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 provides negative pressure wound therapy at 80 mmHg at 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 severely exuding wounds each PICO dressing is intended to be used for 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 moderately 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:
- Superficial and deep incisional surgical site
- Post-operative Seroma infections for high risk patients in Class I and II wounds
- Dehiscence in wounds
- 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.
- Naps 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
- Post-operative Seroma infections for high risk patients in Class I and II wounds
- Dehiscence in wounds

Note: When used on closed incisions for the reduction of SSL, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class III/IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space and perioperative 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-sterile and unsterilized tissue.
- 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 aerial evacuation.
- 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 vein ulcerations. For more information including application see section 10.2.

5. Important information

5.1 Pump Placement Warning

The PICO 14 pump contains a MAGNET. Keep the PICO 14 pump at least 4 inches (10cm) 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 Magnetic Compatibility.

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.
- 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.

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 mixtures 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 wounds in close proximity to blood vessels or delicate fascia

2. If pain, reddening, odor, sensitization or a sudden change in volume or color of wound fluid occurs during use, contact your healthcare professional right away.

3. When using the PICO 14 System, ensure that the skin is healthy and not dehisced. It is important to visually inspect the skin regularly, especially in the first week of treatment to ensure that negative pressure wound therapy is effectively 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 for 90 days after discharge 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 are designed to reduce fluid ingress, it is important that the absorbent dressings (e.g. film dressings) are not placed over the apex of the dressing as this will impair the intended evaporation of moisture through its outer layer.

8. The PICO dressing should be removed before eating or drinking or when the dressing requires a change. Any medical devices or castings 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 a softening preparation is recommended.

11. 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 the integrity of the dressing and cause an effect on the wound.

13. The use of negative pressure wound therapy presents a risk of tissue ingrowth into foam when it is used for non-vital tissue. A potential dressing failure may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.

14. The PICO 14 System may be applied 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 dressing from the wound site to the exit of the Dressing System.

15. The pump must be protected from sources of fluid e.g. from incontinence or spillages.

16. Discontinue use of the PICO 14 pump if fluid ingress is observed.

17. When removing the PICO 14 dressing, a suction source should be applied to the dressing. Whilst disconnected, ensure the end of the tubing attached to the dressing is facing down so that water does not enter the pump.

18. Do not take the pump apart.

19. The PICO dressing should only be used with PICO pumps.

20. Do not alter or cut tubing configuration or pull on the tubing or soft port.

21. Do not cut the PICO dressing pad as this may lead to loss of negative pressure wound therapy application.

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 extended over the wound so that the port and blocking the therapy. Remove the other remaining handle(s) and smooth the dressing onto the wound and the surrounding skin. The port should be uppermost from the dressing centrally over the wound to reduce the chance of wound fluid ingress.

23. If necessary, irrigate the wound with sterile saline and pat the wound dry.

24. If after 100 seconds the device has not been activated, ensure the end of the fluid ingress tubing is facing down.

25. The PICO dressing should be removed from the wound before a change in dressings, and when performing wound care or assessing the wound.

26. The PICO dressing should be removed from the wound and the soft port before any surgical drain is inserted. The drainage port should be positioned uppermost on intact skin and not extended over the wound so that the port and blocking the therapy. Remove the other remaining handle(s) and smooth the dressing around the wound to prevent resealing. Repositioning or if required border is not resealed.

27. Once the dressing is in position, the patient requires dressings from the tray.

28. This device has not been evaluated for abdominal and thoracic cavity.

8. Adverse Reactions

Excessive bleeding is a serious risk associated with the application of suction to wounds which could result in death or serious injury. Carefully consider 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 sudden or abrupt changes in the volume or color of exudate.

9. Definitions

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

- 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.

- Deep incisional SSI involves deep soft tissues of the incision (for example, fascial and muscle layers) and occurs within 30 days after any NHSN operative procedure.


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 dressings are 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).

10.2. Application

The dressing should only be applied by a healthcare professional.

1. Remove any excess fluid from the wound surface prior to applying 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. The soft port should be placed flat on the wound and the surrounding skin. The port should be uppermost from the dressing centrally over the wound to reduce the chance of wound fluid ingress into the wound. Remove the other remaining handle(s) and smooth the dressing around the wound to prevent resealing. Repositioning or if required border is not resealed.

3. Once the dressing is in position, cover the dressing with dressings from the tray.

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. If after 100 seconds the device has not been activated, ensure the end of the fluid ingress tubing is facing down.

6. Press the orange button to start the application of negative pressure wound therapy. The green LED lighting on the front panel of the PICO 14 pump should flash to start (Indicates pump working to establish therapy). Depending on the size of the wound, the pump should take up to 20 seconds to establish therapy. If 100 seconds the pump has not established therapy, the orange light 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.

9. Place top carrier on the strip after each one has been applied. These strips maintain the seal and ensure sufficient contact with skin.

10. In a difficult area, 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 (0.25 in). The additional layer of dressing is not twisted or trapped between clothing.

11. Please note that if at any time the fixation strips are removed, the dressing should also be removed. Apply new dressings and pressure 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 recommendations and contraindications for both products.

The PICO 14 System can be used with compression for the treatment of venous leg ulcers.

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, but no serious adverse events were noted. The device was well tolerated.

Pressure should be kept at any time for more than 2 minutes. If after 100 seconds the device has not been activated, ensure the end of the fluid ingress tubing is facing down.

10.4. Dressing change

Dressings should only be changed by a healthcare professional.

1. Dressing should only be changed when the 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 at least once 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 for wounds in close proximity to blood vessels or delicate fascia. The level of exudate on the wound (size/type), 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 tissue level or absorbent capacity of 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 change button to reinflate the therapy.

3. Based on dressing change frequency, further dressings may be required, see Section 10 – Instructions for use.

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.
10.4. 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 dressing and the PICO dressing should be changed 2 to 3 times a week, according to local protocol and manufacturer’s instructions. Gauze should loosely fill the dressing at one corner and peel back until it has been fully removed.

11. General use

11.1. Showering and bathing

Light showering is permissible; however, the PICO 14 System should be disconnected before showering 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 System 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 PICO 14 System may be cleaned and restarted by pressing the orange button. All indicators will turn off. The customer or the user of the PICO 14 System should assure that it is used in such an environment.

11.3. Inserting or Changing Batteries

Remove the back cover from the PICO 14 System 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.

11.4. 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, ALCICOFLEX Antimicrobial Barrier Dressing may be used under PICO dressings.

11.5. To remove a dressing

Dressings should only be removed by a healthcare professional.

1. Stop the PICO 14 System 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 off the dressing 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 the pump disposed of according to local regulations.

13. PICO 14 System compatibility with other diagnostic procedures

The PICO 14 System is intended for use in the electromagnetic environment specified below. According to EN 60601-1, the PICO 14 System is intended for uncontrolled environments e.g. home use (IEC60601-1-11). 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.

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.

Guidance and manufacturer’s declaration – electromagnetic immunity

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

Immunity test

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Immunity level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic shielding</td>
<td>±8 kV contact</td>
</tr>
<tr>
<td>Conduction (RF)</td>
<td>±2 kV, ±4 kV, ±6 kV, ±8 kV, ±15 kV air</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines</td>
</tr>
<tr>
<td>Surge IC 61000-4-5</td>
<td>±0.5 kV, ±1 kV Line-to-line</td>
</tr>
<tr>
<td>Voltage dips, short interruptions</td>
<td>±0 kV, ±2 kV, ±4 kV, ±6 kV, ±15 kV</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>30 A/m or 50 or 60 Hz</td>
</tr>
<tr>
<td>Conducted RF IC 61000-4-6</td>
<td>3 Vrms ±150 kH to 80 MHz</td>
</tr>
<tr>
<td>Radiated RF IC 61000-4-3</td>
<td>10 V/m ±20% to 2.7 GHz</td>
</tr>
</tbody>
</table>

Compliance level

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Compliance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic environment</td>
<td>±2 kV, ±4 kV, ±6 kV, ±8 kV, ±15 kV air</td>
</tr>
</tbody>
</table>

Electromagnetic environment – guidelines

Floors should be wood, concrete or tile. If floors are synthetic, the relative humidity should be at least 30%.

Recommended separation distance:

\[ d = 0.58 \, \text{VP} \]

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, should be less than the compliance level in each frequency range. 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 an electromagnetic environment specified below. The customer or the user of the PICO 14 System should be aware that stringent electromagnetic environment requirements are established in surgical areas to reduce electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) 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.

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

<table>
<thead>
<tr>
<th>Separation distance according to frequency of transmitter (m)</th>
<th>150 MHz to 300 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.7 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>d = 0.5√P (W)</td>
<td>0.25</td>
<td>0.10</td>
<td>0.05</td>
</tr>
<tr>
<td>d = 0.175√P (W)</td>
<td>0.05</td>
<td>0.05</td>
<td>0.02</td>
</tr>
<tr>
<td>d = 0.01√P (W)</td>
<td>0.05</td>
<td>0.05</td>
<td>0.03</td>
</tr>
<tr>
<td>d = 0.01√P (W)</td>
<td>0.05</td>
<td>0.05</td>
<td>0.03</td>
</tr>
<tr>
<td>d = 0.01√P (W)</td>
<td>0.05</td>
<td>0.05</td>
<td>0.03</td>
</tr>
<tr>
<td>d = 0.01√P (W)</td>
<td>0.05</td>
<td>0.05</td>
<td>0.03</td>
</tr>
</tbody>
</table>

NOTE 1: At 80 MHz and 900 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 alarms. The pump should be carried so that it is accessible and the patient or healthcare professional can check the status routinely if there is a fail or in case of damage.

Table: Display/Indicator status.

<table>
<thead>
<tr>
<th>Display/Indicator status</th>
<th>Possible cause</th>
<th>Comments/troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>All indicators off</td>
<td>The pump is in standby.</td>
<td>Replace the batteries and press the orange button to restart therapy.</td>
</tr>
<tr>
<td></td>
<td>The pump has completed its course of negative pressure wound therapy.</td>
<td>The pump may be heard running occasionally as it maintains the negative pressure. This is normal.</td>
</tr>
<tr>
<td></td>
<td>The batteries have depleted.</td>
<td>The pump is not being applied.</td>
</tr>
<tr>
<td>Green ‘OK’ and orange ‘leak’ indicators flash</td>
<td>System is functioning properly. No issues.</td>
<td>Check the pressure dressing.</td>
</tr>
<tr>
<td>Green ‘OK’ indicator flashes</td>
<td>System is functioning properly but the batteries are low.</td>
<td>Replace the batteries.</td>
</tr>
<tr>
<td>Orange ‘leak’ and orange ‘leak’ indicators flash</td>
<td>A high air leak has been detected.</td>
<td>Replace the pump and dressing with a new one and press the orange button to restart therapy.</td>
</tr>
<tr>
<td>Orange ‘leak’ and orange ‘leak’ indicators flash</td>
<td>A high air leak has been detected and the batteries are low. Therapy is not being applied.</td>
<td>Replace the battery.</td>
</tr>
<tr>
<td>Orange ‘dressing full’ indicator flashes</td>
<td>Dressing is saturated or filter is blocked. Therapy is not being applied.</td>
<td>Replace the pump and dressing with a new one. Also replace the batteries and press the orange button to restart therapy.</td>
</tr>
<tr>
<td>Orange ‘dressing full’ and orange ‘leak’ low indicators flash</td>
<td>A pump error has been detected.</td>
<td>Replace the pump and dressing.</td>
</tr>
</tbody>
</table>

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.