MEDICAL TECHNICAL PRODUCTS
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Model 2000 Ophthalmic Surgical System

Operator's Manual

75-9002 Rev F

Contents

This Operator's Manual is intended for the Medical Technical Products (MTP) Model 2000 Ophthalmic Surgical System (Model 2000). The Model 2000 is:

- A sophisticated surgical tool designed for ophthalmic/cataract surgeons.
- Intended to be used only by ophthalmic/cataract surgeons familiar with extracapsular cataract extraction (ECCE) and/or phacoemulsification ('phaco').
- Manufactured to be reliable, safe, intuitive, and very easy to operate.
- Manufactured by MTP and, since Jun 17, 1994, MTP has been permitted by the United States Food & Drug Administration to market the Model 2000.
- Manufactured conforming to the International Standard ISO 13485:2003.
- Electrically safe per applicable IEC 60601-1 medical electrical equipment requirements.

To safely operate the Model 2000, the operator must read this manual carefully and become familiar with all its warnings.

1.1 How to Use this Manual

This Operator's Manual is your guide to the Model 2000. Read the entire Operator's Manual carefully before operating the Model 2000. The surgical team should be experienced with the Model 2000 and is, more importantly, solely responsible for the correct settings for all surgical procedures.

This Operator's Manual is organized to enable the operator to:

- Know/understand the Model 2000 product specifications.
- Learn to correctly/safely setup and use the Model 2000.
- Be aware of the Model 2000 warnings when using the Model 2000.
- Become familiar with the necessary Model 2000 maintenance.
- Order replacement Model 2000 components and accessories.
- Perform field evaluation tests and limited field service when reporting any suspected nonconformance.
- Understand intraocular pressure maintenance.

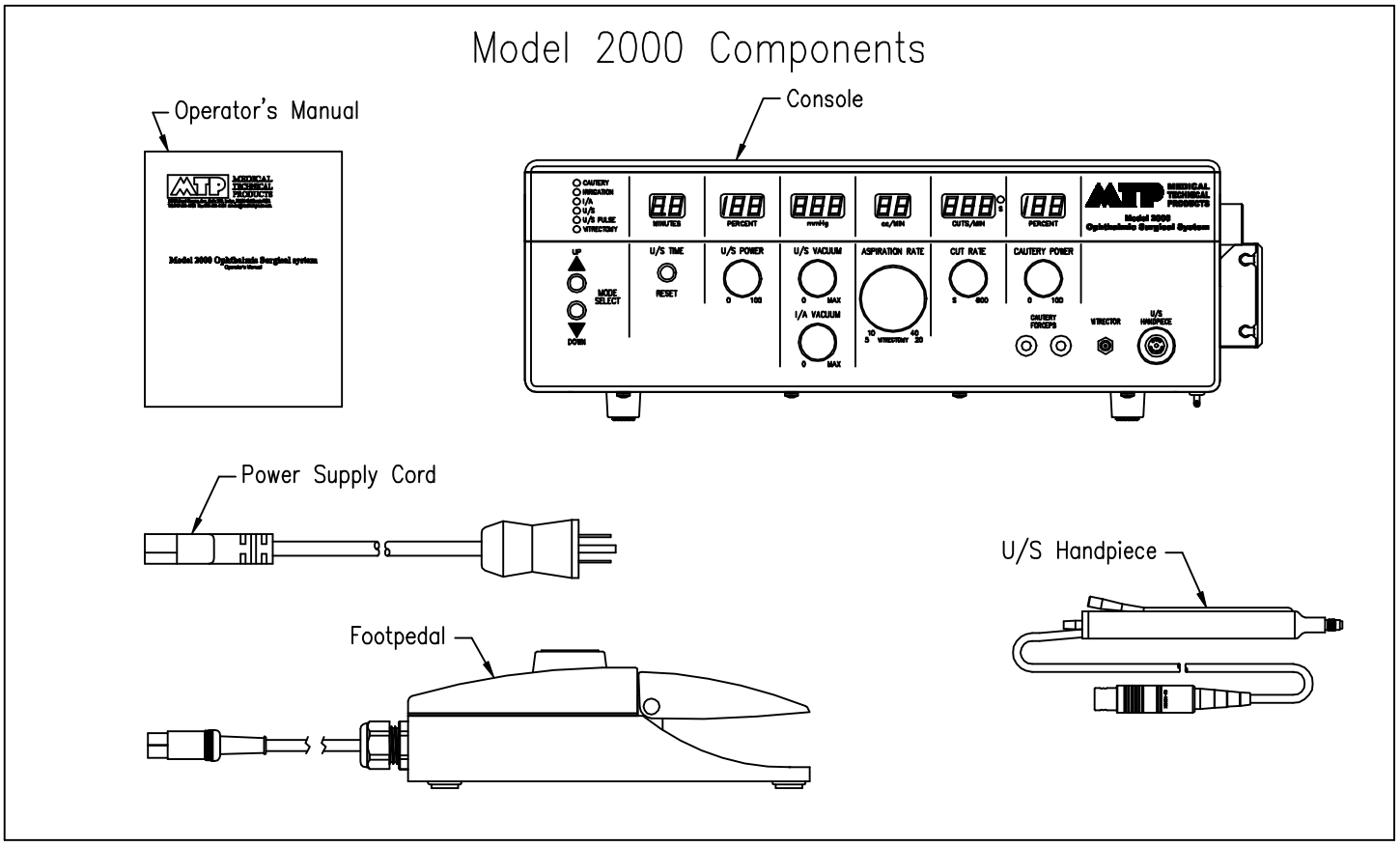
1.2 Unpacking and Inspection

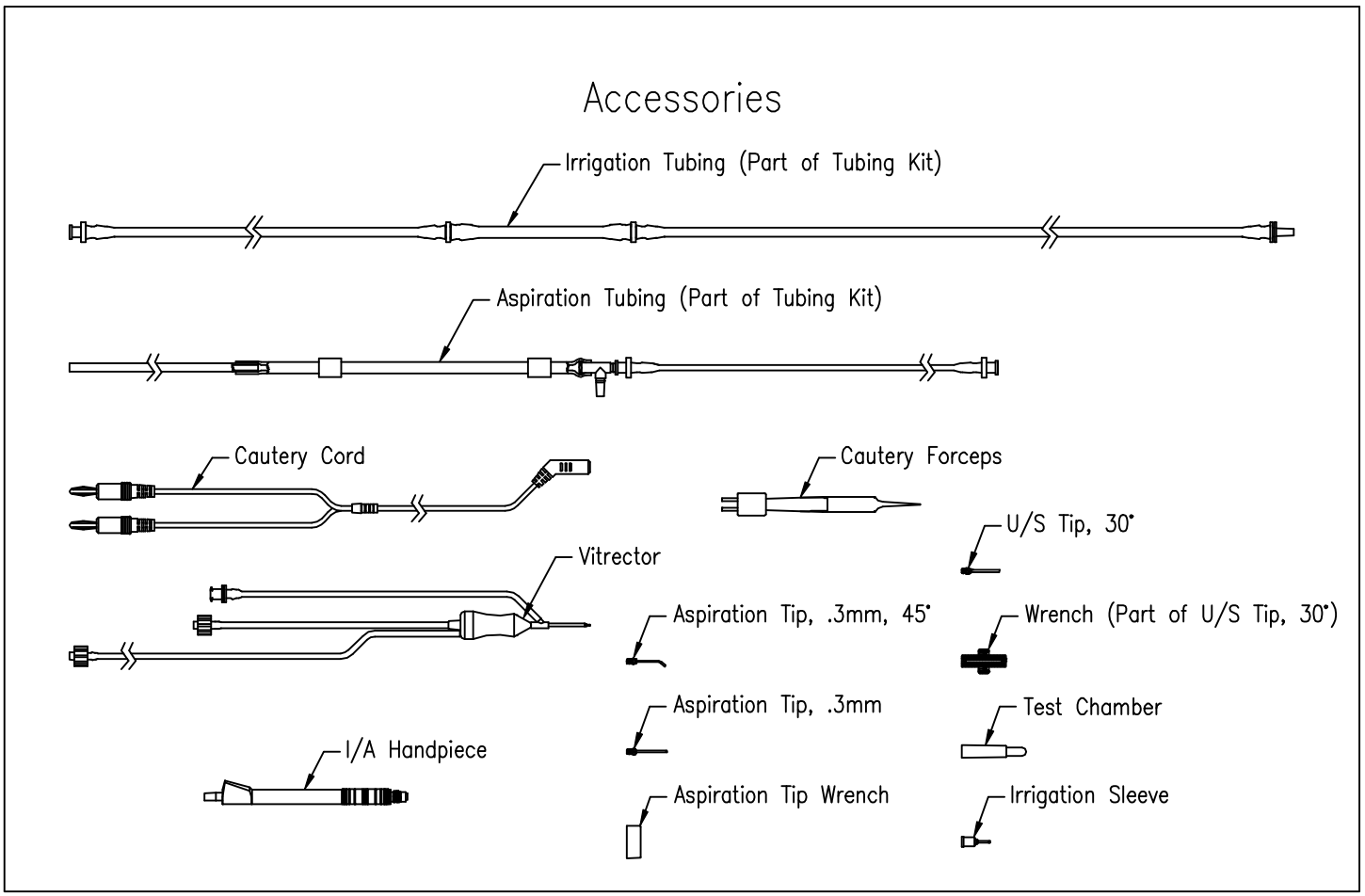
Your Model 2000 has been carefully inspected/tested for any/all nonconformances and carefully packaged prior to shipment. Please inspect for shipping damage. If the shipping container is damaged to the extent that its contents may be damaged, do not attempt to unpack. Immediately notify the freight company and MTP. Further, unpack only in the presence of the freight company representative.

If the shipping container appears intact, carefully remove its contents from the shipping container and check for loose, broken or missing items. Please compare the Packing List/Invoice with the received items and report any discrepancy to MTP.

Shipping container and packing material should be saved in the event of any return.

1.3 Components and Accessories





1.4 Product Specification

Prior to using the Model 2000, familiarize yourself with its specifications:

- Features and Benefits
- Modes
- Controls
- Functions

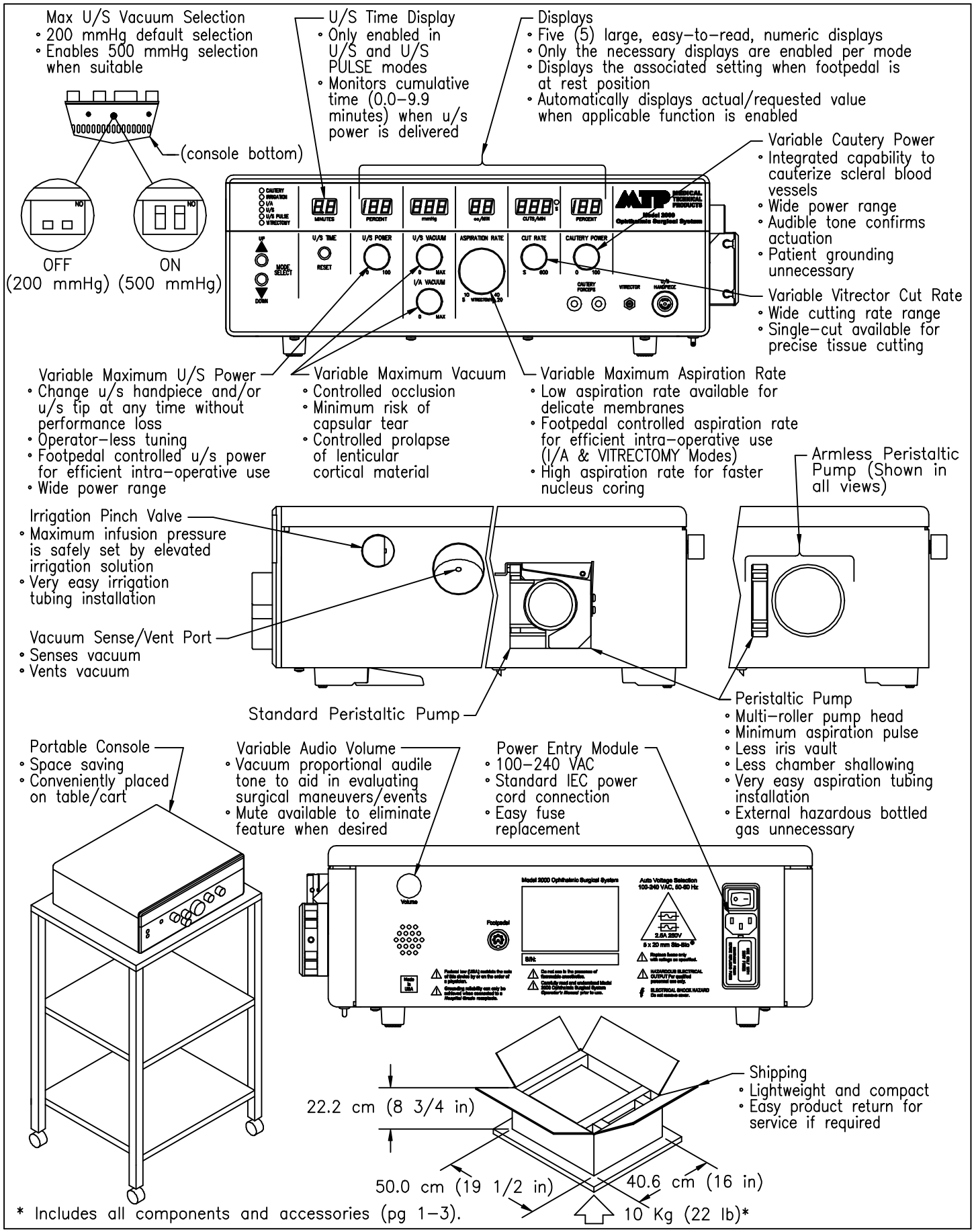
Briefly, the Model 2000 operator can easily enter any one (1) of six (6) independent modes at any time by depressing UP/DOWN switches to scroll to the desired mode:

- CAUTERY
- IRRIGATION
- I/A
- U/S
- U/S PULSE
- VITRECTOMY

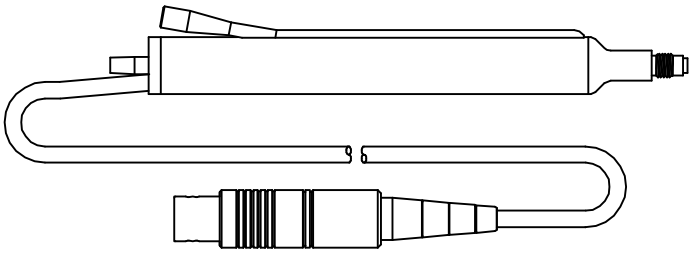
For maximum operator simplicity, only applicable displays are enabled in each mode as identified in Model 2000 Modes (Section 1.4.2). Typical selected settings are shown to acquaint the new operator. Setting ranges are specified in Model 2000 Modes (Section 1.4.2) as well as Model 2000 Controls (Section 1.4.3).

Once the mode is selected and the associated controls set per the ophthalmic/cataract surgeon's specifications, the footpedal will determine which functions are enabled. Model 2000 Functions (Section 1.4.4) defines each function when depressing the footpedal treadle from its rest position through sequential positions.

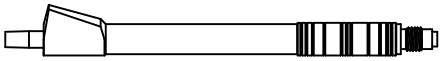
1.4.1 Features and Benefits (1/2)



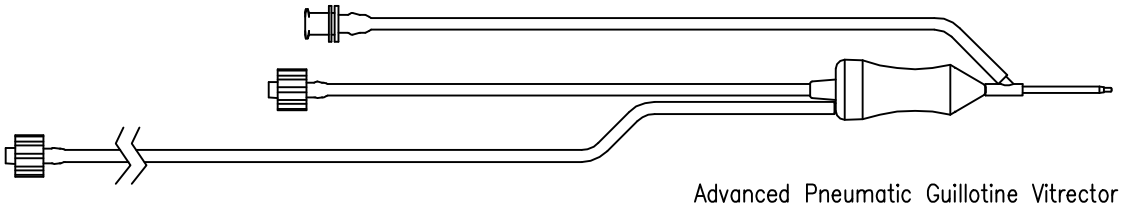
1.4.1 Features and Benefits (2/2)



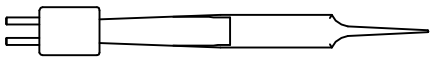
Advanced U/S Handpiece Design
- Lightweight
- Corrosion free
- Balanced
- Ease of use with deep eye/ heavy brow patients
- No disassembly required



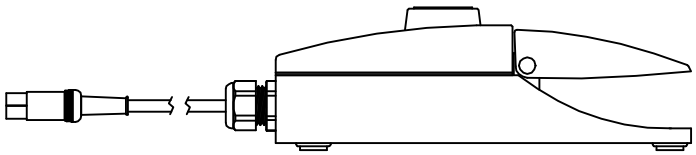
Advanced I/A Handpiece Design
- Lightweight
- Corrosion free
- Balanced
- No disassembly required



Advanced Pneumatic Guillotine Vitrector
- Anterior segment vitrectomy capability
- Integral irrigation
- Very easy setup with installed tubing kit

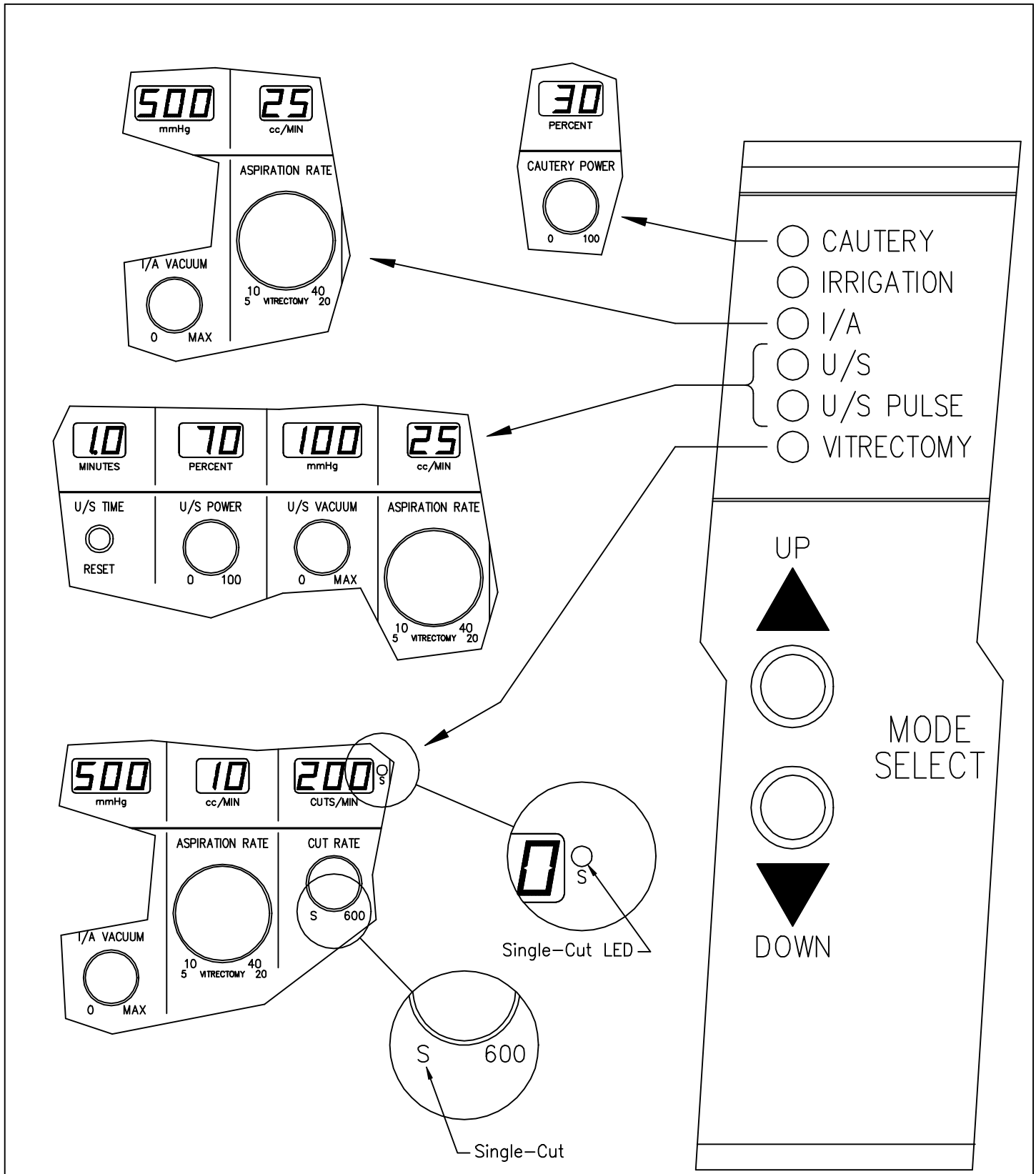


Cautery Forceps
- Very easy setup
- Versatile
- Precise target tissue heating



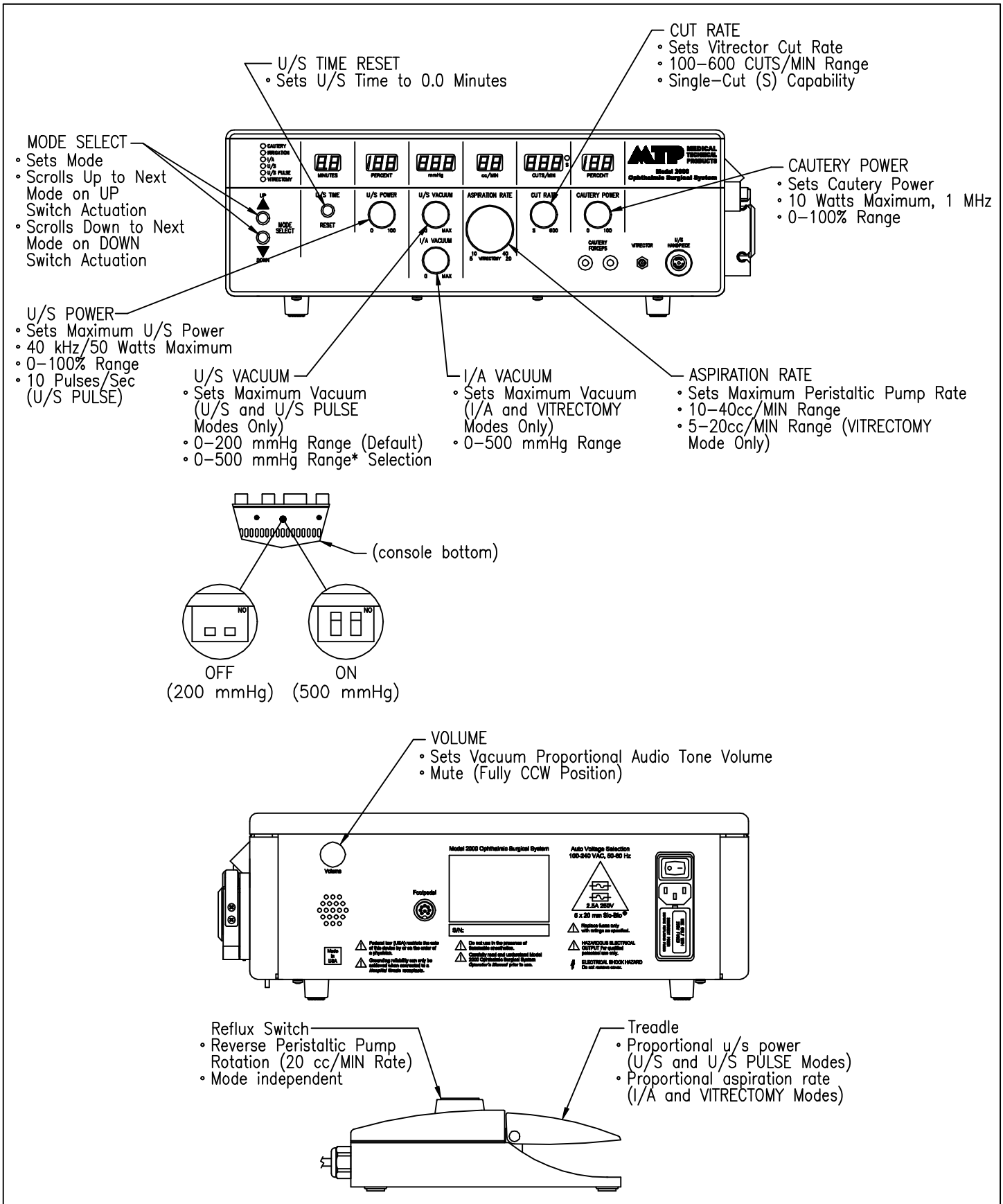
Advanced Footpedal Design
- Footpedal proportional u/s power (U/S and U/S PULSE modes)
- Footpedal proportional aspiration rate (I/A and VITRECTOMY modes)
- Mode independent reflux available on-demand
- Audible/vibrational knock to indicate footpedal treadle position

1.4.2 Modes



Note: Except for U/S TIME, numerical displays shown with their associated controls represent typical selected settings. Footpedal is at rest position.

1.4.3 Controls

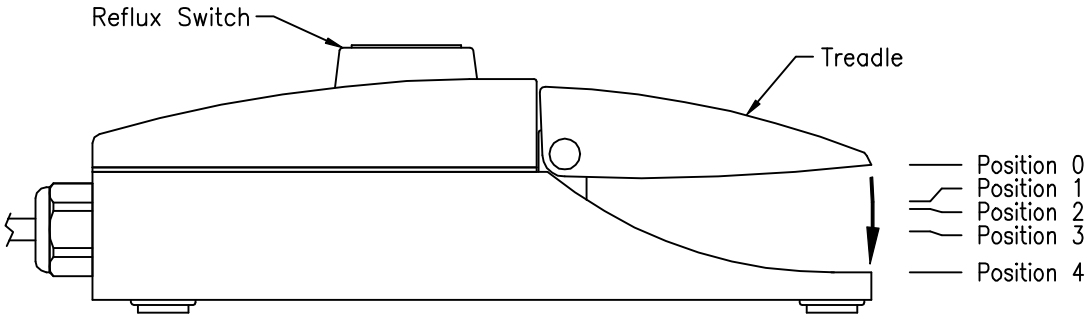


* For safe operation, 0–500 mmHg u/s vacuum range selection requires vigilant u/s handpiece testing during setup (Section 2.2.1).

1.4.4 Functions

Function	Description
IRR	Irrigation pinch valve is actuated, permitting the elevated irrigation solution to safely maintain intraocular pressure.
ASP	Enables footpedal proportional aspiration rate via peristaltic pump, permitting required vacuum for effective aspiration. Actual vacuum and requested aspiration rates displayed whenever footpedal treadle ≥ Position 2 with maximum aspiration rate at position 4. Peristaltic pump actuation is only enabled when selected maximum vacuum has not been exceeded. Any vacuum generated by the peristaltic pump is automatically and safely vented whenever footpedal treadle position is returned ≤ Position 2.
U/S^C Continuous	Enables footpedal proportional u/s power to be delivered to the attached u/s handpiece with maximum u/s power at Position 4. Requested u/s power is displayed whenever footpedal treadle postion ≥ Position 3. Aspiration rate is fixed at the selected aspiration rate.
U/S^P Pulsed	Same as U/S^C except u/s power is pulsed at 10 pulses/sec.
CUT	Vitrector is actuated at selected cut rate whenever footpedal treadle position is ≥ Position 2.
REFLUX	Actuates reverse peristaltic pump rotation (20 cc/MIN).
CAUT	Electrically heats target tissue held by the cautery forceps at the set cautery power.

Functions vs Mode



	Mode						
Treadle Position	CAUTERY	IRRIGATION	I/A	U/S	U/S PULSE	VITRECTOMY	VITRECTOMY (Single–Cut)
Position 0	–	–	–	–	–	–	–
Position 1†	–	IRR	IRR	IRR	IRR	IRR	IRR
Position 2†	CAUT	IRR	IRR+ASP*	IRR+ASP	IRR+ASP	IRR+ASP*/CUT	IRR+ASP*
Position 3†	CAUT	IRR	IRR+ASP*	IRR+ASP+U/S^C*	IRR+ASP+U/S^P*	IRR+ASP*/CUT	IRR+ASP*/CUT
Position 4	CAUT	IRR	IRR+ASP*	IRR+ASP+U/S^C*	IRR+ASP+U/S^P*	IRR+ASP*/CUT	IRR+ASP*/CUT
Reflux Switch	REFLUX	REFLUX	REFLUX	REFLUX	REFLUX	REFLUX	REFLUX

* Surgeon variable via treadle position.

† Audible/vibrational knock indicates entry into new position.

Model 2000 Operator's Manual Section 2 Usage Instructions

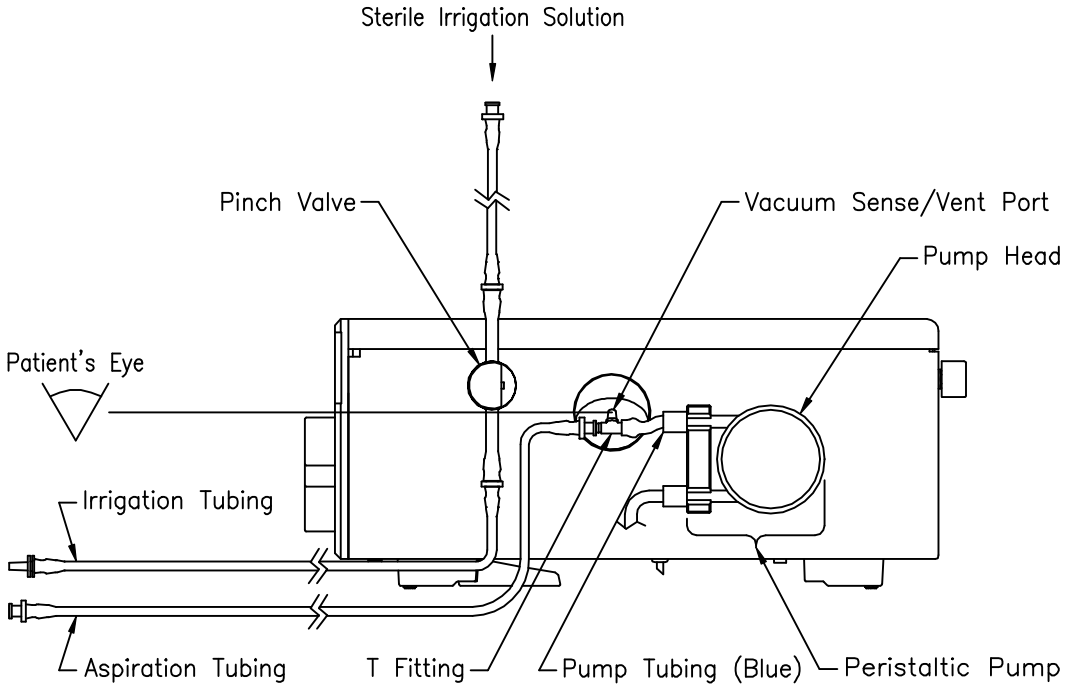
This section contains important information for using the Model 2000. Prior to using the Model 2000, familiarize yourself with the Model 2000 product specifications (Section 1.4).

The **Model 2000 Quick Reference** (Section 4.1) is an easy guide to assist the operator in using the Model 2000.

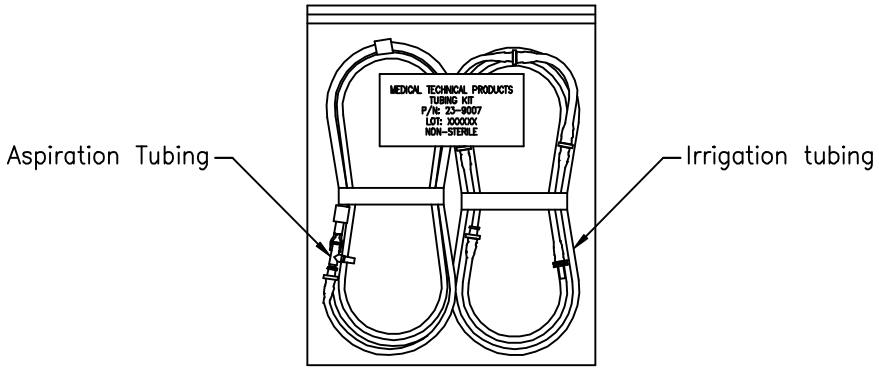
2.1 Tubing Kit Installation

WARNING! Packaged in Non-Sterile Condition

WARNING! To enable correct console operation & avoid possible console damage, position the console at the patient's eye height as shown.

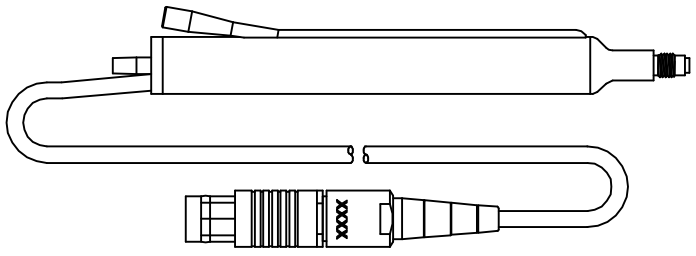


- All tubing kit handling must be made using the appropriate aseptic technique following Model 2000 Cleaning/Sterilization Instructions (Section 3.2).
- Install irrigation tubing as illustrated. Insertion into pinch valve is aided if tubing is stretched during insertion. Install aspiration tubing by routing the pump tubing (blue) around the pump head and conclude with firmly inserting the T fitting into the vacuum sense/vent port.

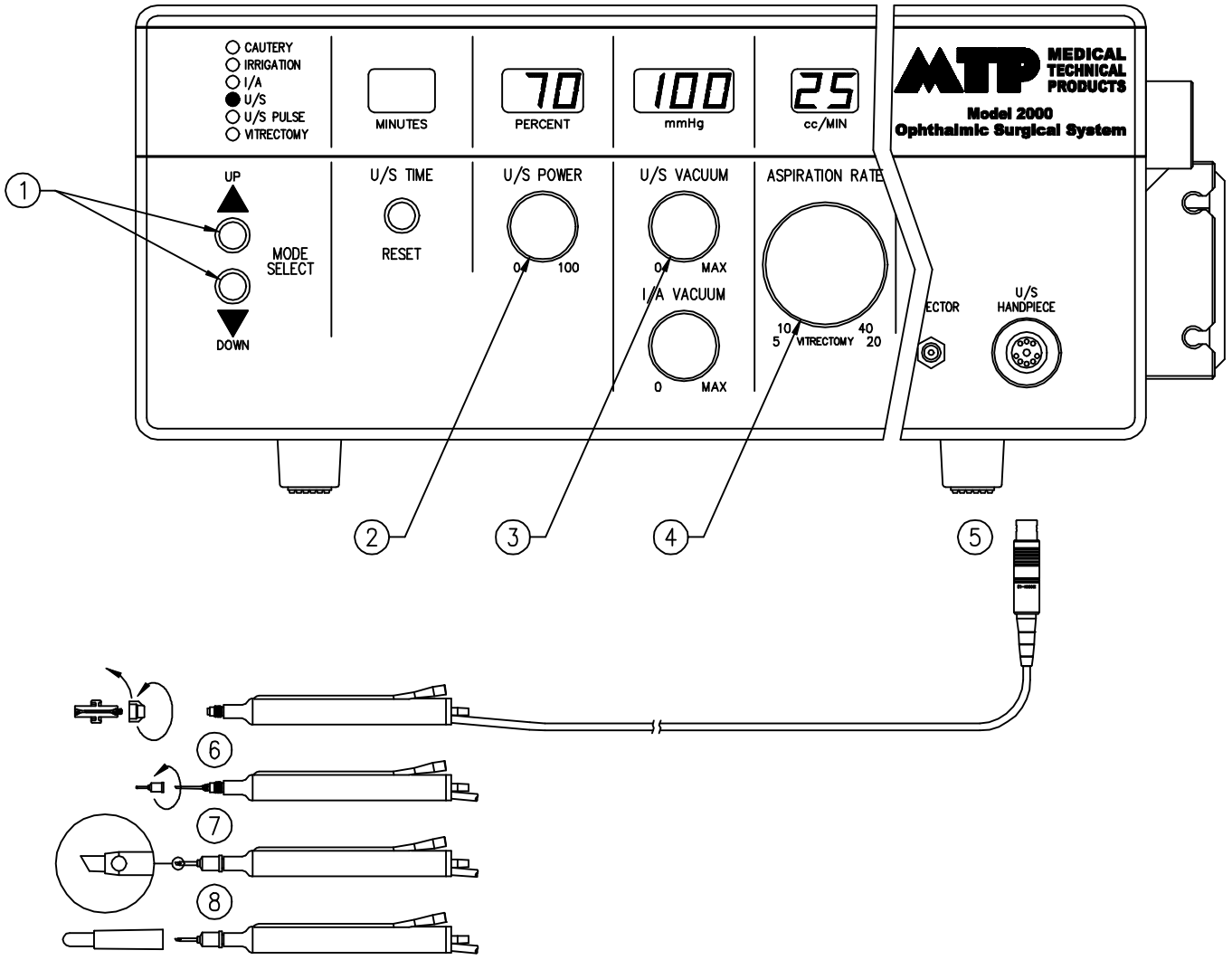


2.2 U/S Handpiece

The u/s handpiece integrates irrigation, aspiration and emulsification. When in U/S or U/S PULSE modes, the cataractuous lens is emulsified and aspirated while maintaining intraocular pressure by irrigation. The u/s handpiece requires no disassembly.



2.2.1 U/S Handpiece Setup (1/3)



(1) Set mode to either U/S or U/S PULSE. If U/S PULSE mode is selected, u/s power is pulsed at 10 pulses/sec when enabled.

(2) Set maximum U/S POWER.

(3) Set maximum U/S VACUUM.

(4) Set ASPIRATION RATE.

(5) Insert u/s handpiece plug into mating console connector.

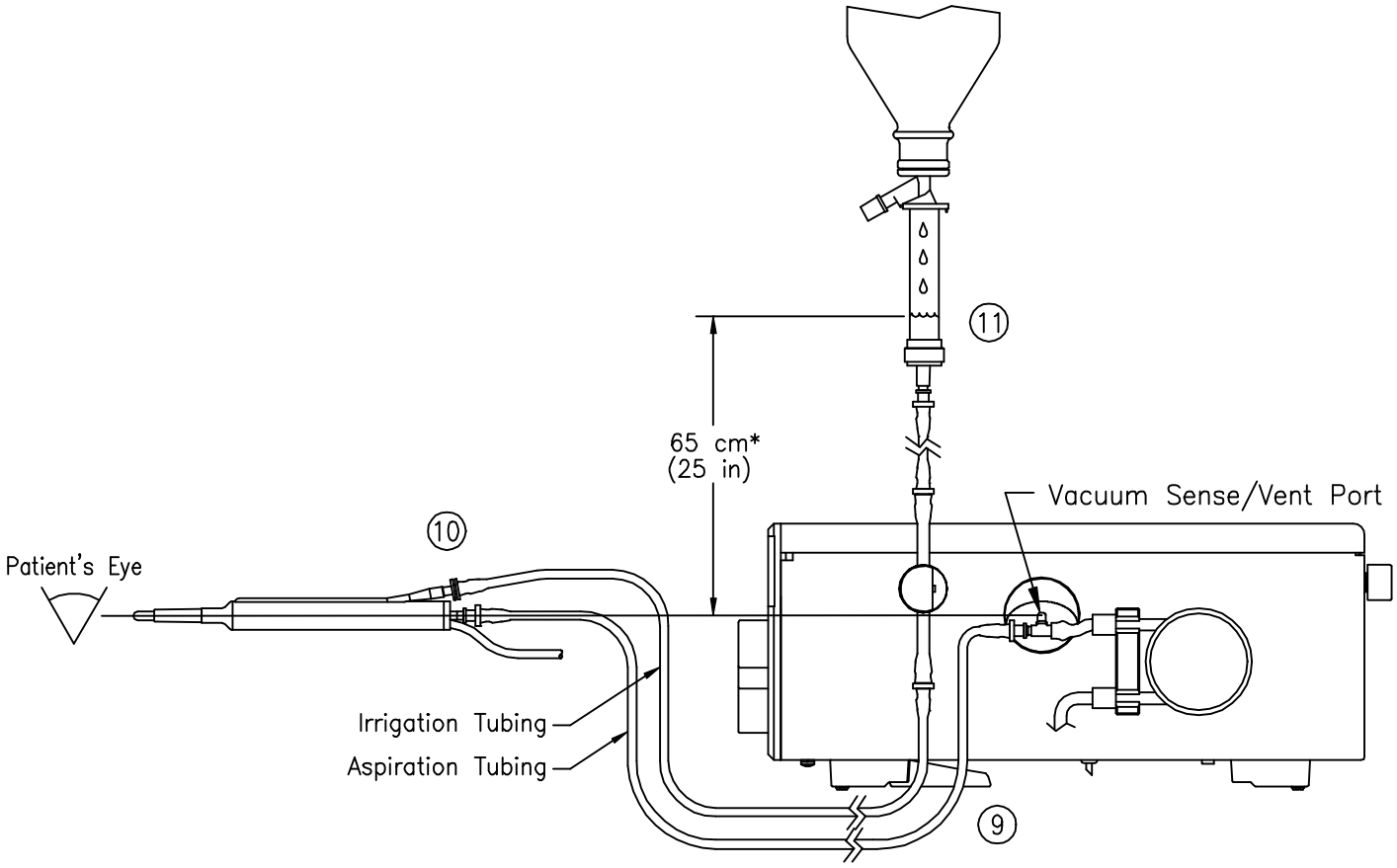
(6) Remove cap from u/s tip holder. Use holder as a wrench to firmly attach u/s tip.

(7) Carefully attach threaded irrigation sleeve over u/s tip.

(8) Install test chamber over irrigation sleeve.

Note: Numerical displays shown represent typical selected settings. Footpedal is at rest postion.

2.2.1 U/S Handpiece Setup (2/3)



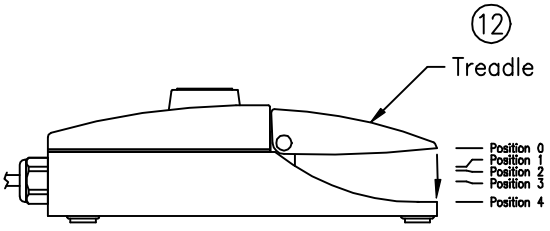
(9) Install tubing kit per Section 2.4.

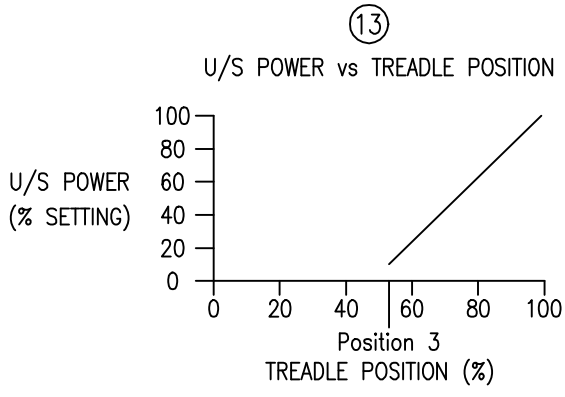
(10) Connect irrigation tubing and aspiration tubing to u/s handpiece.

(11) Connect sterile irrigation solution container to irrigation tubing and elevate 65 cm* above the patient's eye and Vacuum Sense/Vent Port.

(12) Evacuate and replace all tubing/test chamber air with sterile irrigation solution by depressing footpedal treadle to Position 2.

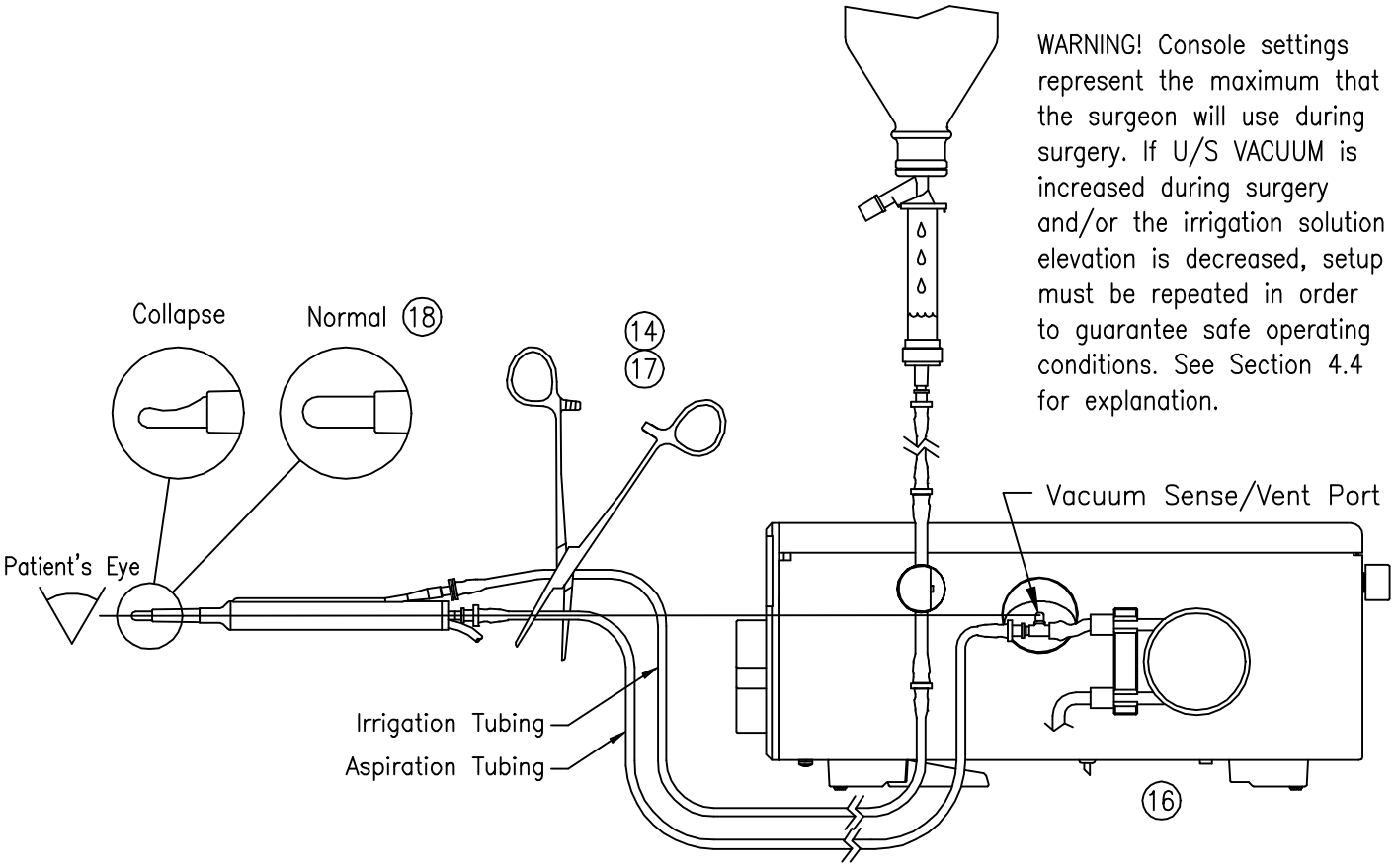
(13) IRR, ASP and U/S^{C,P} functions will respond as previously tabulated (Section 2.3). Delivered u/s power is proportional to treadle position as graphically illustrated.





* Typical elevation.

2.2.1 U/S Handpiece Setup (3/3)



WARNING! Console settings represent the maximum that the surgeon will use during surgery. If U/S VACUUM is increased during surgery and/or the irrigation solution elevation is decreased, setup must be repeated in order to guarantee safe operating conditions. See Section 4.4 for explanation.

(14) Pinch aspiration tubing with hemostat. Locate clamp as close to u/s handpiece as possible. Verify that the test chamber is at the same height as the vacuum sense/vent port.

(15) Depress footpedal treadle to Position 2.

(16) Note peristaltic pump start and stop. If peristaltic pump does not remain stopped >5 seconds do not proceed.

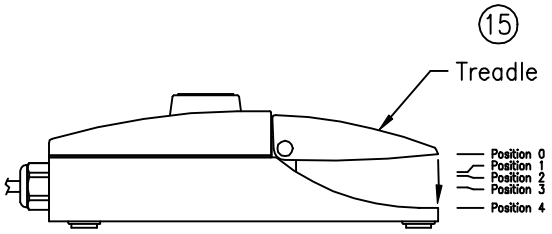
(17) Release clamp (hemostat).

(18) Note no change in test chamber. Fully release footpedal treadle (Position 0). Proceed to 19.

If test chamber collapse occurs, complete the following as required, then repeat test until no change in test chamber is observed.

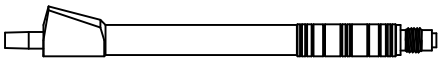
- Make sure all connections to the u/s handpiece are secure.
- Avoid severe bends/kinks in all tubing.
- Make sure the u/s handpiece is free of obstructions.
- Increase irrigation solution elevation.
- Decrease maximum U/S VACUUM setting.
- Replace u/s tip (19 GA) with u/s tip (20 GA).

19. Remove test chamber. System is now ready for surgery.

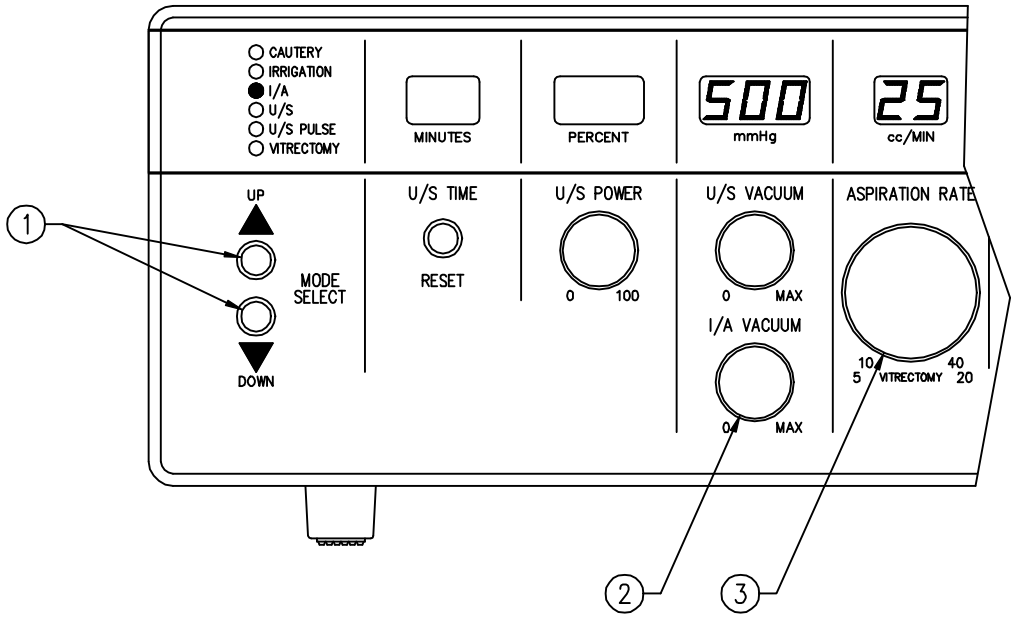


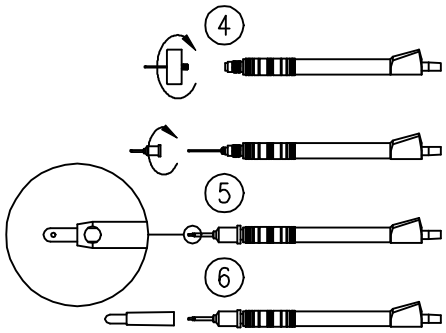
2.3 I/A Handpiece

The I/A handpiece integrates irrigation and aspiration. When in I/A mode, cortical material is removed via aspiration while maintaining intraocular pressure by irrigation. The I/A handpiece requires no disassembly.



2.3.1 I/A Handpiece Setup (1/2)





(1) Set mode to I/A.

(2) Set maximum I/A VACUUM.

(3) Set maximum ASPIRATION RATE.

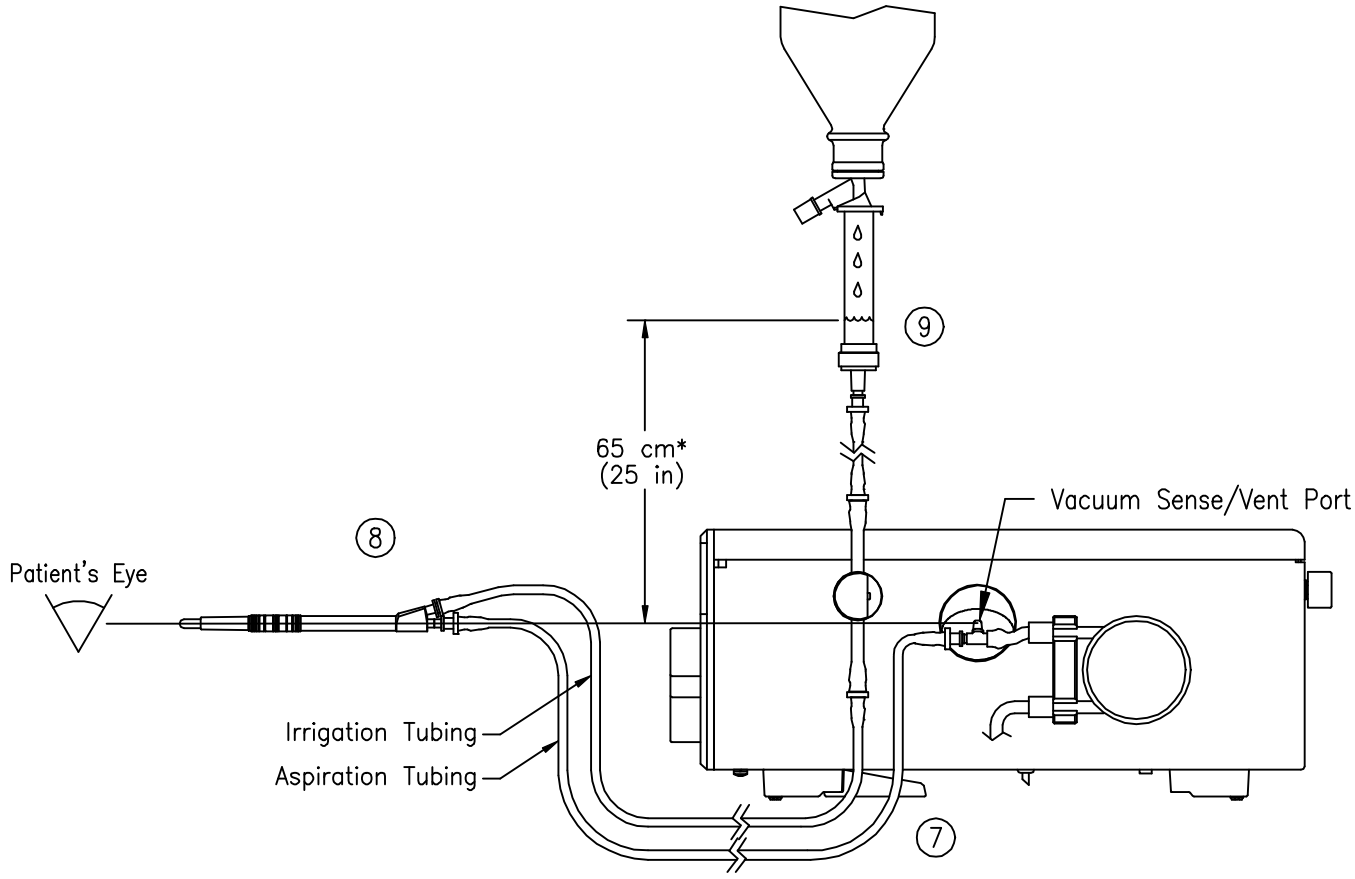
(4) With aspiration tip wrench, firmly attach aspiration tip.

(5) Carefully attach threaded irrigation sleeve over aspiration tip.

(6) Install test chamber over irrigation sleeve.

Note: Numerical displays shown represent typical selected settings. Footpedal is at rest position.

2.3.1 I/A Handpiece Setup (2/2)



(7) Install tubing kit per Section 2.4.

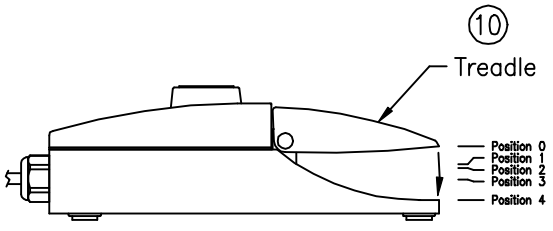
(8) Connect irrigation tubing and aspiration tubing to I/A handpiece.

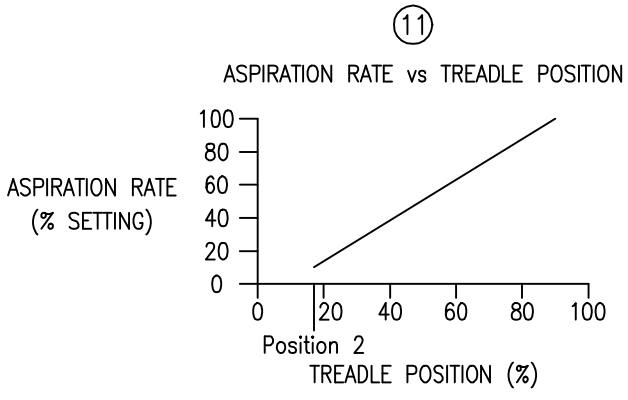
(9) Connect sterile irrigation solution container to irrigation tubing and elevate 65 cm* above the patient's eye and Vacuum Sense/Vent Port.

(10) Evacuate and replace all tubing/test chamber air with sterile irrigation solution by fully depressing footpedal treadle (Position 4).

(11) IRR and ASP functions will respond as previously tabulated (Section 2.3). Aspiration rate is proportional to the treadle position as graphically illustrated.

12. Remove test chamber. System is now ready for surgery.

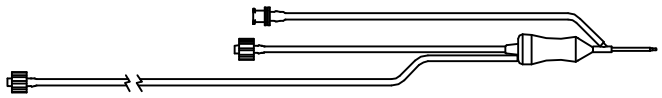




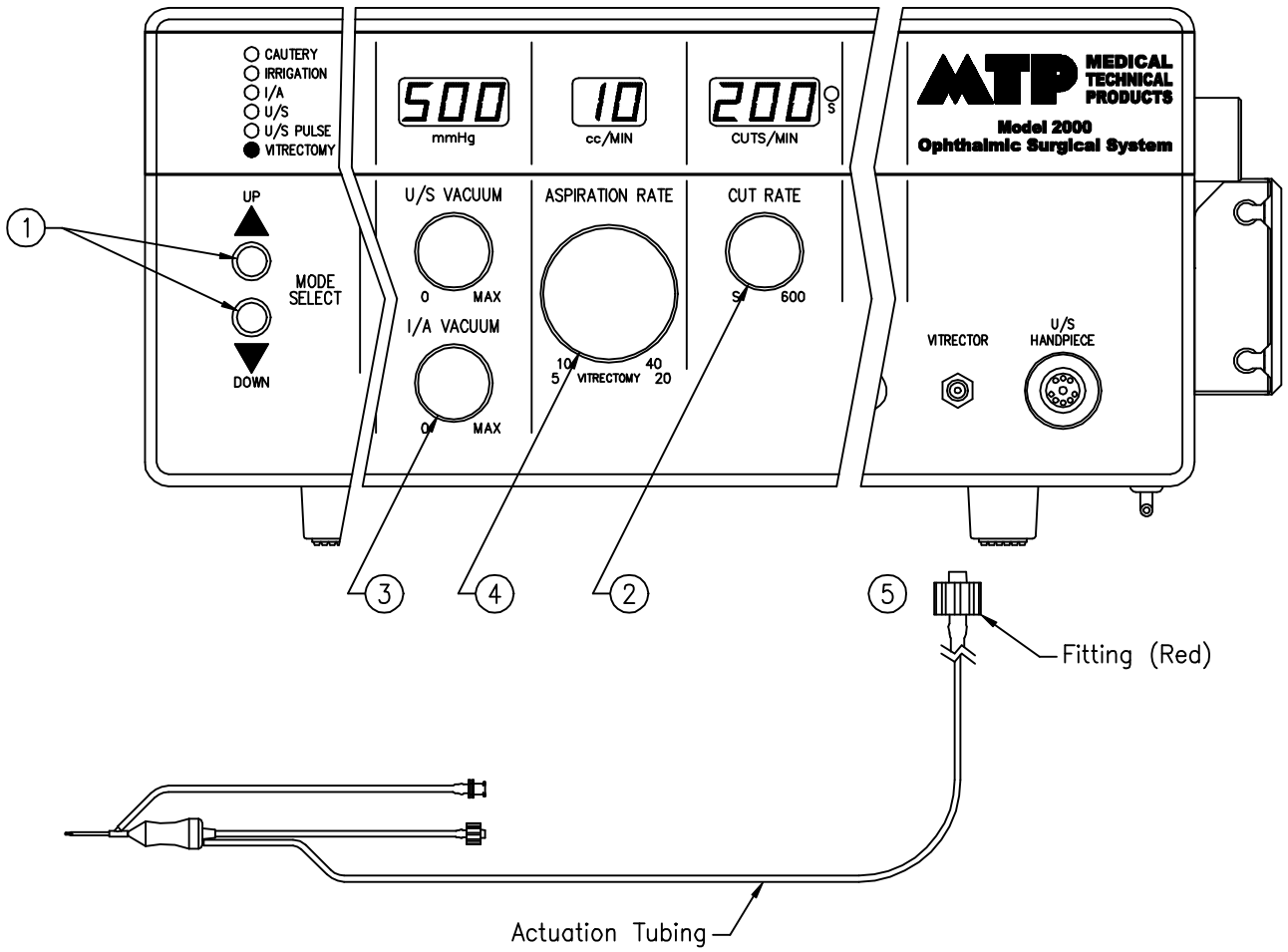
* Typical elevation.

2.4 Vitrector

The vitrector integrates irrigation, aspiration and cutting. When in VITRECTOMY mode, cut tissue is aspirated from the eye while maintaining intraocular pressure by irrigation. The aspiration port is close to the vitrector tip, thus permitting the vitrector to cut a variety of different tissues including vitreous. The vitrector is fully preassembled and requires no lubrication.



2.4.1 Vitrector Setup (1/2)



(1) Set mode to VITRECTOMY.

(2) Set CUT RATE (>100 CUTS/MIN).

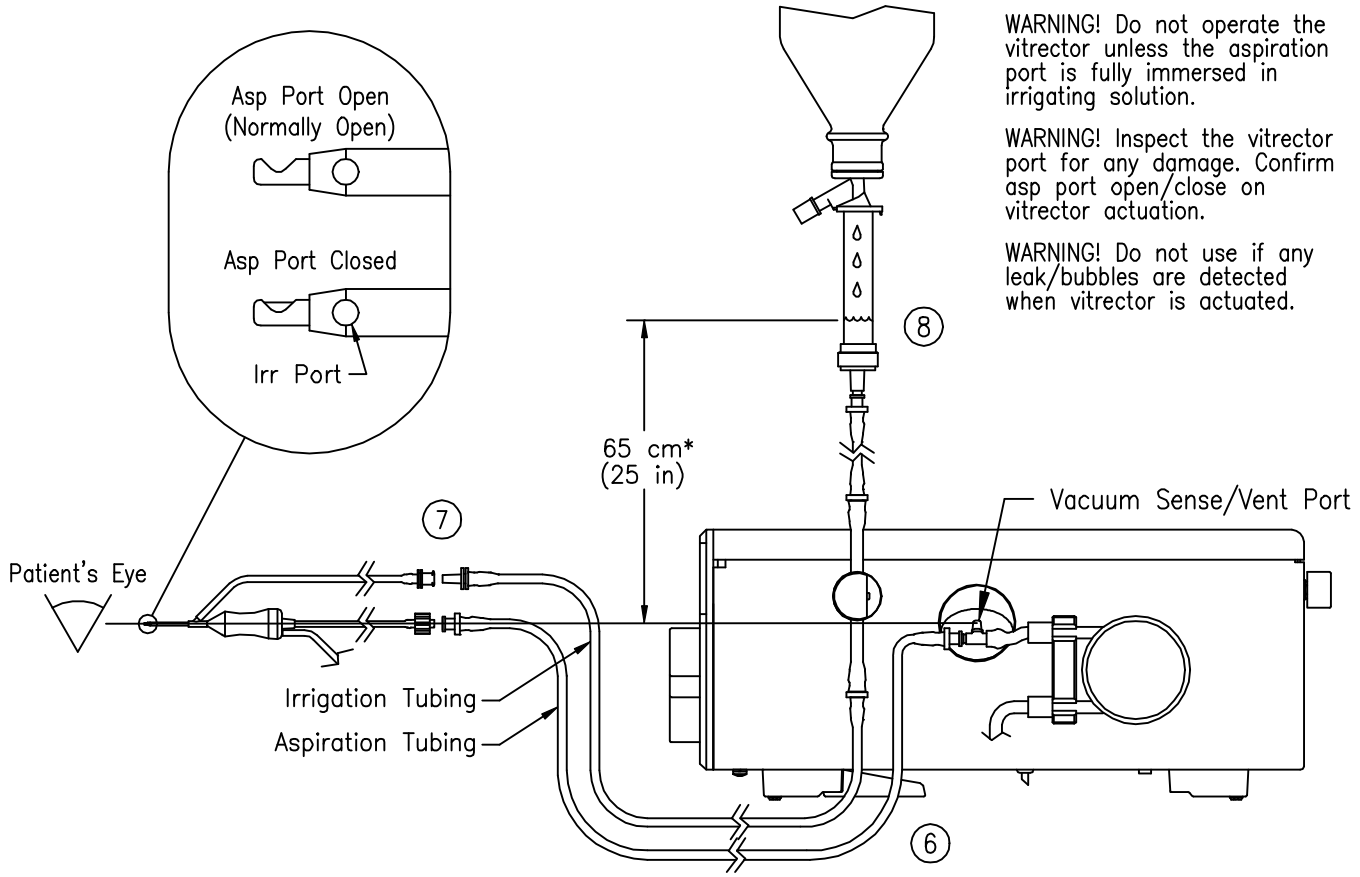
(3) Set maximum I/A VACUUM.

(4) Set ASPIRATION RATE.

(5) Attach actuation tubing to mating pneumatic connector.

Note: Numerical displays shown represent typical selected settings.

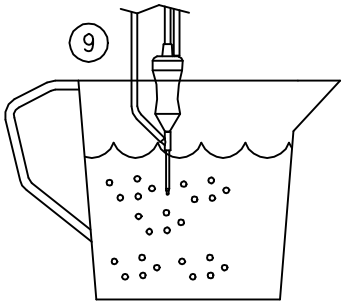
2.4.1 Vitrector Setup (2/2)



WARNING! Do not operate the vitrector unless the aspiration port is fully immersed in irrigating solution.

WARNING! Inspect the vitrector port for any damage. Confirm asp port open/close on vitrector actuation.

WARNING! Do not use if any leak/bubbles are detected when vitrector is actuated.



(6) Install tubing kit per Section 2.4.

(7) Connect irrigation tubing and aspiration tubing to Vitrector.

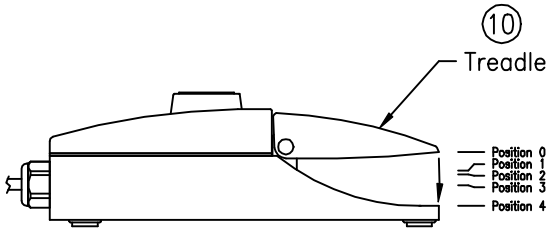
(8) Connect sterile irrigation solution container to irrigation tubing and elevate 65 cm* above the patient's eye and Vacuum Sense/Vent Port.

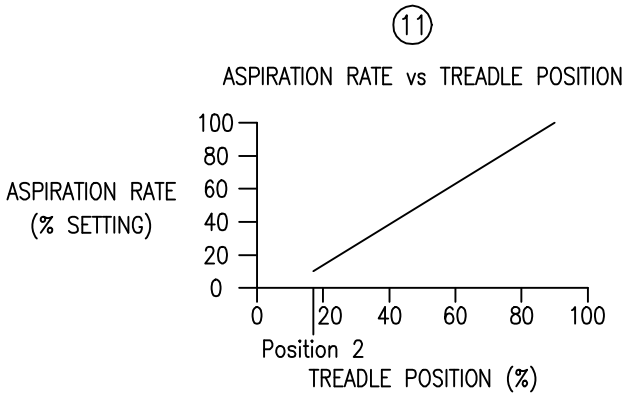
(9) Fully immerse the asp/irr ports in sterile irrigation solution.

(10) Evacuate and replace all tubing air with sterile irrigation solution by fully depressing footpedal treadle to Position 2.

(11) IRR, ASP and CUT functions will respond as previously tabulated (Section 2.3). Aspiration rate is proportional to the treadle position as graphically illustrated.

12. System is now ready for surgery.

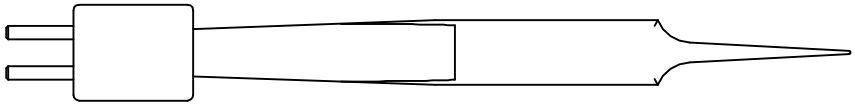




* Typical elevation.

2.5 Cautery Forceps

WARNING! Do not use cautery on patients with cardiac pacemakers.



CAUTION! To ensure safe cautery operation, cables should always be positioned to avoid patient contact.

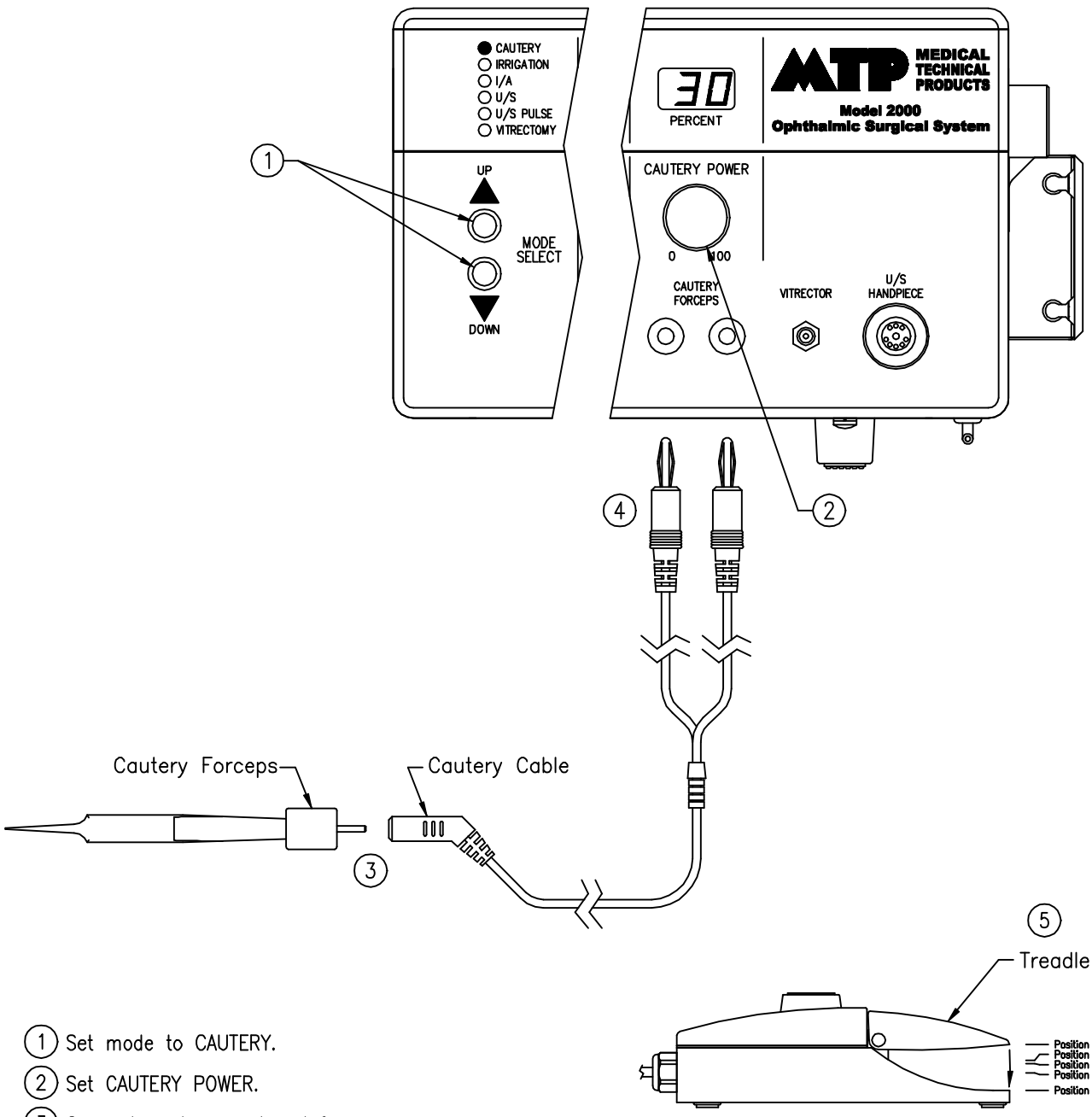
CAUTION! To reduce the risk of accidental burns, caution should always be taken when operating high frequency surgical equipment.

CAUTION! Do not use in the presence of flammable agents or solvent vapors.

CAUTION! Cautery activation may cause adverse interference with electronic equipment operation.

CAUTION! Cautery cables must be regularly checked for possible insulation damage.

2.5.1 Cautery Forceps Setup



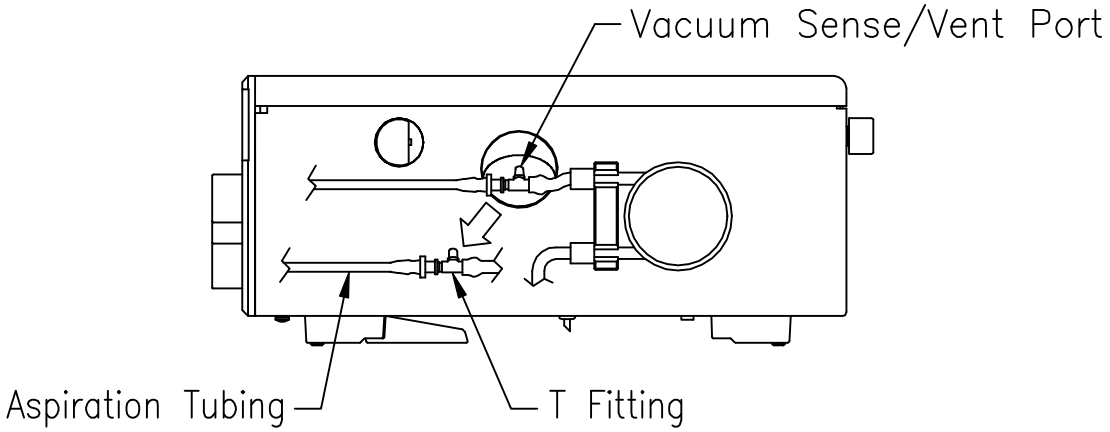
1. Set mode to CAUTERY.
2. Set CAUTERY POWER.
3. Connect cautery cord and forceps.
4. Connect cautery cord plugs into mating connectors.
5. Caut function will respond as previously tabulated (Section 2.3). A high frequency audio tone will be emitted to indicate CAUT function actuated.

Note: Numerical display shown represents typical selected setting.

3.1 Console Care (1/2)

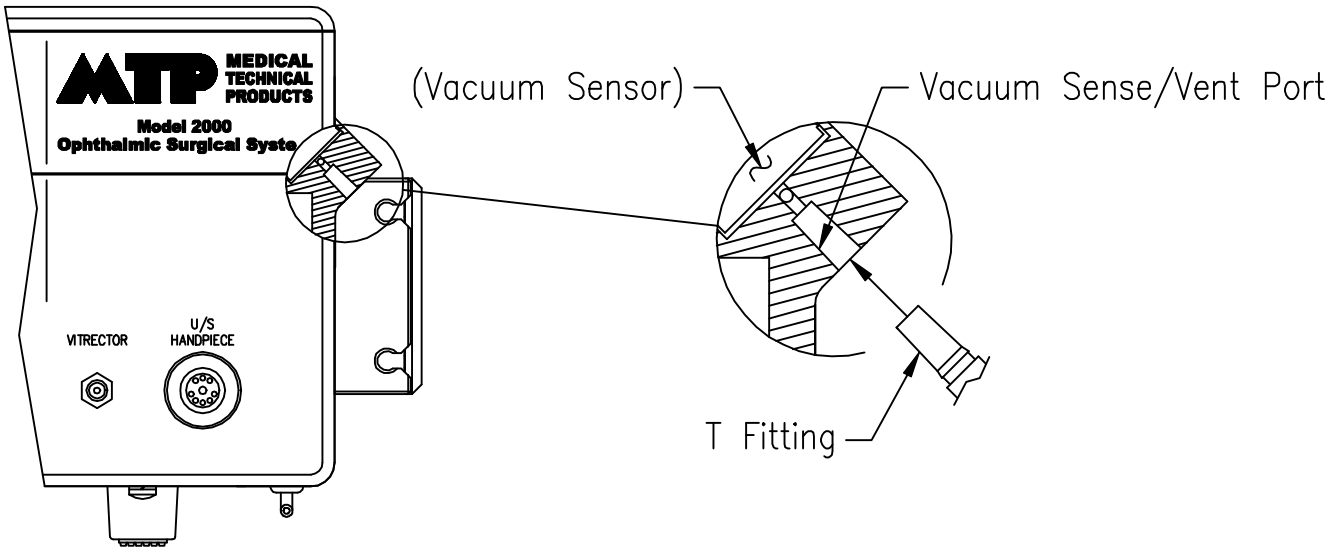
WARNING!

Remove mating aspiration tubing's T fitting from Vacuum Sense/Vent Port prior to attempting to clean, evacuate irrigation solution, and/or dislodging any obstruction.

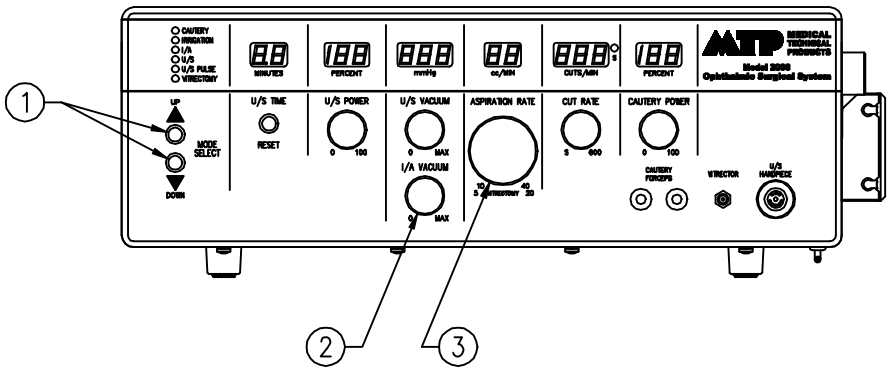


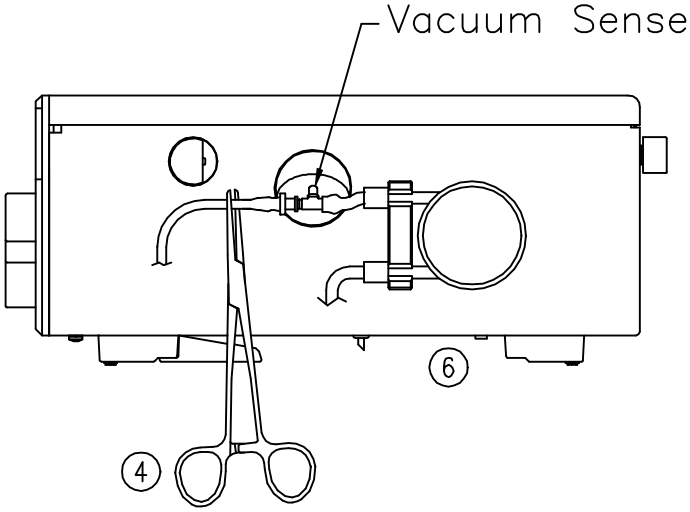
WARNING!

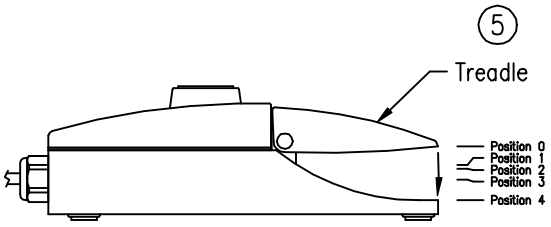
Do not insert any tool or device into the Vacuum Sense/Vent Port. Vacuum Sense/Vent Port is intended to be used only with the mating aspiration tubing's T fitting.



3.1 Console Care (2/2)







Following use, any fluid remaining in the console's Vacuum Sense/Vent Port should be aspirated per procedure:

1. Set mode to I/A.
2. Set I/A VACUUM to 500 mmHg.
3. Set ASPIRATION RATE to 40 cc/MIN.
4. Pinch aspiration tubing with hemostat.
5. Fully depress footpedal treadle (Position 4).
6. Note peristaltic pump stop. Fully release footpedal treadle (Position 0).
7. Repeat steps 5 – 6 as required.

3.2 Cleaning/Sterilization Instructions (1/2)

WARNING! Packaged in Non–Sterile Condition

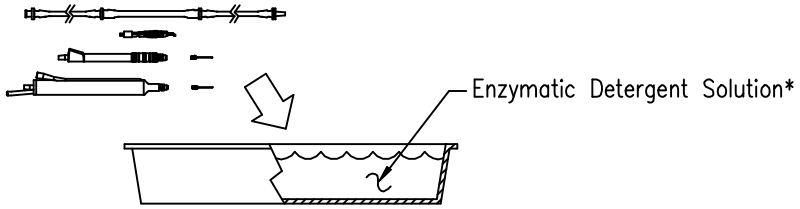
- All items should be carefully handled and protected from mishandling. Additionally, all items should be carefully examined for functionality, deterioration, and damage through mishandling that may have occured during prior use. Do not attempt repair.
- Reuse demands that items are thoroughly cleaned (Wash, Flush, Rinse, and Dry) prior to sterilization. Further, MTP has determined that items can be resterilized after each use per MTP's cleaning/sterilization instructions.
- Cleaning and sterilization should occur in facilities that are adequately equipped, monitored, and staffed by trained personnel.

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

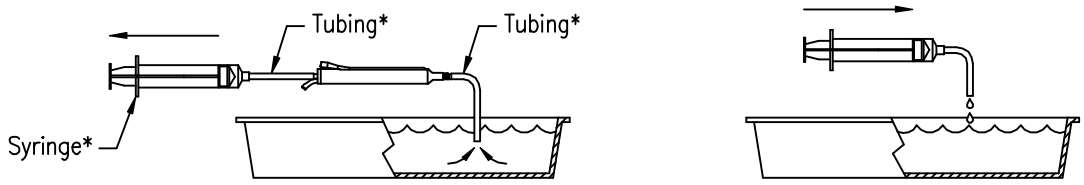
WARNING! The only exception to these cleaning instructions are vitrectors. Soaking would permit the enzymatic detergent solution and/or distilled/deionized water to invade the internal spaces causing damage. Replace "Soaking" with a wipe soaked with the applicable enzymatic detergent solution or distilled/deionized water, removing all tubing and immersing only the vitrector's needle portion in the applicable enzymatic detergent solution or distilled/deionized water.

Wash

- Immediately prior to initial and subsequent use, carefully disassemble all items and soak in enzymatic detergent solution.



- Connect syringe and tubing as illustrated. Draw enzymatic detergent solution into the syringe. Disconnect syringe and expel solution. Repeat 2X. Repeat for each fluid pathway.



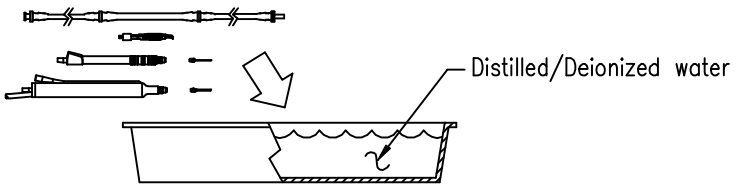
* Not supplied.

(Flush)

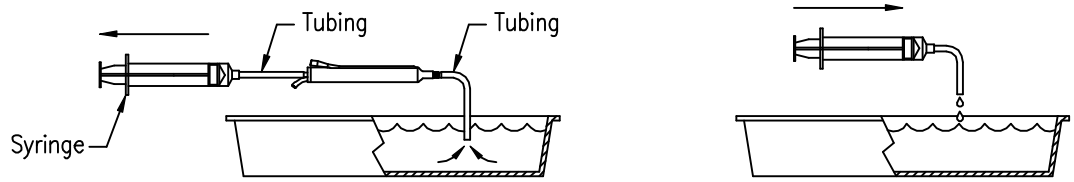
3.2 Cleaning/Sterilization Instructions (2/2)

Flush

- Soak in distilled/deionized water.

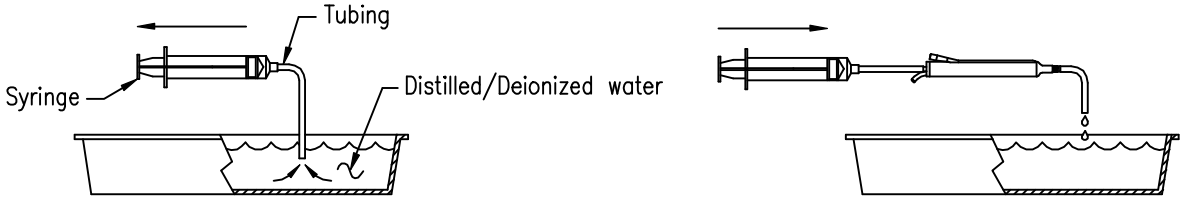


- Connect syringe and tubing as illustrated. Draw distilled/deionized water into the syringe. Disconnect syringe and expel solution. Repeat 2X. Repeat for each fluid pathway.



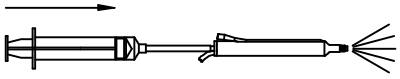
Rinse

- Fill syringe as illustrated with distilled/deionized water. Expel the distilled/deionized water. Ensure the free flow of distilled/deionized water occurs when expelling. Repeat 2X. Repeat for each fluid pathway.



Dry

- Expel empty syringe and tubing. Repeat 2X. Repeat for each fluid pathway.



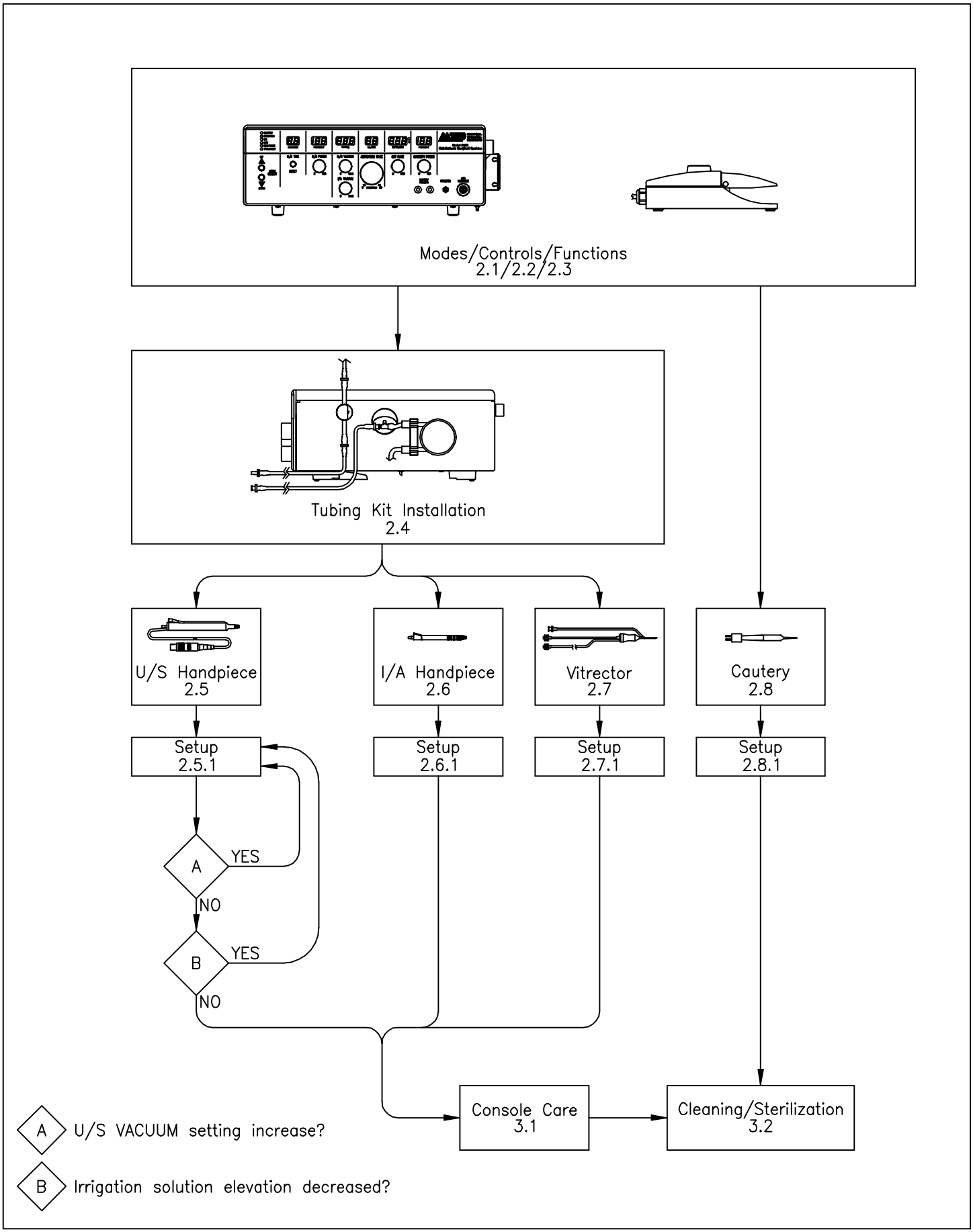
Sterilize

- Sterilize all items at a maximum temperature of 270°F (132°C) using validated procedures for surgical instruments. Alternately, autoclave per American Association of Medical Instrumentation (AAMI) guidelines and/or ISO 11134 Sterilization of Health Care Products – Requirements for Validation and Routine Control – Industrial Moist Heat Sterilization to obtain a Sterility Assurance Level (SAL) = 10^{-6}.

CAUTION! Allow electromechanical items to air cool after sterilization. Do not insert u/s handpiece plug into mating receptacle until completely dry to avoid electrical arcing damage to plug and/or mating receptacle.

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.

4.1 Quick Reference



4.2 Ordering Information

U/S handpiece and accessories have limited life expectancies and will require replacement. MTP has made special efforts to supply these items with the highest quality. However with repeated sterilization at hostile temperatures and pressures to effectively kill living organisms, the item will necessarily degrade. With careful handling/cleaning/sterilization however, the user should enjoy long useful lives with each item. To enable easy ordering, MTP has listed these items below. When ordering, simply provide description and quantity ordered to your distributor.

Item	Description
1	U/S Handpiece
2	U/S Tip, 30°
3	Irrigation Sleeve (Pkg 5)
4	Test Chamber (Pkg 5)
5	I/A Handpiece
6	Aspiration Tip, .3mm
7	Aspiration Tip, .3mm, 45°
8	Aspiration Tip Wrench
9	Tubing Kit
10	Vitrector
11	Cautery Forceps
12	Cautery Cord

4.3 Intraocular Pressure (IOP) Maintenance (1/2)

IOP is exactly equal to the elevated irrigation solution height above the patient's eye, less flow related losses. In the case where there is little irrigation/aspiration flow, a typical 65 cm height equates to an IOP of 48 mmHg. That is, the patient's eye is pressurized by the irrigation solution elevation as illustrated (pg 4-5).

IOP must decrease, however, due to the frictional losses accompanying irrigation flow. As with most liquids, the irrigation solution clings to all solid surfaces during flow, shearing each microscopic layer with decreasing velocity as shown at the top of the illustration. The short arrow lengths near the irrigation sleeve inner surface and the u/s tip outer surface represent this reduced velocity.

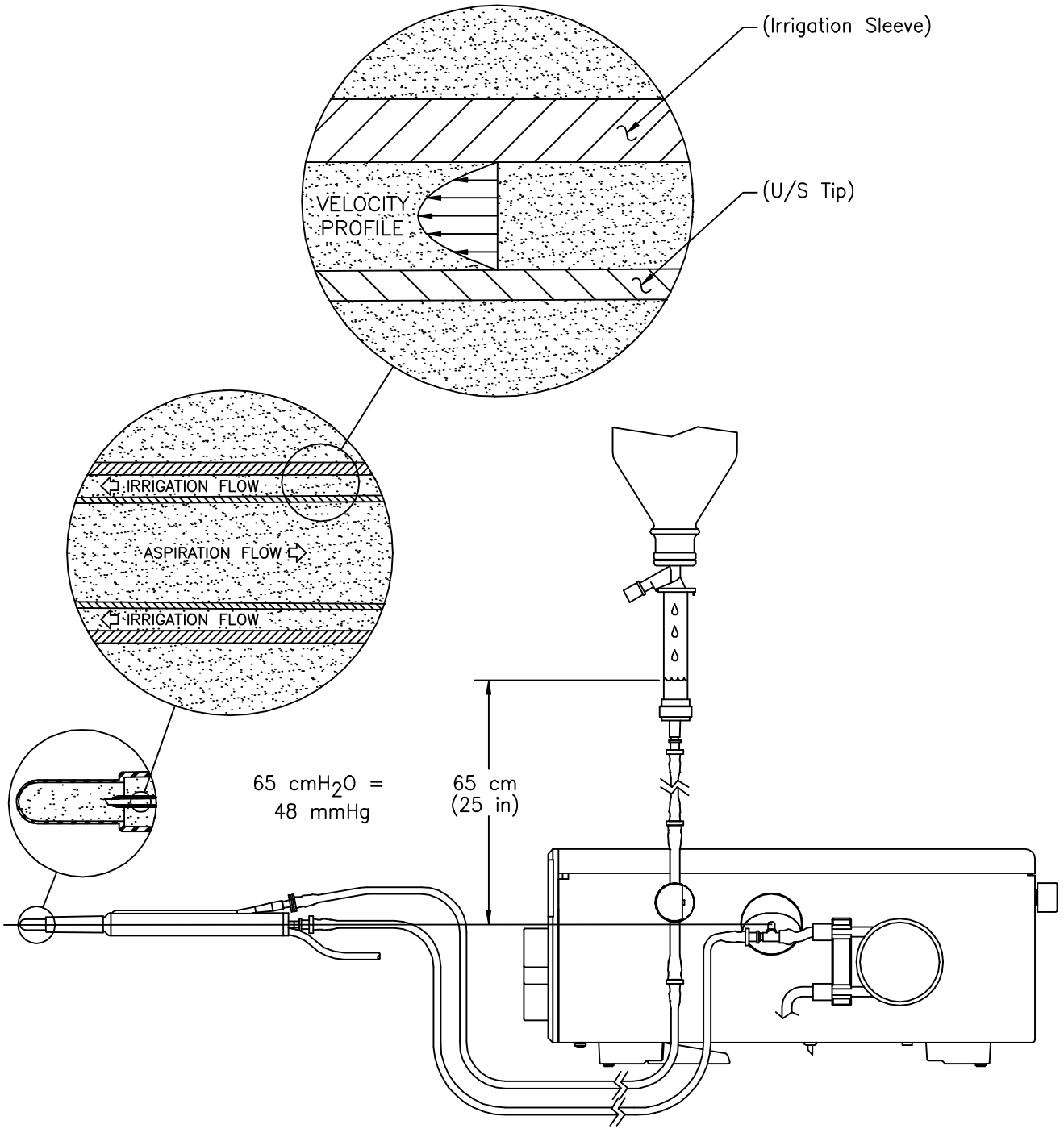
The greater the irrigation flow, the greater the IOP decrease. Of course, irrigation flow is equal to the sum of both aspiration flow and incisional wound leakage. In a typical example, the incisional wound leakage might be 5 cc/min. Adding 25 cc/min for aspiration flow would yield a total irrigation flow of 30 cc/min. From the IOP vs Irrigation Flow graph, IOP would decrease from 48 mmHg to 44 mmHg due to the incisional wound leakage and to 23 mmHg when aspiration flow is enabled.

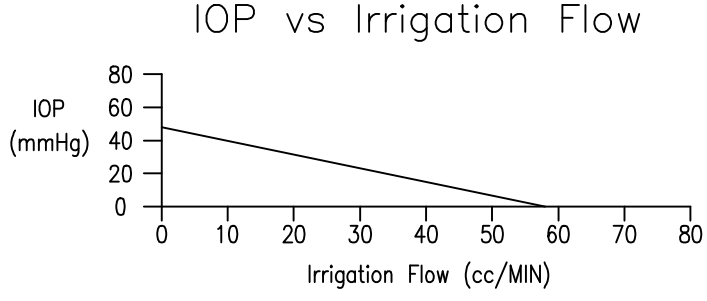
The greatest decrease in IOP occurs, however, during phacoemulsification. Typically, the u/s tip is occluded and vacuum is permitted to increase to the maximum vacuum per the U/S VACUUM setting. When the occluded nuclear fragment is subsequently emulsified, a high transient flow occurs until the IOP and vacuum attain steady state conditions. This high transient flow significantly increases the resistive pressure loss and, if high enough, can depressurize the eye and cause corneal injury. To avoid corneal injury, a simple setup test must be performed.

In Section 2.2.1, the test chamber simulates the patient's eye. Sudden occlusion removal is simulated with hemostat release. If the test chamber is observed to collapse, then the IOP decrease was sufficient to yield IOP < 0 mmHg. Referring to the same graph, transient irrigation flow in this case exceeded 58 cc/min.

If test chamber collapse occurs, setup must be adjusted to maintain the simulated IOP > 0 mmHg during this high transient flow condition. This safe condition is achieved by either increasing the pressurizing irrigation solution elevation and/or decreasing the U/S VACUUM setting with the goal to maintain IOP > 0 mmHg.

4.3 Intraocular Pressure (IOP) (2/2)





5.1 Field Evaluation Tests (FETs)

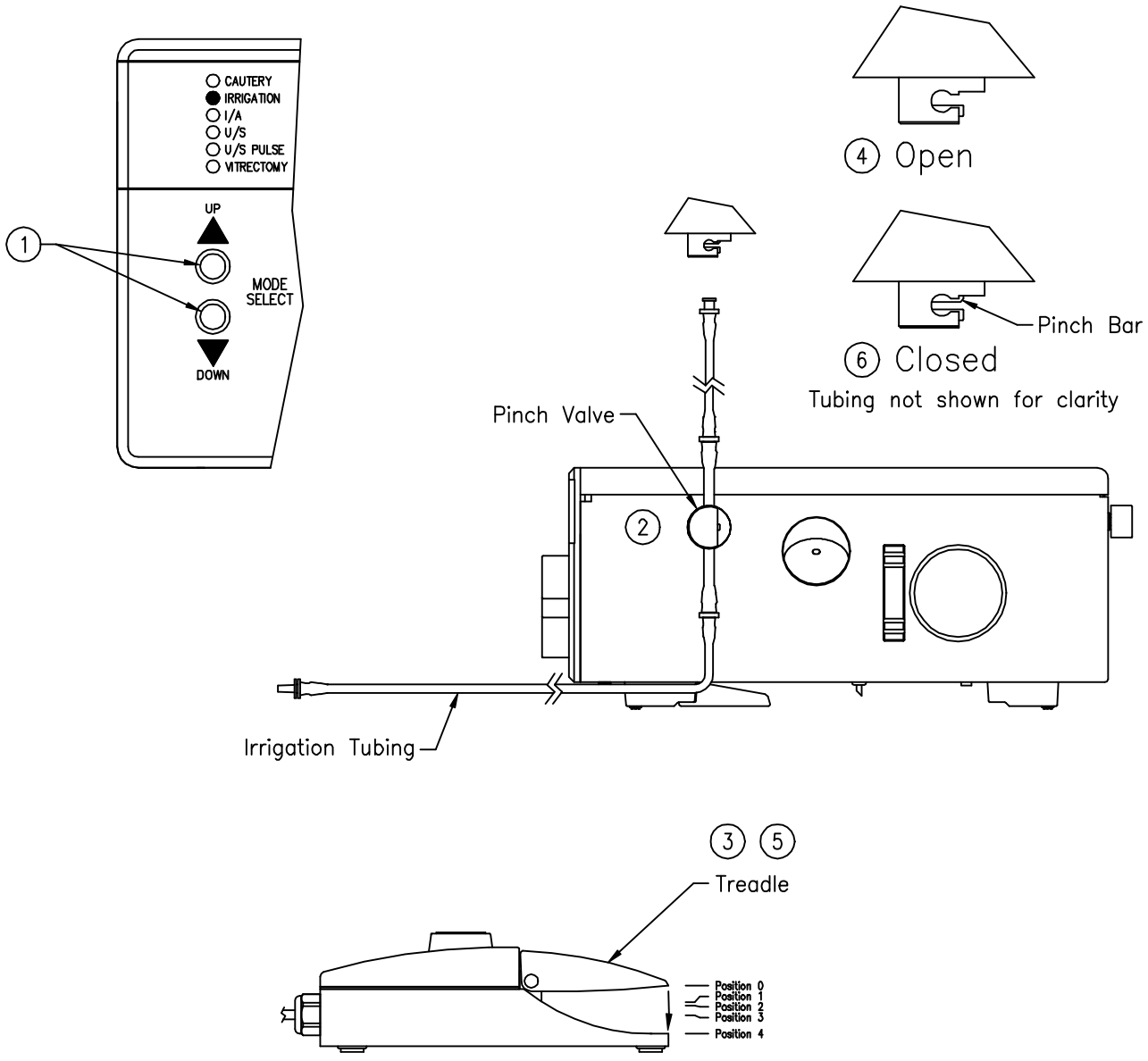
When reporting or suspecting any nonconformance, MTP recommends performing the applicable FET:

- IRRIGATION FET
- I/A FET
- U/S FET
- U/S PULSE FET
- VITRECTOMY FET
- CAUTERY FET

Performing the applicable FET enables MTP to assist most efficiently. Each FET, divided into applicable functions per mode, was carefully written with easy-to-follow instructions and illustrations.

The operator or the distributor is permitted to perform any FET. Once the nonconformance is confirmed, please report to MTP referencing the FET and the specific numbered item(s). MTP will promptly reply with any suggestion to remedy the nonconformance. If unable to remedy the nonconformance, MTP will authorize return to MTP, or an authorized service center for prompt remedy.

5.1.1 IRRIGATION FET



(1) Set mode to IRRIGATION.

(2) Install irrigation tubing as illustrated.

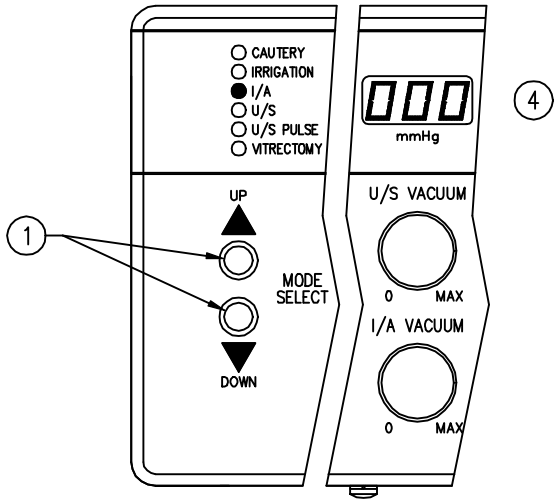
(3) Depress footpedal treadle to Position 1.

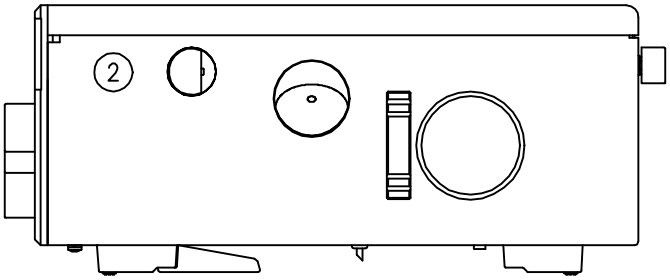
(4) Observe pinch valve actuation to open position (pinch bar fully retracted).

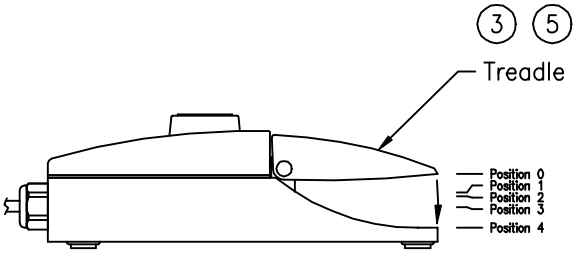
(5) Fully release footpedal treadle (Position 0).

(6) Observe pinch bar in closed position.

5.1.2 I/A FET (1/4)







(1) Set mode to I/A.

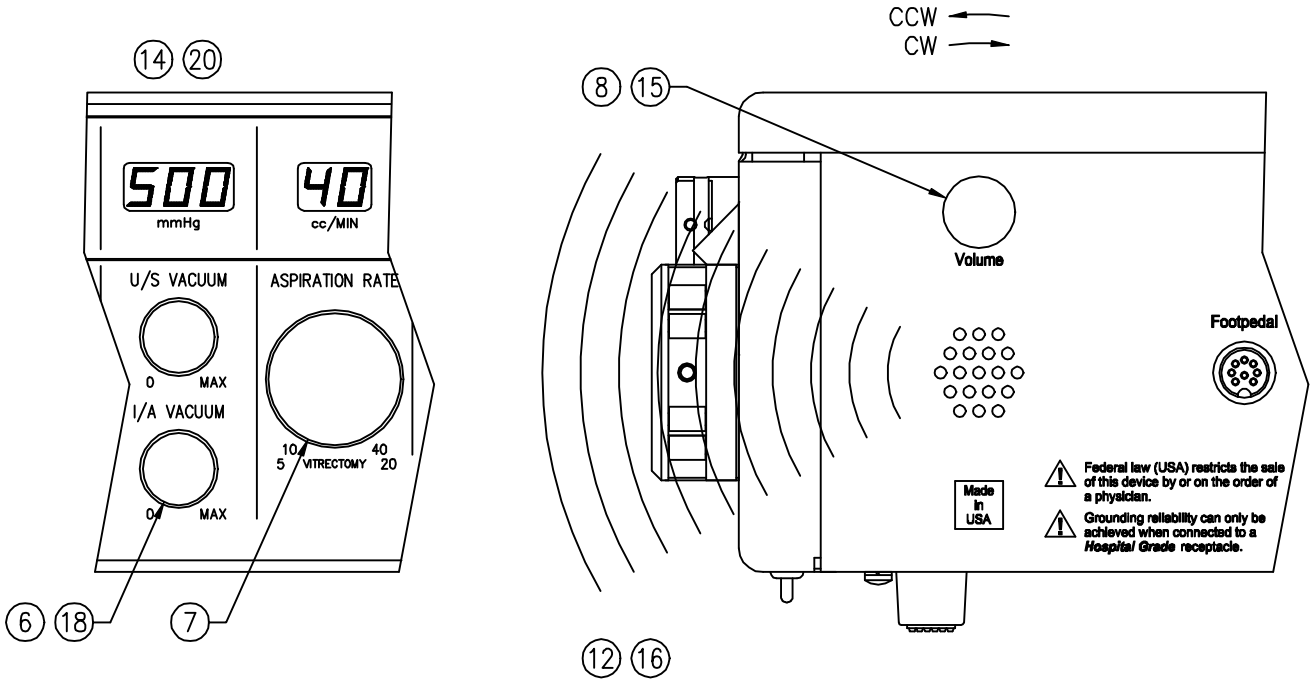
(2) Confirm tubing kit not installed.

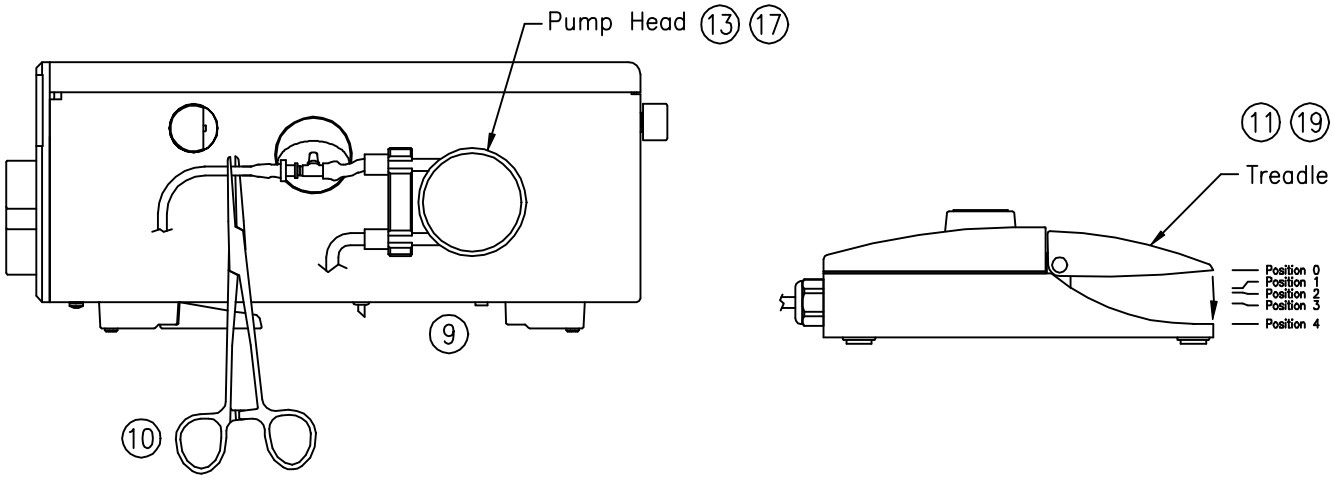
(3) Depress footpedal treadle to Position 2.

(4) Observe vacuum ≤ 002 mmHg.

(5) Fully release footpedal treadle (Position 0).

5.1.2 I/A FET (2/4)





(6) Set I/A VACUUM to 500 mmHg.

(7) Set ASPIRATION RATE to 40 cc/MIN.

(8) Set Volume fully CW.

(9) Install aspiration tubing as illustrated.

(10) Pinch aspiration tubing with hemostat.

(11) Fully depress footpedal treadle (Postion 4).

(12) Observe audio frequency increase.

(13) Allow vacuum to increase until pump stops.

(14) Observe vacuum 500±50 mmHg.

(15) Set Volume fully CCW.

(16) Observe audio volume decrease to zero volume (mute).

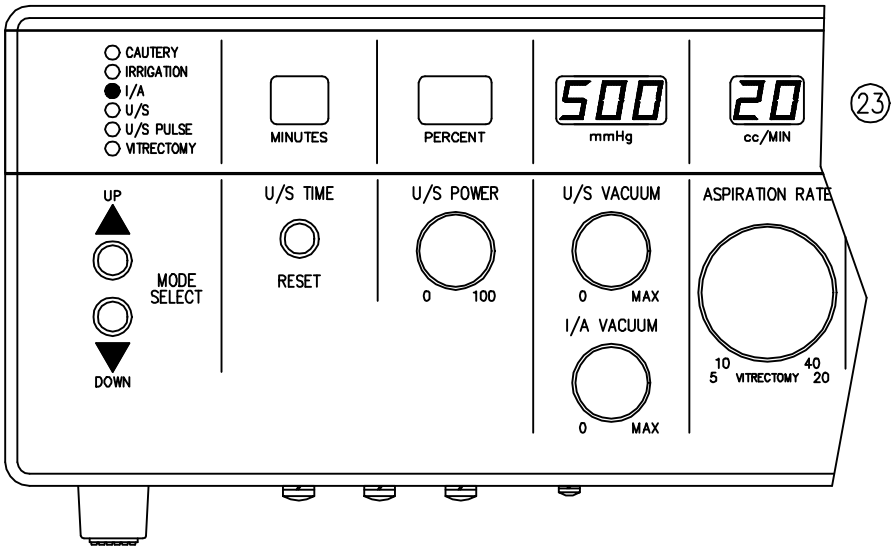
(17) Observe pump stop/restart elapsed time > 5 sec.

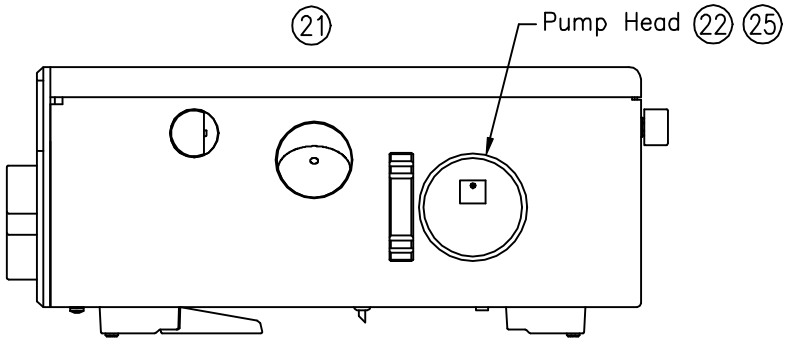
(18) Set I/A VACUUM to minimum setting (CCW).

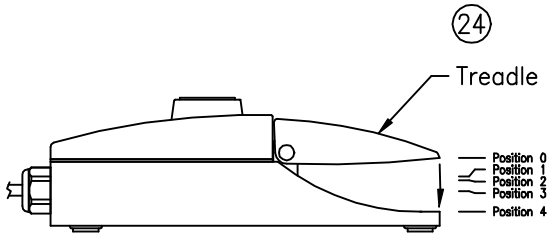
(19) Fully release footpedal treadle (Position 0) and immediately fully depress footpedal treadle (Position 4).

(20) Observe first vacuum indication ≤ 10 mmHg.

5.1.2 I/A FET (3/4)







(21) Remove hemostats and aspiration tubing.

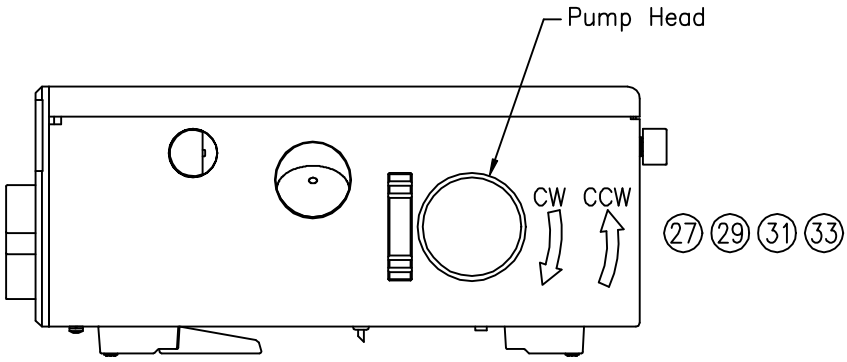
(22) Attach tape to pump head and mark with prominant dot.

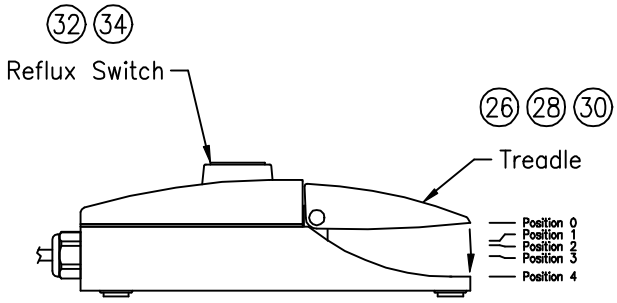
(23) Set ASPIRATION RATE to 20 cc/MIN.

(24) Fully depress footpedal treadle (Position 4) for 60 sec, then fully release footpedal treadle (Position 0).

(25) Observe number of pump head revolutions during (24) is 50 ± 10.

5.1.2 I/A FET (4/4)





(26) Depress footpedal treadle to Position 2.

(27) Observe pump head slow CW rotation.

(28) Gradually depress footpedal treadle slowly.

(29) Observe pump head CW rotation speed increase.

(30) Fully release footpedal treadle (Position 0).

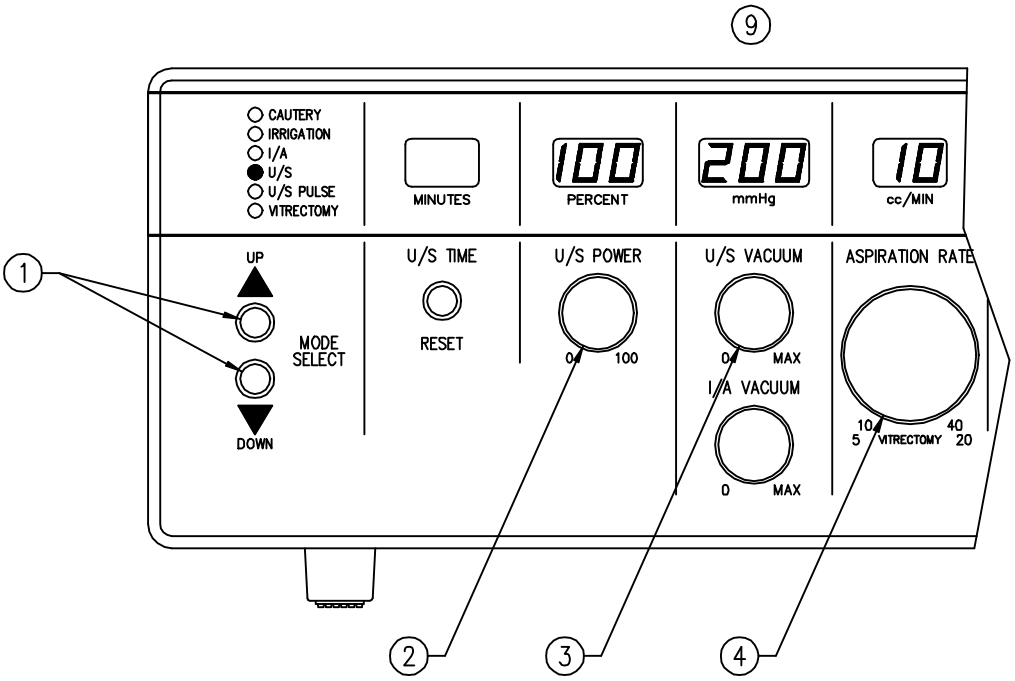
(31) Observe pump head non–rotation.

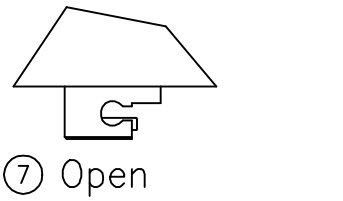
(32) Depress reflux switch.

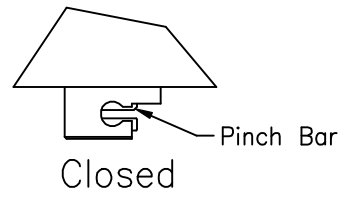
(33) Observe pump head CCW rotation.

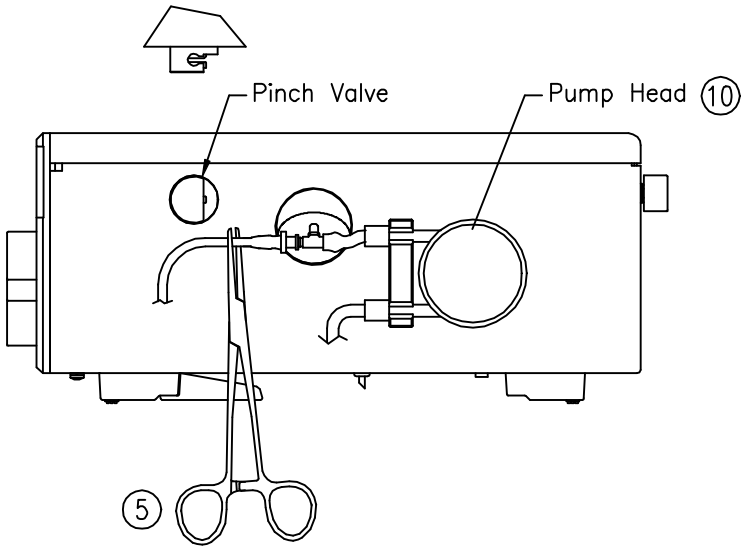
(34) Release reflux switch.

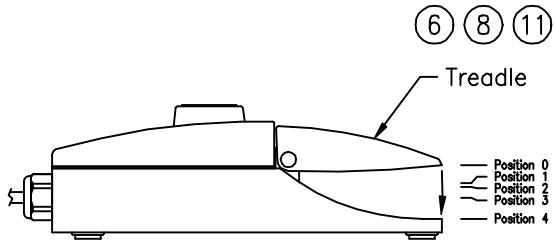
5.1.3 U/S STD FET (1/2)





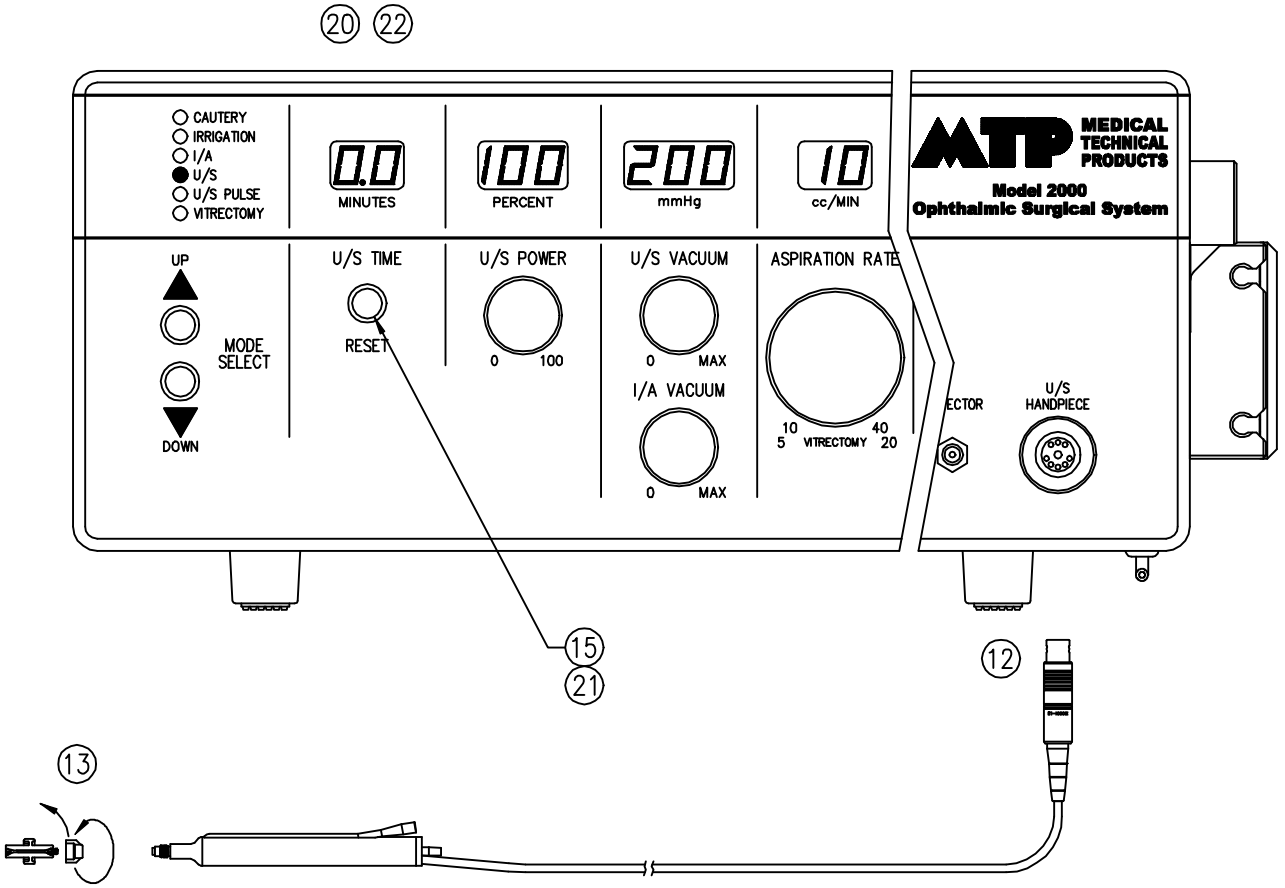


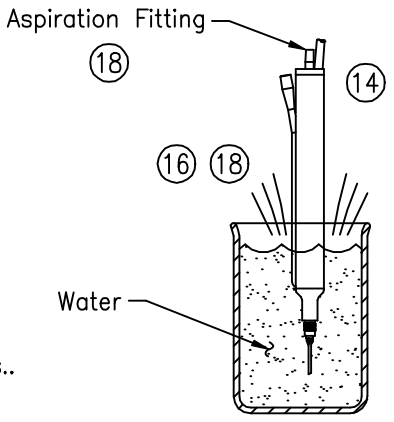


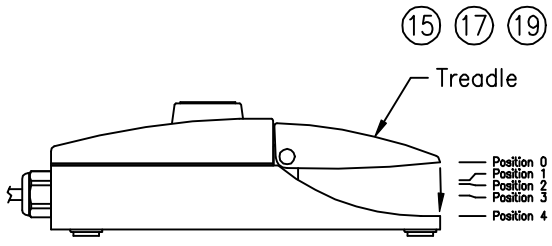


1. Set mode to U/S.
2. Set U/S POWER to 100%.
3. Set U/S VACUUM to 200 mmHg.
4. Set ASPIRATION RATE to 10 cc/MIN.
5. Install aspiration tubing as illustrated with hemostat.
6. Depress footpedal treadle to Position 1.
7. Observe pinch valve actuation to open position (pinch bar fully retracted).
8. Depress footpedal treadle to Position 2.
9. Observe vacuum increase to 200 ±20 mmHg.
10. Observe pump head non-rotation when vacuum reaches 200 ±20 mmHg.
11. Fully release footpedal treadle (Position 0).

5.1.3 U/S STD FET (2/2)







(12) Insert u/s handpiece into mating console connector.

(13) Remove cap from u/s tip holder. Use holder as a wrench and firmly attach u/s tip.

(14) Immerse u/s handpiece in water as illustrated.

(15) Actuate U/S TIME RESET switch.

(16) Depress footpedal treadle to Position 3 and hold ≥ 6 seconds..

(17) Observe low sound intensity of u/s handpiece.

(18) Gradually depress footpedal treadle fully (Position 4).

(19) Observe increased sound intensity of u/s handpiece and water presence at u/s handpiece aspiration fitting.

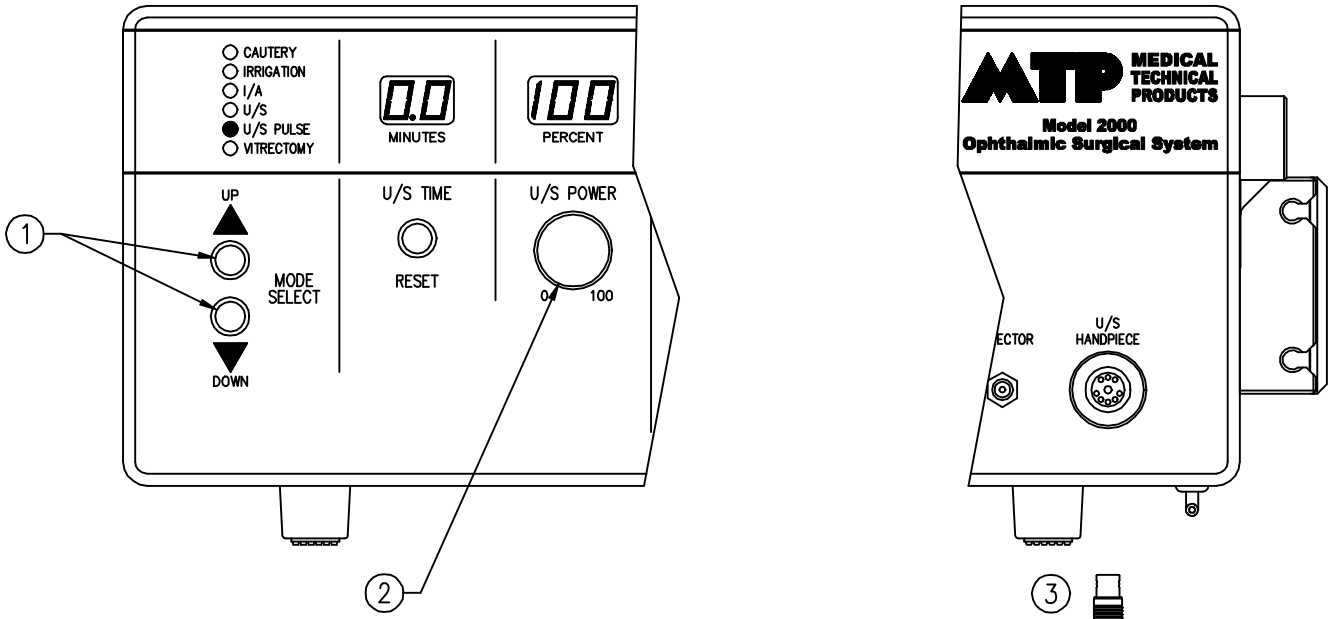
(20) Fully release footpedal treadle (Position 0).

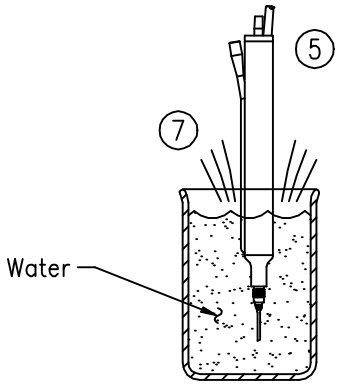
(21) Observe u/s time > 0.0 minutes.

(22) Actuate U/S TIME RESET switch.

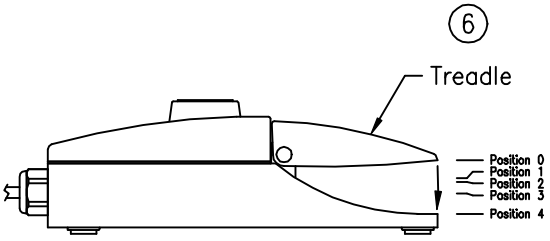
(23) Observe u/s time = 0.0 minutes.

5.1.4 U/S PULSE FET

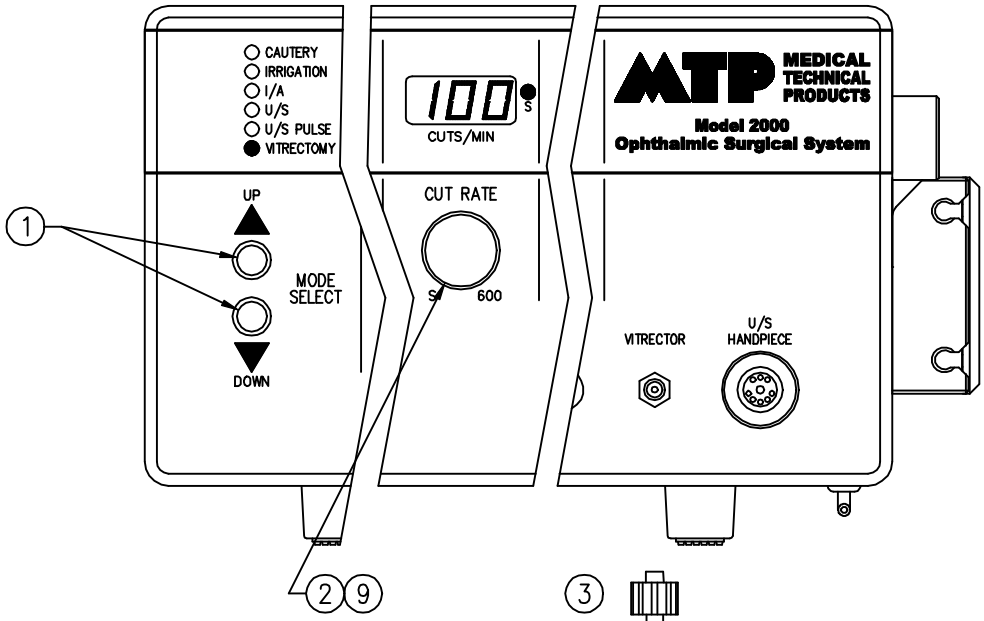


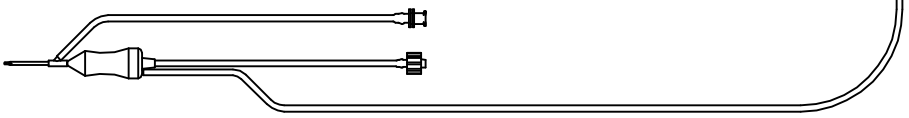


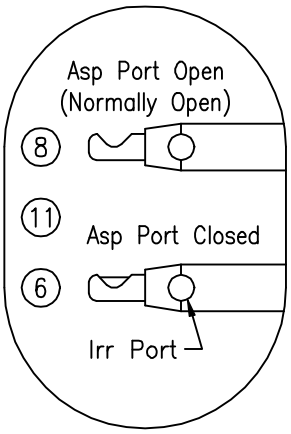
1. Set mode to U/S PULSE.
2. Set U/S POWER to 100%.
3. Insert u/s handpiece into mating console connector.
4. Remove cap from u/s tip holder. Use holder as a wrench and firmly attach u/s tip.
5. Immerse u/s handpiece in water as illustrated.
6. Fully depress footpedal treadle (Position 4).
7. Observe pulsing sound of u/s handpiece.

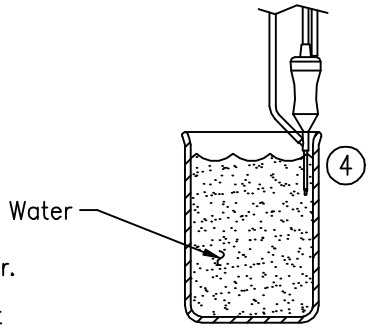


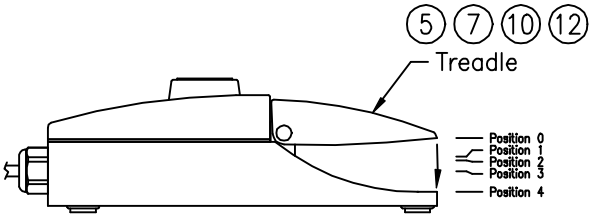
5.1.5 VIT FET











(1) Set mode to VITRECTOMY.

(2) Set CUT RATE to S (Single–Cut).

(3) Attach actuation tubing to mating pneumatic connector.

(4) Immerse vitrector in water as illustrated with asp port against wall of clear glass container.

(5) Fully depress footpedal treadle (Position 4).

(6) Observe asp port closed.

(7) Fully release footpedal treadle (Position 0).

(8) Observe asp port open.

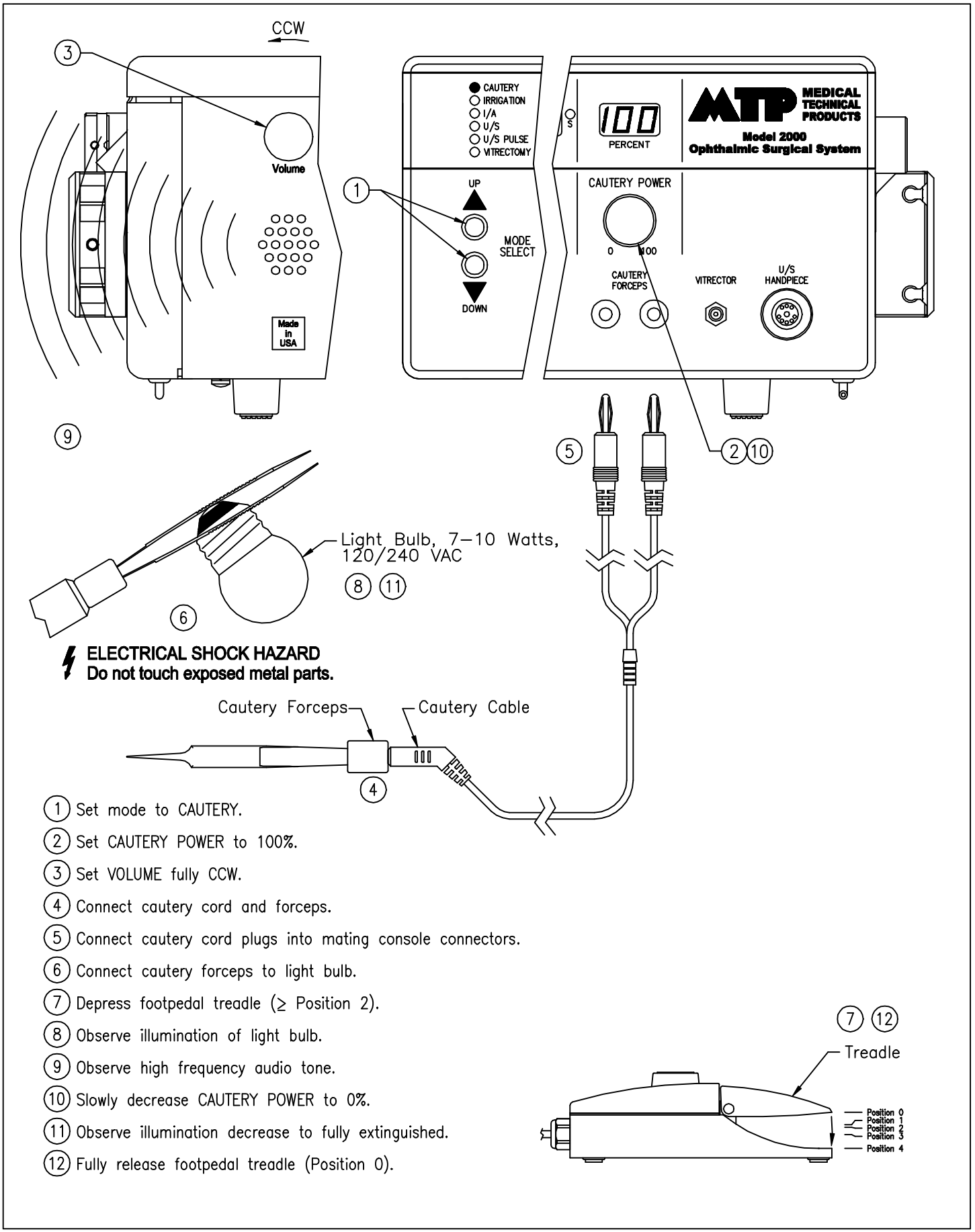
(9) Set CUT RATE to 100 CUTS/MIN.

(10) Fully depress footpedal treadle (Position 4).

(11) Observe asp port open and close repeatedly.

(12) Fully release footpedal treadle (Position 0).

5.1.6 CAUTERY FET



1. Set mode to CAUTERY.
2. Set CAUTERY POWER to 100%.
3. Set VOLUME fully CCW.
4. Connect cautery cord and forceps.
5. Connect cautery cord plugs into mating console connectors.
6. Connect cautery forceps to light bulb.
7. Depress footpedal treadle (≥ Position 2).
8. Observe illumination of light bulb.
9. Observe high frequency audio tone.
10. Slowly decrease CAUTERY POWER to 0%.
11. Observe illumination decrease to fully extinguished.
12. Fully release footpedal treadle (Position 0).

5.2 Field Service

MTP will permit field service, especially to assist the international distributor to remedy customer-reported console nonconformances. Please note that a qualified technician/engineer is required prior to attempting any in-warranty or out-of-warranty nonconformance remedy. Field service should only be attempted by a qualified technician/engineer.

To confirm any reported nonconformance, MTP suggests performing the appropriate FET (Section 5.1) prior to attempting any nonconformance remedy.

On confirming the reported nonconformance, MTP recommends the powerful swapping method to isolate the nonconforming console assembly:

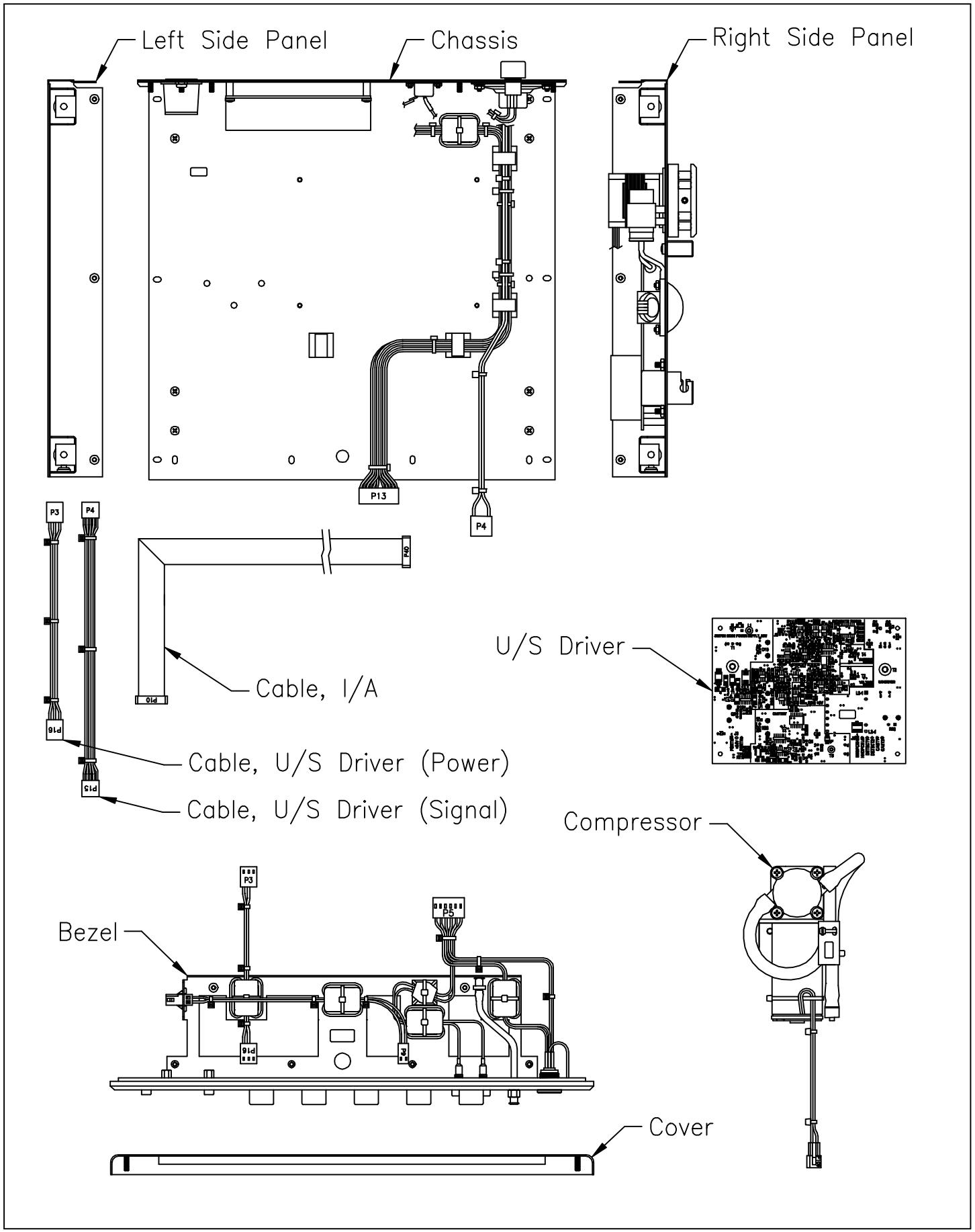
- Front Panel
- Right Side Panel
- Chassis
- U/S Driver
- Compressor
- Cables (3x)

If the nonconformance moves with the swapped assembly, the nonconforming assembly has been isolated. If not, same effort is repeated with a different assembly until the nonconforming assembly has been isolated.

Please note that the assemblies are interchangeable without need for re-calibration. Further, only keyed mating connectors were utilized, thus preventing inadvertent misconnection that could result in electrical damage to the swapped assemblies.

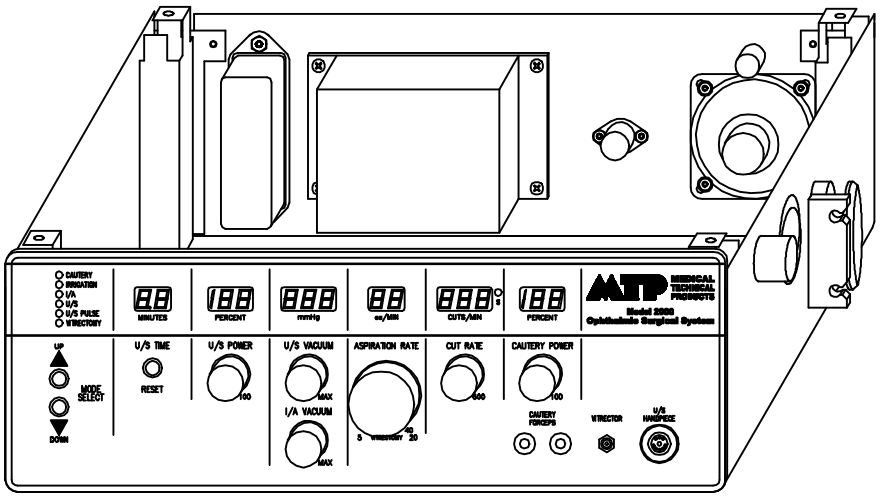
The powerful swapping method isolates the nonconforming assembly with both positive and negative indications of the swapped assembly nonconformance. That is, when the nonconforming assembly is swapped, the formerly nonconforming console is remedied and the previously conforming console is nonconforming. The swapping method very accurately isolates the nonconforming assembly. Further, to the international distributor's relief, using costly diagnostic instruments is unnecessary.

5.2.1 Console Assemblies Identification



5.2.2 Swapping Method

Nonconforming Console:

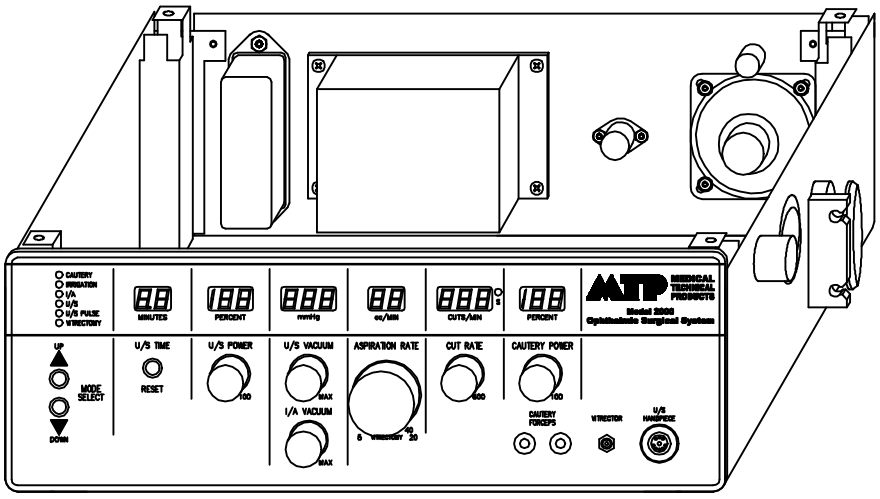


SWAP*

Assemblies:

- Bezel
- Right Side Panel
- Chassis
- U/S Driver
- Compressor
- Cables (3X)

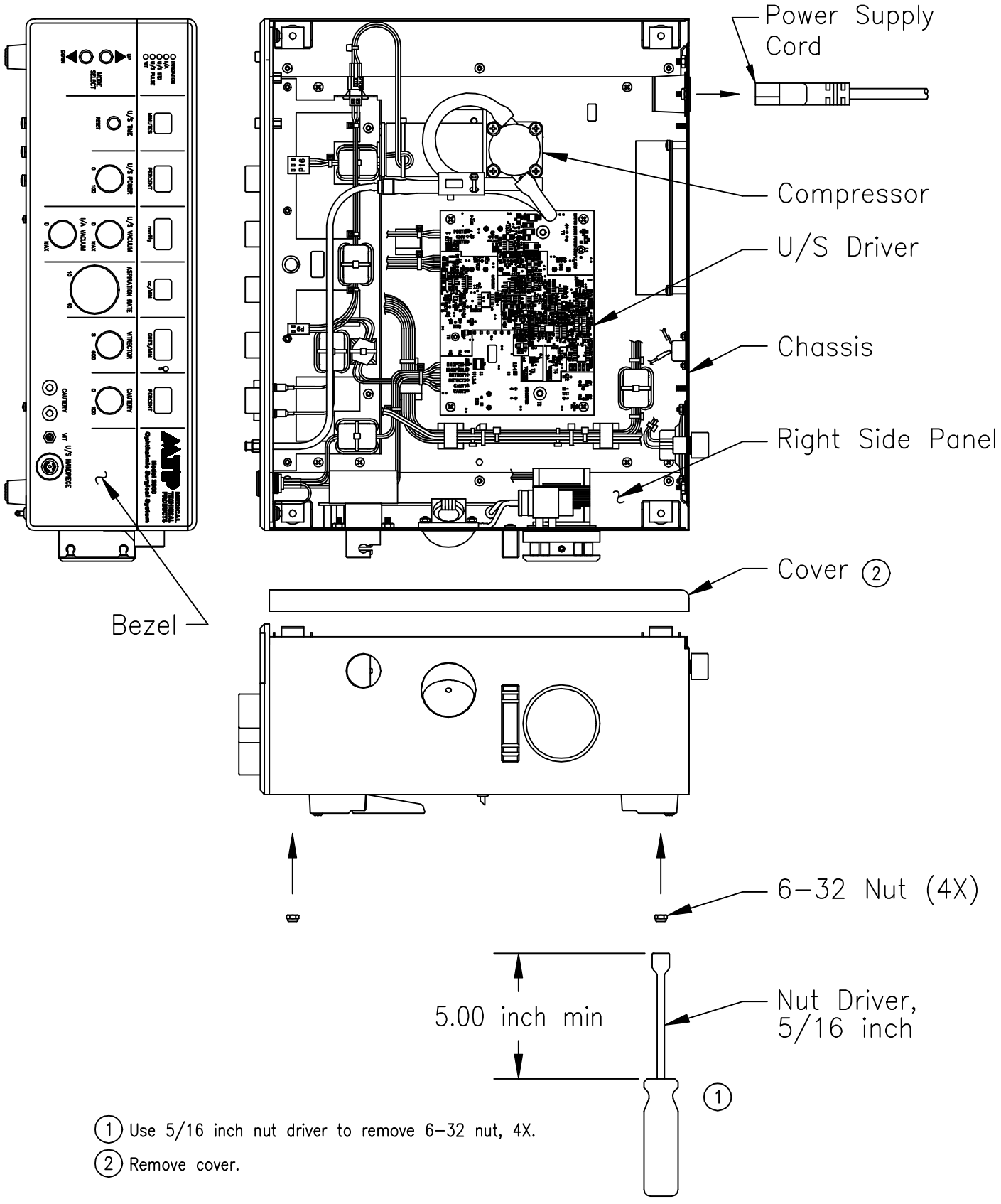
Conforming Console:



* Only one (1) assembly is selected per swap to isolate nonconforming assembly.

5.2.3 Console Disassembly (1/3)

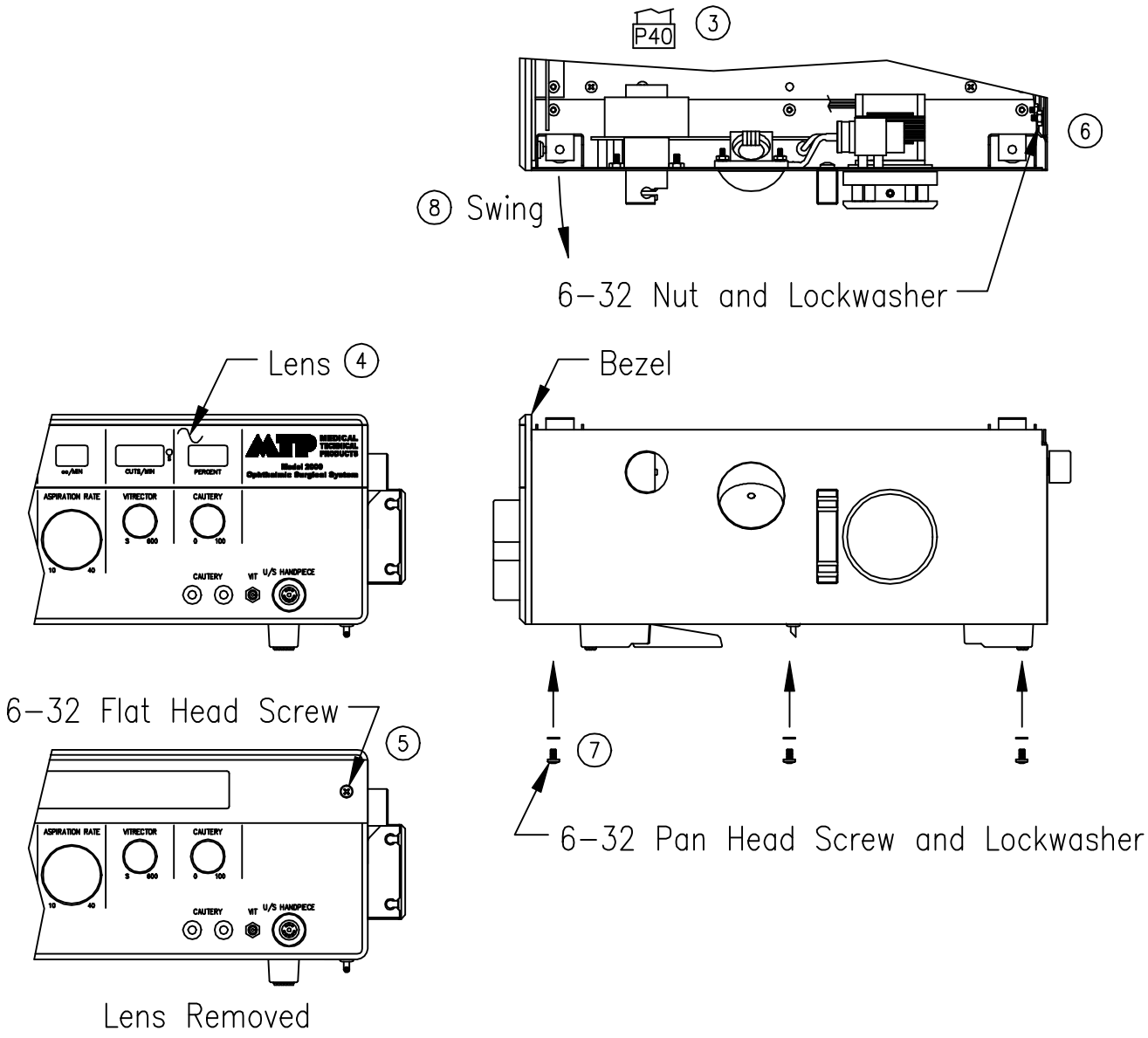
WARNING! Unplug Power Supply Cord Prior to Dissassembly



(1) Use 5/16 inch nut driver to remove 6-32 nut, 4X.

(2) Remove cover.

5.2.3 Console Disassembly (2/3)



3 Unplug P40.

4 Carefully pry lens from bezel. Use soft plastic tool. CAUTION: Do not scratch, mar or blemish lens or bezel finish. Apply release paper (wax paper) to back of lens to prevent adhesive contamination.

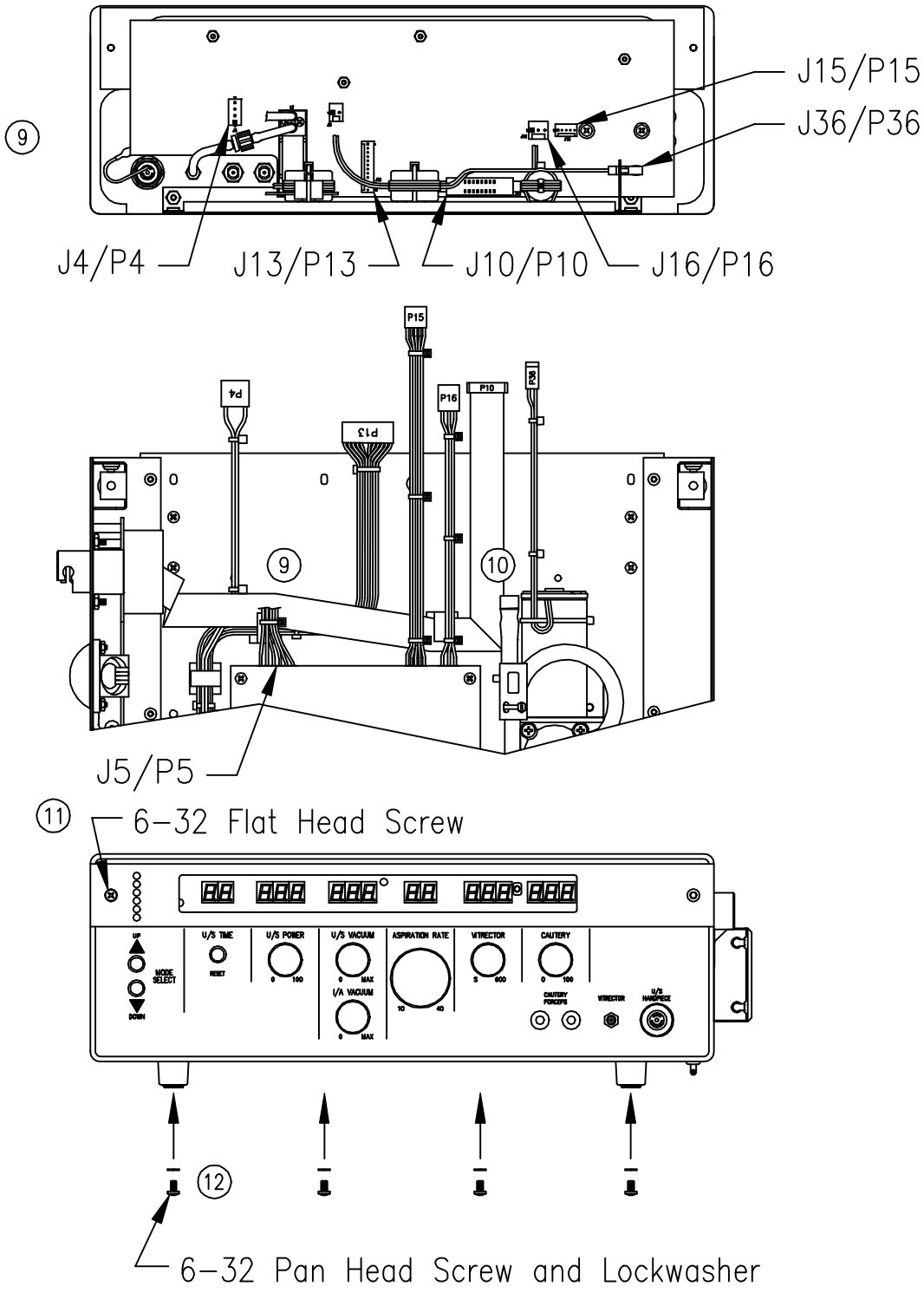
5 Remove 6–32 flat head screw using Phillips screwdriver.

6 Remove 6–32 nut and lockwasher using 5/16 inch wrench.

7 Remove 6–32 pan head screw and lockwasher, 3X, using Phillips screwdriver.

8 Swing right side panel in an arc to clear bezel. Slide right side panel off 6–32 stud in rear panel.

5.2.3 Console Disassembly (3/3)



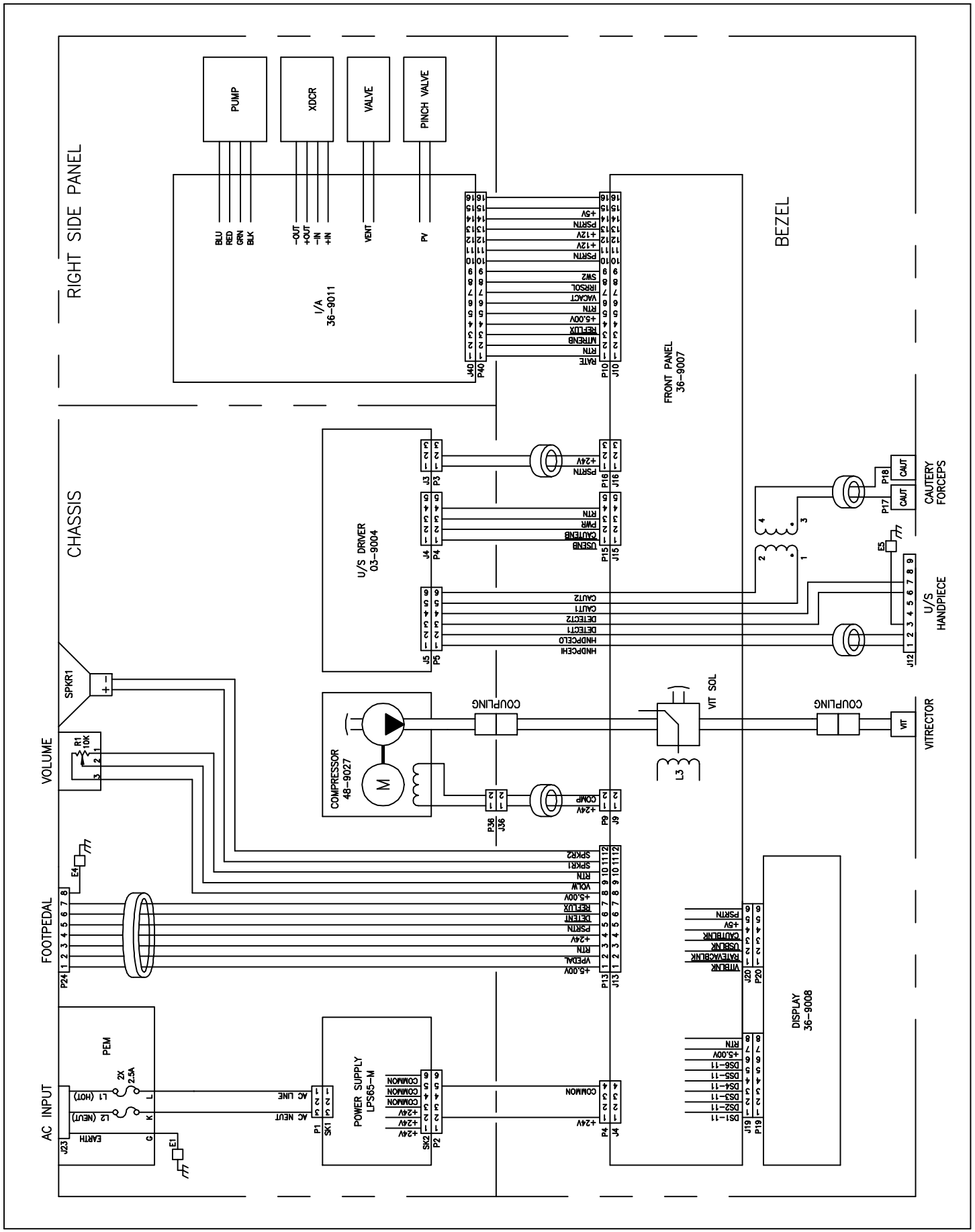
(9) Unplug P4, P5, P10, P13, P15, P16, P36.

(10) Disconnect tubing coupling (ccw turn/twist).

(11) Remove 6-32 flat head screw using Phillips screwdriver.

(12) Remove 6-32 pan head screw and lockwasher, 4X, using Phillips screwdriver.

5.2.4 Interconnect Diagram



5.3 Product Return Instructions

To obtain remedy of any nonconformance, the customer must obtain *Returned Material Authorization (RMA)* prior to returning the product to MTP, or an authorized MTP service center.

If a non-USA customer, please do not return any product to MTP using commercial airlines. Please return product, accompanied by a concise nonconformance description, with transportation charges prepaid via United Parcel Service (UPS), Airborne Express/DHL, Federal Express (Fedex), or Express Mail Service (EMS). Be sure that the Air Waybill clearly includes:

- ✓ *Country of Origin*: USA
- ✓ *Description*: Surgical Ophthalmic Instrument (Service/Repair)

To avoid Customs delay, MTP recommends including:

DECLARATION FOR FREE ENTRY OF RETURNED AMERICAN PRODUCTS

Reason for Return: *Service/Repair*
Estimated Charge: $250.00 USD
Harmonized Code: Schedule B 9018.50.0000
Description: Surgical Ophthalmic Instrument
Federal Tax Identification Number (EIN): 33-0327223

FDA Registration: 2025303
Product Code: HQC
Classification Device Name: Phacofragmentation System
FDA Regulation: Ophthalmic Devices 21CFR part 886.4670
Device Classification: Class II
Certificate to Foreign Government: Certificate 2528-3-2004
Approved 510(k) Substantial Equivalence Determination: K940084
Medical Device Listing (MDL): Q013706

MTP declares that the information given above is true and correct to the best of its knowledge and belief. Additionally, the articles described above were manufactured in the United States and are returned without having been advanced in value by any manufacturing process or by any other means. No drawback bounty, or allowance has been paid or admitted thereon, or on any part thereof. If any notice of exportation of articles with benefit of drawback was filed upon exportation of the merchandise, such notice has been abandoned.

5.4 MTP's Limited Liability

The Model 2000 is intended for use by medically-trained/qualified ophthalmic/cataract surgeons who bear full responsibility for safe use at all times. Further, to repeat MTP's earlier instruction (**Section 1 Introduction**), *the operator must read this manual carefully and become familiar with all its warnings.*

MTP makes no medical recommendation. Use of the Model 2000 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 such 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.

5.5 Limited Warranty

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 such 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.