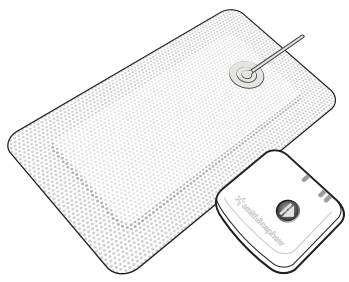
Smith & Nephew Record	
ITEM:	PICO Hard Port IFU 1.6v pump (US only)
CODE:	
THIS BSC:	18101203 / 64741
PREV BSC:	xxxxxxxx / xxxxx
DATE:	04.11.2015
REVISION:	05

STRAWBERRY Record			
Job No:	2163		
Dims:	252 x 297mm		
Colours: (Match to coated stock PMS	■ Black		
Artwork	MP	Checked	SA

smith&nephew

PICO◇

Single Use Negative Pressure Wound Therapy System



18101203 64741

PICO◇ is supplied sterile, single use. Do not use if package is open or damaged.

1. Description

The PICO Single Use Negative Pressure Wound Therapy System consists of a pump and two sterile dressing kits. The PICO pump maintains negative pressure wound therapy (NPWT) at 80 mmHg (nominal) +/- 20 mmHg to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film.

PICO is intended for use in wound sizes (surface area x depth) up to 400 c.c. which are considered to be low to moderately exuding.

The kit is intended to be used for a maximum of 7 days on low exuding wounds and 6 days on moderately exuding wounds. Therapy duration of the kit may be less than indicated if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing or environmental conditions, result in more frequent dressing changes.

2. Indications for use

PICO 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.

Examples of appropriate wound types include:

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

PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

3. Contraindications

The use of PICO is contraindicated in the presence of:

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

4. Warnings

1. 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 discontinue therapy, leave dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.
2. The use of anticoagulants does not deem a patient inappropriate for treatment with PICO however hemostasis must be achieved before applying the dressing. 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 and considered throughout the therapy.
3. At all times care should be taken to ensure that the pump and tubing does 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 negative pressure is blocked.
4. 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 while under negative pressure.
5. In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. Remove the dressing if it is positioned in a location that will interfere with defibrillation.
6. **MR Unsafe.** PICO is not 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 prescribing this therapy.
8. PICO is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
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 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.
   - Noncompliant or combative.
   - Suffering from wounds in close proximity to blood vessels or delicate fascia.
2. PICO dressings should only be applied by a healthcare professional. Dressings are not to be removed or changed by the patient.
3. 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 circulation.
5. PICO does not contain audible alarms. The pump should be carried so that it is accessible and the patient/ healthcare professional can check the status routinely.
6. Although PICO 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.
7. 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.
8. 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.
9. Where PICO is used on patients with fragile skin, a skin protectant such as 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.
10. If reddening or sensitisation occurs discontinue use and contact the treating healthcare professional.
11. Do not use PICO with oil-based products such as petrolatum as it may compromise establishing an effective seal.
12. The use of negative pressure presents a risk of tissue ingrowth into foam when this is used as a wound filler. When using foam filler with PICO, tissue ingrowth may be reduced by using a wound contact layer or by increasing the frequency of dressing changes.
13. PICO 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 Single Use Negative Pressure Wound Therapy System.
14. Pump must be protected from sources of fluid e.g. from incontinence or spillages. Discontinue device use if fluid ingress is observed.
15. When showering the PICO pump should be disconnected from the dressing. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.
16. Do not take the pump apart.
17. The dressing should not be used with any other suction pump.
18. Do not alter or cut tubing configuration or pull on the tubing.
19. Do not cut the dressing as this may lead to loss of NPWT application.
20. Always ensure that the dressing is positioned centrally over the wound. The port should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the port and potentially blocking the negative pressure is minimised.
21. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move the device out of the x-ray or scanner range. If the device has been taken into the CT scan or x-ray range, check that it is functioning correctly following the procedure.
22. This device 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.
23. High temperatures and humidity may reduce wear times of dressings.
24. During transport, there is a potential for radio frequency interference that could affect PICO performance. If the device malfunctions, replace batteries. If not corrected, contact your caregiver to replace the device. PICO is not intended for use aboard aircraft, the batteries should be removed during air travel.
25. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if PICO is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.

6. 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. Notify the healthcare professional of any sudden or abrupt changes in the volume or the color of exudate.

7. Instructions for use

7.1. Guidance on wound suitability for management with PICO

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

As a guide:

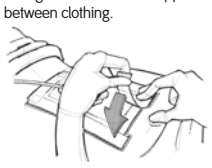
Depth – Wounds greater than 0.5cm (¼ in.) in depth are likely to require a foam or gauze NPWT filler to ensure adequate treatment of all the wound surfaces. Wounds treated with the larger dressing sizes of the PICO system should generally be no more than 2cm (⅘ in.) in depth.

Exudate – PICO is intended for use on wounds where the level of exudate is low (nominally 0.6g of liquid exudate/cm² of wound area/24 hours) to moderate (nominally 1.1g of liquid exudate/cm² 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.

7.2. 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 to reduce the chance of wound fluid coming into contact with the port. 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 port and blocking the negative pressure. Remove the other two handles and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.

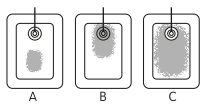
3. Once the dressing is in place, remove the pump and the batteries from the tray. Insert the batteries. Replace the cover. Following this all three lights should flash once. (Refer to Table 1).
4. Join the pump to the dressing by twisting together the tubing connectors. Press the orange button to start the application of negative pressure. The green light will start to flash (indicates system working OK, see Table 1). Depending on the size of the wound, the pump should take up to 30 seconds to establish negative pressure wound therapy.
   If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. To troubleshoot refer to section (ii) of Table 1.
5. If using SKIN PREP prior to application of the fixation strips (see Precautions), wipe the area surrounding the dressing and allow skin to dry.
6. Apply the fixation strips to each of the four sides of the dressing. 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 (⅖ 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.

7.3. Dressing change

1. Dressings should be changed in line with standard wound management guidelines, typically every 3-4 days. 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 PICO is used on infected wounds. At the healthcare professional's discretion a PICO dressing may be left in place for up to 7 days.
2. Inspect the 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 7.2, 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, a new PICO Single Use Negative Pressure Wound Therapy System kit will be required dependent on whichever of the following occurs first - either when both dressings have been used or after 7 days when the pump automatically stops functioning (all the lights will turn off at this point).
4. The dressing should be disposed of as clinical waste. The batteries should be removed from the pump; and both batteries and pump disposed of according to local regulations.
5. For additional information on disposal requirements see: www.possiblewithpico.com

7.4. Use with fillers and wound contact layers

PICO is compatible with standard gauze and foam fillers used in traditional NPWT 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 to the surface of the wound. Avoid over packing.

PICO may be used over the top of a non-adherent layer if required, for example over a skin graft.
On infected wounds or wounds at risk of infection, ACTICOAT◇ Flex silver-coated antimicrobial dressings may be used under PICO.

8. General use

8.1. Showering and bathing

Light showering is permissible; however, the pump should be disconnected (see Precautions) and placed in a safe location where it will not get wet. 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 top of the tube.

8.2. 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.

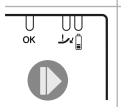
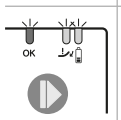
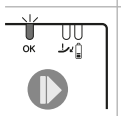
9. Faults and technical assistance

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

Table 1 – Pump status indication, alarms and faults

PICO has visual alarms to let the user know when there is an issue. PICO does not contain audible alarms. The pump should be carried so that it is accessible and the patient/ healthcare professional can check the status routinely.

Section (i) – Normal function

Display status	Indicator status	Possible cause	Comments/trouble shooting
	All lights off.	The pump is OFF.	The therapy has been paused. Pressing the orange button will restart the therapy and the green light will flash.
		The pump has reached the end of its life.	After 7 days of therapy the pump will automatically cease functioning, in this case all the lights will turn off. Pressing the orange button will not provide a green flashing light.
		The batteries are no longer functional.	If the pump has had less than 7 days usage, the batteries may not be functional and should be replaced as below.
	All lights flash once.	This reflects the pump self test once batteries have been inserted and the cover has been replaced.	This is expected.
	Green 'OK' light flashes.	Dressing applied, and full system is functioning properly.	The pump may be heard running occasionally as it maintains the negative pressure. This is normal. If this occurs frequently (several times an hour) smooth down the dressing to remove any creases that may be allowing air into the system. NPWT is still being applied in this situation.
		No issues.	

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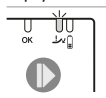
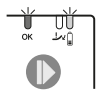
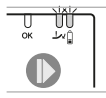
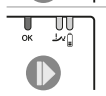
REVISION:	05

STRAWBERRY Record			
Job No:	2163		
Dims:	252 x 297mm		
Colours: (Match to coated stock PMS	■ Black		
Artwork	MP	Checked	SA

Section (ii) – Alarms and faults

Display status	Indicator status	Possible cause	Comments/trouble shooting
	Amber 'leak' light flashes.	Air leak detected possibly due to a creased dressing/ border/strip.	Smooth down the dressing and the strips to remove any creases that are allowing air into the system.
		Pump is in auto pause. NPWT is not being applied to the wound.	Press the orange button to restart the therapy. The green "OK" light will flash as the pump tries to establish therapy.
		The pump will auto pause for 1 hour and then will automatically try to re-establish therapy if no remedial action is taken.	If the air leak remains, the amber leak light will start to flash after approximately 30 seconds. If this happens, repeat smoothing actions and press the orange button. If the leak is resolved the green light will continue to flash.
	Green 'OK' light flashes.	System on and functioning properly.	Change of batteries required in <24 hours. Pause the therapy by pressing the orange button.
	Amber 'battery low' light flashes.	Battery power low.	Push open the battery cover at the top of the pump and remove the old batteries. Insert 2 new lithium (L91) batteries. Replace the cover. Press the orange button, the therapy will re-start and the green light will flash.
	Amber 'leak' light flashes.	Creased dressing/ border/strip.	Address air leak as above.
	Amber 'battery low' light flashes.	Battery power low.	Change of batteries or device required in <24 hours as above.
	All lights solidly illuminated.	Pump failed.	Contact S&N representative.
		System is not usable.	Apply new pump and dressing.

10. Specifications

Maximum Dimensions	85 x 85 x 25mm (3.5 x 3.5 x 1.0")
Weight	<120g
Operating Time	7 days
Battery Type	Lithium AA (L91)
Power (Battery)	3V DC
Ingress Protection	IP24
Maximum Vacuum	100 mmHg
Mode of Operation	Continuous
Patient Protection	Type BF
Storage/Transport	5 – 25°C, 10 – 75% RH 700 to 1060 mbar atmospheric pressure
Operating Environment	5 – 35°C, 10 – 95% RH 700 to 1060 mbar atmospheric pressure
Compliance	IEC 60601-1: 2005 IEC 60601-1-2: 2014 CAN/CSA C22.2

11. Safety and electromagnetic compatibility

When used in accordance with the manufacturer's instructions, PICO complies with the general requirements for safety of electrical medical equipment IEC 60601-1 and the electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2.

Electromagnetic compatibility

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against electromagnetic interference typical of medical installations and home use environment. Portable and mobile RF communication equipment can affect Medical Electrical Equipment.

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

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8kV contact +/- 15 kV air	+/- 8kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 cycles	Not Applicable	Not Applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	10 Vrms 150kHz to 80MHz	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	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. Interference may occur in the vicinity of equipment marked with the following symbol: 
Enclosure port immunity IEC 61000-4-3	60601-1-2: 2014 Table 9	60601-1-2: 2014 Table 9	

Note 1: At 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.

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 PICO is used exceeds 3V/m, PICO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating PICO.

WARNING: PICO should not be used adjacent to, or stacked with other electrical equipment and that if adjacent or stacked use is necessary, PICO should be observed to verify normal operation in the configuration in which it will be used.

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.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz $d= 0.35\sqrt{p}$	800 MHz to 2.7 GHz $d=0.7\sqrt{p}$
0.01	Not applicable	0.04	0.07
0.1	Not applicable	0.11	0.22
1	Not applicable	0.35	0.7
10	Not applicable	1.11	2.21
100	Not applicable	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance 'd' in metres (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.

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.

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Group 1	PICO 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 RF emissions characteristic of PICO make it suitable for use in hospital, transport and home-use environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions. IEC 61000-3-3	Not Applicable	

Cautions

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 labelling.

PICO is packed in the UK with individual components made in the following countries:

Dressing – UK
Fixation strips – Belgium
Pump – China
Batteries – Origin as marked

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

UNITED STATES Smith & Nephew, Inc.,
Advanced Wound Management,
3909 Hulen Street, Fort Worth, TX 76107.
Customer Care Center: 1 800 876-1261

Covered by or for use under U.S. Pat. 7964766, 8080702, D642594, D648353.
Date of issue 11/2015

12. System variants

8 sizes of dressing are available in kits which contain 2 dressings, 1 pump and secondary fixation strips:

10cm x 20cm / 4in. x 8in.	66800951
10cm x 30cm / 4in. x 11¾in.	66800952
10cm x 40cm / 4in. x 16in.	66800953
15cm x 15cm / 6in. x 6in.	66800954
15cm x 20cm / 6in. x 8in.	66800955
15cm x 30cm / 6in. x 11¾in.	66800956
20cm x 20cm / 8in. x 8in.	66800957
25cm x 25cm / 10in. x 10in.	66800958

Carry bag

The pump may be carried in the patient's pocket. Alternatively, a bag for carrying the pump is also available. This can be ordered with the following code:

PICO Carry bag 66800918

13. Glossary of symbols

	Equipment Classification: Isolation Type BF applied part
	Single use. Do not re-use
	Manufacturer
	International classification
	Keep dry
	Lot Number
	EU: Not for general waste
	Storage temperature
	CE Mark
	Attention: See instructions for use
	MR 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
	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