neen

inner strength, outer confidence

MADE IN THE UK

CE 0088

For more information on this and other products in the NEEN range please visit:
www.performancehealth.com

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NEEN Pericalm manual (English, French, Spanish, Chinese)

Pericalm™

Instruction Manual – GB
Mode d'emploi – FR
Manual de Instrucciones – ES
说明书 – SC

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Symbols on the unit and case

	Caution! (electrical output).
	Follow operating instructions! Failure to do so could place the patient or operator at risk.
	Neuromuscular Stimulation (STIM) and EMG Triggered Stimulation (ETS) should not be used by patients fitted with demand style cardiac pacemakers. Please seek advice from your health supervisor.
 TYPE BF	Patient's shock protection type: BF (Body floated) Equipment. Floating isolated applied part. It is only intended for connection to patient's skin but has floating input circuits. No connections between patient and earth.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Manufacturer's LOT/Batch number. Present it together with SN number when you report a technical fault or claim a warranty return.
SN	Manufacturer's serial number of the unit. Present it together with LOT number when you report a technical fault or claim a warranty return.
	Name and address of Manufacturer.
	Date of manufacture.
CE 0088	Conformity indication with the essential health and safety requirements set out in European Directives. 0088 - Notified Body identification (LRQA Ltd.).
	This product should be kept dry.
IP20 on the unit	This is an indication for protection against ingress of water and particulate matter. The mark IP20 on your unit means: your unit is protected against solid foreign objects of 12.5mm dia and greater. Not protected against water.
IP02 on the case	IP02 on the carrying case means: Protected from the ingress of water droplets from a shower of rain.
	Do not dispose in normal dustbin (see page 16 for the disposal instructions).

Language Contents

Contents

This instruction manual is valid for the Neen PERICALM™ unit. It is published by Performance Health International Ltd. Performance Health International ltd., does not guarantee its contents and reserves the right to improve and amend it at any time without prior notice.

Amendments will however be published in a new edition of this manual.

Warnings

- This unit must be used with the guidance of a Physiotherapist, Doctor or Continence Advisor.
- Type BF equipment, Continuous Operation.
- Do not insert lead wires into a mains power supply.
- Do not immerse the unit into water or any other substance.
- The unit is not protected from the ingress of water droplets from a shower of rain if used outside the carrying case.
- Do not use the unit in the presence of a flammable anaesthetic gas mixture and air or with oxygen or nitrous oxide.
- If using rechargeable 9 Volt PP3 Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect the PERICALM™ Continence directly to a battery charger or to any other mains powered equipment.
- Never connect the PERICALM™ directly to a battery charger or any other mains powered equipment.
- Patient Electrodes are for single patient use only.
- Use only CE approved vaginal or anal electrodes i.e. PERIFORM®+ or ANUFORM®.
- Store in a cool dry place out of direct sunlight
- Keep out of reach of children.
- Do not use this stimulator on your facial area unless you are under strict guidance from a qualified Clinician.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.

- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- No modification of this equipment is allowed!

Indications for use

- Pelvic pain
- Stress incontinence
- Urge incontinence

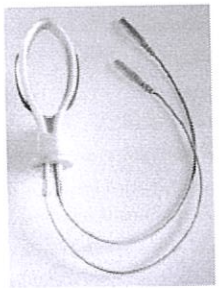
Introduction

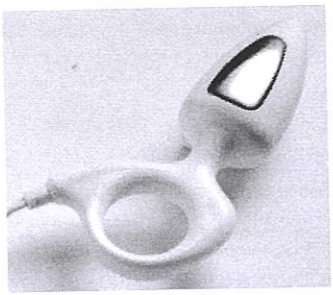
Neuromuscular stimulation is the electrical stimulation of muscle and nerve fibres that has been historically used as a form of pain relief and pain prevention.

Therapists and Doctors have an increasing understanding of the mechanisms which exist between muscles and nerves that in turn, makes it possible to stimulate the neuromuscular system with precise electrical signals to achieve a desired response.

The PERICALM™ is one of a new breed of modern neuromuscular stimulators. It is a digital, dual channel unit and is used in the treatment of patients suffering with symptoms of Stress Incontinence, Urge Incontinence and a combination of the two. The PERICALM™ also has a program for a pelvic floor workout, for pain relief and has three customisable programs so the user can set their own parameters.

The PERICALM™ should be used in conjunction with a PERIFORM® + (vaginal electrode), an ANUFORM® (anal electrode) or surface electrodes. These need to be purchased separately.





Customer Care

We welcome constructive comments for the future

Contraindications & Precautions

Before using this equipment you must first seek the advice of your Physiotherapist, Doctor or Continence Advisor.

Read this operating manual before using the PERICALM™

The PERICALM™ should not be used:

- By patients fitted with a demand style cardiac pacemaker unless so advised by their Doctor
- During pregnancy [unless medically advised]
- By patients with undiagnosed pain conditions
- By patients with undiagnosed skin, vaginal or anal conditions
- With patients who have diminished mental capacity or physical competence who cannot handle the device properly
- On anaesthetised or desensitised skin
- When driving a vehicle or operating potentially dangerous equipment
- If you have recently had any urinary tract infection or vaginal infection treated prior to using the unit
- If you have any active disease in the area
- If there is any tissue damage in the area until it is healed

Do not place electrodes:

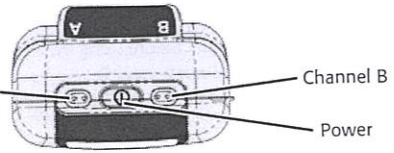
- Over carotid sinus nerves
- Over larynx or trachea
- Inside mouth
- Over the area of the heart unless so advised by your Doctor
- On your facial area unless under strict guidance from a qualified Clinician
- Take further advice before using if you have diabetes or uncontrolled blood pressure
- If you have had any abnormal cervical smears - do not use the unit until you are returned to 'normal' time between smears
- The patient should only use the unit as prescribed

If considering using the ANUFORM® (anal electrode) do not use if:

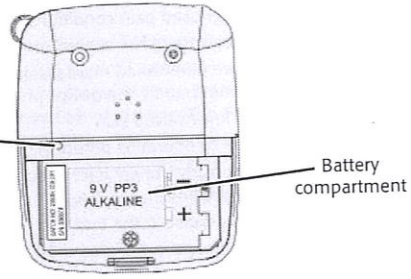
- You are suffering with acute haemorrhoids
- You have an anal fissure
- You have an acute attack of IBD (Crohns / Ulcerative Colitis) of the lower bowel

Description of PERICALM™ Unit & Functions

Top



Rear



Front

*** PRG button** Selects the desired programs - PR, STR1-2, URGE, FURG, PFW, MEM1-3.

*** SET button** Hold down for three seconds. Changes the parameters Pulse Rate, Pulse Width and Time for custom programs MEM1-3.

Quick Start Instructions

1. Insert a 9 volt PP3 Alkaline battery into the battery compartment. (Can also use a rechargeable Nickel Hydride battery (which has a longer life than the Ni-Cad rechargeable batteries)
2. Insert lead wire/s to channel A, and B if both channels are to be used. Note: only one channel is required if using PERIFORM* + or ANUFORM*.
3. Attach lead wire/s to electrodes (vaginal, anal or surface electrodes).
4. Attach electrodes to correct body position. You should check with your healthcare professional if you are in any doubt where to place electrodes.
5. Switch on the unit by pressing the Power button
6. Press the PRG (Program) button to select one of the programs as detailed on page 11.
7. To start press channel A+ and B+ button if you are using both channels until you reach the comfortable intensity.
8. To stop the program, press the Power button which will turn the unit off.

Lock Button

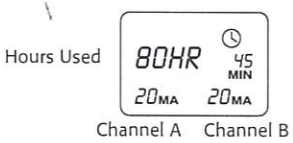
A 'concealed' Lock button is included on the PERICALM™ which locks the customised or built in programs. It also allows the clinician to accurately monitor 'home compliance' of the patient between appointments.

To Lock the Unit

1. Select the pre-set or customised program required. In the case of a customised program, make sure that the pulse width, frequency, time etc. are set-up correctly.
2. Remove the battery cover and using a thin rod, gently press on the lock button as shown in the diagram on page 8 until you hear a double beep. The unit is now 'locked' and cannot be altered until 'unlocked'

To Unlock the Unit

Remove the battery cover and press the lock button with a thin rod until a single beep is heard. Now the LCD will display the average mA used on each channel and the total hours the unit has been in use as shown in the diagram. To return to normal 'unlocked' operation, simply press PRG.



Setting up the Customised Programs MEM1-3

1. Select MEM1 for a constant program by pressing the PRG button on the front panel.
2. Hold down the SET button for three seconds to enter the setup menu. The Hz symbol will flash.
3. Press the A+ or A- button select the desired Rate (Hz) from 2 to 100 Hz.
4. Press the SET button to select the Pulse width (µS). The µS symbol will flash.
5. Press the A+ or A- button to select the desired Pulse Width from 50 to 450 µS.
6. Press the SET button to select the time. The MIN symbol will flash and number of minutes will appear on the display.
7. Press the A+ or A- button to select the desired time from 5 to 60 minutes.
8. Press the SET button to select the work time in seconds WORK will appear on the display. SEC symbol will flash.
9. Press the A+ or A- button to select the desired work time from 2 to 99 seconds.
10. Press the SET button to select the rest time in seconds REST will appear on the display. SEC symbol will flash
11. Press the A+ or A- button to select the desired rest time from 2 - 99 seconds.
12. Press the SET button to select the ramp up time in seconds RAMP will appear on the display. SEC symbol will flash
13. Press the A+ or A- button to select the desired ramp time from 0.2 - 9.9 seconds.
14. Pressing the SET button again will bring you back to the Rate setting.
15. Press the PRG button to save the program. Repeat the above procedure to re-program.

Note: You must press the PRG button before locking the unit.

Continence Treatment Programs

Programs	Hz Rate	PW µS	Ramp up time in seconds	Work time in seconds	Rest time in seconds	Overall time in seconds
PAIN RELIEF PR	2	175	1	Cont	Cont	25 min
STRESS 1 STR1	30	200	1	5	5	25 min
STRESS 2 STR2	35	210	1	5	10	25 min
URGE URGE	10	210	1	5	6	25 min
FREQUENCY/URGE FURG	10	250	1	5	10	25 min
PELVIC FLOOR WORK OUT AND LACK OF SENSITIVITY (34 MIN) PFW	**6 Sequential phases:** Phase 1: 2Hz for 4 min, Phase 2: 10Hz for 10 min, Phase 3: 15Hz for 5 min, Phase 4: 20Hz for 5 min, Phase 5: 30Hz for 5 min, Phase 6: 10Hz for 5 min All phases are 5 seconds work, 5 seconds rest at 220 µS, 0.8 seconds ramp.					
CUSTOMISED MEM 1	2 - 100	50 - 450	0.3 - 9.9	2 - 99	2 - 99	5 - 60
CUSTOMISED MEM 2	2 - 100	50 - 450	0.3 - 9.9	2 - 99	2 - 99	5 - 60
CUSTOMISED MEM 3	2 - 100	50 - 450	0.3 - 9.9	2 - 99	2 - 99	5 - 60

The parameters in the table are suggested parameters only and should be used as that.

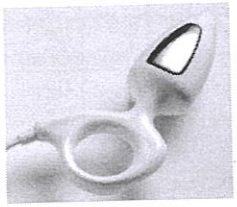
Please refer to the ACA Notes on Good Practice or The Chartered Society of Physiotherapy Guidelines, to view the most up to date neuromuscular electrical stimulation parameters.

As a clinician, you may prefer to use your own parameters to treat patients and it is then ideal for you to use the customisable programs MEM1-3.

Electrode Types & Tips

Both internal and external electrodes can be used with this unit.
They are single patient use only.

Internal electrodes:
021972 PERIFORM® + (vaginal electrode) 011503 ANUFORM® (anal electrode)



External self adhesive electrodes:
012571 50x50mm
012572 90x50mm
012574 30mm diameter
012575 50mm diameter

Tips

- If using an internal electrode, after use always wash it in warm soapy water, rinse and dry thoroughly and carefully store it for your next treatment session.
- Never let anyone else use your electrode.
- Follow all instructions provided with the electrode.
- If using self adhesive electrodes always cleanse the skin with soap and water, then rinse and dry well in order to ensure good adhesion of the electrodes.
- Clip away hairy skin using scissors, do not shave the area
- After using surface electrodes, place them back on the plastic film they were packaged in and store them in a cool place i.e. the fridge.
- After repeated use, the sticky surface on the electrode will eventually become dry. This surface is water based so by adding a few drops of water will give you a few extra days of electrode life back!
- If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.
- The electrodes conductive material is water- based. If it becomes saturated (e.g. from perspiration), it will lose its adhesive qualities. After use leave the electrodes face up overnight to dry out (replace on plastic film in the morning). At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will increase the electrode life by few more days.

Care & Maintenance

Control Unit:

- Wipe the surface after use with a damp cloth or antiseptic wipe.
- Do not use cleaning sprays or alcohol based cleaning solutions.
- Store in a cool dry place out of direct sunlight.

Battery:

- To change the battery, open the battery door on the rear of the control unit by pressing down on the raised rib pattern just below the belt clip. Lift the battery out of the compartment. This is very easy and can be done by the user.
- Check periodically for any discharge from the battery.
- Remove battery completely from unit if not in use for any extended period of time (typically one week).
- Low battery indicator of 6.9 volts shown on LCD display. When flashing change battery for a new one.
- Preferably use a PP3 alkaline battery.

Lead Wires:

- The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
- Examine lead wires before each treatment for loose connections or damage
- Avoid twisting the lead wires.
- Wipe lead wires after use with a damp cloth or antiseptic wipe.
- Avoid immersion of the lead wires in water when cleaning.
- Do not autoclave.
- Store the lead wires carefully after each use.

Self-Adhesive Electrodes:

- Check the short connectors have not become separated from the electrodes
- Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to conductive gel rendering the electrodes ineffective Vaginal / Anal Probes.
- Check the connectors have not become separated from the probe
- Before & after use always wash it in warm soapy water, rinse and dry and carefully store.
- Never let anyone else use your electrode.
- Follow all instructions provided with the electrode.

Caution: Static electricity may damage this product.

NOTE: Only Performance Health International Ltd., or appointed distributors/ importers are approved to undertake servicing.

Troubleshooting

The PERICALM™ is designed to detect any poor or intermittent connection across the electrodes and to cut off the stimulation output (mA) when it does so. This is for safety. It is designed to prevent the user from inadvertently turning up the output stimulation current in the presence of a poor or intermittent connection and then experiencing a large unexpected powerful surge in the stimulation, if and when the connection is re-established.

If you experience a problem when using with internal probes, eg. PERIFORM®+ or ANUFORM®, it may be due to a poor connection of the two stainless steel electrode plates on shaft of the probe with your body. If the probe is not fitting weel or momentarily becomes disconnected, for example, when you shift position, you will see the "0" mA symbol flashing on and off and the current will have been cut off.

If this occurs:

- Try to pull up the pelvic floor by lifting up the probe - this may re-establish the connection.
- If the internal environment is dry, use a suitable, approved water based lubricant such as KY (do not use standard creams or grease as the lubricant must be electrically conductive).
- The position which leads to lack of conductivity: The best position to conduct electrical stimulation using the vaginal probe is to stand up. However, with the shape of Vaginal Probes on the market it is not ideal to stand up as the probes tend to fall out. We recommend that the next best position is to sit down and lean back slightly.
- If you think the probe itself is not working, wash it and hold it, using your first finger and thumb to make a connection across the electrode plates. Connect it to the stimulator as normal, increase mA and, if the probe is functioning correctly, you will feel the stimulation mildly tickling your hand. Try another probe to compare.
- Check if the dual conductor lead wire cable is not broken, as it might be bent or pulled out too much which results in no conductivity: try another cable. To check if the cable is good, cross the red and black pins together so the metal is touching and increase mA. If the cable conducts the electricity, the mA will go above 10mA and you may feel the stimulation mild tickling in your fingers which holds the crossed pins.

Disposal

Information on disposal for users of Waste Electrical & Electronic Equipment (WEEE) for private households:

Electrical and electronic products including batteries should not be mixed with general household waste. For proper treatment, recovery and recycling, please take these products to designated collection points, where they will be accepted on a free basis.

Specifications

1. Dual channel: individually isolated circuits.
2. Amplitude: 0 - 80 mA into 500 Ohm load; indication only. Actual mA will tend to be less than indicated due to electrode impedance: at 1000 Ohms load (Electrodes in poor condition) the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.
3. Type: Constant Current, maximum output voltage 180 Volts +10 / -30 Volts
4. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.
5. Selectable pulse width: 50 µS – 450 µS (10% accuracy)
6. Pulse Rate selection: in the continuous mode 2 – 100 Hz (5% accuracy)
7. Time duration of the treatment: 5 - 60 minutes. (Custom programs only)
8. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
9. Open Electrode Detect: If an open circuit is detected at the output of channel A or B by: a probe not being attached, or with a probe attached but not in position, when the unit intensity is ramped up to 5mA the output current will be reset at zero.
10. Ramp up time 0.3 - 9.9 seconds.
11. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on.
12. Physical dimensions: 80 x 67 x 45 mm.
13. Weight: 90 grams without battery, 125 grams with battery.
14. Environmental conditions for storage & transport: -25 to +70 degrees Centigrade, 15-93% Humidity.
15. Battery: 9V PP3 Alcaline. Expected average battery set life [of standard 800 mAh, alkaline]: 32 hours.
16. Expected service life: 5 years. Careful use and maintenance extends the life of the unit over the service life limit.

Table 201: Guidance and manufacturer's declaration – electromagnetic emissions

The PERICALM™ product is intended for use in the electromagnetic environment specified below. The customer or the user of the PERICALM™ product should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The PERICALM™ product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PERICALM™ product is suitable for use in all establishments, including domestic establishments 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 IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 202: Guidance and manufacturers declaration – electromagnetic immunity

The PERICALM™ product is intended for use in the electromagnetic environment specified below. The customer or the user of the PERICALM™ product should ensure that it is used in such an environment, and that precautions regarding that environment are heeded.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment– guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at characteristic levels of a typical location in a typical commercial or hospital environment.

Table 204: Guidance and manufacturer's declaration – electromagnetic immunity

The PERICALM™ productis intended for use in the electromagnetic environment specified below. The customer or the user of the PERICALM™ product should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the PERICALM™ product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ (150 kHz to 80 MHz), $d = 1.2\sqrt{P}$ (80 MHz to 800 MHz), $d = 2.3\sqrt{P}$ (800 MHz to 2.5GHz), 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: ((•))

NOTE 1: At 80 MHz and 800 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 PERICALM™ product is used exceeds the applicable RF compliance level above, the PERICALM™ product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PERICALM™ product.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206: Recommended separation distances between portable and mobile RF communications equipment and PERICALM™ product

The PERICALM™ product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PERICALM™ product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PERICALM™ product 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		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 output 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.

Warranty

Performance Health International Ltd., provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 2 years from the date of purchase.

If Performance Health International Ltd., is satisfied that the product/s is defective the purchaser may return this unit/s to Performance Health International Ltd., or the appointed distributor for repair or replacement with a new unit.

All returns must first be authorised by Performance Health International Ltd., in advance. The liability of Performance Health International Ltd., under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

Customer Service

If you have any questions contact our Customer Service Team:
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www.performancehealth.co.uk

The Neen PERICALM™ is CE Approved.

CE
0088

Design Registration Applied for.