HydroCision

HydroSurgery System

Product Manual

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About this manual

This Operators Manual has been developed to provide the user with the information necessary to operate and maintain the SpineJet HydroSurgery System. It is important that all medical personnel that operate this device read and understand all the information contained within this Operating Manual. This material is not meant as a substitute for formal training on the SpineJet HydroSurgery systems, which may be required by local, regional or state protocol. As with any medical device please consult your local medical director or governing agency for further information and requirements. If you have any questions or concerns regarding this manual or product please contact Hydrocision Customer Care at one of the following for assistance:

Hydrocision Customer Care
Phone: 1-888-747-4470
Fax: 1-978-600-5058
www.Hydrocision.com
www.WashAwayBackPain.com

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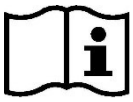
Equipment Symbol Descriptions

	**Single Use Only**
	**See instructions for use**
Rx only	**USA law restricts this device to sale by or on the order of a physician**
	**User interface – knob**
	**Footswitch**
“Error”	**Caution**
	**Type BF Applied Part**
	**Console Disposal: Do not throw the console in the trash, return to the manufacturer for proper disposal**
	**Equipotentiality, used to connect various electrical components together to the same potential. E.g. for local bonding**
	**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

Voltage

Caution: See IFU

Manufacturer

Date of Manufacture

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.

Contraindications

There are no contraindications for this device.

Clinical and Training information

Operators must be trained to set up and operate the SpineJet Hydrosurgery System in a medically approved manner including standard hospital procedures.

Warnings

1. The HydroCision HydroSurgical Console is designed to receive only HydroCision handpieces. Connecting handpieces from other manufactures to the HydroCision console could result in damage to the equipment and / or injury to the operator of the system and may not be covered by warranty.

2. Please refer to HydroCision Instructions for Use for the single use handpieces prior to performing surgical procedures for warnings specific to the individual devices.

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

4. No modification of this equipment is allowed

5. This equipment is classified in its intended purpose as transient. Normally intended for continuous use for less then 60 minutes.

6. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

7. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HydroCision HydroSurgical Console including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment should result.

8. Use of accessories, transducers and cables other then those specified or provided by the manufacturer of this equipment could result in increased electromagnetic immunity of this equipment and result in improper operation.

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 Assembly 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 (if applicable) and connection of the disposable pump assembly to the power console, fluid supply, and waste container 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. Particular precaution should be made to avoid unintended puncture of the annulus.

7. 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.

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

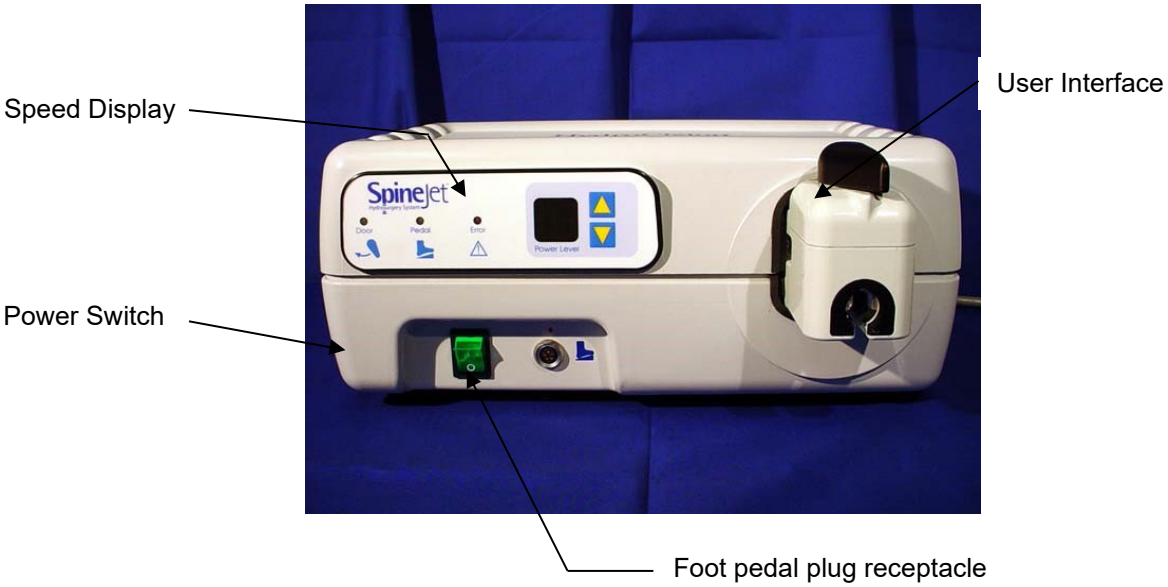
9. To prevent clogging of the device tip, avoid applying excessive force with the cutting edge of the device that would release cartilage fragments larger than the device's evacuation tube opening.

10. This device can cut soft tissue.

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.



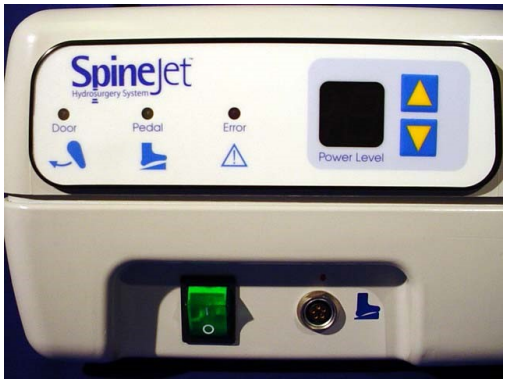
System Components

The SpineJet® HydroSurgery System contains four basic components: a disposable pump and tubing assembly; a disposable handpiece; a power console; and a foot switch. The disposable pump and tubing assembly may be supplied directly connected to the disposable handpiece as one integrated assembly, or they may be supplied as separate disposable Quick Connector and disposable handpiece assemblies. In either case, a 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 Assembly.

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.

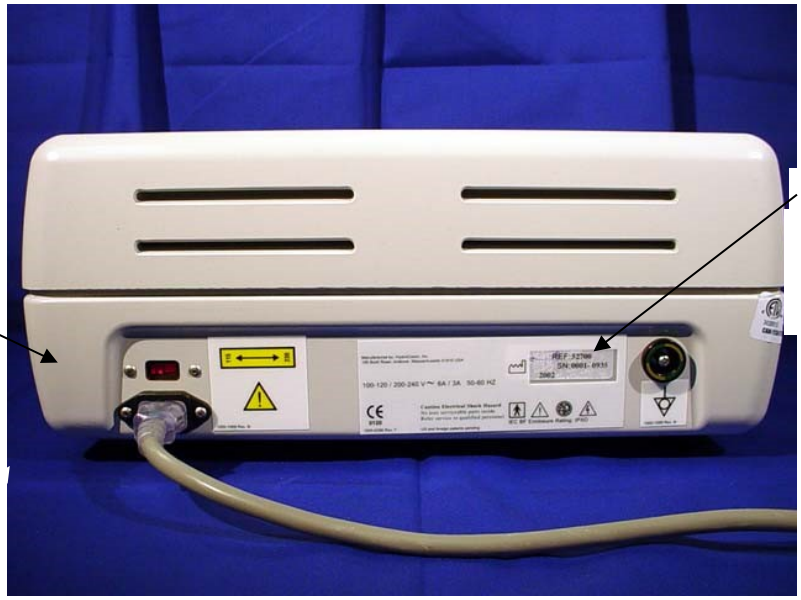
The foot switch receptacle receives the cable connector from the external foot switch to allow remote operation of the system. The Foot Switch is the only means of actuating the device. It allows for direct surgeon control over console activation.

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



Voltage Switch

Equipotentiality plug
e.g. ground bonding for local electrical components

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

Disposable Assemblies

Refer to the Instructions for Use supplied with the disposable assemblies for instructions on their proper use.

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 1000-1507) 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 1000-1507)

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 1060 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 console meets the requirements of IEC 60601-1-2 ed 4.0 (2014-02)
Note: the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment may not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Note: Internal errors may occur. A Hardware Fault screen displays an error code. Please record the error code and turn the power off to reboot system.

If the HydroCision HydroSurgical console has a electromagnetic interference that could effect the performance of the device the effect would potentially cause a degradation in the operation of the user interface and make the device inoperable. If this occurs and the console performance is lost or degraded the operator should take mitigation actions to correct prior to using such as moving the console further from the Electromagnetic interference.

If the console still has degraded performance after mitigation please contact Hydrocision customer care for analysis to ensure basic safety and performance meet specifications or if service is needed to bring the performance and maintenance of the expected units serviceable life.

SYSTEM SET-UP

This section provides the procedures for assembling and testing the 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.
4. To safely terminate operation of equipment flip switch to OFF setting.

Set-up of the Disposable Assemblies

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, pump, and tubing; do not use if damaged.

3. Attach the selected SpineJet handpiece to the Quick Connector (if applicable) 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 (a light vacuum, <10mm HG, will have a minimal impact on 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. For devices that use a Quick Connector, the handpiece can be changed by the following procedure:
    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 Disposable Assemblies 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 Assembly 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 clean with:

- ketones (MEK, acetone, etc.) or
- abrasive cleaners.

Do not disinfect or sterilize the Console.

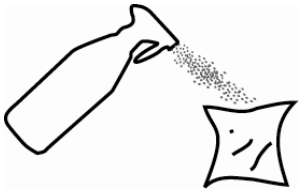
Do not spray or pour cleaning solutions directly on the Console.

Do not allow cleaning solutions to accumulate on the Console.

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

The Console is chemically resistant to most common hospital grade instrument cleaning solutions and non-caustic detergents. The following list of approved cleaning solutions may be used to clean the Console:

- Isopropyl alcohol
- Mild detergent solution
- Diluted chlorine bleach (30 mL/L water)
- Ammonia based cleaners
- Glutaraldehyde-based cleaners
- Hydrogen peroxide
- Chlorhexidine



Cleaning the Controller

1. Use only approved cleaning solutions.
2. Moisten a clean cloth with the cleaning solution; do not spray or pour cleaning solutions directly on to the Controller.
3. Wipe the surface of the Controller, taking care not to leave excess residual cleaner on the Controller. If fluid ingress is detected, set the Console aside for an extended period of time to allow it to dry.

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 Classifications

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

Mode of Operation: Transient

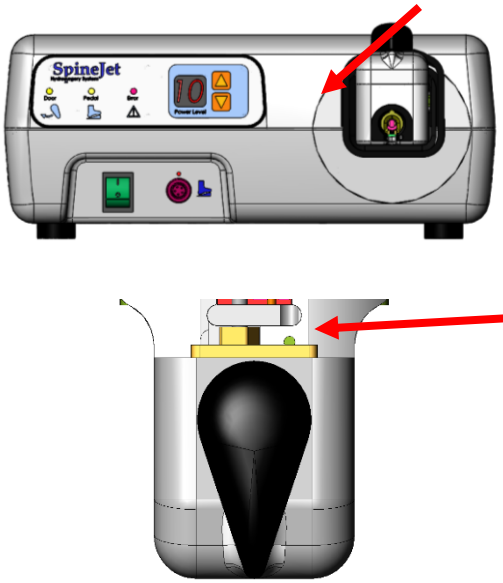
Intended Product life and reliability

HydroCision Fluidjet Surgical Systems Power Consoles are durable re-usable devices whose lifetime will be determined by customer usage. All of the devices subsystems are repairable or replaceable. Based on reliability of the product design it is intended to have a product life of 5 years based on a use in its intended use environment.

Electrical Safety Testing

Product Description: **SpineJet® Hydrosurgical Console**
Classification: **Class I / Type BF equipment**
Requirements: **IEC 60601-1:2005 +A1:2012**

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)

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.

EMC Requirements for the HydroCision Console

The HydroCision Console meets all applicable requirements of IEC/EN 60601-1-2 for electromagnetic compatibility. The HydroCision console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Appendix.

Portable and mobile RF communications equipment can affect the operation of the HydroCision console.

The following is a list of cables that are used with the HydroCision Console that comply with the applicable sections of the EMC standard.

• Power Cord Length: 15 feet

• Foot Pedal Length: 10 feet

• HydroCision HydroSurgical disposable handpiece (i.e. TenJet) Length: 10 feet

Use of cables or accessories other than those specified, with the exception of cables and accessories sold by the manufacturer of the HydroCision HydroSurgical System as replacement parts for the internal components, may result in increased EMMISIONS or decreased IMMUNITY of the HydroCision HydroSurgical System.

ELECTROMAGNETIC INTERFERENCE RISK

The console meets the requirements of IEC 60601-1-2 ed 4.0 (2014-02)
Note: the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment may not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

If the HydroCision HydroSurgical console has a electromagnetic interference that could effect the performance of the device the effect would potentially cause a degradation in the operation of the user interface and make the device inoperable. If this occurs and the console performance is lost or degraded the operator should take mitigation actions to correct prior to using such as moving the console further from the Electromagnetic interference.

If the console still has degraded performance after mitigation please contact Hydrocision customer care for analysis to ensure basic safety and performance meet specifications or if service is needed to bring the performance and maintenance of the expected units serviceable life.

TABLE 1: Guidance and Manufacturer's Declaration, Electromagnetic Emissions, for the HydroCision HydroSurgical System.

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

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF emissions CISPR 11	Group 1	The HydroCision HydroSurgical System uses RF Energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	The HydroCision HydroSurgical System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings use for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

TABLE 2: Guidance and Manufacturer's Declaration, Electromagnetic Immunity, for the HydroCision HydroSurgical System.

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

Immunity Test	EN 60601 test level	Compliance level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vm 0.15 MHz- 80 MHz 6Vm in ISM bands between 0.15MHz and 80 MHz 80% AM at 1kHz	3 Vm 0.15 MHz- 80 MHz 6Vm in ISM bands between 0.15MHz and 80 MHz 80% AM at 1kHz	Portable and mobile RF Communications equipment should be used no closer to any part of the HydroCision HydroSurgical System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d + 1.2 \sqrt{P}$ $d + 1.2 \sqrt{P}$ 80 mHz to 800mHz $d + 1.2 \sqrt{P}$ 800 mHz to 2.5 gHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from the 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80%AM at 1 KHz	3 V/m 80 MHz – 2.7 GHz 80%AM at 1 KHz	

NOTE 1: At 80 mHz and 800 mHz, 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.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones, and land mobile radios, amateur radio, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess 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 HydroCision HydroSurgical System is used exceeds the applicable RF Compliance level above, the HydroCision HydroSurgical System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorientating or relocating the HydroCision HydroSurgical System.

b. Over the frequency range 150 kHz to 80 mHz, field strengths should be less than 3 V(rms)/m.

TABLE 3: Recommended Separation Distances between Portable and Mobile RF Communications and the HydroCision HydroSurgical System.

The HydroCision HydroSurgical System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help HydroCision HydroSurgical prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HydroCision HydroSurgical System as recommended below, according to the maximum outpower 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 kHz to 800 mHz $d = 1.2 \sqrt{P}$	800 kHz to 2.5 gHz $d = 1.2 \sqrt{P}$
0.01	0.12	0.12	0.12
0.1	0.38	0.38	0.38
1	1.2	1.2	1.2
10	3.8	3.8	3.812
100	12	12	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) 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 in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 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.

TABLE 4: Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse Modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800, IDEN 820. CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802. 11 b/g/n, RFID 2450 LTE Band 7	Pulse Modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

THE MANUFACTURER SHOULD CONSIDER REDUCING THE MINIMUM SEPARATION DISTANCE, BASED ON RISK MANAGEMENT, AND USING HIGHER IMMUNITY TEST LEVELS THAT ARE APPROPRIATE FOR THE REDUCED MINIMUM SEPARATION DISTANCE. MINIMUM SEPARATION DISTANCES FOR HIGHER IMMUNITY TEST LEVELS SHALL BE CALCULATED USING THE FOLLOWING EQUATION:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL IN V/m.

If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.