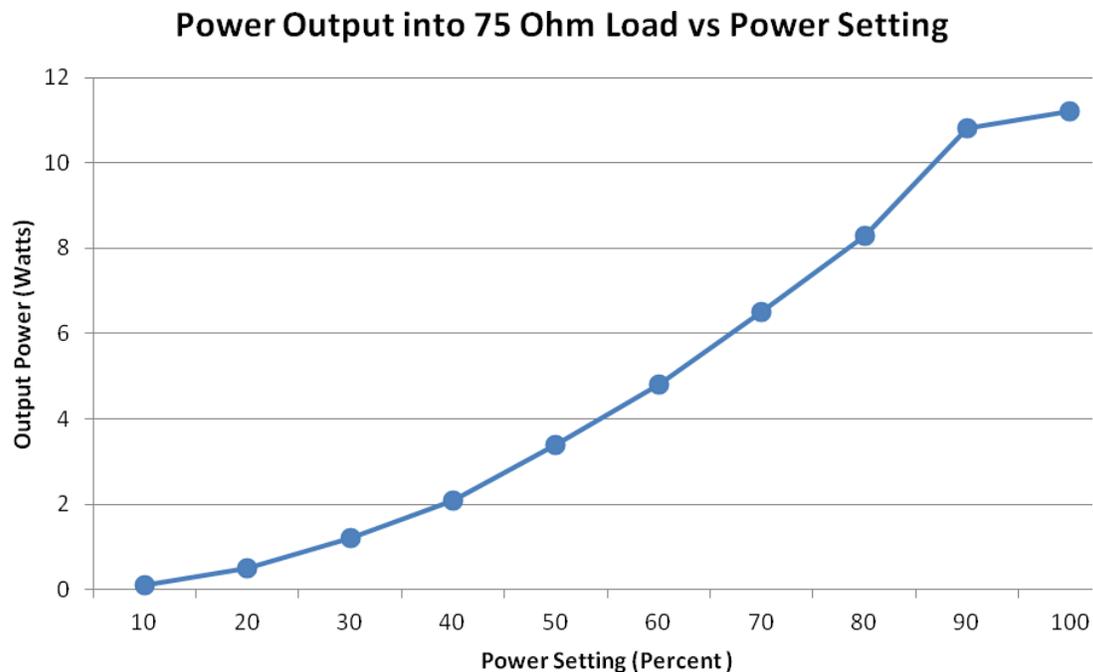
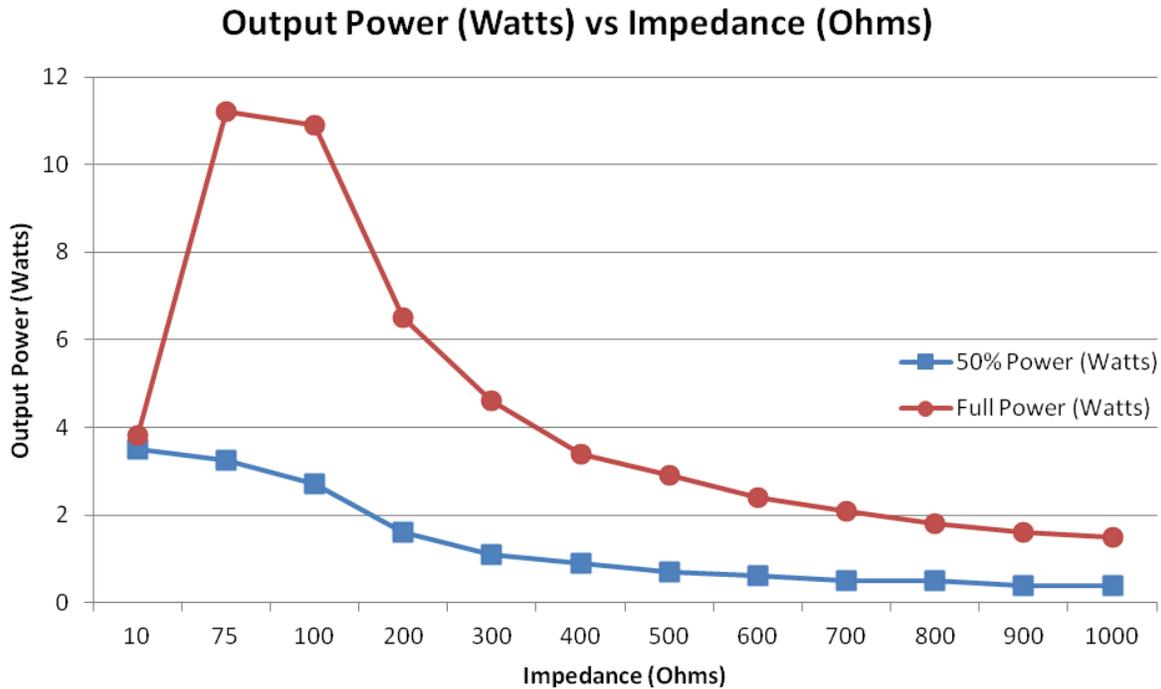


Figure 11-2 shows the power output levels for each control setting.



11.0 SYSTEM PERFORMANCE (continued)

Figure 11-3 shows the power output levels versus impedance at full power & 50% power.



11.1 EMC REQUIREMENTS FOR THE MODEL 3000

The Model 3000 Phacoemulsification System (Model 3000) meets all applicable requirements of IEC/EN 60601-1-2 for electromagnetic compatibility. The Model 3000 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section of the manual.

Portable and mobile RF communications equipment can affect the operation of the Model 3000.



The 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 properly.

The following is a list of cables and other accessories that are used as part of the COMPLETE Model 3000 package and comply with sections 36.201 and 36.202 of the EMC Standard IEC60601-1-2 (E):

Power cord	17031-S2-8	18/3 SJT / NEMA 5-15P	96 inch
U/S Handpiece	01-899145	3xAWG26 / DIN 9p	81 inch
	01-899530	3xAWG24 / DIN 9p	81 inch
Footpedal	553-0006-001	5xAWG28 / DIN 12p	120 inch
Cart cord	551-0032-001	5xAWG22 / DIN 6p	16 inch

Use of cables or accessories other than those specified, with the exception of cables and accessories sold by the manufacturer of the Model 3000 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Model 3000.

11.1 EMC REQUIREMENTS FOR THE MODEL 3000

TABLE 1: Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The Model 3000 Phacoemulsification System (Model 3000) is intended for use in the electromagnetic environment specified in this table. The customer or user of the Model 3000 should ensure that the system is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF Emissions CISRP 11	Group 1	The Model 3000 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 environment.
RF Emissions CISRP 11	Class A	The Model 3000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

TABLE 2: Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The Model 3000 is intended for use in the electromagnetic environment specified in this table. The customer or user of the Model 3000 should ensure that the system is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV (Contact) ± 8 kV (Air)	± 6 kV (Contact) ± 8 kV (Air)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV (Power supply lines) ± 1 kV (Input/Output lines)	± 2 kV (Power supply lines) ± 1 kV (Input/Output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	2 kV (Line to Ground) 1 kV (Line to Line)	2 kV (Line to Ground) 1 kV (Line to Line)	
Voltage Dips, Short interruptions, and voltage variations. Power supply input lines. IEC 61000-4-11	< 5% U_T < 95% dip in U_T for 0.5 cycle 40% U_T 60% dip in U_T for 5 cycles 70% U_T 30% dip in U_T for 25 cycles < 5% U_T < 95% dip in U_T for 5 sec	< 5% U_T < 95% dip in U_T for 0.5 cycle 40% U_T 60% dip in U_T for 5 cycles 70% U_T 30% dip in U_T for 25 cycles < 5% U_T < 95% dip in U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 3000 requires continued operation during power mains interruptions, it is recommended that the Model 3000 be powered from an uninterruptible power supply or battery.
Power Frequency (50 / 60Hz) Magnetic Field IEC 61000-4-8	3 A(rms)/m	3 A(rms)/m	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 AC Mains voltage prior to application of the test level.

11.1 EMC REQUIREMENTS FOR THE MODEL 3000

TABLE 3: Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The Model 3000 Phacoemulsification System (Model 3000) is intended for use in the electromagnetic environment specified in this table. The customer or user of the Model 3000 should ensure that the system is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 kHz 3 V(rms) /m 80 MHz to 2.5 GHz	3 Vrms 3 V(rms) /m	<p>Portable and mobile RF Communications equipment should be used no closer to any part of the Model 3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><u>Recommended Separation Distance:</u></p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 1.2 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where (<i>P</i>) is the maximum output power rating of the transmitter in watts (<i>W</i>) according to the transmitter manufacturer and (<i>d</i>) is the recommended separation distance in meters (<i>m</i>).</p> <p>Field strengths from the fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>

NOTE 1: At 80MHz and 800MHz, 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 Model 3000 is used exceeds the applicable RF Compliance level above, the Model 3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Model 3000.

^b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V(rms) /m.

11.1 EMC REQUIREMENTS FOR THE MODEL 3000

Table 4: Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the Model 3000 Phacoemulsification System

The Model 3000 Phacoemulsification System (Model 3000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or end user of the Model 3000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 3000 as recommended in the following table, according to the maximum OUTPUT power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (WATTS)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (METERS)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.12
0.1	0.38	0.38	0.38
1.0	1.2	1.2	1.2
10.0	3.8	3.8	3.8
100.0	12.0	12.0	12.0

For transmitter rated at a maximum output power not listed in this table, the recommended separation distance (d) in meters(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 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.

MODEL 3000 PHACOEMULSIFICATION SYSTEM

Operator's Manual



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