

+ User guide

Back at home, not back in hospital



Smith+Nephew

PICO[◇] 7

Single Use Negative Pressure
Wound Therapy System

PICO[◇] 14

Single Use Negative Pressure
Wound Therapy System

Helping you get **CLOSER TO ZERO[◇]**
delay in wound healing







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wound therapy + orthopaedic
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burns + assessment + orthopa

Introduction

This user guide will outline important information to help health care professionals (HCPs) with PICO[®] Single Use Negative Pressure Wound Therapy (NPWT) system. The handbook will answer basic questions about the therapy. It is also intended to help HCPs inform patients about their therapy with PICO.

For detailed product information, including indications for use, contraindications, effects, precautions, warnings, and important safety information, please always consult product's Information for Use (IFU) prior to use.

PICO 7

Single Use Negative Pressure Wound Therapy System

PICO 14

Single Use Negative Pressure Wound Therapy System



What is PICO[◇] ?

PICO is a single use Negative Pressure Wound Therapy system. The PICO system works via multiple mechanisms of action. These include removal of exudate, compressive forces that aid in the reduction of oedema, protection of the wound environment from outside contaminants that ultimately promote a healing environment. The PICO system consists of a disposable NPWT pump that connects to an innovative dressing that manages fluid through absorption and evaporation^{1,2,3,4,5,6}.

PICO has been proven to reduced surgical site complications⁸ and kick start chronic wounds into a healing trajectory^{9,10} . Through early or prophylactic use, PICO is clinically effective to both prevent infection⁸ and promote healing^{9,10} when compared with standard care across a number of wound aetiologies (e.g. closed surgical incisions, chronic hard to heal wounds, venous leg ulcers)

The PICO system is available in a 7 day pump duration (PICO 7) and a 14 day pump duration (PICO 14).



How does the PICO[◇] system work?

Activating the PICO System

Insert the batteries into the pump, following the indicated direction inside the compartment cover and replace the cover. Join the pump to the dressing by twisting together the tubing connectors. If the long tubing is not required the soft tube can be connected directly to the pump.

Press the **orange button** to start the application of negative pressure.

Depending on the size of the wound and the pump used (either PICO 7 or PICO 14) the pump may take up to 100 seconds to establish negative pressure.

When negative pressure is established only the **green 'OK' indicator** will remain flashing.

Battery

On the front of the pump, the **green 'OK'** and **orange 'battery low'** indicators will flash together when the batteries need changing.

On the reverse of the pump, the battery cover can be slid on and off, with visual arrow indicators to simplify the insertion and removal of batteries.⁷



Press the **orange button** to pause the therapy. Slide the battery cover off from the top of the pump and replace with two new alkaline AA batteries. Put the cover back on and press the **orange button** to restart your therapy.

Air Leaks

If an air leak has been detected, an **orange 'leak' indicator** will flash. You will hear the pump make a buzzing sound as it tries to get to the right vacuum.



Smooth down around the outside of your dressing including the strips with your hands to remove any creases. Ensure that the tube connectors have been twisted together securely.

Press the **orange button** to restart your therapy. If the air leak remains, the **orange 'leak' indicator** will flash again after approximately 60 seconds.

Please contact your healthcare professional if you have continuous issues with the flashing **orange 'leak' indicator**.

Dressing

The dressings have a wear time of up to 7 days depending on the amount of fluid from the wound.^{1,7} This will depend on the size, type, drainage amount and position of the wound. Dressing changes are at the HCP's discretion, in line with standard wound management guidelines.



If the dressing is saturated or the filter is blocked, the **orange 'dressing full' indicator** will flash.



Dressing properly positioned and this is acceptable to be left in place



Dressing requires change



Dressing requires change

People living with PICO[®]

General activity

The PICO pump is completely portable and may be carried in a pocket or on the person's belt, depending on the size and location of the wound. It is advisable to keep the pump accessible in order to make routine status checks.

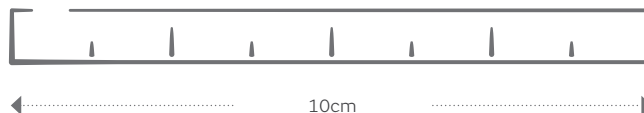


Pump Placement

The PICO Pump contains a magnet. Keep the PICO pump at least 10cm away from other medical devices at all times. Failure to do so can cause interference with other medical devices.

Extension tubes are included to enable the pump to be positioned more than 10cm away from any systems that could be affected.

This warning applies to ALL users including patients, caregivers, healthcare professionals and all persons close to the system. Please refer to the Frequently Asked Questions for additional detail.



Sleeping

Make sure that the PICO Pump is placed somewhere safe and cannot be pulled off a table or cabinet onto the floor during sleep.

Washing and Showering

Light showering is permissible; however, the pump should be disconnected and placed in a safe location where it will not get wet. Whilst disconnected the dressing should not be exposed to a direct spray or submerged in water. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube.

Please refer to the Frequently Asked Questions for details on how to disconnect the pump.

Travel

Persons prescribed therapy with PICO can travel on an aircraft, train and boat whilst it is in operation. Special care must be taken regarding pump positioning when in close proximity to other people (please refer to the Safety section).

During transport there is a potential for radio frequency interference that could affect PICO performance. If the PICO Pump malfunctions, replace batteries using the instructions in the Battery section. Please refer to the Frequently Asked Questions section for more detailed explanations.



Frequently asked questions

Are there audible alerts?

PICO^o does not contain audible alerts.

Can PICO be used with foam and gauze negative pressure wound fillers?

PICO is approved for use with foam and gauze negative pressure wound fillers. The use of a filler will increase the frequency of dressing changes to 2-3 times per week.

Can the PICO dressing be cut?

The PICO dressing pad should not be cut as this may lead to loss of Negative Pressure. To improve conformability in awkward areas the film border may be cut up to 1cm away from the edge of the pad.

Compatibility of PICO

Medical therapy/ diagnostic procedure	PICO Pump	PICO Dressings
Defibrillation	Compatible	Compatible
Magnetic Resonance Imagine (MRI)	NOT Compatible	Compatible
Hyperbaric Oxygen (HBO)	NOT Compatible	NOT Compatible

How to change a dressing?

PICO Dressings should only be applied, changed and removed by a HCP only.

For closed surgical incisions the dressing should exceed the entire length of the incision and the port should not be placed directly on the incision.

For low or moderately exuding acute and chronic wounds the dressing should generally be no more than 25% of the dressing pad area.



Press the **orange button** and disconnect the dressing from the PICO pump. Open new dressing pack.

Peel off the central release handle and place the dressing centrally over the wound. Placed on intact skin and not extending over the wound to prevent fluid pooling around the soft port.

Remove the other two handles and smooth the dressing around the wound to prevent creasing. Join the pump and dressing tubes by twisting together the connectors.

Press the **orange button** to start 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 negative pressure wound therapy).

Depending on the size of the wound and the pump used (PICO 7 or PICO 14) the pump can take up to 100 seconds to establish NPWT.

Apply the fixation strips to each of the four sides of the dressing, ensuring the strips overlap the dressing boarder by approximately 1cm. Ensure the tubing is not twisted or trapped between clothing.



How do I know the system is working normally?

While the PICO[®] Pump is working correctly, the green 'OK' indicator will flash continuously. The pump may be heard running occasionally as it maintains the negative pressure. This is normal.

The dressing should have a slightly wrinkled appearance and feel firm to the touch.

The pump life ends and it automatically stops functioning at 7 days for the PICO 7 and 14 days for the PICO 14 (all the indicators will turn off at this point).

How to disconnect the pump in preparation for washing or showering?

The pump should remain connected to the dressing at all times unless there is a requirement to disconnect the pump – such as the need to wash or shower.

Firstly press the **orange button** to pause the therapy. Unscrew the two parts of the connector. Place the pump somewhere safe. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube whilst the pump is disconnected.

Once ready to reconnect the pump, join the pump and dressing tubes by twisting together the connectors. Press the **orange button** to start 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 negative pressure wound therapy).

Depending on the size of the wound, the pump should take up to 100 seconds to establish NPWT.

How to dispose of the PICO Pump

Dispose of the used PICO 7 dressing as clinical waste. If therapy is completed, the batteries should be removed from the pump and both batteries and the pump disposed of according to local regulations.

Magnet safety

The PICO Pump contains a magnet. Keep the PICO pump at least 10cm away from other medical devices at all times. Failure to do so can cause interference with other medical devices.

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 Pump at least 10cm away from other systems:

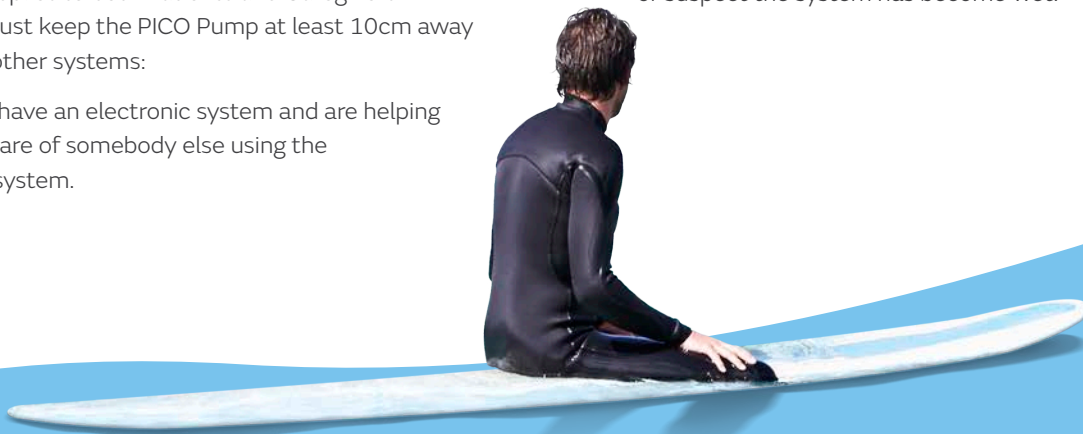
If you have an electronic system and are helping take care of somebody else using the PICO system.

If you are wearing the PICO Pump in a public area where you may come in close contact with someone else who has an electronic medical system.


What happens if the system gets wet?

Do not let the pump get wet. Protect it from the sources of fluid e.g. from incontinence or spillages. Do not use PICO if it is wet or has previously been wet. In addition, the dressing should not be exposed to a direct spray or submerged in water.

Please advise people to contact their HCP if they note or suspect the system has become wet.



Ordering codes

		PICO 7 device		PICO 14 device	Multipack with	PICO 7Y device
		+ 1 dressing	+ 2 dressings	+ 2 dressings	5 dressings	+ 2 dressings
Dressing sizes	Code	Code	Code	Code	Code	Code
	Multisite small 15cm x 20cm	–	66802000	66802040	66802020	–
	Multisite large 20cm x 25cm	–	66802001	66802041	66802021	66802031
	10cm x 20cm	66802012	66802002	66802042	66802022	–
	10cm x 30cm	66802013	66802003	66802043	66802023	–
	10cm x 40cm	66802014	66802004	66802044	66802024	–
	15cm x 15cm	–	66802005	66802045	66802025	–
	15cm x 20cm	–	66802006	66802046	66802026	–
	15cm x 30cm	–	66802007	66802047	66802027	–
	20cm x 20cm	–	66802008	66802048	66802028	–
	25cm x 25cm	–	66802009	66802049	66802029	–

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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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