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PULSAR MS

ANTERIOR SEGMENT SURGERY SYSTEM

INSTALLATION AND OPERATING MANUAL

OPTIKON 2000 S.p.A.

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OPTIKON 2000 S.p.A. is an ISO 9001 and ISO 13485 certified company that manufactures surgical and diagnostic devices for ophthalmology.

All OPTIKON 2000 products are manufactured in compliance with the requirements of Directive 93/42/EEC on medical devices.

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1. DISCLAIMER

OPTIKON 2000 S.p.A. requires the user of this system to carefully read specific warnings found in this manual. It is responsibility of the user to provide its personnel with a thorough understanding of the equipment operation before use. In no event shall Optikon 2000 S.p.A. be liable for any injury, incidental or consequential damages incurred by the purchaser, users or patients as a result of operation of the product.

Use of this system is a matter of professional medical judgment. Optikon 2000 S.p.A. is not responsible for any clinical problem resulting from mishandling this equipment and makes no medical recommendations.

OPTIKON 2000 S.p.A. declares to be responsible for the safety, reliability and performance only if:

- updates, calibrations and repairs are carried out by personnel which has been authorised by OPTIKON 2000 S.p.A.;
- the system is used in compliance with the user instructions;
- the mains electric installation to which the system is connected complies with the IEC Safety Regulations.

IMPORTANT NOTICE

Every effort has been made so that all the illustrations and information precisely represent the product and its operation as they were at the time this manual was printed. It is possible, however, that during the existence of this manual modifications have been made in order to continue to effectively satisfy the needs of the users. At times, such modifications are made without advance notice

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2. LIMITED WARRANTY CONDITIONS

All OPTIKON 2000 S.p.A. instruments and accessories sold and installed in the European Union are guaranteed against manufacturing and material defects for ONE YEAR from the invoicing date. Warranty on consumable material is limited to the first use of the apparatus.

For the warranty conditions outside the European Union, contact your authorised OPTIKON 2000 S.p.A. distributor.

All items under warranty will be repaired or replaced free of charge.

The warranty includes the research for the defect's cause, repair of the failure and final inspection of the unit or components.

This warranty does not cover any problems which are the result of improper use, accidents, incorrect use and tampering or modifications made by persons who are not part of the authorised OPTIKON S.p.A. technical service.

OPTIKON 2000 S.p.A. reserves the right to verify, in case of failures, if the instrument and/or its accessories have been modified or tampered with in any way, or if they have been damaged by improper use.

OPTIKON 2000 S.p.A. also reserves the right to modify the instrument and/or its accessories in the event operating techniques require such modifications.

The warranty is not valid if the serial number of the instrument and/or accessories attributed by OPTIKON 2000 S.p.A. is missing, tampered with and/or unreadable.

The warranty does not include the expenses for returning the instrument and accessories: all charges for shipping, packaging etc. shall be borne by the buyer.

In the event of an explicit request for work by OPTIKON technicians, all travelling and lodging expenses shall be charged to the customer.

OPTIKON 2000 S.p.A. is not liable for damages caused during transport. If this occurs, the customer must immediately notify the carrier that handled the delivery.

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3. WARNINGS

Care in the handling of PULSAR surgical system constitutes one of the basic operating room principles which should always be adhered to, and no list of warnings can replace such care.

The warnings below provide the operator with suitable instructions to assure safe, trouble free performance.

General warnings

- Before using the system, all medical personnel concerned must carefully read and understand the instructions contained in this user manual. Do not attempt to use the system if it does not work as defined in the operating procedures described herein.
- The use of the system must be limited to qualified medical personnel who are able to fully understand the potential risks connected with the use of the instrument and are suitably trained on the prevention and management of possible clinical complications.
- Before each operation, carry out the surgical configuration and operating procedures described herein. Do not use the system if it does not work properly and the “Troubleshooting Guide" section does not provide a satisfactory solution.
- Before using a surgical or non-surgical accessory with the PULSAR unit, verify its compatibility with the PULSAR apparatus, declared on the documents attached to the individual accessories.
- Sound emission capability of the equipment is tested at power-on. Verify that an acoustic signal is emitted during system initialization.
- Use of accessories and cables other than those provided with the unit may result in an increase of the emissions or in decreased immunity of the system. Portable and mobile communications equipment can affect the performance of the unit.
  - Carefully follow the instructions when installing and using the unit , in order to prevent harmful interferences with other devices in the vicinity. If the unit causes harmful interferences to other devices (determined by turning

the unit off and on), the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the other devices.
- Increase the distance between the equipment.
- Connect the unit into an outlet on a circuit different from that to which the other devices are connected.
- Consult your local distributor or OPTIKON 2000 technical assistance

Environmental warnings

- The system should never be used in the presence of flammable anaesthetics, disinfecting agents, cleaning agents, etc., due to possible fires or explosion.
- The use of flammable anaesthetics (N_2O), (O_2), should be avoided unless they are removed by a gas aspiration system.
- To ensure safe operation, do not install the system in a location where it may be exposed to heating appliances or radiators, direct sunlight or any other source of heat with extremely high temperatures.
- Install the PULSAR system so that the ventilation openings are not obstructed.
- Dispose waste collection fluids according to the local laws/regulations on disposal of organic materials.
- Do not dispose of the "PULSAR" unit as unsorted municipal waste. Dispose of it separately according to local electrical and electronic equipment disposal laws/regulations.

Electrical warnings

- The unit is already set up for use with a power supply voltage of 220V. Check that the local voltage is the same as that predetermined on the unit. Otherwise, prepare the unit for the local power supply voltage. In the countries where the local voltage is 100 - 120 V, replace the fuses of the unit with the appropriate fuses supplied. These operations must be carried out exclusively by appropriately trained personnel.
- To reduce the risk of electric shocks, do not remove the protective cover. Request the intervention of authorised service personnel.
- Connect the console of the PULSAR unit to a mains having the characteristics shown on the console's rear panel. To guarantee safety, a hospital grade power cord and plug must be used, the unit must be grounded.

- Before connecting the unit to the mains, or disconnecting it, make sure that the main switch of the console is off.
- When the PULSAR unit is not in use, keep the main switch turned off.
- To allow time for cooling, the fuses must be replaced after the main switch has been turned off for a few minutes.
- Replace the fuse with one of the same type, as indicated on the rear panel of the console.

Diathermy

- Risk of burns or fire; do not use diathermy near conductive materials such as metal bed parts, inner-spring mattresses, and the like. Renew electrode cables upon evidence of deterioration.
- Use only original OPTIKON 2000 S.p.A diathermy cables.
- Severe RF burns can result if the diathermy output current is diverted to the operator by careless handling.
- When the bipolar diathermy handpiece and a monitoring system are used at the same time, all the electrodes of the monitoring system that are not protected by resistors or high frequency inductors should be placed as far away as possible from the diathermy electrodes.
- The cable of the bipolar diathermy should not touch the patient or other cables.
- Always use the lowest output diathermy power level which is compatible to the surgical application.
- An evident low output level or a faulty operation of the bipolar diathermy handpiece, even though the equipment has been set for a normal use, may indicate a bad contact in the electrodes connection.
- Excessive diathermy for the level of power selected could indicate a fault. In this case, stop using the system at once.
- During bipolar diathermy handpiece operation, do not use flammable anaesthetics, nitrogen monoxide, oxygen, unless they are vented by a suitable aspiration system.

- Flammable materials such as disinfecting agents and cleaning agents should be evaporated before using the bipolar diathermy handpiece. Some materials such as cotton wool or gauze, if soaked with oxygen, can catch fire because of the sparks caused by the equipment in its normal use.
- There is a possible risk for patients carrying cardiac stimulator or stimulating electrodes because of RF interference caused by diathermy generator. The stimulator itself can fail. Should any doubt arise, apply to the cardiology division for advice.
- Caution: Possible interference with other medical equipment when the bipolar diathermy handpiece is in use.

Handpieces

- Do not allow the tip of the vitrectomy probe, diathermy, or I/A handpiece to touch metallic objects.
- Do not attempt to alter the shape of any part of a handpiece.
- Do not attempt to separate the plug from the cable.
- Do not store or use a handpiece if wet or moist.

I/A

- Carefully observe the indications of **"Irrigation/Aspiration Tubing Set-up"** paragraph in this manual. The failure to follow these indications could have serious consequences.
- Correct set-up of irrigation and aspiration lines is critical to ensure proper operation of the PULSAR unit.
- Use only original OPTIKON 2000 S.P.A. tubing sets.
- Do not prime or tune the handpiece while the tip is in the eye of the patient; this could result in patient injury.
- Check that the BSS bottle is placed at or above the patient's eye level.

- Before starting an intervention, ensure that the volume of available irrigation solution is sufficient and monitor it throughout the intervention.

- Make sure that the quantity of aspirated fluids does not exceed the maximum capacity of the collection bag, as this may result in an hazardous situation to the patient or the operators.

- During the operation constantly monitor the saline solution level in the irrigation bottle. If the amount of saline solution is deemed insufficient for completing the operation, immediately inform the surgeon and proceed to replace the irrigation bottle according to the following procedure:

1. Interrupt the surgical procedure and remove the handpiece's tip from the incision.
2. Close the clamp on the infusion set's line.
3. Unhook the bottle from the I.V. pole when the bottle is almost empty.
4. Remove the infusion set's spike from the bottle, being careful not to touch it with your hands and not to allow it to come into contact with any non-sterile material.
5. Insert the infusion set's spike in the cap of the new bottle and hook it to the I.V. pole.
6. If the drip chamber becomes completely empty, squeeze it to fill it with saline solution until it is approximately 50% full.
7. Reopen the irrigation clamp.

Note: If air bubbles are observed in the infusion set's line or in the irrigation line, ask the surgeon to activate just irrigation until the bubbles have been expelled, before reinserting the surgical instrument's tip in the patient's eye

U/S

- Do not activate the phaco U/S handpiece with the phaco tip in air. The ultrasonic power should be applied to the phaco handpiece with the phaco tip immersed in a test chamber filled with infusion fluid or in a beaker of sterile fluid at ambient temperature. Otherwise handpiece damage may result.

- Do not check vibration by placing hand or finger against handpiece tip. Prolonged exposure to or direct contact with the vibrating tip may cause damage to healthy tissue.

- Always use the lowest ultrasonic output power level which is compatible to the surgical application.
- The phaco handpiece must be connected to the PULSAR irrigation/aspiration system and must not be used without it.
- Excessive U/S for the level of power selected could indicate a fault. In this case, stop using the system at once.

Vitrectomy

- Do not activate the vitrectomy handpiece with the tip in air. The tip should always be test run in a beaker of sterile solution. Testing in air will cause irreparable damage to the tip.

Footswitch

- Never lift or move footswitch by the cable. Damage may result.
- The footswitch is not autoclaveable.

Sterilization

- The re-use of materials labelled as “For single use” may be cause of malfunctions and/or infections which could severely affect patient’s safety.
- All reusable accessories are supplied non sterile. They must be first cleaned, then sterilized in autoclave as indicated on the relevant instructions for use. They could be damaged by the use of other sterilization methods, like hot air or “chemclave” sterilization.
- All disposable accessories are provided in a sterile condition and labelled as such. Do not sterilize them after use.

4. SYMBOLS

Table shown below reports some I.E.C. approved symbols and their meanings. In the absence of sufficient space, these symbols are often used on medical instruments to enable quick and simple communication of information and warnings. At times two or more symbols are combined together in order to obtain special meanings.

These are the symbols used on the PULSAR label. Before using the unit, familiarize yourself with the symbols and definitions provided in the table.

SYMBOLS PUBLISHED BY IEC

SYMBOL	DESCRIPTION
	MANUFACTURER (AND DATE OF MANUFACTURE, WHERE APPLICABLE)
	ALTERNATING CURRENT
	DIRECT CURRENT
	EQUIPOTENTIALITY
	WARNING
	ON (POWER: CONNECTION TO THE MAINS)
	CLOSED (CONNECTED TO MAINS)
	TYPE B APPLIED PART
	TYPE BF APPLIED PART
	SEPARATED WASTE COLLECTION FOR ELECTRICAL/ELECTRONIC EQUIPMENT
	RF EMISSION
	SEE OPERATING INSTRUCTIONS

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5. GENERAL INFORMATION

5.1 SYSTEM DESCRIPTION

PULSAR is a unit for anterior segment surgical procedures on the human eye. Reliability and versatility, combined with sound engineering design, make PULSAR unique among similar devices currently available on the world market. It is designed to perform irrigation, irrigation/aspiration, phacoemulsification, anterior vitrectomy and bipolar diathermy coagulation procedures.

PULSAR operates with time saving simplicity and is easy to use thanks to the LCD (Liquid Crystal Display) touch-screen user interface.

It can be operated with factory set parameters, or user defined setup parameters (user programs). All functions and operational parameters are independently set up by pressing the appropriate soft keys on the touch-screen. Once the selected function has been set up, it may be executed in real-time by simply depressing the footswitch.

The aspiration is equipped with a peristaltic pump system. The anticollapse system eliminates pulsation and increase fluid suction precision. Vacuum is programmable from 5 to 500 mmHg, step 5 mmHg.

Irrigation flow and Intra Ocular Pressure are regulated by the height of the irrigation source.

Gravity fed reflux from BSS irrigation source provides reverse flow in a perfectly sterile environment.

Versatility is assured by the wide range of available accessories, which provide the surgeon with the facility to undertake most ophthalmic procedures. All microsurgical handpieces are ergonomically designed for comfort in use and maximum manual dexterity. Custom option and variety of accessories allow tailoring “OPTIKON PULSAR” to your specific needs. Clear audio/visual alerts indicate situations requiring attention, plus ensuring patient safety.

The PULSAR unit is optimally safeguarded and built according to the latest INTERNATIONAL SECURITY STANDARDS. All possible safeguards are built-in so that the equipment will not react on inappropriate manipulations.

5.2 TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATIONS
Manufacturer.....	OPTIKON 2000 S.p.A. via del Casale di Settebagni, 13 00138 Rome - Italy
Model:.....	PULSAR Minimal Stress
Regulatory conformity:.....	93/42/EEC Directive on medical devices
Technical standards:.....	EN 60601-1 ; EN 60601-1-1 ; EN 60601-1-2
ENVIRONMENTAL SPECIFICATIONS	
Storage.....	temp. range between –10°C and +70°C, humidity 10-100% (non-condensing)
Operating	temp. range between +10°C and +40°C, humidity 30-75%
ELECTRICAL SPECIFICATIONS	
Input voltage:.....	selectable at 100/120/220/230 Vac
Frequency	50/60 Hz
Power consumption:	90 VA (Standard) 125 VA (peak)
Fuses:	220-240 Volt: 2 A T
.....	100-120 Volt: 4 A T
IRRIGATION	
Fluid delivery:	Gravity fed – eye pressure determined by the height of irrigation source
Valving element:	solenoid
Control:	System footswitch
ASPIRATION	
Aspiration pump types:.....	peristaltic
Actuating medium:.....	Pressurized air from external source
Default vacuum range:	User programmable

PARAMETER	SPECIFICATIONS
Available vacuum range:	5 to 500 mmHg
Default flow rate:	User programmable
Available flow rate range:	2 to 50cc/min
Available aspiration rise time: ...	2 to 50cc/min
Surgeon mode (linear aspiration):	Linear aspiration (vacuum and/or flow rate) from 0 to preset linearity controlled via system footswitch
Safety device:.....	Vacuum sensor; monitors the vacuum in the aspiration line
Control:	System footswitch

VIT (VITRECTOMY)

Handpiece type:	Pneumatically powered guillotine cutter (VIT)
Cutting mode:.....	Reciprocating motion
Default cut rate:	User programmable
Available cutting rate:	From 60 to 700 cuts per minute
Single cut:	Single cut mode available
Port size:	Adjustable from 0,2 to 0,7mm (reusable cutters only)
Actuating medium:.....	Pressurized air from internal source
Operating pressure:.....	190 KPa (27,5 +0/-1.5 PSI)
Surgeon mode (linear cut):	Linear cut rate from 0 to preset controlled via system footswitch
Control:	System footswitch

DIATH (DIATHERMY)

Type:	Bipolar generator – generator stops when RF power is not needed
Operating frequency:	2 MHz
Nominal power:.....	7W (450 Ohm LOAD)
No load max. voltage:	100 V
Default bipolar power:	User programmable
Available bipolar power:	5 to 100%. SURGEON MODE (linear power): Allows linear control of the DIATHERMY power via system footswitch depression
Handpiece type:	Bipolar microforceps, slim stat pencil eraser, intraocular diathermy handpieces
Diathermy cable:	Two poles, 26 gauges, 75 ohm, steam autoclavable. Use only original OPTIKON 2000 SpA diathermy cable
Control:	System footswitch

PARAMETER	SPECIFICATIONS

PHACOEMULSIFIER

Handpiece type:	piezoelectric
Frequency	Approx 40 KHz
Tip stroke:	From 0 to 100 µm
Power:	Panel or linear control of the U/S power via system footswitch depression
U/S Mode:	Linear or Panel; Continuous, Short Pulse (1,2,3,4,5,6,8,10,13,16,20,25,32,40Hz), Single Burst, Multi-Burst, Continuous Burst
U/S Timer:	From 0.00 minutes to 59.59 minutes
Timer EPT:	From 0.00 minutes to 59.59 minutes – equivalent Phaco Time display

CLASSIFICATION OF THE INSTRUMENT ACCORDING TO IEC 60601-1

Type of protection against electric shocks	Class 1
Degree of protection against electric shocks:	
Diathermy	Type BF, floating both at high and low frequencies
U/S	Type B
Degree of protection against harmful ingress of water	IPX1
Degree of protection against harmful ingress of water (footswitch):	IPX8
Degree of safety of application in the presence of a flammable anaesthetic mixture:	Not suitable

DIMENSIONS

Height	16 cm
Width	37 cm
Depth	40 cm
Weight	14 Kg

NOTES
1) The weight and dimensions indicated are approximate
2) Specifications subject to variations without advance notice.

5.3 CIRCUIT DIAGRAMS

Optikon 2000 S.p.A. will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are repairable.

5.4 EMC TABLES

5.4.1 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Pulsar MS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Pulsar MS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage 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	

5.4.2 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	• ±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 material, the relative humidity should be at least 30%
Electrical/fast transient/burst IEC 61000-4-4	• ±2 kV for power supply lines • ±1 kV for input/output lines	• ±2 kV for power supply lines • ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	• ±1 kV differential mode • ± 2kV common mode	• ±1 kV differential mode • ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	• <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 PULSAR MS requires continued operation during power mains interruptions, it is recommended that the PULSAR MS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable. The equipment does not contain any magnetically sensitive components.?	Power frequency magnetic field should be at level characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2.5 GHz	3 Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PULSAR MS, including cables, than the recommended separation distance calculated from he equation applicable to the frequency of the transmitter. Recommended separation distance: d= 1.2 √P d= 1.2 √P 80MHz to 800 MHz d= 2.3 √P 800MHz to 2.5 GHz where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: A

NOTE:
U_T is the a.c. mains voltage prior to application of the test level
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note2: 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) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access 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 (equipment or system) is used exceeds the applicable RF compliance level above, the (equipment or system) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pulsar MS unit.

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

5.4.3 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND PULSAR MS

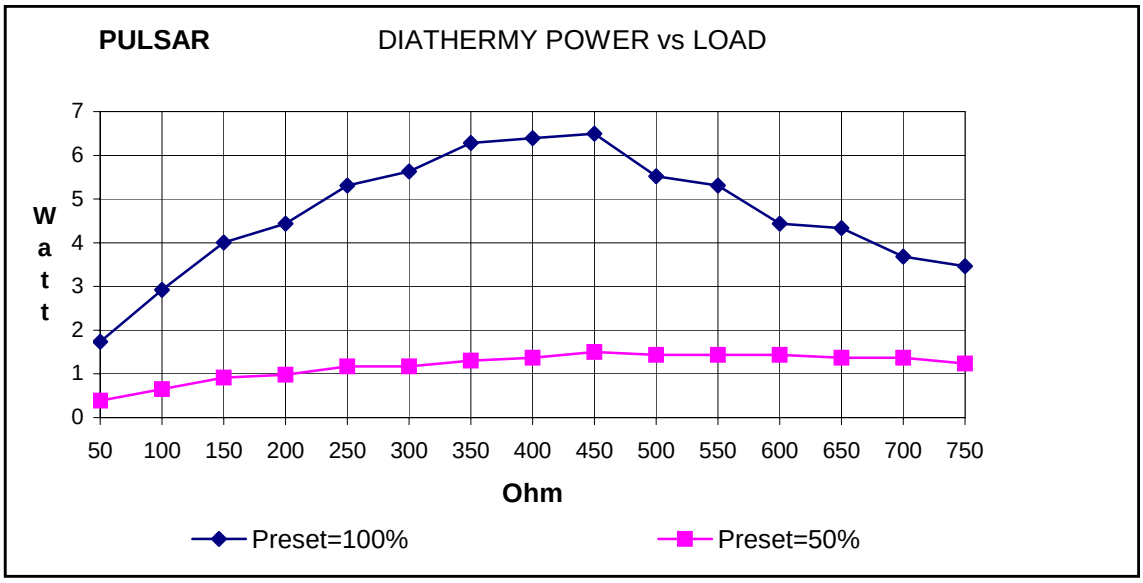
Pulsar MS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Pulsar MS can help preventing electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Pulsar MS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d= 1.2 \sqrt{P}$	80 MHz to 800 MHz $d= 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

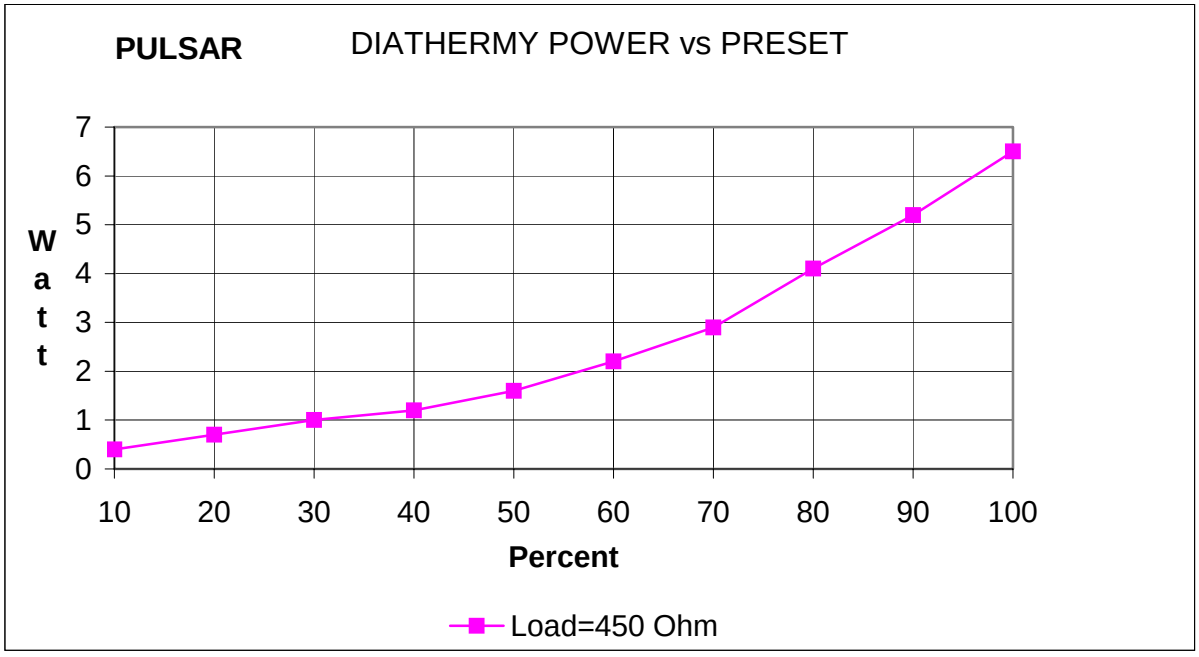
For transmitters rates at maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE:
Note 1- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

5.5 DIATHERMY POWER CHARACTERISTICS



Diathermy power vs load



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Diathermy power vs preset

6. INSTALLATION AND MAINTENANCE

6.1 INTRODUCTION

This section details a recommended installation procedure for the PULSAR surgery system.

The operational checks, carried out after the installation of the system to verify the proper functioning of the instrument, must be carried out exactly as indicated and must never be considered as recommended practice or encouragement for any surgical procedures.

To bring your PULSAR surgery system in operation, a series of cable and tubing connection for control console, footswitch, handpieces and I/A system must be made.

Follow the installation and operation instructions carefully in a step by step manner and, within a short time, you will have gained all the knowledge needed for successful operation of your PULSAR surgery system.

6.2 UNPACKING AND INITIAL INSPECTION

The unit has been packed to reduce the risk of damage during shipping to a minimum. Open the package and examine the components. When opening the package, handle all the components with care. When cutting the packing material, be careful not to damage the contents. If the package or contents are damaged, notify the carrier (post office, railway or shipping agent) and Optikon 2000 as soon as possible. Check that the contents correspond to those indicated on the attached shipping documents. Immediately report any discrepancies to Optikon 2000.

6.3 INSTALLATION PROCEDURE

To install the system, proceed as described below

1. Open the package of the apparatus and its accessories.
2. Place the PULSAR unit on the I.V. pole cart or on a stable surface.
3. Unwrap the handpieces and microsurgical instruments, place them in a secure location to prevent accidental dropping.

NOTE:
It is the responsibility of the user to clean and sterilize the handpieces, tips, I/A tubing and other microsurgical reusable instruments.

4. Check that the mains voltage corresponds to the one indicated on the rear panel.
5. Connect the linear footswitch cable to the "FOOTSWITCH" socket (fig. 3-5). Turn the retaining ring clockwise to secure the plug.
6. If the cart with automatic I.V. Pole is available, connect it to the I.V. Pole connector (fig. 3-6). The PULSAR tests if the automatic I.V. pole is present when the unit is switched on; therefore be sure that the pole is connected and powered.
7. Check that the available A.C. supply voltage corresponds to the one selected on the rear panel.
8. If the 181004 cart is used, leave the PULSAR mains switch into the on position and utilise the cart mains switch to power on/off the system.
9. Connect the remote control to the REMOTE CONTROL socket (Fig. 3-3) on the control panel's rear panel.

6.4 IRRIGATION/ASPIRATION SYSTEM SET-UP

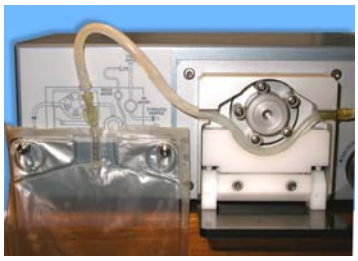
For proper I/A lines setup, follow the procedure outlined below (refer to Fig. 2)

1) Carefully open the peristaltic pump’s protection cover by pulling on the upper edge; the tubes' presser will open automatically, thus allowing the aspiration line to be installed.

2) Gently stretch the supplied irrigation tube and insert through the perpendicular intake port down into the side slot of the irrigation pinch valve.

3) Slightly flatten the reflux tube and insert it into reflux pinch valve. Attach the reflux's female connector to the "T" connector's side outlet.

4) Line the outlet (tube to the pump) connection of the **A**nterior **C**hamber **S**urge **S**uppression **S**ystem (**ACS**^{3}) to the dot of "**UNLOCK**" marking. Engage the ACS^3 in its receptacle, then rotate it 30° clockwise to line the outlet to the dot of "**LOCK**" marking. **Confirm that the cap of the ACS^3 is fully tightened.**



5) Insert the tube exiting the ACS3 system into the slot on the pump's right side, guide the tube around the rotor, downward, and then through the slot on the pump's left side. Close the pump's cover.

NOTE:
When using a reusable tubing set, tighten the ACS3 sensor's cover by screwing it firmly in place.

4) Close the pump's cover. The tubes' presser will move automatically, locking the tubes into the proper position. The aspiration line's end, located to the left of the pump, must be connected to the collection pouch.

5) Insert the drip chamber spike into the BSS bottle and hand the bottle to the I.V. pole.

6) Connect the end of the irrigation and aspiration lines to the corresponding connectors of the desired surgical handpiece.

Always run the I/A priming procedure before using the ultrasound handpiece. This procedure will test correct installation and operation of the I/A tubing pack and it will prime the line with fluids, thus avoiding possible malfunctions and injury to the patient.

7. EQUIPMENT OPERATION

7.1 EQUIPMENT DESCRIPTION

DISPLAY

The PULSAR unit is equipped with an interactive touch-screen LCD (Liquid Crystal Display). The user interface consists of simple screens specifically constructed for each function that show in the foreground the basic parameters and the sub-functions of the unit. By means of the keyboard on the front panel, the user can select the equipment function and adjust the relevant parameters by touching the screen in the appropriate areas. Actual and preset values for each parameter are displayed. The seven-section display to the right of the front panel shows the height of the I.V. pole. If a sterile drape is placed on the monitor the equipment can be operated by a sterile scrub nurse.

IRRIGATION SYSTEM

Irrigation in the PULSAR system is gravity fed. Fluid flow rate and IntraOcular Pressure (IOP) are determined by the infusion source height. A pinch valve allows sterile on/off control of the irrigation via the system footswitch or via the <IRR> button on the user's graphic interface. An orange LED on the <IRR> key indicates that the pinch valve is on.

Irrigation valve uses a linear solenoid which provides a high force and a quick response. A solenoid is a specially designed electro-magnet used to convert electrical energy into mechanical action: when the solenoid is energized by depressing the footswitch, the irrigation valve plunger is retracted allowing the irrigating solution to flow by gravity. When de-energized (footswitch released), the plunger closes the irrigation, thus preventing the fluid movement.

The PULSAR can control an automatic electric I.V. pole that provides adjustment of the irrigation source height.

ASPIRATION SYSTEM

The OPTIKON 2000 PULSAR surgery system delivers aspiration through the action of its peristaltic pump.

Fluids and particulate materials are aspirated at the distal end of the tip and subsequently deposited in a collection bag of the disposable or reusable circuit.

For safety the unit incorporates a negative pressure sensor that checks the negative pressure value in the aspiration line and regulates the pump's operation. The

negative pressure is read with a "closed system": a sterile membrane in the ACS3 cassette completely separates the negative pressure sensor from the sterile fluids.

The PULSAR unit's pump is controlled by a powerful microprocessor. The vacuum level can be preset from the control panel or checked by the surgeon by means of the footswitch (linear method).

VITRECTOMY (VIT)

The vitrectomy probe basically consists of two parts: the cutter tip (blade) and the body containing the drive mechanism actuated by compressed air coming from PULSAR console.

The probe uses the single acting actuator principle: Here air power is used to make the unit out-stroke (extend). Once the pressure has been removed, the return (in-stroke) is achieved by mechanical means, in this case by a built-in spring.

The tip contains the cutting element consisting of a matched outer (fixed) and inner longitudinally reciprocating tube.

The inner tube, used for aspiration, has a front end blade with sharpened outer edge. The front end of the outer tube has a side opening for cutting and aspiration. The tissues are cut and simultaneously aspirated by the longitudinal reciprocating action of the inner tube, generated by pneumatical impulses received from the control console.

The extremely close tolerances between the inner and outer tube create a mild constant tension to provide a self sharpening effect. It is evident that such precision plus the guillotine design results in an ideal cutting property. The cutting speed (from 60 to 700cuts/min) and vacuum level (from 5 to 500mmHg) are adjustable with the mode selection and function keys on the control console.

BIPOLAR DIATHERMY

The bipolar diathermy uses Radio Frequency (RF) currents to produce heating in body tissues, thus causing coagulation. The energy of a powerful RF oscillator (inside the control panel) is imparted to a pair of electrodes (small pinch valves or diathermy probes) that are applied to the biological tissues to be treated. The body tissue becomes the dielectric of a capacitor, and dielectric losses cause coagulation of the tissue. Dielectric loss phenomenon ensures that only the precise area of tissue is coagulated. The application of bipolar high frequency RF output additionally minimizes undesired neuromuscular stimulation and eliminates the need of a plate thereby reducing patient hazard. The PULSAR unit provides adjustable output power from 0.1 to approximately 7 watts @ 450 ohm, which is ideal for ophthalmic procedures.

PHACOEMULSIFICATION

The OPTIKON 2000 S.P.A. piezoelectric U/S handpiece contains a piezo transducer designed to vibrate at a frequency of 40 KHz and end strokes of about 100µm.

The U/S handpiece piezo transducer comprises three distinct structures: PIEZOELECTRIC CERAMIC ELEMENT, BODY and the surgical titanium alloy TIP.

The **PIEZOELECTRIC CERAMIC ELEMENT** converts the electric energy provided by the OPTIKON 2000 S.P.A. PULSAR control console directly into a mechanical vibratory motion of 40,000 cycles per second (40 KHz).

The **BODY** amplifies and mechanically transmits the motion of the piezoelectric ceramic to the surgical tip.

The **TIP** vibrates longitudinally at high velocity thus enabling a fragmentation of tissue very locally, around tip's contact surface. The OPTIKON 2000 S.P.A. titanium alloy tips can be re-used and have a long life.

The internal energy loss processes of the piezo ceramic element leads to a warm up of piezo transducer during high frequency vibration work, therefore the aspirated fluid from the eye is also used for heat dissipating.

The ***Minimal Stress*** logo indicates an exclusive patented feature of our phacoemulsifier, which leads to an extraordinary innovation in the phaco surgery.

This feature has been achieved by measuring the phaco tip movement (stroke) in real time. This information is used by the microprocessor in order to stabilize the stroke of the tip.

The main advantages of this system are:

- U/S Power preset indicates the effective tip stroke and corresponds to **microns of tip movement.**
- Different phaco handpieces are equalized and compensated against the typical degradation of efficiency due to aging.
- The amount of tip vibration is no longer affected by diversity in cataract hardness as well as temperature fluctuations in the handpiece.
- Reduction of corneal burns is likely to be expected as the required average energy and peak energy are lower compared to standard phacoemulsification.
- Reduction of bouncing of cataract fragments.
- Handpieces can be tested by the equipment in order to verify their efficiency, avoiding to operate when below the acceptable limits.

Ultrasonic power can be delivered in Continuous or Pulsed mode.

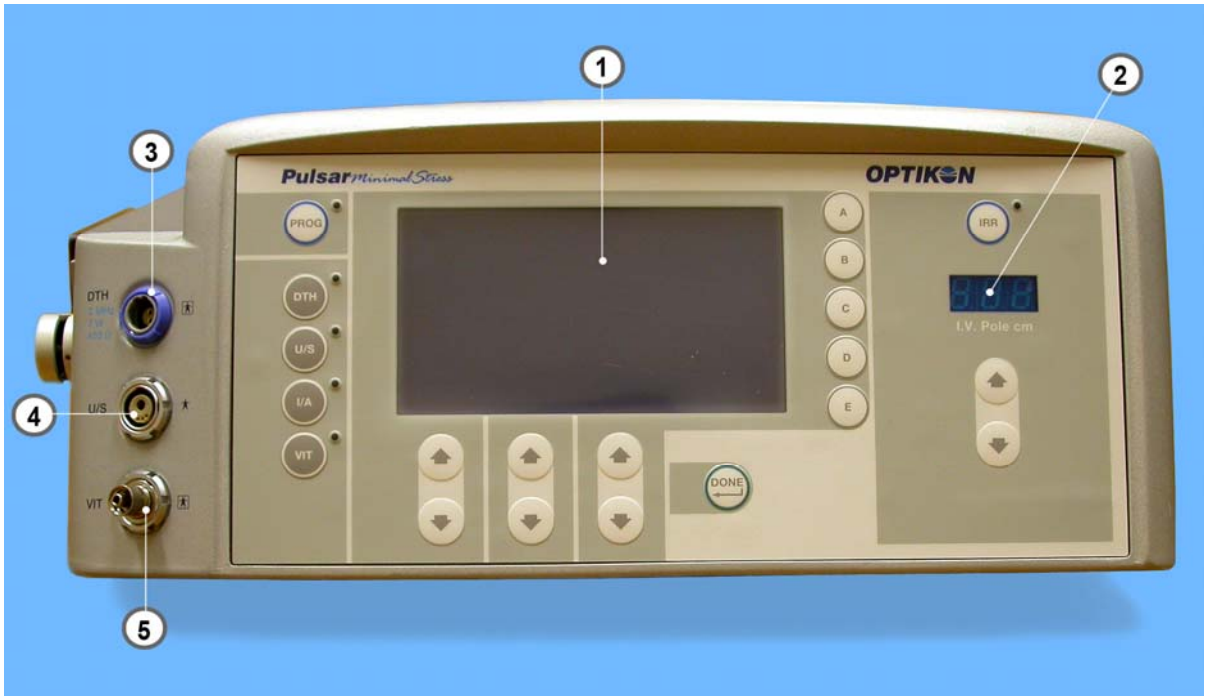
Continuous phaco power provides continuous uninterrupted phaco power to the handpiece and requires no pulse rate settings.

Pulsed phaco power causes the power to be pulsed at predetermined intervals when the footswitch is in position 3. Within the Pulsed Mode settings the surgeon can also select:.

- **Pulsed 1-40Hz** is available in linear or panel power**.** It generates periodic pulses of U/S power. The user may select from a range of 1-40 pulses/sec.
- **Single Burst.** Delivers a single burst of U/S power of 120 ms duration. The surgeon must return to footswitch position 2, pause for approx. ½ sec and then depress it back into position 3 to obtain an additional burst.
- **Multi Burst.** Generates bursts of U/S power of 80 ms duration, with additional bursts deployed beginning at approx. 1 burst per second when foot position 3 is first entered. As the footswitch is depressed further, the frequency of bursts will increase up to a maximum rate of 4 bursts per second.
- **Continuous Burst.** Delivers an 80 ms burst duration. As the footswitch is depressed through position 3, the bursts will get closer and closer together. At maximum depression of the footswitch the bursts will blend together and the equipment will deliver continuous U/S power.

7.2 EQUIPMENT LAYOUT

This section contains information on the configuration of the apparatus. All operating controls and adjustments are identified and described further on. Sockets and other elements on the front panel are described in Fig. 1. Left side (pump side) of the equipment is described in fig. 2. Rear panel connectors are identified in Fig. 3.



Front view (Fig. 1)

1) LCD DISPLAY

This display allows the operator to do the following:

- View the current functions
- Read all actual and preset values
- Program the equipment and footswitch

2) ALPHANUMERIC DISPLAY

View the height of the I.V. pole if it is connected to the instrument.

3) DIATHERMY SOCKET

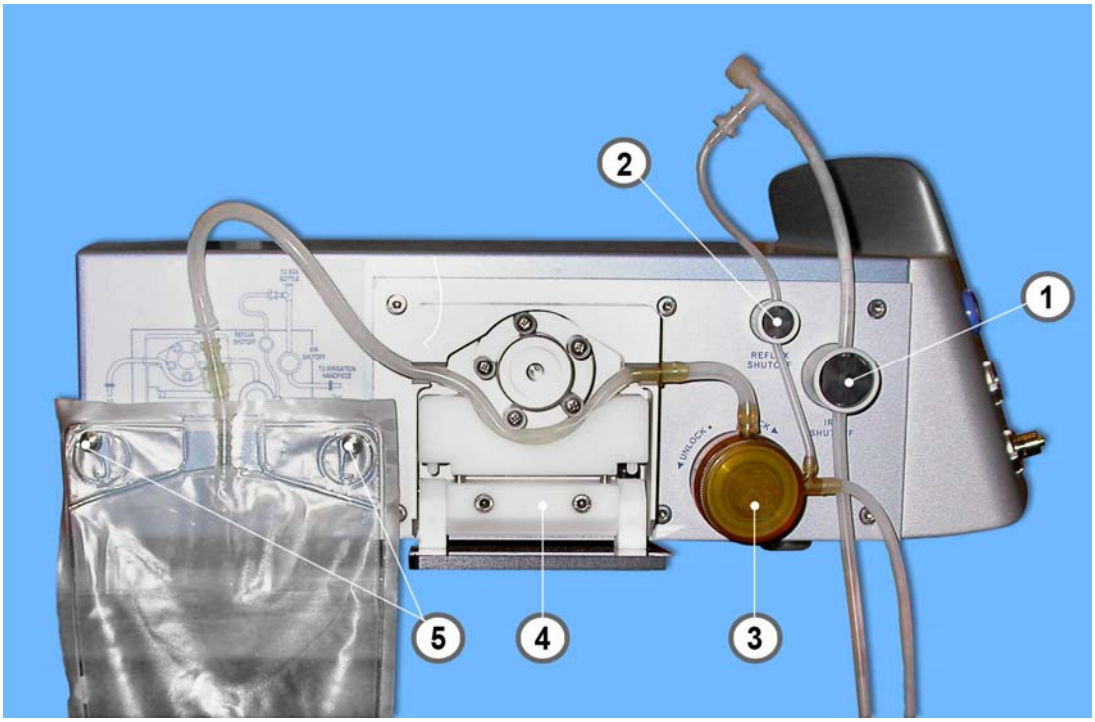
Bipolar diathermy handpiece cable fits into this socket.

4) U/S (Phaco) SOCKET

U/S handpiece cable plugs into this socket.

5) VITRECTOMY SOCKET

The activation line of the vitrectomy handpiece cable plugs into this socket.



Left side view (Fig. 2)

1) IRRIGATION PINCH VALVE

The irrigation line is run through this valve. The valve allows starting and stopping irrigation at surgeon's demand.

2) VENTING AND REFLUX PINCH VALVE

The Reflux/Venting pinch valve permits introduction of fresh BSS solution in the aspiration line, thus releasing the vacuum in the line, and eventually, reversing direction of flow.

3) ACS3 VACUUM SENSOR

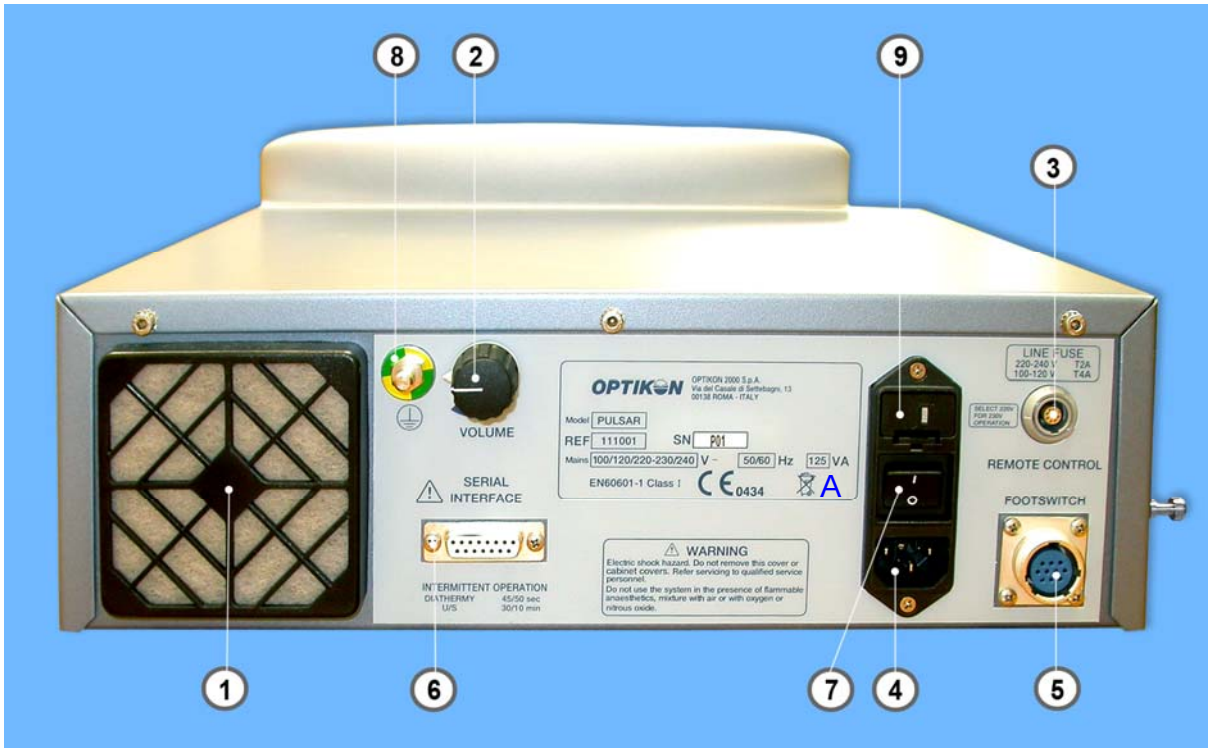
The ACS3 vacuum sensor monitors the vacuum level in the aspiration line in a sterile manner. It also prevents sudden vacuum surges, thus stabilizing the anterior chamber.

4) PERISTALTIC PUMP

This pump allows peristaltic aspiration in the PULSAR unit.

5) COLLECTION BAG SUPPORTS

These two brackets support and hold in place the collection bag at the end of the aspiration path.



Rear panel (fig. 3)

1) COOLING FAN

Removes hot air from the unit.

2) VOLUME CONTROL KNOB

This control knob allows adjustment to the surgeon's taste of the loudness of voice and sounds generated by the PULSAR unit.

3) REMOTE CONTROL

This is the remote control connector.

4) POWER

Mains input. The same module contains the power switch, the mains fuses, and the input voltage selector switch.

5) FOOTSWITCH CONNECTOR

This is the system footswitch connector socket. Footswitch depression activates the PULSAR functions.

6) I.V. POLE CONNECTOR

This connector provides a direct interface to the OPTIKON 2000 SpA automatic I.V. pole.

7) POWER (ON/OFF MAINS SWITCH GROUP)

The main switch turns the unit on/off. The mains fuses and the mains power cord socket are located on this switch.

8) UNIT'S GROUND CONNECTOR

This connector allows you to connect the PULSAR unit to the system's ground.

9) FUSE CARRIER

It contains the mains fuses. The voltage selector switch, located on the fuse carrier's cover, must be set for the voltage that is available in the zone in which the unit is to be used.

NOTE:
The abbreviations used on the unit and its user interface are defined as follows:

CUT RATE = Vitrectomy cutting rate (cuts per minute)
DTH = Bipolar diathermy
I/A = Irrigation/Aspiration
U/S = Ultrasounds
PROG = program area
IRR = Irrigation
LINEAR = Linear control mode (Linear footswitch control)
PANEL = Panel control mode
VIT = Vitrectomy

7.3 USER INTERFACE

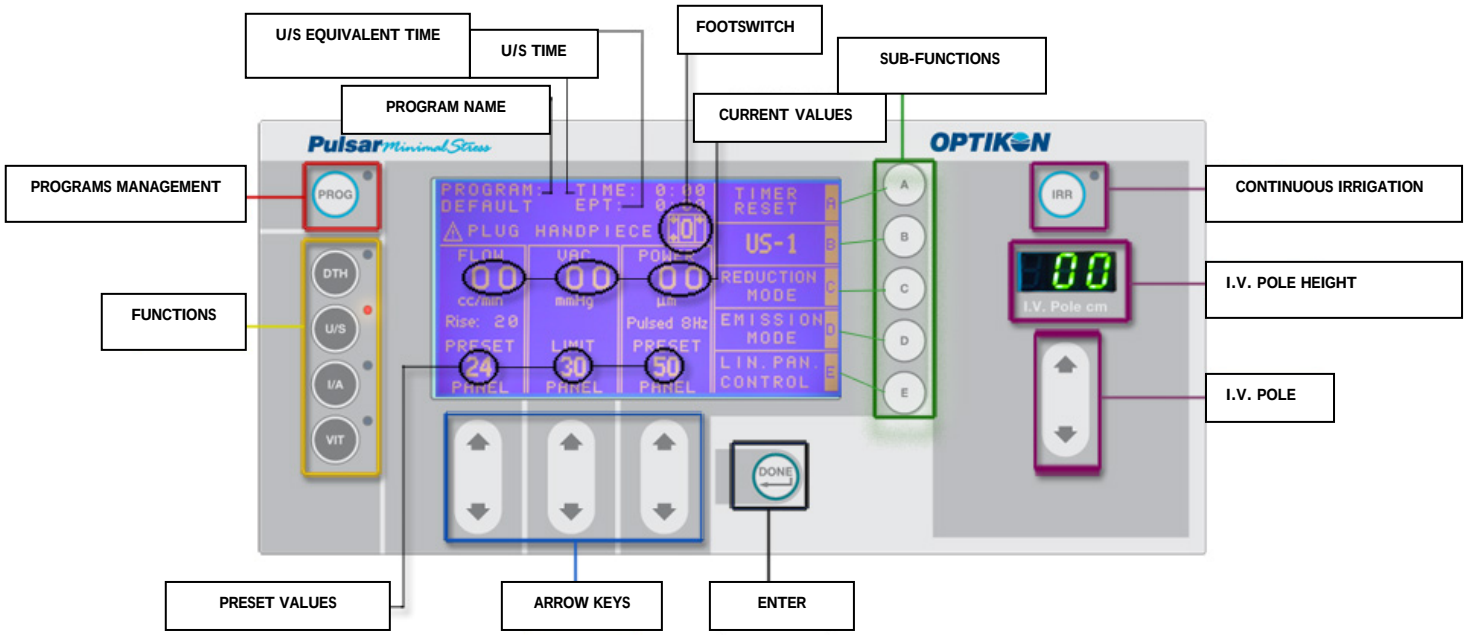
The PULSAR unit is equipped with an interactive touch-screen LCD (Liquid Crystal Display). The user interface consists of simple screens specifically constructed for each function that show in the foreground the basic parameters and the sub-functions of the unit. By means of the keyboard on the front panel, the user can select the equipment function and adjust the relevant parameters by touching the

screen in the appropriate areas. The seven-section display to the right of the front panel shows the height of the I.V. pole. If a sterile cloth is placed on the monitor, the unit can be activated by a sterile instrument nurse.

The PULSAR system's user interface is structured so as to be easily understandable. On the left side of the panel are located the keys for selecting the instrument's four main functions (DTH = DIATHERMY, U/S = PHACOEMULSIFIER, I/A = IRRIGATION ASPIRATION, and VIT = VITRECTOMY) as well as the PROG function for storing programs.

The display is located in the middle of the control panel; it shows the screen for the selected function each time. The PULSAR unit's user interface was developed so that the preset and effective values of the parameters are always visible in the foreground in dedicated windows. To adjust (increase or decrease) a specific value, the user must press the arrow keys <UP> and <DOWN> located at the bottom of the display next to the fields to be modified. Once the parameter's values or the functioning modes have been modified, an asterisk will appear next to the program name to indicate that the program has been modified.

For a better explanation of user interface glossary and layout see following figure.



Function screen

The <DONE> key allows the instrument to return to the standard view mode. The letters to the right of the display make it possible to modify the instrument's settings. The box to the right of the control panel regards the settings of the BSS bottle, the IRR key makes it possible to have continuous irrigation (the illuminated

orange LED next to the IRR key indicates that the operating mode is continuous irrigation), and the numerical display indicates the height of the bottle when the cart 181004 is connected. The <UP> and <DOWN> arrow keys raise and lower the bottle.

NOTE:

The knob located under the front panel of the Pulsar MS can be used to adjust the brightness of the display.

7.4 VOICE PROMPTING

In an operating room, the console of the unit is often located behind the surgeon who, as a consequence, cannot use the monitor to check the state of the machine or monitor the operating conditions for any irregularities.

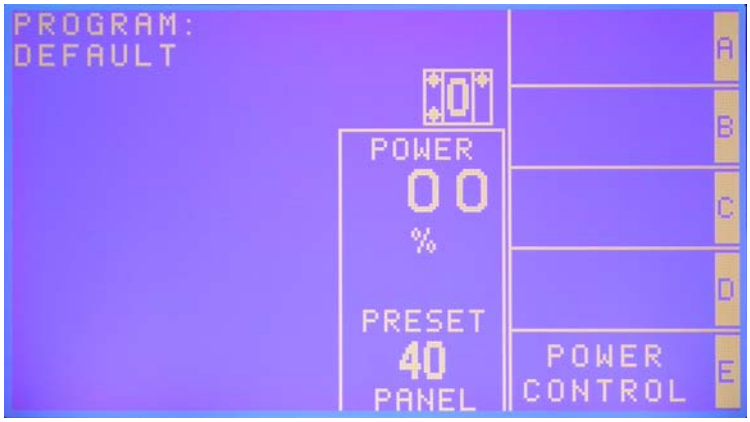
Because of that, the PULSAR unit not only is provided with an audio frequency synthesizer capable of generating sounds of opportune volume and frequency, but it also features a human speech synthesizer.

The speech synthesizer is used to confirm function selection (DIATH, I/A, VIT etc.).

8. EQUIPMENT OPERATION

8.1 BIPOLAR DIATHERMY

User Interface



Parameter windows available
- *Power*

- Irrigation parameters
  - Status *IRR* (ON/OFF)
  - *I.V. Pole height*

- Diathermy parameters
  - Power % (0–100%)
  - Mode (linear/panel)

Operation

Touching the DTH function key, DTH screen will be displayed and the blue LED corresponding to the key will light up. For footswitch operation please refer to the relevant selection.

1) Insert the plug of the desired handpiece connecting cord into the "DTH" socket on the control console (fig. 1-3)

2) Touch the "DTH" key to select the bipolar diathermy mode. The speech synthesizer announces "DIATHERMY." The window of the corresponding parameters will show the energy output (middle value on the POWER window) and the preset mode (the value at the bottom).

3) If you are satisfied with the actual settings, just go to step 5.

4) Preset power value can be adjusted by means of the <UP>/<DOWN> arrow keys next to the POWER window (below). If you are uncertain about the power to use, it is always advisable to begin with a low setting (such as 30%) eventually increasing it gradually up to obtain desired surgical effect. The bipolar diathermy can operate both in **fixed panel power control mode** or **linear surgeon power control mode**. In the latter case, the delivered power is linearly controlled by footswitch depression from 5% to preset limit. To switch from LINEAR SURGEON mode to FIXED PANEL or vice-versa, use POWER CONTROL, <E> key.

NOTE:
Adjusting a parameter will not undo the default parameters. To recall the default parameters or to permanently store the new settings in the machine memory, see paragraph "8.7. TO RECALL OR STORE A PROGRAM".

5) When diathermy is activated by depressing footswitch, diathermy power is delivered to the handpiece and an audible tone of continuous pitch is automatically generated to alert the operator.

6) Excessive diathermy for the level of power selected could indicate a fault. In this case, stop using the system at once.

NOTE:
The diathermy system is complemented by a comprehensive range of ancillary equipments including bipolar pencil erasers, microforceps and various probes tailored to surgeon specific requirements.

8.2 I/A (IRRIGATION/ASPIRATION)

User Interface

- Parameter windows available
  - *FLOW (aspiration flow)*
  - *VAC (limit vacuum)*
- Irrigation parameters
  - Status (ON/OFF)
  - *I.V. Pole height*
- Aspiration parameters
  - Vacuum *mmHg* (5 – 500)
  - *Flow rate cc/min (2-50)*
  - Mode (linear/panel)

Touching the I/A function key, the IRRIGATION/ASPIRATION screen will be displayed and the orange LED corresponding to the key will light up. Swapping between memories I/A 1 and I/A 2 can also be achieved by means of the footswitch. For footswitch operation please refer to the relevant section.

Operation

1) Touch the <I/A> button on the LCD screen to select the Irrigation/Aspiration mode. When the <I/A> button is pressed, the voice synthesizer will announce "I/A one." Two windows are displayed on the Irrigation/Aspiration screen: the flow (FLOW) window and the vacuum (VAC) window.
2) Select required I/A tip and gently insert into the coaxial I/A handpiece.
3) Fit the silicone sleeve over the I/A tip cap. The sleeve should be gently pressed onto the tip cap until the sleeve clears the aspiration port on the I/A tip.
4) Attach the I/A tubes from the installed irrigation aspiration lines by pushing the end fittings into the corresponding fittings on the handpiece tubing.
5) Set I.V. pole height in the Irrigation window so that the BSS bottle is hung 50 to 70 centimetres higher than the patient eye level.
6) Press the <B> key to switch between mode I/A 1 e I/A 2.

7) The set values of flow and vacuum level can be adjusted by means of the <UP> and <DOWN> arrow keys next to the corresponding windows; for both sizes it is possible to have the set control panel mode (PANEL) or the linear surgical control mode (LINEAR). In the latter case, the delivered power is linearly controlled by footswitch depression from 5% to preset limit. To switch from LINEAR SURGEON mode to FIXED PANEL or vice-versa, use FLOW CONTROL, <D> key.

8) To activate IRRIGATION press the footswitch beyond its rest position. IRRIGATION can also be activated by "CONTINUOUS IRRIGATION" button, <IRR> key.

9) Depress footswitch beyond mechanical detent n. 1 to activate IRRIGATION and ASPIRATION at the VACUUM and FLOW preset limit (if in PANEL mode). If in LINEAR mode, the footswitch will linearly control FLOW and VACUUM level. In this case pressing the footswitch from stop 1 to the end position causes the level of the FLOW to vary linearly from 2 cc/min and the level of the VACUUM to vary linearly from 5 mmHg to their maximum set levels.

The vacuum level is automatically reduced to zero and a simultaneous VENTING occurs whenever the footswitch is released.

AUDIBLE ALARM

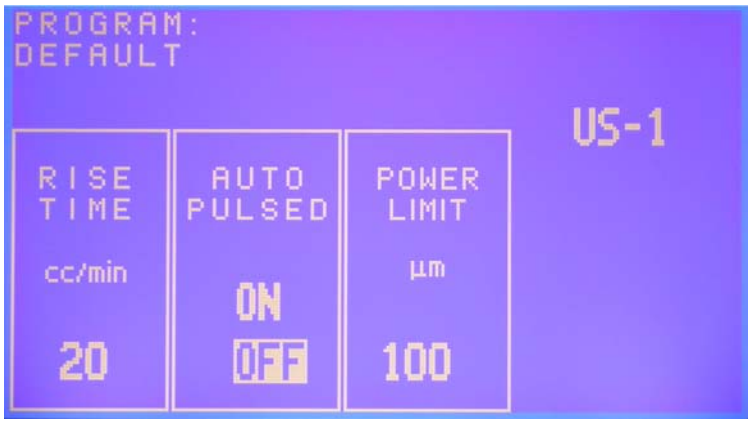
An audible sound of varying frequency indicates vacuum level reached into the collection tank (lower frequency with low vacuum level and higher frequency with high vacuum level).

> **CAUTION**
> Aspiration should always be tested in a beaker of sterile solution.

8.3 PHACOEMULSIFICATION

User Interface

Main U/S box



Reduction Mode U/S box

- Parameter windows available
  - *FLOW (aspiration flow)*
  - *VAC (limit vacuum)*
  - *POWER (U/S energy)*
- Irrigation parameters
  - Status (ON/OFF)
  - *I.V. Pole height*
- Aspiration parameters
  - Vacuum *mmHg* (5 – 500)
  - *Flow rate cc/min (2-50)*
  - *RiseTime cc/min* (2-50)
  - *Mode* (linear/panel)
- Ultrasound parameters
  - *Phaco tip stroke µm* (5 – 100)
  - *Mode* (linear/panel)
  - *U/S Rate* (Continuous, Short Pulse, Single Burst, Multi-Burst, Continuous Burst)
  - *Pulse frequency* (1,2,3,4,5,6,8,10,13,16,20, 25,32,40 bursts/sec)
  - *Timer* (reading and reset key)
  - *Equivalent Phaco Time*

Touching the U/S Function Key will display U/S memory 1 screen (U/S 1). In order to display U/S Memory 2 screen (U/S 2), touch the <B> key. Further depression activates U/S 3. Swapping between memories U/S 1, U/S 2 and U/S 3 can also be achieved by means of the footswitch. For footswitch operation please refer to the relevant section.

Operation

When the <U/S> key is pressed to select the ultrasound mode, the voice synthesizer will announce "US 1." The ultrasound window will display the emission mode (continuous, burst, or pulse), the phacoemulsifier timer, the EPT time, and the timer reset (TIMER RESET).

1) Screw the desired titanium tip into the end of the phaco handpiece, using care to properly engage the threads. Finger tighten the tip.
2) Carefully advance the ring spanner aperture over the titanium tip (being careful not to touch the tip) so that the aperture fully engages the circular head at the base of the tip and positioned against the end of handpiece. Once engaged, grasp the tip circular head with ring spanner and tighten the tip snugly by rotating clockwise. **Do not over tighten**
3) Remove the ring spanner.
4) If needed gently slide the threaded silicone sleeve over the U/S tip and engage the sleeve threads. Slowly tighten the sleeve onto the handpiece until the end of the sleeve leaves the amount of U/S tip exposed as preferred by the surgeon. Orient the irrigation portholes on the sleeve onto the horizontal plane.

CAUTION
Use of a tool other than the ring spanner supplied with the system, or improper use of the ring spanner, may cause damage to the tip and handpiece. In case of damage, it is possible that titanium particles detach from tip during surgery.

NOTE:
To disassemble the tip, follow the reverse order from assembly procedure

5) The handpiece is now ready to accept the irrigation/aspiration tubing from the PULSAR unit.
6) Attach the ASPIRATION tube from the I/A tubing set by pushing the end fitting into the corresponding fitting on the ultrasound handpiece.
7) Attach the IRRIGATION tube from the I/A tubing set by pushing the end fitting male Luer lock into the corresponding fitting on the ultrasound handpiece.
8) Set the I.V. pole height in the Irrigation window so that the BSS bottle is hung 50 to 70 centimetres higher than the patient eye level.
9) Adjust the vacuum level of PULSAR in the Aspiration window according to the operator needs.

10) Adjust the flow rate of the PULSAR unit in the FLOW window according to the operator needs.

CAUTION

Always test the balance between irrigation and aspiration settings by using the test chamber: fill the test chamber with irrigating solution and fit it on the irrigation sleeve. Fill the test chamber with irrigating solution and fit it on the irrigation sleeve.

Place the test chamber to the same level of the patient's eye and activate aspiration at the levels set for subsequent surgery.

Bend the aspiration line close to the handpiece, wait for the vacuum to rise to the preset level.

Release the aspiration tube; the test chamber should not collapse. If it collapses, reduce the vacuum setting or increase the irrigating solution height. Do not proceed until the correct balance is obtained.

11) Plug the electrical connector of the handpiece into the U/S socket (Fig.1, No.4) on the equipment front panel.

12) From the POWER window, use the <UP> and <DOWN> arrow keys to adjust the level in relation to the travel of the tip (phacoemulsifier power).

13) Selecting the <REDUCTION MODE> field <C> key will cause you to enter a sub-screen where it is possible to adjust the following parameters: RISE TIME (2-50 cc/min) which, in the case of an obstructed tip, forces the pump speed to match the selected value, AUTO PULSED (ON/OFF) which modifies the mode of emission of the ultrasounds from continuous to pulsed (8 Hz), and POWER LIMIT (5-100 microns) which reduces the value of the travel of the tip of the handpiece to the set value. To return to the standard U/S mode once the parameters have been set, you simply need to press the <DONE> key.

14) Selecting the <EMISSION MODE> field <D> key will cause a small menu to be opened which allows you to select the power energy mode (continuous, Pulsed 1-40Hz, Single Burst, Multi-Burst, Continuous Burst). To return to the standard U/S mode once the parameters have been set, you simply need to press the <DONE> key.

15) Selecting the <LIN. PAN. CONTROL> (linear, panel, control) field <E> key will cause to be displayed the fields that allow switching from the LINEAR mode to the SET CONTROL PANEL mode or vice versa. Key <C> for controlling the pump speed <FLOW CONTROL>, key <D> for the vacuum limit <VAC CONTROL>, and

key <E> for the ultrasound power <POWER CONTROL>. To return to the standard U/S mode once the parameters have been set, you simply need to press the <DONE> key.

16) To reset the timer, touch the <A> key corresponding to the <TIMER RESET> field.

17) Excessive diathermy for the level of power selected could indicate a fault. In this case, stop using the system at once.

The message “Plug Handpiece” displayed on the screen indicates that the phaco handpiece is not connected or it is not recognized.

The message “Please Prime” indicates that priming procedure is required.

The touch of the Prime soft key activates the priming procedure; the I/A lines are tested for correct installation, for proper functioning and completely filled with BSS solution.

I/A priming procedure can be skipped in some special circumstances, i.e. when it is necessary to replace the ultrasound handpiece or tip after a successful priming. To skip the I/A priming procedure, depress the system footswitch beyond position #3: a pop-up window will ask you to confirm if you want really to skip the Priming.

A preliminary simple test named **Tuning** is required whenever a phaco handpiece is plugged in.

Tuning ensures that the handpiece has suitable response for the equipment.

Tuning is executed automatically executed by the equipment at the end of the priming procedure.

> **CAUTION**
> Don't try to tune the tip in air as tip damage may result.

Also, tuning is automatically accomplished at the first footswitch depression.

If the tuning procedure fails, the message “Please Check Tip” appears for 4 seconds and the user is required to prime once again.

CAUTION

Although the PULSAR is equipped with the Minimal Stress circuitry to limit the amount of ultrasound energy delivered to the eye, still some care must be taken to avoid damages (corneal burns) to the endothelium of the eye.

Always use the minimum level of ultrasound energy which is suitable to remove the cataract.

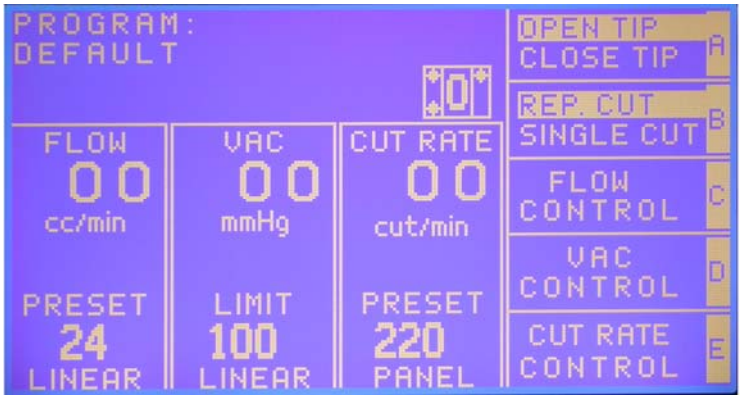
The incision should not be too tight around the sleeve, allow some irrigating solution leakage.

Do not stress the incision by torsions while trying to reach fragments of nucleus in the eye.

When the phaco tip is fully engaged in the nucleus, aspiration flow stops and the tip is not correctly cooled down. Do not activate Ultrasound for long time or at high energy levels while the tip is occluded.

8.4 VITRECTOMY

User Interface



- Parameter windows available
  - *FLOW (aspiration flow)*
  - *VAC (limit vacuum)*
  - *Cut rate*
- Irrigation parameters
  - *Status* (ON/OFF)
  - *I.V. Pole height*
- Aspiration parameters
  - *Vacuum mmHg* (5 – 500)

Flow rate cc/min (2-50, peristaltic mode only)

  - *Mode* (linear/panel)
- Cutter Parameters
  - *Cut rate cuts/min* (60-2000)
  - *Mode* (linear/panel)
  - *Tip port* (open/closed)
  - *Cut type* (multiple/single)

Operation

Touching the VIT function key will cause the VITRECTOMY memory screen to be displayed. For footswitch operation please refer to the relevant section.

1) Attach the IRRIGATION tube from the I/A lines by pushing the end fitting male Luer lock into the corresponding fitting on the semi-disposable scleral guide tubing (female Luer lock).
2) Attach the ASPIRATION tube from the I/A lines by pushing the end fitting into the corresponding fitting on the semi-disposable vitrectomy handpiece tubing (male Luer lock).
3) Connect the vitrectomy handpiece tubing (longer tube) female Luer lock connector to the control console "VIT" connector (Fig.1, No.5).
4) Touch <VIT> key on the LCD screen to select the Vitrectomy mode. <VIT> soft key is depressed and the speech syntetizer announces “VITRECTOMY”. Cutter window will display preset cutting rate (CUT RATE), cutting mode (REP. CUT and SINGLE CUT), <OPEN TIP> and <SINGLE> toggle keys.
5) Adjust aspiration by means in the Aspiration window (see I/A operation).

6) If it is desired to operate in the closed tip mode, touch the <A> key until the message <CLOSE TIP> appears. Press <A> again to return to the open tip mode.

7) The cutting speed can be adjusted by means of the <UP> and <DOWN> arrow keys below the field <CUT RATE>.

8) If it is desired to operate in the single cut mode, touch the <B> key until the message <SINGLE CUT> appears. Press <B> again to return to the repetitive cutting mode.

9) Adjust the cutting port size on the vitreous cutter (semi-disposable model only).

NOTE:
Port size adjustment is accomplished by gently pushing and rotating the tip collar relative to the handle to one of four detent positions. Each detent position varies the cutting port by approximately 0.2 mm. Rotating the tip collar counter - clockwise (facing the base end) reduces the size of the cutting port from 0.7 mm fully open to 0.2 mm narrow opening

10) To eliminate air from the reflux line use the footswitch to activate the "REFLUX" function (refer to section 8.6) until the aspiration line is fully filled.

11) Depress footswitch beyond standby position to activate irrigation. Irrigation can also be activated by the "CONTINUOUS IRRIGATION" button located on the footswitch or by pressing the <IRR> soft key on the front panel.

12) Depress footswitch beyond mechanical detent #1 to activate IRRIGATION and ASPIRATION. If in LINEAR mode, the footswitch will linearly control VACUUM level. In this condition the footswitch depression from detent #1 to max travel linearly varies the VACUUM level from 5 mmHg to the preset maximum level.

13) If footswitch is programmed for single linear mode, depress the main pedal beyond mechanical detent #1 to activate vitrectomy (besides irrigation and aspiration); rotate the main pedal to the right to disable vitrectomy. If in LINEAR mode, the footswitch will linearly control CUT RATE level. In this condition the footswitch depression from detent #1 to max travel linearly varies the CUT RATE level from 60 mmHg to the preset maximum level.

14) If footswitch is programmed for double linear mode rotate the main pedal to the right to activate vitrectomy. If in SURGEON mode, the footswitch will linearly control CUT RATE level. In this condition the rotation of the main footswitch linearly varies the CUT RATE level from 60 mmHg to the preset maximum level.

The vacuum level is automatically reduced to zero and a simultaneous VENTING occurs whenever the footswitch is released.

NOTE:

a. Semi-disposable vitrectome 123001 is reusable and autoclavable approximately 10 times.
b. Changing a parameter will not undo the default parameters. To recall the default parameters or to permanently store the new settings in the machine memory, see paragraph "8.7. TO RECALL OR STORE A PROGRAM".

CAUTION
Vitreous cutter tip should always be test run in a beaker of sterile solution. Testing in air will cause irreparable damage to the blade.

CAUTION
Aspiration should always be tested in a beaker of sterile solution.

8.5 AUTOMATIC I.V. POLE

If the automatic I.V. pole is connected to the PULSAR, the irrigating solution bottle will move to the programmed position when the equipment is turned on. The operator can adjust the bottle position using the UP/DOWN rocker footswitch and/or the <UP>/<DOWN> soft keys of the Irrigation windows.

To permanently store the new settings in the machine memory, see paragraph "8.7. TO RECALL OR STORE A PROGRAM".

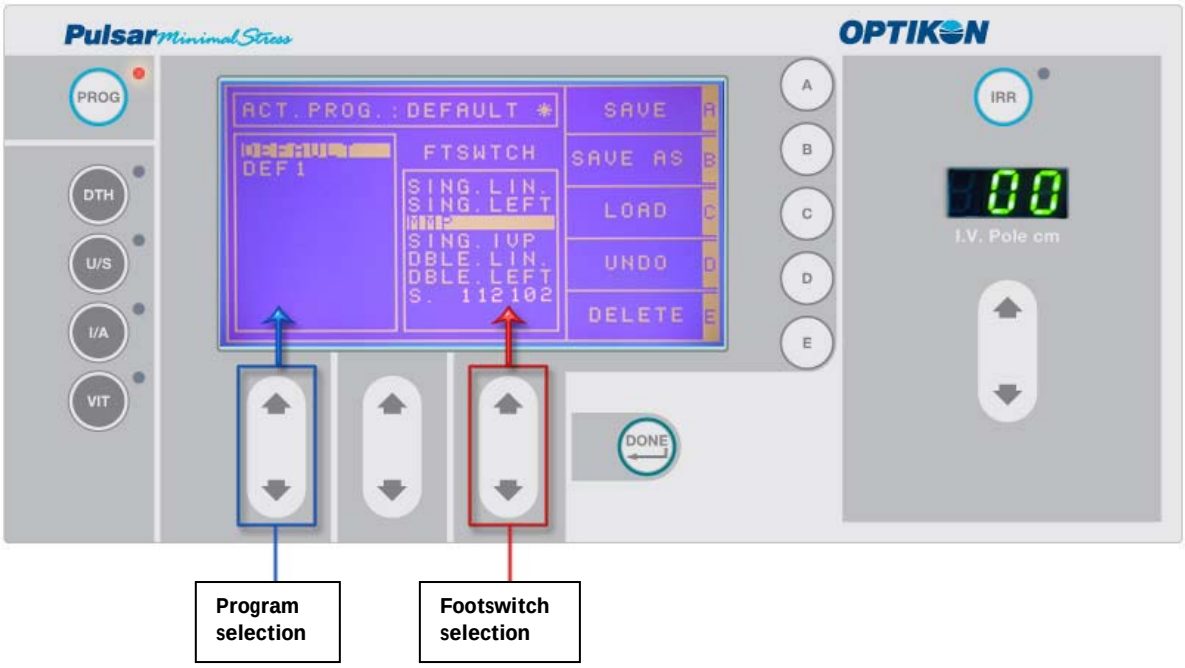
8.6 FOOTSWITCH

A SPLASH-PROOF footswitch allows the surgeon to control various modes of instrument operation. The footswitch connects to the rear panel of the control console (Fig.3, No.5).

The PULSAR unit can be programmed to use the footswitch 112101. The footswitch can be used in a single or double linear (for right-handed and left-handed people), MMP, and IVP modes. The functions that can be activated in each mode are summarized in the following paragraphs.

To select a different pedal, touch the <PROGRAM MODE> soft key on the function main screen. The program screen will be displayed. In the middle box under "FTSWTCH" appears the list of the available pedals; at this point select the desired pedal by means of the <UP> and <DOWN> arrow keys on the front panel next to the pedals window (below). Touch the <DONE> key to return to the function main screen.

To definitively store the selected pedal in the program, refer to section 8-7

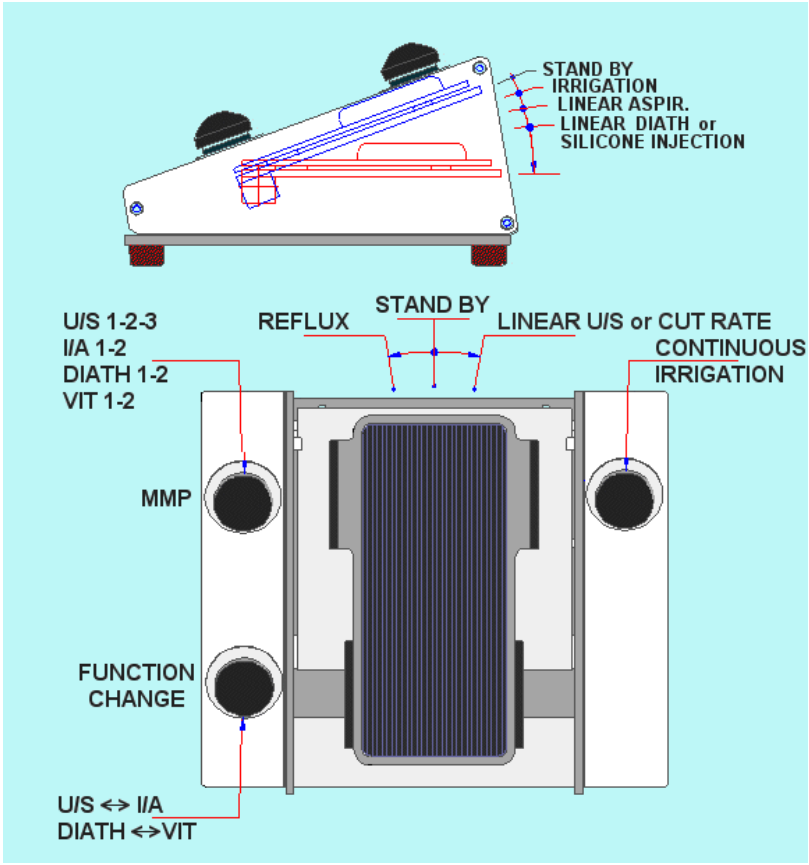


Program and pedal selection

NOTE:
For the correct functioning of the unit select the pedal control mode that is compatible with the pedal that is effectively attached to the control panel.

- **FOOTSWITCH 112101 USED IN DOUBLE LINEAR MODE ("DBLE. LIN.")**

As can be seen in the figure, the pedal unit consists of a main pedal that can be moved vertically and/or horizontally and three separate buttons that activate CONTINUOUS IRRIGATION, switching between MMP 1-2 and MMP 1-2-3 (depending on the active function), and the Function Change.



When the main pedal is slightly depressed, the "IRRIGATION" valve opens, permitting saline solution to enter the infusion handpiece.

When the main pedal is pressed beyond the first mechanical detent (MECH. DETENT 1), the pump is activated, thus allowing irrigation and aspiration to be active simultaneously. Pressing on the pedal again will linearly increase the degree of negative pressure if the LINEAR control mode was selected for the negative pressure.

When the main pedal is rotated to the user's right, the vitreous cutter (or the phacoemulsifier handpiece) is activated. If the linear control mode was selected, a further rotation of the main pedal to the right will increase the cutting speed (or the amplitude of oscillation of the phacoemulsifier tip).

When the main pedal is rotated to the user's left, REFLUX through the aspiration line will occur immediately. Reflux is a "reverse" flow caused by opening the REFLUX valve which allows balanced saline solution to enter the aspiration line. A low-frequency (800 Hz) warning sound will be generated by the instrument.

When the main pedal is pressed beyond the second mechanical detent (MECH. DETENT 2), diathermy, if selected, will be activated. If the linear control mode was selected, a further press on the main pedal will increase the level of diathermy emission.

"CONTINUOUS IRRIGATION" switch reverses the state of the IRRIGATION pinch valve which if close opens, if open closes.

The MMP button allows the surgeon to switch between Memory 1, 2, and 3 in U/S and Memory 1 and 2 in DIATH, I/A, and VIT.

The Change Function button makes it possible to change from U/S to I/A and vice versa or from VIT to DIATH and vice versa.

When the CONTINUOUS IRRIGATION is activated, there is an immediate gravity fed irrigation through the handpiece.

Audible and visual feedback is provided as indication of selected modes, and associated alarm conditions.

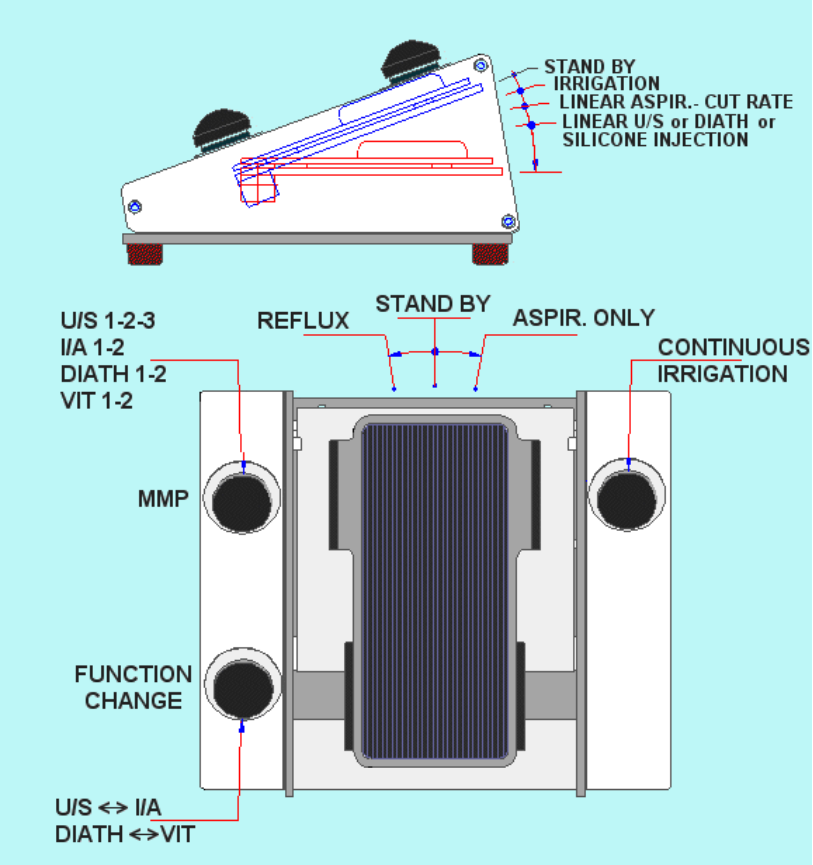
The pedal programmed for double linear mode for left-handed users "DBLE. LEFT" (refer to section 8.7) behaves in the same manner as the double linear mode with the sole change that the functions set for the horizontal rotation of the pedal have been inverted.

- **FOOTSWITCH 112101 USED IN SINGLE LINEAR MODE (SING. LIN.)**

As can be seen in the figure, the pedal unit consists of a main pedal that can be moved vertically and/or horizontally and three separate controls that activate CONTINUOUS IRRIGATION, switching between "MMP 1-2" and "MMP 1-2-3" (depending on the function activated), and the Function Change.

When the main pedal is slightly depressed, the "IRRIGATION" valve opens, permitting fluid to enter the infusion set.

When the main pedal is depressed beyond detent #1, the selected pump is activated, causing aspiration and irrigation to occur simultaneously. If linear control mode for VACUUM (and/or flow, if in peristaltic mode) is selected on the console, further depression of the pedal will increase aspiration level linearly.



When the surgeon presses the main pedal beyond the first detent, this also activates the vitrectomy scalpel. If linear control mode for CUT RATE (PHACO TIP STROKE) is selected on the console, further depression of the pedal will increase the cutting rate (phaco tip stroke). To disable vitrectomy, rotate the main pedal to the right; ASPIRATION and IRRIGATION still remain active. If continuous irrigation is active, aspiration (and, eventually, cutting) will begin immediately after a slight depression of the pedal; this will extend the available travel for linear control.

In the U/S mode when the main pedal is pressed beyond the second detent, the phacoemulsifier handpiece is activated. Further depression of the pedal will increase the phacoemulsifier handpiece travel (U/S power) (if the linear control mode is active) or the Burst Emission frequency. If continuous irrigation has been

activated, ultrasound will be activated as soon as the pedal has been pressed beyond the first detent; this will extend the available travel for linear control.

In the U/S mode, if both aspiration and phacoemulsifier have been set in the linear mode, the power level of aspiration and ultrasound will gradually increase by pressing the pedal until it is completely pressed down.

When the main pedal is rotated to the surgeon's left an immediate REFLUX through the aspiration line of the connected handpiece occurs. REFLUX is a back flow caused by the REFLUX valve opening allowing fresh BSS solution in the aspiration line. A sound of low pitch (800 Hz) is heard.

Whenever the main pedal is depressed beyond detent #2 DIATHERMY, if selected, is activated.

"CONTINUOUS IRRIGATION" switch reverses the state of the IRRIGATION pinch valve which if close opens, if open closes.

The MMP switching control allows the user to switch between Memories 1, 2, and 3 in U/S and Memories 1 and 2 in I/A mode.

The switching control for changing the function makes it possible to switch from U/S mode to I/A mode and vice versa and from VIT mode to DIATH mode and vice versa.

When the CONTINUOUS IRRIGATION is activated, there is an immediate gravity fed irrigation through the handpiece.

Audible and visual feedbacks are provided as indication of selected modes, and associated alarm conditions.

The pedal programmed for single mode for left-handed users "SING. LEFT" (refer to section 8.7) behaves in the same manner as the single linear mode with the sole change that the functions set for the horizontal rotation of the pedal have been inverted.

If the pedal is set to the "MMP" mode (refer to section 8.7), the REFLUX function is set on the pedal button located above and to the left (MMP), while the MMP functions, which permit the user to switch between memories 1, 2, and 3 in the U/S mode and memories 1 and 2 in the I/A mode, are set by means of the horizontal rotation of the pedal (right rotation to increase and left rotation to decrease).

In the "IVP" mode (refer to section 8.7) the pedal button located above and to the left raises the I.V. pole and the button located below and to the left lowers the I.V. pole.

- **FOOTSWITCH 112101 USED IN SINGLE LINEAR MODE (SING. LIN.)**

In the "IVP" mode (refer to section 8.7) the footswitch button located above and to the left raises the I.V. pole and the button located below and to the left lowers the I.V. pole. In the “IVP” mode it is possible to switch between Memories 1, 2, and 3 in the U/S mode and between Memories 1 and 2 in the I/A modes by rotating the footswitch to the right.

- **FOOTSWITCH 112102 SINGLE LINEAR**

When the main pedal is slightly pressed, the IRRIGATION valve opens, permitting the fluid to enter the infusion circuit.

Pressing the main pedal beyond stop 1 starts the pump, which activates aspiration and irrigation simultaneously. If the VACUUM linear control mode is selected on the control panel, a further press on the footswitch will increase the aspiration level in a linear manner.

In the vitrectomy mode when the surgeon presses the main pedal beyond stop 1, this also activates the vitrectomy scalpel. If the linear mode is selected for the CUTTING SPEED, a further press on the footswitch will increase the cutting speed.

In the U/S mode when the main pedal is pressed beyond stop 2, the phacoemulsifier handpiece is activated. A further press on the footswitch will increase the phacoemulsifier tip travel (U/S power) (if the linear control mode is active) or the Burst Emission frequency.

In the U/S mode, if both aspiration and phacoemulsifier have been set in the linear mode, the power level of aspiration and ultrasound will gradually increase as the footswitch is pressed, until it is completely pressed down.

When the surgeon presses the switch located to the left of the pedal, an immediate REFLUX will occur through the aspiration line of the connected handpiece. REFLUX is a reverse flow caused by opening the specific valve that allows fresh balanced

saline solution to enter the aspiration line. The unit will emit a low audible signal (800 Hz).

Pressing the main pedal beyond stop 2 activates DIATHERMY, if it has been selected.

The button located above and to the right of the footswitch controls the CONTINUOUS IRRIGATION; it reverses the condition of the IRRIGATION valve which, if closed, will open, and if open, will close.

When CONTINUOUS IRRIGATION is activated, gravity causes immediate irrigation to enter the handpiece.

The audible and visual confirmation signals indicate the modes that have been selected and the corresponding alarm conditions.

CAUTION
FOOTSWITCH 112102 OPERATES ONLY BY SELECTING THE ITEM “S. 112102” IN THE FOOTSWITCHES AREA.
If you have footswitch 112102, it is advisable to save in the programs area a work program with footswitch 112102 selected so that it will not be necessary to reset the footswitch each time the instrument is turned on.

NOTE:

The Vacuum level is automatically reduced to zero whenever the footswitch is released.

CAUTION
The footswitch is not autoclaveable.

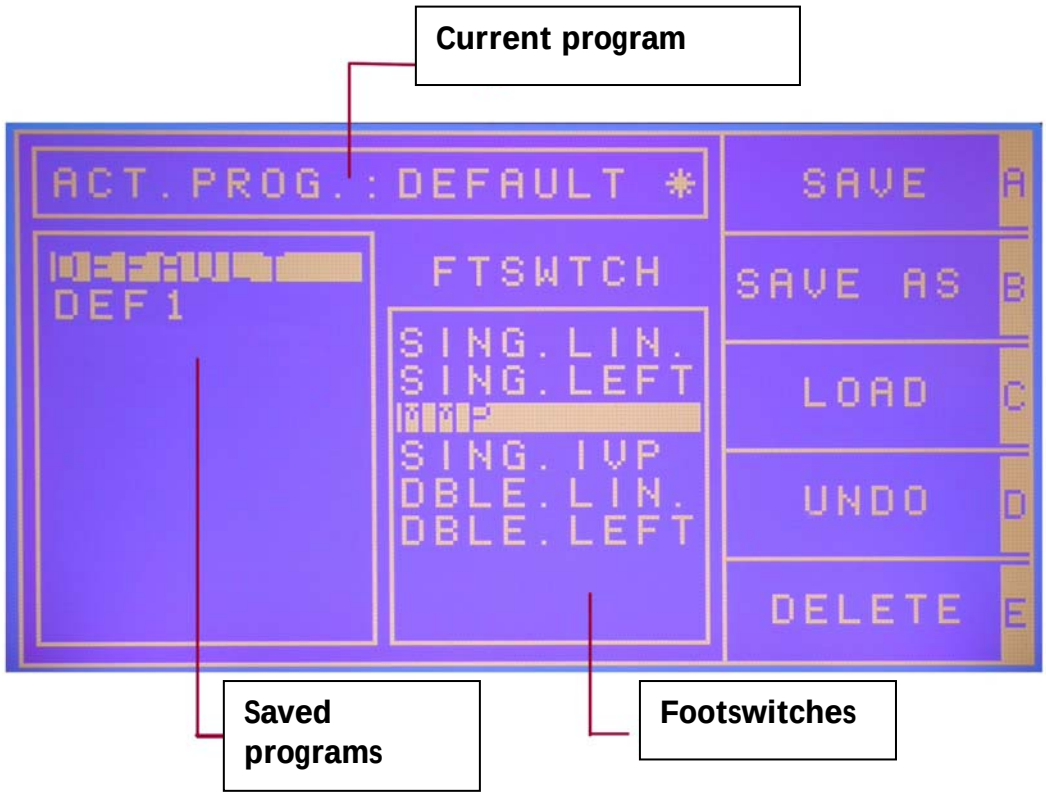
8.7 TO RECALL OR STORE A PROGRAM

All the PULSAR unit's preset parameters can be adjusted independently to meet the needs of the individual user, who can program the parameters, save up to ten user programs in the system, and store them for approximately ten years.

The active program's name is indicated in the "ACT. PROG." window located at the top of the interface screen.

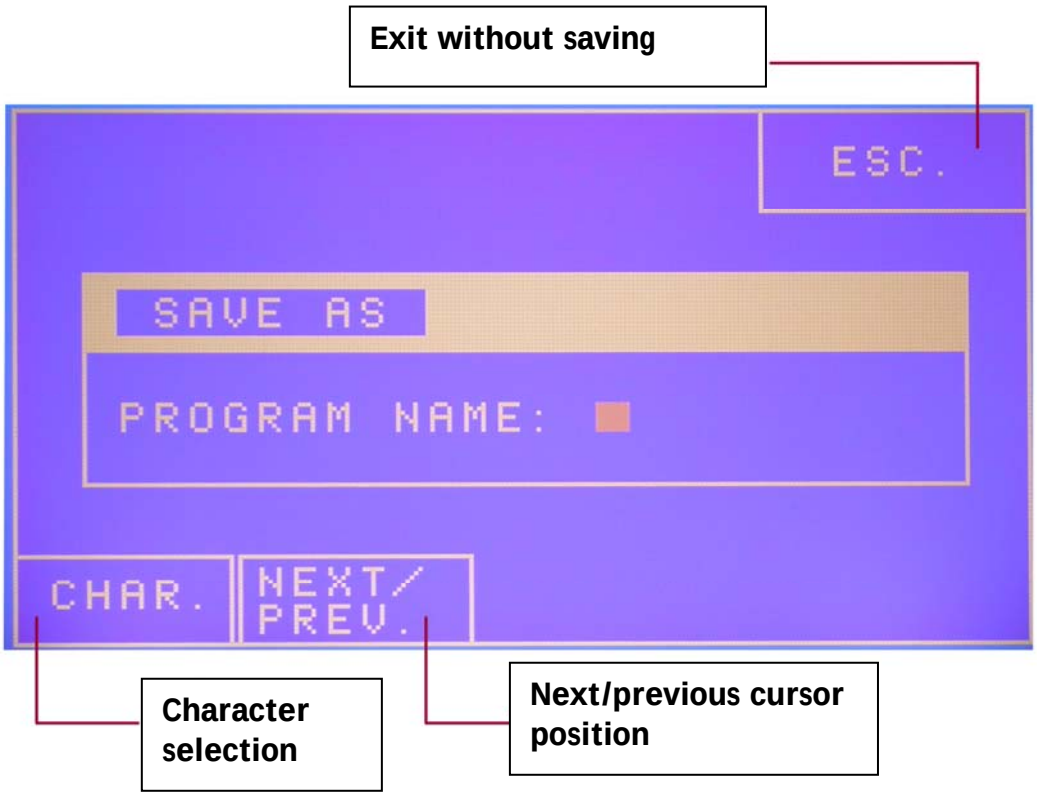
To create and store a new program or modify the active program, first adjust the unit's various parameters by means of the respective windows within the functions themselves; an asterisk will appear next to the program's name to indicate that the

program has been modified. Then touch the <PROG> Program mode button. The Programs screen will appear and will display the active program and the asterisk next to it which indicates that it has been modified.



Programs Screen

To permanently save the modifications to a program, press "SAVE" key <A> (it is not possible to save modifications to the DEFAULT program). To save modifications to a new program, press "SAVE AS" key <B>.



SAVE AS box

Set the name using the <UP> arrow keys next to the "CHAR" and "NEXT/PREV." windows. The "CHAR" key allows you to change the letter and the "NEXT/PREV." key allows you to advance to the next letter. Lastly press <DONE>; a window will appear informing you that it has been saved. Press <DONE> to return to the programs area.

To load a different program from the one that is set, select it using the arrow keys next to the programs area and press "LOAD" key <C>.

To undo all the modifications made to the active program's parameters, press "UNDO" key <D>.

To permanently delete a program on the list, first select it using the arrow keys near the programs area. After you have selected the program that you would like to delete, press "DELETE" key <E>.

The PULSAR unit can be programmed to use footswitch 112101. The footswitch can be used in single or double linear (for right-handed and left-handed people), MMP, and IVP modes.

To set a different pedal, from the FTSWTCH box select the desired pedal by means of the <UP> and <DOWN> arrow keys on the front panel next to the pedals window

(below). An asterisk will appear in ACT. PROG. to indicate that the program has been modified. Press "SAVE" key <A> to permanently save the modification.

8.8 SHUTDOWN PROCEDURE

NOTE:
If the Pulsar surgical system is not used for an extended period, follow the procedure described below.

1) Press the “POWER” switch to turn off the console.
2) Disconnect the power cable from the rear panel of the console. Grasp the plug, not the cable.
3) Disconnect the footswitch control from the rear panel of the console.
4) Close the stopcock of the circuit for dosing via I.V. drip.
5) Remove the irrigation and aspiration lines from the handpiece and from the control panel.
6) Remove the handpiece connectors from the control panel and place the protective caps back on their tips.
7) See the chapter **“Cleaning, sterilization and maintenance”.**

9. CLEANING, STERILIZATION AND MAINTENANCE

The medical personnel are responsible for keeping the instruments and equipment in the best operating conditions. The simple steps described below constitute a practical guideline for defining a suitable care and maintenance program.

9.1 CLEANING

9.1.1 UNIT

1) Periodically clean the front panel with a soft cloth dampened with distilled water. If necessary, use neutral detergent only. Do not use alcohol, solvents or abrasives on the console.

2) Do not use alcohol, solvents or abrasives on the console.

9.1.2 ACCESSORIES

The most common causes for rust and corrosion are the following: incomplete cleaning and drying of the instruments after use; chemical agents or sterilizing solutions; cleaning with tap water; leftover residues of laundry detergent in the operating room cloths; detergents with unsuitable pH levels (the ideal pH is 7); an autoclave that does not work properly. The main causes of corrosion, however, are residues of blood and salt.

1) Immerse and completely rinse all the microsurgical instrument parts immediately after use, as specified in the relative user instructions.

2) Rinse all the handpieces' irrigation and aspiration lines with a generous amount of lukewarm distilled water and dry them with compressed air. **AVOID EXCESSIVE PRESSURE.**

9.2 STERILIZATION

9.2.1 UNIT

1) The console, footswitch and I.V. pole cannot be sterilized. For cleaning please refer to the indications given in the relevant instructions for use.

9.2.2 SINGLE USE ACCESSORIES

Do not reuse microsurgical instruments which are labelled for single use.

9.2.3 REUSABLE ACCESSORIES

1) Reusable microsurgical instruments must be thoroughly cleansed before the steam sterilization. When proceeding otherwise, residues can bake during steam sterilization providing a protective layer preventing micro organisms being destroyed effectively. Furthermore, any adhering contaminants might damage plastic items in particular, due to the high temperatures Do not subject any of the microsurgical instruments to “chemclave” or to hot air sterilization.

2) For detailed information on cleaning, decontamination and sterilization of the reusable surgical instruments, refer to the relevant instructions for use.

9.3 MAINTENANCE

9.3.1 UNIT

1) Store the PULSAR surgery system in a clean dry location at room temperature.

2) Remove I/A tubing after each use.

3) To maintain optimal performance for the entire life of the equipment, an annual maintenance and calibration program must be defined. Contact your Optikon 2000 authorised distributor/service centre.

NOTE:
To keep the system safe, check the unit’s conformity with electric current leakage limits according to standard EN60601-1 at least once a year. Contact the bioengineering division of your facility or your Optikon 2000 authorised distributor/service centre.

9.3.2 ACCESSORIES

1) Avoid dropping or mishandling handpieces and accessories. It is critical that these components be handled with outmost care and inspected thoroughly after each use for any damage or wear.

2) Periodically lubricate all external "O" rings on handpieces, cannulas, I/A handpiece, and connectors etc.. with silicone grease or oil. **DO NOT OVER-LUBRICATE**

3) Periodically inspect the fluidic lines, fittings, and handpieces for any damage or wear.

4) Reassemble all parts before storing.

5) Place tip protective caps over all handpieces before wrapping and storing.

CAUTION

1) Do not use synthetic detergents or oil-based soaps
2) Be sure that the diathermy handpiece is completely dry before using it, as RF currents may find a path through wet surfaces.
3) Vitrectomy handpieces should never be completely immersed in distilled water as the water may enter the high pressure membrane chamber thus causing malfunction.

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10. TROUBLESHOOTING GUIDE

10.1 WARNINGS

When the "U/S" Ultrasound function is selected, the following messages may appear in the status box in the centre of the screen:

	ENGLISH	ITALIANO
	MESSAGE	**MESSAGGIO**
1	Plug handpiece	Collegare il manipolo
2	Please prime...	Inizializzare il sistema
3	Check tip	Controllare la punta
4	Phaco ready	Ultrasuoni pronti
5	Weak handpiece	Manipolo poco efficiente

10.2 MISCELLANEOUS PROBLEMS

The troubleshooting guide lists some of the anomalies that may occur in the unit's operation, the related symptoms and corrective actions. If the problems with the PULSAR surgical system persist even after having carried out the corrective actions below, contact an OPTIKON 2000 authorised service centre.

SYMPTOMS	*CORRECTIVE ACTION*
	Mains power supply
PULSAR completely inoperative:	a) A.C. power cord not connected. Connect power cord to control console and the mains. b) A.C. line fuse blown. Replace it.

SYMPTOMS	*CORRECTIVE ACTION*
	Irrigation System
No irrigation flowing:	a) Irrigation pinch valve closed. Check by pressing the footswitch and verify that the irrigation pinch valve opens and BSS solution is available. b) Irrigation tube is disconnected from the handpiece. Connect irrigation tube to the handpiece. c) Kinked or damaged irrigation tubing. Check for kinks and straighten. Verify damage and replace if necessary. d) Closed clamp on connecting tube to irrigation source. Release clamp to activate irrigation. e) Vent valve located on drip chamber closed. Open the vent valve.
	Aspiration System
Poor or missing aspiration:	a) I/A tubing set not properly installed. Double check tubing installation. b) I/A tubing connectors not properly inserted into the corresponding connectors on the surgical handpiece. Insert them properly. c) I/A tubing set damaged. Exchange for new one. d) Low "VAC" level. Adjust to slightly higher level. e) Obstructed tip or handpiece or tubing. Check for occlusions and clear all debris.
	Priming errors
Vac offset: "VAC OFFSET ERR"	Some vacuum is present although aspiration pump has not been activated. a) Initialization was restarted after a previous error of the presence of negative pressure. Open the irrigation clamp and restart priming procedure. b) Vacuum sensor needs calibration. Contact nearest sales/service office to recalibrate the unit.
Major leakage:	There is a major leakage in the I/A system:

SYMPTOMS	*CORRECTIVE ACTION*
"MAJOR LEAKAGE"	a) Test chamber is not installed on the sleeve. Ensure that the test chamber is properly installed on the sleeve. b) I/A lines are not connected to the handpiece. Connect the I/A lines from the cassette to the phaco handpiece.
No irrigation: "NO IRRIGATION"	No irrigation flowing, irrigation clamp on the line from the drip chamber is closed. Open the clamp and restart priming procedure.
Aspiration occluded: "ASPIRAT OCCLUD"	The aspiration line is partially occluded. Handpiece and tip may have not been properly cleaned before sterilization. Replace tip and/or handpiece.
Minor leakage: "MINOR LEAKAGE"	There is a minor leakage in the I/A system. a) I/A connectors are not fully engaged in the handpiece connectors. Push connectors in. b) The tube or the test chamber is not correctly assembled. Verify that the test chamber is fully engaged on the sleeve and that the sleeve is properly positioned on the handpiece.
Check the tip: "CHECK TIP"	a) Loose titanium tip. Screw the tip properly into the handpiece by using ring spanner. b) Damaged titanium tip. Inspect the tip and replace if necessary. Damaged U/S handpiece. Replace it.

VIT (Vitrectomy)

Vitrectomy handpiece will not operate when the footswitch is depressed.	a) You are involuntarily hitting aspiration only footswitch (left side). Press main footswitch only. b) Handpiece connector not properly engaged. Ensure that the connector is properly engaged. c) Faulty handpiece. Replace it.

Diathermy System

No diathermy power output to the handpiece when footswitch is depressed.	a) Loose connection of cable to console or to handpiece (in case of microforceps). Insert plug appropriately. b) Faulty diathermy handpiece. Replace it. c) Some dirt on probe tip. Clean it.

Control Console

Gas leaks from panel connector when connecting vitrectomy handpiece.	a) Female Luer connector not properly engaged. Ensure that connector is fully engaged by gently twist locking it. b) Damaged connector. Replace it.
Audible gas leaks from the console.	Tube fittings or valve or solenoid valve needs servicing. Contact nearest sales/service office.
Console malfunctions.	Console malfunctions. Return console to supplier or contact nearest sales/service office.

Phacoemulsification

Check the tip. “CHECK TIP”	a) Loose titanium tip. Screw the tip properly into the handpiece by using ring spanner. b) Damaged titanium tip. Inspect the tip and replace if necessary. c) Damaged U/S handpiece. Replace it.
Poor U/S power.	a) Insufficient U/S power preset. Increase U/S power preset. b) Footswitch not fully depressed. Depress the footswitch to max travel. c) Defective titanium tip. Replace it. d) Weak handpiece. Piezoceramics normally deteriorate with use and sterilization cycles. Send handpiece to the OPTIKON 2000 S.P.A. Service centre. e) Aspiration level is too low. An insufficient aspiration level may not hold the nucleus fragments properly during emulsification. Increase the vacuum level while taking care to maintain a proper fluidic balance.
Weak handpiece. “WEAK HANDPIECE”	The handpiece is weak and cannot deliver more than 50 µm. Give the handpiece to an OPTIKON 2000 authorized service centre to repair.

Footswitch

Footswitch does not energise the active equipment section.	a) The PULSAR unit is off. Switch the unit on. b) Footswitch is not connected**.** Connect it.

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