



Introduction

VivereX™ system is a medical therapeutic device which apply controlled negative pressure to the wound bed. VivereX™ system includes a non-sterile single use battery powered device and should be used with a sterile NPWT dressing set. VivereX™ is equipped with necessary safety visual indicators and performs Negative Pressure Wound Therapy (NPWT) by a continuous mode. VivereX™ device is intended to be used for ten days for one patient, which means no risk for cross contamination. Applying negative pressure results in transferring wound exudate to the NPWT dressing. The NPWT dressing contains of 5 layers and is designed to manage the wound exudate in two different mechanisms, by which VivereX™ system increases dramatically the dressing life time:

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

1. Description:

VivereX™ system consists of a single use device which provides therapy for up to ten days, 2x AA Alkaline batteries, 4 pieces of fixation strips for secure fixation of the dressing and a wound dressing set in one of 7 possible sizes as following :

- | | |
|---------------------|---------------------|
| • VivereX™ unit | Ref No. : PDI600100 |
| • (12.5 x 12.5) cm | Ref No. : PDI600201 |
| • (12.5 x 18.75) cm | Ref No. : PDI600202 |
| • (12.5 x 25) cm | Ref No. : PDI600203 |
| • (12.5 x 35) cm | Ref No. : PDI600204 |
| • (12.5 x 40) cm | Ref No. : PDI600205 |
| • (17.5 x 22.5) cm | Ref No. : PDI600206 |
| • (17.5 x 32.5) cm | Ref No. : PDI600207 |

2. Indications for use:

VivereX™ system is suitable for use in both hospital and home care setting. Wound types which is appropriate includes:

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|---|-----------------------------------|
| 1. Acute wound | 5. Diabetic ulcers |
| 2. Chronic wound with small or medium secretion | 6. Surgical clean closed incision |
| 3. Skin graft or flaps and donor site | 7. Subacute dehisced wounds |
| 4. Pressure ulcers | 8. Trauma wounds |
| | 9. Burn injury grade I and II |

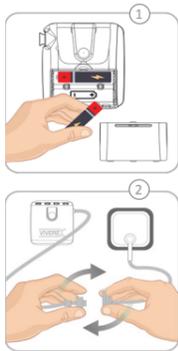
3. Contraindications:

VivereX™ system is contraindicated for:

- Wounds with malignancy except in palliative care
- Wounds with untreated osteomyelitis
- Wounds with untreated non-enteric fistula
- Wounds covered by necrotic tissue
- Wounds with exposed bone, blood vessels, nerves, organs or anastomotic site
- Tracheostomy and surgical drain
- Wounds in patients with known allergy to silicone, nylon or acrylic glue.

4. Instruction to use VivereX™ device:

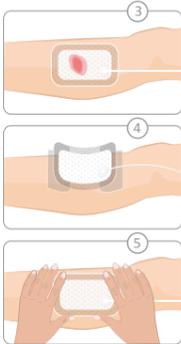
- Insert two AA batteries into the battery compartment on the back side of the VivereX™ device, in the correct orientation (1). Alkaline batteries are recommended. Do not use rechargeable battery, the device will not work. All indicators flash twice indicating the device is ready to use. Secure the battery compartment cover.
- Twist luer connectors together to connect the dressing tube to VivereX™ device (2).
- Use extension tube if a longer distance between dressing and the device is required.
- Ensure the tube is free from kinks and not blocking the flow between the dressing and VivereX™ device.
- Press the power button on the front of the VivereX™ device to start the device. The green indicator start to flash, indicating that the device is on.
- The device can be heard functioning while contraction of the dressing confirms the start of NPWT.
- 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.
- 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.
- VivereX™ will automatically stop functioning ten days after start date.
 - Note: The dressing should be removed as soon as possible or VivereX™ should be replaced with a new one.
- To turn off the device, press the power button.
- If you require any assistance in setting up,



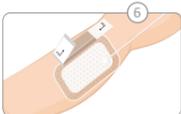
using or maintaining the VivereX™ system, or if any unexpected alerts or fault are encountered, please contact Sunmedic.

5. Instruction to apply the dressing:

- Using appropriate technique remove hair from area close to the wound in order to fix dressing better to the skin.
- Prepare the wound in accordance to the Wound Bed Preparation principals.
- Dry the skin around the wound.
- If the dressing is used on a sensitive skin, wipe the skin around the wound with a supportive solution to protect the skin, prior to the application of the fixation strips.
- For wounds with moderate volume of secretion, the size of the dressing should be approximately 4 times larger than the wound surface.
- Wounds area with greater than 3 mm in depth should be covered by 10 mm thick Polyurethane foam prior to application of the dressing.
- Keep in mind that the part of the dressing containing suction port should be placed proximal and outside of the wound over an area of healthy skin (3).
- Remove the protective layer from the central part of the dressing and apply this part over proximal portion of the wound.
- Remove the rest of the protective layer from the dressing and place the dressing on to the wound (4).
- Smooth the dressing with your two hands or pull out the dressing edges to prevent creasing (5).
- Reposition the dressing if required to ensure avoiding creasing.
- Connect the dressing to the device using luer connectors (2). Use extension tube if it is required.
- Use fixation strips to support and maintain an adequate sealed dressing. Apply the fixation



strips with a 1cm (0.4 in.) overlap to all sides of the dressing in order to secure a seal dressing during the wear time (6).



6. Battery change:

The unit is supplied with 2 AA batteries which should provide power to the unit for 10 days. 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. (See section 20).

7. 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 as clinical waste in accordance with the local hospital protocols. Recycling of the device and batteries should be in accordance with the European Waste Electrical and Electrical Equipment directive (WEEE) where applicable or local regulations.

8. Important issues that patients should be advised about:

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

9. Taking shower with VivereX™ dressing:

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

10. Cleaning VivereX™ device:

The device may be wiped clean with mild disinfectant solution or soapy water. Avoid spilling liquid on the device as liquids can cause malfunction of VivereX™ device and possibly be a safety hazard.

11. Warnings:

- The use of anticoagulants does not mean that treatment with the VivereX™ system is inappropriate, but because of an increased risk of bleeding, these patients should be monitored continuously with caution, preferably, in a treatment center.
- 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.
- Sharp edges of the bone should be removed or covered in order to avoid damage to the veins or internal organs, leading to bleeding.
- To minimize the risk of bleeding, remove the dressing carefully.
- 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.
- Ensure that the dressing is not placed close to Sympathetic nerve.
- In case of pediatric patients the size and weight should be taken into

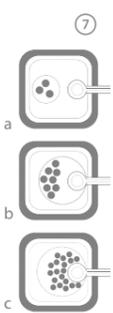
consideration.

- Do not use the dressing if the package is damaged.
- Disconnect the device if defibrillation is required. Remove the dressing if its location interferes with defibrillation.
- VivereX™ device is not MR compatible and should not be taken into MR environment.
- VivereX™ device is not compatible with the hyperbaric oxygen environment.
- VivereX™ device should not be used in the presence of flammable anesthetic mixtures.
- Care should be taken to carry device in a way that it does not cause damage, or tourniquet or strangulation to the patient.
- Care should be taken that the tubing is not twisted under the patient's body as this may block therapy.
- 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.

12. When to change the dressing:

A common wear time for a silicone dressing is three to seven days. This period of time 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 sign of leak which has been difficult to solve.



13. How to change the dressing:

- Press the power button to turn the device to «Off» mode.
- Wait until the dressing is back to its original state.
- Stretch the fixation strips away from the skin.

- Lift the dressing and remove it with caution horizontally from the surface of the wound.
- Observe the dressing for wound exudate volume, color and odor.
- Wash the wound with an appropriate wound cleanser if necessary.
- Apply a new dressing as described in section (5).
- Connect to the device and press the power button to restart the therapy.

14. To change VivereX™ device:

VivereX™ device has a life time of ten days. If leak, change dressing and battery indicators illuminate continuously, it indicates that VivereX™ is expired. Press the power button. Disconnect the device from the dressing and connect a new device as described in section (4).

15. Precautions:

- Do not cover the dressing with layers of adhesive film because it reduces the evaporation of the wounds secretion and decrease the dressings life time.
- Support the fragile skin closed to the wound with skin protecting material like Hydrocolloid pad or supportive solution.
- The VivereX™ pump should not be used with other NPWT accessories other than those mentioned in Section (17).
- If the dressing covers circumferentially the extremity monitor the distal circulation carefully and if any sign of ischemia is present, remove the dressing.
- Discontinue using VivereX™ system in case of allergic reaction to the dressing.
- Infected wounds should be treated by appropriate infection treatment and frequent wound inspections.
- Do not take VivereX™ device apart or modify.
- Any surgical drain should be placed away from the dressing.
- Do not cut the dressing as this cause malfunction of the dressing.
- 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 proximal to it.
- VivereX™ system is a single use device and should not be used on more than one patient.
- The dressing and the device should not be exposed to sunshine or heat.
- Do not use the device if the battery cover is missing.

- Disconnect the device from the dressing when taking shower. Do not submerge the dressing into water.
- The time needed for minimum and maximum transport/storage temperature to be converted to range of the operational temperature will be approximately 30 minutes.
- 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.

16. Alerts and faults:

VivereX™ device is equipped with visual indicators to make patient aware of if there is an issue. Refer to section (20) 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.

17. Required components for VivereX™ system:

- VivereX™ Pump unit
- AA Alkaline batteries X 2
- Instructions for use
- Sterile dressing
- Extension tube and sterile adhesive fixation strips which are supplied with dressing

18. 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 product must be used in accordance with these instructions for use and related labeling.

19. Glossary symbols for VivereX™ device:

Symbols	Definition	Symbols	Definition	Symbols	Definition
	ON OFF		Device is operating correctly		Serial number
	Alert leak through dressing		Dressing need to be changed		Keep out of reach of children
	Battery alert		Caution		Do not charge
	Consult instructions for use		Expiry date		Do not open or dismantle
	CE mark (EU)		Do not use if package is damaged		Do not short circuit
	Non-sterile		Sterilized using ethylene oxide		Do not mix different types of batteries
	voltage (3v)		Do not reuse		MR unsafe
	Manufacturer		Date of manufacture		Latex free
	Keep dry		Fragile handle with care		Do not insert battery incorrectly
	Temperature limit -25°C -13°F		Do not deform or damage		Do not dispose of in fire
	Equipment classification isolation type BF		Not for general waste (EU)		Do not mix old and new batteries
	Do not resterilize		Do not drop		Do not mix old and new batteries
	Risk of explosion		Keep away from sunlight	—	—
	Reference number		Batch code	—	—

20. Troubleshooting:

Possible cause(s)	Troubleshooting/Comments
All indicators are off	

- | | |
|---|--|
| <ol style="list-style-type: none"> The unit is turned off. The batteries are inserted in wrong orientation. The batteries have depleted. | <ol style="list-style-type: none"> Press the power button to start therapy. Check if the batteries are placed in correct direction. Replace batteries and press power button. |
|---|--|

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.

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.

Possible cause(s)	Troubleshooting/Comments
A significant leak exit. NPWT is not established.	The unit will be turn off after 30s. if NPWT has not been established due to air leak. The unit will automatically restart after one hour. Check dressing's border and smooth out if any creasing is observed. Check and secure tube-unit connectors. Press power button to restart the unit.

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

Possible cause(s)	Troubleshooting/Comments
The dressing is filled to capacity or the tube is blocked.	Health care giver to change the dressing. Press power button to restart the therapy.

Possible cause(s)	Troubleshooting/Comments
The dressing is filled to capacity or the tube is blocked. NPWT is not established. The battery power is low.	Health care giver to change the dressing and replace the batteries. Press power button to restart the therapy.

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

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.

Possible cause(s)	Troubleshooting/Comments
The unit is expired.	The unit has life span of 10 days, after which the therapy will be ceased. Health care giver to apply a new unit and change the dressing.

21. Safety and electromagnetic compatibility:

The VivereX™ Negative Pressure Wound Therapy System complies with the general requirements for safety of electrical medical equipment IEC 60601 and electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2.

22. 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 intended use to maintain a nominal negative pressure of <120 mmHg.

23. Technical Specifications:

Unit weight (excluding batteries)	<100g
Dimensions	Height: 84 mm width: 73mm Thickness: 22 mm
Electrical data (Power Supply)	
Power battery	3 V DC/battery
Input current	Max 300mA
Battery type	2 x AA, 2 x 1.5 V, non-rechargeable
Vacuum mode	Continuous
Maximum vacuum	120 mmHg
Operating time, once batteries installed	10 days
Ingress protection	IP22
Patient protection	Type BF
Mobility: Portable	Carrying clips included
Operation environment	5 – 40°C (41-104F), 15-90% RH, 700-1060 mbar atmospheric pressure
Storage/transport temperature	-25 to +70°C (-13 to +158F), 15-90% RH, 700-1060 mbar atmospheric pressure
Altitude range	< 2000 m
Sterility	Non sterile
Programmable Electronic Medical System (PEMS) identifier	SNPC1
Material of construction	Pump (molded parts) – Polycarbonate/ ABS Tubing-PVC(DEHP free)
Compliance	Directive 93/42/EEC Class IIa