

User Manual



STERILE EO

CE 0123

1. Device Name

- 1) Device name:
Disposable Electronically Pulsed Lavage Suction Apparatus
- 2) Model No.: **W-203**

2. Indications (Intended Use)

- 1) This device is used together with normal sterile saline or other applicable solutions, vacuum extractor. Vacuum extractor is not a must.
- 2) This device can be used for open wound cleaning, soft tissue cleaning, surgical operation location cleaning.
- 3) This device is suitable to be used in operation room, emergency room and treatment room.

3. Features

- 1) This device is easy to use and portable with significant cleansing effect.
- 2) This device is powered by mercury-free AA alkaline batteries.
- 3) This device is portable and can be installed and handled easily.
- 4) This device is suitable for any kind of open wound cleansing.
- 5) This device cleans the wound completely with proper pressure.
- 6) This device avoids cross contamination with its disposability.
- 7) This device removes waste solution with suction, when the waste pipe connected with vacuum extractor.

4. Elements

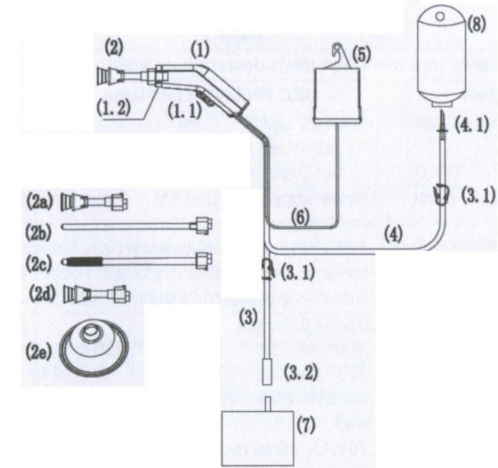
- 1) This device is a portable and internal battery-powered.
- 2) This device consists of DC motor, compression pumps, handpiece, enclosure, batteries, and nozzles.
- 3) When squeeze the trigger power is on. When power is turned on, DC motor drives the compression pumps in reciprocating motion, engender cavity volume changes, thus it can breathe in and out the solution. The power is DC battery. There is low power position (DC 9V), high power position (DC 15V) and stop tap position. Different nozzles can be fitted on during operation.

5. Components

- 1) This device consists of **Handpiece (1)** 【Including DC motor, Compression pumps, Trigger (1.1), Nozzle lock (1.2), Enclosure.】, **Nozzle (2)** 【Including Fan Spray Nozzle (Short Nozzle) (2a), Femoral Nozzle (Long Nozzle) (2b), Femoral Brush Nozzle(Long Nozzle) (2c), Shower Spray Nozzle(Short Nozzle) (2d), Large Splash Shield(2e) and other nozzles.】, **Waste pipe (3)** 【Including Clamp (3.1), Connecting pipe (3.2).】, **Irrigation pipe (4)** 【Including Clamp (3.1), Luer fitting (4.1).】, **Battery bag(5)**, **Power wire(6)**.
- 2) The **Vacuum extractor (7)** and **Irrigation bag (8)** are not including in this device, but prepared by medical institution.

The negative pressure of **Vacuum extractor (7)** within the range of 5kPa to 40kPa shall be adjustable. The **Irrigation bag (8)** use normal sterile saline or other applicable solutions (Not suitable for viscous solutions).

- 3) Accessories: **Nozzle (2)**.
- 4) Detachable parts: **Nozzle (2)**.
- 5) Applied parts: **Nozzle (2)**.
- 6) Associated devices: **Vacuum extractor (7)** and **Irrigation bag (8)**.











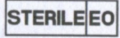














Device structure diagram

6. Operating Instructions

- 1) Inspect the package. Do not use if inner package is damaged.
- 2) See user manual and attached documents.
- 3) Open the package, and install **Nozzle (2)** to **Handpiece (1)**. Press down the **Nozzle lock (1.2)** to lock the **Nozzle (2)**.
- 4) Connect the **Waste pipe (3)** with **Vacuum extractor (7)** (if prepared). Vacuum extractor is not a must.
- 5) Use the **Luer fitting (4.1)** to spike the **Irrigation bag (8)**.
- 6) Hang up or place the **Battery bag (5)**. The **Battery bag (5)** should be hung up on the same horizontal with the **Irrigation bag (8)** and avoid the liquid from **Irrigation bag (8)** spillage on the battery bag.
- 7) Use the **Nozzle (2)** to aim the wound. Squeeze **Trigger (1.1)** to activate the device and start irrigation. The **Trigger (1.1)** have low power position with symbol short “—”, high power position with symbol long “——”, and stop tap position with symbol “O” .
- 8) Slide **Clamp (3.1)** can control the liquid flow in the **Irrigation pipe (4)** and **Waste pipe (3)**. Please lock the **Clamp (3.1)**, when you stop operating the device.
- 9) It can suck the waste solution concurrently while spraying or after, if **Vacuum extractor (7)** is prepared.
- 10) Press **Nozzle lock (1.2)** upward first, when withdrawing the **Nozzle (2)**.
- 11) The **Large Splash Shield (2e)** is to be used in conjunction with the short nozzle.
To install: pinch soft head of short nozzle, insert into the opening of this shield and slightly pull in opposite directions to fixate the shield on the nozzle head.
To uninstall: pinch soft head of short nozzle and remove.

7. Symbol Descriptions

The following symbols may appear in this user manual and on the labels. Some of the symbols represent standards and compliances associated with the device and its use.

	Consult instructions for use.		Do not reuse.
	Authorized Representative in the European Community.		Use by date.
	CE marking of conformity.		DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Caution: Consult the accompanying documents.		
	Date of manufacture.		Sterilized using ethylene oxide.
	Manufacturer.		Do not use if package is damaged.
	Serial number.		Catalogue number.
	This symbol on the trigger side means stop tap position.		Batch code. (Lot number.)
	This symbol on the trigger side means low power position. (DC 9V).		This symbol on the trigger side means high power position. (DC 15V).
	Keep away from sunlight.		Type B applied part.
	This way up.		Storage temperature limit.
	Fragile, handle with care.		Keep away from rain. (Keep dry.)

8. Specification

- 1) Power source (Ratings): 15V DC, 10×1.5V AA (LR6) alkaline batteries.
- 2) Power rating: 37.5W.
- 3) Handpiece dimension: About 185mm * 55mm * 40mm (Long * Wide * High).
- 4) Net weight: About 0.9kg.
- 5) Flow rate (high power position): Not less than 0.9L/minute.
- 6) Maximum irrigation length (high power position): Not less than 2.5 meters.
- 7) Decibel: Less than 75db (A).
- 8) Solution form: Fog-like and thread-like.
- 9) Sterilization: Sterilized using ethylene oxide before delivery.
- 10) Valid period: Two years.
- 11) Operation time: Total operation time of each device shall not exceed 5 minutes.

9. Classification

- 1) Internal electrical power source equipment.
- 2) Type B applied part.
- 3) IPX0.
- 4) Not category AP / APG equipment.

10. Contraindications

Not found.

11. Adverse Effect

Not found.

12. Warning and Precautions

- 1) This device is only for qualified professionals' operation.
- 2) This device should not be used after the expiry date shown on the pack.
- 3) This device is for single patient use only. Do not reuse the device.
- 4) Prior to each use, inspect the package. Do not use if package is damaged.
- 5) This device is not evaluated as category AP or APG equipment. This device is not suitable for use in the presence of flammable anesthetic mixtures with air or oxygen or nitrous oxide.
- 6) No modification of this equipment is allowed.
- 7) Except the Nozzle, there is no replaceable part and accessory within the unit.
- 8) This device is sterilized using ethylene oxide before delivery. Sterilization validity is two years.
- 9) Follow current local /national regulations to properly dispose the device after use.

13. Disposal of the Batteries

- 1) This device contains alkaline batteries. The battery will be utilizable and safe, if the device is used before date of expiry.
- 2) Follow local/national current regulations to properly recycle or dispose the batteries after use.
- 3) Do NOT cut the power wire at any time to prevent short-circuit, which may cause overheating of the battery pack and result in a potential fire risk. In case of short circuit, do not pour liquid over it nor cover it, simply leave it and dispose after it is cooled down. There is a very slim chance of short circuit but proper means of disposal is highly recommended.
- 4) To safely remove the batteries please either open the battery pack by hand or pry with a tool.

14. Maintenance, Cleaning and Sterilization

- 1) This device is maintenance free and doesn't require routine maintenance.
- 2) This device doesn't contain user repairable parts and doesn't need repair.
- 3) This device is for single patient use only. There is no cleaning or sterilization requirement for the user.

15. Electromagnetic Compatibility Descriptions

15.1 Conform to the requirements of IEC 60601-1-2:2014 and EN 60601-1-2:2015.

15.2 Instructions for use of electromagnetic compatibility

- 1) The ME EQUIPMENT or ME SYSTEM is suitable to be used in operation room, emergency room and treatment room.
- 2) **Warning:** Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- 3) **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 4) This device doesn't contain user repairable cables, transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION.
- 5) **Warning:** 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 Disposable Electronically Pulsed Lavage Suction Apparatus (W-203), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 6) **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 might 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.

15.3 Technical description of electromagnetic compatibility

- 1) All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life. Disposable use product. Do not change any parts of the product.
- 2) Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions (CISPR 11)	Group 1
RF emissions (CISPR 11)	Class A
Harmonic emissions (IEC 61000-3-2)	N/A
Voltage fluctuations/ flicker emissions (IEC 61000-3-3)	N/A

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity test	IEC 60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±6 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV
Electrical fast transient / burst IEC 61000-4-4	Power supply lines: ±2 kV input/ output lines: ±1 kV 100 kHz repetition frequency	N/A
Surge IEC 61000-4-5	line(s) to line(s): ±0.5kV, ±1 kV. line(s) to ground: ±0.5kV, ±1 kV, ±2 kV.	N/A
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U _T 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _T 1 cycle And 70% U _T 25/30 cycles Single phase: at 0 0% U _T 250 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	50Hz: 30 A/m 60Hz: 30 A/m	50Hz: 30 A/m 60Hz: 30 A/m
Conducted RF IEC 61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz 80 % AM at 1 kHz	3 V/m 80 MHz to 2700 MHz 80 % AM at 1 kHz

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
	Test frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity test level (V/m)
Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE PORT	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430– 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28

IMMUNITY to RF wireless communications equipment)	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
5785							

16. Environmental Requirements

1) Storage conditions:

This device should be stored in non-corrosive gases, cool, dry, and ventilated place.
Temperature: -10°C ~ +40°C; Humidity: ≤95%RH; Air pressure: 50kPa ~ 106kPa.

2) Operating conditions:

Temperature: 5°C ~ 30°C; Humidity: ≤80%RH; Air pressure: 86kPa ~ 106kPa.

17. Manufacturer

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18. EC Representative

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