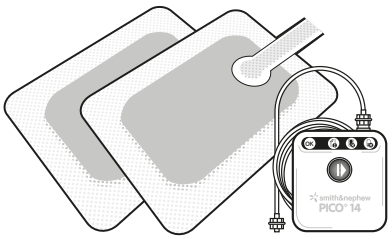
Healthcare Professional User Manual



smith&nephew PICO◇ 14

Single Use Negative Pressure Wound Therapy System User Manual

QUIET PUMP	UP TO 14 DAYS	HIGH AIR LEAK TOLERANCE	DRESSING FULL 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 14 days	Pump has high tolerance to air leaks	Dressing full 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

The PICO◇ 14 Single Use Negative Pressure Wound Therapy System 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 14 kit. **ENSURE THAT THE PICO 14 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 14 pump contains a magnet.

1. Description

The PICO 14 System consists of a pump, extension tube, batteries, sterile dressings and fixation strips. The PICO 14 pump maintains negative pressure wound therapy at 80 mmHg (nominal) to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film. PICO soft port is designed with an integrated filter to prevent liquid ingress into the soft port tubing and into the PICO 14 pump.
The PICO 14 System is intended to be used for up to 14 days on low to moderately exuding wounds. For low exuding wounds each PICO dressing is intended to be used up to 7 days. For moderately exuding wounds each PICO dressing is intended to be used for up to 4 days. For 14 days use on moderate exuding wounds additional dressings will be required (available for purchase separately).
Low exuding wounds are considered to be up to 0.6g of liquid exudate/cm² of wound area/24 hours. Moderate exuding wounds are considered to be up to 1.1g of liquid exudate/cm² of wound area/24 hours. 1g of exudate is approximately equal to 1ml of exudate. The PICO System is demonstrated to be effective for up to 7 days for aiding in reducing the incidence of surgical site infection.
The frequency of dressing changes can be affected by multiple factors such as wound type, wound size, rate or volume of exudate, orientation or environmental conditions. Additional dressings are available to purchase separately, as required.

2. Indications

PICO 14 Single Use Negative Pressure Wound Therapy System 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. PICO 14 Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.
Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
  - Venous leg ulcers – the PICO 14 System can be used in combination with graduated compression therapy in the management of venous leg ulcers.
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions for up to 7 days, PICO 14 Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and II wounds
- Post-operative Seroma
- Dehiscence

Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.

3. Contraindications

The PICO 14 System 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.

The PICO 14 System should not be used for the purpose of:

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

4. PICO 14 System with graduated compression therapy

The PICO 14 System with graduated compression therapy may be used to treat venous ulcerations.
For more information including application see section 10.2.

5. Important information

⚠ Pump Placement Warning

The PICO 14 pump contains a MAGNET. **Keep the PICO 14 pump at least 4 inches (10 cm) away from other medical devices at all times.** As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. See Section 6 Magnet Warning

For more information on electromagnetic immunity and electromagnetic emissions see section 15 Electromagnetic compatibility of the PICO 14 System.

6. Warnings

1. **⚠ Magnet Warning**
   The PICO 14 pump contains a MAGNET. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. The PICO 14 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 14 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 14 System.
   - If the patient is wearing the PICO 14 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 dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.
3. Hemostasis must be achieved before applying the dressing, although the use of anticoagulants does not deem a patient inappropriate for treatment with the PICO 14 System. 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.
4. At all times care should be taken to ensure that the pump, tubing and connectors do not:
   - Lie in a position where it could cause pressure damage to the patient.
   - Trail across the floor where it 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 therapy is blocked.
5. Sharp edges or bone fragments in a wound must be covered or removed prior to using the PICO 14 System due to risk of puncturing organs or blood vessels while under negative pressure wound therapy.
6. In the event that defibrillation is required, remove the dressing if it is positioned in a location that will interfere with defibrillation.
7. **MR Unsafe.** You must remove the PICO 14 pump from the dressing before entering the MRI suite. Do not bring the PICO 14 pump into the MRI scan room. The device presents a projectile hazard.
8. Safety and effectiveness in pediatric population (<22 years old) has not been evaluated. Patient size and weight should be considered when prescribing this therapy to this population.
9. The PICO 14 System is unsuitable for use in areas where there is danger of explosion (e.g oxygen rich environments such as Hyperbaric oxygen unit).
10. The PICO 14 System contains small parts which could represent a choking hazard for young children. Keep out of the reach of children.
11. The PICO 14 System is not suitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.
12. PICO dressings should only be applied, changed or removed by a healthcare professional.
13. Each PICO dressing (including Multisite) must be used to dress one wound only.
14. Keep the PICO 14 System away from pets, pests and other animals that could damage the PICO 14 System.
15. No modification of this equipment is allowed.
16. When using the PICO 14 System with graduated compression therapy you must comply with indications and contraindications for both products.

7. Precautions

1. **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 wound 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.
2. If pain, reddening, odor, sensitization or a sudden change in the volume or color of wound fluid occurs during use, contact your healthcare professional right away.
3. Where the PICO 14 System 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.
4. Where PICO dressings are used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wound should be maintained to check for signs of infection. The use of the PICO 14 System does not preclude the need to continue to develop and follow a comprehensive infection management protocol.
5. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing or the use of negative pressure wound therapy on ischemic limbs does not compromise circulation.
6. The PICO 14 pump 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.
7. 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 dressing as this will impair the intended evaporation of moisture through its outer layer.
8. The PICO dressing should not be covered by rigid immobilization devices or casts which might apply excessive pressure and cause tissue injury at the wound site, especially where the tubing enters the dressing.
9. Prolonged placement of rigid or opaque materials over the PICO dressing may prevent the regular inspection and assessment of the wound, and disrupt scheduled or required dressing changes.
10. 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.
11. Do not use PICO dressings with oil-based products such as petrolatum as it may compromise establishing an effective seal.
12. The use of negative pressure wound therapy presents a risk of tissue ingrowth into foam when this is used as a wound filler. When using foam filler with the PICO 14 System, tissue ingrowth may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.
13. The PICO 14 System may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin. Any surgical drain should be routed under the skin away from the edge of the dressing and function independently of the PICO 14 System.
14. The pump must be protected from sources of fluid e.g. from incontinence or spillages. Discontinue use of the PICO 14 pump if fluid ingress is observed.
15. When showering the PICO 14 pump should be disconnected from the dressing. Whilst disconnected, ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube.
16. Do not take the pump apart.
17. The PICO dressing should only be used with PICO pumps.
18. Do not alter or cut tubing configuration or pull on the tubing or soft port.
19. Do not cut the PICO dressing pad as this may lead to loss of negative pressure wound therapy application.
20. 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 therapy is minimized.
21. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if the PICO 14 System is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.
22. 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.
23. The PICO 14 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. Dressings should not be applied if they have passed their expiry date or have been stored outside of their sterile pouch. Dressings must not be used if they have become contaminated.
24. High temperatures and humidity may reduce wear times of PICO dressings.
25. The PICO 14 System is intended for use in both a hospital and homecare setting. The system can also be used in aircraft, train and boat transportation. Special care must be taken regarding pump positioning when in close proximity to other people (see magnet warning).
26. During transport there is a potential for radio frequency interference that could affect the PICO 14 pump performance. If the PICO 14 pump malfunctions, replace batteries. If not corrected, contact your healthcare professional to replace the system.
27. When applying dressings next to one another, ensure the dressing borders do not overlap.
28. This device has not been evaluated for abdominal and thoracic cavity.
29. The following statements describe conditions that may require special care for the safe and effective use of the PICO 14 System:
    - use near vagus nerve (bradycardia)
    - patient with spinal cord injury (stimulation of sympathetic nervous system)

8. Adverse Reactions

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 wound and dressing for any evidence of a change in the blood loss status of the patient. Monitor the patient for signs of any sudden or abrupt changes in the volume or the color of exudate.

9. Definitions

According to the latest recommendations (CDC 2020), superficial and deep incisional SSIs are defined as follows:

- A superficial incisional SSI involves only skin and subcutaneous tissue of the incision and occurs within 30 days after any National Healthcare Safety Network (NHSN) operative procedure.
- A deep incisional SSI involves deep soft tissues of the incision (for example, fascial and muscle layers) and occurs within 30 or 90 days after the NHSN operative procedure.

Reference: *CDC 2020. SSI – Procedure-associated Module 2020. Available from: https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. [Accessed 04/11/2020]*

10. Instructions for use

10.1. Guidance on wound suitability

PICO dressings should be used on wounds which fit comfortably within the area of the pad, 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. PICO dressings (including Multisite) must be used to dress one wound only. As a guide:

10. Instructions for use (continued)

10.1. Guidance on wound suitability (continued)

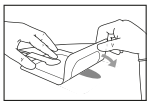
Depth - Wounds greater than 0.5cm (¼ in.) in depth are likely to require a foam or gauze negative pressure wound therapy filler to ensure adequate treatment of all the wound surface. Wounds treated with the PICO 14 System should generally be no more than 4.5 cm (1 ¾ in.) in depth and must not contain exposed arteries, veins, nerves or organs (see Section 3 - Contraindications).

Exudate – the PICO 14 System is intended for use on wounds where the level of exudate is low (up to 0.6g of liquid exudate/cm^2 of wound area/24 hours) to moderate (up to 1.1g of liquid exudate/cm^2 of wound area/24 hours). 1g of exudate is approximately equal to 1ml of exudate. When used on a moderately exuding wound, the size of the wound should generally be no more than 25% of the dressing pad area.

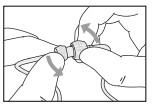
10.2. Application

The dressing should only be applied by a healthcare professional.

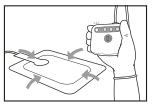
1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the first release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the soft port. Ensure the dressing lies flat to the wound and the surrounding skin. The port should be uppermost from the wound (depending on the patient's primary position), placed on intact skin and not extending over the wound to prevent fluid pooling around the soft port and blocking the therapy. Remove the other remaining handle(s) and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.



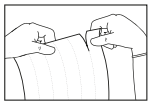
3. Once the dressing is in place, remove the pump and the batteries from the tray.
   Warning: The PICO 14 pump contains a MAGNET.
   Keep the PICO 14 pump at least 4 inches (10 cm) away from other medical devices at all times. (See Section 6 Magnet Warning)
4. The direction in which the batteries should be placed is indicated inside the battery compartment. Insert batteries. Replace the cover. Following this all four indicators should illuminate for 3 seconds.
5. Join the pump to the dressing tubes by twisting together the connectors. The soft tube can be directly connected to the pump if long tubing is not required.

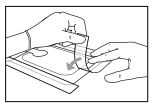


6. Press the orange button to start the application of negative pressure wound therapy. The green OK indicator and orange air leak indicator will start to flash together (indicates pump working to establish therapy). Depending on the size of the wound, **the pump should take up to 100 seconds to establish therapy**. If after 100 seconds the system has not established therapy, just the orange air leak indicator will flash. To troubleshoot refer to section 16.



7. If using NO-STING SKIN-PREP° prior to application of the fixation strips (see section 7 . Precautions), wipe the area surrounding the dressing and allow skin to dry.
8. Apply the fixation strips all the way around the dressing border. Remove top carrier on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressing. 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 border by approximately 1cm (2/5 in.). Ensure tubing is not twisted or trapped between clothing.
   Please note that if at any time the fixation strips are removed, the dressing should also be replaced. If desired, gel patches may be applied in addition to the fixation strips to help achieve or maintain a seal.





10.3. Use of the PICO 14 System with graduated compression therapy

When using the PICO 14 System with graduated compression therapy you must comply with indications and contraindications for both products.
The PICO 14 System can be used with compression for the treatment of venous leg ulcerations.

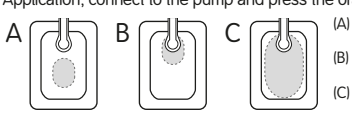
Ensure all tubing including flat soft port tubing is not in contact with skin.
When using compression therapy ensure the flat soft port tubing runs over the top of the first layer and beneath subsequent layers.

In a clinical study using the PICO Single Use Negative Pressure Wound Therapy System with compression therapy in venous leg ulcers, device-related adverse events included maceration, increase in ulcer size, blistering, and irritation. Care should be taken when combining these therapies, consider more frequent wound monitoring. Please discontinue combination use if maceration or increase in wound size is observed.

10.4. Dressing change

Dressings should only be changed by a healthcare professional

1. 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, however, when using a filler with the PICO 14 System, the dressing should be changed 2 to 3 times a week. The orange dressing full indicator on the pump will flash if it detects a full dressing or blocked filter. More frequent dressing changes may be required depending on the level of exudate, condition of the dressing, wound type/size, orientation of the dressing, environmental considerations or other patient considerations; e.g. when the PICO 14 System is used on infected wounds. Additional dressings for the PICO 14 System are available for purchase separately.
2. Inspect the PICO dressing regularly. If the dressing appears ready for changing (see diagrams A-C), press the orange button and disconnect the dressing from the pump. The fixation strips should be stretched away from the skin and the dressing lifted at one corner and peeled back until it has been fully removed. Apply another dressing as per section 10.2. Application, connect to the pump and press the orange button to reinitiate the therapy.



(A) Dressing properly positioned and is acceptable to be left in place
(B) Dressing requires change – Port may block with fluid
(C) Dressing requires change – Absorbent area is full

3. Based on dressing change frequency, further dressings may be required, see Section 18 – System Variants.
4. The PICO dressing should be disposed of as clinical waste.
5. The pump life ends and it automatically stops functioning at 14 days (all the indicators will turn off at this point). The batteries should be removed from the pump; and both batteries and pump disposed of according to local regulations.
6. For additional information on disposal requirements speak to your Smith & Nephew representative.

10. Instructions for use (continued)

10.5. 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 a 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 the surface of the wound. Avoid over packing.

10.6. 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 Antimicrobial Barrier Dressing may be used under PICO dressings.

10.7. To remove a dressing

Dressings should only be removed by a healthcare professional.

1. Stop the PICO 14 pump by pressing the orange button - All indicators will turn off.
2. Remove the pump from the dressing by untwisting the connectors.
3. Remove the PICO dressing by stretching the fixation strips away from the skin. Lift the dressing at one corner and peel back until it has been fully removed.
4. The PICO dressing 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.

11. General use

11.1. Showering and bathing

Light showering is permissible; however, the PICO 14 pump should be stopped and disconnected (see section 7. Precautions) and placed in a safe location where it will not get wet. The PICO dressing should not be exposed to a direct spray or submerged in water. While disconnected, ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube. After showering and bathing the PICO 14 pump should be reconnected to the dressing and restarted by pressing the orange button.

11.2. Cleaning

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.

11.3. Inserting or Changing Batteries

Remove the back cover from the PICO 14 pump to access the battery compartment. The direction in which the batteries should be placed is indicated inside the battery compartment. Insert batteries. Replace the cover. Following this all four indicators should illuminate for 3 seconds. After changing the batteries, press the orange button to restart the pump.

12. Specifications

Pump Dimensions	65 x 78.5 x 21mm (2.6 x 3.2 x 0.9in)
Pump weight (including batteries)	<108g
Operating Time	14 days
Battery Type	2 x AA 1.5V (LR6/FR6)
Power (Battery)	3V DC
Ingress Protection	IP22
Maximum Vacuum	100 mmHg
Mode of Operation	Continuous
Patient Protection	Defibrillation-proof type BF
Short Term Storage / Transport Conditions	-13F to +41F allowable for up to 7 days
Storage / Transport Conditions	41°F – 77°F 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, IEC60601-1-6 & IEC60601-1-11 Certified To CSA STD C22.2 # 60601-1

13. PICO 14 System compatibility with other diagnostic procedures

The PICO 14 pump and PICO dressings are compatible with defibrillation. If in the event that defibrillation is required, remove the dressing and pump if it is positioned in a location that will interfere with defibrillation. PICO dressings are MRI compatible, however, the PICO 14 pumps are not MRI compatible. The PICO 14 pump is unsuitable for use in areas where there is danger of explosion (e.g oxygen rich environments such as Hyperbaric oxygen unit).

14. Safety of the PICO 14 System

When used in accordance with the manufacturer's instructions, the PICO 14 System complies with the General Requirements for Safety of Electrical Medical Equipment (IEC 60601-1). The PICO 14 System is intended for uncontrolled environments e.g. home use (IEC60601-1-11). The PICO 14 System has no Essential Performance, and no extra specific precautions are needed regarding basic safety.

15. Electromagnetic compatibility of the PICO 14 System

The PICO 14 System 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 PICO 14 System 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.

Guidance and manufacturer's declaration – electromagnetic immunity

The PICO 14 System is intended for use in the electromagnetic environment specified below.
The customer or the user of the PICO 14 System 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 14 is a battery powered device.	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line	PICO 14 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°, 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 cycles 0% UT (100% dip in UT) for 250 cycles 0% UT (100% dip in UT) for 300 cycles	PICO 14 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 healthcare environments
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 14 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 14 is used exceeds the applicable RF compliance level above, the PICO 14 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:

Guidance and manufacturer's declaration – electromagnetic emissions the PICO 14 System

The PICO 14 System is intended for use in the electromagnetic environment specified below. The customer or the user of the PICO 14 System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Group 1	The PICO 14 System 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 PICO 14 System 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 the PICO 14 System.

Portable and mobile RF communication devices (mobile telephones) can affect the PICO 14 System.

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

The PICO 14 System 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.

WARNING: 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 PICO 14 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m):		
	150 kHz to 80 MHz $d = 0.58\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.175\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 0.35\sqrt{P}$
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

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.

16. Troubleshooting

The PICO 14 System has visual indicators to let the user know when there is an issue. The PICO 14 System 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.

Display/Indicator status	Possible cause	Comments/troubleshooting
 All indicators off	The pump is in standby. The pump has completed its course of negative pressure wound therapy. The batteries have depleted.	Negative pressure wound therapy is paused. Press the orange button to restart negative pressure wound therapy. Pressing the orange button will not restart negative pressure wound therapy. Healthcare professional to apply new pump and dressing if further negative pressure wound therapy is required. If the pump has not yet completed its course of negative pressure wound therapy, replace the batteries.
 Green 'OK' and orange 'leak' indicators flash	The pump is working to achieve negative pressure wound therapy but has not reached the intended pressure.	Wait up to 100 seconds. Assess whether negative pressure wound therapy has been established.
 Green 'OK' indicator flashes	System is functioning properly. No issues.	The pump may be heard running occasionally as it maintains the negative pressure. This is normal.
 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.
 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).	Smooth down the dressing and strips to remove any creases. Press the orange button to restart therapy. If the air leak remains, the orange 'leak' indicator will flash again after approximately 100 seconds. Ensure that the tube connectors have been twisted together securely.
 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. (Note: the pump will automatically try to restart therapy after 1 hour).	Resolve the air leak according to instructions above. Also replace the batteries and press the orange button to restart therapy.
 Orange 'dressing full' indicator flashes	Dressing is saturated or filter is blocked. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour).	Healthcare professional to replace the dressing with a new one and press the orange button to restart therapy.
 Orange 'dressing full' and orange 'battery low' indicators flash	Dressing is saturated or filter is blocked and the batteries are low. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour).	Healthcare professional to replace the dressing with a new one. Also replace the batteries and press the orange button to restart therapy.
 All indicators solidly illuminated	A pump error has been detected. The pump can no longer apply therapy.	Healthcare professional to apply a new pump and dressing.

17. 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 labeling.

18. System variants

Dressing size	Dual dressing kits*	Fluid management packs**
Multisite small 15cm x 20cm / 5.9in. x 7.9in.	N/A	66022020
Multisite large 20cm x 25cm / 7.9in. x 9.8in.	N/A	66022021
10cm x 20cm / 3.9in. x 7.9in.	66022042	66022022
10cm x 30cm / 3.9in. x 11.8in.	66022043	66022023
10cm x 40cm / 3.9in. x 15.7in.	66022044	66022024
15cm x 15cm / 5.9in. x 5.9in.	66022045	66022025
15cm x 20cm / 5.9in. x 7.9in.	66022046	66022026
15cm x 30cm / 5.9in. x 11.8in.	66022047	66022027
20cm x 20cm / 7.9in. x 7.9in.	66022048	66022028
25cm x 25cm / 9.8in. x 9.8in.	66022049	66022029

* Dual dressing kit comprising of 2 dressings, 1 pump and pump clip, secondary fixation strips. Low exuding wounds – up to 14 day system. Additional dressings are required for moderately exuding wounds (available separately).

** Fluid management packs comprising of 5x individually packaged sterile dressings, secondary fixation strips

19. Glossary of symbols

- Follow instructions for use
- OK — Pump is functioning properly
- **Warning: The PICO 14 pump contains a MAGNET.** The PICO 14 pump must be positioned at least 4 inches (10cm) away from other medical devices that could be affected by magnetic interference. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. See Section 6 Magnet Warning.
- Air leak detected
- Dressing change needed
- Low battery
- Start/pause/resume therapy
- Rx only — Caution: Federal (USA) law restricts this device to sale by or on order of a physician
- Single Use. Do not reuse.
- LOT — Lot number
- EU: Not for general waste
- 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
- NON STERILE — Non-Sterile
- Caution
- Do not use if the package is damaged
- Storage temperature
- Manufacturer
- Date of manufacture
- Consult instructions for use
- Keep product out of sunlight
- Keep dry
- Relative humidity limits
- Atmospheric pressure limits
- Healthcare Professional
- CE — CE Mark

20. Contact information

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

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
Date of issue 04/2022

21. Clinical Summary

As per the Indications for use, PICO° Family devices can be used for different wound types, including closed surgical incisions. To assess the benefit of PICO in being able to reduce certain surgical site complications, a systematic literature review was performed. A summary of the clinical data used in this review is available at https://ifu.smith-nephew.com.