RENASYS EDGE NPWT

Patient information

SmithNephew

RENASYS EDGE
Negative Pressure Wound
Therapy System

Introduction

This manual will provide you with important information regarding the Smith+Nephew **RENASYS◊ EDGE** Negative Pressure Wound Therapy (NPWT) System. This manual will be helpful in answering basic questions about the therapy. Please keep this manual in a safe place with other healthcare documents.

For specific instructions on operation of the device, please review the Home Helathcare Manual.

RENASYS◊ EDGE
Negative Pressure Wound Therapy System

What is **RENASYS◊ EDGE** NPWT?

RENASYS EDGE is a Negative Pressure Wound Therapy (NPWT) device that is applied to your wound to help promote healing by drawing out excess fluid and contaminants.

This type of therapy for wound management is widely used in both hospitals and at home

Your nurse:

Nurse contact number:

Your doctor:

Home health agency:

Other useful numbers:

Distributor information:

How does it work?

The **RENASYS◊ EDGE** System consists of a device, a canister and a wound dressing kit.

The dressing is placed on the wound bed and covered with a clear film. Once sealed, it is attached to the device through tubing and a canister. The device then draws fluid from the wound into the canister.

The clear film helps to prevent bacteria from entering the dressing.[1] It also helps promote the formation of new blood vessels[2,3] and has been shown promote lymphatic drainage,*[4] which will help the wound to heal.

The **RENASYS EDGE** device is electrical and can be plugged into an electrical outlet OR can operate on its internal battery for up to 24 hours.†[5] This allows you to move around while receiving treatment from the device (depending on the position of the wound, the rest of your treatment, and recommendations provided by your nurse or doctor).

*As demonstrated *in vivo*
†Tested at -80mmHg and -125mmHg

How many hours a day do you need to use the therapy?

To receive the full benefit of the therapy, follow the recommendations given by your clinician.

How long will it take to improve your wound?

The length of time that the therapy takes to improve a wound is different for every patient. It will depend on your general condition, the size and type of wound that you have, and the treatment you have been prescribed. In many cases, an improvement in the wound can be seen when the first dressing is changed, but in some cases, it may take several weeks.

The therapy may be used to close the wound completely, or may be stopped sooner than this, and replaced with a different type of dressing.

Your nurse or doctor will discuss when, and why, it will be stopped when they assess your wound at each dressing change.

Will it be painful?

The first time the therapy device is turned on, you may feel a slight pulling or drawing sensation. The level of discomfort may vary between patients. If you experience any pain, please speak to your nurse or doctor for advice.

What will the dressings look like when the therapy is being delivered?

The dressings will shrink when the therapy is being delivered, and the Transparent Film Dressing will look wrinkled and will be firm to the touch.

How many hours a day do you need to use the therapy?

To receive the full benefit of the therapy, follow the recommendations given by your clinician.

How often will the dressings have to be changed?

Your clinician will determine how often your dressing needs to be changed. Both gauze and foam dressings will usually need to be changed 2–3 times a week, but in some cases, it may be more often than this. This will depend on the size, type, drainage amount and position of your wound.

All dressing changes must be performed by a trained clinician.

*Tested at -80mmHg and -125mmHg

Will the dressing changes hurt?

Some people may experience slight discomfort during dressing changes, specifically during cleaning of the wound, depending on the type and position of the wound. If you feel any discomfort or pain, please tell the person who is changing your dressing. This way, they will be able to give you advice to help ease the discomfort.

Can you move around while on the therapy?

Usually, patients using the therapy can move around, but this will depend on the position of the wound, the rest of your treatment, and recommendations provided by your nurse or doctor. If you can move around, the therapy device can be unplugged and operated on the battery back-up for up to 24 hours.*[5]

Position of therapy device, while therapy is being delivered:

The therapy device should be at the same height as the wound or slightly higher.

How do I know if the RENASYS◊ EDGE Therapy device is working?

A green OK light, located next to the therapy screen of the device, will illuminate telling you that the therapy is on and vacuum is working properly. If the device is set to CONTINUOUS mode (recommended), the CONTINUOUS

icon will be displayed on the screen. If the device is set to INTERMITTENT mode, the INTERMITTENT icon will be displayed on the screen.

It is important to monitor the activity of the device while you are using it.

Showering and washing

The device and power supply are electronic and cannot be exposed to water. If water or other liquids get into the device, turn it Off and contact your clinician.

When bathing or showering, you must disconnect the device and protect both ends of tubing using the tethered caps. You will need to reconnect to the therapy device as soon as you have finished showering or washing. Connect the tube back to the canister and turn the device on. You can shower or wash with dressings in place, as long as you do not soak them. Refer to the manual for full instructions for use.

Does the dressing have a raisin-like appearance?

(If so, it is working properly.)

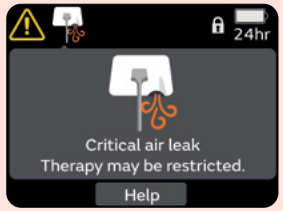
Gauze with Soft Port

Foam with Soft Port

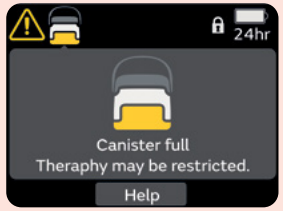
What happens if the **RENASYS EDGE** device alarms?

RENASYS EDGE device is equipped with alarms and alerts to indicate an error which requires user intervention. Most problems are easily solved, for example:

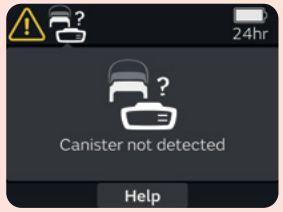
- "Blockage" – If there is a blockage, or kink in the tubing, or the canister is full, the alarm will sound. The canister should be changed or the tubing blockage removed.



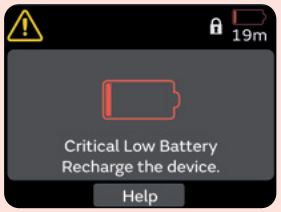
- "Air Leak" – The device will show an alert when a moderate air leak is detected and will show an alarm when a critical air leak is detected. Check the dressing seal or the tubing connection.



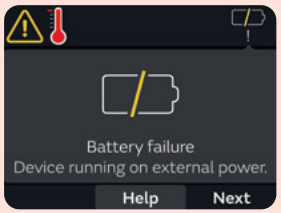
- "Canister Full": The device has detected that the canister is full. Solve by changing the canister with a new one.



- "Canister Missing": The device cannot detect a correctly connected canister. Solve by reattaching or replacing the canister. Refer to the manual for full instructions for use.

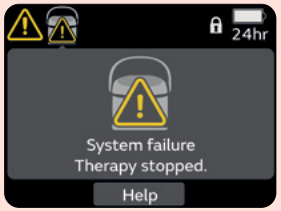


- "Low Battery" – The device will provide an alert when there is less than 2½ hours remaining and an alarm when there less than 20 minutes remaining. Solve by plugging electrical cord into power outlet as soon as possible.



- "High Vacuum or Battery Failure" – The device has detected an internal or battery failure. Switch off and restart the device

- "Too Hot": The device will provide an alert if the battery temperature is too high for charging, and an alarm if the running temperature is too high. Solve by removing the device from any covering or bag, and moving the device into a cooler environment to help it cool down.



- "Therapy Paused Too Long": The device has been paused for more than 30 minutes. Solve by starting the therapy by pressing Play/Pause button

Call your nurse or doctor immediately if:

- You notice a big change in the color or amount of the fluid in the canister, for example if it changes from clear to cloudy or bright red
- You see the canister fill rapidly with blood
- Your wound looks more red than usual or has a foul smell
- The skin around your wound looks reddened or irritated
- The dressing feels or appears loose
- You experience pain

If you have any other questions, please speak to your nurse or doctor.

Purpose of the device (Indications for use)

The **RENASYS◊ EDGE** device is indicated for patients who would benefit from a suction device (NPWT), as it may promote wound healing via removal of fluids, including irrigation fluids and body fluids, wound exudate and infectious materials.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps
- Grafts

When the device should not be used (Contraindications)

RENASYS EDGE pump should not be used on people with:

- Untreated osteomyelitis
- Exposed arteries, veins, organs or nerves
- Necrotic tissue with eschar present
- Exposed anastomotic site
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Non-enteric and unexplored fistulas

Warnings and precautions

General

- Clinicians should not rely on this Home Healthcare User Manual alone, as it does not contain all information related to safety and operating the system. Please seek the separate Clinician User Manual supplied with the pump.
- Do not use it on anyone other than the prescribed patient.
- This product should only be used as prescribed by your clinician and in accordance with this user manual and labeling.

Monitoring

- Monitor your dressing and pump during operation. Contact the treating clinician if:
  - Your wound looks more red than usual or has a foul smell
  - The skin around your wound looks red or irritated
  - There is a change in fluid color
  - You experience an increase in pain
- If you see blood within the canister, stop therapy and contact a clinician immediately.

Dressings

Wound dressings should only be changed by a clinician.

Hygiene and sterility

- Users should wash their hands before and after disconnecting the pump from the dressing to reduce the risk of cross contamination.
- Before disconnecting the pump from the dressing ensure that the quick click connectors are held:
  - Higher than the pump and wound height
  - Away from a location where the wound fluid may contaminate the patient or any other people

This will reduce the risk of cross contamination.

Pump Operation

- Place the pump upright on a level surface during use.
- When placed on an uneven surface, the pump may become unbalanced as fluid fills the canister.
- Do not use the pump or any accessories if they are damaged or not functioning properly, contact the treating clinician if you need a replacement part.
- If the **RENASYS◊ EDGE** pump emits an unusual noise, stop using the pump and contact the treating clinician for a replacement.
- Do not attempt to dismantle or modify the pump or any accessories. No maintenance can be performed by patients or lay caregivers.
- Do not operate the pump self-test feature in a dusty environment as it may damage the pump.
- Do not swallow any small parts removed from the system.

Accessories/AC power

- Ensure the pump can always safely be removed from mains power in an emergency situation.
- The electrical installation of the room must comply with the appropriate electrical wiring standards.
- The pump is only to be used with Smith+Nephew authorized parts and dressings. Only use the power supply provided by Smith+Nephew to charge the pump. Use of any other products has not been proven safe and effective with the **RENASYS EDGE** pump.

Showering

- The pump and power supply are electronic and cannot be exposed to water. If water or other liquids get into the pump, turn it Off and contact your clinician.
- When bathing or showering, you must disconnect the pump and protect both ends of tubing using the tethered caps.

Pump Placement

- The cords and tubing could cause strangulation or a trip hazard. Keep them away from your head and neck and be aware of tubing placement around children and animals.
- Do not lie on the pump or tubing as this may cause a pressure injury.

Other Equipment/Environments

- Due to danger of explosion, do not use the pump:
  - Near an oxygen tank or oxygen generator
  - Within a Hyperbaric Oxygen (HBO) chamber
  - Near the source of any flammable anesthetic gases

Canisters

- Canisters should be changed at least once a week even if it is not full.
- Do not wait for the canister full alarm to sound to change the canister.

Disposal

- Used canisters are single patient use and contain contaminated waste.
- They should be disposed of as guided by your clinician. The pump should be returned to the treating clinician.

Smith+Nephew

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Shaping what's possible in wound care

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You must only use the **RENASYS System** as directed by your healthcare professional and in accordance with the product's packaging and inserts.

The information presented about the **RENASYS System** is for educational, informational and illustrative purposes only. It does not constitute and is not a substitute for medical advice.

Only your healthcare professional can advise whether any treatments referred to may be suitable for you and your condition, including the **RENASYS System**, and of the associated risks, benefits and possible outcomes.

Not everyone who receives a product or treatment will experience the same or similar results; results may vary depending on a number of factors, including each patient's specific circumstances and condition, and compliance with the applicable Instructions for Use. Smith+Nephew is not responsible for the selection of any treatment by a healthcare professional to be used on a particular patient.

Looking for more information?
Scar the QR below for:

- Customer Care contacts
- Troubleshootings videos
- Basic Operation videos

References: 1. Smith+Nephew 2016. Investigation into the bacterial barrier properties of RENASYS Transparent Film dressings under wet/wet conditions. Internal Report. WRPTW141-237.V2. **2.** Ma Z, Shou K, Li Z, *et al*. Negative pressure wound therapy promotes vessel destabilization and maturation at various stages of wound healing and thus influences wound prognosis. *Exp Ther Med*. 2016;11(4):1307–1317. **3.** Xia CY, Yu AX, Qi B, *et al*. Analysis of blood flow and local expression of angiogenesis associated growth factors in infected wounds treated with negative pressure wound therapy. *Mol Med Rep*. 2014;9(5):1749–1754. **4.** Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): hematoma/seroma and involvement of the lymphatic system. *Wound Repair Regen*. 2011;19(5):588–596. **5.** Smith+Nephew 2022. How the RENASYS EDGE Negative Pressure Wound Therapy System provides continuity of care to the patient. Internal Report. EO.AWM.PCS270.003.V1.