Pump Setup

Set Y-Connector

Toggling Y-Connector On or Off is unavailable when therapy is locked.

Ensure the Y-Connector Mode is On if:

- There are two dressings connected to the pump.

Setting Y-Connector On when only one dressing is connected to the pump may cause nuisance alarms.

Ensure the Y-Connector Mode is Off if:

- There is one dressing connected to the pump.

Setting Y-Connect Off when two dressings are connected to the pump may prevent the blockage alarm from sounding.

Caution: The pump will only detect a blockage if both connections are blocked and will not detect a blockage existing in only one of the Y-connected dressings. Therapy will not be delivered through the blocked dressing. Regularly monitor the patient during therapy to ensure both dressings are compressed.

To change Y-Connector settings

- If therapy is being delivered, pause therapy by pressing .
- Press the Menu button, scroll down using the button to highlight Y-Connector then press the Change button to toggle the Y-Connector On or Off.
- The Y-Connector icon will appear on the therapy screen if On has been selected.

Information on Continuous and Intermittent Modes

The pump features two therapy modes: Continuous and Intermittent.

Continuous Therapy Mode

In continuous mode, the pump will maintain the selected therapy level until therapy is stopped or changed. The target pressure is displayed in the center of the therapy screen. Therapy levels can be selected from a range of 25–200 mmHg by pressing the + or - buttons.

To turn Continuous Therapy Mode On

- If intermittent therapy is being delivered, pause therapy by pressing .
- Press the Menu button, highlight Intermittent Mode press Change to turn Intermittent Mode Off.
- A pop-up will show displaying 'The pump will apply continuous pressure', press Continue.
- Press Home, then press to start therapy.
- The continuous icon will appear on the therapy screen.

Intermittent Therapy Mode

In intermittent therapy mode the pump will alternate between two target pressure levels at a set cycle time.

To turn Intermittent Therapy Mode On

- If continuous therapy is being delivered, pause therapy by pressing .
- Press the Menu button, highlight Intermittent Mode press Change to turn Intermittent Mode On.
- To change the intermittent mode settings press Edit.
- Use the , and OK buttons to set the desired intermittent mode settings.
- Review the settings on screen. Press Continue to begin therapy or Edit to change the settings.
- The intermittent icon will appear on the therapy screen.

The compression rate cannot be altered in intermittent mode. Adjustments can not be made to intermittent mode when therapy is locked.

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During Therapy

During treatment, you can access Tutorials, Activity Logs, System Info or Settings from the therapy screen by pressing the Menu button. Scroll down using the button to highlight your chosen item then press the Select button.

Tutorials

The RENASYS® EDGE pump contains tutorials that provide guidance on many of the pump features. A list of available tutorials will show when Tutorials is selected.

- Scroll through the list using the button, highlight the tutorial you would like to watch then press the Select button.

Activity Logs

Activity Logs display the pump activity since it was last reset. The pump is reset when the Restore Defaults option is selected, which can be found in Service Mode.

- Select Activity Logs to see the Activity Summary over the last four days.

- To scroll through the individual activity summaries of each day press the Next button.
- To view a more detailed list of the activity logs press the Logs button.

System Information

System Info displays a list of information, which includes; the date of the last self-test, the serial number, the software version, the operational time, the pump health the battery health, regulatory information and patent information.

To scroll through this information press the Back and Previous buttons.

Power Saving Mode

The RENASYS® EDGE pump will enter power saving mode after 120 seconds of inactivity. The screen display will turn off to conserve battery life. Press any multifunction button to wake the display.

PICO Transition

When the RENASYS® EDGE pump detects that the canister was changed without filling up to its capacity, the pump may provide a recommendation for the clinician to either:

- Consider changing the canister less frequently, or
- Transfer the patient to PICO Single-Use Negative Pressure Wound Therapy (NPWT), if clinically appropriate

Preparing For a Shower

The pump and power supply operate electrically and must not come into contact with water. When showering ensure that the pump is paused and disconnected from the patient's dressing(s).

1. Pause therapy by pressing .
2. Hold the tubing higher than the wound then disconnect the canister tubing from the dressing tubing by squeezing the canister quick click connectors and gently pull the connectors apart.
3. Close the tethered caps over both quick click connectors to protect both sides of tubing and prevent leakage.

Caution: When bathing or showering the patient, you must disconnect the pump and protect both ends of tubing using the tethered caps.

Service and Maintenance

Service Mode

Service Mode has several options to aid the user when servicing or resetting the pump for use. These include:

- View Service Guide
- Perform Self-Test
- Restore Defaults
- View Error Logs

Scroll down using the ✓ button, highlight the option you want then press the Select button.

Service mode is unavailable when therapy is locked.

Restore Defaults should be selected whenever the pump is being prepared for use with a new patient.

- Scroll down using the ✓ button, highlight the Restore Defaults then press the Select button
- Press Confirm to restore the pump to the factory presets listed in the following table:

All log information	Deleted
Continuous Therapy	125 mmHg
Intermittent Therapy	125 mmHg for 5 minutes, 25 mmHg for 2 minutes
Y- Connector	Off
Alarm Volume	High
Display Brightness	Auto

- Press Cancel to maintain the current settings.

Caution: Never attempt to service the pump while connected to the patient.

Do not attempt to dismantle or modify the pump or any accessories. No maintenance can be performed by patients or caregivers.

Pump Service Life

The expected life of the RENASYS® EDGE pump is 5 years. If the pump gives a warning that a component has failed at any point the pump must be returned to Smith+Nephew.

Self-Test

The pump has a self-test function that provides information on the pump's health. The self-test function allows users to perform self-checks and will report a failure if a technical fault is detected.

A self test is due after two weeks without use, or every six months during use. If a self test is due, a notification will display every time the pump is powered on.

- It is advised that clinicians carry out the self-test when prompted on start-up. Patients are advised to press No when prompted, skip the self-test and inform their clinician that a self-test is due.

Please follow the instructions on the screen to carry out the self-test. If the self-test is carried out and completed with no errors, the user can continue to use the pump. If the self-test has failed, please contact a Smith+Nephew representative.

A self test cannot be performed when therapy is active or the device is locked. To initiate a self test without a prompt, pause therapy and ensure the device is unlocked (Use a small blunt tool to press the recessed lock/unlock button to unlock the device). Use the on screen menu to select service mode, then choose self test.

Caution: Do not operate the pump self-test feature in a dusty environment as it may damage the pump

Returning the Pump

Prior to returning the pump and power supply to your Smith+Nephew authorized representative, the pump and power supply must be cleaned according to the steps outlined under the **Cleaning** section of this user manual.

The pump and power supply should be returned within the original shipping carton or transit case. If returning the pump and power supply in a transit case, place the pump into the molded insert and place the power supply in the compartment as shown on the inside label.

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Service and Maintenance

Caution: There are no repairable parts inside the pump. Do not attempt to open the pump. Contact your Smith+Nephew representative, distributor or authorized provider if repair is required. No modification of this equipment is allowed.

Battery Operation and Charging

To allow the user greater mobility, the pump contains a lithium ion rechargeable battery. A fully charged battery will last for up to 12 hours.

If battery operation is required for first use of the pump, the battery requires a full charge. The battery must be charged with the power supply until the battery indicator is full.

To charge the battery

1. Connect the power supply into the charging outlet on the pump.
2. Plug the power supply into an electrical (AC) outlet.
3. Confirm that the S:N logo on the face of the pump is illuminating.

When the pump is fully charged and powered On 🔋 will show in the top right of the screen. The pump will indicate when the battery is low. A low battery will first give an alert. A critically low battery will sound an alarm and the Battery Warning Light 🪫 will illuminate. Plug the pump into an electrical (AC) outlet as soon as possible when a battery alarm occurs.

The battery can be charged both during pump operation without interrupting therapy and when pump is turned Off and not in use. It is recommended to keep the pump plugged in during use when the patient is not mobile. If the pump is fully charged and is not going to be used further, disconnect the power supply from the pump and electrical outlet.

If the S:N logo is not illuminated when the pump is connected to mains power, contact your Smith+Nephew representative to replace the pump.

Operation and Storage Conditions

The RENASYS® EDGE system and components should be kept within the environmental limits listed below.

Short Term Storage and Transport Temperature	-13°F to 158°F / -25°C to 70°C
Long Term Storage	41°F to 104°F / 5°C to 40°C
Operating Temperature	41°F to 104°F / 5°C to 40°C
Relative Humidity	15% to 93% RH
Atmospheric Pressure	700 mbar to 1,060 mbar

Some battery discharge may occur in storage, especially at high temperatures. It is recommended that the unit is charged before storing. If the pump is stored for longer than 6 months, the battery should be charged before use.

If the pump indicates that the battery is not fully charged after more than 4 hours of continuous charge, contact your Smith+Nephew representative or authorized provider.

Caution: If the pump has been stored at temperatures below freezing, it must be brought to room temperature prior to use or the pump may be damaged.

Between Patients

When the RENASYS® EDGE pump is prepared for a new patient the following maintenance activities must be performed:

- Cleaning,
- Disinfecting,
- Restore defaults settings (See **Service Mode** Section).

Cleaning

Caution: Do not use solvents or abrasives that will degrade plastic housing and rubberized push buttons or the screen.

Caution: Do not immerse/submerge any part of the pump in fluid or use an excessively wet cloth. No fluids should be allowed to enter the pump. If any liquids penetrate the pump, contact your local distributor.

Caution: If the device is damaged in any way, it must be returned to Smith+Nephew.

Cleaning the RENASYS° EDGE Pump

Cleaning of the power supply and outer casing should be performed to remove any soil or debris whenever there is a change in patient in the following steps:

1. Turn Off the pump and disconnect from the AC power before cleaning and disinfecting to prevent electrical shock.
2. Wipe down the surface with a dampened cloth or disposable wipe. Warm soapy water or a neutral pH7 based detergent/ disinfectant or antimicrobial agent that is safe for use with plastics may be used.
3. Visually inspect the surface for debris or soils that have not been removed and repeat cleaning steps if necessary.

During use it is recommended that the surface of the pump be cleaned as soon as it is soiled, using a damp cloth or disposable wipe and then wiped dry with another cloth or disposable wipe. Always follow facility protocols or local regulations for cleaning and handling of potentially infected or bio-hazardous materials.

Cleaning the Carry Bag

Carry bags are for single patient use and should be discarded when the patient ends the treatment with RENASYS° EDGE system.

Carry bags may be cleaned during the patient's treatment as follows:

1. Wipe clean using a soft cloth dampened with a warm water and mild soap solution. A soft brush may be used if necessary.
2. Wait one minute before wiping clean with a soft cloth dampened with water only.

Disinfecting the Pump

1. After cleaning, the RENASYS° EDGE pump may be disinfected using these recommended solutions:

- Diluted solution of 100ml (chlorine) bleach and 1l of warm water.
- Disposable wipes moistened with 70% Isopropyl Alcohol (70%IPA).
- Intermediate disinfectant agents (such as Sporicidin®, Disinfectant) that are safe for use on plastic may be used. Follow manufacturer's instructions carefully.

2. Following disinfection, wipe down the pump with a damp cloth to remove residual chemical residues.

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Alarms and Alerts

The RENASYS° EDGE pump is equipped with alarms and alerts to indicate an error which requires user intervention. In the event of an alarm or an alert, an audible tone will sound, an alarm/alert screen will display and the Alarm/Alert light ⚠ will illuminate.

Information on Alarms

If an alarm occurs a hazard exists that needs to be attended to immediately to prevent therapy becoming compromised. If an alarm occurs the pump will sound every 20 seconds until resolved. In some cases the pump may temporarily stop delivering therapy until the issue has been resolved.

Information on Alerts

An alert warns the pump user that there is a potential problem about to occur. If an alert occurs the pump will sound every 20 minutes until the issue is resolved. Alerts can be dismissed, however this will remove the alert screen but will not resolve the issue.

Some alarms allow the audible alarm to be muted for 15 minutes by pressing the mute button 🔇. If the cause of the alarm is not resolved within this time the audible alarm will recommence. If the audible alarm has been muted and a new alarm state occurs, the audible alarm sounds, and the screen will display the new alarm. When multiple alarm states are present, pressing next will alternate between alarm screens.

Caution: Alarms are not intended to replace physical inspection and monitoring of the pump, canister and tubing by clinicians. There are scenarios that may occur during therapy that can impact alarm functionality. Therefore, it is important that the patient, pump and wound dressing are monitored regularly to ensure therapy is being delivered.

- When the Y-Connector is connected to two dressings and the Y-Connector mode is on, the pump will only detect a blockage if both connections are blocked. The pump will not detect a blockage existing in only one of the Y-connected dressings; meaning that therapy will not be delivered through the blocked dressings. Regularly monitor the patient to ensure both dressings are compressed during therapy (See the **Set Y-Connector** section for more information).
- The blockage alarm will occur when the pump detects a blockage between the canister and where the dressing tubing interfaces with the transparent film. The blockage alarm will not assert if the RENASYS° soft port opening is not aligned with the dressing opening, or a blockage occurs within the wound dressing. Regularly check the dressing and tubing to ensure exudate is being gathered into the canister.
- If a blockage is present in the system and an air leak occurs between the blockage and the pump the alarm may not assert. Ensure that all connections are secure and there are no air leaks present. Potential sources of air leaks include:
  - Cracked or damaged canister.
  - Misplaced o-ring within the quick click connector or canister outlet.
  - Damaged or tear in the dressing tubing or quick click connector.

Regularly check that the dressing still has compression.