# SmithNephew RENASYS<sup>\*</sup> EDGE

Negative Pressure Wound Therapy

# Home Healthcare User Manual

RENASYS<sup>°</sup> EDGE device 66803126 only

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# Welcome to your RENASYS° EDGE pump Home Healthcare User Manual

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# Introduction

This RENASYS° EDGE Home Healthcare User Manual will give you important information about the Smith+Nephew RENASYS° EDGE Negative Pressure Wound Therapy (NPWT) System.

This pump and canister is given to you by a clinician. This Home Healthcare User Manual will help you operate and look after the pump. The pump and its accessories must be used following the instructions included in this Home Healthcare User Manual.

The RENASYS° EDGE pump should only be used with Smith+Nephew RENASYS° products.



# What is RENASYS° EDGE NPWT?

RENASYS<sup>6</sup> EDGE is a therapy system that is placed on your wound. The pump, canister and tubing may help promote wound healing by removing wound exudate (wound fluid) and infectious materials. This type of therapy for wound management is widely used in both hospitals and at home.

# How does it work?

The RENASYS° EDGE system consists of a pump, 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 pump through tubing and a canister. The pump then reduces air pressure at the wound and draws fluid from the wound into the canister. The clear film helps to prevent bacteria from entering the dressing.

The RENASYS° EDGE pump is electrical (Class II) and can be plugged into an electrical outlet. The pump is an internally powered device and can operate on its internal battery for up to 24 hours. This allows you to move around while receiving treatment from the pump.

## 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.

# Introduction

# How often will the dressings be changed?

Your clinician will determine how often your dressings need to be changed. Dressings will usually be changed 2–3 times a week. In some cases the dressings may be changed more often. This will depend on your wound's size, type, position and drainage amount. All dressing changes must be performed by a trained clinician.

# Will it be painful?

When therapy is turned on and the dressing draws down on the wound, you may experience a pulling feeling. The level of discomfort may vary between patients, please contact your clinician if you have concern.

Some people may experience discomfort during dressing change. Specifically during the cleaning of the wound. If you feel any discomfort, contact your clinician.

# Can you move around during therapy?

Usually, patients using the therapy can move around. This will depend on the position of your wound and if your clinician thinks this is suitable for you. If you can move around, the pump can be unplugged from the mains power. The pump can operate on a full battery for up to 24 hours.

# 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 require. Discuss this with your clinician for more information.

# Topics to discuss with your clinician

To avoid the risk of misuse, your clinician may deem it appropriate to train you on some of the topics included in this manual, including:

- Pump Description and Navigation
- Introduction
- Warnings + Precautions

- During Therapy
- Alarms, Alerts and Troubleshooting
- Accessories

Pump Setup

# What can the pump be used for

# Indications for use

The RENASYS<sup>o</sup> EDGE pump is indicated for patients who would benefit from a suction pump (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

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

# What the pump should not be used for

# Contraindications

Please note, the RENASYS<sup>6</sup> EDGE pump should not be used on people with:

- Untreated osteomyelitis
- Exposed arteries, veins, organs or nerves

Malignancy in wound (with enhance quality of life)

- Necrotic tissue with eschar present
- Exposed anastomotic site

# 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, or
  - you experience an increase in pain.

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- exception of palliative care to
- Non-enteric and unexplored fistulas

# Warnings and Precautions (cont.)

• 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<sup>6</sup> 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

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# Warnings and Precautions (cont.)

the pump. Use of any other products has not been proven safe and effective with the RENASYS  $\pm$  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, or
  - 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. EN ES FR PT

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# **Pump Description and Navigation**

## The System

The pump is designed to provide negative pressure wound therapy to a closed environment over a wound, in order to remove exudate (wound fluid) 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.



**Caution:** Wound dressings should only be changed by a clinician.

**Caution:** 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.

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

Information on additional accessories can be found in the **Accessories** section of this manual.



# **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. This button will illuminate when therapy is ready to be started.

**C**. When illuminated, the **Mute button** can be used to mute an alarm or alert.

**D.** The RENASYS<sup>o</sup> EDGE pump has a **full-color therapy screen**.

**E.** Place a near-field communication (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 button. **G. System OK Light** shows that therapy is On and everything is normal.

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

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

J. Three multifunction buttons can be found underneath the screen. The functions of the multifunction buttons vary and are displayed at the bottom of the screen.

K. The recessed Lock/Unlock button can be found to the right of the multifunction buttons. This is used by clinicians only. EN ES FR PT

#### Accessories

## **Power Supply**

The RENASYS° EDGE pump can be plugged into an electrical (AC) outlet to charge the battery. The pump also includes an internal battery which means you can be mobile for up to 24 hours on a full charge. More information about charging can be found in the **Pump Setup** section.

#### **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 300 ml 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. Unclip the flap at the front of the carry bag.
- 3. Feed the canister tubing though 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:** Ensure the pump remains in the upright position while using the carry bag.

**Caution:** It is recommended not to charge the pump while it is in the carry bag as this may heat up the pump and cause the pump to stop charging. The pump will continue to operate. Remove the pump from the carry bag or move it into a cooler environment to help cool it down. The battery will start charging again when the pump cools.

#### **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.

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





# **Pump Setup**

This section includes information about setting up the pump, changing settings and starting/restarting therapy.

Your clinician will set the pump therapy settings depending on your therapy needs. The clinician will use their Clinician User Manual to set your therapy. Your clinician will tell you how often to use the pump and when to contact them.

## What the Pump Looks Like When Running Correctly

When the pump is working correctly, the 🛞 symbol will display at the top of the pump therapy screen. The System OK Light of will also display on the face of the pump.

The Alarm/Alert Light / will display on the face of the pump and the therapy screen will show a status icon if a problem needs your attention. See the Troubleshooting and Icons and Symbols Glossary sections for more information. After 120 seconds of inactivity the screen will switch off to save power (see Power Saving Mode and Waking the Display section).

## Canisters

Only use Smith+Nephew RENASYS<sup>o</sup> EDGE canisters with the RENASYS<sup>o</sup> EDGE pump. Canisters are not sterile.

Canisters should be changed at least once a week, or when the contents reach the maximum fluid volume lines (300 ml or 800 ml fluid volume lines). Check canisters regularly to watch fluid levels, to make sure they are below the canisters maximum fluid volume level.

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

Caution: Make sure you position the pump, tubing and cables appropriately so that they do not wrap around your neck or limbs or cause a trip hazard.

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

Caution: If you see blood within the canister, stop therapy and contact a clinician immediately.



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# Pump Setup (cont.)

# **Pump Orientation**

The pump should be placed the correct way up (see below) on a hard, flat surface while delivering therapy.



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

# **Battery Operation and Charging**

The pump can be plugged into an electrical outlet while therapy is on. The RENASYS<sup>°</sup> EDGE pump is designed to be used with the RENASYS<sup>°</sup> EDGE power supply only.

**Caution:** The power supply may become warm while charging the pump. Do not position the power supply close to your body or under blankets or clothing while charging.

## Caution: Keep pump away from direct heat sources during charging.

The pump has a battery indicator in the top right corner of the screen. When the pump is turned On and plugged in to charge, a lightning bolt **(F)** will display in the battery indicator. If the Battery Warning Light **()** on the righthand side of the screen lights up or a battery alarm occurs, plug the pump into an electrical outlet to avoid the pump turning Off during therapy.

## To charge the battery

- 1. Connect the power supply into the charging port on the pump.
- 2. Plug the power supply into an electrical (AC) outlet.
- 3. Confirm that the battery charging lightning bolt symbol **I** is present at the top of the screen.

On a full charge the internal battery can run for up to 24 hours. It takes 4 hours to fully charge the internal battery.

If the **SN** logo is not illuminated when the pump is connected to mains power, contact your clinician to replace the pump.



## Turning the Pump On or Off

- 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.
- When starting up the pump for the first time, you will be asked to adjust a couple of settings. Follow the instructions on the screen.
- After the settings have been adjusted, during future start ups you will be taken to an optional welcome tutorial.
- If the pump shows a self-test notification, please refer to the **Self-Test** section in this manual.
- To switch Off the pump press and hold the left multifunction button U 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.

#### Power Saving Mode and Waking the Display

The RENASYS<sup>°</sup> 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.

While in power saving mode, the system OK light will display on the face of the pump when the pump is running correctly. The alarm/alert light will display on the face of the pump if a problem needs attention.



# Setting Therapy

Your clinician will select the appropriate pressure.

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

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



#### Starting/Restarting Therapy

Press the Play/Pause therapy button 🕺 to start therapy.

As the pump begins delivering therapy. It will display the pump down progress and run a leak check to make sure the pump, canister and tubing is sealed. If a leak is found in the pump, canister and tubing the pump will show a leak alarm. See the **Alarms/Alert** and **Troubleshooting** sections for more information.

The compression rate is set at medium as a default. This can be made faster or slower by pressing the **slower** or **faster** buttons. Get advice from your clinician on when it's appropriate to change the compression rate.

When the pump is working correctly a 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, the system OK light will also appear on the face of the pump. The screen will turn off after 2 minutes to save power, to wake it, press any of the three multifunction buttons.

#### **Pausing Therapy**

- Therapy can be paused by pressing the Play/Pause therapy button
- When paused (11) will show in the top left of the screen.
- If the pump is left paused for 30 minutes, it will produce a Therapy paused too long alert
- If the pump is left paused for 60 minutes, it will automatically restart therapy



# Lock/Unlock Feature

The lock/unlock feature is used by clinicians to lock the correct therapy settings to make sure patients are safe. The pump will lock after 2 minutes of stable therapy.

When the pump is locked some functions will not be available.

# **Changing 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 
   ✓ button. 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 are displayed press the ok button.

# To change the Time

- Press the Change button to choose between 24hr clock or 12 hour clock with AM/PM then press the OK button.
- Use the  $\blacksquare$  and  $\blacksquare$  buttons to set the hours and minutes.
- If using AM/PM use the And A 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 turn the 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.

#### **Continuous and Intermittent Modes**

The pump features two therapy modes: Continuous and Intermittent. This will be set by your clinician. In continuous mode, the pump will deliver therapy constantly. In intermittent mode the pump will alternate between two target pressure levels at a set cycle time.

Adjustments cannot be made to therapy when the pump is locked.

#### Treatment of two wounds with a RENASYS° Y-Connector

If there are two dressings connected to the pump, your clinician will have set the Y-Connector mode to on and this icon 🕎 will display on the therapy screen. If you only have one dressing connected to the pump and can see the icon please contact your clinician.

Changing Y-Connector on or off is unavailable when therapy is locked

**Caution:** When using a Y-Connector, the pump will only find a blockage if both connections are blocked.

# **Changing Canister**

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. If you need to change your canister follow the instructions below.

## **Removing a Canister**



Wash your hands before and after this procedure, and before and after disconnecting the tubing.



Pause therapy if it is being delivered by pressing <sup>(1)</sup>.

**Caution:** When disconnecting the tubing, make sure you are away from other people to limit the risk of contamination. Hold the quick click connectors above the level of the wound to make sure exudate (wound fluid) does not leak from the tubing.



To disconnect the canister tubing from the dressing tubing, squeeze the canister quick click connectors and gently pull the connectors apart.

# Changing Canister (cont.)



Attach the tethered caps to both quick click connectors to protect the tubing and prevent leakage.



Press the release button. The button will click and the canister will come loose.



Pull the pump away from the canister.

#### **Canister Disposal**

Disposal of used canisters should follow facility protocols or local guidance relating to handling of potentially infected or bio-hazardous materials.

**Caution:** If you see blood within the canister, stop therapy and contact a clinician immediately.

#### **Inserting a New Canister**



Remove the paper tape from around the canister tubing. Open the tubing to its full length.



Position the canister so that the tubing is at the rear of the pump. Position the pump over the canister making sure that the canister and pump line up.



Push the pump down onto the canister until you hear a click from the release button.

Change or replace canisters that have been dropped, mishandled or appear cracked or damaged even if no visible signs of damage are present. This ensures the correct operation of software alarms for leaks and blockages.



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



Start therapy by pressing 🔟.

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# Showering

The pump and power supply operate electrically and must not come into contact with water. When showering you will need to disconnect the pump from your wound dressing.

The clear film placed on top of your wound and dressing tubing are water resistant. You may be able to shower or wash with the dressings in place, as long as you do not soak them. Please consult your clinician for guidance.

## **Preparing for a Shower**



Wash your hands before and after this procedure, and before and after disconnecting the tubing.



Pause therapy if it is being delivered by pressing <sup>(1)</sup>.

**Caution:** When disconnecting the tubing, make sure you are away from other people to limit the risk of contamination. Hold the quick click connectors above the level of the wound to make sure exudate (wound fluid) does not leak from the tubing.



To disconnect the canister tubing from the dressing tubing, squeeze the canister quick click connectors and gently pull the connectors apart.



Attach the tethered caps to both quick click connectors to protect the tubing and prevent leakage.

## **During Showering**

Once disconnected, keep the RENASYS<sup>°</sup> EDGE pump in a dry place while you shower.

**Caution:** Do not take electrical parts of the pump into the shower.

# After Showering



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



Start therapy by pressing 🔊.

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# **During Therapy**

Below are some key things to look out for during use of the pump.

## The amount of fluid in the canister.

The canister should be changed when the contents reach the maximum fluid volume line. The pump will show a canister full alarm when the canister is full (see the **Alarms and Alerts** and **Troubleshooting** sections). If it appears full, do not wait for the alarm to change the canister. A completely full canister may also cause a blockage alarm.

## Blood in the canister or tubing

Monitor the canister, tubing and dressing for the presence of blood. If you notice blood contact your clinician immediately.

## The dressing

The dressing should have a wrinkled appearance and be firm to the touch. If the dressing is not compressed, press down around the edges of the transparent film. If the dressing compresses you have sealed the dressing. If the dressing remains

#### System OK Lights to the right of the screen.

- 🕟 If you see this lit, therapy is On and everything is normal.
- / If you see this lit, there is an alarm/alert state and attention is required.
- If you see this lit, the pump needs to be plugged in to a mains power supply.

If no LEDs are showing the pump may be turned Off or need to be charged.

## The battery indicators.

If any of the following happens, plug the pump into a mains power supply.

- The battery indicator turns orange in the status indicator bar,
- A battery alarm/alert shows on the therapy screen,
- The battery warning light illuminates

## Any alarms/alerts that may be displayed on the screen.

In the event of an alarm or alert. An audible tone will sound, the alarm/alert light will show and an alarm/alert screen will show on screen. For more information read the Alarms and Alerts or Troubleshooting sections. EN ES FR PT

# During Therapy (cont.)

During treatment you can view Tutorials, Activity Logs, System Info or Settings. From the therapy screen press the Menu button. Scroll down with the Methods button to highlight your chosen item. Then press the Select button.

## Tutorials

The RENASYS<sup>°</sup> EDGE pump has tutorials that give information on many of the pump features. A list of available tutorials will show when Tutorials is selected.

Scroll through the list with the 
 button. Highlight the tutorial you would
 like to watch. Then press the 
 Select button.

# Activity Logs

Activity Logs display the total pump activity since reset and provides information on the therapy that has been delivered.

- Scroll through different activity summaries by pressing the **Next** button.
- To view a detailed list of activity settings and alarms press the **Logs** button.



## System Information

System Info displays a list of information about the pump. Including the date of the last self-test, serial number, software versions, operational time, pump health, battery health, regulatory information and patent information. To scroll through this information press the **Next** and **Back** buttons.

#### Service Mode

Service Mode is for clinician and biomedical engineer use only.

This feature is unavailable when therapy is locked.

# **Cleaning and Maintenance**

#### Cleaning

As you use the RENASYS<sup>o</sup> EDGE pump and accessories, your clinician should clean it on a regular basis to ensure good hygiene.

Make sure to turn off the pump and unplug before cleaning.

The pump may be wiped clean with a cloth dampened either with warm soapy water or a diluted bleach solution (100 mL bleach: 1 L warm water). Wipe the pump again with a damp cloth using clean water. Dry the pump with a clean cloth to ensure the pump does not remain wet.

The carry bag and straps can be cleaned using a soft cloth dampened with a warm water and mild soap solution. A soft brush may be used if necessary. Wait one minute before wiping clean with a soft cloth dampened with water only.

#### Maintenance

Your clinician will ensure the pump has been properly maintained prior to your use. The carry bag and straps are single patient use and should be provided new in the manufacturer's packaging. Your pump should last the duration of your therapy. If a replacement is needed, your clinician will provide the items needed.

# **Operation and Storage Conditions**

The RENASYS<sup>°</sup> EDGE system and components should be kept within the environmental limits listed below.

Operating Conditions		
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	
Storage Conditions		
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	

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# **Cleaning and Maintenance**

#### Self-Test

When the pump is due a self-test, a self-test notification will display every time the pump is powered on. The pump will ask 'Would you like to run a self test?'. Press No and contact your clinician that a self test is required on your pump. The pump can still be used to perform therapy.

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

# **Alarms and Alerts**

The RENASYS $^{\circ}$  EDGE pump has alarms and alerts to show if a problem needs user intervention. If the alarm does not stop, contact your clinician to inform them of the alarm or alert condition.

## If an alarm occurs:

A problem exists that needs to be attended to straight away. The problem may cause therapy to become compromised or in some cases temporarily stop the delivery of therapy. You will see and hear the following:

- An alarm screen will display,
- The alarm/alert light M will light,
- An audible tone will sound every 20 seconds until the problem is fixed.

An alarm cannot be dismissed and must be attended to straight away.

All alarms are determined to be 'low priority' and require user awareness.

If the pump indicates a High Vacuum Alarm or a System Failure Alarm, then the pump has stopped delivering therapy

#### If an alert occurs:

The pump is warning the pump user that there is a potential problem about to occur. You will see and hear the following:

- An alert screen will display,
- The alarm/alert light <u></u>will light,
- An audible tone will sound every 20 minutes until the issue is fixed.

An alert can be dismissed. This will remove the alert screen but will not resolve the issue.

# Alarms and Alerts (cont.)

#### **Mute Alarms**

Some alarms allow the audible alarm to be muted for 15 minutes by pressing the mute button  $\bigotimes$ .

- Blockage Alarm
- Canister Full Alarm
- Critical Leak Alarm
- Canister Missing Alarm

If the cause of the alarm is not fixed within this time, the audible alarm will start again. If the audible alarm has been muted and a new alarm state occurs. The audible alarm will sound, and the screen will display the new alarm. When multiple alarm states are present, pressing **Next** will alternate between alarm screens.

# Troubleshooting

Only attempt troubleshooting if your clinician has has given you permission to do so.

When an alarm sounds, the RENASYS° EDGE pump screen will display information about the alarm. The pump includes **Help** on how to resolve each alarm. When the alarm/alert shows on the pump screen, press the **Help** key. If the alarm cannot be resolved using the **Help** function, the table below provides further troubleshooting advice. If the alarm/alert does not stop, do not delay in contacting your clinician.

**Caution:** Do not switch the pump on and off during an alert or alarm. This will reset the pump and the alarm/alert will continue once therapy is started.

Blockage Alarm	
What has happened?	What to do next
What has happened? What has happened? The pump has found a blockage. This blockage may be: In the canister In the tubing	<ol> <li>What to do next</li> <li>Pressthe Help button and follow on screen instructions. If alarm persists continue with steps below.</li> <li>Disconnect the canister tubing from the dressing tubing. Squeeze the canister quick click connectors and gently pull the connectors apart.</li> <li>Leave the tethered (connected) cap open on the canister quick click connector. Close the tethered (connected) cap of the dressing connector.</li> </ol>
	<ol> <li>If the alarm continues, the blockage is in the canister. Replace the canister. Read the <b>Changing Canister</b> section of the manual for more information.</li> <li>If the alarm stops, the blockage is in the tubing of the dressing. Do not delay in contacting your</li> </ol>
	clinician, your dressings may need to be changed.
	6. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

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# Moderate Air Leak Alert and Critical Air Leak Alarm

What has happened?	What to do next
The pump has	1. Press the <b>Help</b> button and follow on screen instructions. If alarm persists continue with steps below.
detected an air leak.	2. In the event of an air leak, the flow meter
• The pump will show an alert when a moderate air leak is detected.	will display on the therapy screen to assist in locating leaks in the pump, canister and tubing. Follow the instructions on screen to resolve the issue.
• The pump will show an alarm when a critical air leak is	3. Do not pause therapy or switch the pump off will while resolving this alarm; the following steps help identify the source of the leak.
detected. The pump will continue to operate but may not	<ol> <li>Look for loose or decompressed dressing appearance. Listen for air moving around the dressing.</li> </ol>
provide the correct	5. Before disconnecting your tubing:
<ul><li>amount of therapy.</li><li>See Alarms and</li></ul>	<ul> <li>Make sure you wash your hands before and after disconnecting the tubing.</li> </ul>
Alerts section for more information.	• Hold the connectors above the level of the pump and your wound when disconnecting.
	<ul> <li>Make sure to disconnect your tubing away from other people to limit the risk of contamination.</li> </ul>
	6. To disconnect the canister tubing from the dressing tubing, squeeze the canister quick click connectors and gently pull the connectors apart. Close the tethered (connected) caps of both connectors.
	7. If the alarm continues, there is a leak in the canister or at the canister to pump connection. Replace the canister. Read the <b>Changing canister</b> section of the manual for more information.
	8. If the alarm has stopped, there is a leak within the wound dressing or tubing. Do not delay in contacting your clinician, your dressing may need to be changed.
	9. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

# **Canister Full Alarm**

What has happened?	What to do next
The pump has	1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below.
detected that the canister is full.	2. Make sure the pump is placed the correct way up. See the <b>Pump Orientation</b> section.
	<ol> <li>Pause therapy by pressing <sup>(1)</sup>. Read the Changing Canister section for more instructions.</li> </ol>
	4. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

# **Canister Missing Alarm**

What has happened?	What to do next
The pump cannot detect a correctly connected canister.	<ol> <li>Press the Help button and follow on screen instructions. If alarm persists continue with steps below.</li> <li>Pause therapy by pressing and reattach or replace capiter. See the Changing Capitar.</li> </ol>
	section for instructions.
	3. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

Low Battery Alert and Critical Low Battery Alarm

What has happened?	What to do next
	1. Press the Help button and follow on screen instructions. If alarm persists continue with
an alert when there	2. Plug the pump into an electrical (AC) outlet as
is less than 2½ hours remaining and an	soon as possible. The pump can be plugged into the electrical (AC) outlet to charge during active
alarm when there	therapy.
less than 20 minutes remaining.	3. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

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# High Vacuum / System or Battery Failure Alarm

What has happened?	What to do next
The pump has	1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below.
detected an internal or battery failure.	2. Switch off and restart the pump. See <b>Turning the</b> <b>Pump On and Off</b> section
	3. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

# Pump Too Hot Alert or Alarm

What has happened?	What to do next
	Attempt to reduce the pump temperature.
The pump will provide an alert if the battery	1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below.
high for charging, and	2. Remove the pump from any covering or bag.
an alarm if the running temperature is too	3. Move the pump into a cooler environment to help it cool down.
high.	4. Make sure there are no air leaks, see the <b>Moderate and Critical air leak</b> for more information.
	5. If the alarm continues after troubleshooting, do not delay in contacting your clinician.

# Therapy Paused Too Long Alert

What has happened?	What to do next
The pump has been paused for more than 30 minutes.	<ol> <li>Restart therapy by pressing (1) as soon as possible. After 1 hour the pump will automatically start therapy.</li> <li>If the alarm continues after troubleshooting, do</li> </ol>
	not delay in contacting your clinician.

Pump Runs Improperly

# **Unusual Noise**

What has happened?	What to do next
If the RENASYS <sup>¢</sup> EDGE pump makes an	Do not use the pump and contact
unusual noise.	your clinician without delay.

Pump Starts Improperly	
What has happened?	What to do next
If the pump appears to start improperly, e.g. no sound or animation screen at start up there may have been a pump failure	Do not use the pump and contact your clinician without delay.
up there may have been a pump faiture.	

What has happened?	What to do next
If the pump does not look as it normally would during run time, there may have been a pump failure.	Do not use the pump and contact your clinician without delay.

Power Indicator Does Not Display		
What has happened?	What to do next	
If the <b>SN</b> logo does not illuminate when the pump is plugged into AC power, there may be a problem with the power supply.	Do not use the pump and contact your clinician without delay.	

Pump Damaged	
What has happened?	What to do next
Any part of the pump is cracked or	Do not use the pump and contact
appears damaged.	your clinician without delay.

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# Specification

## **Essential Performance**

Essential performance of the RENASYS° EDGE Pump, for safe operation, is to maintain the vacuum delivered by the pump within its specification for pressure selected, to provide Negative Pressure Wound Therapy (NPWT). Contact your Smith+Nephew representative, distributor or authorized provider if service or additional guidance is required.

#### Vacuum

Continous Therapy Levels	25, 40, 60, 80, 100, 125, 150, 175, 200 mmHg
Intermittent Therapy	High: 40, 60, 80, 100, 125, 150, 175, 200 mmHg
Levels	Low: 25, 40, 50 mmHg
Intermittent Therapy	High 5, 8, 10 mins
Cycles Times	Low: 2,3,5 mins
Alarms	
Frequency	20 seconds
Priority	Low
	Low: 55 dB
Auditory Sound Level	Medium: 65 dB
	High: 75 dB
Indicator Color	Yellow
<b>Overall Alarm Delays</b>	
Over Temperature	60 seconds
High Vacuum	360 seconds
Leak/Low vacuum	45 seconds
Blockage	300 seconds
Canister Full	120 seconds
Critical battery	60 seconds
Battery failed	300 seconds
Pump failed	2 seconds
Battery	
Operating time	>24 hours (therapy) when operating at 125mmHg
Ingress protection	IP34
	Enclosure protected against ingress of small
	objects (>2.5 mm in width) and light water spray
Maximum pump tempera	ture (°C)
LCD screen	52.1 °C
USB compartment	52.2 °C
Rear lower housing	43.7 °C

All of RENASYS<sup>6</sup> EDGE pump and dressings are considered applied parts. All of the applied parts are type BF (body floating) defibrilliation proof parts.

# Warranties

#### LIMITED WARRANTY

For Warranty Terms and conditions, please refer to your country specific element at the following link:

https://www.smith-nephew.com/key-products/terms--conditions-and-warranties---products/

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lcon an	d Symbol Glossary		
Pump bu	ittons	Therapy	screen icons
	Play/Pause button		Y-Connector Mode
	Mute Button	S	Intermittent Mod <b>e</b>
	Canister Release Button	R	Continuous Mode
	Recessed Lock/Unlock Button	Status b	ar icons
	Three Multifunction Buttons		Paused
Pump lig	yhts	ОК	System OK
ОК	System OK Light	$\triangle$	Alarm/Alert
	Battery Warning Light		Critical Air Leak
$\triangle$	Alarm/Alert Light		Moderate Air Leak
S₽N	External Power Indicator		Blockage
Battery	icons	?	Canister Missing
24hr	Full Charge Battery		System Failure/High Vacuum
1hr	Low Battery		Pump Too Hot Alert
<b>1</b> 30m	Critical Low Battery		Pump Too Hot Alarm
10%	Charging		Paused Too Long
100%	Fully Charged		Canister Full
	Battery Failure	â	Locked
			Bluetooth On
			Muted

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# Icon and Symbol Glossary

# Additional symbols

	Direct current	93% 15%	Relative humidity limitation
	ETL listing mark	*	Keep away from
	Manufacturer		
(1)	Refer to instruction manual/booklet		
	Caution refer to		Serial number
$\sim$	Do not use if package is	$(\mathbf{X})$	Single use: do not reuse
	damaged	LOT	Batch code
IP34	Enclosure protected against ingress of small objects (>2.5 mm in width) and light water spray	MR	MRI Unsafe keep away from magnetic resonance imaging (MRI) equipment
	Keep dry	REF	Product catalogue number
5°C/ 104°F	Storage limit temperature	X	EU: WEEE 2012/19/EU symbol not for general waste
	Date of manufacture	F©	Federal Communications Commission Identifier
$R_{\!X}$ only	Caution: U.S Federal law restricts this device to sale by or on order of a		Near-field communication (NFC)
	physician	Ð	Riological wasto symbol
┤★╟	Defibrilliation proof type BF applied part	Ś	blological waste symbol
$((\bullet))$	Intentional Radiator		
MD	Medical Device		
UDI	Unique Device Identifier		

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#### Smith+Nephew Customer Care contact details

#### Canada

24/7 Clinical Hotline and Customer Care Center: 1-800-463-7439 Live representative: 8:00am-6pm ET, Monday to Friday After hours & weekends: Please select option 1 for English then follow the prompts to leave avoicemail and the on-call clinician will return your call in minutes.

#### USA

24 hour Smith+Nephew contact number: 1-800-876-1261

Your clinician's contact details		
Name:		
Contact number:		

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