6. Apply the fixation strips to each of the wounds or where the level of exudate is low (nominally 0.5 g of liquid exudate/ cm² of wound area/hour). If exudate is significantly limited, apply a thin layer of secondary dressing.

7. Exudate – PICO is intended for use on wounds where the level of exudate is low (nominally 0.5 g of liquid exudate/ cm² of wound area/hour). If exudate is significantly limited, apply a thin layer of secondary dressing.

8. Application

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 central release handle and place the dressing centrally over the wound. The pump should be taken up to 30 seconds to establish negative pressure. If PICO has not been established the pump will stop after 15 seconds. If the dressing is not established within 30 seconds, use the Dressing Change Indicators (see the therapy) to ensure the therapy have an increased risk of infection, ACTICOAT™ Flex silver-coated dressings are intended.

9. Instructions on wound care

7.1. Guidance on wound suitability with management with PICO

PICO should be used on wounds which fit comfortably within the area of the pad, observing precautions on positioning the therapy and not extending over the wound.

7.2. Application

Table 1 – Pump status indication, alarms and faults

<table>
<thead>
<tr>
<th>Display status</th>
<th>Indicator status</th>
<th>Possible cause</th>
<th>Comments/trouble shooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>All lights off</td>
<td>The pump is OFF</td>
<td>The pump has reached the end of life.</td>
<td>The batteries are no longer functional.</td>
</tr>
<tr>
<td>Pump flashing</td>
<td>The pump has been paused.</td>
<td>The orange button will remain flashing and the green light will flash.</td>
<td></td>
</tr>
<tr>
<td>All lights off</td>
<td>The system is in test mode.</td>
<td>The orange button will remain flashing and the green light will flash.</td>
<td></td>
</tr>
<tr>
<td>All lights on</td>
<td>The system is in operation.</td>
<td>The orange button will remain flashing and the green light will flash.</td>
<td></td>
</tr>
</tbody>
</table>

7.4. Use with fillers and wound contact layers

PICO can be used for the treatment of standard grade and foam dressings used in traditional NPWT where this is clinically appropriate. For example the use of a thin layer of a wound-dressing layer. If a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to the dressing change frequency.

7.5. Cleaning

Adherence to clinical directives concerning hygiene is of prime importance. The pump should be wiped down with a damp cloth after each use and then dried with a dry cloth. This practice helps to prevent contamination of the therapy.

8. General use

8.1. Showering and bathing

Light showing is permissible; however, the therapy should be removed from the patient's environment and not extend over the wound.

8.2. Clearing

9. Faults and technical assistance

If your device develops a fault or there are signs of damage, refer to Table 1.

• Becoming twisted or trapped under clothing or bandages so that the negative pressure is blocked.
• Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO due to risk of puncturing organs or blood vessels.

5. In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. The dressing repair is to position it in a location where it will not interfere with defibrillation.

6. MRI compatibility: PICO is MRI compatible. Do not take PICO into the MRI suite.

7. PICO has not been studied on pediatric patients. Patient size and weight should be considered when using the therapy.

8. PICO is unstable for use in areas where there is a high risk of dermal erosion (e.g. hyperbaric units).

9. PICO is not suitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.

5. Precautions

1. Precautions should be taken in the following types of patients who are at high risk for bleeding complications:

• Receiving anticoagulant therapy or platelet aggregation inhibitors or aspirin.
• Having weakened or fragile blood vessels or organs or in areas where the dressing site is not fully healed (e.g. anastomoses, infection, trauma or ulceration).
• Suffering from difficult wound management.
• Unmaintained for treatment of all the wound surfaces.

4. Where PICO is 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.

3. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing does not compromise of bleeding.

2. PICO dressings should only be applied by a healthcare professional. Dressings should not be removed until the dressing has been changed by the patient.

1. Where PICO is 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.

4. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing does not compromise of bleeding.

3. PICO does not contain audible alarms.

2. The pump should be carried so that it is easy to access by the patient's healthcare professional can check the status routinely.

1. ALthough PICO can be used under clothing/hugging, it is important that occlusive materials (e.g. film dressings, are not applied onto the skin as the tissue will be impaired by the reduction in oxygen through that layer of the skin.

7. The PICO dressing should not be covered by rigid immobilisation devices or casts which might apply excessive pressure and cause tissue injury at the wound site, especially where the tubing enters the dressing.

6. 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.

5. Where PICO is used on patients with fragile skin, a protective barrier such as SKIN-PREP™ should be used on areas of skin where friction is likely to occur. Application of frictional dressing may otherwise result in skin stripping.

4. If repositioning is required, care should be taken to ensure the dressing is facing down so that water does not enter the top of the tube.

3. Do not take the pump apart.

2. The therapy has been paused. The orange button will remain flashing and the green light will flash.

1. After 4 days of therapy the pump will automatically cease functioning. In this case all the lights will turn off (PICO), and the orange button will provide a visual indication that the pump is ready to perform in case the amber light indicator will illuminate. To troubleshoot refer to section fit of Table 1.

1. The pump has reached the end of life.

2. The batteries are no longer functional.

3. If the pump has had less than 7 years usage, the batteries may need to be replaced. Consider replacing them as below.

4. Once the dressing is in place, remove the pump and tubing connections.

5. Press the orange button to start the application of negative pressure. The green indicator will start to flash (indicates pump working to establish NPWT). Once the pump and tubing connections have been established the pump will wait for 15 seconds to allow the negative pressure to be established. If NPWT has not been established the pump will shut down after 30 seconds and the amber light indicator will illuminate. In this situation the amber light indicator will illuminate. To troubleshoot refer to section fit of Table 1.

1. The orange light indicates that the therapy is indicating a fault. Please refer to the therapy’s instructions for troubleshooting.
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial environment. 30 A/m

RF transmitters, an electromagnetic site survey should be conducted to assess the electromagnetic environment due to fixed radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment, fixed transmitters, such as base stations for radio (cellular/cordless) telephones and portable communications equipment (transmitters) and PICO as recommended below, according to communications equipment (transmitters) and PICO as recommended below, according to

Recommended separation distances between portable and mobile RF communications equipment and PICO

The healthcare professional or the user of PICO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and PICO as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>Not applicable</td>
</tr>
<tr>
<td>0.04</td>
<td>Not applicable</td>
</tr>
<tr>
<td>0.05</td>
<td>0.04</td>
</tr>
<tr>
<td>0.1</td>
<td>0.04</td>
</tr>
<tr>
<td>0.15</td>
<td>0.15</td>
</tr>
<tr>
<td>0.2</td>
<td>0.15</td>
</tr>
<tr>
<td>0.25</td>
<td>0.25</td>
</tr>
<tr>
<td>0.3</td>
<td>0.25</td>
</tr>
<tr>
<td>0.5</td>
<td>0.25</td>
</tr>
<tr>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

For transmitters used at maximum output power listed above, the recommended separation distance of PICO in metallic environment is calculated using the equation applicable to the frequency of the transmitter. P is the maximum power rating of the transmitter in watts according to the transmitter manufacturer.

Note: At 80 MHz and 500 MHz, the separation distance for the highest 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.

Guidance and manufacturer's declaration – electromagnetic emissions

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

13. Glossary of symbols

- **Equipment Classification**
- **Isolation Type**
- **RF applied part**
- **Single use. Do not re-use**
- **Manufacturer**
- **International classification**
- **Keep dry**
- **Lot Number**
- **EU: Not for general waste**
- **Storage temperature**
- **CE Mark**
- **Caution**
- **MRI Unsafe – Keep away from magnetic resonance imaging (MRI) equipment**
- **Do not use if the package is opened or damaged**
- **Keep product out of sunlight**
- **Leak alert**
- **Date of manufacture**
- **STERILISED**
- **Product is sterilised by Ethylene Oxide**
- **Battery power indication**
- **Pump is functioning properly**
- **Caution: Federal (USA) law restricts this device to sale by or on order of a physician**
- **Start/pause/resume therapy**
- **Follow instructions for use**
- **Consult instructions for use**

---

**Table 9**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power frequency (50/60Hz)</td>
<td>30 A/m</td>
</tr>
<tr>
<td>Magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
</tr>
<tr>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td>Conducted RF</td>
<td>±5 V/500 kHz</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>±1 V/500 MHz</td>
</tr>
<tr>
<td>Electromagnetic emissions IEC 60601-3-3</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Cautions</td>
<td>This user guide 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 guide and all applicable labeling.</td>
</tr>
</tbody>
</table>