

The SIMPULSE™ VARICARE™ Suction/Irrigator

Instructions for Use



Do Not Reuse / Single Use



Do Not Resterilize

STERILE | **EO**



Contains phthalates

R_x only

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1 (2003), ANSI/AAMI ES60601-1 (2005),
AND CAN/CSA-C22.2 NO. 60601-1 (2008)

Product contains no user serviceable parts


BAIRD

DAVOL INC.



PK3797784
1311R

WARNINGS:

1. Do not resterilize.
2. This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
3. Do not use in an oxygen-enriched atmosphere due to explosion hazard.
4. Do not incinerate the batteries as this can cause a risk to the environment.
5. Do not recharge batteries, put in backwards, or mix with used or other battery types as these actions may cause explosion or leakage leading to personal injury or can cause a risk to the environment.
6.  After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.
7. Follow Occupational Safety and Health Administration (OSHA) standards or Universal Precautions for bloodborne pathogens (29 CFR-1910.1030). These may be found by searching the OSHA web site at www.osha.gov.
8. In order to limit contact with infectious agents from mist and splashing, personnel using or patient exposed to the SIMPULSE™ VARI-CARE™ Suction/Irrigator must wear personal protective equipment.
9. To prevent possible exposure of other patients to aerosol, the patient should be treated in a private area, enclosed with walls and doors, separate from other patients.
10. Use continuous suction at 60-100 mmHg to keep operative or wound site clean.
11. Keep splash shield in contact with wound/periwound at all times to prevent aerosolization.
12. VARI-CARE™ is approved as a Class A device per IEC 60601-1-2 for use in a hospital or health care setting. Testing for use in other environments (i.e. home use) has not been performed and may affect the operation of other devices in the same environment.

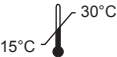
NOTE: Please reference the Davol edited version of "Loehne HB. Pulsatile Lavage with Suction. In: Sussman C, Bates-Jensen BM, eds, Wound Care - A Collaborative Practice Manual for Physical Therapists and Nurses, ed 2. Gaithersburg MD: Aspen Publishers, Inc.; 2001: 643 - 660" for detailed information on Infection Control and Personal Protective Equipment. For a copy of this article, please contact Davol at 1-800-562-0027.

PRECAUTIONS:






1. Single use*.
2. If package is damaged or open, do not use product.
3. Read all instructions prior to use.
4. Do not submerge handle in liquid as this may compromise efficiency of the pump or alter the pH of the liquid.

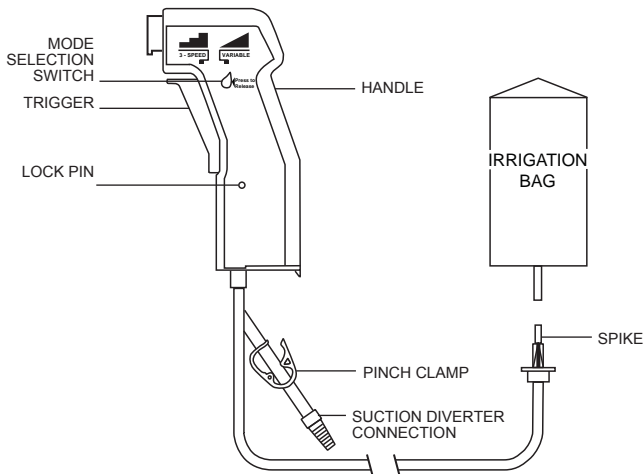
STORAGE:

Temperature: 15°C to 30°C (approx. 59°F to 86°F)

Relative Humidity: 30% to 65% (Non-Condensing) 

SAFETY INFORMATION AND SYMBOLS DEFINITION

	Danger: Explosion Hazard. Do not use in the presence of flammable anesthetics.	IPX4	Protected against ingress of splashing water.
	Do Not Reuse / Single Use		Do not resterilize
	Consult Instructions for Use		Type B applied part



INDICATIONS

The SIMPULSE™ VARI-CARE™ Suction/Irrigator is designed to provide controlled powered irrigation during general surgical procedures and for the cleansing and debridement of burns or wounds. The pulsatile action of the pump helps to remove blood, tissue debris and foreign matter from the operative or wound site. When connected to a suction source, the device aspirates fluids and debris from the operative or wound site.

PRINCIPLE OF OPERATION

The SIMPULSE™ VARI-CARE™ Suction/Irrigator motor-driven bellows pump is powered by four alkaline batteries, size AA, 1.5 volts each, which have an expected shelf life of four years. The batteries, motor, and bellows pump are all located inside the pistol grip handle.

*Continuous use on a single patient is allowed only when SIMPULSE™ Suction/Irrigators (REF 0067010, REF 0067570, REF 0057570) are used in conjunction with the SIMPULSE™ VARI-CARE™ Suction Diverter Wound Tips (REF 0067810, REF 0067820, REF 0067880). These single use suction diverter tips have a suction tube attached directly to the tip. Fluid aspirated during the cleansing of a wound is diverted away from the SIMPULSE™ Suction/Irrigator.

SETUP

To set up the system, you will need the following:

- SIMPULSE™ Tip or SIMPULSE™ Suction Diverter Tip (0067XX0 series)
- Irrigation bag(s)
- Suction canister, tubing and suction source
- Dual spike adapter (0037690), optional.

STEP 1: OPEN THE PACKAGE

The circulating nurse opens the package and delivers the contents onto the sterile field.

STEP 2: CONNECT THE IRRIGATION FLUID

1. The scrub nurse:

- a) if using one irrigation bag, passes the SIMPULSE™ VARI-CARE™ Suction/Irrigator spike to the circulating nurse.
- b) if using two irrigation bags, connects the dual spike adapter to the SIMPULSE™ VARI-CARE™ Suction/Irrigator spike ensuring it is fully inserted and passes the dual spike tubing to the circulating nurse.
- c) removes the lock pin to release the trigger.
- d) removes tip protector then inserts the SIMPULSE™ Tip or SIMPULSE™ Suction Diverter Tip.

NOTE: If using the Suction Diverter Tip, refer to the instructions accompanying the tip set.

2. If using one irrigation bag, the circulating nurse removes the spike cap and spikes the irrigation bag with the SIMPULSE™ VARI-CARE™ Suction/Irrigator spike. (McGAW® and ABBOTT® bottles will need their vented spike adapter).
3. If using two irrigation bags, the circulating nurse closes slide clamps on dual spike adapter, removes the spike caps, and spikes the irrigation bags with the adapter spikes. (McGAW® and ABBOTT® bottles will need their vented spike adapters). Open slide clamps when ready to prime.
4. The scrub nurse primes the unit with the mode selection switch set to the continuous variable mode (see figure 2).
5. The unit is primed by fully depressing the trigger until irrigant exits the tip.
6. The circulating nurse may squeeze the irrigation bag to facilitate priming

STEP 3: CONNECT TO SUCTION SOURCE

The circulating nurse attaches the suction tubing to patient inlet port of suction canister and connects outlet port to a suction source.

NOTE: For non-O.R. usage, one clinician may do the entire setup.

STEP 4: USE

1. The SIMPULSE™ VARI-CARE™ Suction/Irrigator offers two modes of use which are selected using the mode selection switch. The first mode indicated by the bar graph icon (see figure 1) is a three-step variable control that allows the user to lock the trigger at low, medium and high settings. The trigger is released by depressing the mode selection switch. The second mode indicated by the triangular graph icon (see figure 2) offers continuous variable control.
2. Turn the mode selection switch to the desired mode.
3. To irrigate, squeeze the handpiece trigger. A whirring sound will be heard. Irrigation flow and force are directly related to trigger depression, e.g. minimal depression of the trigger will yield minimal flow and force while increasing trigger depression will increase flow and force.
4. To change tip, release trigger to turn off irrigation flow. Grasp tip and pull straight out from handle. Insert desired tip.
NOTE: If using the Suction Diverter Tip, refer to the instructions accompanying the tip set.
5. The white pinch clamp on the suction tubing connection can be used to turn suction on and off as desired.

AFTER USE

1. Ensure Suction tubing is empty and then disconnect Suction connection from Suction Source.
2. Ensure irrigation tubing is empty and then disconnect spike from irrigation bag.
NOTE: Failure to remove fluids from all tubing may lead to spillage.

BATTERY REMOVAL

The batteries, which power the product, may be disposed of separately by releasing the latch on the bottom of the handpiece, pulling out the battery holder, and removing the batteries from the holder.

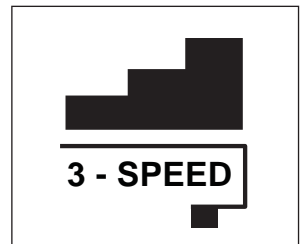


Fig. 1 Three step variable mode.




Fig. 2 Continuous variable mode.

EMC TABLES

Guidance and manufacturer's declaration – electromagnetic emissions		
The SIMPLUSE™ VARI CARE™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the SIMPLUSE™ VARI CARE™ device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SIMPLUSE™ VARI CARE™ device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SIMPLUSE™ VARI CARE™ device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SIMPLUSE™ VARI CARE™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the SIMPLUSE™ VARI CARE™ device 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The SIMPLUSE™ VARI CARE™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the SIMPLUSE™ VARI CARE™ device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800MHz $d = 2.3 \sqrt{P}$ 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, ⁸ should be less than the compliance level in each frequency range. ⁹ 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.

- 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 SIMPLUSE™ VARI CARE™ device is used exceeds the applicable RF compliance level above, the SIMPLUSE™ VARI CARE™ device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SIMPLUSE™ VARI CARE™ device.
- b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SIMPLUSE™ VARI CARE™ device			
The SIMPLUSE™ VARI CARE™ device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SIMPLUSE™ VARI CARE™ device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SIMPLUSE™ VARI CARE™ device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W (Watt)	Separation distance according to frequency of transmitter m (metres)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0.01	0.116667	0.116667	0.233333
0.1	0.368932	0.368932	0.737865
1	1.166667	1.166667	2.333333
10	3.689324	3.689324	7.378648
100	11.66667	11.66667	23.33333

The transmitter rated maximum output power 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.

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