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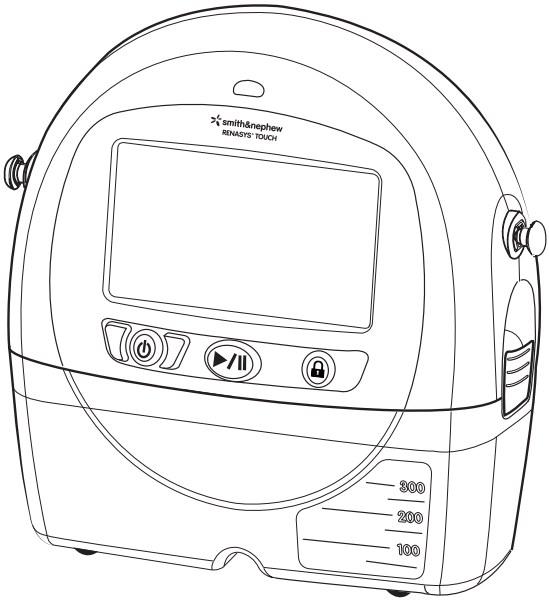
smith&nephew

RENASYS◇ TOUCH

Negative Pressure Wound Therapy



Clinician User Manual
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smith&nephew
RENASYS◇ TOUCH
Negative Pressure Wound Therapy

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Introduction

This user manual contains important information regarding the safe and effective operation of the RENASYS® TOUCH Negative Pressure Wound Therapy (NPWT) device (REF 66801791). This device is intended for use by or on the direction of a trained and licensed physician. This manual is intended to aid in the training of personnel and to provide a reference for experienced users. Also included are instructions for operating device, preventive maintenance, cleaning and return.

The RENASYS TOUCH is intended for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

RENASYS TOUCH is also intended for use in residential settings and nursing homes where product use is conducted by or under the supervision of a qualified healthcare professional.

To ensure that the device is safe for use in residential settings, this device is compliant with the IEC medical equipment and medical electrical safety standard 60601- 1-11 for use of medical devices in the home healthcare environment. This standard includes the use of a double insulated Class II power supply and Class II power cord.

Important information Monitoring NPWT

Carefully monitor the patient, device, and dressing frequently to determine if there are any signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of Negative Pressure Wound Therapy (NPWT). The frequency should be determined by the clinician based on individual characteristics of the patient and wound. NPWT devices are not designed to detect or issue an alarm condition based on the presence of bleeding or pooling. These conditions may only be detected by frequent monitoring.

Special attention to the risks of bleeding or loss of NPWT should be considered when prescribing for use in the Home Environment.

NPWT may be impacted by various conditions related to system configuration, set-up and individual characteristics of the patient and wound (e.g. exudate characteristics, patient anatomy). Alignment of the port to the opening in the drape, use of a bridging technique and choice of dressing configuration based on wound characteristics may impact NPWT vacuum delivery over the course of therapy. Exudate volume, viscosity and consistency may influence fluid removal or occlusion formation. A full canister, incorrect device orientation and device/tubing height relative to the wound can contribute to loss of NPWT and exudate accumulation within the wound, which could lead to maceration, infection, or unrecognized bleeding.

Monitor the wound for infection and ensure that all wound filler is removed at each dressing change to reduce the risk of infection.

Skin grafts should be closely monitored to ensure NPWT is being delivered.

Review Contraindications, Warnings & Precautions before use.

Indications for use

RENASYS TOUCH is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy), as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates 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 and grafts

Contraindications

Use of RENASYS TOUCH is contraindicated in the presence of:

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

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Warnings

1. Carefully monitor patients for signs of bleeding, which may lead to interruption in therapy and hemodynamic instability. If such symptoms are observed, immediately discontinue therapy, take appropriate measures to control bleeding, and contact treating clinician.
2. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that, if disrupted, may increase the risk of bleeding.
3. Do not use directly on exposed blood vessels or organs. Sharp edges such as bone fragments must be covered or removed prior to initiating therapy, due to risk of puncturing organs or blood vessels drawn closer under the action of negative pressure.
4. NPWT has not been studied on pediatric patients. Patient size and weight should be considered when prescribing the device.
5. Foam or gauze must not be tightly packed or forced into any wound area. Over-packing may interfere with distribution of NPWT evenly across the wound. This may decrease the ability of the wound to properly contract and permit exudate to remain in wound.
6. In the event defibrillation is required, disconnect device from wound dressing prior to defibrillation. Remove wound dressing only if its location will interfere with defibrillation.
7. Device is not MRI compatible. Do not bring device into MRI suite. Prior to entering MRI suite, disconnect device from dressing. Dressing can remain intact on patient.
8. Device is unsuitable for use in areas where there is danger of explosion (e.g., hyperbaric oxygen unit).
9. When operating, transporting or disposing of device and accessories, there is risk of infectious liquids being aspirated or contamination of device assembly through incorrect use. Universal precautions should be observed whenever working with potentially contaminated components or equipment.
10. Device and canister kits are provided non-sterile and should not be placed within a sterile field.
11. A Y-connector should only be used when applying two dressings to a single wound. The system will only detect a blockage if both connections are blocked.

Precautions

1. More frequent device and wound dressing monitoring should be taken for patients who are or may be:
   - Suffering from infected blood vessels
   - Receiving anticoagulant therapy or platelet aggregation inhibitors, in addition to patients with intrinsic coagulation problems such as low platelet counts
   - Actively bleeding or have friable blood vessels or organs
   - Suffering from abnormal wound hemostasis
   - Untreated for malnutrition
   - Noncompliant or combative
   - Suffering from wounds in close proximity to blood vessels or friable fascia.

   When monitoring patients for delivery of therapy, ensure wound dressing is free of air leaks, fully compressed and firm to the touch.
2. As a condition of use, device should only be used by qualified and authorized personnel. User must have necessary knowledge of the specific medical application for which NPWT is being used.
3. For patients with high risk of bleeding, use 300ml canister. Ensure the 300ml canister viewing is checked frequently for signs of bleeding.
4. The dressing seal may be lost or pooling may occur, without alarm activation, when an occlusion forms on the wound side of the dressing. Viscous, purulent or serosanguineous drainage may contribute to occlusion of the dressing. Regular monitoring of device and dressing is required to ensure full delivery of therapy and exudate removal. Ensure the wound dressing is free of air leaks, fully compressed and firm to the touch whenever therapy is active.
5. Underlying structures, such as bone, tendons, ligaments and nerves should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing to ensure protection and minimize the risk of damage from direct contact with the dressing.
6. To minimize the risk of bradycardia, do not place NPWT in proximity to the vagus nerve.
7. In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue use of NPWT and immediately seek medical assistance.
8. When treating enteric fistulas, do not place NPWT dressing in direct contact with exposed bowel.

Cover the wound bed, including fistula opening, with non-adherent gauze or with one layer of saline moistened gauze. Alternatively, consider isolating the fistula using an ostomy bag and dress the rest of the wound appropriately to avoid the wound being bathed in effluent from the enteric fistula. During the course of treatment patient's fluid levels must be closely monitored.

9. Avoid use of circumferential dressings except in cases of oedema or heavily exuding extremities, where this technique may be necessary to maintain a seal. Consider using multiple drapes to minimize risk of decreased distal circulation. Regularly assess distal pulses, and discontinue therapy if changes in circulation are detected.
10. Monitor patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. As NPWT is not intended to directly treat infection, if there are any signs of systemic infection or advancing infection at wound area, contact treating clinician immediately.
11. If multiple pieces of foam or gauze are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimize the risk of retention and possible infection.
12. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from device is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
13. Do not use a dressing kit with breached or damaged packaging.
14. Use of NPWT presents a risk of tissue in-growth. Tissue in-growth may be reduced by reducing therapy pressure, using a wound contact layer or increasing the frequency of dressing changes.
15. NPWT should not be painful. If patient reports discomfort, consider reducing pressure setting and use of a wound contact layer. Pressure setting is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage and integrity of dressing seal.
16. Maintain regular monitoring of device and wound site during therapy to ensure therapeutic treatment and patient comfort.
17. Device is only to be used with Smith & Nephew authorized components. Use of any other products has not been proven safe and effective with RENASYS® TOUCH device.
18. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position device and tubing appropriately to avoid risk of a trip hazard. Device and system tubing should be positioned no more than 19 in or 50cm higher than the wound to ensure optimization of therapy and prevent therapy interruption.
19. When bathing or showering patient must disconnect from device, protecting both ends of tubing using tethered caps. Ensure aeration disc located near quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.
20. If any liquids penetrate device, discontinue use and return to your Smith & Nephew authorized provider for service.
21. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move device out of x-ray or scanner range.
22. Do not use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
23. AC mains power can only be removed by disconnecting power cord or AC power supply. Take care in positioning the device to allow access to the power jack.
24. If power supply or power cord is damaged, wires are frayed or exposed, do not use power. Contact your Smith & Nephew representative for a replacement.
25. 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.**
26. Canisters are single use. Do not reuse.
27. Do not apply SECURA® No-sting barrier film wipes directly to open wounds. SECURA No-sting barrier film is flammable. Use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children. For external use only.
28. As with all adhesive products, apply and remove dressing carefully from sensitive or fragile skin to avoid blistering and skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of periwound skin.

29. If patient must be disconnected, the ends of the dressing tubing and canister tubing should be protected using tethered caps to avoid leakage of fluid and cross contamination.

30. Due to its smaller diameter, the RENASYS®-G 10Fr Round Drain Gauze Kit and Accessory Kit are not recommended for use with RENASYS TOUCH, as reduced pressure in the wound bed may lead to pooling or maceration.

Physician orders

Prior to placement of RENASYS TOUCH, the medical professional treating the wound must assess how to best use the system for an individual wound. It is important to carefully assess wound and patient to ensure clinical indications for Negative Pressure Wound Therapy (NPWT) are met.

All orders should include:

- Wound location, size and type
- Smith & Nephew Wound Dressing Kit
- Pressure settings
- Frequency of dressing changes
- Adjunctive dressings

Device description

The RENASYS® TOUCH device is designed to provide Negative Pressure Wound Therapy to a closed environment over a wound in order to evacuate exudates from the wound site to a disposable container, which may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

The closed environment is created by applying a RENASYS sterile wound dressing to the wound site and connecting the sealed wound to the suction device. The RENASYS TOUCH device contains integrated global cellular technology that allows device location, billing and maintenance data to be sent to a secure Internet website providing clinical access to device information.

The RENASYS TOUCH device has two main user interface areas: the full-color touchscreen and the three buttons below the touchscreen.

The three buttons below the touchscreen are used to power On and Off the device, Start and Pause Therapy, and Lock and Unlock the user interface.

The status indicator at the top of device illuminates green when therapy is active or yellow to indicate an alarm state. The status indicator is not illuminated when therapy is not active.

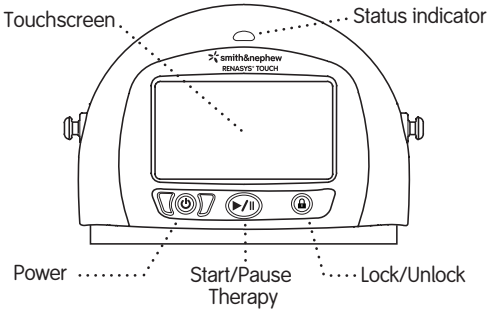
The RENASYS TOUCH device runs on AC mains power or can be used on internal battery power to allow the user greater mobility. Using the external AC power supply and power cord, the device can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy. When the device is plugged in, the external power indicator next to the power jack illuminates green to indicate the device is connected to an external power supply. When the device is On, the battery indicator on the touchscreen will display a lightning bolt to indicate the battery is charging. RENASYS TOUCH is designed to be used with a RENASYS TOUCH power supply.

Attachment knobs are located on the left and right sides of the device. These features are used to attach the carry strap and IV pole/bed clamp accessories.

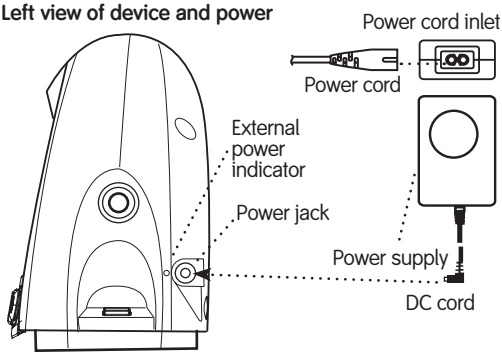
The rear of the device houses the speaker and identification label. The odor filter, USB port and air exhaust outlet are located behind the rear access door.

The underside of the device houses the inlet port, replaceable o-ring and barcode label are located on the underside of the device.

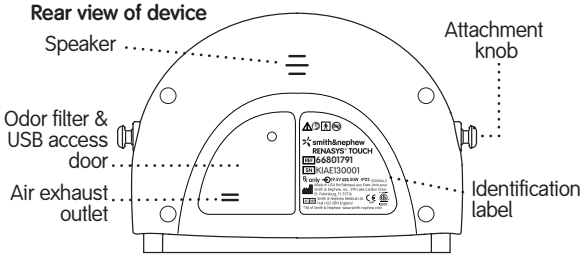
Front view of device



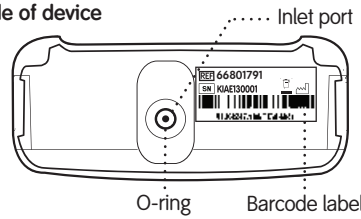
Left view of device and power



Rear view of device



Underside of device



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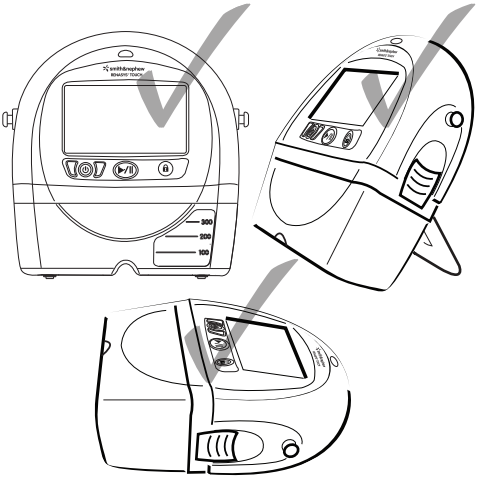
Device orientation during use

The device is designed to operate the upright position. Device orientation, rate at which fluid enters the canister and how exudate solidifies can impact filter occlusion. Operation in the upright position optimizes canister volume and alarm functionality. The device should be orientated to face the user's position when in stationary use.

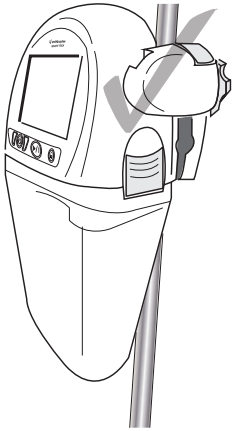
Proper use/correct orientation

The 300ml canister has a kickstand and rubber feet. The device can stand in the upright position with the 300ml canister attached. Open the kickstand for additional stability and to change the viewing angle.

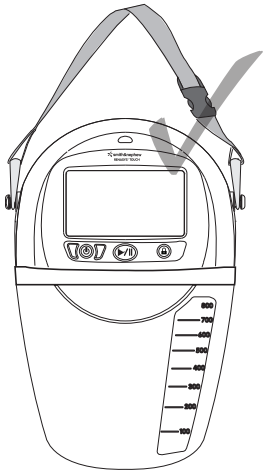
The 800ml canister does not include a kickstand or rubber feet. The IV pole/bed clamp or carry strap accessories can be used to mount the device in the upright position.



300ml canisters only



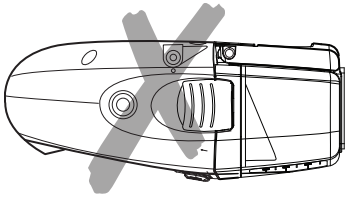
300ml or 800ml canisters with clamp



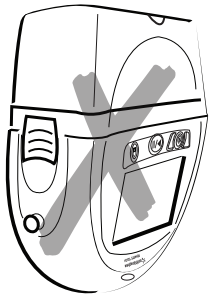
300ml or 800ml canisters with carry strap

Incorrect orientation

Caution: Operating the device in a face-down position could result in damage to the device and inadvertent changes to therapy settings. Operating the device in an inverted position could impact filter occlusion resulting in a blockage alarm and requiring a change of canister.



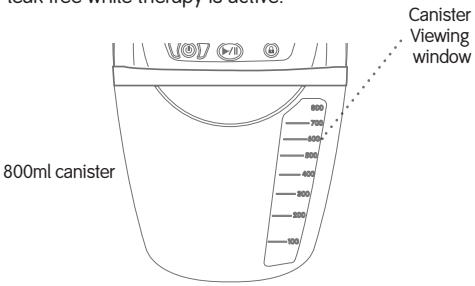
300ml or 800ml canisters



300ml or 800ml canisters

Dressing changes

1. Foam dressings should be changed every 48 to 72 hours after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur no less than 3 times per week.
2. Gauze dressings should be changed 48 hours after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur 2-3 times per week.
3. In the event of heavy drainage, drainage with sediment, or when blood is present, regular monitoring and more frequent dressing changes may be required.
4. When dressing a wound involving difficult to seal anatomy or exposure to external moisture, frequent inspection of the dressing is recommended to ensure a seal is maintained. Ensure wound dressing is fully sealed and firm to the touch.
5. Ensure all wound filler material placed in the wound has been removed before redressing the wound. If foam dressing adheres to the wound, apply normal saline into the wound dressing and wait for 15-30 minutes before gently removing the foam. Appropriately discard used wound dressings observing your institution's protocol for medical waste handling.
6. As with all adhesive products, apply and remove the dressing carefully from sensitive or fragile skin to avoid skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of periwound skin.
7. Check the dressing regularly. Monitor the patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. If there are any signs of systemic infection or advancing infection at the wounded area, contact the treating clinician immediately.
8. Sealed dressings should be firm to the touch and leak free while therapy is active.



Canister selection

Only use Smith & Nephew RENASYS® TOUCH canisters with the RENASYS TOUCH device.

RENASYS TOUCH canisters use an integral two stage bacterial filter for protection of the device against overflow and the spread of aspirated micro-organisms.

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

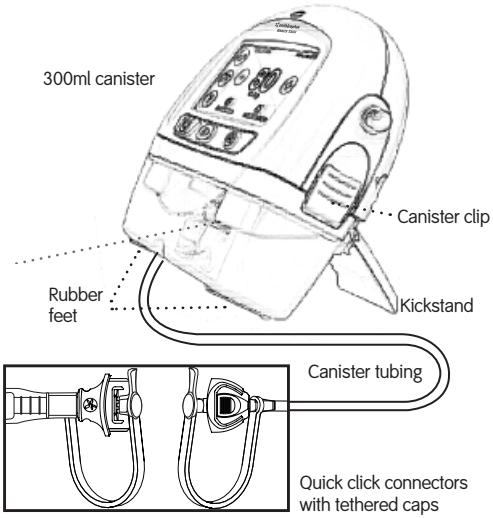
Canisters should be changed at least once a week, whenever there is a change of patient, or when the contents reach the maximum volume indication (300ml or 800ml fill line) in the viewing window. **Do not wait for the Canister Full alarm to sound to change canister.**

For patients with high risk of bleeding, use the 300ml canister. Canisters may have to be changed regularly within single patient treatments if exudate levels are high. Check canisters regularly to monitor exudate levels, ensuring they are below the canister maximum volume indication.

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

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

Note: Change or replace canisters that have been dropped or mishandled even if no visible signs of damage are present to ensure correct operation of software alarms for leak and blockage.



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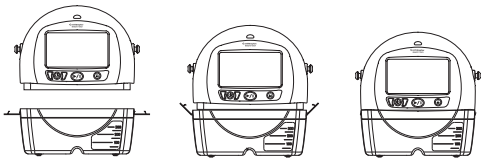
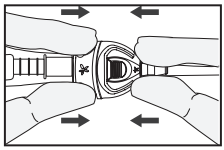
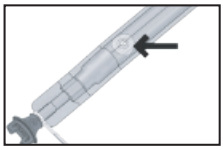
Installing canister

1. Ensure therapy is paused or device is Off.
2. Remove paper tape around canister tubing and release tubing to full length.
3. Open canister clips on both sides of the canister.
4. Position the canister so that the viewing window is facing forward.
5. Push canister gently over inlet port on the bottom of the device.
6. Engage both canister clips. Canister clips will click when properly engaged.
7. Connect the dressing to the canister tubing by pushing quick click connectors together. Quick click connectors will click when properly engaged.



300ml and 800ml canisters

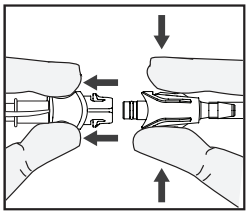


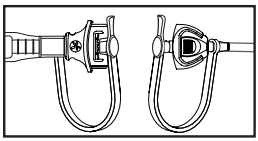


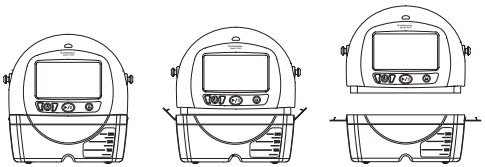
Note: Do not cover the aeration disc for proper delivery of therapy.

Removing/changing canister

1. Pause therapy or turn device Off.
2. Hold quick click connectors above wound to help ensure exudate does not leak from tubing.
3. Disconnect canister tubing from dressing tubing by applying pressure to the canister quick click connector and gently pulling connectors apart.
4. Close the tethered caps of both quick click connectors to protect both sides of tubing and prevent leakage.
5. Release canister clips on both sides of device and gently pull canister away from device.







300ml or 800ml canisters

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

Turning on device

Ensure the battery is fully charged if battery operation is required for first use of the device.

Press and hold the **Power** button below the touchscreen for 2 seconds to power On (or power Off) the device.

The touchscreen illuminates and initiates the start up sequence: the Smith & Nephew start up screen will display, the status indicator will flash yellow then green, the device sounds an audible tone, then the Welcome screen will display. The Home screen will display upon completion of the start up sequence.

Note: When the device is nearing time for the annual maintenance check, an annual maintenance notification will display when powering On the device. To close this notification screen and continue to the Home screen, press the Accept icon.

Navigating the touchscreen interface

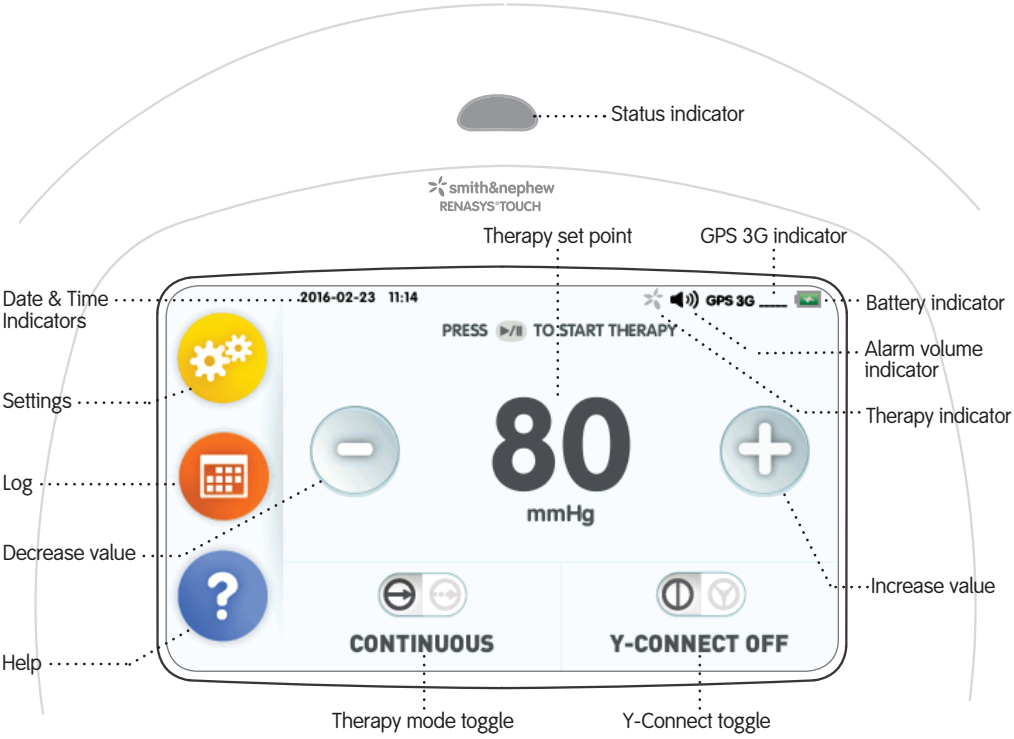
The screen on the RENASYS® TOUCH device is touch sensitive.

Tap the touchscreen to make a selection.

Slide your finger up, down or across the screen to scroll.

Note: The touchscreen should only be actuated by finger. Using pens or other pointed objects may damage the screen

Home screen *(Continuous therapy mode shown)*



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Setting therapy

The prescribed therapy setting is a decision that the clinician must make based on an assessment of the particular wound. These general guidelines should be adhered to:

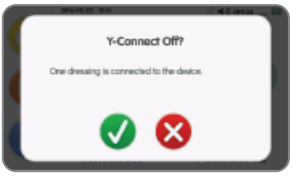
- 40–120mmHg is the recommended therapeutic pressure range.
- NPWT should never be painful. If the patient reports discomfort, consider reducing the pressure setting.
- Outside the recommended optimal therapeutic pressure range of 40 – 120mmHg, the broader operating range of 25 – 200mmHg is provided to support clinical discretion on pressure set-point.

The device will display the therapy set point.

Set Y-Connect

A Y-connector should be used when applying two dressings to a single wound. Select Y-Connect On to adjust the blockage alarm to account for two dressings connected to the device. Select Y-Connect Off if only one dressing is connected to the device. Press the **Y-Connect** toggle icon to switch between Y-Connect Off and Y-Connect On . Press the Accept icon to confirm your selection.

Press the Cancel icon to maintain the current setting.



Note: Therapy must be paused to change Y-Connect setting. This feature is unavailable in Patient Mode

Caution: The system will only detect a blockage if both connections are blocked. The system will not detect a blockage existing in one of the Y-connected dressings; therapy will not be delivered through the blocked dressing.

Setting Y-Connect On when only one dressing is connected to the device may cause nuisance alarms. Setting Y-Connect Off when two dressings are connected to the device may prevent blockage alarm from sounding.

Caution: Due to its smaller diameter, the RENASYS-G 10 Fr Round Drain Gauze Kit and Accessory Kit are not recommended for use with RENASYS TOUCH, as reduced pressure in the wound bed may lead to pooling or maceration.

Set therapy mode

The device features two therapy modes: Continuous and Intermittent.

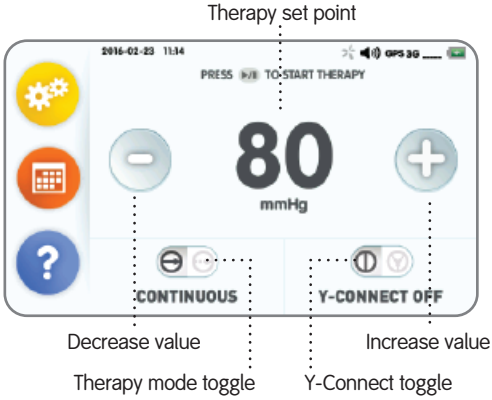
Press the **Therapy Mode** toggle icon to switch between Continuous and Intermittent therapy.

Note: Therapy must be paused to change therapy mode.

Continuous therapy mode

In Continuous mode, the device will maintain the selected therapy level until therapy is stopped or changed. The therapy set point is displayed in the center of the screen. Therapy levels can be selected from a range of 25–200mmHg by pressing the **Decrease** and **Increase** icons.

(*Continuous therapy mode shown*)



Intermittent therapy mode

Intermittent therapy mode provides both intermittent and variable therapy set point options. The device will alternate between set points of active therapy and low (variable) or no (intermittent) therapy at set cycle times.

To adjust the therapy set points and cycle times:

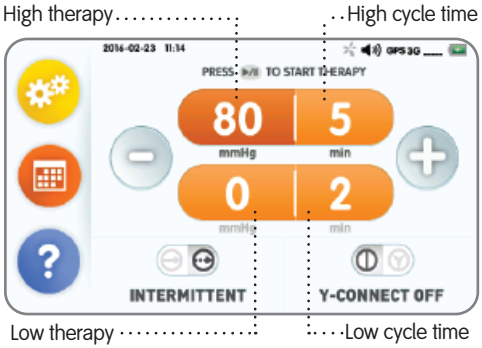
1. Select to highlight the setting that needs adjustment.
2. Press the **Decrease** or **Increase** icon to select therapy set points and cycle times with the following range.
   - High therapy: 25–200mmHg
   - Low therapy: 0–180mmHg (will not equal or exceed High therapy)
   - High cycle time: 3,5,8,10 minutes
     Low cycle time: 2,3,5,8,10 minutes

Intermittent therapy is not recommended for:

- Highly exuding wounds
- Wounds with tunnels or undermining
- Wounds in difficult areas where maintaining a seal is problematic
- Patients who experience pain during intermittent therapy

Note: Therapy must be paused to change cycle times.

(*Intermittent therapy mode shown*)



Starting therapy

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

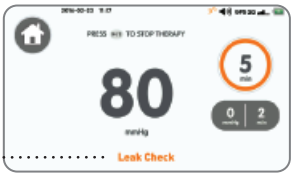
Caution: Ensure the device and system tubing are positioned level with or below the wound and are away from any direct sources of heat.

Press the **Start/Pause Therapy** button below the touchscreen to start therapy.

As the device begins delivering therapy, it will perform a leak check to determine if the system is sealed or if there is a significant leak in the system.

(Intermittent therapy mode shown)

Leak Check



Seal Achieved

Delivering Therapy

When therapy is active, the therapy indicator at the top of the screen will rotate orange and status indicator on top of the device illuminates green.

If a significant leak is detected in the system, the device will indicate a leak alarm. Refer to "Alarms/ Troubleshooting" section for more details.

To return to Home screen while therapy is active, press the **Home** icon on the Delivering Therapy screen. After 10 seconds without user interaction, the touchscreen will automatically return to the Delivering Therapy screen. If you have navigated to the Help menu or the Flow Meter within the Settings menu, the touchscreen will automatically return to the Delivering Therapy screen after 3 minutes without user interaction.

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Pause therapy

Therapy may be paused by pressing the **Start/Pause Therapy** ▶/II button.

When paused, the touchscreen will return to the Home screen, the status indicator will not be illuminated and the therapy indicator will be gray.

Lock/Unlock feature

To lock the user interface when therapy is active, press and hold **Lock/Unlock** button below the touchscreen for 2 seconds. Once locked, a lock symbol will appear behind the therapy set point and the device will enter Sleep mode.

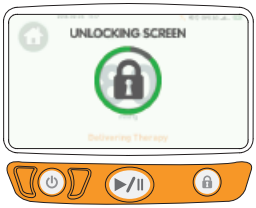
While in Sleep mode, the touchscreen will go dark for user comfort and to conserve battery life. The status indicator continues to illuminate green to indicate the device is delivering therapy.

In the event of an alarm, the device will automatically unlock and the alarm screen will display.

The device will automatically Lock and enter Sleep mode after 5 minutes without user interaction when therapy is active.

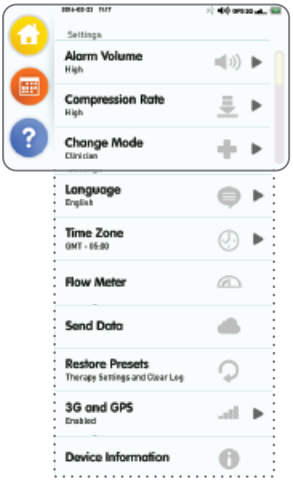
Note: The Lock function locks the touchscreen and Start/Pause Therapy button – Power button is not locked.

To unlock user interface, press and hold the **Lock/Unlock** button for 2 seconds.



Settings

Settings contains a menu of user preferences, device functions and device information. Scroll up and down to view all selections.

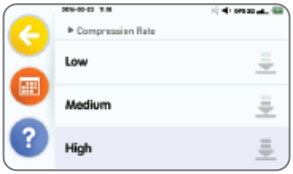


Alarm volume

Select **Alarm Volume** from the **Settings** menu and choose low, medium or high to adjust alarm volume. The device will issue a sample tone as you make your selection. Alarm volume indicators on the Settings menu and at the top of screen will update based on the selection.

Compression rate

The compression rate limits the target pressure change in a given period of time to a maximum amount. Selecting the high compression rate will result in the most rapid dressing draw down. Select **Compression Rate** from the **Settings** menu and choose low, medium or high. The Compression Rate indicator on the Settings menu will update based on the selection.



Note: Therapy must be paused to change Compression Rate.

Change mode

The device has three user modes: Clinician, Patient and Maintenance.

Clinician Mode provides healthcare providers full access to features and settings.

Patient Mode prevents inadvertent changes to therapy settings by restricting access to the following features:

- Therapy settings: therapy set points, cycle times, therapy mode and Y-connect selection will display on the touchscreen but cannot be changed.
- Settings menu selections: Restore Presets and 3G and GPS will display in the settings menu but cannot be selected.

Maintenance Mode allows authorized service personnel access to reset the Annual Maintenance timer. Refer to "Annual Maintenance" section under "Alarms/Troubleshooting" section for details.

To switch between modes, select **Change Mode** from the **Settings** menu and choose Clinician or Patient.

A password is required to switch between Clinician and Patient modes. Enter the numeric password (3141) and press the **Accept** icon.

To delete a number that was entered incorrectly, press the **Back** icon. To exit the screen without entering a password, press the **Cancel** icon.

Note: Patient Mode restricts access to therapy settings and specific device features. It is recommended that clinicians set the device to Patient Mode once therapy settings have been selected to prevent inadvertent changes to settings.

Language

To change the language, select **Language** from the **Settings** menu and choose desired language from provided list. Scroll up and down to view all selections.

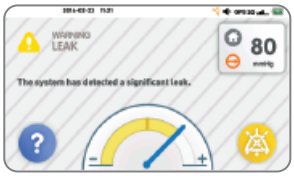
Time zone

Select **Time Zone** from the **Settings** menu and choose desired time zone from the available list to change the displayed date and time at the top of the touchscreen.

Flow meter

The Flow Meter provides a visual indication of the rate of air flow in the system to help determine if the system is properly sealed or if there are leaks. The gauge will turn yellow if a significant leak is detected. To access the Flow Meter, select **Flow Meter** from the **Settings** menu.

In the event of a leak alarm, the Flow Meter is displayed on the alarm screen to assist in locating leaks in the system.



Send data

The RENASYS TOUCH device contains integrated global cellular technology that allows device location, billing and maintenance data to be sent to a secure Internet website. The device will transmit data every

hour if the 3G and GPS setting is Enabled, the device is connected to the cellular network and the device is connected to AC mains power. The device will transmit data every two hours while running on battery power. The device must be powered on to transmit data.

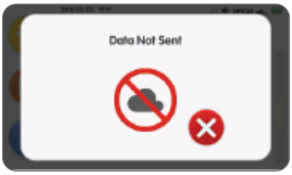
It is recommended to manually initiate a data transmission at the conclusion of a patient's therapy and before selecting Restore Presents in the Settings menu to ensure device data is communicated.

To manually initiate a data transmission:

1. Ensure 3G and GPS setting within the Settings menu is enabled.
2. Ensure adequate signal strength by checking the GPS 3G status indicator at the top of the screen.
3. Select Send Data from the Settings Menu.
4. Press Accept icon to initiate data transmission or Cancel icon to cancel and return to the Settings Menu.

The screen will display the status of the transmission and then return to the Settings menu once the transmission is complete.

If the transmission fails, the screen will display a Data Not Sent notification.



Press the Cancel icon to return to the Send Data screen.

Note: This feature is unavailable if 3G and GPS are turned off. Refer to 3G and GPS under the Settings.

Restore presets

Restore Presets should be selected whenever the device is prepared for use with a new patient.

Select **Restore Presets** from the **Settings** menu and press **Accept** icon to restore the device to the factory presets below:

- All Log information is reset to zero.
- Continuous Therapy: 80mmHg
- Intermittent Therapy: 80mmHg for 5 minutes; 0mmHg for 2 minutes
- Y-Connect: Off
- Compression rate: High
- 3G GPS: Enabled
- Alarm volume: High

Press the **Cancel** icon to maintain the current settings.

Note: This feature is unavailable in Patient mode.

3G and GPS

The RENASYS TOUCH device contains integrated global cellular technology that allows device location, billing and maintenance data to be sent to a secure Internet website.

The device will transmit data every hour when the 3G and GPS are Enabled, the device is connected to the cellular network and the unit is connected to AC mains power. The device must be powered On to transmit data.

When the 3G and GPS are Disabled the device will not transmit data and Send Data in the Settings menu cannot be selected to manually initiate a data transmission. To turn on or off the 3G and GPS, select 3G and GPS from the Settings menu and select Enabled to turn on or Disabled to turn off the functionality.

Note: This feature is unavailable in Patient mode.

Device Information

To display a list of device information, such as serial number, battery charge remaining, software information and annual maintenance timing, select **Device Information** from the **Settings** menu to view.

Therapy Log

The Therapy Log displays Total Patient Therapy (accumulated active therapy days, hours and minutes since last Restore Presets) and provides information on therapy that has been delivered to the patient in two display formats: Overview and Detailed view.

Select the Log toggle icon to switch between Overview and Detailed view.

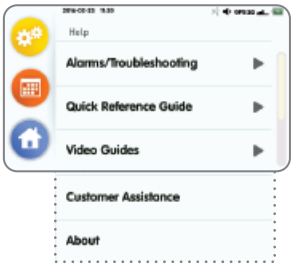
Overview displays a bar graph of total therapy hours per day. Scroll left or right to view additional days.

Detailed view displays a history of events, including therapy settings, alarms and device status. Scroll up and down to view additional days.

Note: Format is Days, Hours, Minutes.

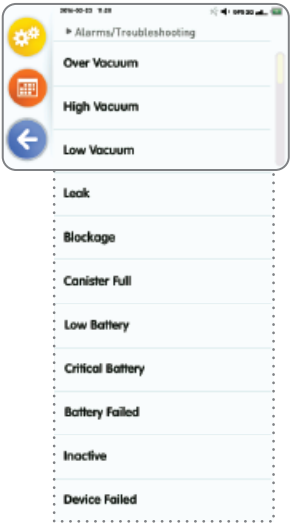
Help

The Help menu provides guidance on device functions and operation, troubleshooting assistance, Smith & Nephew contact information, and licensing details. Scroll up and down to view all selections.



Alarms/Troubleshooting

Descriptions of each alarm are provided with step-by-step instructions to assist in resolving the alarms. Select **Alarms/Troubleshooting** from the **Help** menu and scroll up and down to view all menu selections. Select the alarm you would like assistance with and scroll up and down to view the instruction steps.



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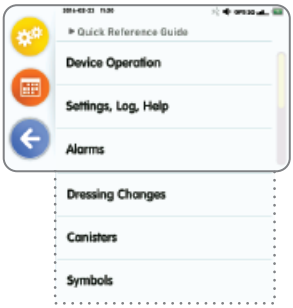
Quick Reference Guide

The Quick Reference Guide is a condensed version of frequently referenced instructions for use. Select Quick Reference Guide from the Help menu and scroll up and down to view all menu selections. Select the operation or feature and scroll up and down to view the instruction and information.



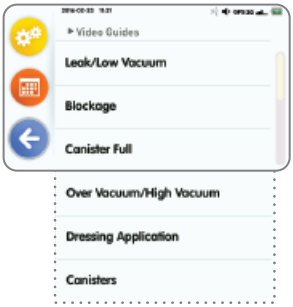
Video Guides

Video guides provide step-by-step audio/video instructions on specific alarm troubleshooting, canister installation and dressing applications.

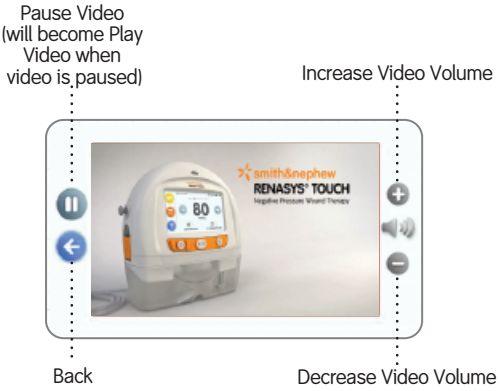
Select Video Guides from the Help menu, scroll up and down to view all menu selections and select a video to view.

Note: Video Guides are intended to be used as reference only. Always consult the user manual for instructions on specific alarm troubleshooting, canister selection and dressing applications.

Note: Therapy must be paused to view video guides.



The video player will display and the video will begin to play.



Press the Pause Video icon to pause the video.

When the video is paused this icon will change to Play Video. Press the Play Video icon to start the video.

The video volume can be adjusted by pressing the Increase and Decrease Video Volume icons.

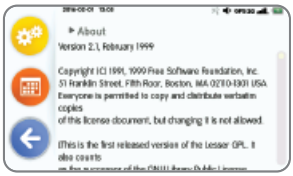
Press the Back icon to return to the Video Guides menu.

Customer Assistance

Smith & Nephew Customer Assistance contact information is provided by country. Scroll up and down to locate the contact information for your country.

About

About contains device licensing information. Scroll up and down to view entire content.



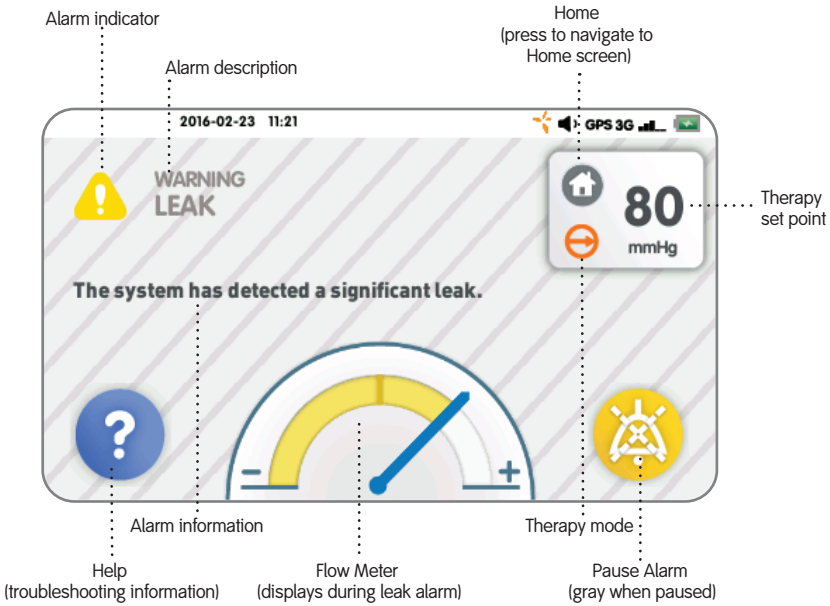
Alarms/Troubleshooting

The RENASYS° TOUCH device is equipped with alarms to indicate an error in the system. All alarms are determined to be "Low Priority" and require user awareness (IEC 60601-1:2005, 3rd edition and IEC 60601-1-8:2006). In the event of an alarm, an audible tone sounds, an alarm screen will display and the status indicator illuminates yellow. The device stops delivering therapy in the occurrence of an Over Vacuum, High Vacuum, unattended Critical Battery, Battery Failed or Device Failed alarm.

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

Some alarms allow the audible alarm to be paused for approximately 2 minutes. The Low Battery alarm allows the audible alarm to be paused for 15 minutes. If the cause of the alarm is not resolved within this time the alarm will recommence. If the audible alarm has been paused and a new alarm state occurs, the audible alarm sounds, and the touchscreen will display the new alarm. When multiple alarm states are present, the device will alternate between alarm screens every 5 seconds.

Alarm screen (*Leak alarm shown*)



Note: Alarm screen icons and features display only when applicable.

Over Vacuum Alarm

The system has detected an excessively high vacuum (>235mmHg), potentially due to device malfunction.

Device stops delivering therapy.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm cannot be paused.

Troubleshooting

1. Power Off and restart the device.
2. If the alarm recurs there is a potential malfunction of the device. Contact your Smith & Nephew authorized representative.

High Vacuum Alarm

The system has detected a high vacuum condition (>15mmHg above the therapy set point), potentially due to device malfunction.

Device stops delivering therapy.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm cannot be paused.

Troubleshooting

1. Power Off and restart the device.
2. If the alarm recurs there is a potential malfunction of the device. Contact your Smith & Nephew authorized representative.

Low Vacuum Alarm

The vacuum level is lower than the therapy set point by >15mmHg for longer than 60 seconds.

The device continues to operate but may not provide prescribed therapy.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen.

Troubleshooting

Do not pause therapy or power Off the device while performing the following steps. Assess the device after each step. Continue to next step only if alarm remains unresolved.

1. Check the wound dressing for air leaks. Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed or cooler in temperature. Address any identified leaks with transparent film or adhesive gel patches.
2. Ensure all connections are secure.
   - Dressing and canister tubing quick click connectors.
   - Y-connector quick click connectors, if applicable.
3. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister tubing quick click connector and gently pulling the connectors apart. Close the tethered caps of both connectors.
   - If the alarm continues, a leak exists within the canister or at the canister to device connection. Replace the canister. Refer to "Removing/changing canister" section of manual for more details. Contact your Smith & Nephew authorized representative if the alarm continues after restarting therapy.
   - If the alarm resolves, a leak exists within the wound dressing or tubing. Reassess and replace as needed.

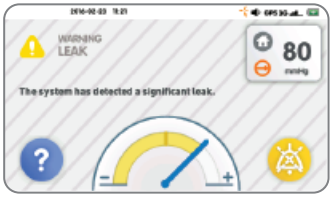
Note: If Low Vacuum alarm is due to a leak in system, the Leak alarm may also be triggered while the Low Vacuum alarm is active.

Leak

The system leak is greater than the allowable maximum leak threshold for > 45 seconds.

The device continues to operate but may not provide prescribed therapy.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen.



Troubleshooting

Do not pause therapy or power Off the device while performing the following troubleshooting steps. Use the on-screen flow meter to help find and correct sources of the leak. Assess the device after each step. Continue to next step only if alarm remains unresolved.

1. Check the wound dressing for air leaks. Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed or cooler in temperature. Address any identified leaks with transparent film or adhesive gel patches.
2. Ensure all connections are secure.
   - Dressing and canister tubing quick click connectors.
   - Y-Connector quick click connectors, if applicable.
3. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister quick click connector and gently pulling the connectors apart. Close the tethered caps of both connectors.
   - If the alarm continues, a leak exists within the canister or at the canister to device connection. Replace the canister. Refer to "Removing/changing canister" section of manual for more details. Contact your Smith & Nephew authorized representative if the alarm continues after restarting therapy.
   - If the alarm resolves, a leak exists within the wound dressing or tubing. Reassess and replace as needed.

Caution - lack of alarms: When a significant air leak is present in system, the Leak alarm will assert. However, if a blockage is present within system it may prohibit detection of a significant leak by the device, resulting in no alarm assertion. Potential sources of a blockage include:

- Physical occlusion in wound dressing (clot in filter, compacted gauze, high volume viscous fluid).
- Physical occlusion in tubing (kink in canister tubing, clot in tubing).
- Misaligned dressing opening to RENASYS® Soft Port aperture. Check dressing regularly to ensure therapy is being delivered.

Blockage

The system has detected a blockage within the canister, or the tubing or the internal canister filter is covered with exudate, which may occur even if canister does not appear visibly full.

Device continues to operate but may not provide the prescribed therapy.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen.

Troubleshooting

Do not pause therapy or power Off the device while performing the following troubleshooting steps. Assess the device after each step. Continue to the next step only if the alarm remains unresolved.

1. If one dressing is connected to the device, press the Home icon to navigate to the Home screen and ensure that the Y-Connect toggle icon is set to Y-Connect OFF .
2. Ensure all tubing and connections are free of any obstructions or kinks.
3. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister quick click connector and gently pulling the connectors apart. Leave open the tethered cap of the canister quick click connector and close the tethered cap of the dressing connector.
    - If the alarm continues, the blockage exists within the canister. Replace the canister. Refer to "Removing/changing canister" section of manual for more details. Contact your Smith & Nephew authorized representative if the alarm continues after restarting therapy.
    - If the alarm resolves, the blockage exists within tubing of the dressing. Reassess and replace as needed.

Note: Device orientation, rate at which fluid enters the canister and how exudate solidifies can impact filter occlusion. To optimize canister volume and alarm functionality, keep the device in the upright position.

Caution–lack of alarms:

- A Y-connector should be used when applying two dressings to a single wound. Setting Y-Connect On when only one dressing is connected to the device may cause nuisance alarms. Setting Y-Connect Off when two dressings are connected to the device may prevent blockage alarm from sounding. When Y-connecting two dressings to the device, regular monitoring of the wound is recommended. Ensure the dressing is fully compressed and firm to the touch. The system will only detect a blockage if both connections are blocked. The system will not detect a blockage existing in one of the Y-connected dressings; therapy will not be delivered through the blocked dressing.
- The blockage alarm will occur when the system detects a blockage between the canister and where the dressing tubing interfaces with the transparent film. A blockage within the wound dressing will not be detected by the system.
- If a blockage is present in the system but an air leak occurs between the blockage and the device, the alarm may not assert. Ensure that all connections are secure and there are no air leaks present in the system. Potential sources of air leaks include:
    - Cracked or damaged canister.
    - Misplaced or worn o-ring within the quick click connector.
    - Misplaced or worn o-ring on the device inlet port.
    - Damaged or tear in the dressing tubing or quick click connector.

Canister Full

The system has detected the canister is nearly full or the internal canister filter is covered with exudate, which may occur even if the canister does not appear visibly full.

Device continues to operate but may not provide the prescribed therapy.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen.

Troubleshooting

Pause therapy before performing the following troubleshooting steps. Assess the device after each step. Continue to the next step only if the alarm remains unresolved.

1. Replace canister and start therapy. Refer to "Removing/changing canister" section of manual for more details.
2. Inspect all tubing and connections for any obstructions or kinks. If alarm continues, contact your Smith & Nephew authorized representative for assistance.

Note: Device orientation, rate at which fluid enters the canister and how exudate solidifies can impact filter occlusion. To optimize canister volume and alarm functionality, keep the device in the upright position.

Low Battery

Battery has up to 2 hours therapy time remaining.

Upon battery depletion the device will stop delivering therapy and power Off.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm may be paused for approximately 15 minutes by pressing the Pause Alarm icon on the screen.
- The touchscreen dims to conserve battery life.

Troubleshooting

1. Plug device into an electrical (AC) outlet as soon as possible. The device can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy.

Critical Battery

The battery has only 3 minutes of therapy time remaining.

Upon battery depletion the device will stop delivering therapy and power Off.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen.
- The touchscreen dims to conserve battery life.

Troubleshooting

1. Plug device into an electrical (AC) outlet as soon as possible. The device can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy.

Battery Failed

Battery within device has failed to charge. Therapy can be continued only by keeping the device plugged into electrical (AC) power.

Device stops delivering therapy and powers Off. It will not power On again unless plugged into an electrical (AC) outlet.

- Status indicator light illuminates yellow when the device is powered On.
- There is no audible alarm.

Note: Battery Failure alarm only displays when device is connected to electrical (AC) power and powered On.

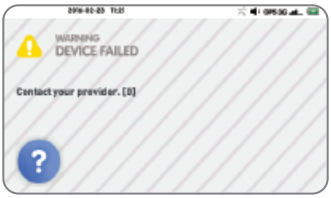
Troubleshooting

1. If the device has been exposed to temperatures outside its recommended temperature range, let the device return to room temperature.
2. Plug device into an electrical (AC) outlet; the device will not operate on battery power. Contact your Smith & Nephew authorized representative to obtain a replacement device.

Device Failed

The device has an unrecoverable error, potentially due to an internal hardware or software error.

Device stops delivering therapy.



- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.
- Audible alarm cannot be paused.

Troubleshooting

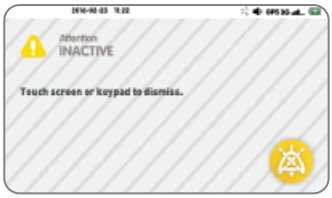
1. Power Off and restart device.
2. If alarm recurs note the failure code and contact your Smith & Nephew authorized representative.

Inactive

The device is powered On and has been left without user interaction for longer than 15 minutes.

Device continues to operate.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.



Troubleshooting

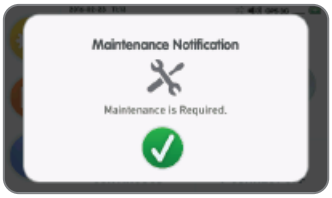
1. Touch anywhere on the screen to resolve alarm.
2. Select vacuum setting and start therapy or power Off device until therapy is required.

Annual Maintenance

The device is nearing time for the annual maintenance check. Therapy can be continued. The annual maintenance notification will display every time the device is powered On.

Device continues to operate.

- Status indicator illuminates yellow.
- Audible alarm sounds every 20 seconds.



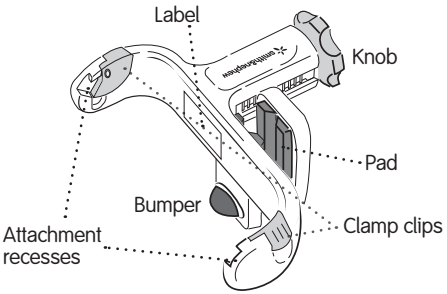
Troubleshooting

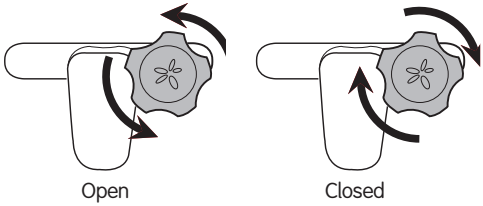
1. Press the Accept icon to close this notification screen and continue to the Home screen. Continue therapy as planned.
2. At the conclusion of the patient's therapy, notify your authorized service provider that annual maintenance is required. The authorized service provider will verify the device is in proper working order and reset the alarm timer.

Accessories

The device can be attached to an IV pole or the head or foot of the patient's bed.

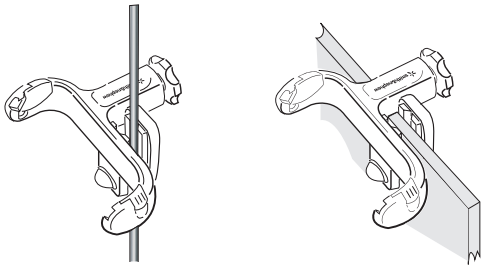
IV pole/bed clamp





Attach clamp to IV pole (up to 51mm/2in dia):

1. Twist knob to open clamp.
2. Align IV pole in center groove of clamp pad.
3. Twist knob to close clamp until firmly seated.

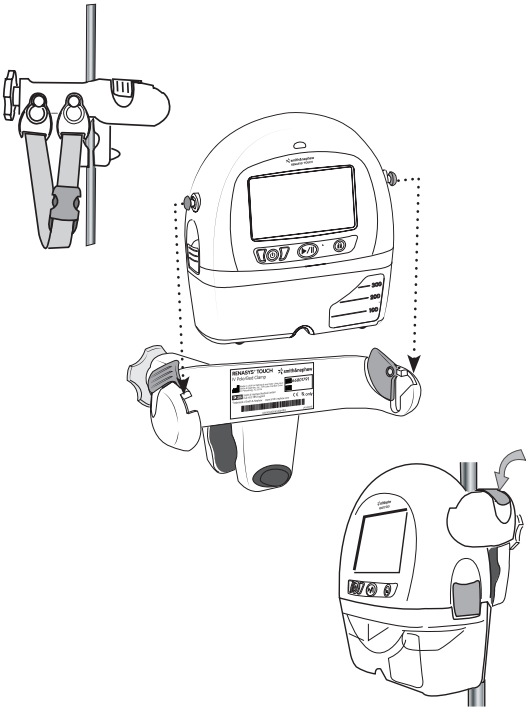


Attach clamp to bed board (up to 76mm/3in):

1. Twist knob to open clamp.
2. Place clamp over bed board.
3. Twist knob to close clamp until firmly seated.

Place device in clamp:

1. The clamp comes equipped with a holder for the carry straps. To utilize, remove carry straps from device and attach them to the carry strap holder on side of clamp (optional).
2. Align device attachment knobs with clamp attachment recesses.
3. Push device gently into clamp attachment recesses. The clamp's orange clips will open during installation.
4. Press down on the orange clamp clips to close.



Remove device from clamp:

1. Lift orange clamp clips.
2. Gently pull device from clamp attachment recesses.

Carry bag

The carry bag is single patient use.

To place device into bag:

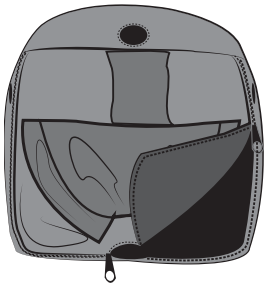
1. Open zippers on the back side of the bag.
2. Remove carry straps from device. Keeping the device in the upright position, slide bag over and down the device. Ensure attachment knobs are accessible through the bag on either side.
3. Close zippers and reattach carry straps.
4. Once fitted, ensure canister tubing can move freely.

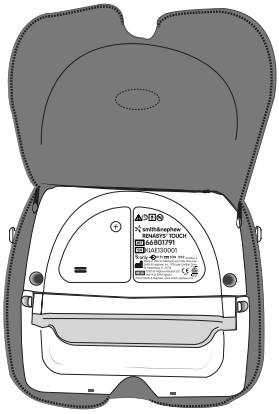
Note: It is recommended to Lock the device when using the carry bag.

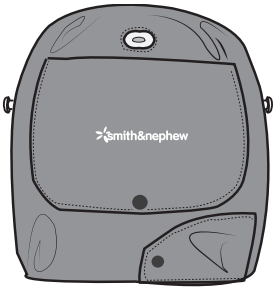
Caution: Ensure the device always remains in the upright position when placing the device in and while using the carry bag.

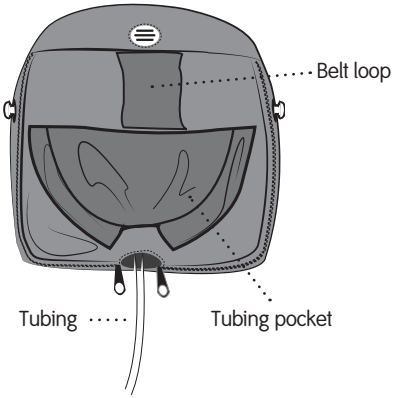
Bag features:

- Excess tubing can be fed through either the tubing hole under the pocket or through the bottom of the bag and coiled into the pocket on back of the bag.
- Flaps on the front of the bag are for the privacy of the user and can be lifted to access the touchscreen and buttons to view the canister.
- The card pocket under the front flap can hold a business card or contact information.
- A belt loop is located on the rear of the bag should you wish to wear the RENASYS® TOUCH at your waist.







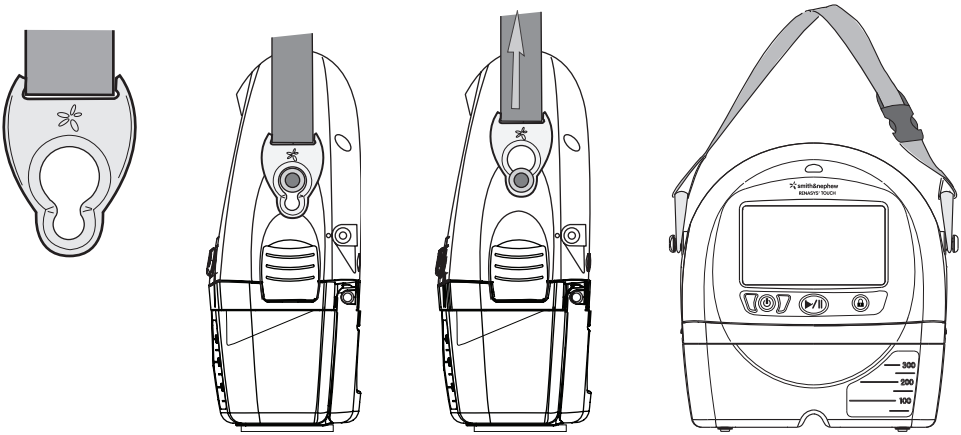


Carry straps

The carry straps are single patient use.

To attach the carry strap to device:

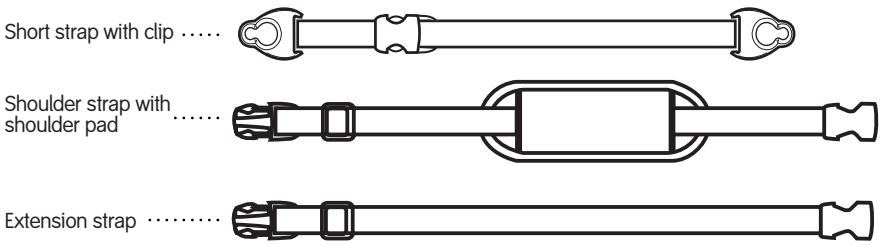
1. Slide the large opening of the carry strap clip over the device attachment knob.
2. Pull up on the carry strap clip. The clip will click when properly engaged. Repeat same process with other strap on opposite side of device.
3. Once both sides are connected to the device they can be joined together to make the short carry strap.
4. Push down on carry strap clip to remove strap from device.



Caution: Ensure the device always remains in the upright position when using the carry strap.

To connect and extend straps:

1. Join the carry strap connectors together for a short carry strap.
2. Join the carry strap connectors to the shoulder strap and/or extension strap connectors to extend the length for carrying on the shoulder or across the body.
3. Place the padded section of the strap against shoulder for maximum comfort when carrying device.



Maintenance

Inspect device for visible signs of damage before each use, including canister and tubing. Do not use if device has been dropped or shows signs of damage. Return damaged device to your Smith & Nephew authorized representative in original packaging supplied.

Visually inspect the device inlet port O-ring for damage and if replacement is needed, consult your service manual or return to your Smith & Nephew authorized service provider.

O-ring and odor filter should be replaced at a minimum once per year as part of the annual maintenance check performed by an authorized service provider.

There are no serviceable parts inside device. Do not attempt to open the device. Contact your Smith & Nephew representative, distributor or authorized provider if service is required.

Caution: Never attempt to service the device while connected to a patient.

Cleaning Precautions

Do not use solvents or abrasives that will degrade plastic housing, rubberized push buttons or touchscreen.

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

Carry bag and carry straps are designed for single patient use.

Cleaning

Cleaning of RENASYS® TOUCH device, power supply outer casing and IV pole/bed clamp should be performed to remove any soil or debris whenever there is a change in patient in the following steps:

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

Carry bag and straps are for single patient use and should be discarded when a patient's therapy is complete.

Carry bag and straps may be cleaned during a single 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.

During use it is recommended that the surface of the device and touchscreen 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. This will prevent soils from drying on the surface of device and remove oils and smudges from the touchscreen. Always follow facility protocols or local ordinances for cleaning and handling of potentially infected or bio-hazardous materials.

Disinfecting

After cleaning, the device may be disinfected as described below.

Recommended solutions for disinfection:

- 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.

Refer to RENASYS TOUCH Service Manual (REF 66801289) for service and maintenance performed on the device after each patient use.

Annual Maintenance

When the device reaches time for the annual maintenance check, an annual maintenance notification will display every time the device is powered On. Refer to "Annual Maintenance" under "Alarms/ Troubleshooting" section for details on the notification. Notify your authorized service provider that annual maintenance is required. The authorized service provider will verify the device is in proper working order and reset the alarm timer.
O-ring and odor filter should be replaced at a minimum once per year as part of the annual maintenance check performed by an authorized service provider.

Battery operation and charging

To allow user greater mobility, the device contains a lithium ion rechargeable battery that requires a full charge before initial use. A fully charged battery will last between 8 to 16 hours. Disconnect the device from AC power prior to mobile use.

When the device is powered On, the battery indicator at the top of touchscreen (see Glossary of Symbols) will display the battery status. The device will indicate when battery is low. In the event of a Low Battery or Critical Battery alarm, an audible alarm sounds, an alarm screen will display, the status indicator illuminates yellow, and the screen dims to conserve battery life. Plug device into an electrical (AC) outlet as soon as possible when a battery alarm occurs.

If battery operation is required for first use of the device, the battery must be charged from AC power until the battery indicator is green.

To charge battery:

1. Connect the power supply DC cord into the device power jack.
2. Connect the power cord into the power supply.
3. Plug the power cord into an electrical (AC) outlet.
4. Verify green external power indicator illuminates.

Battery charges both during device operation without interrupting therapy and when device is turned Off and not in use. It is recommended to keep device plugged in during use when patient is not mobile. The device can be used on battery power to allow user greater mobility. If device is fully charged and is not going to be used further, disconnect power supply and power cord from device and electrical (AC) outlet.

Caution: Keep device away from direct heat sources during charging.

Caution: Charging the device while in the carry bag may result in elevated operating temperature that causes the device to suspend charging until it cools. The device continues to operate. To reduce the operating temperature of the device, remove it from carry bag or move it into an environment with a lower ambient temperature. When the device cools, charging will resume automatically.

Caution: Care should be taken to ensure the power supply used for charging is not covered by blankets or clothing to avoid a fire hazard.

Returning the device

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

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

Storage and battery maintenance

The device should be stored between 5°C to 40°C (41°F to 104°F) for optimal battery performance but can be stored between -25°C to 70°C (-13°F to 158°F) for short periods of time. Some battery discharge may occur in storage.

If the device is stored for longer than 6 months, battery should be fully charged before use.

If the device indicates that battery is still charging after more than 8 hours of continuous charge, contact your Smith & Nephew distributor or authorized provider.

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

EN

Electromagnetic compatibility RENASYS° TOUCH

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2007. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and manufacturer's declaration - electromagnetic immunity
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV I/Os	± 2 kV for power supply lines ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	same same same same	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery
NOTE *U_T is the a.c. mains voltage prior to application of the test level*			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8		400 A/m 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile communications equipment should be separated from the device by no less than distances calculated/listed below: **Recommended separation distance:** $d = 0.35\ \sqrt{P}$ $d = 0.175\ \sqrt{P}$ (80 MHz to 800 MHz) $d = 0.35\ \sqrt{P}$ (800 MHz to 2.5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20 V/m	

NOTE 1: At 80 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds 3V/m, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic emissions RENASYS° TOUCH (REF 66801791)

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-2	Comply	

WARNING: The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter (m):**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
(W)	d = 0.35 √P	d = 0.175 √P	d = 0.35 √P
0.01	0.03	0.02	0.03
0.1	0.1	0.05	0.1
1.0	0.3	0.2	0.3
10	1.1	0.5	1.1
100	3.5	1.7	3.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Radiofrequency radiation exposure information

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the Smith & Nephew accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

Antenna Statement

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Canadian Department of Communications Compliance Statement

CAN ICES-3(B)/NMB-3(B)

Specifications

Vacuum	
Continuous Therapy Levels	25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200mmHg
Intermittent Therapy Levels	High: 25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200mmHg Low: 0, 25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180mmHg
Intermittent Therapy Cycle Times	High: 3, 5, 8, 10 minutes Low: 2, 3, 5, 8, 10 minutes
Alarms	
General (all alarms)	
Priority	Low
Auditory Sound Level	Low: 60 dB Medium: 68 dB High: 74 dB (1 metre from device)
Indicator Color	Yellow
Overall alarm delays	
Over vacuum	Less than 5 seconds
High vacuum Continuous Mode Intermittent Mode	 180 seconds 60 seconds
Low vacuum	60 seconds
Leak	45 seconds (not time based)
Blockage	120 seconds
Canister full	45 seconds
Low battery	Immediate
Critical battery	Immediate
Battery failed	30 seconds
Inactive	15 minutes
Annual maintenance	Immediately following startup sequence
Device failed	30 seconds
Power Requirements	
Device input voltage	19.5 VDC
Device input power	50 W
Mains Adapter	Smith & Nephew REF 66801286 Input: 100-240VAC, 50/60HZ, 10-35VA Output: 19.5VDC, 2.6A, 50W Fuses: Internal electronic fuse, not user changeable

Physical	
Dimensions	180 x 190 x 76mm (7" W x 7.5" H x 3" D) with 300ml canister
Weight	1.1 kg (2.4 lbs) with 300ml canister
Sound Level	
Normal Operations	No alarms: <43.7 dB
Battery	
Operating Time	~ 10-16 hours (therapy) when operating from 25mmHg to 120mmHg ~ 8 hours (therapy) at 200mmHg
Type	Lithium-ion
Compliance	UL 2054 / IEC 62133
Safety Protection	
Protection Against Electric Shock	Device internally powered; external power supply. Class II.
Patient Protection	Type BF
Ingress Protection	IP22
Environmental	
Short term storage and transport temperature	-25 to 70°C (-13 to 158°F)
Long term storage temperature	5 to 40°C (41 to 104°F)
Operational temperature	5 to 40°C (41 to 104°F)
Relative Humidity	15% to 93% RH
Atmospheric Pressure	700mbar to 1,060mbar

Compliance	
	UL 60601-1
	IEC 60601-1
	IEC 60601-1-2
	IEC 60601-1-6
	IEC 60601-1-8
	IEC 60601-1-11
	IEC 62366
	IEC 62304
	CAN/CSA C22.2
	RTCA/DO-160G
	IEC CISPR 25
	EN 50121-3-2 – Part 3-2
	ISO 14708-4
	FCC IC: 2AEAJ-66801791
	IC ID: 20634-66801791
	Wireless directive 99/5/EC
	Wireless directive 2014/53/EU

Intended location of operation

This equipment may be operated in:

BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY
LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI
SE	UK	US	AU	NZ	CA	ZA						

Replacement parts and accessories

The following products are available from Smith & Nephew. Contact Smith & Nephew Customer Assistance for availability and ordering information.

Part description	REF (product catalog number)
RENASYS® TOUCH Device	66801791
RENASYS® TOUCH Class 2 Power Supply	66801286
RENASYS TOUCH Power Cords	
Australia and New Zealand Power Cord	66801560
China Power Cord	66801561
Japan Power Cord	66801562
Brazil Power Cord	66801563
North America & Philippines Power Cord	66801564
United Kingdom Power Cord	66801565
Continental Europe Power Cord	66801566
South Africa and India Power Cord	66801567
RENASYS TOUCH Clinician User Manual	66801792
RENASYS TOUCH Home Healthcare User Manual	66801793
RENASYS TOUCH 300ml Canister with solidifier	66801273
RENASYS TOUCH 800ml Canister with solidifier	66801274
RENASYS TOUCH 300ml Canister without solidifier	66801275
RENASYS TOUCH Carry Strap	66801276
RENASYS TOUCH Carry Bag	66801277
RENASYS TOUCH IV Pole/Bed Clamp	66801278
RENASYS TOUCH Transit Case	66801279
RENASYS TOUCH Service Manual	66801794
RENASYS TOUCH O-ring	66801283
RENASYS TOUCH Odor Filter	66801284

Caution statements

In order to ensure safe and proper performance, the following conditions must be met:

- All assembly, operation, adjustment, maintenance and/or repair should be carried out by qualified personnel authorized by Smith & Nephew.
- No modification of this equipment is allowed.
- If device is damaged, the performance could be affected; do not use device. Contact your Smith & Nephew authorized representative.
- Use only the AC power cord provided with the device to prevent the potential for electrical shock hazard.
- If power supply or power cord are damaged, wires are frayed or exposed, do not use; use device's battery power.
- When necessary, the device may be isolated from AC supply mains by removing the detachable AC power cord.
- The electrical installation of the room must comply with the appropriate electrical wiring standards.
- The product must be used in accordance with this User Manual and all applicable labeling.

Battery Cautions

- This product contains a lithium ion battery that is not serviceable by the user.
- Recharging of the battery should only be done using Smith & Nephew approved power supply and power cord specifically designed for use with this product.
- Follow local guidelines and the battery label for proper disposal.
- Improper disposal of the lithium ion battery may result in fire, explosion and burns.
- Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100°C.
- Handle damaged or leaking batteries with caution to avoid injury.
- Failure to comply with these conditions will void any pertinent warranties.

This User Manual is not intended as a guarantee or warranty. It is intended only as a guide. For medical questions, please consult a physician. For additional product information, or a specific product question, please refer to the numbers listed in the "Global Customer Assistance" section of this User Manual.

Radio communication statements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by Smith&Nephew could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Essential performance (IEC 60601-1:2005, 3rd Edition)

Essential Performance of the RENASYS° TOUCH, for safe operation, is to maintain the vacuum delivered by the device within its specification for pressure selected, to provide Negative Pressure Wound Therapy (NPWT).

Confirmation of the proper device operation should only occur with BioMedical Engineering assistance. Contact your Smith & Nephew representative, distributor or authorized provider if service or additional guidance is required. These conformational checks are expected to occur between patients.

Declaration of Conformity

Hereby, Smith&Nephew, declares that this RENASYS TOUCH is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. The declaration of conformity may be consulted at www.smith-nephew.com/DoC.pdf.

Hereby, Smith&Nephew, declares that this RENASYS TOUCH is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC and the DoC in the language of the manufacturer.

LIMITED WARRANTY LIMITATION OF REMEDIES/LIABILITY:

The Smith & Nephew negative pressure wound care electro-mechanical device ("Device") is warranted against defects in workmanship and materials for the warranty period specified below ("Warranty Period"). Smith & Nephew reserves the right to discontinue any Device or change any Device's specifications or designs from time to time. For any Device that fails to meet the foregoing warranty, this warranty provides and is restricted to replacement or repair (onsite service not included) as elected by Smith & Nephew in its sole discretion. If Smith & Nephew replaces a Device under this warranty and requests Customer to return the Device that was replaced, Customer will be invoiced, at Smith & Nephew's then current list price, for the replacement Device if Customer does not return the replaced Device within thirty (30) days after Smith & Nephew's shipment of the replacement Device. This warranty does not cover and is voided by any of the following: (i) a warranty claim not made within the first to occur of expiration of the Warranty Period or thirty (30) days following the failure of the Device to perform as warranted; (ii) a Device packaged or labeled by someone other than Smith & Nephew or its authorized agents; (iii) a Device not used in compliance with the specifications, instructions or claims for use of the Device; (iv) a Device used in conjunction with disposables, accessories or any other products not specified for use with the Device; (v) a Device used in conjunction with expired or reprocessed disposables, accessories or other products specified for use with the Device; (vi) modification of the Device; (vii) damage due to misuse, reprocessing, alteration, unauthorized repair or negligent handling or damage due to lack of care by the owner, user, or handler of the Device including but not limited to storage, handling or cleaning; and (viii) any other damage inflicted to a Device by the owner, user or handler. This warranty applies only to the original buyer from Smith & Nephew or its authorized distributor and is not transferable.

THIS WARRANTY IS THE SOLE WARRANTY OF SMITH & NEPHEW. ALL OTHER WARRANTIES OF ANY KIND OR DESCRIPTION WHATSOEVER, INCLUDING WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY AND FITNESS FOR A PARTICULAR PURPOSE, EXPRESSED OR IMPLIED, ARE EXCLUDED TO THE FULLEST EXTENT PERMITTED BY LAW.

Device	Warranty Period
RENASYS® NPWT electro-mechanical devices (inclusive of the power cord and power supply)	Two (2) years from date of delivery to original buyer

CUSTOMER'S SOLE REMEDY, AND SMITH & NEPHEW'S SOLE LIABILITY, FOR ANY CLAIM WILL BE THE REPAIR OR REPLACEMENT BY SMITH & NEPHEW AS PROVIDED FOR IN THIS WARRANTY. EXCEPT FOR THIS LIMITED LIABILITY OF SMITH & NEPHEW, SMITH & NEPHEW UNDER NO CIRCUMSTANCES WILL BE LIABLE FOR ANY (A) CLAIM, FOR DAMAGES OR OTHERWISE, WHETHER ARISING FROM BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND WHETHER OR NOT BASED ON OR FLOWING DIRECTLY, INDIRECTLY OR AS A CONSEQUENCE OF A WARRANTY CLAIM, BREACH OF CONTRACT, A TORT, BREACH OF LAW, OR ANY OTHER CAUSE OR LEGAL THEORY, OR (B) DIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, LOSSES OR EXPENSES ARISING FROM THIS AGREEMENT OR ITS PERFORMANCE OR LACK THEREOF, OR IN CONNECTION WITH THE SALE OR USE OF, OR INABILITY TO USE, THE DEVICE, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFIT OR ANTICIPATED SAVINGS, LOSS OF ANTICIPATED PROFIT, COST OF COVER FOR REPLACEMENT OR ALTERNATIVE PRODUCT, ECONOMIC LOSS, LOSS OF DATA, WASTED EXPENDITURE OR LOSS OF REPUTATION OR GOODWILL.

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Icon and symbol glossary

Operation buttons

Power Press and hold for 2 seconds to power On or Off device

Start/Pause Therapy Press to begin therapy. Press to pause therapy when therapy is active

Lock/Unlock Press and hold for 2 seconds to lock or unlock touchscreen and Start/Pause Therapy button

Status indicator

Green	Therapy is active All conditions normal
Yellow	Alarm state Attention required
Off	No therapy; inactive

External power indicator

Green	Device connected to power supply
Off	Device not connected to power supply

Status bar

YYYY-MM-DD	Date
HH:MM	Time

Therapy indicator

- Not delivering therapy: gray
- Delivering therapy: rotating orange

Alarm volume indicator

- High volume: three bars
- Medium volume: two bars
- Low volume: one bar

3G GPS indicator

GPS 3G
- High signal strength

GPS 3G
- No signal strength

Battery indicator

- Batterie Battery full/charged: green: vert
- Battery charging: lightning bolt
- Battery low: yellow
- Battery critically low: empty with red line
- Battery failure: gray with red line

Home and delivering therapy screens

Increase set point

Decrease set point

Continuous therapy mode
Maintains selected therapy level

Intermittent therapy mode
Cycles between selected set points of active therapy and low/no therapy

Y-Connect Off
Select if connecting one dressing to device

Y-Connect On
Select if connecting two dressings to device

Navigate to **Home** screen

Interface locked
When displayed behind therapy set point, indicates touchscreen and **Start/Pause Therapy** button are locked

5 min
Current Intermittent therapy cycle time

0 mmHg | 2 min
Next Intermittent therapy set point and cycle time

Menu navigation

Settings
Press to access the settings menu

- Alarm volume
- Compression rate
- Change mode Clinician
- Change mode Patient
- Change Mode Maintenance
- Language
- Time zone
- Flow meter
- Send Data
- Restore Presets
- 3G GPS
- Device information

Therapy log
Press to access the log screen

- Overview Toggle
- Detailed View Toggle

Help*
Press to access Help menu

- Start Video
- Pause Video
- Increase Video Volume
- Decrease Video Volume

Home*
Press to navigate to the Home screen

Back*
Return to the previous screen

Accept
Press to continue task

Cancel*
Press to cancel task or close screen

Alarm screens

Alarm indicator
Indicates an error in the system

Return to Alarm Screen
Press to return to alarm screen you navigated away from

Help
Press for troubleshooting assistance

Pause Alarm
Press to temporarily silence audible alarm

Alarme Alarm silenced
Audible alarm is temporarily silenced

Active Therapy display and Home icon
Displays active therapy set point and therapy mode (Blank if therapy is not active)

Press to navigate to Home screen

Continuous therapy

Intermittent therapy

Flow Meter
Assists in locating leaks in the system

* Note: icons may appear in different colors on different screens

Direct current

ETL listing mark

Manufacturer

Refer to instruction manual/booklet

Caution refer to instruction

Do not use if package is damaged

Biological risk

IP22 Enclosure protected against ingress of small objects and dripping water

STERILE EO Sterilized using Ethylene oxide

U.S.A Federal Communications Commission identifier

For products with additional instructions inside the package

Keep dry

25°C/ -13°F 70°C/ 158°F Storage temperature limit

Date of manufacture

EU: WEEE symbol not for general waste

15% 93% Relative humidity limitiation

Keep away from sunlight

70kPa 106kPa Atmospheric pressure

MR MRI Unsafe keep away from magnetic resonance imaging (MRI) equipment

EC REP Authorized European representative

Class II equipment IEC 60417-5172

0682 CE mark for radio equipment and telecommunication terminal equipment

Single use: do not reuse

LOT Batch code

SN Serial number

REF Product catalogue number

Input Port IEC 60878-5034

0086 CE mark

Non-ionizing electromagnetic radiation

Rx only Caution: U.S. Federal law restricts this device to sale by or on the order of a physician

Defibrillation-proof type BF applied part

Recycle