

Power Console with Irrigation Pump / Foot Pedal / MIS Irrigation Kit

REF SMXM-2034-L-EMC-FDV / SMXM-0034-10AV / SMXM-0034-11AV

Instruction for use

Product Code : SP-002462 / SP-002461 / SP-002460

Trade Code : P65-002-0001 / P65-002-0002 / P65-001-0006-SK

SMXM-2034-L-EMC-FDV
 Power Console



SMXM-0034-10AV
 Foot Pedal



SMXM-0034-11AV
 MIS Irrigation Kit

GENERAL DESCRIPTION

The Paragon FJ2000 Power Console is an electronic control system for operating the SMXM-0034-N and SMXM-0034-N20 handpieces. These handpieces drive drills, K-wires, and saws through the control of a foot pedal.

SMXM-2034-L-EMC-FDV is a control console for driving micro tool system. It generates the signals necessary to run the motor and compatible equipment at the desired speed and direction as controlled by the operator. The speed is adjusted either by a rotary knob on the equipment or by a foot pedal connected to the front of the console.

IMPORTANT INFORMATION

This manual has been written to help describe the procedures required to keep the SMXM-2034-L-EMC-FDV Power Console system operating properly.

Throughout the manual, the following terms are used to identify tips and precautions that will help avoid accidental injury to patients or personnel, or prevent damage to the system.



Read the operating instruction carefully before use. Failure to follow may cause damage or injuries.

DEFINITIONS: NOTE - WARNING - CAUTION

Please read this manual and follow its instructions carefully. The words NOTE, WARNING, and CAUTION carry special meaning and should be carefully reviewed.

NOTE: Indicates special information to make maintenance easier or important instructions more clear.

WARNING: Indicates that the safety of the patient and/or hospital personnel could be at risk.

CAUTION: Indicates special service procedures or precautions that must be followed to avoid damaging the instrument and/ or system components.



- GENERAL WARNINGS -

- WARNING:** Grounding reliability can only be achieved when the equipment is connected to equipment receptacle marked "Hospital Only" or "Hospital Grade."
- WARNING:** Disconnecting the supply cord will isolate the console from the supply mains on all poles simultaneously.
- WARNING:** Prevent risk of fire. Use only Paragon cables to connect to the instrument.
- WARNING:** Prevent explosion Hazard. Equipment and components are not suitable for use in the presence of flammable anesthetics or oxygen.
- WARNING:** Prevent electric Shock. **DO NOT** remove cover.
- WARNING:** Type BF rating may only be maintained if the instrument is not used to bridge between the patient and ground.
- WARNING:** Ensure that there is no electromagnetic interference between this device and other devices in use.
- WARNING:** Prior to use, all system components (console, cables, handpiece, modules, and accessories) should be inspected to detect any damage or malfunction. **DO NOT** use any component if damage is apparent.
- WARNING:** Prior to use, all system component manuals should be reviewed for important warnings and instructions for use.

⚠️ - GENERAL WARNINGS -

WARNING: Eye protection must be worn when operating any power equipment. Dislodged burs, blades, or bone fragments can result in eye injury, blindness, or contamination of the eye from patient tissue or body fluids.

WARNING: If any corrosion or debris is detected in/on the instrument, it must be considered contaminated. Either replace the instrument immediately or remove it from the sterile field and reprocess. If the instrument looks damaged or shows signs of excessive wear, it should not be used.

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

WARNING: Ensure the GREEN button from the foot pedal is OFF when changing between modules.

WARNING: Ensure the port switch is turned to the side corresponding to the selected port (white or blue).

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

CAUTION: Risk of overbalance due to sitting or stepping on console. DO NOT sit on or step on console.

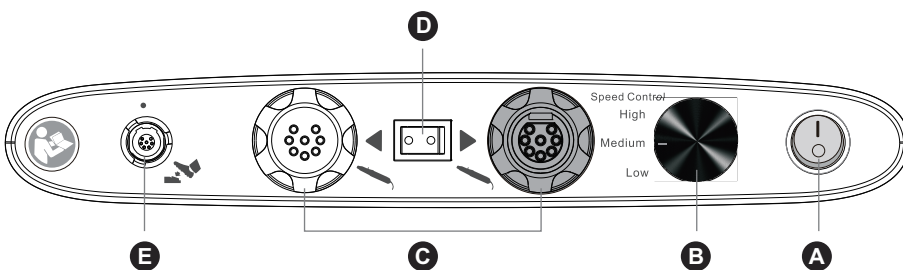
NOTE: Continuous Operation with Short Time Loading.

NOTE: All personnel should become familiar with the power equipment before it is set up for use in any procedure. Personnel inserviced should include, but not limited to, central processing personnel, members of the surgical team, and the bioengineering department.

NOTE: There is no need to select power voltages, just select the proper power cord.

Intended users are surgeons, physician's assistants, orthopedic operating room nurses, and circulating nurses.

SMXM-2034L-EMC-FDV Power Console



System Indicators

- | | |
|--|--------------------------|
| A ON/OFF Power Switch | E Foot Pedal Port |
| B Speed Control (Low / Medium / High) | F Fluid Bag Bar |
| C Handpiece Port | G Pump |
| D Port Switch | |



Assemble the Power Console

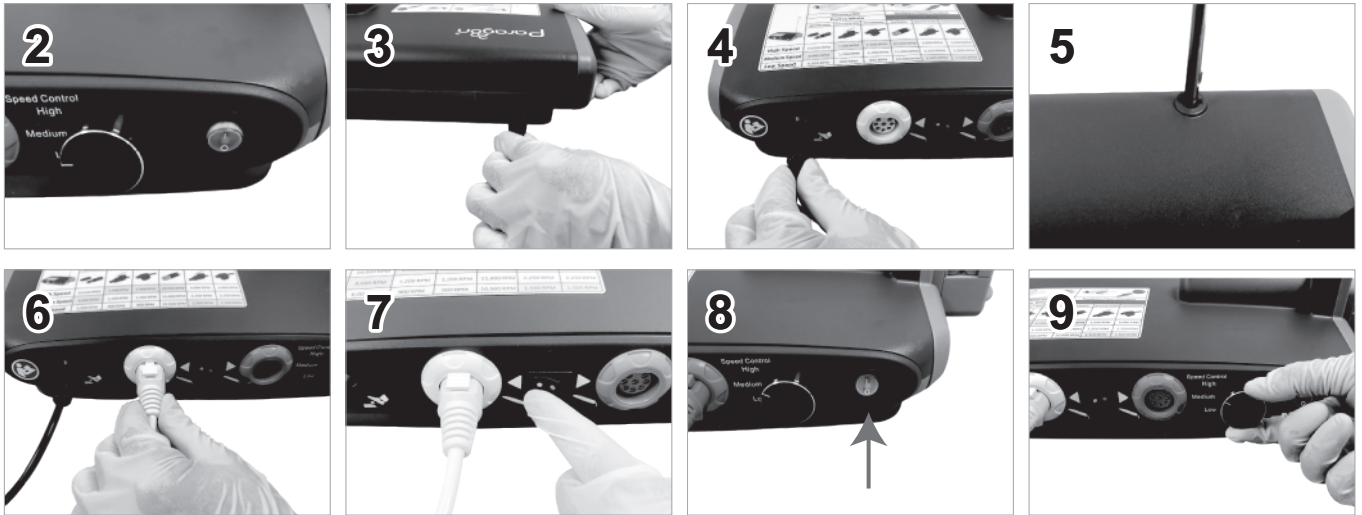
Non-sterile Person:

1. Open the pack and remove all of the items.
2. Ensure Power Switch **A** is at OFF "O" position first.
3. Plug the power cord to the back of the Console.
CAUTION: DO NOT twist or force the plug into the outlet. Doing so could bend the pins in the cable and damage the cable and/or the console.
4. Plug the foot pedal to the foot pedal port **E**.
DO NOT twist or force the plug into the receptacle.
5. Insert the fluid bag bar **F** to the power console and make sure to fit in the directional slot.
6. Plug the handpiece to the hanpiece port with the same color as the plug (white or blue) **C**. **DO NOT** twist or force the plug into the receptacle.

7. Turn the port switch **D** to the selected port side.
8. Turn ON the power console with the ON/OFF power switch **A**.
9. Choose the speed on the speed control **B**.

NOTE: The "OFF" position is designated by "O" and the "ON" position is designated by "I".

CAUTION: Check all surgical accessories before attaching them to the handpiece. Make sure that blades, drills, burs, and/ or cannulae are not dull or bent. Check that accessories lock correctly into the handpiece before operating the power instrument.



SMXM-0034-10AV Foot Pedal

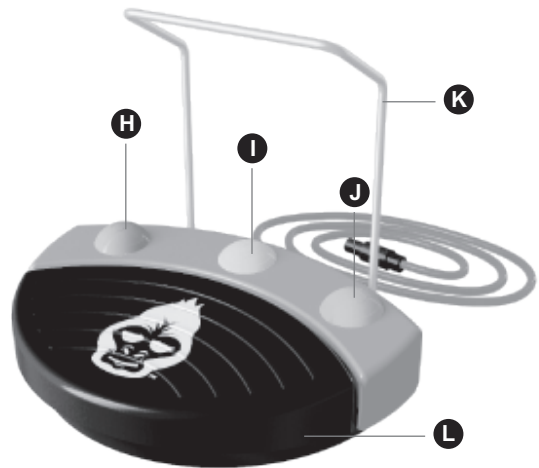
System Indicators

- H** BLUE button : irrigation ON/OFF
- I** GREEN button : safety UNLOCK/LOCK
- J** PURPLE button: change direction REVERSE/FORWARD
- K** Foot Hook
- L** Pedal

Assemble the Foot Pedal

Non-sterile Person:

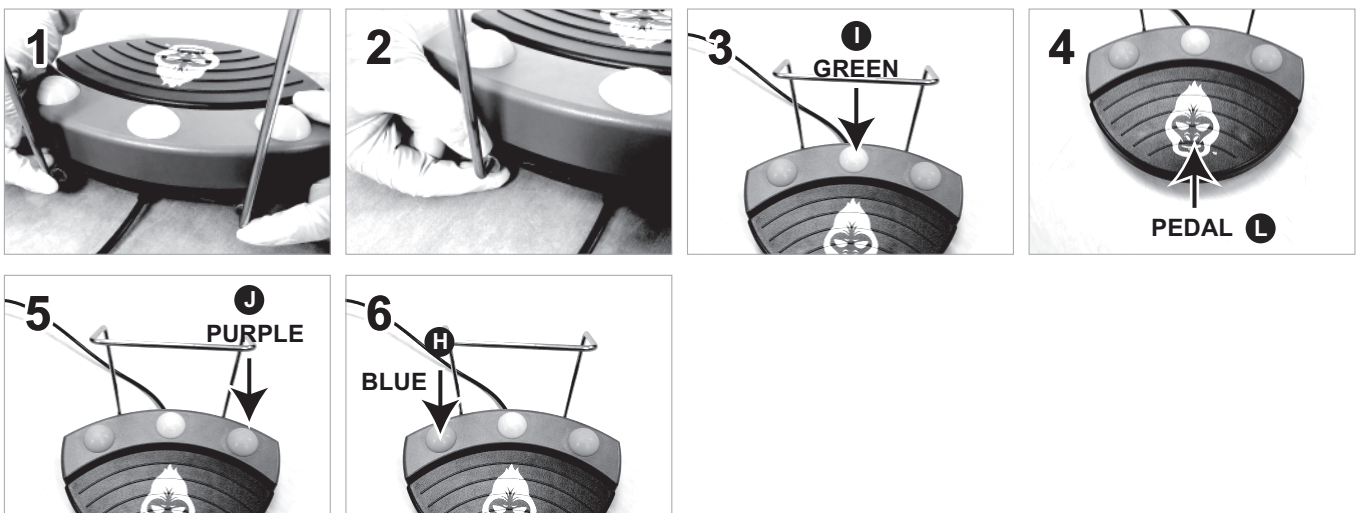
1. Insert the foot hoop **K** on the back of the foot pedal.
2. Tighten the screws for foot hook.
3. Press GREEN button **I** to UNLOCK foot pedal. (Green light ON)
4. Press the pedal **L** to operate handpiece. The speed can be continuously adjusted with the pedal.
5. Press PURPLE button **J** to change motor direction. Purple light ON: reverse (counter clockwise) Purple light OFF: forward (clockwise) default setting



6. Press BLUE button **H** to turn ON/OFF irrigation function
Blue light ON: ON
Blue light OFF: OFF

NOTE :

- Use the foot hook **K** to reposition the foot pedal.
- Press the GREEN button once again to LOCK the foot pedal, preventing unintentional activation. (Green light OFF)

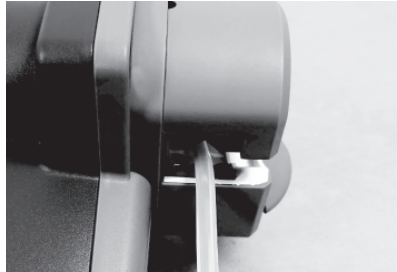
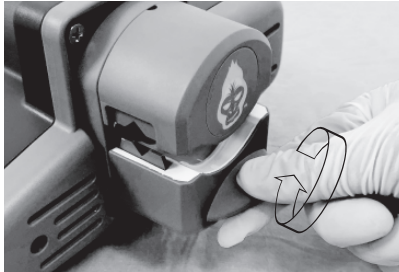
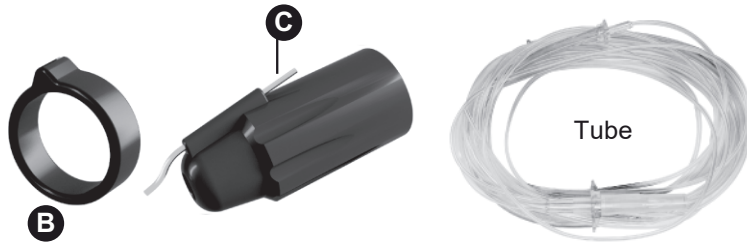


SMXM-0034-11AV MIS Irrigation Kit (Optional)

Installation

Non-sterile Person:

Open the pump by turning counter clockwise, make sure to insert the tube into the V aperture, and close the pump by turning clockwise.

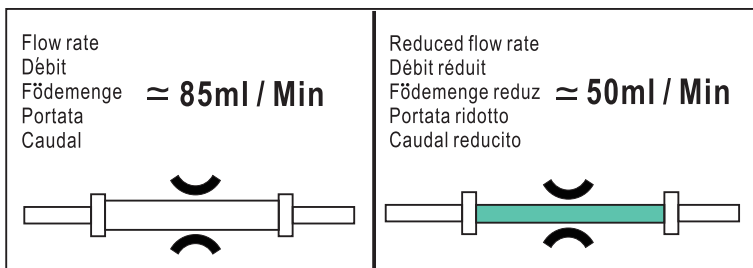


Hang the irrigation solution to the fluid bag bar.



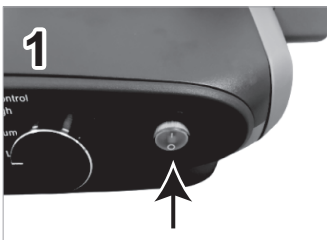
Insert the spike into the irrigation solution.

NOTE: Irrigation flow differs according to which section of the tube is inserted to the pump.



Dismantle the Power Console

Non-sterile Person:



1. Ensure Power Switch **A** is at OFF "O" position first.
2. Unplug the handpiece from the hanpiece port **C** . **DO NOT** twist or force the plug.
3. Unplug the foot pedal from the foot pedal port **E** . **DO NOT** twist or force the plug.
4. Unplug the power cord from the back of the Console.

CAUTION: To avoid difficult dismantle, this equipment should be placed in a barrier-free space.

CAUTION: **DO NOT** twist or force the plug. Doing so could bend the pins in the cable and damage the cable and/or the console.

ROUTINE CLEANING

Remove the AC Power Cord; wipe Power Console and Foot Pedal with a damp cloth, then with an alcohol-absorbed cloth.







NOTE: Precautions should be taken to avoid allowing any moisture inside of any console opening and/ or power cord.

- TROUBLESHOOTING -

Problem	Possible Cause	Solution
Power console has no power	Fuse is damaged	Please contact Customer Service.
	Power supply is damaged	Please contact Customer Service.
Handpiece does not work	Power console is not powered ON	Turn ON the power.
	Handpiece is not connected or poor contact with power console	Remove and reconnect the handpiece. If this does not correct the problem, please contact Customer Service.
	Foot pedal is not connected or poor contact with power console	Remove and reconnect the foot pedal. If this does not correct the problem, please contact Customer Service.
	Safety button on the foot pedal is in LOCK mode (Green light OFF)	Press the safety button (Green) to unlock the foot pedal.
	Port switch on the power console is not switched to the corresponding port color or the switch is damaged	Turn the port switch to the corresponding port color. If this does not correct the problem, please contact Customer Service.
	PCB fault	Please contact Customer Service.
Handpiece works with the foot pedal in lock mode	PCB fault	Please contact Customer Service.
Handpiece stops suddenly	Overload protection is activated	Wait until the handpiece has cooled down.
No irrigation fluid coming out from tube	Tube is jammed in the pump	Open the pump and readjust the tube, make sure the tube is within the V shape aperture.
	The pump is damaged	Please contact Customer Service.
Can not insert the module on the handpiece	Handpiece twist lock is locked	Turn the handpiece twist lock to UNLOCK.
Module is loose	Handpiece twist lock is locked	Turn the handpiece twist lock to UNLOCK.
Irrigation button's light is ON, but the pump does not work	PCB fault	Please contact Customer Service.
Irrigation button's light is OFF, but the pump works	PCB fault	Please contact Customer Service.
Safety button's light is ON, but the handpiece does not work	PCB fault	Please contact Customer Service.
Safety button's light is OFF, but the handpiece works	PCB fault	Please contact Customer Service.
Forward/Reverse button's light is OFF, but the handpiece works counter clockwise (reverse)	PCB fault	Please contact Customer Service.
Forward/Reverse button's light is ON, but the handpiece works clockwise (forward)	PCB fault	Please contact Customer Service.

Specifications

- AC Input Voltage 100~240 V / 50~60Hz / Max. 4.2A~2.1A
- DC Voltage output 24V
- Peak current protection at 16.6A /400W MAX.
- Fuse type : UFE @ 250V/6A FL

Port in White				Port in Blue			
Speed and Torque	MIS Module	Automatic K-Wire	Cannulated AO	Speed and Torque	Saw Module	Automatic K-Wire	Cannulated AO
							
HIGH	10,000 RPM	1,500 RPM	1,500 RPM	HIGH	20,000 RPM	3,000 RPM	3,000 RPM
	0.237 Nm	1,577 Nm	1,577 Nm		0.027 Nm	0.178 Nm	0.178 Nm
MEDIUM	8,000 RPM	1,200 RPM	1,200 RPM	MEDIUM	15,000 RPM	2,250 RPM	2,250 RPM
	0,189 Nm	1,261 Nm	1,261 Nm		0.020 Nm	0,134 Nm	0,134 Nm
LOW	6,000 RPM	900 RPM	900 RPM	LOW	10,000 RPM	1,500 RPM	1,500 RPM
	0,142 Nm	0,946 Nm	0,946 Nm		0.013 Nm	0,089 Nm	0,089 Nm

Operation

- Temperature: 10°C~25°C
- Relative Humidity: 30%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa
- Altitude limit: 2,000 meters

Transportation and Storage

- Temperature: -10°C~+40°C
- Relative Humidity: 15%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa

Spair Parts

AP-US	Power Cord US 110V
AP-EU	Power Cord EU 220V
AP-UK	Power Cord UK 220V
AP-001	Fluid Bag Bar Foot
AP-002	Hook
AP-003	Screw for Foot Hook

WARRANTY, SERVICE AND REPAIR

Periodic inspection and service is essential to keep precision Paragon instruments running properly. If repairs are required, they can be accomplished quickly with minimum disruption to the hospital's schedule.

Paragon warrants its SMXM-2034-L-EMC-FDV Power Console to be free from defects in material and workmanship in their manufacture for a period of 1 year from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge.



























This warranty is void in the event of:

- Abuse, misuse, or use in other than normal surgical environments
- In the event of disassembly, alteration, or repair not authorized by the manufacturer
- If the product has not been used in a reasonable manner and/or in compliance with the written instructions provided by the Manufacturer.

All other expressed or implied warranties of fitness and merchantability are excluded here from, and manufacturer shall have no liability of any kind for incidental or consequential damages.

WARNING: Repairs or alterations to Paragon products made by anyone other than Paragon or an Authorized Paragon Repair Facility will void that product's warranty, and the customer will be responsible.

Labeling Symbols

	Refer to instruction manual/booklet		Date of manufacture
	General warning sign / Caution		Medical Device
	Keep Dry		Consult instructions for use
	Sterilized using ethylene oxide		Non-sterile
	Catalog number		Do not use if package is damaged
	Batch code		Do not re-use
	Distributor		Do not re-sterilize
	Importer		Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner
	Complies with EU directives		Humidity limitation
	Manufacturer		Atmospheric pressure limitation
	Authorized representative in the European Community		Temperature limit
	Swiss Authorised Representative		
	UK Responsible Person		
	Use by date		
	BF Type		



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