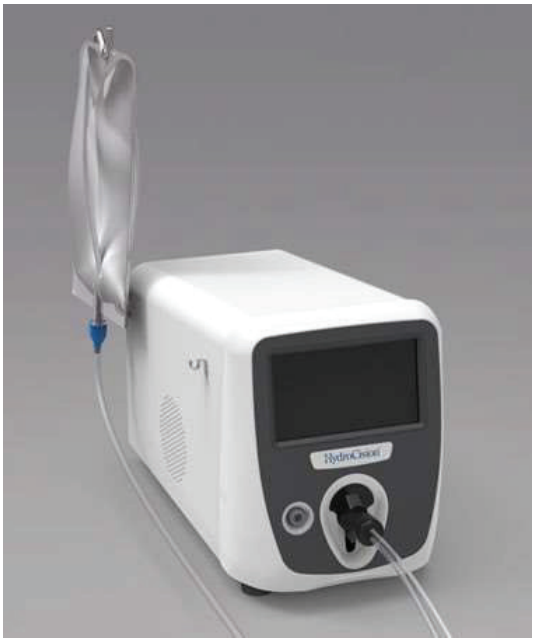
HydroCision™

82 - Series Console

Product Manual



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About This Manual

This product manual has been developed to provide the user with the information necessary to operate and maintain the HydroCision™ console. It is important that all medical personnel handling this device read and understand all the information contained within this manual.

This material is not a substitute for formal training as 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.

No information on surgical procedures is given in this manual. HydroCision, Inc. claims no responsibility or liability from any surgical technique practiced.

Pay close attention to warnings and precautions in this manual. Warnings and precautions are intended to protect individuals from serious bodily harm and protect the HydroCision console from damage.

If you have any questions or concerns regarding this manual or require further information on this product, please contact HydroCision Customer Care for assistance:

HydroCision Customer Care

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Email customercare@hydrocision.com

Contents

Prescription Information

Device Indications

The HydroCision™ console is indicated for orthopedic surgical procedures where the cutting, lavage, debridement, and removal of soft and hard tissue are required.

Contraindications

There are no contraindications for the HydroCision console.

Warnings

1. The HydroCision console is designed to be compatible only with HydroCision single use devices. Connecting other manufacturers' devices to the HydroCision console could result in operator injury or damage to the equipment that may not be covered by warranty.
2. Please refer to the HydroCision single use device IFU prior to performing surgical procedures for warnings specific to use of those individual devices.
3. To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
4. Do not modify this equipment.
5. This equipment is classified in its intended purpose as transient; it is normally intended for continuous use of less than 60 minutes.
6. Avoid use of this equipment adjacent to, or stacked with, other equipment. If such use is necessary, all equipment should be observed to verify normal operation.
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 console, including cables specified by the manufacturer. Not doing so could result in compromise of console performance.
8. Use of accessories, transducers, and cables other than those specified or provided by HydroCision could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Precautions

1. A thorough understanding of the principles and techniques involved in spine, orthopedic, or applicable surgical procedures is essential to avoid patient and medical personnel injury and damage to the device or other medical instruments.
2. Read all the instructions carefully. Failure to properly follow instructions may lead to electrical, mechanical, and/or thermal injury and cause improper functioning of the device.
3. Examine all components before use. Do not use if any component is suspected to be damaged or not working properly and contact HydroCision customer care.
4. Please refer to the HydroCision single use device IFU prior to performing surgical procedures for precautions specific to use of those individual devices.
5. HydroCision single use devices are not designed to withstand the rigors of reprocessing or re-sterilization, discard after use.
6. Federal (USA) law restricts this device to sale by or on the order of a physician.

HydroCision System Components

The HydroCision System contains three basic components: HydroCision console with a regionally configured power cord, a foot pedal, and a single use device for specific applications.

HydroCision Console

The HydroCision console is an electrically powered device. It comes with a regionally configured power cord and is designed to work with single use HydroCision devices. The HydroCision console provides the power to pressurize sterile fluid and deliver it at a high velocity to the distal tip of the handpiece.

Foot Pedal

The foot pedal allows remote activation of the console during the procedure. It also allows the user to increase or decrease the settings on the console to control the pressure and speed of the saline stream exiting the handpiece tip.

Single use HydroCision Device

The single use HydroCision device is connected to the HydroCision console via the pump cartridge interface located on the front of the console. The pump cartridge pressurizes the sterile saline, which flows through the tubing to the tip of the handpiece as a high-velocity stream of saline.

Environmental Requirements

The HydroCision console and system should be used in a professional healthcare facility environment that is suitable for surgery.

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

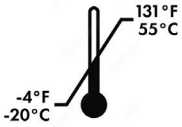
Temperature (product use)	40°F (4°C) – 100°F
(38°C) Temperature (storage)	-4°F (-20°C) – 131°F (55°C)
Humidity	0% - 100%, noncondensing
Atmospheric pressure	500-1500 mbar

Please refer to Appendix 1 for further guidance on electromagnetic environment requirements.

Glossary of Symbols

The table below provides symbols that are found on the HydroCision console and their definitions. It is important to become familiar with the symbols and their definitions before setting up and operating the console.

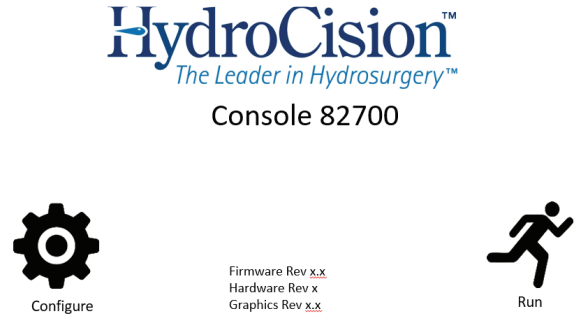
Symbols on the HydroCision console and packaging

No.	Symbol	Definition	No.	Symbol	Definition
1	**REF**	Product Catalog number	**10**		Off
2	**SN**	Serial number	**11**		On
3	**QTY**	Number of units in the package	**12**		Explosion hazard: Do not use in the presence of flammable anesthetics
4		See Instructions For Use **(IFU)**	**13**		Caution: Electrical shock hazard
5		Storage temperature	**14**		Protect packaged product from direct sunlight or heat source
6		Foot pedal	**15**		Keep packaged product in dry storage
7		Equipment classification: Type BF Applied Part	**16**		Manufacturer
8		Console disposal: Do not throw the console in the trash. Dispose the console according to local regulations.	**17**		Date of Manufacture
9		Equipotentiality: used to connect various electrical components together to the same potential (e.g., for local bonding).	**18**		Increase or Decrease

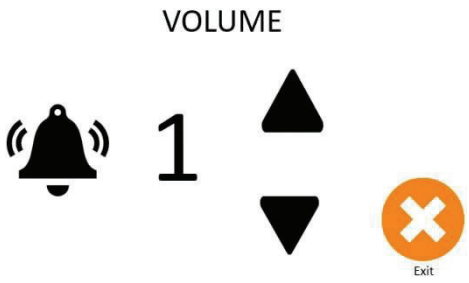
Operating the HydroCision Console

1. Connect the power cord to the console and a grounded 15-amp electrical outlet.
2. Turn the console on using the ON/OFF switch on the back of the console.
3. Follow the instructions on the display screen as described below.

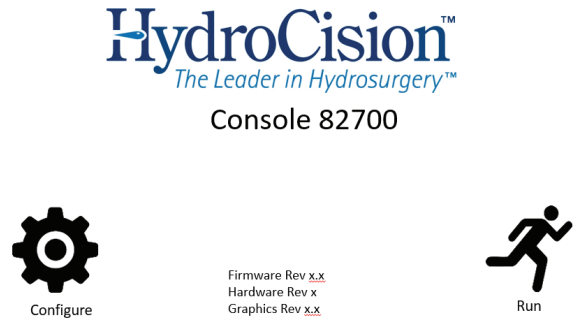
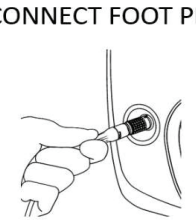
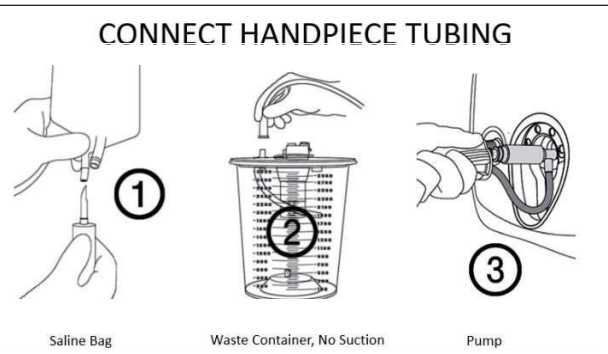
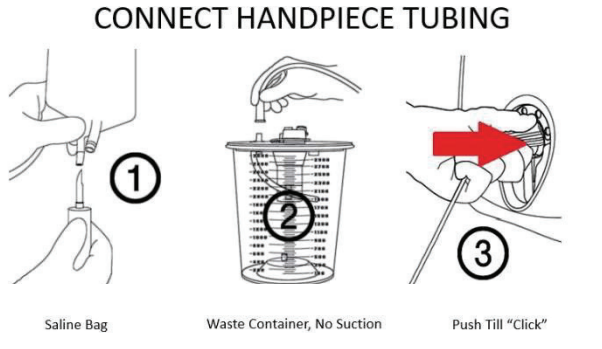
Install Procedure

The Startup screen appears as the default screen each time the power is turned on. Select Configure to set up a new console. Select Run to use console for a procedure.	
The CONFIGURE screen displays four selections: • Language to change language. • Volume to adjust the volume of audio alerts. • Service for use by HydroCision service department. • Exit to return to Startup screen	
On LANGUAGE screen, select a language or Next to view additional language choices. Once a selection is made, you'll return to the CONFIGURE screen.	
Select Back to go to the previous Language choices. Once a selection is made, you'll return to the CONFIGURE screen.	

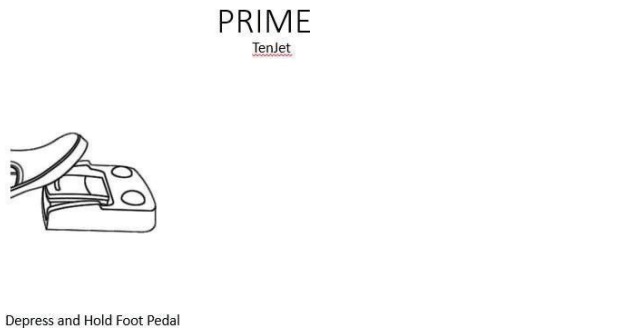
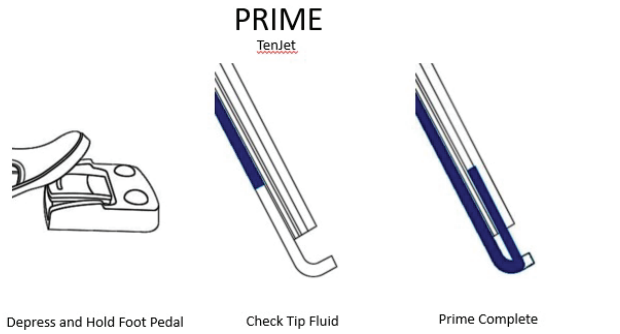
Install Procedure (Cont.)

Select Volume to set the volume level of the audio alert. The Console has the option to alert the user at 1-minute intervals for the first 4 minutes of run time.	
Use the up and down arrows to select the desired volume level. If you do not wish to be alerted, set the volume to 0. Press Exit to return to the CONFIGURE screen.	
Press Exit on the CONFIGURE screen to return to the Startup screen.	

System Set-up for a Procedure

To use the system for a procedure, select Run and follow the directions on the screens.	
Connect the foot pedal to the console. Align the red dots before firmly inserting the connector.	
• Connect the saline bag spike to the saline bag and open the clamp to initiate the saline flow through the tubing. • Connect the waste tube to the waste container, keeping one port open. • Align pin on the black flange of the pump cartridge with the hole in the nest and insert cartridge firmly. If you have difficulty inserting the cartridge, please check the alignment between the pin and the hole.	
If the screen does not advance, pull the pump cartridge out, check for alignment, and reinsert firmly until you hear a click and the screen advances to PRIME.	

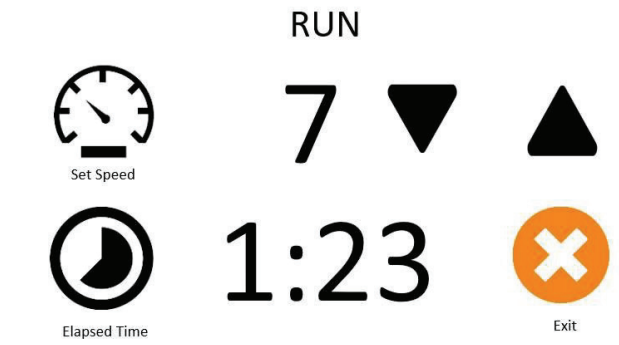
System Set-up for a Procedure (Cont.)

After all connections are made, the console is ready to prime. Depress and hold down the foot pedal to prime the single use device for the procedure.	
The screen will indicate once the device is primed. Release the foot pedal to advance to the run screen.	

Console Use During the Procedure

The screen advances to the RUN screen once the device is primed.

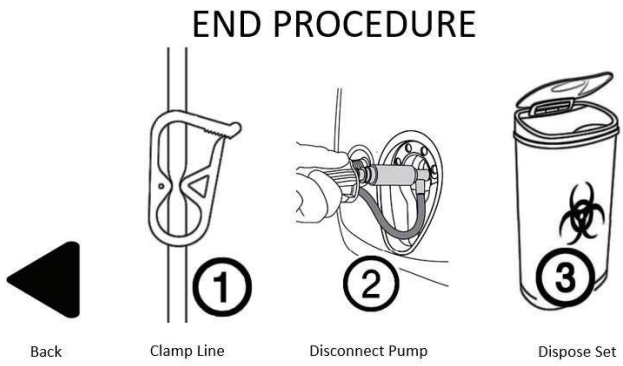
- Select the desired power setting using the up and down arrows on the screen or using the controls on the foot pedal.
- Advance the handpiece to the pathology to be treated using standard techniques.
- Depress the foot pedal to start the procedure and activate the flow of saline to the tip of the handpiece.
- Release the foot pedal to stop the flow of saline to the tip of the handpiece.
- Select Exit to end the procedure and release the cartridge. The screen will advance to END PROCEDURE.



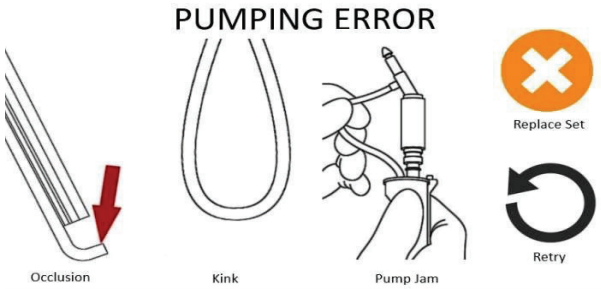
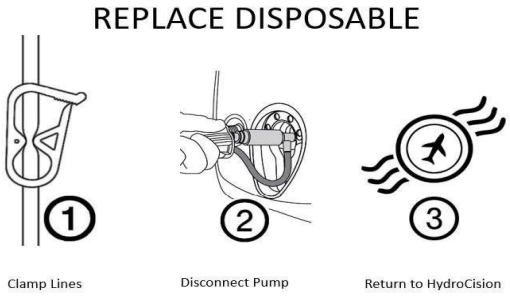
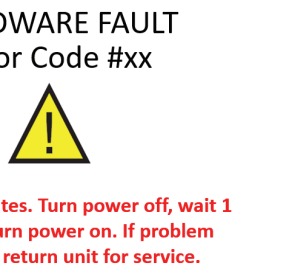
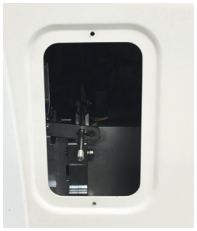
If you select EXIT accicentally, select BACK on the END PROCEDURE screen to return to the RUN screen.

At the end of the procedure,

- Clamp the tube connected to the saline bag.
- Disconnect tube connected to the waste container and the pump cartridge. Once the cartridge is disconnected, the screen returns to the start-up screen.
- Using standard practices, dispose the single-use device, tubing, and saline bag.
- Clean and disinfect the console using instructions described on page 14.
- Turn off the console.



Troubleshooting

Pumping errors that prevent saline flow out of the device tip may occur because of an occlusion, kinked tubing, or issue with the pump cartridge cartridge. Please try to identify the cause and resolve the issue. Select Retry to run console. If the issue cannot be resolved, select Replace Set to connect another single-use device. The screen will advance to REPLACE DISPOSABLE screen.	
Prior to replacing the device, clamp and disconnect the saline bag spike, disconnect the waste tube, and the pump cartridge. Note: Connecting a new device will bring the user to PRIME screen and require repriming of the system. Contact your sales representative or HydroCision Customer Care to discuss the situation.	
Should a Hardware Fault error code appear, please note the Code number. Leave the console on for five minutes, turn the power off, wait one minute, and turn the power back on. If the fault persists, contact HydroCision Customer Care to return the console for servicing.	
If the pump cartridge gets stuck in the console and cannot be disconnected with the unit on or off, it can be removed manually. • Using a #2 Phillips screwdriver, remove the side panel cover on the right side of the unit.	
• Lift the handle, pull the pump cartridge out, and replace the cover.	

Trouble Shooting (Cont.)

Symptom	Cause	Remedy
Leakage at cartridge connection	Some leakage is expected.	If the saline flow at the tip appears to be normal, continue to use. Otherwise, contact customer care.
Excessive spray or dripping at tip	Obstruction of waste tube (e.g., bone chip, or other foreign material).	Take foot off the foot pedal, remove sterile device from surgical field, and remove obstruction from instrument tip using forceps.
	Some spraying is expected as saline jet strikes the back wall of the evacuation lumen.	If the saline evacuation at the needle tip appears to be normal, continue to use. Otherwise, contact customer care.
	Waste tube is not draining properly.	Lower waste tube and waste cannister Such that the end of the tube is at the lowest point possible.
	Waste tube is obstructed, kinked, pinched.	Lower waste tube and waste cannister such that the end of the tube is at the lowest point possible.
Console is running, but no saline flow through the tip No Fluid Detected Error	No fluid supply.	Replace saline bag if empty, unclamp tube connected to the saline bag, check spike connection, squeeze saline bag to ensure flow through the tubing.
	Air in inflow tube.	Squeeze saline bag to ensure flow through the tubing, reprime or run the console at setting 10 until saline flows through the system.
Console does not turn on, there is no power	Power cord not connected properly.	Ensure that the power cord is connected to the back of console and wall outlet.
	Wall outlet does not have power.	Use wall outlet that has power.
	Power switch in off position.	Turn on.
Console does not run, power is on	Foot pedal not attached.	Attach foot pedal securely.
	Foot pedal is damaged.	Replace foot pedal.
	Over-current situation has occurred (unknown cause).	Turn off main power switch, wait 1 minute, turn power back on.
	High pressure tube between the pump cartridge and the device is obstructed and cannot be cleared.	Discard disposable device and replace with a new unit. Contact customer care.

Cleaning and Maintenance

CAUTION: Unplug the unit before starting any cleaning or maintenance of the console.

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

Cleaning the Console and the Foot Pedal

Disconnect the console from the electrical power source. Wipe down console and foot pedal with a clean, damp cloth. 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 and the foot pedal:

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

CAUTION:

Do not immerse, spray, or pour cleaning solutions directly on the console. Do not allow cleaning solutions to accumulate on the console. If fluid ingress is detected, set the console aside for an extended period to allow it to dry. Do not sterilize or immerse in disinfectant solution.
Do not clean with ketones (MEK, acetone, etc.) or abrasive cleaners.

Replacing the Power Cord

If the power cord is damaged, disconnect the plug first from the wall socket and then from the console without pulling on the cord itself. Contact HydroCision Customer Care to order a replacement power cord.

Replacing the Foot Pedal

If the foot pedal is damaged, it should be disconnected from the console. Contact HydroCision Customer Care to order a replacement foot pedal.

Cleaning the Fan Slots

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

Console Disposal

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

System Specifications

HydroCision Console

Only HydroCision approved equipment should be connected to the HydroCision Console.

Equipment classification	Class 1 Device
Applied part classification	Type BF
IEC Enclosure classification	IPX3
Mode of operation	Transient

Front Panel

Foot pedal socket
Touchscreen user interface
Pump cartridge interface

Rear Panel

Power switch: ON/OFF
Power inlet: IEC 60320-1 c14 style power inlet with dual fuse holder
Power input rating: 100-240 VAC, ~9.2 A, 50-60 Hz

Power Cord

Detachable AC power cord with a ground plug and a three-pin hospital grade connector Regionally configured

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 Amp	< 5000 µ Amp

Intended Product Life and Reliability

HydroCision 82-Series console is a durable, re-usable device; its lifetime will be determined by customer usage. Based on reliability of the product design, the console is intended to have a product life of 5 years based on use in its intended environment. All the device subsystems, such as the power cord and the foot pedal, are repairable or replaceable.

Product Part Numbers, Dimensions, Weights

HydroCision Console

Part number	82700
Dimensions	16 x 9 x 10 inches (406.4 x 228.6 x 254 mm)
Weight	28 pounds (12.7 kg)

Foot Pedal

Part number	83537
Dimensions	4 x 6 x 1.5 inches (152.4 x 152.4 x 38.1 mm)
Cable length	10 feet (3.04 m)
Weight	1 pound (0.45 kg)
IEC Enclosure classification	IP68

Power Cord

Part number	1000-1057
Cable length	15 feet (4.56 m)
Weight	1 pound (0.45 kg)

Safety

There are no significant risks of reciprocal interference posed by the presence of the HydroCision console during routine use.

Electromagnetic Interference Risk

The HydroCision 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 the console.

If an electromagnetic interference affects the performance of the console, operation of the user interface may be compromised, making the console inoperable. If abnormal performance is observed, the operator should take mitigation actions, such as moving the console farther from the electromagnetic interference.

If console performance remains compromised, please contact HydroCision Customer Care.

APPENDIX 1:

Electromagnetic compatibility (EMC) requirements for the HydroCision Console

The HydroCision Console meets all applicable requirements of IEC/EN 60601-1-2 for electromagnetic compatibility. The 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 used with the HydroCision console that comply with the applicable sections of the EMC standard.

- Power cord Length: 15 feet (4.56 m)
- Foot pedal Length: 10 feet (3.04 m)

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

TABLE 1:

Guidance and Manufacturer's Declaration - Electromagnetic Emissions for the HydroCision Console

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

Emissions Test	**Compliance**	**Electromagnetic Environment: Guidance**
RF emissionsCISPR 11	Group 1	The HydroCision console 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 console 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 Console

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

Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Electro**S**tatic **D**ischarge **(ESD)** IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4kV, ± 8kV, ±15kV Air	± 8 kV contact ± 2 kV, ± 4kV, ± 8kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic materials, the relative humidity should beat least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000 4-5	0.5 kV, 1 kV, 2 kV line to ground 0.5 kV, 1 kV line to line	0.5kV, 1 kV, 2 kV line to ground 0.5 kV, 1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations onpower supply input lines	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HydroCision console requires continued operation during power mains interruptions, it is recommended that the console be powered from an uninterruptible power supply or a battery.
IEC 61000-4-11	0% U_T; 1 cycle	0% UT_T; 1 cycle	
	AND	**AND**	
	70% U_T, 25/30 cycles	70% U_T, 25/30 cycles Single	
Voltage interruptions	Single Phase at 0°	Phase at 0°	
	0% U_T, 250/300 cycles	0% U_T, 250/300 cycles	

NOTE: U_T is the AC mains voltage prior to application of the test level.

TABLE 2 (continued):

Guidance and Manufacturer's Declaration - Electromagnetic Immunity for the HydroCision Console

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

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment Portable and mobile RF Communications equipment should be used no closer to any part of the HydroCision console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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	d + 1.2 √ P d + 1.2 √ P 80 mHz to 800mHz d +1.2 √ P 800 mHz to 2.5 gHz
Radiated RF IEC61000-4-3	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	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 beless than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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.

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 console is used exceeds the applicable RF Compliance level above, the HydroCision console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HydroCision console.

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 Console

The HydroCision console is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the console can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HydroCision console 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 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 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)	Maximum Power (W)	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse Modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz Deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse Modulation [b]) 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900 TETRA800, iDEN 820. CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse Modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse Modulation [b] 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	.02	0.3	9
5500						
5785						
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the MEEQUIPMENT or ME SYSTEM may be reduced to 1m. The 1 m test distance is permitted by IEC 61000-4-3						
For some services, only the uplink frequencies are included. The carrier shall be modulated using a 50 % duty cycle square wave signal. As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not representactual 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:

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

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