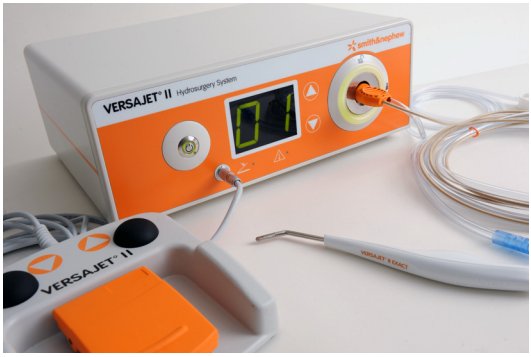
smith&nephew

VERSAJET® II

Hydrosurgery System



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User guide

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VERSAJET◇ II
Hydrosurgery System

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Indications

The VERSAJET II Hydrosurgery System is intended for wound debridement (acute, chronic wounds and burns), soft tissue debridement and cleansing of the surgical site in applications that, in the physician's judgment, require sharp debridement and pulsed lavage irrigation.

Safety

The VERSAJET II system is designed for use by qualified and trained medical professionals. It is recommended to study this user guide, paying particular attention to all Warnings and Precautions, prior to any surgical procedure. Improper system use or set up, or failure to follow this user guide may cause injury or damage not covered under the warranty.

Warnings

- This device should be used with particular care in patients with hemophilia or other blood clotting disorders and in patients receiving anti-coagulant medication.
- This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.
- This device is not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen.
- Increasing console power settings will lead to more aggressive tissue removal. Use caution near delicate vessels and structures, such as neurovascular bundles.
- The VERSAJET II handpieces are designed for connection only to the VERSAJET II system console. DO NOT attempt to connect to any other equipment.
- The VERSAJET II Plus handpieces provide more aggressive debridement and excision when compared to the VERSAJET II Exact handpieces. VERSAJET II Plus is appropriate for wounds that require aggressive, yet selective, removal of tissues that are tough, heavily necrotic, contaminated or burnt. Users should be aware that just as with any sharp instrument, care and attention must be maintained while using the VERSAJET II Plus handpieces near delicate vessels and structures.
- VERSAJET II is intended primarily for use in the operating room environment. Only the 45 degree VERSAJET II Exact handpieces (66800041 and 66800042) are suitable for use outside the operating room. Attention to universal infection control procedures should be applied when using the device outside the controlled environment of the operating room.
- The 15 degree, 14mm VERSAJET II Exact handpiece (66800040) and all of the VERSAJET II Plus handpieces (66800043, 66800044 and 66800045) should not be used outside the operating room due to the potential of excessive misting or spraying.
- If the VERSAJET II Exact 45 degree handpieces are used outside the operating room, ensure the floor immediately surrounding the treatment area is covered and any splashes cleaned after treatment is complete.

Precautions

- Always begin debridement procedures at the lowest power setting and increase as necessary to the optimal setting for the type of tissue being debrided to avoid unintended tissue removal.
- In order to avoid unwanted procedural delays, assure the system is fully operational prior to administration of anesthesia.
- When used on wounds where bone, tendon or other hard tissue may be encountered during the debridement procedure, excessive spraying and/or misting may occur due to the interruption of the stream of sterile saline by hard tissues.
- Spraying or misting is more frequent at lower power settings due to less pressure. Spraying or misting may be reduced by keeping the waste evacuation tube straight.
- As with all surgical procedures, the VERSAJET II operator and other clinical personnel should follow the universal precautions for infection control (including the use of surgical gloves, facemask that covers the mouth and nose, protective eye goggles, protective clothing and anti-slip shoe covers).

- For optimal results when debriding hard or leathery eschar resulting from burn injuries, it is recommended to first debride the eschar using sharp debridement techniques followed by the use of VERSAJET II to complete debridement or excision of the wound.
- It is recommended that prior to clinical use of VERSAJET II, all operators of the device should be trained in the proper use of VERSAJET II. Smith & Nephew has developed a training program; contact your local market representative for details concerning VERSAJET II training.
- Do not allow saline bag to empty, this could allow air to enter the supply tube. Air in the supply tube will temporarily lower device efficiency and may require re-priming of the system.
- Select an appropriate sized waste container for the proceedure.
- Connecting the waste evacuation tubing hose, or any container connected to it, to a vacuum source is not recommended and may increase the aggressiveness of tissue removal.
- Monitor fluid level of waste container and empty as needed.
- Subsequent debridement procedures may be necessary for complex or highly contaminated wounds.
- Do not touch the high pressure jet in the operating window of the handpiece.
- Use only sterile saline solution with this device.
- Examine all components before use. If you believe a component to be faulty, damaged or suspect, DO NOT USE. Contact your local Smith & Nephew VERSAJET II representative.
- Pre-heating saline prior to use with VERSAJET II is not recommended. Due to the use of high pressure, some heating of the saline will occur during use.
- The higher the console power setting, the more pressure being applied with the handpiece tip or the longer the saline jet is in contact with the wound area, the greater the possibility of unintended tissue damage.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Each VERSAJET II disposable handpiece is intended for SINGLE-USE ONLY. DO NOT RE-STERILIZE. Discard after use. The VERSAJET II handpieces are not designed to withstand the rigors of reprocessing or re-sterilization; device performance will be compromised and sterility can not be assured.
  Refer to our company position regarding the reprocessing and reuse of single-use only medical devices in Appendix A of this manual or visit our website *www.versajet.info*

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System components

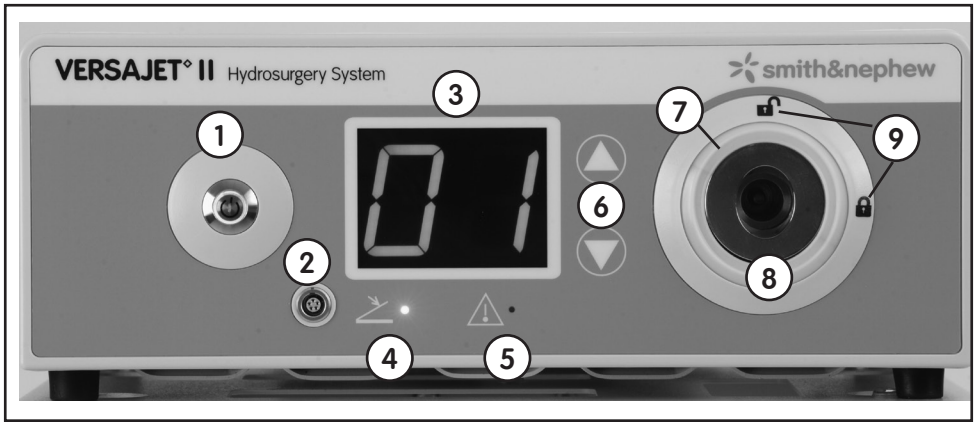
The VERSAJET II system consists of three primary components:

- Console with footswitch (reusable equipment)
- Single-use handpiece assembly
- Power cord – regionally configured

Console

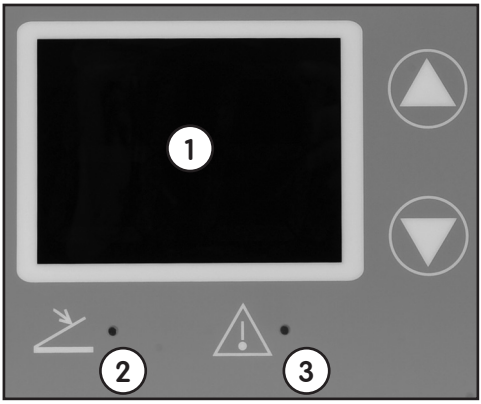
The VERSAJET II console is an electrically powered device that drives the VERSAJET II handpieces. The console is provided with an attachable footswitch and power cord.

Front panel layout



1. **Illuminated power switch** – turns the power ON and OFF
2. **Footswitch socket** – interfaces with the footswitch
3. **Power display** – displays power setting
4. **Footswitch connection indicator (LED)**
5. **System fault indicator (LED)**
6. **Power controls** – allows the user to sequentially select power settings from 1 (lowest) through 10 (highest)
7. **Illuminated green light ring** – indicates positive handset engagement
8. **Pump interface** – interfaces and secures the handpiece pump assembly to the console
9. **Key lock symbols** – directs user to the open (UNLOCKED) and the closed (LOCKED) handpiece pump positions

Power display and fault indicators



1. **Power display** – displays power setting

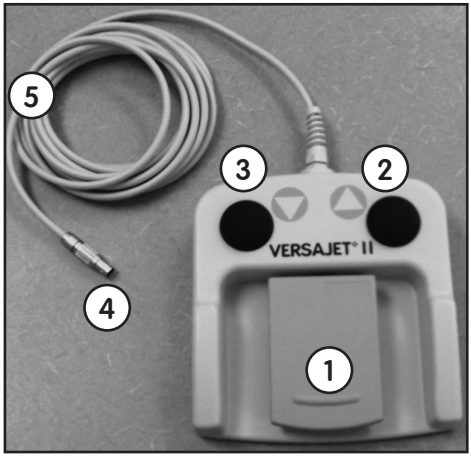
01 = lowest power setting

10= highest power setting

Fault indicators – illuminate if a fault is present

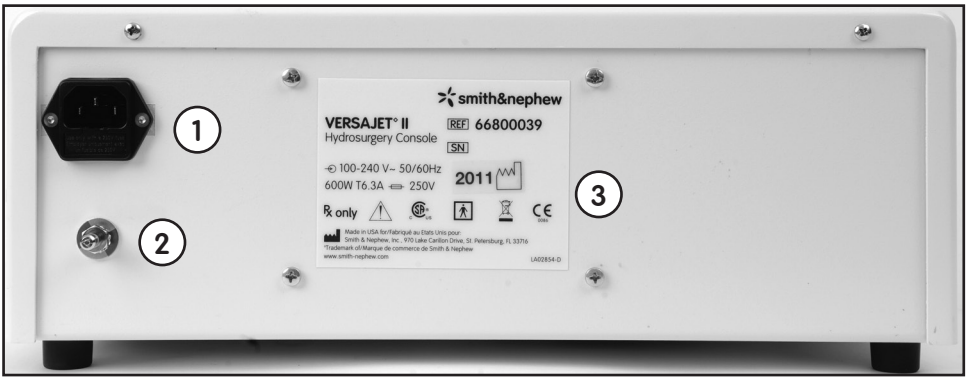
2. **Footswitch not connected indicator**
   – an amber LED will illuminate when the footswitch is not fully connected or is a defective footswitch
3. **System fault indicator**
   – a red LED will illuminate indicating a power fault or an out of tolerance pressure condition
   - If a fault occurs, the console should be sent back to the manufacturer for service. DO NOT attempt to open the unit to perform repair.

Footswitch



1. **Footswitch pedal** – depressing the footswitch pedal activates the cutting jet
2. **UP toe button** – depressing the toe button next to the UP arrow increases the power setting
3. **DOWN toe button** – depressing the toe button next to the DOWN arrow decreases the power setting
4. **Footswitch connector** – connects the footswitch to the footswitch socket on the console
5. **Footswitch cable** – connects the footswitch connector to the footswitch

Rear panel layout



1. **Input power cord socket** – interfaces with the detachable power cord through a three prong socket
   • The power cord provides electrical power to the console from an electrical outlet. For details of available power cords, please refer to the Ordering Information section.
2. **Protective earth ground terminal (equipotentiality)** – allows connection to the main system ground for testing the equipment
3. **Device label** – contains information and symbols specific for device

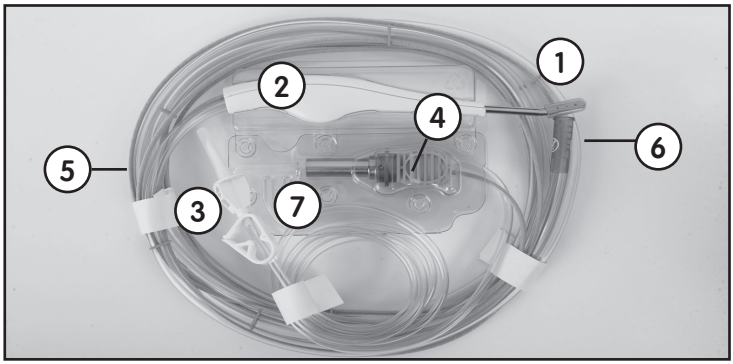
Handpiece components

Single-use handpiece assembly

The VERSAJET II single-use handpiece assembly is a sterile device and should be disposed of after use.

The handpiece has an operating window located at the instrument's distal tip. When the system is in operation, a stream of pressurized saline travels across the opening and creates a localized vaccum effect. By applying/passing the operating window over the debridement area the user can excise non-viable tissue and contaminants.

WARNING: The VERSAJET II handpiece is designed for connection only to the VERSAJET II Hydrosurgery System Console (66800039). Do NOT attempt to connect to any other equipment.

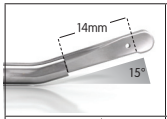
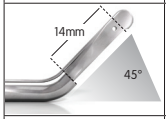
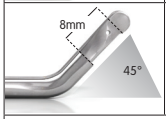
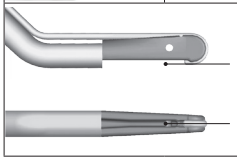


1. **Instrument tip** – the metal tip with a small, precise opening where a high velocity stream of sterile saline selects and excises non-viable tissue and contaminants contained in the operating site • the instrument tip contains the evacuation oriface
2. **Handpiece** – an ergonomic handle supporting the instrument tip; receives the high-pressure line and waste evacuation line at the proximal end (white)
3. **Inflow tube** – a clear tube with white spike and pinch clamp that connects to a saline bag
4. **Pump cartridge** – couples with the pump interface on the console (orange)
5. **High pressure tube** – a tube that carries pressurized saline to the distal tip of the handpiece
6. **Waste evacuation tube** – a clear tube with a blue connector end that carries evacuated fluid, non-viable tissue and contaminants to an appropriate waste container
7. **Clam shell** – a clear plastic enclosure that holds the handpiece and pump cartridge

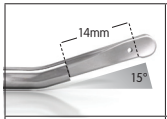
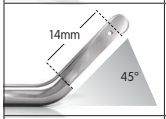
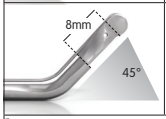
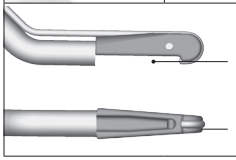
Handpiece options

The VERSAJET II handpiece is available in two styles – Exact and Plus.

VERSAJET II Exact handpieces

	Order no.	Description
	66800040	VERSAJET II Exact disposable handpiece (15°/14mm)
	66800041	VERSAJET II Exact disposable handpiece (45°/14mm)
	66800042	VERSAJET II Exact disposable handpiece (45°/8mm)
		

VERSAJET II Plus handpieces

	Order no.	Description
	66800043	VERSAJET II Plus disposable handpiece (15°/14mm)
	66800044	VERSAJET II Plus disposable handpiece (45°/14mm)
	66800045	VERSAJET II Plus disposable handpiece (45°/8mm)
		

System set-up

This section provides the procedures for set up and operation of the VERSAJET II system.

CAUTION:

Before connecting the device to an electrical outlet, ensure that you have selected the appropriate power cord for the local power requirements and that the device is connected to a socket that meets the system requirements. Failure to do so may cause damage to the equipment and void the warranty.

Console set-up

Connecting the footswitch

Connect the footswitch connector into the footswitch socket on the front of the console, ensuring the red dots on the connector and socket are aligned. Position the footswitch for convenient access.

Power cord socket

Insert the female end of the power cord into the three-prong socket on the back of the console. Connect the other end of the power cord to an appropriate electrical outlet.

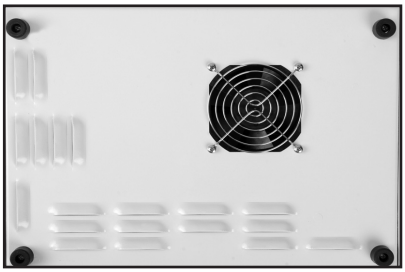
Turning the console ON

Press the power switch. The display will illuminate to indicate that power is supplied.

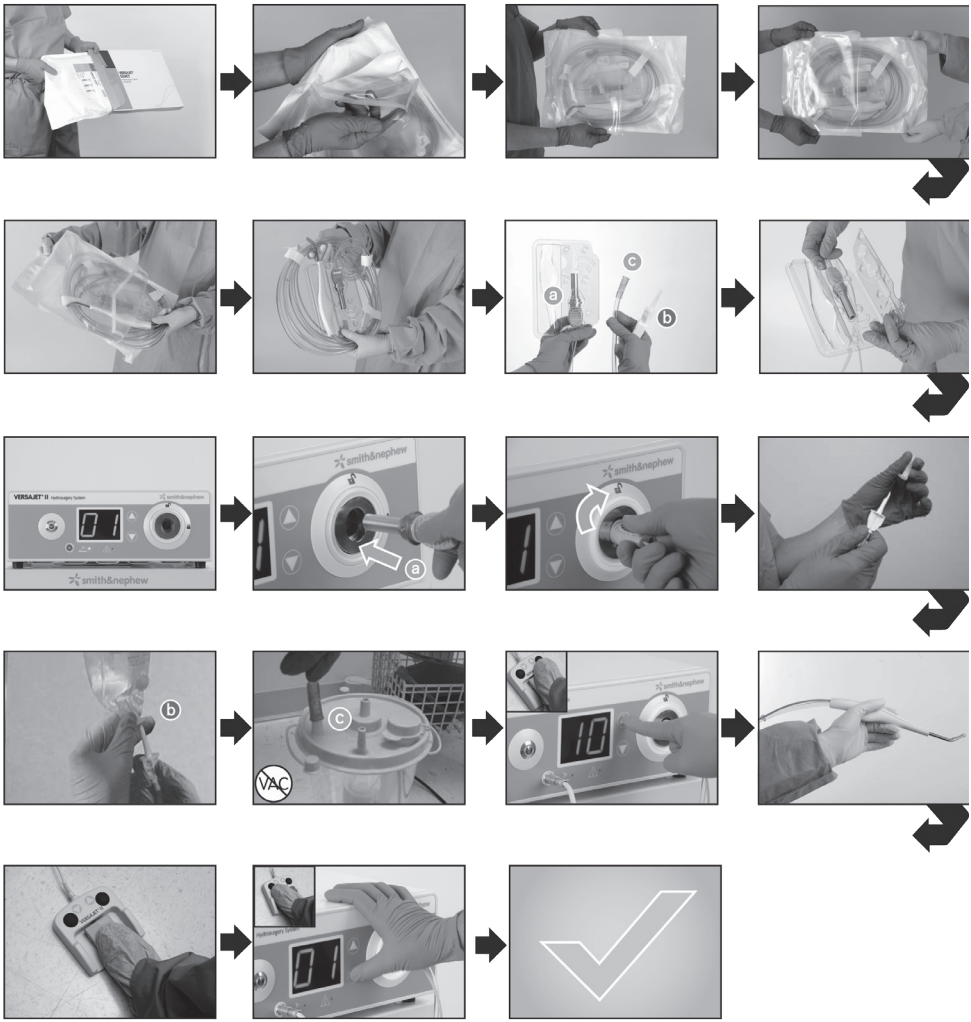
CAUTIONS:

Do NOT block the air vents on the bottom of the console. Air vents allow circulating air to cool the console.

After each use, thoroughly clean the console, footswitch and power cord. Please refer to the Cleaning and Maintenance section.



Handpiece quick set-up pictorial guide



Single-use handpiece set-up and system priming

1. Remove the pouch from carton. Inspect pouch to ensure seals are intact and pouch is undamaged. Open the pouch ensuring that the sterility of the inner pouch is not compromised. Aseptically, transfer inner pouch and contents to the sterile field.
   Note: Chart labels are on the outer pouch.
2. Inspect inner pouch to ensure seals are intact and pouch is not damaged. Open inner pouch, remove the sterile contents and place securely in the sterile field. Avoid tangling and knotting of hoses.
3. Remove white handpiece from clam shell and place in sterile field. Do not remove pump cartridge (orange handle) from clam shell tray.
4. Remove the white paper tape from coiled tubing. Uncoil the various tubing lines. Maintain aseptic technique for the white handpiece and several feet of tubing to allow access to the surgical site. Hand off the inflow tube, orange pump cartridge in clam shell tray and waste evacuation line to the circulator nurse for final system set up.
5. The circulator nurse should remove the orange pump cartridge from the clam shell and insert into the pump interface located on the front of the console until fully seated and then turn clockwise to the 3 o'clock position. When locked correctly, the circular light surrounding the pump interface should illuminate green.
6. **CAUTION:** Only insert the saline bag spike AFTER the orange pump cartridge has been securely locked in the console. Failure to do so may result in fluid leakage from the pump cartridge.
7. Remove sterile cover from bag spike and insert into sterile saline supply bag. Ensure that the clip on the saline inflow line is open.
   Note: The saline bag MUST be a minimum of 24in/60cm above the console for the system to prime.
8. Attach end of waste evacuation tubing (blue tip) to waste container. DO NOT connect to a port containing a filter or to the port labeled VACUUM. You must ensure that there is an additional open port on the waste containers lid. Ensure there are no kinks or other external obstructions in saline supply, high-pressure and waste evacuation hoses.
9. Insert the footswitch connector into the footswitch socket on the front of the console until the connector locks in place. The red dot on the footswitch connector should be aligned with the red dot on the footswitch socket. Position the footswitch for convenient access.
10. Insert the female three-prong plug of the power cord into the back of the console and the other end into an electrical outlet. Press the power switch located on the front of the console.
11. Remove the protective cover from the tip of handpiece.
12. While holding the handpiece at a safe distance, set the console power setting to 10. Depress the footswitch and keep the system running until saline reaches the distal tip of the handpiece. An audible hissing sound and a visible saline jet aimed down the evacuation oriface, indicates the system is primed. Priming takes approximately 30 seconds. Release the footswitch and reduce the power setting to 1 before use.
13. **CAUTION:** Once the system has been primed with saline, do not allow the saline bag to empty. An empty bag can cause air to enter the system and require re-priming of the system. Tubing should be clamped when changing saline bags.
14. Begin debridement procedures starting at the lowest power setting and increase as necessary to the optimal power setting for the type of tissue being excised or debrided.
15. If the evactuation oriface becomes blocked with foreign matter, a reduction in device efficiency or the presence of spray from the insturment tip may result. To eliminate the obstruction, remove the handpiece from the wound site, release the footswitch and remove the obstruction with forceps. Do not touch the opening in the high-pressure jet with forceps. Once the obstruction is removed, depress the footswitch and check for steady stream of sterile saline flow. If the obstruction is not completely removed, repeat

procedure or check that the waste evacuation tube is not pinched by forceps, stepped on or that the collection container is full.

16. After completing the procedure, turn OFF the console, by pressing the power switch located on the front of the console. Disconnect the handpiece from the pump interface, by turning the orange pump assembly counterclockwise to the 12 o'clock position. Remove the pump cartridge by pulling it straight out. Discard handpiece in accordance with your healthcare facility's standard guidelines for biohazardous waste disposal.

Console maintenance and cleaning

Maintenance

The fan slots and other vents on the bottom of the console should be kept free from obstructions and periodically inspected for excessive build-up of dust and/or foreign material.

The pump interface should be inspected periodically for build-up of deposits and/or debris. A damp cloth with mild detergent can be used to remove material. Do not soak the inside. Excessive fluid can cause damage.

If the power cord or footswitch are damaged, these should be replaced. Please refer to Appendix B, Ordering Information section.

Further information on user performance and safety testing can be found in Appendix C 'VERSAJET II Console Performance and Safety Check'.

This is also available for download at *www.versajet.info*

Cleaning

Follow your healthcare facility's standard procedures for decontaminating surgical equipment to decontaminate the console, footswitch and power cord.

The following are the recommendations for console decontamination: Wear protective gloves, gown and eye wear. Wipe all surfaces of the console and footswitch with a disposable towel or cloth soaked in the disinfectant solution. Sporicidin® Disinfectant (1.12% glutaraldehyde 1.93% phenol/phenate) or an equivalent high-level disinfectant is recommended. Dilute the disinfectant solution according to the manufacturer's instructions. After disconnecting the footswitch and power cord from the console, wipe down all exposed surfaces of both components in accordance with the guidance for the console. Dispose of towels, gloves and gown in accordance with your healthcare facility's standard guidelines for biohazardous waste disposal or as prescribed by the environment in which the console was used.

This procedure should be performed after each console use.

Disposal of the console and accessories

At the end of the console's useful life, it should be disposed of in accordance with local laws and regulations. For compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC), equipment that has reached the end of its useful life may be returned to equipment manufacturer. Please contact Customer Care at 1-800-876-1261 (USA only) or local Smith & Nephew representative to return a console for repair or replacement.

Troubleshooting guide

Symptom	Cause	Remedy
No/intermittent electrical power	Power cord not connected or connected loosely at console or electrical outlet Note: The console will default to power level 1 if power is interrupted	Ensure that power cord is: • Fully seated into the back of the console and electrical outlet • Not damaged and free of defects • For replacement power cord contact Customer Care at 1-800-876-1261 (USA only) or local Smith & Nephew representative
	Power not present at electrical outlet	• Ensure that the electrical outlet has power • Connect to a different electrical outlet
	Console power switch not illuminated	• Press power switch; power switch should become illuminated
Footswitch LED	Footswitch not connected properly	• Observe red alignment dots on footswitch connector and footswitch socket are properly aligned • Ensure the footswitch connector is fully inserted
Console not responding to footswitch and footswitch connector indicator is NOT illuminated	Footswitch obstructed	• Ensure that there are no objects obstructing the footswitch from being depressed or releasing
	Footswitch inoperative	• Order replacement footswitch (66800472) from Customer Care at 1-800-876-1261 (USA only) or local Smith & Nephew representative
System fault LED illuminated	Power fault caused by over-current	1. Turn console OFF by pressing power switch 2. Ensure power cord is connected to an appropriate power source. If necessary try a different electrical outlet 3. Wait at least 5 seconds after turning OFF 4. Turn console ON by pressing power switch
	System over-pressure condition out of tolerance	• Ensure the yellow high pressure tube on handpiece is not kinked, obstructed or tangled • If error light is still illuminated, replace handpiece • Contact Customer Care, 1-800-876-1261 (USA only) or local Smith & Nephew representative to arrange a return

Symptom	Cause	Remedy
Handpiece does not prime ***Note: Priming takes approximately 1 min at power level 10***	No/obstructed fluid supply	• Ensure saline bag is full and fluid flows freely • Check that pinch clamp is fully open • Check high pressure tube for kinks, obstructions or leaks • Ensure saline bag is set at a level higher than the console • Reconnect or replace as necessary
	Air in inflow line	• While keeping handpiece at a safe distance set console power level to 10 and depress footswitch to purge all air in inflow tube • Note: To expedite, the pinch clamp can be used to pull fluid through the inflow tube • Caution: Ensure power level is set to 1 after priming is complete. Ensure continuous flow of saline. DO NOT allow saline bag to empty completely before changing
Excessive spray/ spattering ***Note: Handpiece should not come into contact with bone tissue as it obstructs fluid flow and causes spraying***	Obstruction of evacuation orifice (debris, tissue or other foreign material)	**1.** Turn console OFF by pressing power switch **2.** Remove obstruction **3.** Turn console ON by pressing power switch **4.** Restore to desired power level
	Obstructed waste evacuation tube	Ensure that: • The distal end of the evacuation tube is connected to a non-filtered port of a waste collection container • Collection container is vented • Evacuation tube is not obstructed, kinked or pinched • Collection container is at lowest possible point below console level • Collection container is not full • Saline supply is above console (provides gravity feed/pressure)
	Fluid jet striking edge of metal evacuation oriface	Replace handpiece. Return initial handpiece by contacting Customer Care at 1-800-876-1261 (USA only) or local Smith & Nephew representative

Glossary of symbols

Equipment classification Isolation type BF applied part	**Single-use** do not reuse	**European representative**
CSA international classification	**Keep dry**	**Lot number**
EU: not for general waste	**Storage temperature**	**Serial number**
Caution: see instructions for use also indicates FAULT on the front panel	**Date of manufacture**	**Product catalog number**
This product and packaging do not contain natural rubber latex	**Place of manufacture**	**Method of sterilization**
Do not use if package is damaged	**Protect from direct sunlight**	**Fuse**
Equipotentiality (protective grounding)	**Green point (UK)**	**Footswitch connection**
Federal (USA) law restricts this device to sale by or on the order of a physician.	**CE mark**	**RoHS compliant**

Technical information

CAUTION: Only VERSAJET II system equipment should be connected to the console.

There are no user serviceable parts within the console. All required service must be performed by the manufacturer.

Contact Customer Care at 1-800-876-1261 (USA only) or local Smith & Nephew representative to return console for repair or replacement.

System specifications

Console	
Front panel	
⏻	Power switch, ON/OFF (I /0)
	Footswitch connection
▲ ▼	Power setting (levels 1 – 10)
	Pump interface
	Lock position (for pump cartridge)
	Unlock position (for pump cartridge)
	Amber footswitch indicator light
⚠	Red fault indicator light
Rear panel	
Prior to connecting the device to an electrical outlet, determine local voltage and electrical supply requirements. Ensure the cable is compatible.	
Power inlet	IEC60320-1 C14 style power inlet with dual fuse holder
Power cord	Detachable hospital grade power cord with C13 plug
Power input rating	100-240 VAC 600 W 50/60 Hz
Fuse ratings	Dual slo-blo type T6.3A/250 VAC 5 x 20 mm fuses
Mode of operation	Continuous
Applied part classification	Type BF
Equipment classification	Class I
Compliance	IEC 60601-1 UL 60601-1 CAN/CSA C22.2 No.601.1
Listing	CSA International

Product dimensions and weights	
Console	
Size	15in W x 11.8in D x 5.8in H 38.1cm W x 30cm D x 14.8cm H
Weight	26lbs/11.8kg
IP classification	IPX1
Footswitch	
Size	7.5in W x 7.25in D x 2in H 19cm W x 18.4cm D x 5cm H
Weight	3lbs/1.1kg
Cord length	15ft/4.6m
IP classification	IPX8
Power cord	
Length	15ft/4.6m

Single-use handpiece environmental conditions	
Unless otherwise stated, the following conditions apply for product use as well as shipping and handling	
Temperature range	
Shipping and handling	-40°F (-40°C) to 125°F (52°C)
Product use	50°F (10°C) to 90°F (32°C)
Humidity range	10% to 90%, non-condensing
Atmospheric pressure	700 to 1060 hPa

Console environmental conditions	
Unless otherwise stated, the following conditions apply for product use as well as shipping and handling.	
Temperature range	
Shipping and handling	-4°F (-20°C) to 131°F (55°C)
Product use	50°F (10°C) to 90°F (32°C)
Humidity range	10% to 90%, non-condensing
Atmospheric pressure	700 to 1060 hPa

Electromagnetic compatibility

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and Manufacturer's declaration – electromagnetic immunity.

The VERSAJET II Hydrosurgery System (66800039) is intended for use in the electromagnetic environment specified below. The customer or the user of the VERSAJET II Hydrosurgery System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	>95% for 10ms 60% for 100ms 30% for 500ms >95% for 5000ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VERSAJET II Hydrosurgery System requires continued operation during power mains interruptions, it is recommended that the VERSAJET II Hydrosurgery System be powered from an uninterruptible power supply or battery.
NOTE U_T is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0,3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the VERSAJET II Hydrosurgery 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 800 MHz) $d = 2.3\sqrt{P}$ (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 metres (m). Field strengths from 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: 

NOTE 1: At 80 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, 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 VERSAJET II Hydrosurgery System is used exceeds 3V/m, the VERSAJET II Hydrosurgery System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VERSAJET II Hydrosurgery System.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's declaration – electromagnetic emissions.

The VERSAJET II Hydrosurgery System (66800039) is intended for use in the electromagnetic environment specified below. The customer or the user of the VERSAJET II Hydrosurgery System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidelines
RF emissions CISPR 11	Group 1	The VERSAJET II Hydrosurgery System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The VERSAJET II Hydrosurgery System is suitable for use in hospital establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for industrial purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

WARNING: The VERSAJET II Hydrosurgery System should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked use is necessary, the VERSAJET II Hydrosurgery System should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and The VERSAJET II Hydrosurgery System (66800039).

The VERSAJET II Hydrosurgery System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The VERSAJET II Hydrosurgery System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The VERSAJET II Hydrosurgery System 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 $d = 3.5\sqrt{P}$	150 kHz to 80 MHz $d = 12\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.35	1.2	0.12	0.23
0.1	1.1	3.8	0.38	0.73
1	3.5	12	1.2	2.3
10	11	38	3.8	7.3
100	35	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 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.

Warranty

Limited one year warranty

Limited Warranty. Smith & Nephew warrants, for a period of one year from the date of sale of the console, that the console ("Product") shall perform to specifications as stated in the product manual. In the event of failure to perform to specifications, Smith & Nephew shall repair or replace the Product at its discretion, at no charge to Customer in accordance with its repair policy, as stated in the Product Terms and Conditions.

In order to keep this product warranty in effect, Customer must promptly notify Smith & Nephew of any defects in writing within thirty (30) days of discovery of such defects or within one (1) year of the sales order.

This warranty does not cover: (i) Products packaged or labeled by someone other than Smith & Nephew or its authorized agents; (ii) Products not used in compliance with the specifications in the product manuals; (iii) Products used in conjunction with single-use handpieces used more than one time; (iv) Products used in conjunction with expired single-use handpieces; (v) defects due to misuse, reprocessing, alteration, unauthorized repair or negligent handling, or defects due to lack of care by the Customer, or assigned user of the Product including but not limited to storage, handling or cleaning.

OTHER THAN THE WARRANTY STATED ABOVE SMITH & NEPHEW, INC., MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE MERCHANTABILITY, OR FITNESS OR SUITABILITY FOR ANY PURPOSE OR USE BY CUSTOMER OF THE PRODUCT.

IN NO EVENT SHALL SMITH & NEPHEW, INC. BE LIABLE FOR ANY ANTICIPATED PROFITS, OR OTHER INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND WHATSOEVER OR LOSS OF TIME INCURRED BY THE CUSTOMER WITH THE PURCHASE OR USE OF THE PRODUCT. FURTHER, SMITH & NEPHEW, INC. SHALL IN NO EVENT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

Appendix A

Company position regarding the reprocessing and reuse of single-use only medical devices

As a manufacturer of single-use medical devices, including multi-use systems with single-use patient contact components, it is our position that these devices are not designed or manufactured to withstand the rigors of reprocessing and therefore should not be reprocessed.

Single-use medical devices are intended to be used on an individual patient during a single procedure and then discarded. They are not intended to be reprocessed and used again. Labeling identifies such devices as single-use and is not intended to be reprocessed and used again.

The use of reprocessed devices may present unacceptable risks to the health and safety of patients and healthcare professionals. Tissue and organ damage as well as cross-infection can result from the reuse of a single-use device, because of practical issues of cleaning single-use devices. Moreover, the rigors of reprocessing can impair the performance and adversely affect the safety of a single-use device, as a result of changes in the physical state of the device.

Appendix B

Ordering information		
66800039	VERSAJET II console • includes footswitch, power cord and user manual	
66800040	VERSAJET II Exact handpiece	15°/14mm
66800041	VERSAJET II Exact handpiece	45°/14mm
66800042	VERSAJET II Exact handpiece	45°/8mm
66800043	VERSAJET II Plus handpiece	15°/14mm
66800044	VERSAJET II Plus handpiece	45°/14mm
66800045	VERSAJET II Plus handpiece	45°/8mm
66800472	VERSAJET II multi-function footswitch	
66800474	VERSAJET II Hydrosurgery System user manual	
66800979	VERSAJET II cart	
66800475	VERSAJET II replacement shelf (retrofit to 50800)	
66800193	Power cord, North America	
66800213	Power cord, United Kingdom	
66800291	Power cord, Central Europe	
66800302	Power cord, South Africa	
66800303	Power cord, Australia/New Zealand	
To order, contact Customer Care at 1-800-876-1261 (USA only) or local Smith & Nephew representative		

Appendix C

Console performance and safety check

Purpose

The purpose of this procedure is to provide a performance and safety check for the VERSAJET® II console (66800039).

Important note: The VERSAJET II console is NOT user serviceable and under no situation should the casing be opened. Any attempt to open the unit by the user will void all warranties and render the user responsible for all subsequent repairs to the unit. Contact your local Smith & Nephew Customer Care representative or sales representative to resolve all console problems.

Scope

This procedure is applicable to the VERSAJET II console as a reference guide for customers and service providers wishing to perform performance checks. Refer to the VERSAJET II Hydrosurgery System manual for additional information on the correct use of the console and its specifications.

Equipment

Table 1

Optical tachometer	Ametek 1726 or equivalent (hospital is responsible for purchase)
Electrical testing equipment	(hospital responsible for purchase)
RPM verification tool (speed stick)	Smith & Nephew part number 15SN-0089 (contact your local sales representative)
Pump interface setting standard tool	Smith & Nephew part number 15SN-0099
VERSAJET II footswitch	Smith & Nephew part number 66800472
VERSAJET II Hydrosurgery System manual	Smith & Nephew part number 66800474

Performance check procedure

A checklist is provided at the end of this document to record the results of the following checks.

Physical appearance check

1. Make sure console is unplugged from electrical power.
2. Check console for visible dents, cracks or missing pieces.
3. Inspect console and fan ventilation slots located on the bottom of the instrument. Remove obstructions, dust or foreign materials using vacuum and/or disposable wipes.
4. Inspect console labels and markings for legibility and partial or missing labels.
5. Using the pump interface setting standard tool (15SN-0099), check that the pump interface rotates freely between UNLOCK and LOCK position and back to UNLOCK.
6. Check footswitch and footswitch cable for signs of exposed wires, loose or missing insulation.
7. Check footswitch mechanical operation for engage and disengage by depressing the footswitch pedal and releasing.
8. Inspect the UP/DOWN toe buttons for excessive wear.
9. Inspect power cord for any frayed or missing insulation; bent, loose or missing plug blades or earth/ground.

System diagnostics check

1. Make sure console is plugged into an electrical outlet.
2. Press the illuminated power switch to the ON position and verify that the switch is illuminated and green in color. Verify the light extinguishes with the switch in the OFF position. Press the power switch to the ON position.
3. When power is turned ON, the VERSAJET II console will perform the following visual sequence for you to verify that system indicator(s) are operating properly.

a. Verify that the footswitch connection LED indicator flashes amber ON/OFF

b. Verify that the system fault LED indicator flashes red ON/OFF

c. Verify that the pump interface illuminated green light ring flashes green ON/OFF

d. Verify that the power display flashes 88 ON/OFF

4. Verify console defaults to power setting 01 when console is turned ON and after the visual sequence is complete.

5. Verify that no system fault is indicated (with red LED). Note: A red LED indicates a system error that will prevent the console from operating. If a system fault is indicated, the console must be returned to an authorized service center for repair.

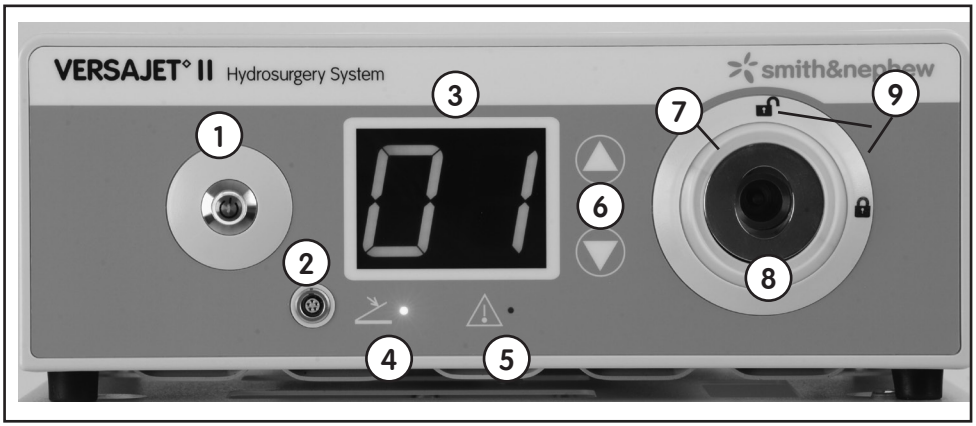
6. Verify the console power setting value changes when arrows are pressed – there are a total of ten different power settings. – Note: test both switches on the front panel and also the corresponding switches on the footswitch.

7. Verify that the pump interface illuminated green light ring is illuminated only when the pump interface setting standard tool is locked in the 3 o'clock position

8. Verify the amber footswitch connection LED is:

   - ON when the footswitch connector is not inserted into the footswitch socket.
   - OFF when the footswitch connector is inserted.

Front panel layout



1. **Illuminated power switch** – turns the power ON and OFF

2. **Footswitch socket** – interfaces with the footswitch

3. **Power display** – displays power setting

4. **Footswitch connection indicator (LED)**

5. **System fault indicator (LED)**

6. **Power controls** – allows the user to sequentially select power settings from 1 (lowest) through 10 (highest)

7. **Illuminated green light ring** – indicates positive handset engagement

8. **Pump interface** – interfaces and secures the handpiece pump assembly to the console

9. **Key lock symbols** – directs user to the open (UNLOCKED) and the closed (LOCKED) handpiece pump positions

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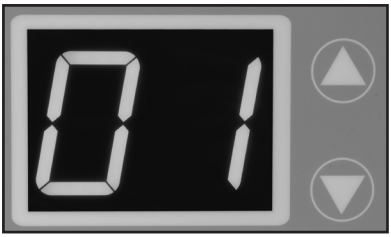
Console speed check

1. Insert the speed stick until fully seated into the opening of the pump interface.

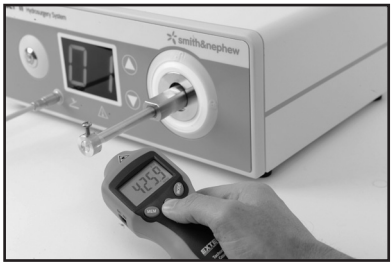
2. Turn the speed stick tool to the LOCKED position.

3. Set the console to the lowest power setting of 01.



4. Depress and hold the footswitch DOWN to allow the console to cycle its motor/transmission.

5. Aim the tachometer optical beam so that the reflector on the speed stick produces an RPM reading.

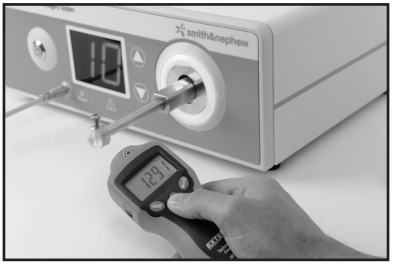


6. Measure speed (specification = 425 ± 50RPM).

7. Set the console to the highest power setting of 10.

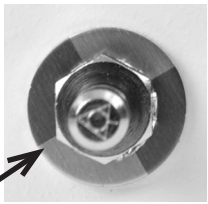
8. Depress and hold the footswitch DOWN to allow the console to cycle its motor/transmission.

9. Aim the tachometer optical beam so that the reflector on the speed stick produces an RPM reading.



10. Measure speed (specification = 1290 ± 100RPM).

Safety check procedure

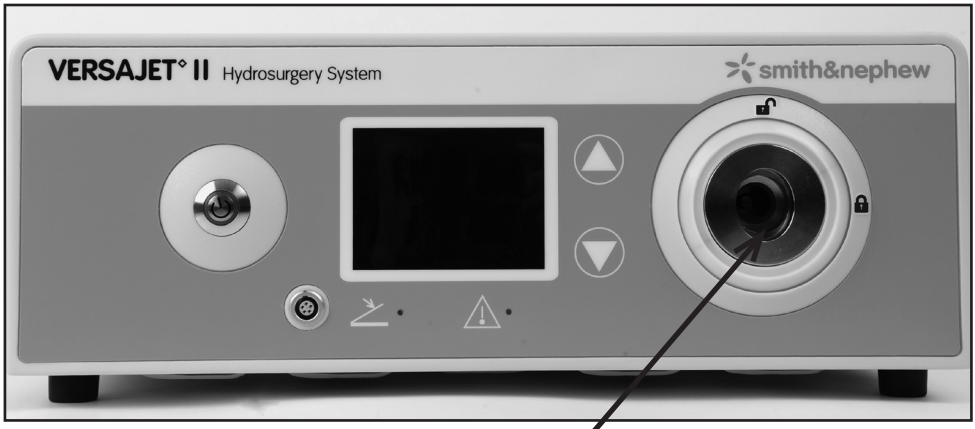


Electrical testing check

Connect console to electrical outlet (AC mains).

Connection to mains grounding is accomplished through use of the grounding post located on the rear panel (see following diagram).

The pump interface is the correct location to establish a connection with the patient applied part.



Attach test lead here.

EN

Product description: VERSAJET II® console - model 66800039

Classification: class I / type BF equipment

Requirements: IEC 60601-1

Table 2

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

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.

Important note

The VERSAJET II console is NOT user serviceable and under no situation should the casing be opened. Any attempt to open the unit by the user will void all warranties and render the user responsible for all subsequent repairs to the unit. Contact your local Smith & Nephew customer care representative or sales representative to resolve all console problems.

Physical appearance check - Caution: console is unplugged and placed on bench for this step				
Step		**Yes**	**No**	**Comments**
1	Check console for visible dents, cracks and missing pieces.			
2	Check that ventilation slots are free from obstructions, dust or foreign materials.			
3	Check that labels and markings are intact and legible with no smudges.			
4	Check that the pump interface rotates between lock and unlock positions and remains in place.			
5	Check footswitch and attached cable for signs of damage or missing insulation.			
6	Check footswitch mechanicals for system activation by depressing and releasing.			
7	Inspece UP/DOWN power controls for excessive wear.			
8	Inspect power cord for any frayed or missing insulation and bent, loose or missing plug blades or earth/ground.			
System diagnostics check - Note: console is plugged in and placed on bench for this step				
9	Adjust main power switch to ON/OFF positions; verify illumination status when ON.			
10	Verify that system indicator(s) are operating properly.			
10a	Verify that the footswitch connection LED indicator flashes amber ON/OFF			
10b	Verify that the system fault LED indicator flashes red ON/OFF			
10c	Verify that the pump interface illuminated green light ring flashes green ON/OFF			
10d	Verify that the power display flashes 88 ON/OFF			
11	Verify console defaults to power setting 01 when unit is turned ON.			
12	Verify system fault indicator red LED does not illuminate.			
13	Verify the console power display value changes when arrows are depressed – there are 10 settings.			
14	Verify that the pump interface illuminated green light ring functions properly.			
15	Verify that the footswitch connection LED indicator functions properly.			
Console speed check - Note: console is plugged in and placed on bench for this step **• A hand held optical tachometer is needed for this step**				
16	Power ON console by pressing illuminated power switch.			
17	Insert the speed stick into the pump interface and turn to the LOCKED position.			
18	Set console to its lowest power setting 01.			
19	Depress footswitch pedal allowing motor and transmission to cycle.			
20	Measure speed per console speed check instructions; verify the RPM is 425 ± 50.			
21	Set console to its highest power setting 10.			
22	Depress footswitch pedal allowing motor and transmission to cycle.			
23	Measure speed per console speed check instructions; verify the RPM is 1290 ± 100.			
Electrical equipment safety check - Note: console is plugged in and placed on bench for this step **• A meter capable of measuring micro amps is required**				
24	Power ON console by pressing illuminated power switch.			
24	Attach test leads to ground plug and pump interface as per electrical testing instructions.			
25	Take readings as per electrical testing instructions to check if leakage is occurring (Table 2).			
26	Disconnect test leads and power OFF by pressing illuminated power switch.			
27	Unplug power cord from electrical outlet and from rear panel of console.			
Summary of results				
28	Overall physical appearance showed no anomalies and unit is clean.			
29	Basic functional setup indicates functions evaluated are operational.			
30	Console speed verification meets specification as defined in test protocol.			
31	Electrical equipment safety testing indicates readings meet requirements.			

• Please photocopy this page when performing the checklist so that you will always have a blank copy. • If any of the Summary Results are "NO" this could be an indication of a need for Service or Repair. • Please contact your Smith & Nephew Customer Care representative immediately at 1-800-876-1261 (USA only). • Have this report available at time of call.

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Customer Assistance

For more information regarding VERSAJET® II Hydrosurgery System, or for additional customer assistance, please refer to the Smith & Nephew Customer Care Details below:

Australia	Smith & Nephew Pty Ltd. 315 Ferntree Gully Road PO Box 242 Mount Waverley Victoria 3149	Tel: +61 3 8540 6777 Fax: +61 3 9544 5086
Austria	Smith & Nephew GmbH Concorde Business Park C3 Österreich A-2320 Schwechat	Tel: +43 1 70 79102 Fax: +43 1 70 79101 info.austria@smith-nephew.com
Belgium	Smith & Nephew SA-NV Kareelovenlaan 3b 1140 Brussel	Tel: +32 2 702 2911 Fax: +32 2 726 1035 info.be@smith-nephew.com
Canada	Smith & Nephew Inc. 2250 Alfred Nobel Boulevard St. Laurent, Quebec H4S 2C9	Tel: 1 800 463 7439 Fax: 1 800 671 9140
Denmark	Smith & Nephew A/S Slotsmarken 14 2970 Hoersholm	Tel: +45 4580 6100 Fax: +45 4580 6151 sn.dk@smith-nephew.com
Finland	Smith & Nephew Oy Äyritie 12 C 01510 Vantaa	Tel: +358 (0)207 866 300 Fax: +358 (0)207 866 320
France	Smith & Nephew SAS Espace Novaxis 25 Blvd. Marie et Alexandre Oyon 72019 Le Mans Cedex 2	Tel: (33) 02 43 83 23 82 (33) 02 43 83 24 14 Fax: (33) 02 43 83 23 83 scw@smith-nephew.com
Germany	Smith & Nephew GmbH Wound Management Osterbrooksweg 71 D-22869 Schenefeld	Tel: +49 (040) 87 97 44 0 Fax: +49 (040) 87 97 44 375 info@smith-nephew.com
Italy	Smith & Nephew Wound Management Via de Capitani, 2A 20041 Agrate Brianza (MI)	Tel: 800 393 060 (numero verde attivo 8.30-18.00) 039 6094223 - 6094224 Fax: 039 6094274 Centro Assistenza Clienti: milan-LOGCSM@smith-nephew.com
Ireland	Smith & Nephew Oxygen Care Ltd. 2 Holfeld Business Park Kilmacanogue Co. Wicklow Ireland	Tel: 01 276 9700 Fax: 01 276 4970 orders@oxygen-care.ie 24 hour clinical support line: Ireland 01 217 0484

Netherlands	Smith & Nephew B.V. Postbus 525 2130 AM Hoofddorp Bezoekadres: Kruisweg 637 2132 NB Hoofddorp	Tel.: 020 654 39 99 Fax: 020 653 20 99 holland.info@smith-nephew.com
New Zealand	Smith & Nephew Limited PO Box 442 Shortland Street Auckland 1140	Tel: +64 9 828 4059 Fax: +64 9 820 2866
Norway	Smith & Nephew A/S Postboks 224 1379 Nesbru Besøksadresse: Nye Vakåsvei 64 1395 Hvalstad	Tel: +47 66 84 20 20 Fax: +47 66 84 20 90 norway@smith-nephew.com
Portugal	Smith & Nephew, Lda. Estrada Nacional n° 10, Km 131 Parque Tejo - Bloco C 2626-445 Forte de Casa Vila Franca de Xira (Portugal)	Tel: +351 21 446 0650 Fax: +351 21 446 0679
South Africa	Smith & Nephew (Pty) Ltd. PO Box 92 Pinetown 3600	Tel: +27 (0)31 242 8111 Fax: +27 (0)31 242 8120
Spain	Smith & Nephew SA Fructuós Gelabert 2 y 4 08970 Sant Joan Despí Barcelona	Tel: +34 93 373 73 01 Fax: +34 93 373 7453
Sweden	Smith & Nephew AB Kråketorpsgatan 20 PO Box 143 431 22 Mönldal	Tel: +46 31 746 58 00 Fax: +46 31 87 05 32
Switzerland	Smith & Nephew AG Glutz Blotzheim-Strasse 1 4502 Solothurn	Tel: +41 32 624 56 60 Fax: +41 32 624 56 81
United Arab Emirates	Smith & Nephew FZE Level 4 National Bank of Abu Dhabi Building Dubai Health Care City PO Box 9715 Dubai	Tel: +971 4 429 9111 Fax: +971 4 429 9100
United Kingdom	Smith & Nephew Wound Mangement Healthcare Ltd. Healthcare House 101 Hessle Road Hull, HU3 2BN	Tel: 01482 222200 Fax: 01482 222211 npwtorders.uk@smith-nephew.com 24-hour Clinical Support Line: UK 0845 120 0167
United States	Smith & Nephew, Inc. 970 Lake Carillon Drive St. Petersburg, FL 33716	Tel: 1 800 876 1261 Fax: 727 392 6914 customercare.largo@smith-nephew.com 1 866 998 NPWT (6798)

Wound Management
Smith & Nephew, Inc.
970 Lake Carillon Drive, St. Petersburg, FL 33716

EC REP Smith & Nephew Medical Ltd.
Hull HU3 2BN
England

CE 0086

www.smith-nephew.com
www.versajet.info
www.globalwoundacademy.com

Customer Care Center
1 800-876-1261
T 727-392-1261
F 727-392-6914

℞ only

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