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VIVERE

A Single use NPWT System

VIVERE+

Made by Sunmedic AB
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Sweden

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EN

Introduction

VivereX(+)™ system is a medical therapeutic device which applies controlled negative pressure to the wound bed. The device is equipped with LED indicators for monitoring and alarm the status of the treatment. VivereX(+)™ also has a pressure sensor programmed to continuously monitor and maintain a target pressure at the wound site. VivereX™ device is intended to be used for 10 days and the VivereX+™ device for 21 days for one patient, which means no risk for cross contamination. Applying negative pressure results in transferring wound exudate to the NPWT dressing. VivereX(+)™ system increases dramatically the dressing life time through its multi-layered design. The VivereX™ dressing manages the wound exudate by two different mechanisms:

- The absorbent layer of the dressing absorbs some of the secretion.
- The dressing allows evaporation of the rest of the wound secretion.

1. Intended users:

Healthcare professionals across various disciplines such as physicians, podiatrists, wound specialists, nurses, nurse practitioners, and physician assistants can utilizing the VivereX(+)™ system. Nevertheless, prior to autonomously utilizing this system, it is imperative for individuals to undergo proper training and attain a requisite level of expertise.

2. Description:

VivereX(+)™ system consists of a single use device, 2 x AA Alkaline batteries, fixation strips, an extension tube and VivereX™ dressings. The VivereX(+)™ set includes 1 pump unit and 2 NPWT dressings. A multipack of 5 NPWT dressings are available in case additional dressings are required to handle necessary amount of wound exudate. The VivereX(+)™ dressing and VivaFoam™ are available in following sizes:

VivreX™ dressing size/ cm		
10 X 20	16 X 16	21 X 21
10 X 30	16 x 21	26 X26
10 X 40	16 X 31	

VivaFoam™ size/ cm	
10 X 7,5 X 3,2	15 X 10 X 1,5
20 X 10 X 3,2	25 X 15 X1,5
25 X 15 X 3,2	

3. Intended purpose:

The VivereX(+)™ system is an innovative and versatile therapeutic solution designed to enhance wound healing through the application of sub-atmospheric pressure. This approach effectively reduces inflammatory exudate and promotes granulation tissue formation. The system is engineered for wounds with low exudate levels, up to 0.5 g/cm²/24 hours, and moderate levels, ranging from 0.5 to 1 g/cm²/24 hours. For wounds with moderate exudate, it is advised that the dressing pad area to be at least four times larger than the wound itself. This ratio ensures the optimal performance and effectiveness of the VivereX(+)™ systems.

4. Indications for use:

VivereX(+)™ is a novel and multifaceted therapeutic system that facilitates the enhancement of wound healing by utilizing sub-atmospheric pressure to mitigate inflammatory exudate and stimulate the formation of granulation tissue. Following wound types with low and medium exudate are appropriate:

1. Acute wounds
2. Chronic wounds
3. Skin graft or flaps and donor site
4. Pressure ulcers
5. Diabetics ulcers
6. Surgical clean closed incisions
7. Subacute dehisced wounds
8. Trauma wounds
9. Burn injury, grade I and II

5. Intended population:

The VivereX(+)™ System is designed for use in adults, children, and neonates. It is suitable for applications in both hospital and home care

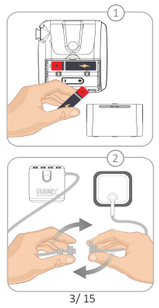
settings. Additionally, patients may continue treatment with the VivereX(+)™ system while in transit, including cars, trains, aircraft, and boats, ensuring continuous care across various environments.

6. Contraindications:

VivereX(+)™ system is contraindicated for:

1. Wounds with malignancy except in palliative care
2. Wounds with untreated osteomyelitis
3. Wounds with untreated non-enteric fistula
4. Wounds covered by necrotic tissue
5. Wounds with exposed bone, blood vessels, nerves, organs or anastomotic site
6. Tracheostomy and surgical drains
7. Wounds in patients with known allergies to silicone, nylon or acrylic glue
8. for aspiration or suction purpose beyond those specified in the indications for use

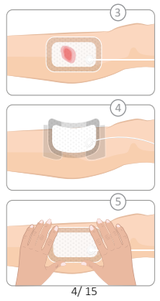
7. Instruction to use:



1. Insert two AA batteries into the battery compartment on the back side of the VivereX(+)™ device, in the correct orientation (1). Alkaline batteries are recommended. Do not use rechargeable battery, the device will not work. All indicators flash twice indicating that device is ready to use. Secure the battery compartment cover.
2. Twist luer connectors together to connect the dressing tube to VivereX(+)™ device (2).
3. Use an extension tube if a longer distance between dressing and the device is required.
4. Ensure the tube is free from kinks and not blocking the flow between the dressing and VivereX(+)™ device.
5. Press the power button on the front of the VivereX(+)™ device to starts the device. The green indicator start to flash, indicating that

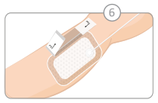
the device is on.

6. The device can be heard functioning while contraction of the dressing confirms the start of NPWT.
7. The leak indicator flashes if the dressing is not sealed (refer to section 20 for troubleshooting). VivereX(+)™ will turn off if the leak is not adequately solved within 30 seconds.
8. Keep VivereX(+)™ in a place close to the patient, where the patient can easily monitor the status of LED indicators e.g., using the belt holder to hang the device on their pocket, outer garments, or belt.
9. The device will automatically stop functioning 10 days after start date in VivereX™ and 21 days in VivereX+™.
10. To turn off the device, press and hold the power button for 3s.
11. If you require any assistance in setting up, using or maintaining the VivereX(+)™ system, or if any unexpected alerts or fault are encountered, please contact Sunmedic or your local distributor.



8. Instruction to apply the dressing:

1. Using appropriate techniques remove hair from area close to the wound to fix the dressing better to the skin.
2. Prepare the wound in accordance to the "Wound Bed Preparation" principals.
3. Dry the skin around the wound.
4. If the dressing is used on sensitive skin, wipe the skin around the wound with a supportive solution to protect the skin, prior to the application of the fixation strips.
5. For wounds with moderate volume of secretion, the size of the dressing should be approximately 4 times larger than the wound surface.
6. Wounds area with greater than 5 mm in depth should be covered by VivaFoam™ prior to application of the dressing. When utilizing a filler, it is recommended that both the filler and the VivereX™ dressing be changed 2 to 3 times per week, in accordance with local clinical protocols.



a. Do not Cut VivaFoam™ over the wound as fragments may fall into the wound.

b. Do not force VivaFoam™ into the wound as this might alter the delivery of negative pressure or block exudate.

7. Take into account that the part of the dressing containing suction port should be placed cranially and outside of the wound over an area of healthy skin (3).
8. Remove the protective layer from the central part of the dressing and apply this part over the proximal portion of the wound.
9. Remove the rest of the protective layer from the dressing and place the dressing on to the wound (4).
10. Smooth the dressing with your two hands or pull out the dressing edges to prevent creasing (5).
11. Reposition the dressing if required to avoid crease.
12. Connect the dressing to the device using luer connectors (2). Use extension tube if it is required.
13. Use fixation strips to support and maintain adequate sealed dressing. Apply the fixation strips with a 1 cm (0.4 in.) overlap to all sides of the dressing in to secure a seal dressing during the wear time (6).

9. Battery change:

The unit is supplied with 2 AA batteries which should provide power to the unit for the period of its lifespan. If the green normal therapy and yellow battery indicators flash, the batteries should be replaced with new ones within 24 hours. If the yellow battery indicator is flashing alone, the battery capacity is too low and the batteries should be replaced within a few hours, preferably immediately. (refer to section 20).

10. Disposal:

Used dressing and fillers should be disposed of as clinical waste in accordance with local hospital protocols. The batteries should be removed from used VivereX(+)™ device and recycled. The device should either be recycled after decontamination or

disposed of as clinical waste in accordance with the local hospital protocols.

11. Important issues that patients should be advised about:

1. Keep the device in a position that allows good visibility of the four LED indicators.
2. Observe routinely the tubing to ensure the tubes are free from kinks and not blocking the flow between the dressing and the device.
3. Keep the device free from dust, and drop down.
4. Do not spray or submerge in water.
5. Contact your healthcare professional if you observe any evidence of damage or sign of malfunction of VivereX(+)™ system.

12. Taking shower with VivereX™ dressing:

1. Press and hold the power button for 3 seconds to put the device in "Off" mode.
2. Disconnect VivereX(+)™ and keep the device in a safe place.
3. The end of the dressing's tube should be facing down, to prevent water entering the tube.
4. The dressing should not be submerged in water or sprayed.
5. After showering reconnect the device as described in section 4.
6. Press power button to turn the device to "On" mode.
7. Ensure that the green indicator flashes, the dressing is contracted, and no yellow indicator is active.

13. Cleaning VivereX(+)™ device:

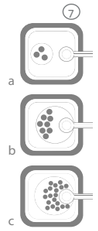
The pump can be cleaned with a damp cloth with soapy water or a gentle disinfectant solution.
Avoid spilling liquid on the device as liquids can cause malfunction of VivereX(+)™ device and possibly be a safety hazard.

14. Warnings:

1. Treatment with the VivereX(+)™ system is allowed in conjunction with the use of anticoagulants, but because of an increased risk of bleeding, these patients should be monitored continuously, preferably, in a health center.
2. In all patients, hemostasis should be done and hemorrhage should be monitored continuously during treatment. If bleeding occurs during treatment

with the VivereX(+)™ system, the device should be stopped immediately and promptly notify responsible physician.

3. Sharp edges of the bone should be removed or covered to avoid damage to the veins or internal organs, leading to bleeding.
4. To minimize the risk of bleeding, remove the dressing carefully.
5. Ensure that the dressing is not in direct contact with vessels, nerves, organs or anastomotic sites. These types of tissue should be covered by natural tissue or non-adhesive dressing.
6. Ensure that the dressing is not placed close to Sympathetic nerve.
7. In the case of pediatric patients the size and weight should be taken into consideration.
8. Do not use the dressing if the package is damaged.
9. Disconnect the device if defibrillation is required. Remove the dressing if its location interferes with defibrillation.
10. VivereX(+)™ device is not MR compatible and should not be taken into MR environment.
11. VivereX(+)™ device is not compatible with the hyperbaric oxygen environment.
12. VivereX(+)™ device should not be used in the presence of flammable anesthetic mixtures.
13. Care should be taken to carry the device in a way that it does not cause damage, or tourniquet or strangulation to the patient.
14. Care should be taken that the tubing is not twisted under the patient's body as this may block therapy.
15. Keep out of reach of children. Swallowing can lead to chemical burns, perforation of soft tissue, and death. Severe burns can occur within 2 hours of ingestion. Seek medical attention immediately.



15. When to change the dressing:

A common wear time for silicone dressing is three to seven

days. This period reduces in case of wound infection or excessive wound secretion. The dressing should be changed in accordance with following guidelines:

- When the "change dressing" indicator is turned "On"
- When the wound exudate has reached or is close to the suction port as in (7b) and (7c).
- When there are repeated signs of leak.

16. How to change the dressing:

1. Press and hold the power button for 3s. to turn the device to "Off" mode.
2. Wait until the dressing is back to its original state.
3. Stretch the fixation strips away from the skin.
4. Lift the dressing and remove it with caution horizontally from the surface of the wound.
5. Observe the dressing for wound exudate volume, color and odor.
6. Wash the wound with an appropriate wound cleanser if necessary.
7. Apply a new dressing as described in section 5.
8. Connect to the device and press the power button to restart the therapy.

17. To change VivereX(+)™ device:

The VivereX™ has a lifespan of 10 days and the VivereX+™ has a lifespan of 21 days. If the "Leakage", "dressing change" and "Replace Battery" lit continuously, it indicates that the VivereX(+)™ lifespan has elapsed. Press the power button for 3s. Disconnect the device from the unit and connect a new device as described in section 4.

18. Precautions:

1. Do not cover the dressing with layers of adhesive film because it reduces the evaporation of the wounds secretion and decreases the dressings life time.
2. Support the fragile skin close to the wound with skin protecting material.
3. The VivereX(+)™ pump should not be used with other NPWT accessories other than those mentioned in section 17.
4. If the dressing covers circumferentially the extremity monitors the distal circulation carefully and if any sign of ischemia is present, remove the dressing.
5. Discontinue using VivereX(+)™ system in case of allergic reaction to the dressing.

6. Infected wounds should be treated by appropriate infection treatment and frequent wound inspections.
7. Do not take VivereX(+)™ device apart or modify.
8. Any surgical drain should be placed away from the dressing.
9. Do not cut the dressing as this can cause malfunction.
10. Place the dressing in a way that the suction port of the dressing will be located on a healthy skin, away from the wound and cranial to it.
11. VivereX(+)™ system is a single use device and should not be used on more than one patient.
12. The dressing and the device should not be exposed to sunshine or heat.
13. Do not use the device if the battery cover is missing.
14. Disconnect the device from the dressing when taking shower. Do not submerge the dressing into water.
15. The time needed for minimum and maximum transport/storage temperature to be converted to a range of the operational temperature will be approximately 30 minutes.
16. X-ray might affect some medical devices. If possible, disconnect and move the device out of the X-ray range. Check the device is functioning correctly, if it has been exposed for X-ray.

19. Alerts and faults:

VivereX(+)™ device is equipped with visual indicators to make patient aware of if there is an issue. Refer to section 24, if your device develops a fault. VivereX(+)™ system does not emit audible alarm and the device should be carried in a way that the visual indicators can be monitored easily.

20. Caution:

These instructions for use are not intended as a guarantee or warranty. They are only intended as a guide. For medical questions, please consult a physician. This productmust be used in accordance with these instructions for use and related labeling.

21. Glossary symbols for VivereX(+)™ device:

Symbols	Definition	Symbols	Definition	Symbols	Definition
	ON/OFF		Device is operating correctly	SN	Serial number
	Alert leak through dressing		Dressing need to be changed		Follow instruction for use
	Battery alert		General warning sign	UDI	Unique Device Identifier
	Consult instructions for use		Expiry date	REF	Catalogue number
CE	CE mark		Do not use if package is damaged	LOT	Batch code
	Non-sterile		Sterilized using ethylene oxide		Keep away from sunlight
EC REP	Authorized representative in the European Community		Do not reuse	MR	MR unsafe
	Manufacturer		Date of manufacture		Latex free
	Humidity limitation		Atmospheric pressure limitation		Risk of explosion
	Temperature limit	Rx only	Prescription use only		Keep dry
	Type BF applied part		Not for general waste		Fragile handle with care
	Do not resterilize		Do not drop	MD	Medical Device
	Importer		Distibutor		Patient information website

22. Adverse reaction:

Excessive bleeding is a significant risk associated with the application of suction to wounds, potentially leading to severe injury or death. Therefore, careful patient selection is crucial, considering the stated contraindications, warnings, and precautions. It is essential to closely monitor the wound and dressing for any changes in the patient's blood loss status. Additionally, observe the patient for any sudden or abrupt alterations in the volume or color of exudate.

23. Troubleshooting:

All indicators are off.

Possible cause(s)	Troubleshooting/Comments
1. The unit is turned off. 2. The batteries are inserted in wrong orientation. 3. The batteries have depleted.	1. Press the power button to start therapy. 2. Check if the batteries are placed in correct direction. 3. Replace batteries and press power button.

All indicators flash twice.

Possible cause(s)	Troubleshooting/Comments
Batteries are inserted in correct orientation. The unit is ready for therapy.	The unit is functioning normal. Press power button to start therapy.

The green is flashing.

Possible cause(s)	Troubleshooting/Comments
The unit is functioning normal.	The unit is frequently heard running to maintain the target pressure at the wound bed.

The leak and replace battery are flashing.

Possible cause(s)	Troubleshooting/Comments
A significant air leak exists. NPWT is not established. The battery power is low.	The air leak should be addressed as above. Replace all batteries.

The leak is flashing.

Possible cause(s)	Troubleshooting/Comments
A significant leak exists. NPWT is not established.	The unit will be turn off after 60s, if NPWT has not been established due to air leak. Check dressing's border and smooth out if any creasing is observed. Check and secure connectors.

The change dressing and replace battery are flashing.

Possible cause(s)	Troubleshooting/Comments
1- The dressing is saturated. 2- The tube is blocked. 3- The battery power is low.	1- Health care giver to change the dressing. 2- Ensure the tube is not kinked. 3- Replace the batteries.

The change dressing is flashing.

Possible cause(s)	Troubleshooting/Comments
1- The dressing is saturated. 2- The tube is blocked.	1- Health care giver to change the dressing (refer to section 13). 2- Ensure that the tube is not blocked.

The green and replace battery are flashing.

Possible cause(s)	Troubleshooting/Comments
The unit is functioning normal but the battery power is low.	Replace the batteries in less than 24 hours.

The replace battery is flashing.

Possible cause(s)	Troubleshooting/Comments
The unit is functioning normal but the battery power is too low.	Replace the batteries within few hours, preferably immediately. Press power button to restart the therapy.

The Leak, change dressing, and replace battery illuminate continuously.

Possible cause(s)	Troubleshooting/Comments
The unit is expired.	The therapy is ceased. Health care giver should apply a new unit and change the dressing, if continued therapy is necessary.

24. Mode of action:

NPWT VivereX system facilitates wound healing by applying continuous or intermittent suction at the wound site, through battery driven pump. This process removes excess fluid, minimizes edema, and enhances blood flow while reducing the risk of infection.

25. Electromagnetic compatibility:

VivereX(+)™ Has been tested and shown to comply with the limits for medical to IEC 60601-1-2-2014 4th edition. These limits and test levels are intended to provide reasonable protection to assure the safety of medical devices with regard to electromagnetic disturbances when VivereX(+)™ is used in a typical medical installation and uncontrolled environment like home use. This equipment can be affected by radio frequency energy and if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If further information or guidance on electromagnetic immunity and emissions is needed, please contact Sunmedic or visit us online at www.sunmedic.se. The VivereX(+)™ Negative Pressure Wound Therapy system complies with the Essential Performance requirements of IEC 60601- Clause 4.3., to achieve its

VivereX(+)™ system set (PDI600111-8, PDI600121-8, PDI600411-8, and PDI600421-8) packaged by Sunmedic AB at Hammargatan 11B, 235 32 Vellinge, Sweden.

VivereX(+)™ pumps (PDI600100-400)
Sunmedic AB
Hammargatan 11B, 235 32 Vellinge, Sweden
CE 0402

VivereX™ FC dressings (PDI600221-8), and VivaFoam™ (PDI600301-5)
Sunmedic AB
Hammargatan 11B, 235 32 Vellinge, Sweden
CE 0402

VivereX™ SC dressings (PDI600211-8)
Zhejiang Longterm Medical Technology Co., Ltd.
ShuangShan Road 277, Fuxi Street, Deqing County
313200 Huzhou City, Zhejiang Province, China
CE 0123

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd
2595AA The Hague, The Netherlands

Importer and Distributor:
Sunmedic AB, Hammargatan 11B
235 32 Vellinge, Sweden

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26. Technical Specifications:

Unit weight (excluding batteries)	<100 g
Dimensions	Height: 84 mm width: 73 mm Thickness: 22 mm
Electrical data (Power Supply)	
Power battery	3 V DC/battery
Input current	Max 300 mA
Battery type	2 x AA, 2 x 1.5V, non-rechargeable
Vacuum mode	Continuous
Maximum vacuum	120 mmHg
Operating time, once batteries installed	10 days for VivereX 21 days for VivereX+
Ingress protection	IP22
Patient protection	Type BF
Mobility: Portable	Carrying bag available
Operation environment	5–40 °C (41–104 °F), 10–75% RH 700–1060 mbar atmospheric pressure
Storage/transport temperature	5–25 °C (41–77 °F), 10–75% RH -20–45 °C (-4–113 °F) in one week
Altitude range	< 2000 m
Sterility	Pump: Non-sterile Dressing & VivaFoam™: Sterile
Programable Electronic Medical System (PEMS) identifier	SNPC1
Material Pump (molded parts)	Polycarbonate / ABS
Material tube	Polyurethane
Material dressing	Polyurethane, silicone, absorbent
Material VivaFoam™	Reticulated open cell polyurethane foam