

Warnings and Precautions (cont.)

Clinical decisions

- If the patient reports discomfort, consider reducing the level of pressure or use a wound contact layer. The pressure setting is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include:
 - location of the wound,
 - volume of the drainage,
 - integrity of the dressing seal.
- Negative Pressure Wound Therapy (NPWT) should remain on for the duration of the treatment. The length of time a patient may be disconnected from the pump is a clinical decision based on individual characteristics of the patient and wound. Factors to consider include:
 - location of the wound,
 - volume of the drainage,
 - integrity of the dressing seal,
 - assessment of the bacterial burden and patient's risk of infection.
- In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue the use of NPWT and immediately seek medical assistance.

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 disinfectants, or
 - near any flammable disinfectants.
- In the event defibrillation is required, disconnect the pump from the wound dressing. Remove the wound dressing only if its location will interfere with defibrillation.
- Remove the pump prior to diagnostic imaging e.g. X ray, CT and PET scanners. If the dressing may interfere with diagnostic imaging, it may also need to be removed prior to testing.

- The pump should be disconnected from the patient's dressing prior to entering an MRI scanner.
- The RENASYS® EDGE pump should be removed from the patient if it will interfere with the placement of monitoring equipment e.g. ECG probes.

Canisters

- The RENASYS® EDGE canister should not be used for any other purposes than those described in this user manual.
- Canisters are for single patient use. Do not reuse.
- Canisters should be changed at least once a week, whenever there is a change in patient or in the event that canister contents reach maximum volume indication (300ml or 800ml fill line). Do not wait for the Canister Full alarm to sound to change canister.
- Therapy should be paused when a canister is not fitted to the pump.

Ending Use

Disposal

- The pump should be returned to Smith+Nephew when no longer required by the facility. Smith+Nephew will dispose of the pump in accordance of the appropriate local regulations.
- The pump contains a lithium ion battery that is not serviceable by the user. Improper disposal of the lithium battery may result in fire, explosion and burns.
- Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100°C (212°F).
- Handle damaged or leaking batteries with caution to avoid injury.
- Used canisters should be disposed of as clinical waste.

Pump Description and Navigation

The RENASYS® EDGE pump is a reusable, multi-patient-use Negative Pressure Wound Therapy (NPWT) pump. The pump connects to RENASYS® Soft Port and RENASYS® dressing kits manufactured by Smith+Nephew. The

RENASYS® dressing kits create a closed wound environment allowing for the delivery of NPWT. The pump has a Bluetooth interface that allows connection to a smartphone or tablet device. The pump also contains a NFC Tag interface allowing the S+N URL to be transferred to a Smartphone to gain access to further pump information and help. The pump also detects canister presence and status through an internal near-field wireless connection.



Pump, power supply, canister and canister tubing are not sterile, dressings are delivered in sterile packaging.

The Pump, Canister and Tubing

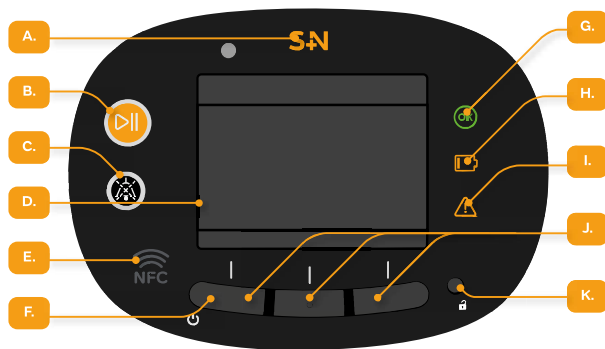
The pump is designed to provide NPWT to a closed environment over a wound, in order to remove exudate from the wound site to a disposable canister, which may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. The pump connects to a disposable canister which collects the exudate and keeps it away from the wound.

Dressings

The pump is only to be used with Smith+Nephew authorized components and dressing kits. Use of any other products has not been proven safe and effective with the RENASYS® EDGE pump. See dressing user manual and packaging for further information.

Wound dressings should only be changed by a clinician. Dressings should be changed in accordance with the dressing change frequency stated in the dressing's user manual and packaging.

Pump Description and Navigation



A. The Smith+Nephew logo will illuminate when the pump is plugged in to a mains power supply.

B. The Play/Pause button is located to the left of the therapy screen, this is used to Start and Pause therapy when required.

C. The Mute button can be used to mute some alarms when pressed.

D. The RENASYS[®] EDGE pump has a full-color therapy screen.

E. Place an NFC enabled phone over this area for a quick link to the manufacturer's website.

F. The left multifunction button is also the power button. The pump can be turned on and off by pressing and holding this multifunction button.

G. System OK Light indicates that therapy is On and everything is normal.

H. Battery Warning Light will indicate when the pump needs to be plugged in to a mains power supply.

I. Alarm/Alert Light will indicate when there is an alarm or alert state and attention is required.

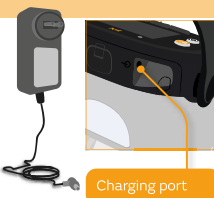
J. Three multifunction buttons are located underneath the screen. The function of these buttons vary and is displayed at the bottom of the screen.

K. The recessed Lock/Unlock button is located to the right of the multifunction buttons. This is used by clinicians to lock the appropriate therapy settings for the patient.

Accessories

Power Supply

The RENASYS[®] EDGE pump operates on AC mains power and includes an internal battery allowing the patient to be mobile. Using the external AC power supply, the pump can be plugged into an electrical (AC) outlet to charge the battery. Charging will not interrupt active therapy. When the pump is connected to a power supply the **SN** logo on the face of the pump will illuminate. The battery indicator on the screen will display a lightning bolt icon to indicate the battery is charging. The RENASYS[®] EDGE pump is designed to be used with RENASYS[®] EDGE power supply only. The RENASYS[®] EDGE power supply is not sterile.

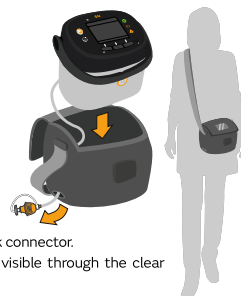


Charging port

Carry Bag

The carry bag is not sterile and for single patient use. Only use the Smith+Nephew carry bag with the pump. The bag will only accommodate a pump with the 300ml canister fitted. To place the pump into bag:

1. Disconnect the canister tubing at the quick click connector and place tethered caps over the tubing ends.
2. Unclick the flap at the front of the carry bag.
3. Feed the canister tubing through one of the slots in the base of the bag.
4. Keeping the pump in the upright position place the pump into the carry bag, then put the carry handle in the forward position.
5. Reconnect the canister tubing to the dressing quick click connector.
6. Ensure the status lights on the face of the pump are visible through the clear window in the flap.



Caution: It is recommended not to charge the pump while it is in the carry bag as this may result in elevated operating temperature, which may cause the pump to suspend charging until it cools. The pump will still continue to operate. To reduce the operating temperature of the pump, remove it from the carry bag or move it into an environment with a lower ambient temperature. When the pump cools, charging will resume automatically.

Carry Strap

The carry strap is not sterile and for single patient use.

To attach the carry strap to the pump:

1. Slide the carry strap ends from below over the handle pivots at each side.
2. Pull up on the strap to secure in place.



Tubing Clip

The canister also comes with a tubing clip to assist with storage of excess tubing.



Caution: Ensure the pump always remains in the upright position when using the carry straps.

Pump Setup

Canister Selection

Only use Smith-Nephew RENASYS® EDGE canisters with the RENASYS® EDGE pump. RENASYS® EDGE canisters use an integral bacterial filter for protection of the pump against overflow and the spread of aspirated micro-organisms.

DO NOT REUSE CANISTERS. Canisters are designed for single patient use. Use of the canisters on more than one patient may result in cross contamination that could lead to infection.

Canisters should be changed at least once a week, whenever there is a change of patient, or when the contents reach the maximum volume indication (300ml or 800ml fluid volume lines) in

the viewing window. Check canisters regularly to monitor exudate levels, ensuring they are below the canister maximum volume indication. The canister should not be used independently of other means to monitor fluid

Do not wait for the Canister Full alarm to sound to change canister.

Canisters are available in two sizes; 300ml and 800ml. For patients with high risk of bleeding, use the 300ml canister. Canisters may have to be changed more regularly within single patient treatments if exudate levels are high.

Canisters are not sterile and should not be used in a sterile field.

Caution: Position pump, tubing and cables appropriately so that they do not wrap around the patient's neck or limb or cause a trip hazard.

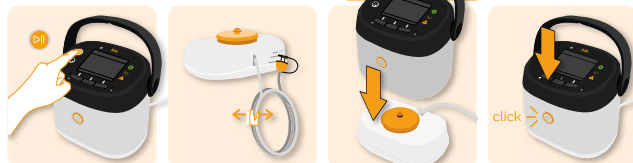
Caution: Do not use the pump without a canister fitted.

Caution: Monitor the canister and tubing for signs of bleeding or infection during use.

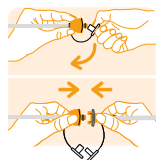
Fluid volume lines



Installing a New Canister



1. Ensure therapy is paused or the pump is Off.
2. Remove the paper tape around the canister tubing and release tubing to full length.
3. Position the canister so that the tubing is facing to the rear of the pump then align the pump over the canister.
4. Push down on the pump until you hear a click from the release button.



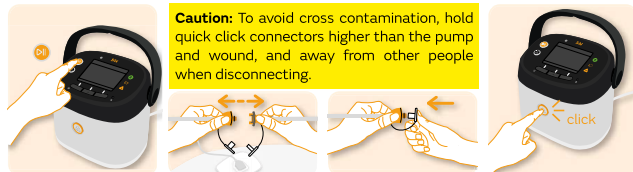
5. Remove the caps from both quick click connectors and push them together until they click.



6. Start therapy by pressing the release button.

Pump Setup

Removing/Changing a Canister



1. If the device is on and therapy is being delivered, pause it by pressing the pause button.
2. Holding the quick click connectors higher than the wound and pump, disconnect the canister tubing from the dressing tubing by squeezing the canister quick click connectors and gently pull the connectors apart.
3. Attach the tethered click caps to both quick click connectors to protect the tubing and prevent leakage.
4. Press the release button, the button will click and the canister will come loose. Pull pump away from canister. To install a new canister see steps above. Once installed press the play button to restart therapy.

Check the new canister for any signs of cracks or damage. If noted, discard and replace the canister.

Change or replace the canister if dropped or mishandled, even if no visible signs of damage are present, to ensure correct operation of software alarms for leak and blockage.

Canister Disposal

Ensure the quick click connector on the removed canister is capped before disposal. Disposal of used canisters should follow facility protocols or local regulations relating to handling of potentially infected or bio-hazardous materials.

Pump Orientation

The pump is designed to operate in the upright position. Operation in the upright position optimizes canister volume and alarm functionality. The pump should be orientated to face the users when in stationary use.

Caution: Operating the pump when not in an upright position may cause a blockage alarm and may require a canister change.





Correct orientation

Incorrect orientation

Pump Setup

Turning On/Off the Pump

- Ensure the battery is fully charged if battery operation is required for first use of the pump.
- **Press and hold** the left multifunction button  for 2 seconds to switch On the pump.
- To switch Off the pump press and hold the left multifunction button  until the screen asks 'Are you sure you want to power down the pump?'. Press the **Yes** button if you would like to turn Off the pump.
- On first time start up you will be prompted to set a language and the date. Please follow the on screen instructions and set the appropriate language and date. After this has been set, subsequent use of the device will offer the user a brief RENASYS® EDGE pump tutorial screen.

To switch On or Off, press and hold the left multifunction button .

When the pump is due a self-test, a self-test notification will display when powering On the pump. To close this notification and continue to the therapy screen, press the **No** button.

Setting Therapy

The treating clinician will prescribe the therapy setting based on an assessment of the individual wound. These general guidelines should be adhered to:

- 40–125 mmHg is the recommended therapeutic pressure range.
- If the patient reports discomfort, consider reducing the pressure setting.
- Outside the recommended optimal

therapeutic pressure range of 40–125 mmHg, the broader operating range of 25–200 mmHg is provided to support clinical discretion on target pressure.



The pump will display the target pressure on the therapy screen.

Before starting therapy, check that the prescribed therapy settings have been properly set.

Caution: When pump is set at 25 mmHg consider placing pump and tubing level with or below the wound. This will ensure the prescribed level of therapy is delivered.

Lock/Unlock Feature

The lock/unlock feature is used by clinicians to lock the appropriate therapy settings to ensure patient safety.

- To Lock/Unlock therapy press and hold the recessed Lock button  to the bottom right of the screen using a small blunt tool (e.g. pen) until the Locked/Unlocked screen is displayed. When locked a  icon will show in the top right of the screen.




- Locking therapy will prevent the patient from changing the pump therapy settings. When the pump is locked, the following settings cannot be used or changed: Intermittent/Continuous Mode, Y-Connector and Service Mode. All other functions are available.

The pump will lock after 2 minutes of therapy.





Pump Setup



Starting Therapy

Press the Play/Pause Therapy button  to start therapy. As the pump begins delivering therapy, it will display pump down progress and perform a leak check to determine if the dressing, canister and tubing is sealed. If a significant leak is detected in the dressing, canister or tubing, the pump will indicate a leak alarm. See **Alarms and Alerts** and **Troubleshooting** section for more details.

The compression rate is set at medium as a default but can be increased or decreased by pressing the **slower** or **faster** buttons. If the patient experiences pain, a slower pump down is advised.

When the pump is working correctly  will appear in the top left of the screen. When therapy is active and the pump is operating correctly a green swoosh will display below the target pressure setting. When the screen is in Power Saving Mode, System OK Light  will also appear on the face of the pump.

Pause Therapy

- Therapy can be paused by pressing the Play/Pause Therapy button .
- When paused  will show in the top left of the screen.




During Use

When the device is in use, always ensure the pump is positioned on a table or hung on an IV pole using the carry handle or strap of the RENASYS® EDGE pump.






Changing Basic Settings





To access the settings menu

- From the therapy screen, press the **Menu** button, scroll down using the  button to highlight **Settings**. Press the **Select** button to enter Settings.
- Scroll using the  and  buttons. Highlight the required settings then press the **Edit** or **Change** button.

To change the Date

- Use the  button to set the month. Use the  and  buttons to set the date and year. When the correct month date and year have been chosen press the **OK** button.

To change the Time

- Press the **Change** button to choose between **24hr** clock and **AM/PM** then press the **OK** button.
- Use the  and  buttons to set the hours and minutes.
- If using **AM/PM** use the  and  buttons to choose am or pm.
- When the correct time has been chosen press the **OK** button.

To change the Alarm Volume

- Press the **Change** button to choose between **Low**, **Med** (medium) and **High**. The pump will issue a sample tone as you make your selection.


To change the Brightness

- Press the **Change** button to choose between **Auto**, **Low**, **Med** (medium) and **High**.

To turn Bluetooth On or Off

- Press the **Change** button to toggle Bluetooth On or Off.
- When the Bluetooth is turned On a Bluetooth symbol  will display on the Status Indicator Bar.

To change the pump Language

- Scroll using the  button to highlight the appropriate language then press the **Select** button.