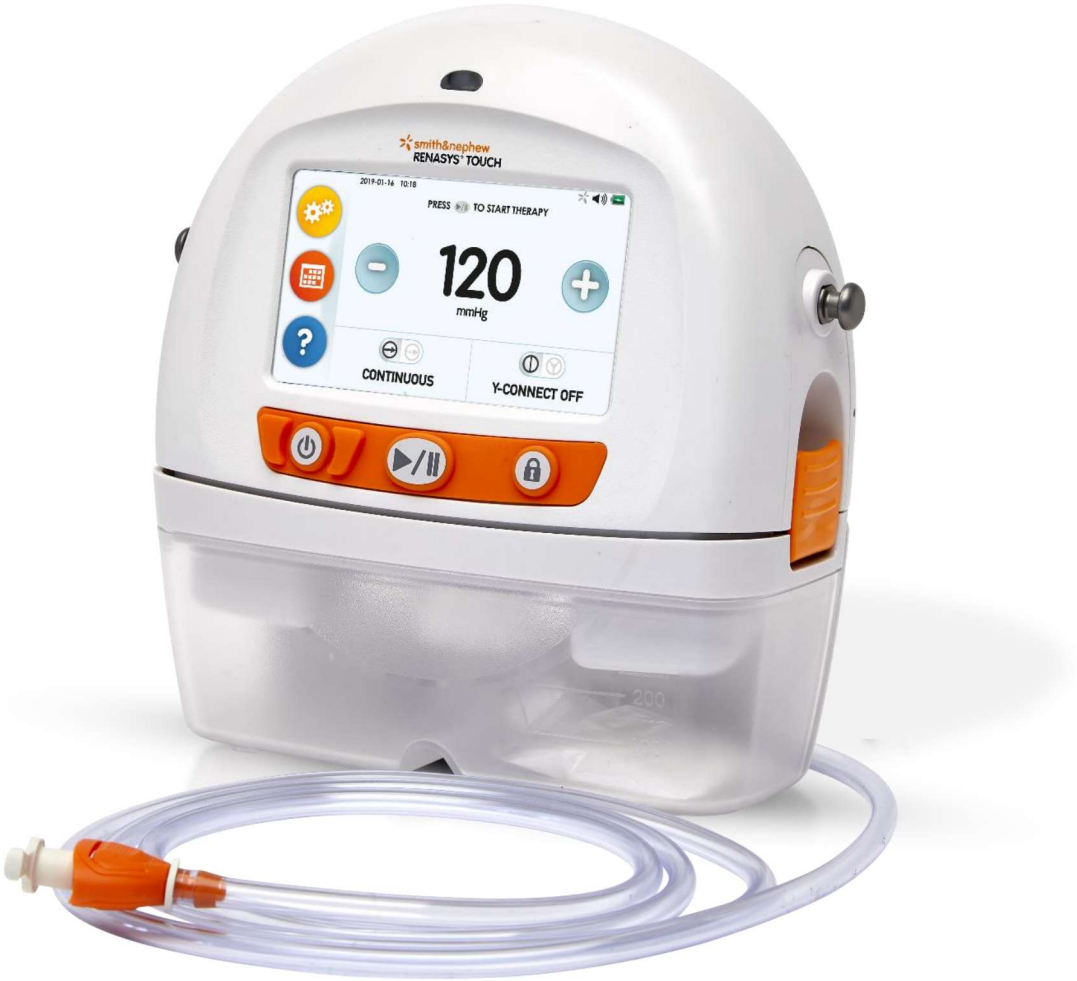
Advanced Wound Management

Smith+Nephew

Tender toolkit

RENASYS◇ TOUCH Negative Pressure Wound Therapy System 66802134



Tender toolkit

This tender booklet has been designed to provide the necessary RENASYS◇ TOUCH information to populate the key tender criteria. The document contains details of product composition, testing data and packaging information plus many FAQs.
For tender queries that cannot be satisfied using the information contained within this booklet please email GB, Wound Product Support.
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Product description

RENASYS TOUCH◇ pump is designed to provide Negative Pressure Wound Therapy (NPWT) to a closed environment over a wound in order to evacuate exudates from the wound site to a disposable canister, 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 dressing to the wound and connecting the sealed wound to the suction pump
**Taken from Instructions for Use (IFU).*

Intended use

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, the 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 use of a double insulated Class II power supply and Class II power cord.

Indications for use

Appropriate wound types include:

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

Contraindications

Use of NPWT is contraindicated in 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
- Exposed anastomotic sites

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 haemostatis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that, if disrupted, may increase 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 pump.

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 the pump from the wound dressing prior to defibrillation. Remove wound dressing only if its location will interfere with defibrillation.

7. The pump is not MRI compatible. Do not bring the pump into MRI suite. Prior to entering MRI suite, disconnect pump from dressing. The dressing can remain intact on patient.

8. Pump is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).

9. When operating, transporting or disposing of pump and accessories, there is risk of infectious liquids being aspirated or contamination of pump assembly through incorrect use. Universal precautions should be observed whenever working with potentially contaminated components or equipment.

10. Pump and canister are provided non-sterile and should not be placed within a sterile field.

11. When using a Y Connector the system will only detect a blockage if both connections are blocked

Precautions

1. More frequent pump 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 difficult wound hemostasis
- Untreated for malnutrition
- Noncompliant or combative
- Suffering from wounds in close proximity to blood vessels or delicate 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, pump 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 canister viewing window 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 pump 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 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 wound bed, including fistula opening, with non-adherent gauze or with one layer of saline moistened gauze. During the course of treatment, patient's fluid levels must be closely monitored.

Precautions

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 pump 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 risk of tissue in-growth. Tissue in-growth may be reduced by decreasing 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 pump and wound site during therapy to ensure therapeutic treatment and patient comfort.

17. Pump is only to be used with Smith & Nephew authorized components. Use of any other products have not been proven safe and effective with RENASYS◇ devices.

18. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position pump and tubing appropriately to avoid risk of a trip hazard.

Precautions

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

20. When bathing or showering patient must disconnect from the pump, protecting both ends of tubing using tethered caps. Ensure aeration disc located near orange quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.

21. If any liquids penetrate device, discontinue use and return to your Smith & Nephew authorized provider for service.

22. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible move pump out of x-ray or scanner range.

23. The pump is not suitable for use in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

24. AC mains power can only be removed by disconnecting power cord. Take care in positioning the pump to allow access to the power jack.

25. 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.

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

27. Canisters are single-use devices. Do not reuse.

28. 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.

29. 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.

30. 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.

31. Due to its smaller diameter, The RENASYS-G 10Fr Round Drain Gauze kit and accessory kit are not reconmeneded for use with RENASYS TOUCH, as reduced pressure in the wound bed may lead to pooling or maceration.

Phyicians 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 ound Therapy (NPWT) are met.

All orders should include:

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

Product codes

Product code	Product description	Market sold
66802134	RENASYS◇ TOUCH	Global, US, Japan

Manufacturing process

Sterile	Product is not sterile
Sterilisation method	N/a
Shelf life	3 years with PPM upgrade for + 3 years
Storage	Short term storage and transport temperature -25℃ to 70℃ Long term storage temperature 5℃ to 40℃ for optimal battery performance. Relative humidity 15% to 93% RH Atmospheric pressure 700mbar to 1060 mbar

S+N Range compatibility

RENASYS- Foam Dressing Kit with Soft Port	66800794 (small), 66800795 (medium), 66800796 (Large), 66800797 (XL) – Global Foam kits 66020794 (small), 66020795 (medium), 66020796 (large), 66020796 (XL) – US Foam kits 66801668 (small), 66801669 (medium), 66801670 (large), 66801671 (XL) – Nordic Foam kits

	66801088 (small), 66801089 (medium), 66801090 (large) – Japanese Foam kits
RENASYS◇-G Gauze Dressing Kit with Soft Port	66800933 (Small), 66800934 (medium), 66800935 (large), 66800936 (XL), 66800961 – Global Gauze kits 66020933 (small), 66020934 (medium), 66020935 (large), 66020936 (XL), 66020961 – US Gauze kits 66801665 – Nordic Sterile Gauze kit
RENASYS AB Abdominal Dressing Kit with Soft Port	66800980 – Global 66021980 – US 66801672 - Nordic
RENASYS Drain Accessory kits	66801252, 66801253, 66801254 – Global
RENASYS-G Drain Gauze Dressing kits	66801256, 66801257, 66801258 - Global
RENASYS White Foam	66801787, 66801788 - Global
Y Connector & Softport	66800971, 66800799 – Global 66020971, 66020799 - US
RENASYS Gel Patch	66801082 – Global inc USA
ACTICOAT◇ Flex 3	66800435, 66800419, 66800409 Global

Country of origin

Product code	Country of Origin	Markets Registered
66802134	US	Global (Including US & Japan)

Selling units

Product code	Product description	Number of pumps per shipper case
66802134	RENASYS◇ TOUCH	1

Packaging dimensions

Product code	Length (mm)	Height (mm)	Depth/Width (mm)
Case			
66802134	310mm	210mm	215mm

Packaging configurations

Product code	Selling unit	Cases per pallet	Layers per pallet	Cases per layer	Pumps per pallet
66802134	Case	96	6	16	96

Global Medical Device Nomenclature (GMDN) Code

The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed terms used to identify medical devices. It is used by regulators, hospitals and manufacturers to identify medical devices that are of the same generic type. The codes below however do not apply in Australia which have their own set of terms to identify medical devices.

GMDN code	47955

Medical device classification

Device classification	Class IIb (EU)

Regulatory clearance date

SKU's	CE Mark
66802134	19th January 2019 FDA Clearance: January 2021 Japan PMDA:

Regulatory standards

☐ UL 60601-1
☐ IEC 60601-1
☐ IEC 60601-1-2
☐ IEC 60601-1-6
☐ IEC 62366
☐ IEC 60601-1-8
☐ IEC 60601-1-1
☐ CAN/CSA C22.2
☐ RTCA/DO-160G
☐ IEC CISPR 25
☐ EN 50121-3-2
☐ ISO 14708-4

☐ IEC 62304 – Software lifecycle

Global trade item numbers/EAN numbers

Product code	Product description	Item barcode
66802134	RENASYS◇ TOUCH	1 Pump: 05000223495046

Therapy settings

Continuous therapy	25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200mmHg
Intermittent therapy	High: 25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 mmHg Low: 0, 25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180 mmHg

Alarms

Alarms	Response from the pump
Priority (for all alarms)	Low
Auditory sound level (for all alarms)	Low: 60 dB Medium: 68 dB High: 74 dB (1 metre from pump)
Indicator colour	Yellow
Over vacuum alarm delay	Less than 5 seconds
High vacuum: Continuous mode Intermittent mode	 180 seconds 60 seconds
Low vacuum	60 seconds
Leak	45 seconds
Blockage	120 seconds
Canister full	45 seconds
Low battery	Immediate
Critical battery	Immediate
Battery failed	30 seconds
Inactive	15 minutes
Annual maintenance	Immediately following start up sequence
Device failed	30 seconds

Specifications

Dimensions (w x h x d):	180mm x 190mm x 76mm (7” x 7.5” x 3”) with 300ml canister

Weight:	1.1kg (2.4 lbs) with 300ml canister
Display:	109.2mm (4.3”) dia. projected capacitive touch (PCAP) display with durable, protective screen overlay
Device sound level:	No alarms: <43.7 dB 1.6.9
Battery:	Lithium ion; UL 2054 / IEC 62133 compliant
Battery operation/charge time:	10 – 16 hours (therapy) when operating from 25mmHg. 8 hours (therapy) when operating at 200mmHg
Lock/unlock button:	Prevents actuation of the touchscreen and Start/Pause therapy button
Patient mode (HHC lock):	Restricts access to therapy settings – set points, cycle times, therapy mode and Y-connector selection, settings menu and maintenance mode.
IEC 60601	2nd, 3rd and 3.1 Edition packages, plus IEC 60601-1-2 3rd and 4th Edition compliant for facility and home healthcare environments
Accessories	Bag, Carry Strap, IV Pole/Bed Clamp
Ingress protection (IP rating)	IP34
Canisters (size)	300ml with and without solidifier, 800ml with solidifier
Languages	English, German, French, Spanish, Italian, Swedish, Finnish, Norwegian, Danish, Netherlands, Portuguese, Turkish, Japanese, Chinese, Thai, Korean, Greek, Russian, Estonian, Lithuanian, Latvian, Polish, Czech, Bulgarian, Hungarian, Croatian, Romanian, Slovakian, Slovenian, Arabic
Size of the RENASYS◇ TOUCH odour filter	24mm x 38mm x 12mm

Latex information

The following products do not contain latex as an ingredient. However we regret, that unless the product is clearly labelled as ‘Latex Free’ we cannot guarantee that its components have not come into contact with latex proteins during manufacture, storage and distribution. (For the full RENASYS range please consult the Product support sharepoint under RENASYS there will be a Latex statement).

Product Description	**Product SKU**
RENASYS TOUCH	66802134
RENASYS TOUCH 300ml cannister	66801275
RENASYS TOUCH 300ml cannister with soldifier	66801273
RENASYS TOUCH 800ml cannister with solidifier	66801274

RENASYS TOUCH use at Height

All testing has been carried out on RENASYS TOUCH 66802134, where no alarms or loss of performance were observed. The pump is considered acceptable for airborne use. The summary below provides further information:

60601-1-2 (Medical electrical equipment. General requirements for basic safety and essential performance) has two main categories, Hospital and Home/uncontrolled. RENASYS TOUCH 66802134 has been cleared for both hospital and home use environments as per 60601-1-2. The standard also directs the manufacturer to specific standards that cover uncontrolled environments such as DO-160G (Environment Conditions and Test Procedures for Airborne Equipment). The standard includes testing that confirms the device can be used on an aeroplan.

RTCA DO-160G. Mechanical Sections in scope:

- Section 8. 8. 3 Random Test procedure for Category U2, Unknown Helicopter frequencies
- Section 8. 7. 2 Random Test procedure, Category R Fixed Wing, Curves C and C1, Robust Random Vibration
- Section 7. 2 Operational Shocks
- Section 4. 6. 1 Altitutde Test

RTCA DO-160G. EMC Sections in scope

- DO-160G Section 21.5 Radiated RF Emissions
- DO-160G Section 21.4 Conducted RF Emissions
- DO-160G Section 20.5 Raidiated Susceptibility
- DO-160G Section 20.4 Conducted Suscpetibility

Service and Repair

For countries located in North and South America (Excluding Brazil), RENASYS◇ TOUCH service and repair will be performed at the Smith & Nephew ASD service and repair centre in Oklahoma City (OKC), Oklahoma, USA. In Brazil, RENASYS TOUCH service and repair will be performed at the Smith & Nephew service and repair centre in Sao Paulo.

For all other markets (Excluding Australia/New Zealand, South Africa and the UK), service and repair will be performed at the Smith & Nephew ASD service and repair centre in Tuttlingen, Germany. In Australia/New Zealand, RENASYS TOUCH service and repair will be performed at the Smith & Nephew service and repair centre in Melbourne.

In South Africa, RENASYS TOUCH service and repair will be performed at the ADP service and repair centre in Pretoria.

In the UK, RENASYS TOUCH service and repair will be performed at the Avensys and or Smith & Nephew Godmanchester service and repair centre in England.

Setting up additional regional service and repair centres for RENASYS TOUCH will be established once market volumes are appropriate and should be discussed with Brett Morgan.

Information and questions regarding the internal service and repair processes and procedures should be directed to:

Brett Morgan, Global Service and Repair Manager, Hull, UK

brett.morgan@smith-nephew.com

Technical support to assist with customer owned and rental fleet pumps is provided through service providers, distributors, selling companies and salesforce troubleshooting. Should further support be required, contact the product support team:

woundproductsupport.gb@smith-nephew.com

System Monitoring Functionality

The principal of the monitoring system of the RENASYS TOUCH System is based on continuously monitoring pressure and the air flow travelling through the system, starting at the RENASYS Softport and finally exhausting via the back of the pump.

The system expects a certain level of air flow based on the settings selected on the device. A small amount of intended air flow enters the system downstream of the pump via the aeration disc which is part of the RENASYS Softport.

If the airflow increases or decreases this correlates to a system state change. If the expected airflow decreases to a pre-defined level, then this correlates to a potential blockage in the system and the device will assert the blockage alarm to inform the user. If the air flow increases from the expected airflow, this correlates to a leak (commonly from the dressing seal around the wound site). The system will respond by increasing the RPM of the pump to a pre-determined ramp up to compensate for the leak. If the air leak in the system exceeds a pre-defined threshold, the system will assert a leak alarm to inform the user.

If the system is performing as expected and the airflow is correct, the rate of the pump will be sufficient to ensure that the correct level of NPWT is being applied to the wound and that excess fluid is withdrawn and collected in the RENASYS TOUCH canister to prevent potential excessive fluid within the wound bed.

Fluid rates are pre-determined based on expected exudate levels for given wound sizes and volumes. The pumping capacity of the device correlates to system settings to deliver the correct level of NPWT. If the system is in 'normal state' than the selected therapy level will be delivered to the wound and the excess fluid removed. This correlation is verified via in *vitro testing*. [1]

FAQs

RENASYS System FAQ's

What is the flow rate of RENASYS TOUCH pumps?

9.25 Litres/minute free flow without canister and tub set.

What intrinsic mechanism is there in the RENASYS system to prevent backflow if machine is powered off?

Firstly the aeration disc (if Soft Port) or the CLP T-piece provides a flow of air that ensures that the air flow, once the machine is powered off, is away from the wound and towards the canister until the vacuum is dissipated. Secondly the gelling agent helps to retain the liquid in the canister (when the canister includes a solidifier).

How does RENASYS TOUCH monitor pressure?

RENASYS TOUCH continuously monitors the pressure delivered and the air flow travelling through the system. If the expected airflow decreases below a pre-defined level, this correlates to a potential blockage and the device will inform the user with an alarm. RENASYS TOUCH also is able to auto correct the system when changes in pressure occur, to overcome a leak state. If a leak can't be compensated by the system, the device will inform the user with an alarm.

Can RENASYS TOUCH deliver and maintain pressure whilst above the wound?

Yes RENASYS TOUCH can deliver and maintain pressure when up to 90cm above the wound.

Can RENASYS TOUCH be taken on an aircraft?

Yes. Certified to all relevant standards that cover this environment.

What performance and safety checks are required between each patient?

- Pump cleaning following the directions provided in the service manual for RENASYS TOUCH.
- Device physical appearance check
- Functionality and alarm checks – complete functionality check, clinician mode, operation check, operation on battery check, blockage alarm check and restore presets as per directions provided in the RENASYS TOUCH service manual

What performance and safety checks are required on an annual basis?

Device vacuum checks as detailed in the RENASYS TOUCH Service manual.
Replace RENASYS TOUCH O-Ring and Odour filter as detailed in the RENASYS TOUCH Service Manual.

What are the limits of temperature, humidity and altitude when operating a RENASYS TOUCH pump?

Operational temperature 5℃ to 40℃
Relative humidity 15% to 93% RH
Atmospheric pressure 700mbar to 1060 mbar

Please outline the steps to enable the clinician mode?

To perform operation checks, pump must be in Clinician mode.
In the Settings menu, scroll to Change Mode.
Press to select Change Mode.
If Patient mode is highlighted, press Clinician mode and enter password (3141) to change to Clinician mode.
If Clinician mode is highlighted, no change is necessary.
Press Back icon to return to Settings menu.
Press Home icon to return to Home screen.

What should you do if the RENASYS TOUCH device that has been used on a patient contaminated with a bacteria?

RENASYS Touch device is a closed system in respect to the fluid system, i.e. no fluid from the wound enters the device. The local market would need to follow their own local guidelines in respect to cleaning the pump. They can also refer to the cleaning statement for RENASYS pumps.

Are there any areas where a RENASYS pump cannot be used?

RENASYS TOUCH is not MRI compatible. Do not bring the device into the MRI suite it is also unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
CT scans and x-ray have the potential to interfere with some electronic medical devices, where possible move the pump out of the x-ray or scanner range. If the pump has been taken into the CT scan or x-ray range, check that it is functioning correctly following the procedure.
If the pump has been at temperatures below freezing, the pump must be brought to room temperature prior to use or the pump unit may be damaged.

RENASYS TOUCH Pump and accessories Specification FAQ’s

What is the weight of a RENASY TOUCH pump?

0.967 kg

What are the dimensions of a RENASYS TOUCH pump?

180mmx190x76mm with 300ml canister

What materials are the RENASYS TOUCH pump constructed from?

Casework: LEXANTM Polycarbonate siloxane copolymer
Odour Filter: Non-woven polyester impregnated with activated carbon
O-ring: viton rubber; 70 shore A
Strap Pins: anodised aluminium
Light Guide: Polycarbonate (Lexan 241 clear)
Odour Filter Door Screw: nylon

What is the pump memory system?

Flash memory. SD Card

What cleaning agents can be used with RENASYS TOUCH pumps?

Please see the approved RENASYS cleaning statement.

What materials are the RENASYS TOUCH carry strap constructed from?

Webbing: Polypropylene
Buckles: Nylon
Shoulder Pad: PVC (foam)/polyester

What materials are the RENASYS TOUCH carry bag constructed from?

Fabric: Polyester, nylon and plastic poppers
Window Material: Clear PVC

What size is the RENASYS Transit case?

336mm x 300mm x 148mm

What is the maximum diameter of IV pole/bed board which the RENASYS TOUCH IV pole/ bed clamp can be attached to?

IV Pole up to 51mm/ 2in in diameter
Bed board up to 76mm/ 3in

Canister Questions

What is the weight of a RENASYS TOUCH 300ml canister?

1.1kg with 300ml canister

What is the weight of a RENASYS TOUCH 800ml canister?

1.27kg with 800ml canister

What are the RENASYS TOUCH canister's filter specification?

In the lid of the canister, (the face of the canister that connects to the pump), there are three filters.

- The primary role of the first filter (the one facing towards the liquid in the canister) is to prevent liquid leaving the canister in a direction towards the pump. The secondary purpose of the first filter is to prevent bacteria from the canister leaving the canister in a direction towards the pump.
- The second filter provides odour protection.
- The third filter is at the exit of the canister to the pump. The primary role of the third filter is to prevent any bacteria that have not been stopped by the first filter progressing any further. The secondary purpose of the second filter is to prevent any liquid that might have breached the first filter, (e.g. due to mechanical failure), from progressing any further.

The mechanism by which these filters function is a combination of size exclusion and surface energy.

What materials are the RENASYS TOUCH canisters constructed from?

Body and Lid: Styrolution clearblend
Filters: The bacterial is hydrophobic and ePTFE membrane Solidifier
Clips: Valox 310
Tubing: Polyvinyl chloride (PVC)
Connector plug; nylon; zytel 101 F
Caps for Connector: Santoprene 271- 87

Are RENASYS TOUCH canisters sterile?

No these are not sterile

What is the maximum capacity of the RENASYS 300ml and 800ml canisters with and without solidifier?

The RENASYS canisters has a indication to measure its capacity. Within the design of the canister, there is also an additional space above this which is used to accommodate the impact of the gelling agent before the activation of the canister full alarm. Hence the solidifier does not affect the amount of fluid displaced in the canister. We do not specify the total capacity of the canister as this is dependent on the orientation of the canister/device when in use. The canister is designed to hold either 300ml or 800ml with or without gelling agent before the canister full alarm activation.

Battery life and Charging

What are the battery's operating conditions when charging?

Operational temperature 5℃ to 40℃
Relative humidity 15% to 93% RH
Atmospheric pressure 700mbar to 1060 mbar

What are the battery's operating conditions when discharging?

Operational temperature 5℃ to 40℃
Relative humidity 15% to 93% RH
Atmospheric pressure 700mbar to 1060 mbar

What is the battery's operating time?

10-16 hours (therapy) when operating from -25mmHg to 120mmHg
8 hours (therapy) at 200mmHg

How Long Does RENASYS TOUCH take to charge?

Approx 3 hours

What is the mains voltage of the Class II power supply – 66801286?

Voltage: 100 – 240 VAC
Frequency: 50/60 Hz
Power Consumption: 10-35VA

What is the low voltage supply from the Class II power supply?

Voltage: 19.5 VDC
Maximum Output Current: 2.6 A
Maximum Power output: 50 W
Fuses: Internal electronic fuse, not user changeable

Bibliography

1) Smith+Nephew Medical LTD Research and Development report, RD/21/106, V01

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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