SpineJet ™

HydroSurgery System

Product Manual

Manufactured by:

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PRESCRIPTION INFORMATION

Device Indications

The HydroCision SpineJet System is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required. Specific functions include cutting, ablation and shaping of soft tissue, and decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and minimally invasive spinal surgeries.

Warnings

1. The HydroCision SpineJet Disposable Assembly should not be activated in close proximity to, or come into contact with, the spinal cord, nerve roots, or major blood vessels to avoid the possibility of injury or damage from the Fluidjet cutting action, locally generated vacuum, or device edges or tip.

2. Do not touch the SpineJet handpiece assembly tip while activated.

3. Do not insert or withdraw the SpineJet handpiece assembly while activated.

4. Inadvertent activation or movement of the SpineJet handpiece assembly outside the field of vision or without adequate assurance of device placement via fluoroscopy or an alternate imaging technology may result in patient injury. Two depth markings are provided on the Curette instruments near the tip to assist in device placement: the narrow band marking serves as a visual warning to turn off the device prior to removal outside the annulotomy; the wide band marking serves as a 3-4 cm depth indicator to use caution and avoid unintended puncture of the annulus.

5. Do not reuse any system component or accessory labeled as SINGLE USE.

6. Attempts to bend the SpineJet handpiece assembly may render the tool unusable or unsafe.

Precautions

1. A thorough understanding of the principles and techniques involved in spinal surgeries is essential to avoid injury to the patient and medical personnel, and damage to the device or other medical instruments.

2. Read all instructions carefully. Failure to properly follow instructions may lead to electrical, mechanical, or thermal injury and cause improper functioning of the device.

3. SpineJet Disposable Handpiece and Quick Connector packaging is supplied sterile. If the package is opened or damaged the sterility of the handpiece will be compromised.

4. Ensure complete connection of SpineJet Disposable Handpieces to the Quick Connector and connection of the Quick Connector to the power console and fluid supply prior to use.

5. The SpineJet handpiece should be inserted, manipulated, and withdrawn carefully from the operative site to avoid possible damage to the device and/or injury to the patient or surgical personnel.

6. Ensure complete connection of SpineJet Handpiece to the power console, fluid supply and waste container prior to use.

7. Particular precaution should be made to avoid unintended puncture of the annulus.

8. Use of the higher settings on the device console will lead to more aggressive tissue removal. Use caution near sensitive tissues, such as neurovascular bundles and blood vessels.

9. It is recommended that the SpineJet handpiece be used on console setting #10 for nucleus, annulus, and endplate cartilage removal.

10. To prevent clogging of the device tip, avoid applying excessive force with the cutting edge of the device that would release cartilage fragments larger than the device's evacuation tube opening.

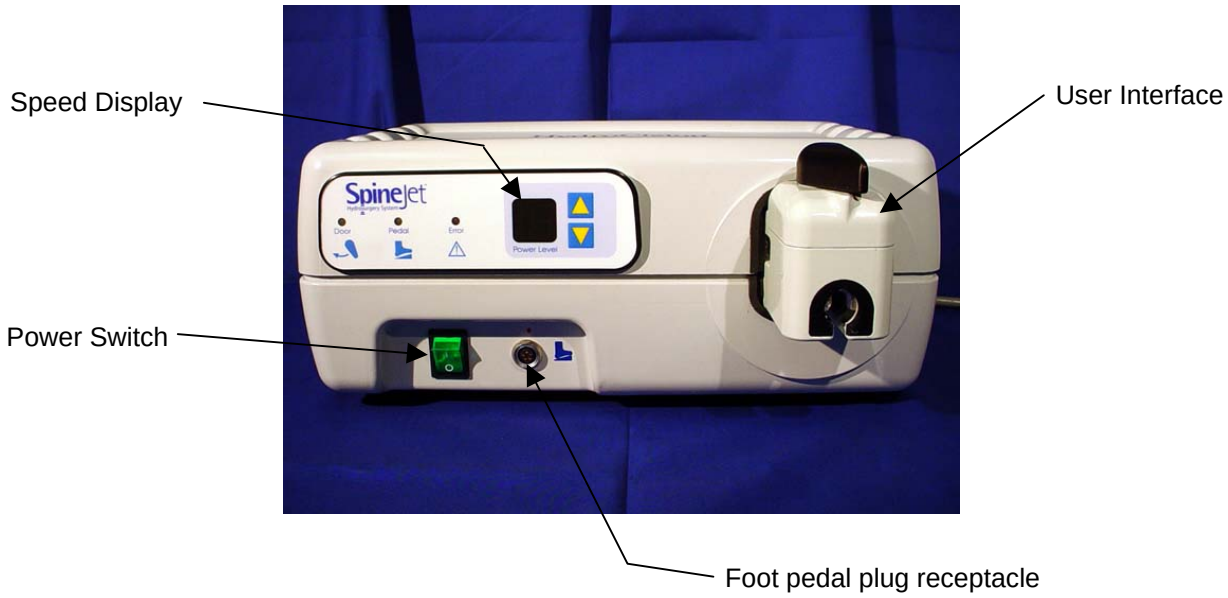
11. This device can cut soft tissue.

Rx Only

PRODUCT DESCRIPTION

Overview of the SpineJet™ HydroSurgery System

The SpineJet product line is the first family of fluidjet product designed specifically for spine surgery. HydroCision products harness the power of water to safely and precisely cut and evacuate tissue within the disc space. The power console pressurizes sterile fluid from a standard 3-liter irrigant supply bag. The pressurized fluid is transported to the disposable handpiece and exits the distal tip as a high-velocity fluidjet. The fluidjet crosses a short gap and is collected in the evacuation tube. Tissue directed into the gap is excised and drawn into the evacuation tube along with the fluidjet. The evacuation tube connects to a standard waste container. Disposable handpiece distal tips may be configured to incorporate mechanical cutting features.



System Components

The SpineJet™ HydroSurgery System contains four basic components: the Disposable Quick Connector, the Disposable Handpiece, the Power Console, and the Foot Switch. The Quick Connector consists of the connect itself, a Pump Cartridge, and hoses. The Pump Cartridge mounts into the user interface located on the front of the Power Console; this connection provides power to the Disposable Handpiece. The Foot Switch provides remote actuation of the Power Console.

The system is designed to work with any Disposable SpineJet Handpiece.

Power Console (P/N 52700)

Front Panel

The Power Switch is on the lower left corner of the front panel. When the system is not in use, this switch should be in the off (0) position.

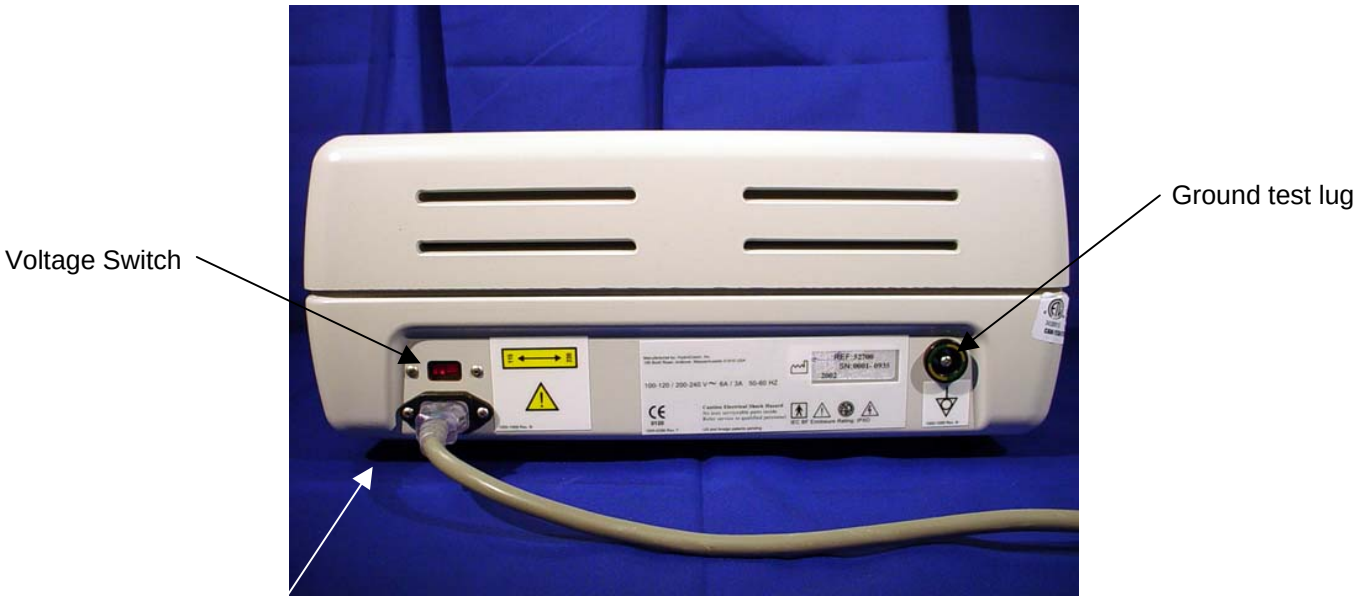
The foot switch receptacle receives the cable connector from the external foot switch to allow remote operation of the system. The Foot Switch is the only means of actuating the device. It allows for direct surgeon control over console activation.

The digital display, located to the left of the up and down-speed control arrows on the center of the panel, defaults to speed level 1, the lowest speed level for the system. The up and down arrows that are immediately adjacent to the digital display can be used to increase or decrease the speed respectively.

Three indicator lights are located to the left of the digital display.

"Door"	When illuminated, an amber **Door light** indicates that the console knob is not completely closed.
"Pedal"	When illuminated, and amber **Pedal light** indicates that the foot switch is not properly connected.
"Error"	When illuminated, a red **Error light** indicated that an over-pressure condition has occurred that can only be cleared by toggling the power switch off and on.

Rear Panel



The Power Cord Receptacle and Power Cord utilized for connection to the electrical supply.

Disposable Quick Connector with Pump Cartridge and Quick Connect

The Disposable Quick Connector consists of two main components: the Connector and Pump Cartridge to pressurize the fluid. In addition to these main components, there are three hoses pre-assembled and included in the system. A bag spike hose allows the fluid from a sterile saline bag to enter the pump cartridge. A high-pressure hose then carries the pressurized fluid from the cartridge to the handpiece via the Quick Connect. The waste hose carries the saline solution and any material collected at the instrument tip from the handpiece to an appropriate waste container.

The Connector consists of a small diameter high-pressure tube, and a larger evacuation tube. The Quick Connect is the point of connection for all SpineJet Disposable Handpieces.

The Disposable Quick Connector controls the flow of sterile saline from the fluid supply bag through the pump cartridge, where it is pressurized, and then directed to the Disposable Handpiece for use at the surgical site. It also ensures removal of tissue debris from the instrument tip into an appropriate waste container.

Foot Switch with Connector (P/N 51537)

The Foot Switch is connected to the Power Console through the receptacle located under the front panel. It allows the surgeon to activate the instrument while working in the sterile surgical field. A missing or poorly connected Foot Switch is indicated when the “pedal” light is illuminated.

Power Cord (P/N 51507) Domestic

The Power Cord provides electrical power to the console from a wall socket.

SYSTEM SPECIFICATIONS

CAUTION

Only HydroCision approved equipment should be connected to this device.

CONSOLE (P/N 52700)

FRONT PANEL:	Illuminated Power Switch, On/Off (1/0)
	Foot Switch Receptacle
	Speed Control for levels 1 through 10
	Amber “Door” indicator Light
	Amber “Pedal” indicator Light
	Red “Error” indicator Light
REAR PANEL:	Power Cord Receptacle
	Input Voltage Selector Switch (115/230)
	Ground Plug
POWER CONSOLE:	AC Power: Detachable cord with a three-pin Hospital Grade connector
SIZE:	18" W x 13" D x 8" H (45.7 cm W x 33.0 cm D x 20.3 cm H)
WEIGHT:	28 pounds (12.7 kg)
POWER:	100-120 / 200-240 V ~ 6A / 3A 50/60 Hz

FOOT SWITCH (P/N 51537)

Size:	3" W x 9" D x 2.5" H (7.6 cm W x 22.9 cm D x 6.4 cm H
Weight:	3 pounds (1.12 kg)

POWER CORD (P/N 51507)

Length:	15 feet (4.6 meters)

DISPOSABLE HANDPIECE ENVIRONMENTAL CONDITIONS

Unless otherwise stated, the following conditions apply for product use as well as shipping and handling:

Temperature Range (Shipping & Handling):	-40°F (-40°C) to 125°F (52°C)
Temperature Range (Product Use):	40°F (4°C) to 100°F (38°C)
Humidity Range:	0% to 100%, noncondensing
Atmospheric Pressure:	500 to 1500 millibar

POWER CONSOLE ENVIRONMENTAL CONDITIONS

Unless otherwise stated, the following conditions apply for product use as well as shipping and handling:

Temperature Range (Shipping & Handling):	-4°F (-20°C) to 131° F (55°C)
Temperature Range (Product Use):	40°F (4°C) to 100°F (38°C)
Humidity Range:	0% to 100%, noncondensing
Atmospheric Pressure:	500 to 1500 millibar

ELECTROMAGNETIC INTERFERENCE RISK

The power console meets the requirements of IEC 60601-1-2 (2001-09)

SYSTEM SET-UP

This section provides the procedures for assembling and testing the SpineJet™ HydroSurgery System.

Set-up of the Console

1. Connect the Foot Switch Cord to the receptacle on the front of the Power Console.
2. Connect the Power Cord to the back of the console and to a 20 amp outlet.
3. Turn the Console on by pressing the Illuminated Power Switch located on the Front Panel.

Set-up of the Quick Connector and Disposable Handpiece

Note: The instructions below are illustrative, refer to the Instructions For Use accompanying disposable products for specific applicable operation details.

1. Circulating Nurse: Ensure that the sealed package is undamaged. Using sterile technique, carefully open the product outer package and present contents to sterile field personnel.

2. Scrub Nurse or Surgeon: Open inner pouch or lid. If present, carefully remove the two tape strips by pulling on the tabs, and release the product. If present, remove the plastic guard from the distal tip of the handpiece. Examine the handpiece assembly and Quick Connector; do not use if damaged.

3. Attach the selected SpineJet handpiece to the Quick Connector by aligning the alignment features on the handpiece handle with corresponding features on the Quick Connector and sliding them into place until the locking tabs click indicating the correct attachment. Do not force the connection.

4. Scrub Nurse or Surgeon: Clip the high-pressure hose/waste hose to the sterile drape.

5. Scrub Nurse or Surgeon: Pass the pump cartridge, high-pressure hose/waste hose, and coiled supply hose with bag spike to the Circulating Nurse.

6. Circulating Nurse: Open the Console nest by turning the knob to the right. Insert the pump cartridge into the nest by pushing the cartridge in until it is fully seated, and close the nest by turning the knob to the left. Attach the waste hose connector to a waste collection container – connection of the waste collection container to a vacuum source is not required and will create continuous suction at the device tip and affect device performance. Remove the sterile cover from the bag spike and insert into an irrigant supply bag. A 3 liter bag is recommended. Ensure that there are no kinks or external obstructions in the supply, high pressure, or waste hoses.

7. Circulating Nurse: Ensure that the foot switch is plugged into the connector on the front of the console and the power cord is plugged into the back of the console. Plug

the power cord into a proper electrical outlet. Turn on the main power switch and check that the power switch is illuminated.

8. Nursing Staff: Once the system has been primed with saline, do not allow the saline bag to empty; an empty bag will allow air into the system and reduce the system's efficiency. Therefore, always change to a new saline bag before the bag in use empties. Take care when switching bags to prevent air from entering system by closing off the supply hose with the pinch clamp. A 3-liter irrigant supply bag will avoid encountering priming difficulties.

9. a) If the device tip becomes blocked with foreign matter, it will typically be noticed by a reduction in device efficiency or the presence of spray from the tip; b) Stop the jet flow by releasing the foot switch; c) Remove the handpiece from the surgical site using care not to come into contact with vital structures; d) Remove the obstruction with forceps taking care not to touch the opening in the high-pressure jet. Once removed, depress the foot switch and check that there is a single coherent jet flow. If the obstruction is not completely removed, repeat procedure.

10. To Change Tools

   a. Depress the two locking tabs at opposite sides on the proximal end of the tool (near the Quick Connector interface) and gently remove the tool from the Quick Connector while keeping the tabs depressed.

   b. Insert the next desired tool as above.

11. After completing the procedure, disconnect the SpineJet Disposable Assembly from the Power Console by turning the nest knob to the right and removing the pump cartridge by pulling it straight out.

AFTER SURGERY

The SpineJet handpiece assembly, Quick Connector, Saline Bag, and waste receptacle collection container may be discarded using standard biohazard disposal procedures.

HOW SUPPLIED

The SpineJet handpiece assembly and Quick Connector are provided sterile.
The contents are sterile unless the package is opened or damaged. Do not resterilize.
Do not use if package is opened or damaged.

STORAGE

Do not store product above 125°F (52°C) or below -40°F (-40°C). Avoid storage near moisture and direct heat.

CAUTION

Each Disposable Universal Connector and Handpiece is intended for SINGLE USE ONLY. Do not resterilize. Discard after use.

MAINTENANCE

Maintaining the Power Console

There are no user serviceable parts within the console, however there are several maintenance items to be observed.

CAUTION

Unplug the unit before starting any maintenance on the console.

The fan slots should be kept free from obstructions and periodically be inspected for excessive build up of dust and/or foreign material. A vacuum cleaner should be used to clean the fan slots of any loose debris.

The slots on the bottom of the console should be kept free from obstructions and be periodically inspected for build up of dust and or foreign material. A vacuum cleaner should be used to clean the slots of any loose debris.

The inside of the console user interface should be inspected periodically for buildup of deposits and or debris. A damp cloth soaked in mild detergent can be used to remove material. Do not soak the inside of the user interface opening. Excessive fluid could cause damage.

At the end of the console's useful life, dispose of the console according to local regulations.

Cleaning the Power Console

Disconnect from electrical power source. Wipe down console and footswitch with a clean, damp cloth. Household all-purpose cleaners can be used to clean all surfaces. DO NOT IMMERSE. Do not sterilize or immerse in disinfectant solution.

CAUTION
Do not sterilize or immerse the Power Console or the Foot Switch.

Replacing the Power Cord

If the power cord is damaged, it can be removed from the Power Console. **FIRST, REMOVE THE PLUG FROM THE WALL SOCKET**. Do not pull on the cord itself. Remove plug from console, again without pulling on the cord. Contact HydroCision customer service (888) 747-4470 to order a replacement power cord.

Replacing the Foot Switch

If the foot switch is damaged, it should be removed from the Power Console. Contact a HydroCision representative to order a replacement foot switch.

TROUBLESHOOTING

SYMPTOM	CAUSE	REMEDY
Excessive spray	Obstruction of evacuation tube (bone chip, or other foreign material)	Remove handpiece from surgical field and take foot off foot pedal and remove obstruction from instrument tip
	Misaligned jet (striking edge of tube or shooting outside instrument)	Stop! Do not use Replace handpiece
	Waste hose is not draining properly	Raise waste hose so collector end of waste hose is lowest point of entire tube
	Waste hose is: Obstructed Kinked Pinched	 Remove obstruction Unkink hose Remove object causing pinch
Motor is turning, but no fluidjet is visible in handpiece	No fluid supply	Attach saline bag or replace saline bag if empty
	Air in supply hose	Pump fluid on high setting until system is purged of all air in supply hose.
Motor does not run, Power Switch light is off	Power cord not attached	Assure power cord is attached to back of console and wall outlet
	Power switch in off position	Turn on
Motor does not run, Power Switch light is on, "Pedal" light is on	Foot switch not attached	Attach footswitch securely
	Footswitch is damaged	Replace footswitch
	Cartridge knob is not fully closed	Completely close cartridge knob
Motor does not run, Power Switch light is on "Error" light is on	Over-current situation has occurred (unknown cause)	Turn off main power switch, wait 5 seconds, turn back power back on
	Over-current situation with a rigid high pressure hose. Handpiece high pressure hose is plugged.	Discard handpiece assembly and replace with a new unit
Motor does not run, Power Switch light is on, "Door" light is on	The knob that closes the User Interface is not completely closed.	Check that the cartridge is seated in the User Interface and turn the knob clockwise to the six o'clock position.

EQUIPMENT SYMBOL DESCRIPTIONS

	**Single Use Only**
	**See instructions for use**
Rx only	**USA law restricts this device to sale by or on the order of a physician**
“Door”	**User interface - knob**
“Pedal”	**Footswitch**
“Error”	**Consult operating instructions**
	**Type BF Applied Part**
	**Connection of the waste hose or any container connected to it, to a vacuum source is not required and will create continuous suction at the device tip and affect device performance.**
	**Off**
	On
	**Explosion Hazard: Do not use in the presence of flammable anesthetics**
	**Caution: Electrical Shock Hazard**
	**Protect packaged product from direct sunlight or heat source**
	**Keep packaged product in dry storage**

EQUIPMENT CLASSIFICATIONS

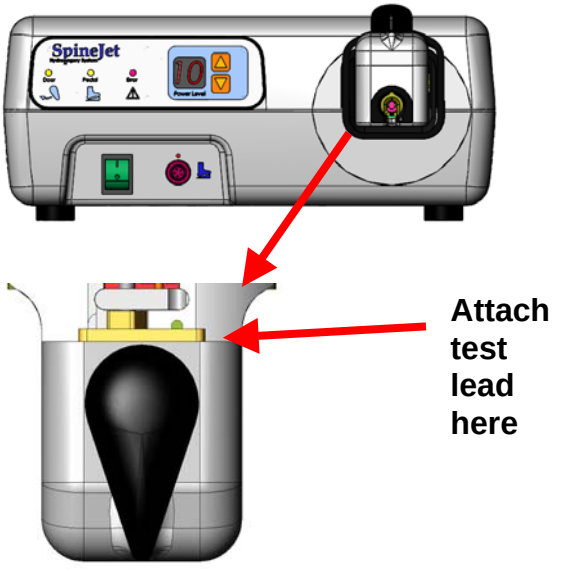
- Class 1 Device
- AC powered equipment
- Type BF applied part
- IEC BF enclosure rating—
  - Console: IPXO
  - Footswitch: IP68

Mode of Operation: Continuous operation

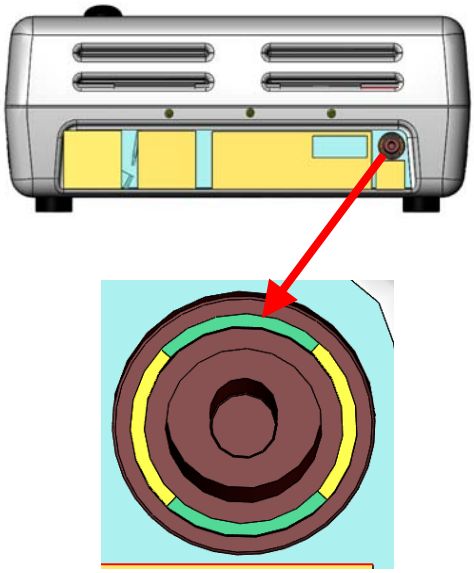
ELECTRICAL SAFETY TESTING

Product Description: **Model 52700 – SpineJet Console**
Classification: **Class I / Type BF equipment**
Requirements: **IEC 60601-1:1990**

Test	Equipment Condition	Limit at 120 V	Limit at 240V
Ground Integrity	Normal	0.2 Ohms	0.2 Ohms
Earth leakage	Normal	< 250 µ Amp	< 500 µ Amp
Earth leakage	Single Fault	< 500 µ Amp	< 1000 µ Amp
Enclosure leakage	Normal	< 50 µ Amp	<100 µ Amp
Enclosure leakage	Single Fault	< 250 µ Amp	< 500 µ Amp
Patient leakage	Normal	< 50 µ Amp	<100 µ Amp
Patient leakage	Single Fault	< 250 µ Amp	< 500 µ Amp
Input VAC applied to Patient applied part	Single Fault	<2500 µ A	<5000 µ A



User Interface – (Patient applied Part)



Ground lug

Notes:

- For EARTH LEAKAGE CURRENT, SINGLE-FAULT CONDITION shall mean the interruption of either power supply conductor, one at a time.
- For ENCLOSURE LEAKAGE CURRENT or PATIENT LEAKAGE CURRENT, SINGLE-FAULT CONDITION shall mean the interruption of either power supply conductor or the PROTECTIVE EARTH conductor, one at a time.
- For PATIENT LEAKAGE CURRENT, SINGLE-FAULT CONDITION shall also mean application of RATED MAINS VOLTAGE to the PATIENT APPLIED PART relative to the PROTECTIVE EARTH conductor.