

# MIRROR™

## OPERATING MANUAL

### POWER DRIVE SYSTEM









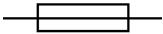






## System components

Qty	Description	Catalog Number
<b>1</b>	<b>Power Drive System</b>	<b>300106</b>
1	Controller	300108
1	Cutter Drive	300107
1	Foot Pedal	300151
1	Power Cord	300152
1	Operating Manual	400005
2	Fuses 5 x 20 mm, 5A – 250V	300155

## Symbol Definitions

	Power OFF
	Power ON
	Type BF Applied Part
	Attention, consult Accompanying Documentation
	Cutter Drive Connection
	Foot Switch Connection
	Caution! Dangerous Voltage
	Hazard Warning! Use Caution
	Fuse Rating
	Input Voltage
	Manufacture Date
<b>IPX0</b>	Degree of protection against the ingress of water "Ordinary"





## DESCRIPTION & INTENDED USE

The MIRROR™ Power Drive System is an electro-mechanical sub system of the MIRROR™ Instrument Set. The Power Drive System includes a Power Drive Controller, a Cutter Drive and a foot activated pedal used to power bone-cutting instruments within the set. Surgical use of the Power Drive System is described in the MIRROR™ Surgical Technique.

The Power Drive Controller requires 100-240 VAC power. The Cutter Drive is detachable from the Power Drive Controller and designed for autoclave sterilization.

The Power Drive System has been designed for continuous operation with intermittent loading, having a duty cycle of 2:00 minutes on and 28:00 minutes off.

Per IEC 60601-1 Electrical Safety Classification, the Power Drive Controller is a Class 1 (third conductor grounded) device. The Cutter Drive is a type BF Applied part.

<b>MIRROR™ Power Drive System Components</b>	
 <p>A black rectangular power drive controller with a control panel on the front. The panel features a power button, a 'READY' indicator light, and an 'ACTIVE' indicator light. Text on the panel includes 'ALEXANDRIA RESEARCH TECHNOLOGIES' and 'TGS UKA'.</p>	 <p>A black, cylindrical cutter drive with a textured grip and a cable attached to the top. The cable has a connector at the end.</p>
<b>Controller</b>	<b>Cutter Drive</b>
 <p>A grey power cord with a standard three-prong AC power plug on one end and a connector on the other.</p>	 <p>A black, rectangular foot pedal with a textured surface and a cable attached to the top.</p>
<b>Power Cord</b>	<b>Foot Pedal</b>

## WARNINGS & PRECAUTIONS

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### 1. Fuses and Line-in Voltage



THIS SYSTEM REQUIRES TWO FUSES TO PREVENT DAMAGE AND ENSURE PROPER SAFETY. DO NOT USE FUSES OTHER THAN THOSE SPECIFIED BY THE MANUFACTURER.

- This Power Drive Controller operates with line and neutral independently fused. Two **5 Amp / 250V SLO-BLO** fuses have been installed in the fuse holder at the factory. To minimize the risk of electric shock, do not operate the controller using the single (load) fuse option.
- A hospital-grade power cord is supplied with this system. Do not use cords other than those supplied by the manufacturer.
- To ensure proper grounding, connect the power cord to only hospital-grade grounded outlets.



DO NOT USE POWER CORD IF IT IS DAMAGED. Contact manufacturer for replacement.

### 2. Power Drive Controller Placement



Place the Power Drive Controller on a cart outside of the sterile field approximately 1.6 M (5 feet) from the operating site where the cords will not present a tripping hazard.



Do not set liquids, heavy objects, or equipment which may generate heat on top of the Power Drive Controller or cords.



DO NOT USE THIS DEVICE IN THE PRESENCE OF FLAMMABLE / EXPLOSIVE ANESTHETIC MIXTURES WITH AIR, OXYGEN OR NITROUS OXIDE.

## Care and Cleaning

- Clean soiled Controller, power cord and foot pedal with a damp cloth and disinfectant solution.
- Do not use harsh detergents, solvents or acids to clean any of the components in this system.
- Always place the system in a secure location where none of the components will fall or be dropped.



DO NOT SUBMERGE ANY COMPONENT OF THIS SYSTEM, INCLUDING THE CUTTER DRIVE.



DO NOT AUTOCLAVE POWER DRIVE CONTROLLER, POWER CORD OR FOOT PEDAL.



THE CUTTER DRIVE MUST BE STERILIZED BEFORE USE. CONSULT THE **Sterilization** SECTION FOR DETAILS ON THE STERILIZATION OF THIS COMPONENT.

- The Cutter Drive is provided lubricated and sealed from the factory. Do not attempt to lubricate the Cutter Drive.
- If any component of this system is damaged or cannot be cleaned properly, contact the manufacture for replacement.



Federal Law restricts the sale of this of this device to or on the order of a physician.



This Power Drive Controller does not contain user serviceable parts. If unit becomes inoperable, DO NOT remove the cover; Contact Manufacture for service.



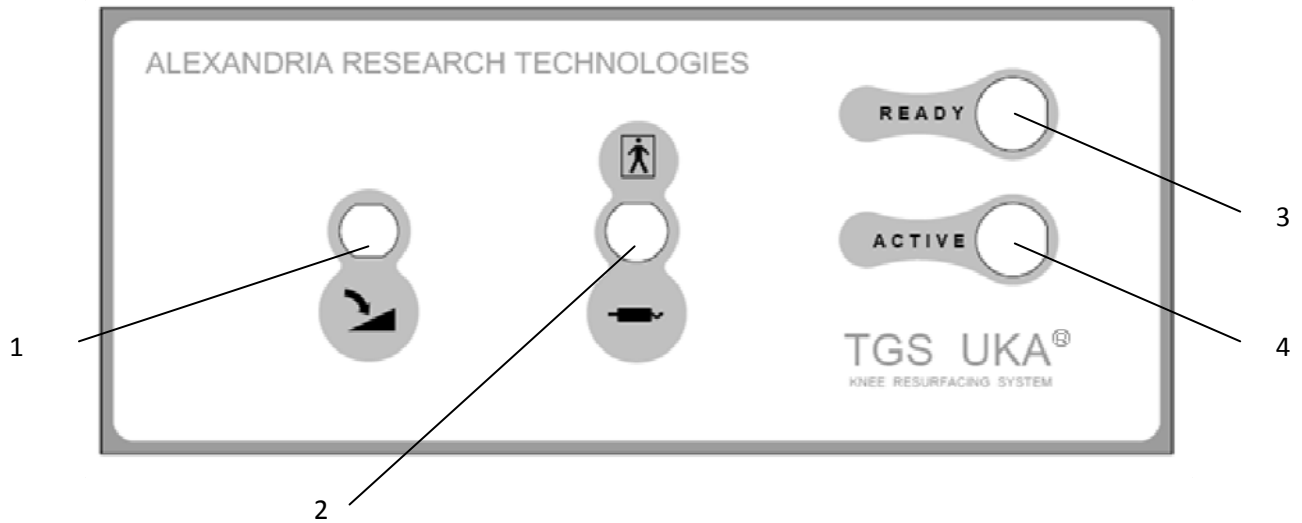
Do not connect devices other than those specified by the manufacture to this Power Drive Controller or to the Cutter Drive coupling.



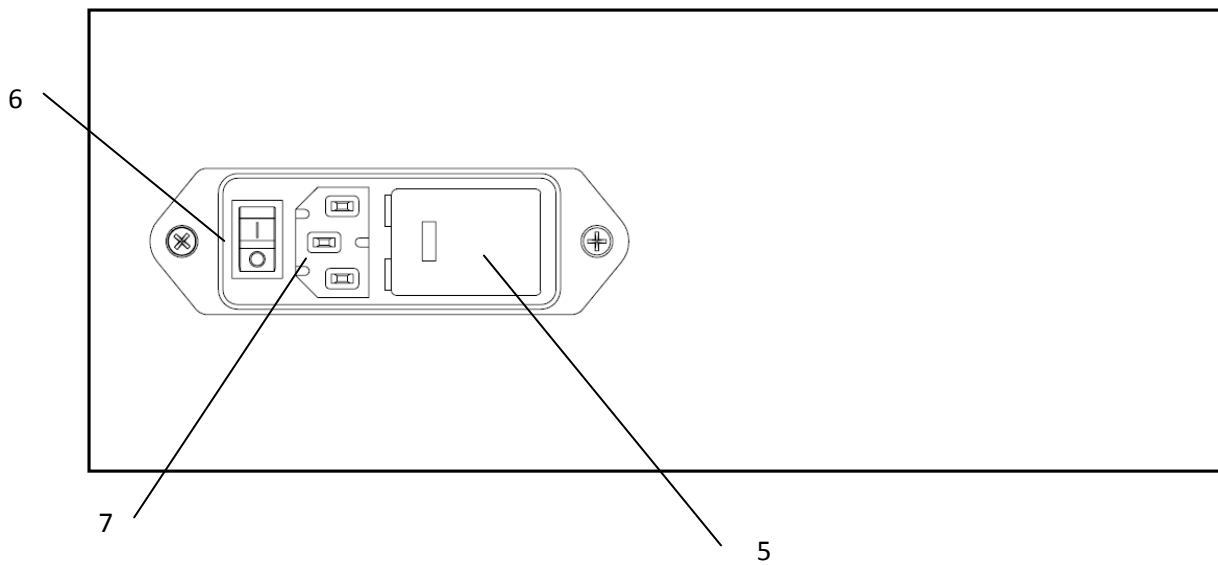
The power cord is to be used for mains disconnection.

Operation

FRONT



REAR



1. Foot pedal receptacle
2. Cutter Drive connection receptacle
3. Power Indicator LED (Green)
4. Active indicator LED (Blue)
5. Fuse panel door
6. Power switch (I/O)
7. AC Line-in receptacle

## 1. Setup

- Connect Power Cord to the back of the Controller.
- Plug Power Cord into 115 VAC Hospital-Grade Grounded outlet.
- Attach foot pedal cord to indicated port on the Power Drive Controller by pressing tube over mating connector.
- Attach Cutter Drive to indicated port on Power Drive Controller, aligning indicators to properly key the connection. To remove, slide the connector housing away from the Power Drive Controller. DO NOT pull on the cord to disconnect.

## 2. Use

- To turn on power to the system, toggle the I/O switch in the rear of the Power Drive Controller.



DO NOT ACTIVATE THE FOOT PEDAL WHILE TURNING ON POWER. AN ERROR MAY OCCUR OR THE CUTTER DRIVE MAY BEGIN SPINNING.

- A green LED on the front of the Power Drive Controller will illuminate to indicate that the system has power and that it may now be used.
- This system is pre-set to the direction and speed that has been optimized for the associated cutting instruments. No adjustments may be made.
- Use Primary Femoral Cutter in accordance with IFU and Surgical Technique.
- The device is ready to use. Use foot pedal to activate cutter. Remove foot from foot pedal to stop the device.
- If the device is not functioning properly contact manufacturer or see the **Troubleshooting** section of this manual.



ATTACHMENTS CONTAIN SHARP CUTTING ELEMENTS WHICH MAY CUT GLOVES AND SOFT TISSUE. TO AVOID INJURY, DO NOT CONTACT THE CUTTING ELEMENTS WHILE THE DEVICE IS IN OPERATION.



DO NOT RUN THE CUTTER DRIVE FOR EXTENDED PERIODS OF TIME AS THIS MAY GENERATE EXCESSIVE HEAT AND DAMAGE THE CUTTER DRIVE.



## Sterilization

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CUTTER DRIVE IS SHIPPED NON-STERILE. CUTTER DRIVE MUST BE STERILIZED PRIOR TO USE.

- Sterilize the Cutter Drive by autoclave at 135°C (275 ° F) for 30:00 minutes in accordance with the *MIRROR™ Care and Cleaning* instructions (Cat. No. 400010).
- DO NOT AUTOCLAVE: Foot Pedal, Power Drive Controller, or Power Cord. Wipe with a light disinfectant cloth.



DO NOT EXCEED 135°C (275 ° F).



DO NOT SUBMERGE ANY COMPONENT OF THIS SYSTEM.



DO NOT USE CHEMICAL CLEANERS OR DISENFECTANTS.



Follow standard hospital procedures for sterilizing, processing and handling of equipment.

## Troubleshooting

Green Power Light does not come.	<ol style="list-style-type: none"> <li>1. Power Drive Controller is not plugged in to wall outlet.</li> <li>2. One or both fuses are blown. See <b>FUSE REPLACEMENT</b> for checking and replacing fuses.</li> </ol>
Cutter Drive does not spin; ACTIVE LED does not light when foot pedal is pressed.	<ol style="list-style-type: none"> <li>1. Error in Power Drive.Cycle power off for 10 sec before turning back on.</li> <li>2. Foot pedal is not connected to Power Drive Controller.</li> </ol>
Cutter Drive does not spin, ACTIVE LED Lights up.	<ol style="list-style-type: none"> <li>1. Cutter Drive is not connected.</li> <li>2. Cutter Drive is mechanically blocked.Remove any attachments to test Cutter Drive function.</li> <li>3. Error in Power Drive Controller. Cycle power off for 10 sec before turning back on to clear error.</li> <li>4. Cutter Drive is damaged. Contact manufacturer.</li> </ol>
Cutter Drive overheats	<ol style="list-style-type: none"> <li>1. Damaged attachment is providing too much resistance. Remove attachment to test Cutter Drive function.</li> <li>2. Cutter Drive/Cutter has been used too aggressively. Allow Cutter Drive to cool before using.</li> <li>3. In the event of overheating, the Power Drive Controller may automatically shut down to prevent damage to the Cutter Drive. To reset the Power Drive Controller, cycle the power off for 10 sec before turning back on. Allow Cutter Drive to cool before using.</li> </ol>



THIS SYSTEM CONTAINS NO USER-SERVICABLE PARTS. DO NOT ATTEMPT TO DISASSEMBLE, REPAIR OR MODIFY ANY COMPONENT OF THIS SYSTEM. CONTACT MANUFACTURER FOR REPAIR.

## Fuse Replacement

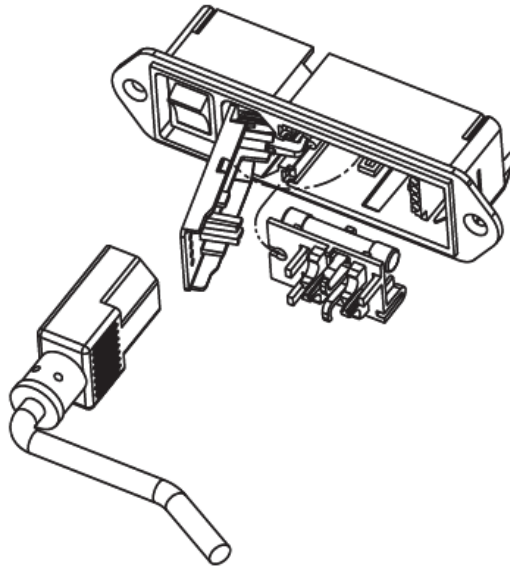


USE ONLY **5 X 20MM** METRIC FUSES CURRENTER RATED FOR: **5 AMP / 250 V SLO-BLO**. Contact manufacturer for replacement fuses.



DO NOT USE IN SINGLE FUSE CONFIGURATION.

## Fuse Installation Instructions



1. Remove power cord.
2. Pry door open at socket.
3. Lift and swing door into socket.
4. Lift fuse holder out of housing.
5. Install two (2) metric fuses.
6. Replace fuse holder into housing.
7. Swing and snap door back in place.

## Specifications

Model Number: 300106

Dimensions: 290mm L x 265mm W x 110mmH  
(11.4" L x 10.4" W x 4.3" H)

Weight: 5 lbs

Mode of Operation: Continuous: intermittent loading

Shipping and Storage: Temperature range within -40°C to +70°C  
Relative humidity range within 10% to 100%  
Atmospheric pressure range within 500 to 1060 kPa

Power Supply: Primary: 100-240 VAC ~ 50-60 Hz, 5.0A  
Secondary: 48 VDC  
Output (to Cutter Drive): 48 VDC

Classification: IEC 60601-1 Class1, Type BF Applied Part

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Scottsdale, AZ 85260  
1(480) 502-3661  
1(888) 229-3661  
[www.CayenneMedical.com](http://www.CayenneMedical.com)

## Compliance Statement

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1. This device complies with EN 60601-1-2 (CISPR Class B) Requirements for electrical medical equipment.
2. This device complies with part 15 of FCC rules; operation of this device is subject to:
  - a) This device may not cause harmful interference.
  - b) This device must accept any interference, including interference that may cause undesirable performance.

In the event that performance of this device is affected by nearby equipment or this device affects the performance of nearby equipment the following actions may help eliminate the interference and restore normal operations:

- a) Move affected devices or equipment further apart.
  - b) Discontinue use of this device.
  - c) Discontinue use of affected device(s).
3. This device is rated **IXPO** against the ingress of water: Ordinary Protection.