



Closed surgical incision
Diabetic foot ulcers
Bed sores
Acute wounds
Chronic wounds
Grafts & flaps

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Introduction:

Vivere x system made by Sunmedic company is a medical therapeutic device which uses controlled negative pressure to heal wounds. Vivere X system includes a non-sterile single use battery powered device, a sterile NPWT dressing set, fixation strips and 2 AA batteries. Vivere X is equipped with necessary safety alarms and performs NPWT (Negative pressure wound treatment) with a continuous negative pressure mode of 80 mmHg. Vivere X device can be used in ten days for one patient. Using Vivere X removes intracellular fluid from the wound environment to the dressing, which in its turn results in increasing blood flow and accelerated wound healing. Vivere x system separates harmful substances and infectious secretions from the surface of the wound using two different mechanisms: 1- The absorbent layer of the dressing absorbs some of the secretions. 2- The dressing allows evaporation of the rest of the wound secretion. Thus, Vivere X system is designed to dramatically increase the dressing life time by maintaining the continuous pressure in the dressing.

A. Description:

Vivere X system consists of a single use device which provides therapy for up to ten days, 2x AA lithium batteries, 4 pieces of fixation strips for secure fixation of the dressings and a wound dressing set in one of 8 possible sizes as following :

- (10 x 10) cm Ref No. : PDI600200
- (10 x 20) cm Ref No. : PDI600201
- (10 x 30) cm Ref No. : PDI600202
- (10 x 40) cm Ref No. : PDI600203
- (15 x 15) cm Ref No. : PDI600204
- (15 x 20) cm Ref No. : PDI600205
- (15 x 30) cm Ref No. : PDI600206
- (20 x 20) cm Ref No. : PDI600207

B. Indications for use:

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

- Acute wound
- Chronic wound with small or medium secretion
- Skin graft or flaps and donor site
- Pressure ulcers
- Diabetics ulcers
- Surgical clean closed incision
- Subacute dehisced wounds
- Trauma wounds
- Burn injury grade I and II

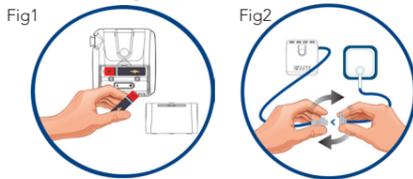
C. Contraindications:

Vivere X system is contraindicated for:

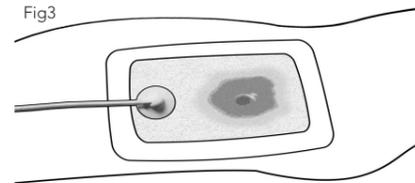
- Wounds with malignancy except in palliative care
- Wounds with untreated osteo myelitis
- Wounds with untreated non-enteric fistula
- Wounds cover by necrotic tissue
- Wounds with exposed bone, blood vessels, nerves, organs or anastomotic site
- Tracheostomy and surgical drain
- Wounds in patients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

D. Instruction to use Vivere X device:

- Insert two AA batteries into the battery compartment on the back side of the Vivere X device, in the correct orientation (Figure 1). Do not use rechargeable battery, the device will not work. Lithium batteries are recommended. All LED flash twice indicating the device is ready to use. Secure the battery compartment cover.
- Twist luer connectors together to connect the dressing tube to Vivere X device (Figure 2).

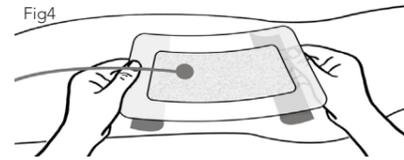


- Use lengthening tube if a longer distance between dressing and the device is required.
- Ensure the tubes are free from kinks and not blocking the flow between the dressing and Vivere X device.
- Press the power button on the front of the Vivere X device to start the device. The power green LED start to flash, indicating that the device is on.
- The pump can be heard functioning while contraction of the dressing confirms the start of NPWT.
- The yellow leak LED flashes if the dressing is not sealed (refer to section R for troubleshooting).
- Vivere X will turn off if the leak is not adequately solved within sixty seconds.
- Keep Vivere X 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.
- Vivere X will automatically stop functioning ten days after start date.
- Note: The dressing should be removed as soon as possible within two hours or Vivere X should be replaced with a new one.
- To turn off the device, press the power button.



E. 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 at least 60-70% larger than the wound surface.
- Wounds area with greater than three mm in depth should be covered by ten 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 outside of the wound over an area of healthy skin (Figure 3).
- Remove the protective layer from the central part of the dressing and apply this part to the center portion of the wound.
- Remove the rest of the protective layer from the dressing and place the dressing onto the wound (Figure 4).
- Smooth the dressing with your two hands or pull out the dressing edges to prevent creasing (Figure 5).
- Reposition the dressing if required to ensure avoiding creasing.
- Connect the dressing to the device using luer connectors (Figure 3). Use lengthening tube if it is required.
- Use fixation strips to support and maintain an adequate sealed dressing. Place the fixation strips by one cm overlap on the all sides of the dressing and the other part over the skin (Figure 6).



F- Battery change:

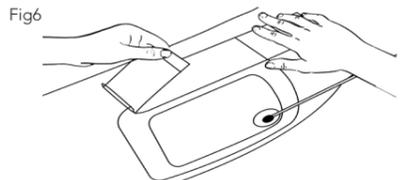
The turn on red battery LED indicate a too low battery power and the batteries should be replaced with new one within 24 hours. preferably immediately. refer to section O.

G- 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 Vivere X 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.

H. 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, out of reach of children and pets.
- Do not spray or submerge on water.
- 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 Vivere X and possibly hazard to patient.
6- Contact your healthcare professional if you ob

serve any evidence of damage or sign of malfunction of Vivere X system.

I. Taking shower with Vivere X dressing.

- Press the power button for three sec to put the device in Off mode.
- Disconnect Vivere X 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 directly submerged in water or sprayed.
- After showering reconnect the device as described in section D.
- Press power button to turn the device in «On» mode.
- Ensure that the green therapy LED flashes, the dressing is contracted and no LED alarm is active.

J. Cleaning Vivere X 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 Vivere X device and possibly hazard to patient.

K. Warnings:

- The use of anticoagulants does not mean that treatment with the Vivere X system is inappropriate, but because of an increased risk of bleeding, these patients should be monitored continuing 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 Vivere X system, the device should be stopped immediately and promptly notified responsible physician.
- Sharp edges of the bone should be removed or covered in order to avoid damage 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 for the patient is required. Remove the dressing if its location interferes with defibrillation.
- Vivere X device is not MR compatible and should not be taken into MR environment.
- Vivere X device is not compatible with the hyperbaric oxygen environment.
- Vivere X device should not be used in the presence of flammable anesthetic mixtures.
- If the device will be off longer than two hours the dressing should be replaced by conventional dressing.
- Care should be taken to carry device hanging by belt holder and the tubing is fixed in a way that it does not cause pressure damage, or tourniquet to the patient.
- Care should be taken that the tubing does not twisted under patient's body so that the therapy will be blocked.

L. 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:

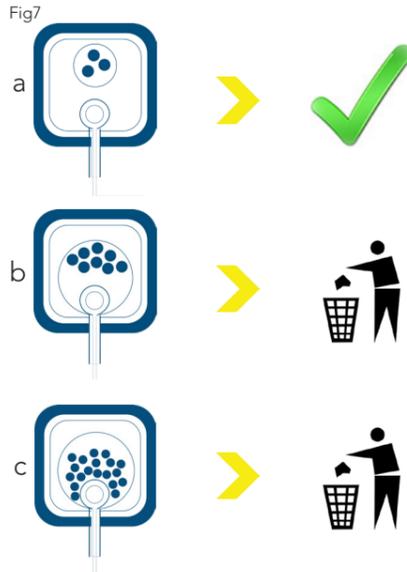
- When the yellow «change the dressing» is turned «On».
- When the wound exudate has reached or is close to the suction port as in figure 7b and 7c.
- When there is repeated leak alarms which has been difficult to solve.

M. 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 E.
- connect to the device and press the power button to restart the therapy.

N- Change Vivere X device:

Vivere X device life time is ten days. No LED will turn on by



pressing the power button. Disconnect the device from the dressing and connect a new device as described in section D.

O. 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.
- Do not use the dressing set with other devices.
- If the dressing covers circumferentially the extremity monitor the distal circulation carefully and if any sign of ischemia is present, remove the dressing.
- Vivere X device may be cleaned by using a mild disinfectant.
- Discontinue using Vivere X 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 Vivere X device apart.
- 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 uppermost to it.
- Vivere X 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 for 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 sink the dressing into water.

P- Alarms and errors

Vivere X device is equipped with visual alarms. Refer to table 1 if your device develops alarm. The device should be carried in a way that the visual alarms can be monitored easily.

Q.Glossary symbols for Vivere X device:

Description	Symbols	Description	Symbols
The device is functioning properly	✓	Caution, consult accompanying documents	!
Battery alert	🔋	On/Off	⏻
Dressing change is needed	📄	Notified Body number for Europe	CE
Leakage in dressing	🚰	Type BF applied part	👤
Consult instructions for use	📖	Not for general waste	🗑️
This device is sale by or on order of a physician	Rx	Do not reuse	🚫
Do not resterilize	🚫	Date of manufacture	📅
Manufacturer	🏭	Expire date	📅
Temperature limits	🌡️	Keep dry	☔
Keep away from sunlight	☀️	Do not drop	🚫
Do not use if package damaged	🚫	Reference Number	REF
Batch code	LOT	MR unsafe	MR
Serial Number	SN	Product is not sterile	NON STERILE
Method of sterilization using ethylene oxide	STERILE EO	Fragile handle with care	🚫

R.Troubleshooting

Possible cause(s)	Troubleshooting / Comments
All indicators off	
The Unit is turned off	Press the power button to restart therapy
The batteries are inserted in wrong orientation	Check if the batteries are inserted in correct orientation.
The batteries have depleted	Replace batteries and press power button

Possible cause(s)	Troubleshooting / Comments
All indicators flash twice	
Batteries are inserted in correct orientation and the Unit is ready for therapy	The Unit is functioning normal. Press power button to start therapy

Possible cause(s)	Troubleshooting / Comments
Green ✓ indicator flashes	
The Unit is functioning normal	The Unit is frequently heard running to maintain negative pressure at the wound bed

Possible cause(s)	Troubleshooting / Comments
Umber leak indicator flashes	
A significant air leak in the system. NPWT is not being established	The Unit will turn off after 30 second if NPWT has not being 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 tubes/Unit connectors. Press power button to restart the Unit

Possible cause(s)	Troubleshooting / Comments
Umber leak and red change battery indicators flash	
A significant air leak in the system. NPWT is not being established. The battery power is low	The air leak should be addressed as above. Change all batteries

Possible cause(s)	Troubleshooting / Comments
Umber change dressing indicator flashes	
The dressing is filled to capacity or the tube is blocked. NPWT is not being established	Health care giver to change the dressing. Press power button to restart the Unit

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

Possible cause(s)	Troubleshooting / Comments
Green ✓ and change battery indicators flash	
The Unit is functioning normal, but the battery power is low	Change batteries within 24 hours

Possible cause(s)	Troubleshooting / Comments
Red change battery indicator flashes	
The battery power is too low. NPWT is not being established.	Replace batteries with new one immediately.

Possible cause(s)	Troubleshooting / Comments
Umber leak and change dressing and red change battery are continuously illuminated	
The Unit is expired	The Unit has lifespan of 10 days, after which the therapy will ceased. Health care giver to apply a new Unit and change the dressing.

Technical specification:	
Unit weight	TBD
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
Vacuum options	80 mmHg ± 20 mmHg
Operating time, once batteries installed	10 days
Ingress protection	IP50
Patient protection	Type BF
Mobility: Portable	Carrying clips included
Operation temperature	5 – 45°C (41-113°F)
Humidity	15% – 85% non-condensing
Storage/transport temperature	-10 – +60°C
Altitude range	< 2000 m
Sterility	Non sterile
Programable Electronic Medical System (PEMS) identifier	SNPC1
Material of construction	Pump – Polycarbonate, ABS
Compliance	Class II
	IEC 60601-1:2005+AMD1:2012, BS EN 60601-1:2006+A12:2014, ANSI/AAMI ES60601 1:2005(R)2012,
	CAN/CSA-C22.2 No. 60601-1:14 IEC 60601-1-2:2014 IEC 60601-1-11:2015