

Troubleshooting

When an alarm sounds, the RENASYS® EDGE pump screen will display information about the alarm. The pump includes **Help** on how to resolve each alarm. If the alarm can not be resolved using the **Help** function, the table below provides further troubleshooting advice.

Do not switch the pump off and on during an alert or alarm this will reset the pump and the alarm/alert will continue once therapy is resumed.

Blockage Alarm

What has happened?	What to do next
 The pump has detected one or more of the following: - A blockage within the canister - A blockage within the tubing - The internal canister filter is covered with exudate. This may occur even if canister does not appear visibly full.	- Press the Help button and follow the on screen instructions. If alarm persists continue with steps below. - If one dressing is connected to the pump, press the Home button icon to navigate to the home screen and ensure that the Y-Connect toggle icon is set to Y-Connect off. - If therapy is set to 25 mmHg consider reducing the height of the pump in relation to the wound. - 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. Ensure the Y-Connector mode is reset to on if appropriate. - If the alarm resolves, the blockage exists within tubing of the dressing. Reassess and replace as needed, and ensure the Y-Connector mode is reset to on if appropriate. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Canister Full Alarm

What has happened?	What to do next
 The pump has detected that the canister is full.	- Press the Help button and follow on screen instructions. If alarm persists continue with steps below. - Ensure the pump is orientated correctly, in an upright position. - Pause therapy by pressing . See Removing/changing canister section for instructions. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Canister Missing Alarm

What has happened?	What to do next
 The pump cannot detect a correctly connected canister.	- Press the Help button and follow on screen instructions. If alarm persists continue with steps below. - Pause therapy by pressing  and reattach or replace canister. See Removing/changing canister section for instructions. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

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Moderate Air Leak Alert and Critical Air Leak Alarm

What has happened?	What to do next
 The pump has detected an air leak. - The pump will provide an alert when a moderate leak is detected - The pump will provide an alarm when a critical leak is detected. The pump will continue to operate but may not provide prescribed therapy. - See Alarms and Alerts section for more information.	- Press the Help button and follow on screen instructions. If alarm persists continue with steps below. - In the event of an air leak, the flow meter will display on the therapy screen to assist in locating leaks in the pump, canister and tubing. Follow the instructions on screen to resolve the issue. - Do not pause therapy or switch off the pump while resolving this alarm; the following steps will help identify the source of the leak. - Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed. - Disconnect the canister tubing from the dressing tubing by holding the connectors above the level of the pump and patient's wound. Apply pressure to the canister tubing quick click connector and gently pull 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 pump connection. Replace the canister. Refer to Removing/Changing Canister sections of the manual for more details. - If the alarm resolves, a leak exists within the wound dressing or tubing. Reassess and replace as needed. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Low Battery Alert and Critical Low Battery Alarm

What has happened?	What to do next
 The pump will provide an alert when there is less than 2½ hours remaining and an alarm when there is less than 20 minutes remaining.	- Press the Help button and follow on screen instructions. If alarm persists continue with steps below. - Plug the pump into an electrical (AC) outlet as soon as possible. The pump can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Pump Too Hot Alert or Alarm

What has happened?	What to do next
 The pump has detected that the running temperature is too high.	Attempt to reduce the pump temperature. - Press the Help button and follow on screen instructions. If alarm persists continue with steps below. - Remove the pump from any covering or bag. - Move the pump out of direct sunlight. - Make sure there are no air leaks, see Moderate and Critical Air Leak for more information. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Continued overleaf >>

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High Vacuum / System or Battery Failure Alarm

What has happened?	What to do next
 The pump has detected a pump, internal or battery failure.	1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below. 2. Switch off the pump and attempt a restart. 3. If the alarm persists after troubleshooting, note the failure code and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Therapy Paused Too Long Alert

What has happened?	What to do next
 The pump has been paused for more than 30 minutes.	1. Restart therapy by pressing  as soon as possible. 2. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Unusual Noise

What has happened?	What to do next
If the RENASYS [®] EDGE pump emits an unusual noise.	Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Power Indicator Does Not Display

What has happened?	What to do next
The power indicator does not light when the pump is plugged in to an external power source to charge.	Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Pump does not switch on

What has happened?	What to do next
The pump does not switch on.	1. Plug the pump into mains power to charge the battery 2. If the pump does not respond after charging, contact Smith+Nephew Medical, Ltd.

Pump Starts or Runs Improperly

What has happened?	What to do next
The pump appears to start improperly such as no start up animation or no sound or if the pump does not look as normal during run time.	Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Pump Damaged

What has happened?	What to do next
Any part of the pump is cracked or appears damaged.	Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.

Electromagnetic Compatibility RENASYS[®] EDGE Pump

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the pump 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 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±6 kV, ±8 kV air ±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 100 kHz Repetition frequency	±0.5 kV, ±1 kV, ±2 kV, ±4 kV For power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial, home healthcare or hospital environment
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±0.5 kV, ±1 kV, ±2 kV, ±4 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground	Mains power quality should be that of a typical commercial, home healthcare or hospital environment
Voltage dips, short AT 0°, 45°, 90°, 135°, 180°, 225°, interruptions and 270° and 315° phases voltage variations 0% UT (100% dip in UT) for 0.5 cycle on power supply input lines IEC 61000-4-11	0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles (NOTE: UT is the a.c. mains voltage prior to application) 0% UT (100% dip in UT) for 250 cycles of the test level	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 00, 1800 phase 5% UT (100% dip in UT) for 0.5 cycle At 00 single phase 70% UT (30% dip in UT) for 5 cycles 25/30 cycles 0% UT (100% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial, home healthcare or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	100 A/m 50 or 60 Hz 150 A/m 50 or 60 Hz 200 A/m 50 or 60 Hz 400 A/m 50 or 60 Hz	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 6 Vrms 150 kHz to 80 MHz In ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz In ISM and amateur radio bands	Portable and mobile communications equipment should be separated from the pump by no less than distances calculated/listed below: Recommended separation distance: d = 0.58√P d = 0.175√P (80 MHz to 800 MHz) d = 0.35√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, 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:

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 pump is used exceeds 3V/m, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump.
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® EDGE Pump (REF 66803126)

Guidance and manufacturer's declaration – electromagnetic emissions for the RENASYS® EDGE pump (REF 66803126)

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

Emissions test	Compliance	Electromagnetic environment - guidelines
RF emissions CISPR 11	Group 1	The pump 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 pump 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 61000-3-3	Comply	

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

Do not use cables and accessories other than those specified or sold by Smith+Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the RENASYS® EDGE pump. Portable and mobile RF communication devices (mobile telephones) can affect the RENASYS® EDGE pump. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RENASYS® EDGE pump (REF 66803126), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The user shall use the Class II power supply 66803146, 66803147, 66803148, 66803149 or 66803150 in a residential environment.

Recommended separation distances between portable and mobile RF communications equipment and the pump

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled and Class II power supply 66801286 is used. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m):		
	800 MHz to 2.7 GHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 0.58\sqrt{P}$	$d = 0.175\sqrt{P}$	$d = 0.35\sqrt{P}$
0.01	0.06	0.02	0.03
0.1	0.02	0.05	0.1
1.0	0.6	0.2	0.3
10	1.8	0.5	1.1
100	5.8	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.

Example Table for EMS Use Environment

Immunity Test	Test Level	Compliance Level	Electromagnetic environment - guidelines
IEC 60601-1-2 ed4.1 All Applicable Clauses RTCA DO-160G	Home Healthcare Levels Section 21.4 (Category M) Section 21.5 (Category M) Section 20.5 (Category R) Section 20.4 (Category Y) Section 18 (Category R(CF)) Section 19 (Category AC)	Home Healthcare Levels Category M Category R Category Y Category R(CF) Category AC	Emergency Medical Services Use – Road Ambulance Emergency Medical Services Use – Air Ambulance Commercial and private airborne
CISPR-25:2016 4th edition EN 50121-3-2 Part 3-2:2017	Level 3 Radiated emissions – 30 MHz to 40 GHz AC Mains Conducted Emissions – 150 kHz to 30 MHz ESD immunity – Contact +/-6 kV, Air +/-8 kV Radiated, radio-frequency, electromagnetic field immunity – 20V/m 80-1000 MHz 10V/m 1400-2000 MHz 5V/m 2000-2700 MHz 3V/m 5100-6000 MHz	Level 3 30 MHz to 40 GHz 150 kHz to 30 MHz Contact +/-6 kV, Air +/-8 kV 20V/m 80-1000 MHz 10V/m 1400-2000 MHz 5V/m 2000-2700 MHz 3V/m 5100-6000 MHz	Vehicles, boats and internal combustion engines Railway rolling stock
	EFT +/-0.5 kV, +/-1 kV +/-2 kV Surge immunity - +/-0.5 kV, +/-1 kV Conducted, radio-frequency, electromagnetic field immunity – 10Vrms	+/-0.5 kV +/-1 kV, +/-2 kV +/-0.5 kV, +/-1 kV 10Vrms	
ISO 14708-4 Ed 1.0 (2008-11-15)	Section 27.103 – 50 mT Section 27.104 – 10 Hz to 30 MHz Section 27.105 – 30 MHz to 450 MHz Section 27.106 – 450 MHz to 3 GHz	50 mT 10 Hz – 30 MHz 30 MHz – 450 MHz 450 MHz – 3 GHz	Mains power quality should be that of a typical commercial, home healthcare or hospital environment
IEC 80601-2-49:2018 Ed 1.0 Medical Electrical Equipment - Part 2-49 IEC 61000-4-9:AEI issued: 03/01/2001	Section 202.8.102 Level 3	Section 202.8.102 Level 3	Mains power quality should be that of a typical commercial, home healthcare or hospital environment Mains power quality should be that of a typical commercial, home healthcare or hospital environment
AIM 7351731 rev 2 (2017-02)	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m 13.56 MHz, 5 A/m 13.56 MHz, 12 A/m 433 MHz, 3V/m	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m 13.56 MHz, 5 A/m 13.56 MHz, 12 A/m 433 MHz, 3V/m	Mains power quality should be that of a typical commercial, home healthcare or hospital environment

Specification

Essential Performance

Essential performance of the RENASYS® EDGE, for safe operation, is to maintain the vacuum delivered by the pump within its specification for pressure selected, to provide Negative Pressure Wound Therapy (NPWT).

Contact your Smith+Nephew representative, distributor or authorized provider if service or additional guidance is required.

Vacuum

Continuous Therapy Levels 25, 40, 60, 80, 100, 125, 150, 175, 200 mmHg

Intermittent Therapy Levels High: 40, 60, 80, 100, 125, 150, 175, 200 mmHg

Intermittent Therapy Cycles Low: 25, 40, 50 mmHg

Times High 5, 8, 10 mins

Alarms Low: 2,3,5 mins

Frequency 20 seconds

Priority Low

Low: 55 dB

Auditory Sound Level Medium: 65 dB

High: 75 dB

Indicator Color Yellow

Overall Alarm Delays

Over Temperature 60 seconds Canister Full 120 seconds

High Vacuum 360 seconds Critical Battery 60 seconds

Leak/Low vacuum 45 seconds Battery failed 60 seconds

Blockage 300 seconds Pump failed 2 seconds

All of RENASYS® EDGE components and dressings are considered applied parts. All of the applied parts are type BF (body floating) defibrillation proof parts.