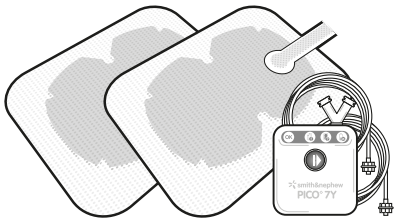
Healthcare professional user manual



smith&nephew

PICO° 7Y

Single Use Negative Pressure Wound Therapy System Healthcare Professional User Manual

QUIET PUMP	7 UP TO 7 DAYS	HIGH AIR LEAK TOLERANCE	CHECK DRESSING INDICATOR	AIRLOCK® LAYER	UP TO 80% EXUDATE EVAPORATION	LOW TO MODERATE	SILICONE ADHESIVE	SHOWER PROOF DRESSING
Pump noise level is below 35dB	System lasts up to 7 days	Pump has high tolerance to air leaks	Check dressing indicator	Airlock layer helps maintain negative pressure across the dressing	Up to 80% of exudate managed through evaporation	Indicated for low to moderate exuding wounds	Silicone gel adhesive dressing	Dressing is showerproof

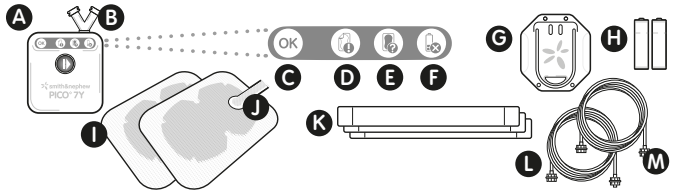
PICO° 7Y is intended for use by or on the direction of a trained and licensed physician in accordance with these instructions for use.

This user manual contains information specific for use by a healthcare professional and is not appropriate for use by patients and caregivers. Information for patients and caregivers is provided in the form of a separate user manual provided with the PICO 7Y system.
ENSURE THAT THE PICO 7Y PATIENT AND CAREGIVER USER MANUAL IS HANDED TO THE PATIENT OR CAREGIVER. Care should be taken to ensure that patients and caregivers understand all warnings and precautions, especially those relating to **pump placement, as the PICO 7Y pump contains a magnet.**
Dressings should only be applied, changed and removed by a healthcare professional.

1. Description

The PICO 7Y pump maintains negative pressure wound therapy at 80 mmHg (nominal) to two wound surfaces simultaneously. Exudate is managed by the dressings through a combination of absorption and evaporation of moisture through the outer film.
The PICO 7Y kit is intended to be used for up to 7 days on low exuding wounds. For moderate exuding wounds the system is intended to be used for up to 4 days. For 7 days use on moderate exuding wounds, additional dressings will be required (available for purchase separately).

1.1. Kit components



- A 1x PICO 7Y Pump
- B Y-connector
- C OK Indicator
- D Leak Indicator
- E Check Dressing Indicator
- F Battery Low Indicator
- G Pump Clip
- H 2x AA Lithium Batteries
- I 2x Large Multisite Dressings
- J Soft Port
- K Fixation Strips
- L 2x Extension Tubing
- M Pump & Tubing Connectors

2. Glossary of symbols

- Follow instructions for use
- OK — OK indicator (refer to Troubleshooting)
- Warning: The PICO 7Y pump contains a MAGNET. Keep the PICO 7Y pump at least 4 inches (10 cm) away from other medical devices at all times. Failure to do so can cause the other medical device to fail which can result in serious harm including death. See Warning number 1. Magnet Warning
- Leak indicator (refer to Troubleshooting)
- Check dressing indicator (refer to Troubleshooting)
- Battery low indicator (refer to Troubleshooting)
- Start/pause/resume therapy (Orange Button)
- Rx only — Caution: Federal (USA) law restricts this device to sale by or on order of a physician
- Single Use. Do not reuse.
- EU: Not for general waste
- LOT — Lot number
- REF — Catalogue number
- International classification
- Defibrillation-proof type BF applied part
- MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
- STERILE EO — Product is sterilised by Ethylene Oxide
- Caution
- Do not use if package is damaged
- Storage temperature
- Manufacturer
- Date of manufacture
- Consult instructions for use
- Keep product out of sunlight
- Keep dry
- CE 0086 — CE Mark
- Relative humidity limits
- Atmospheric pressure limits
- Expiry date
- Healthcare professional symbol

3. Indications for use

PICO 7Y is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO systems are suitable for use both in a hospital and homecare setting.

4. Contraindications

4.1. PICO 7Y is contraindicated for:

- Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life).
- Previously confirmed and untreated osteomyelitis.
- Non-enteric and unexplored fistulas.
- Necrotic tissue with eschar present.
- Exposed arteries, veins, nerves or organs.
- Exposed anastomotic sites.

4.2. PICO 7Y should not be used for:

- Emergency airway aspiration.
- Pleural, mediastinal or chest tube drainage.
- Surgical suction.

5. Important information

Pump Placement Warning

The PICO 7Y pump contains a MAGNET. **Keep the PICO 7Y pump at least 4 inches (10 cm) away from other medical devices at all times. Failure to do so can cause the other medical device to fail** which can result in serious harm including death.

See Warning number 1. Magnet Warning

For more information on electromagnetic immunity and electromagnetic emissions see section 19. Electromagnetic compatibility of PICO 7Y.

6. Warnings

1. The PICO 7Y pump contains a MAGNET that can cause other medical devices in close proximity to fail, leading to serious harm including death. The PICO 7Y pump must be positioned at least 4 inches (10cm) away from other medical devices that could be affected by magnetic interference. These include but are not limited to:
   - Implantable Cardioverter-Defibrillator (ICD)
   - Pacemakers
   - Insulin Pumps
   - Shunt Valves
   - Neurostimulators
   - Cochlear Implants

   THIS WARNING APPLIES AT ALL TIMES TO ALL USERS.
   This applies to both patients and caregivers.
   You must keep the PICO 7Y pump at least 4 inches (10cm) away from other devices:
   - If you have an electronic medical device and are helping take care of somebody else using the PICO 7Y system.
   - If the patient is wearing the PICO 7Y pump in a public area where they may come in close contact with someone else who has an electronic medical device.
2. **Certain patients are at high risk of bleeding complications which, if uncontrolled, could potentially be fatal. Patients must be closely monitored for bleeding.** If sudden or increased bleeding is observed, immediately disconnect pump, leave dressings in place, take appropriate measures to stop bleeding and seek immediate medical assistance.
3. Hemostasis must be achieved before applying the dressings, although the use of anticoagulants does not deem a patient inappropriate for treatment with PICO 7Y. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that may increase the risk of bleeding, if disrupted. Frequent assessment must be maintained throughout the therapy.

6. Warnings (continued)

4. **PICO dressings should only be applied, changed or removed by a Healthcare Professional**
5. PICO 7Y is unsuitable for use in areas where there is danger of explosion (e.g. Oxygen rich environments such as hyperbaric oxygen units).
6. PICO 7Y is unsuitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.
7. Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO 7Y due to risk of puncturing organs or blood vessels while under Negative Pressure Wound Therapy.
8. Each PICO dressing (including Multisite) must be used to dress one wound only.
9. At all times care should be taken to ensure that the pump and tubing and connectors do not:
   - Lie in a position where they could cause pressure damage to the patient.
   - Trail across the floor where they could present a trip hazard or become contaminated.
   - Present a risk of strangulation or a tourniquet to patients.
   - Rest on or pass over a source of heat.
   - Become twisted or trapped under clothing or bandages so that the air-path delivering Negative Pressure is blocked.
10. **MR Unsafe** - Keep away from magnetic resonance imaging (MRI) equipment. The PICO 7Y pump is MR Unsafe. Do not take the PICO 7Y pump into the MRI scan room. The device presents a projectile hazard.
11. PICO 7Y has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.
12. The system contains small parts which could represent a choking hazard. Keep out of the reach of children.
13. Keep PICO 7Y away from pets, pests and other animals that could damage the PICO 7Y device.
14. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30cm (12 inches) to any part of the PICO 7Y device (66022031). Otherwise, degradation of the performance of this equipment could result.

7. Precautions

1. The PICO 7Y pump contains a magnet. See Warning number 1. Magnet Warning.
2. **Precautions should be taken in the following types of patients who are at high risk of bleeding complications:**
   - Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.
   - Having weakened or friable blood vessels or organs in or around the wounds as a result of, but not limited to; anastomoses, infection, trauma or radiation.
   - Suffering from difficult wound hemostasis.
   - Untreated for malnutrition.
   - Non-compliant or combative.
   - Suffering from wounds in close proximity to blood vessels or delicate fascia.
3. Monitor for pain, reddening, odor, sensitization or a sudden change in the volume or color of wound fluid occurs during use.
4. Where PICO 7Y is used to bolster skin grafts, it is important to visually inspect the system regularly, especially in the first week of treatment to ensure that Negative Pressure Wound Therapy is continually applied and a seal is maintained.
5. Where PICO dressings are used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wounds should be maintained to check for signs of infection.
6. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing or the use of Negative Pressure Wound Therapy on ischaemic limbs does not compromise circulation.
7. PICO 7Y does not contain audible alerts. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely.
8. Although PICO dressings can be used under clothing/bedding, it is important that occlusive materials e.g. film dressings, are not applied over the pad area of the dressings as this will impair the intended evaporation of moisture through their outer layers.
9. The PICO dressings should not be covered by rigid immobilisation devices or casts which might apply excessive pressure and cause tissue injury at the wound sites, especially where the tubing enters the dressings.
10. Prolonged placement of rigid or opaque materials over the PICO dressings may prevent the regular inspection and assessment of the wounds, and disrupt scheduled or required dressing changes.
11. Where PICO dressings are used on patients with fragile skin, a skin protectant such as NO-STING SKIN-PREP® should be used on areas of skin where fixation strips are to be applied. Inappropriate use or repeated application of fixation strips may otherwise result in skin stripping.
12. Do not use PICO dressings with oil based products such as petrolatum as it may compromise establishing an effective seal.
13. The use of Negative Pressure Wound Therapy presents a risk of tissue ingrowth into foam when this is used as wound filler. When using foam filler with PICO 7Y, tissue ingrowth may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.
14. PICO 7Y may be used in conjunction with surgical drains provided the dressings are not placed over tubing where it exits the skin. Any surgical drains should be routed under the skin away from the edge of the dressings and function independently of the PICO 7Y system.
15. The pump must be protected from sources of fluid e.g. from incontinence or spillages. Discontinue PICO 7Y use if fluid ingress is observed.
16. When showering, the PICO 7Y pump should be disconnected from the dressings. While disconnected, ensure the end of the tubing attached to the dressings is facing down so that water does not enter the tubes.
17. Do not take the pump apart.
18. The dressings supplied should only be used with PICO 7Y pumps.
19. Do not alter or cut tubing configuration or pull on the tubing or soft ports.
20. Do not cut the PICO dressing pad as this may lead to loss of Negative Pressure Wound Therapy application.
21. When applying dressings next to one another, ensure the dressing borders do not overlap.
22. Always ensure that the PICO dressing is positioned centrally over the wound. The soft port should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the soft port and potentially blocking the air-path is minimized.
23. 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 the system is functioning correctly following the procedure.
24. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if PICO is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.
25. The PICO 7Y system is single use only. Use of any part of this system on more than one patient may result in cross contamination that may lead to infection.
26. High temperatures and humidity may reduce wear time of PICO dressings.
27. The PICO 7Y system is intended for use both in a hospital and homecare setting. the system can also be used in aircraft, car, train, and boat transportation. Special care must be taken regarding pump positioning when in close proximity to other people. See Warning number 1. Magnet Warning.
28. During the transport there is a potential for radio frequency interference that could affect PICO 7Y performance. If the PICO 7Y pump malfunctions replace the system.

8. Adverse reaction

Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions is essential. Carefully monitor the wounds and dressings for any evidence of a change in the blood loss status of the patient or any sudden or abrupt changes in the volume or the color of exudate.

9. Instructions for use (Healthcare professional only)

9.1. Guidance on wound suitability

PICO dressings should be used on wounds which fit comfortably within the area of the pad (generally no more than 25% of the dressing pad area), observing precautions on soft port positioning (on intact skin and not extending over the wound). PICO Multisite dressings are designed to enhance conformability when dressing awkward anatomical areas. Each PICO Multisite dressing must be used to dress one wound only. As a guide:
Depth - Wounds greater than 0.5cm (1/4 in.) in depth are likely to require a foam or gauze Negative Pressure Wound Therapy filler to ensure adequate treatment of all the wound surfaces. Wounds treated with the PICO 7Y system should generally be no more than 2cm (4/5 in.) in depth.
Exudate – PICO 7Y is intended for use on wounds where the level of exudate is low (up to 0.6g of liquid exudate/cm² of wound area/24 hours) to moderate (up to 1.1g of liquid exudate/cm² of wound area/24 hours). 1g of exudate is approximately equal to 1ml of exudate.

9.2. Use of PICO dressings with fillers

PICO dressings are compatible with standard gauze and foam fillers used in traditional Negative Pressure Wound Therapy where this is clinically appropriate – for example on a defect wound. When filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to local clinical protocol and manufacturer's instructions. Gauze should loosely fill to the surface of the wound. Avoid over packing.
The use of Negative Pressure Wound Therapy presents a risk of tissue ingrowth into foam when this is used as wound filler. When using foam filler with PICO 7Y, tissue ingrowth may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.

9.3. Use of PICO dressings with non-adherent layers

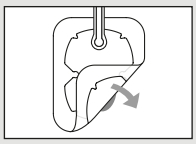
PICO dressings may be used over the top of a non-adherent layer if required. On infected wounds or wounds at risk of infection, ACTICOAT™ Flex 3 and ACTICOAT™ Flex 7 may be used under PICO dressings.

9.4. Application

1. **Dressings should only be applied, changed or removed by healthcare professionals.**
If part of your clinical guidelines remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry with sterile gauze.

2. Using a clean technique, peel off the first piece of backing plastic. If possible ensure that the soft port is positioned higher than the wound (depending on the patient's primary position). Ensure that the soft port is placed over intact skin and not extending over the wound. These steps will prevent fluid blocking the air-path delivering negative pressure. Ensure the dressing lies flat to the wound and the surrounding skin. If the soft port is not placed higher than the wound, the system will function as normal but the wear time of the dressing may be reduced.

3. Remove the remaining backing plastic and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.

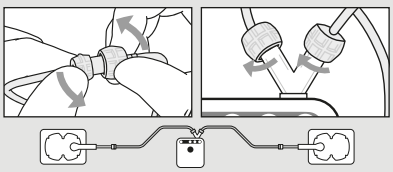


4. Repeat step 2 - 3 for the second dressing. Ensure the dressings do not overlap.

The PICO 7Y pump contains a MAGNET. **Keep the PICO 7Y pump at least 4 inches (10 cm) away from other medical devices at all times. Failure to do so can cause the other medical device to fail** which can result in serious harm including death. See Warning number 1. Magnet Warning

5. Once the dressings are in place, remove the pump and the batteries from the tray. The direction in which the batteries should be placed is indicated inside the battery compartment. Insert the batteries. Following this all four indicators should illuminate for 3 seconds. Replace the cover.

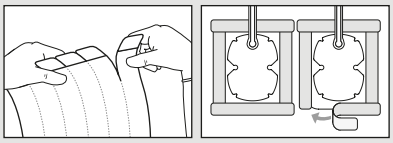
6. Join the pump and dressings by twisting together the connectors. Extension tubes are included or the soft port tubes can be directly connected to the pump.
If extension tubes are not used for initial application, they should be retained for dressing change.



7. Press the Orange Button to start the application of the therapy. **The green OK indicator and orange leak indicator will start to flash together (indicates pump working to establish therapy).** Depending on the size of the wounds, **the pump can take up to 100 seconds to establish therapy.** Once therapy is established just the OK indicator will flash. If after 100 seconds the system has not established therapy, just the orange air leak indicator will flash. Refer to Section 15, Troubleshooting.

8. If using NO-STING SKIN-PREP prior to application of the fixation strips (see Precaution 11) wipe the area surrounding the dressings and allow skin to dry.

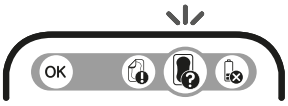
9. Apply the fixation strips all the way around the dressing border. Remove the printed top layer on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressings. In awkward areas, it may be useful to apply the strips to help achieve a seal prior to switching on the pump. Place each strip so that it overlaps the dressing borders by approximately 1cm (2/5in.).



10. Ensure tubing is not twisted or trapped between clothing. Please note that if at any time the fixation strips are removed, the dressing(s) should also be replaced. If desired, gel patches may be applied in addition to the fixation strips to help achieve or maintain a seal.

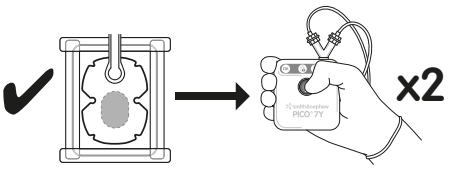
11. If extension tubes have not been used for initial application, remember to retain for dressing change. A pump clip is supplied to attach the pump to clothing if required.

10. Check dressing indicator



When this indicator flashes, the condition of the dressings needs to be checked. The indicator will flash routinely every 24 hours as a reminder to check the dressings.

See Section 11. Dressing change

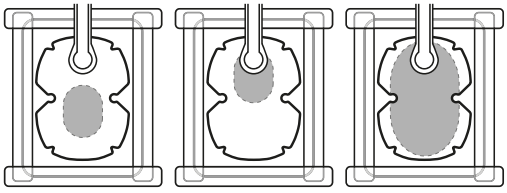


If no dressing change is required, refresh the device by pressing the Orange Button **TWICE**.

11. Dressing change

Dressings should only be applied, changed or removed by healthcare professionals

Dressings should only be changed in line with standard wound management guidelines, typically every 3-4 days. At the healthcare professional's discretion a PICO dressing may be left in place for up to 7 days. More frequent dressing changes may be required depending on the level of exudate, condition of the wound(s) or other patient considerations, e.g. when PICO 7Y is used on infected wounds. Additional dressings for use with the PICO 7Y pump are available for purchase separately. Inspect the PICO dressings regularly. If either dressing appears ready for changing, remove the dressing as per Section 13 and apply another dressing as per Section 9.4.



A
OK
Acceptable to be left in place

B
Change
Soft port may block with fluid

C
Change
Absorbent area is full

Based on dressing change frequency, further dressings may be required, see Section 20 System variants. PICO Multipack does not contain extension tubes. **Extension tubes must be retained for dressing change.**

12. Replacing the batteries

If the Battery Low indicator flashes, the batteries in PICO 7Y will require changing. To change the batteries:

1. Remove the back cover from PICO 7Y to access the battery compartment.
2. Remove the used batteries and dispose of in accordance with local regulations.
3. Insert new batteries in the orientation indicated inside the battery compartment.
4. Replace the back cover, all four indicators should illuminate for 3 seconds.
5. Press the Orange Button to resume therapy.

13. Dressing Removal

Dressings should only be applied, changed or removed by healthcare professionals

1. Stop the PICO 7Y pump by pressing the Orange Button - All indicators will turn off.
2. Remove the pump from the dressings by untwisting the connectors.
3. Remove the PICO dressings by stretching the fixation strips away from the skin. Lift the dressings at one corner and peel back until it has been fully removed.
4. The PICO dressings and fixation strips should be disposed of as clinical waste in accordance with local protocol. The batteries should be removed from the pump; and both batteries and pump disposed of according to local regulations.
5. For additional information on disposal requirements speak to your Smith & Nephew representative.

14. Cleaning, showering and bathing

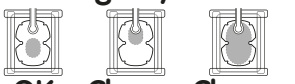
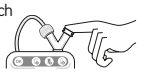
Adherence to clinical directives concerning hygiene is of prime importance. The pump may be wiped clean with a damp cloth using soapy water or a weak disinfectant solution.

14.1. Showering and bathing

Light showering is permissible; however, the PICO 7Y pump should be disconnected and placed in a safe location where it will not get wet. The PICO dressings should not be exposed to a direct spray or submerged in water. While disconnected, ensure the ends of the dressing tubes are facing down so that water does not enter the tubes.

15. Troubleshooting

PICO 7Y has visual indicators to let the user know when there is an issue. PICO 7Y does not contain audible alerts. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely in case there is a fault or in case of damage.

Indicator status	Possible cause	Comments/troubleshooting
 All indicators off	The pump is in standby.	Therapy has been paused. Press the Orange Button to resume therapy.
	The pump has completed its course of therapy.	Pressing the Orange Button will not restart therapy. Healthcare professional to apply new pump and dressings if further therapy is required.
	The batteries have depleted.	If the pump has not yet completed its course of therapy, replace the batteries. See section 12. Replacing the batteries.
 Green 'OK' and orange 'Leak' indicators flash	The pump is working to achieve therapy but has not reached the intended pressure.	Depending on the size of the wound the pump may take up to 100 seconds to establish therapy.  Pump will then flash green 'OK' indicator OR orange 'Leak' indicator.
 Green 'OK' indicator flashes	Pump is functioning. **Dressing may be full, refer to section 11. Dressing change.** Pump may be heard running occasionally as it maintains negative pressure.	**Dressing may be full.**  **OK** Acceptable to be left in place; **Change** Change required; **Change** Absorbent area is full **Dressings should only be applied, changed or removed by healthcare professionals** Dressings should be regularly monitored.
 Green 'OK' and orange 'Battery Low' indicators flash	System is functioning properly but the batteries are low.	Replace the batteries and press the Orange Button to restart therapy. See section 12. Replacing the batteries.
 Orange 'Leak' indicator flashes	A high air leak has been detected. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour).	1. Smooth down the dressings and strips to remove any creases. 2. Ensure that the tube connectors have been twisted together securely. 3. Press the Orange Button to restart the pump. 4. If the air leak remains the orange 'Leak' indicator will flash again after approximately **100 seconds** (depending on the size of the wound). One of the dressings may have a leak. To identify which of the dressings has a leak, follow these steps: 1. Untwist one of the tubes from the Y-connector. 2. Cover the open branch of the Y-connector with a finger and press Orange Button to resume therapy.  3. If the green 'OK' indicator flashes, connect the dressing and repeat steps 1-3 for remaining dressing. However If the leak remains, the orange 'Leak' indicator will flash again after approximately 100 seconds. If the leak persists the dressing may need changing, refer to Section 11 Dressing change.
 Orange 'Check Dressing' indicator flashes	Pump is functioning properly however check dressings. (see section 10. Check dressing indicator)	Check the dressings. See section 10. Check dressing indicator.
 Orange 'Leak' and orange 'Battery Low' indicators flash	A high air leak has been detected and the batteries are low. Therapy is not being applied.	Replace batteries. See section 12. Replacing the batteries. Then troubleshoot air leak as above.
 All indicators solidly illuminated	A pump error has been detected. The pump can no longer apply therapy.	Apply new pump and dressings.

16. Cautions

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. The product must be used in accordance with this user manual and all applicable labelling.

17. Specifications

Pump Dimensions	65 x 95 x 21mm
Weight	<100g
Operating Time	7 days
Battery Type	2 x AA 1.5V (FR6)
Power (Battery)	3V DC
Ingress Protection	IP22
Maximum Vacuum	100 mmHg
Mode of Operation	Continuous
Patient Protection	Defibrillation-proof type BF
Storage/Transport	41°F - 77°F (-13°F to +41°F allowable for up to 7 days), 10 – 75% relative humidity, 700 to 1060 mbar atmospheric pressure
Operating Environment	41°F - 104°F, 10 – 95% relative humidity, 700 to 1060 mbar atmospheric pressure
Compliance	Conforms to: AAMI STD ES60601-1, IEC STDS 60601-1-6 and 60601-1-11
	Certified to: CSA STD C22.2 # 60601-1

18. Safety of PICO 7Y

When used in accordance with the manufacturer's instructions, PICO 7Y complies with the General Requirements for Safety of Electrical Medical Equipment (IEC 60601-1). PICO 7Y is intended for uncontrolled environments e.g. home use (IEC 60601-1-11). The PICO 7Y system has no Essential Performance and no extra specific precautions are needed regarding basic safety.

19. Electromagnetic compatibility of PICO 7Y

PICO 7Y 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 PICO 7Y is used in a typical medical installation and uncontrolled environment like home use.

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.

19.1. Guidance and manufacturer's declaration – electromagnetic immunity

PICO 7Y is intended for use in the electromagnetic environment specified below. The customer or the user of PICO 7Y 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, ±8 kV, ±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	PICO 7Y is a battery powered device.	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line	PICO 7Y is a battery powered device.	Not applicable
Voltage dips, short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°, 180°, 225°0, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0° single phase 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cydes 0% UT (100% dip in UT) for 250 cycles 0% UT (100% dip in UT) for 300 cycles	PICO 7Y is a battery powered device.	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital or home use 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	PICO 7Y is a battery powered device.	Portable and mobile communications equipment should be separated from the device by no less than distances calculated/listed below: **Recommended separation distance:** d = 0.58 √P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9	10 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9	d = 0.175 √P (80 MHz to 800 MHz) d = 0.35 √P (800 MHz to 2.7 GHz)

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 PICO 7Y is used exceeds the applicable RF compliance level above, the PICO 7Y 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 10 V/m. 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:

19.2. Guidance and manufacturer's declaration – electromagnetic emissions PICO 7Y

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	PICO 7Y 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	PICO 7Y 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	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

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.

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 PICO 7Y device.

Portable and mobile RF communication devices (mobile telephones) can affect PICO 7Y.

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

PICO 7Y 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 (W)	Separation distance according to frequency of transmitter (m):		
	150 kHz to 80 MHz d = 0.58√P	**80 MHz to 800 MHz** d = 0.175√P	**800 MHz to 2.7 GHz** d = 0.35√P
0.01	Not applicable	0.02	0.03
0.1	Not applicable	0.05	0.1
1.0	Not applicable	0.2	0.3
10	Not applicable	0.5	1.1
100	Not applicable	1.7	3.5

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.

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.

20. System variants

PICO 7Y Single Use Negative Pressure Wound Therapy system
Low to moderately exuding wounds – up to 7 day system.
2 x large Multisite dressings, 1 pump & pump clip, fixation strips, 2 extension tubes.
PICO 7Y System 66022031
Additional dressings are required for moderately exuding wounds (available separately)

PICO Fluid Management Pack
For use with PICO Single Use Negative Pressure Wound Therapy Systems
5 x individually packaged dressings, fixation strips

10cm x 20cm	66022022	15cm x 30cm	66022027
10cm x 30cm	66022023	20cm x 20cm	66022028
10cm x 40cm	66022024	25cm x 25cm	66022029
15cm x 15cm	66022025	Small Multisite	66022020
15cm x 20cm	66022026	Large Multisite	66022021

PICO 7Y is packed in the UK with individual components being made in the following countries: Dressing – UK, Fixation strips – Origin as marked, Pump – China, Pump clip – China, Batteries – Origin as marked, Tubing - UK

UNITED STATES Smith & Nephew, Inc.,
Smith & Nephew, Inc.
5600 Clearfork Main Street,
Suite 600 Fort Worth, TX 76109
Customer Care Center: 1-817-900-4000

Smith & Nephew, 101 Hessle Road, Hull, HU3 2BN, England.

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