

H A N D B O O K



 Peritron

Caution: In the USA, Federal law restricts this device to sale by or on the order of a health practitioner.



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INTRODUCTION

In the clinic, Peritron™ is used for objective assessment of the strength and endurance of pelvic floor muscle contractions and for teaching pelvic floor exercises.

At home, Peritron™ provides feedback for pelvic floor exercises.

In operation, air displaced from the detachable Vaginal or Anal Sensor travels to a pressure sensor in the Display Unit via a connecting tube. The signal from the sensor is interpreted by a microprocessor and displayed either numerically in centimetres water pressure (these units can be changed – see P26) or as a multi-range bar-graph for biofeedback. Audio feedback can also be used.

Peak, average, gradient readings for a contraction and its duration may be recalled. The Peritron™ also calculates “area under the curve”.

Two buttons control all functions.

Optional collar for the vaginal sensor ensures repeatable depth of insertion.

Operating Instructions are summarized on the enclosed “Quick Start” guide

Detailed Operating Instructions start on page 13.



Peritron™ cat 9300V is supplied with the vaginal sensor.

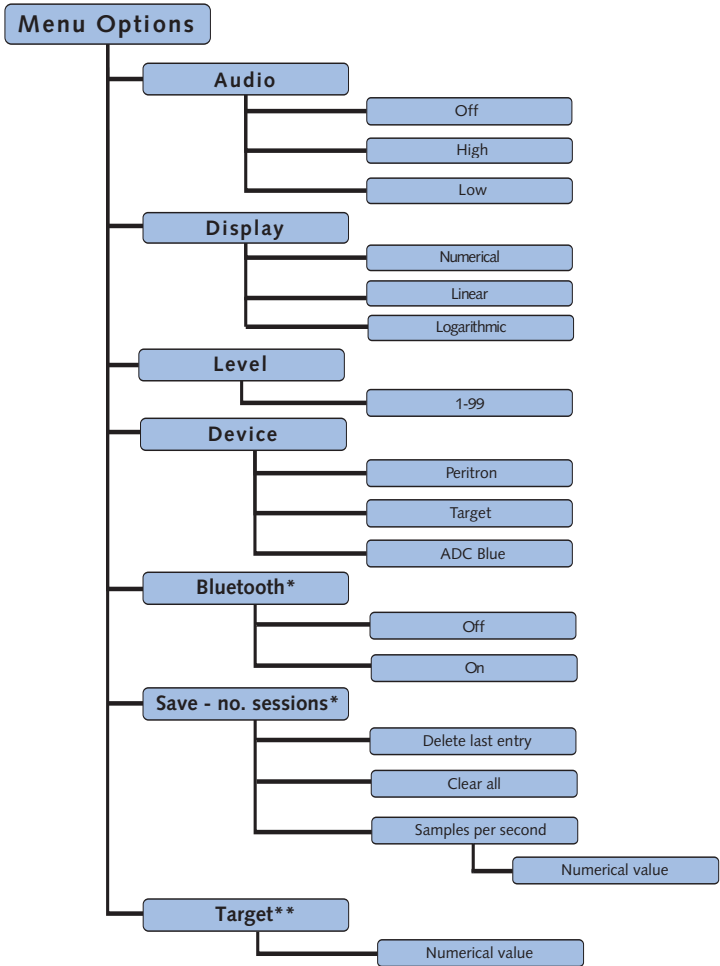
Peritron™ cat 9300A is supplied with the anal sensor.

Peritron™ cat 9300AV is supplied with both sensors.



ABOUT PERITRON

MENU AND OPERATING QUICKSTART GUIDE



* Optional

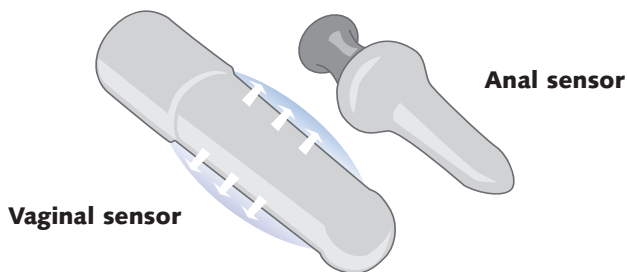
** Only available when in Target Mode

BUTTON	FUNCTION
Zero Button	<ul style="list-style-type: none"> • On – press and hold for 1 second • Off – press and hold for 3 seconds • Zero – press briefly (also resets statistics)
Toggle Button (3WTS) - In	<ul style="list-style-type: none"> • Press briefly to open the options menu • Press briefly to accept a changed option value (item flashes to show change has been accepted) • Hold in to cancel a changed value and return to the previous menu option • Hold in to return from the option menu to normal operation
Toggle Button (3WTS) - Up	<ul style="list-style-type: none"> • Access Statistics (when in normal operation) – hold up to toggle through Peak, Duration, Average, Gradient, Area under Curve. Release when a statistic name is showing to view the statistic. Display returns to normal 3 seconds afterwards • Toggle up through menu options • Toggle up through option values
Toggle Button (3WTS) – Down	<ul style="list-style-type: none"> • Toggle down to save a session • Toggle down again to stop saving a session • This will save sessions for later uploading to another Bluetooth enabled device.

OPTION	DESCRIPTION
Audio	<p>This option enables the user to turn on and off Audio feedback (a continuous musically pitched tone). The Audio feedback level is dependent upon the user's level of activity and the difficulty 'LEVEL' setting.</p> <p>The Audio volume is available in three levels, either High or Low or Off.</p>
Display	<p>This option enables the user to toggle between a Bar Chart display and a numerical (digital) display.</p> <p>To turn the Bar Chart on, select the 'LIN' or 'LOG' value. LIN represents a linear chart where each bar represents the same step size in pressure, LOG is a logarithmic chart where step size increases (becomes more difficult) as the pressure increases.</p>
Level	<p>This option determines the level of difficulty in the exercises feedback. It is used by the Bar Chart display and Audio feedback levels to ensure that the range of input activity can be tailored to a particular individual's strengths. It can be thought of as a level of sensitivity in the feedback.</p>

OPTION	DESCRIPTION
	<p>The level value ranges from 1 to 99 with 1 being the easiest (i.e. most sensitive) and 99 being the most difficult. In more complicated terms, each increment in the level refers to a step increase of approximately 5 cmH₂O; therefore a level setting of 1 refers to a full scale deflection when the user achieves 5cm H₂O. If the level is set to 10 (default), a full scale deflection needs the user to go from 0 to 50 cmH₂O.</p> <p>Being able to alter the level of difficulty enables the feedback (Bar Chart or Audio) to be more relevant and attainable for each user).</p> <p>Use the Up/Down toggle buttons to select the 'Level' value.</p>
Device	<p>This option is not available on all models. This option allows a user to alter the Devices core functionality between:</p> <ol style="list-style-type: none"> 1. Peritron™ device (A perineometer for measurement of Pelvic Floor activity) 2. Target device (A pressure based device for assessment of various muscular activities) 3. ADC Blue Device (An alternative non-pressure display of the analogue input on the second channel of the unit. Typically from an EMG. Information received on the second analogue channel is usually sent wirelessly to a receiving PC if Bluetooth functionality is enabled. By selecting the device as an ADC Blue device, the LCD on the unit displays the second channel values instead of the pressure input value. NB this reading is in millivolts)
Bluetooth	<p>This option enables and disables the Bluetooth module. (This option is not available in some markets.)</p> <p>Disable the Bluetooth module by selecting 'Off' from the option values. Turning off the Bluetooth module when not in use saves battery power.</p> <p>Enable the Bluetooth module by selecting 'ON' from the option values. When starting the Bluetooth module from the options menu, the LCD will display the 'init' message until the module is ready, at which point it will briefly display an 'ON' message. The blue LED will flash intermittently to show that the Bluetooth module is enabled.</p>
Save	<p>This option allows the user to save an exercise session to the internal memory, for upload to another device via Bluetooth. Single entries can be deleted or all entries can be deleted. The quality of the data to be saved can be determined by setting the numerical value on the samples per second option. Only available on Bluetooth equipped Peritron.</p>
Target	<p>When set to Target mode, the user aims to achieve a preset target pressure (contraction strength). Bar chart and audio feedback is given to indicate whether the user is below, on or above target. Set the numerical value to the desired target level.</p>

ABOUT THE SENSORS



Both the vaginal sensor and the anal sensor consist of an air-tight seamless silicone rubber sheath over a skeleton that allows the central section to be pressed in radially in response to a muscular contraction.

Silicone rubber was chosen for its high biocompatibility (ie none of the allergic responses associated with latex), excellent flexibility, high durability.

The wall thickness of the sheath has been kept to a minimum to ensure it transmits pressure with high sensitivity unaffected by temperature over the physiological range.

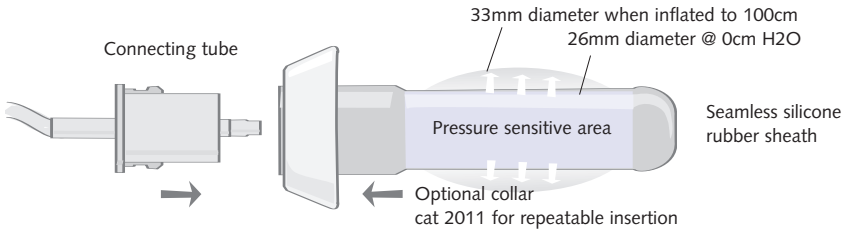
There are no joins or crevices in the contact surfaces to trap contaminants.

Sensors should be washed in warm soapy water with tubes connected prior to initial use.

Single user sensors are recommended. For such a personal item, users usually prefer their own sensor. Single user sensors eliminate the risk of cross contamination and the practitioner is relieved of the responsibility for the compliance of staff and the effectiveness of necessarily rigorous and time-consuming disinfection procedures.

Repairs. Being a sealed unit, a sensor cannot be repaired or dismantled. If a sensor fails or if the sheath loses its tension it should be replaced. See page 33 for ordering information.

VAGINAL SENSOR Cat 2005



Peritron™ and the PFX home exerciser both use vaginal sensor cat 2005.

Connecting tube with end fittings

Tube cat 2041 is 80cm long and has a 'T' with a one-way valve for optional air inflation. A tube 160cm long may be made by joining two tubes end-to-end.

Depth of insertion

Normally the sensor is inserted until 1cm of the sheath remains outside. Optional sensor collar 2011 ensures repeatable depth of insertion and simplifies patient training. It is especially useful for ensuring repeatability during clinical trials.

Lubricant

When necessary, use a water-based lubricant. It is important to wash it off immediately afterwards with soap and water otherwise it will soak into the sheath and cause it to lose tension.

Care of the sensor after use

1. Disconnect the monitor from the tube. With the sensor still attached to the other end of the connecting tube, wash the contact surfaces of both, using hand soap and warm water.
2. Rinse the sensor and tube connector in water, separate them and dry both. Shake out any water that may have entered accidentally and allow both parts to dry in air.
3. Return the sensor and tube to the case

Tip: *To prevent deterioration of the seals during storage always separate the connecting tube from both Peritron™ and the sensor*

Technical note: *The sensor requires 3-4 cm/H₂O to cause it to start to deform. After the initial deformation the resistance to further deformation is 1-2 cm/H₂O. Thus, once zeroed, the reading on Peritron™ will lag the true pressure in the sensor by 1-2 cm/H₂O.*

Optional inflation of the vaginal sensor

For every patient, the initial Peritron™ reading after insertion will depend on the geometry of the vagina, her oestrogen status, time since intercourse and stage of her menstrual cycle. It may be possible to compensate for some of the variability of this initial reading by inflating the sensor to a preset pressure after insertion. Also, an inflated sensor provides a larger and firmer surface to 'squeeze' against.

100 cm reading on Peritron™ is suggested as a suitable pressure to inflate the sensor after insertion.

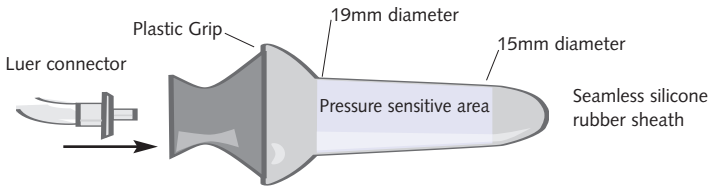
Inflation technique

1. Insert the sensor
2. Increase Peritron™ reading to 100 by syringe inflation with air via the 'T' in the connecting tube
3. Zero Peritron™ by pressing the button once, 'squeeze-and-lift'
4. Take reading(s)

Tip: *A 50 ml syringe is the most convenient. After reaching the inflation pressure, pull back the plunger of the syringe to seat the one-way valve in the inflation 'T'. Detach the syringe.*

Technical note: *Laboratory testing indicates that inflation tends to 'stiffen' the sensor and reduce its sensitivity of response. Inflating to 100 cm reduces response by about 20%. However, in the clinic this may be more than compensated for by the greater effect achieved by contracting against a firmer, larger surface.*

ANAL SENSOR Cat 3010



It is customary to use the anal sensor at atmospheric pressure ie without inflation.

Connecting tubes

Peritron™ 9300A is supplied with a 80cm PVC tube cat 3040 with a male luer connector for the anal sensor cat 3010.

Lubricant

A water-based lubricant may be used if necessary. Some practitioners use disposable mini latex sensor covers as sensor covers.

After each use

the sensor should be washed immediately in a pH neutral anti-bactericide or proteolytic enzyme cleaner and rinsed.

The Peritron display unit can be wiped clean with a damp cloth with a mild detergent if necessary. The Peritron is not water resistant, do not immerse in water to clean.

Caution: Any lubricant allowed to remain on the sheath will soak into the microporous surface causing it to lose tension and require replacement.

Technical note: The stiffness of the sheath of the sensor tends to reduce the actual pressure reaching the Peritron™ display unit. In laboratory trials, the Peritron™ reading was $\approx 75\%$ of the actual applied pressure. The effect is linear over the normal operating range. Therefore, if the true pressure is required it may be determined by dividing the Peritron™ reading by 0.75. eg when Peritron™ reading is 38cm, actual applied pressure is 50cm.

OPERATING INSTRUCTIONS

1 Use the connecting tube to join the display unit to the sensor. Use a slight twisting action when making the connection.

During assembly, handle the sensor by the rigid part of the neck to ensure the sheath remains fully round.

To eliminate the possibility of cross contamination, one sensor per user is recommended.

DISPLAY



2 Activate the Peritron™ by pressing and immediately releasing i.e. 'clicking' the power button.

It will usually display a figure of 1.0 to 2.5 when turned on. Zero the display by clicking the power button again. Even after "zeroing" the display, it may show a positive or negative number such as - 0.1. Remember this unit is 10 times more accurate than the previous model so is extremely sensitive.

If the Display is blank or shows LOBAT, fit new AA alkaline or lithium (preferred) batteries in rear compartment.



ONE CLICK 'ON'
ANOTHER CLICK
TO '0'

3 Select the operating mode by using the 3-way toggle switch (3WTS). This switch is used by pressing it up, down, or in.

Press the 3WTS in once to access mode menu. The 3WTS moves up, down and in. Press the 3WTS up (towards the tube connector) or down (away from the tube connector) to see the various modes. The words, AUDIO, DISPLAY, LEVEL, DEVICE, BLUE, SAVE, will scroll across the screen. Press the 3WTS



3 continued

in to select a mode. Press the 3WTS in once to select it and then up or down to see the settings – e.g. OFF, LO, or HIGH. Press the 3WTS in briefly while a setting is displayed to select that option. When it has been selected the name of the setting will flash on the screen and a three-tone beep will be emitted (if AUDIO is on). Pressing in the 3WTS and holding for 3 seconds will return you to the main display.

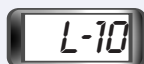
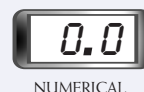
The first mode in the menu is AUDIO. Choose either OFF, LO or HIGH (volume). This will give the user audio biofeedback. It is not possible to choose LO or HIGH when Bluetooth is on as the multimedia display on your PC takes the place of the audio biofeedback on the display unit.

The second mode is DISPLAY. Choose either NO for a NUMERICAL display or LIN for a BAR display. (A row of vertical bars – more bars = higher pressure, linear progression) Choose LOG for a bar display with logarithmic progression. The LEVEL setting does affect the Bar display. When set to Level 10, 8 bars will equal 50cm/H₂O in either Log or Linear mode. If set to Level 20, 8 bars will equal 100cm/H₂O, and so on.

If necessary, in numerical or bar mode re-zero the Display at any time by clicking the power button once.

NOTE: The readout in NUMERICAL mode can register negative values. e.g. -1.3 The Display cannot register negative values when in a FEEDBACK mode.

The third mode is LEVEL. Select from 1 to 99. The higher the number the harder the patient will have to work to get some Audio or Visual biofeedback. Level 10 is the default setting.



3 continued

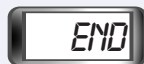
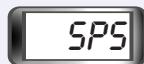
The fourth mode is DEVICE. Select PERI (Perineometer), Target or ADC BLUE. For doing pelvic floor assessment and training you need to select PERI (this is the default setting). For more information about TARGET and ADC Blue modes, please see page 25.



The fifth mode is BLUE. Select either ON or OFF. Select ON to transmit data to another Bluetooth enabled device. Select OFF to save battery power. When transmitting data the power button and the 3WTS are disabled. This mode is disabled if you have not purchased the Bluetooth option. (not available in USA). If you wish to SAVE a session to the display unit while Bluetooth is enabled, you must start the save before the Bluetooth transmission starts. You must then stop the PhysioLog software running on the PC before ENDING the SAVE on the display unit.



The sixth mode is SAVE. Press the 3WTS down to start saving a session to the internal memory (green light will flash while session is saving). Press the 3WTS down again to stop saving. The word END will appear on the screen. Each session will be numbered but no other identifier is given. Please make notes to help identify which session is associated with a particular patient on a given date. When saving data the power button and the 3WTS are disabled (Except the downward direction of the 3WTS which ENDS the save), so that the data being saved cannot be interrupted. The SPS option in SAVE mode allows you to adjust the length of a session that may be stored. SPS stands for Samples Per Second. Set at a value of 1, the data will be sampled every 100 milliseconds, if set at 2 every 200 milliseconds, and so on. Set at 1, you could store a session 13.55 minutes long, at 2 you could store 27.09 minutes, and so on. In other words, the higher the value, the lower the frequency of the data, but the longer the duration of the data that can be saved.



3 continued

Vaginal Sensor

In use, handle the sensor by the tail of the connector of the connecting tube.

AFTER OPTIONAL
INFLATION



Sensor Insertion

With user supine, a pillow or two under the head for comfort, knees at 90°, 45° angle between thighs and the mattress, knees and feet 30 cm (12 inches) apart, insert the sensor until 1.0 cm of the blue sheath is still visible.

Some users will find a crook laying position (lateral laying knees drawn up to about 45 degrees) more effective.

When repeatable depth of insertion is essential e.g. during clinical trials, we recommend use of Sensor Collar cat 2011.

If the patient is tense she may bear down on the sensor and create artificially high readings. It may help her to relax if she is asked to attempt to minimize the reading after insertion.

Optional Inflation (ref page 11)

After insertion, the sensor may be inflated to provide a standard base line for the contraction reading and to provide a firmer, larger, surface to contract against.

Suggested Inflation Protocol

With Peritron™ in Numerical display mode, insert the sensor. Use a syringe in the 'T' of the connecting tube to introduce air until the reading reaches 100 cm. Pull back on the plunger to seat the valve in the 'T' and disconnect the syringe.

4 Anal Sensor

(it is not general practice to inflate the anal sensor)

Insert sensor with patient in left lateral position and knees drawn up at about 45°.

Tip: *For highest accuracy and repeatability the user must be in the same position each session and the sensor must be inserted the same amount.*

CAUTION - Lubricant

Use water-based lubricant if necessary.

Be sure to wash it off afterwards with soap and water as long-term exposure may cause the silicone rubber sheath to lose tension.



TYPICAL READING
AFTER INSERTION
30-70

5 Zero the Display by pressing and releasing the button once.

Anal Sensor. *If this step is omitted, during relaxation feedback, the readings will decrease e.g. if reading on insertion is 50.0, readings on relaxation will be 49.2, 48.4, 47.8 etc.*

If Peritron™ is zeroed after insertion, readings on relaxation will be progressively more negative eg 0.0, -1.3, -2.6, -3.1 etc.



THIS FIGURE MAY
VARY QUITE
QUICKLY TO 0.2 OR
MORE OR LESS

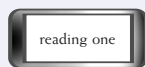
6 Measuring the Contraction

Vaginal Sensor: Ask the patient to 'squeeze-and-lift' strongly and 'hold' as long as possible.

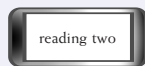
Anal Sensor: Ask the patient to squeeze or relax as required.

There will be a new reading every 0.6 seconds when in the numerical mode and ten times per second when in feedback mode.

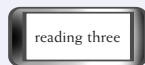
To discourage users bearing down on the sensor it may be helpful to have them read out aloud the changing values.



0.6 SECONDS



1.2 SECONDS



1.8 SECONDS

6 Evaluation the Contraction

Peak and Average readings. After the contraction you can 'recall' the peak, duration, average, gradient, and area under curve readings by holding the 3WTS up and releasing it when the name of the figure you want is on the screen. i.e. If you want the average reading, hold the 3WTS up until AVE appears on screen and then release it. The figure will be briefly displayed. The reading will cycle between these values for the most recent contraction i.e. since Peritron™ was last 'zeroed', or switched off and on again (power cycle).

For automated collection of statistics and detailed data analysis and multimedia biofeedback you need PhysioLog™ Pro software. Visit our website for details.

Duration (in seconds - from when pressure goes above 5cmH2O to when it drops below again)

Average (area under curve / duration)

Peak (max value in cmH2O)

Gradient (in cmH2O/second. This is the peak value divided by the time taken to achieve the peak - it is a measure of onset speed (better muscles, faster onset)

Area under curve (duration x average in cm-sec)
Sampled ten times per second. Divide this figure by ten to compare it with the figure obtained manually at one reading per second.

PRESS FOR
2 SECONDS



NEXT



NEXT



NEXT



NEXT



7 Withdraw the sensor.

Switch off by clicking and holding down the power button or wait for auto-off after four minutes.

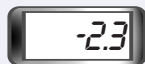
Cleaning the Sensor. After use, the sensor should be washed with soap and warm water and dried.

Vaginal sensor - refer to page 10

Anal Sensor - refer to page 12

Disconnect. It is good practice to separate the sensor/tube/monitor after use as to leave them coupled together for long periods could lead to deterioration of the seals.

THE READING WILL
BECOME NEGATIVE,
IE MINUS THE
'REST' PRESSURE OF
STEP FOUR e.g.



ABDOMINALS vs PELVIC FLOOR

About 40% of women are unable to perform a voluntary 'squeeze-and-lift' pelvic floor contraction. They require instruction. Peritron™ is invaluable in this situation as its super-sensitive feedback will respond to you clients first 'flickers', thereby motivating them to keep trying.

Abdominals vs pelvic floor

The transversus abdominus and the pelvic floor muscles tend to work together. That is, a pelvic floor contraction usually is accompanied by a contraction of the abdominals. Patients should be taught to not involve rectus abdominus or the gluteal muscles at all, if accurate measurements are needed.

As Peritron™ is measuring total pressure, it has no sure way of telling you whether it is responding to a downwards push of the abdominals or a sideways and upwards 'squeeze' of the pelvic floor.

A digital examination will enable you to determine which group of muscles is making a greater contribution to the Peritron™ reading. Palpating the abdominals and gluteals will indicate if they are overactive. Attempting to push out the sensor is a sure sign that the abdominals are overwhelming the contribution made by the pelvic floor.

If the pelvic floor exercise is being done correctly you may notice a slight anterior tilt of the sensor (towards the anus).

Your aim is to see your clients pelvic floor making an ever increasing contribution to the readings on the Peritron™.

Simultaneous EMG and Pressure Biofeedback (optional)

In between the 3WTS and the tube connector on the Peritron™, you will notice a keyhole shaped socket. With the Bluetooth and PhysioLog software option, you are able to connect an EMG device to the Peritron™ and have the EMG data and the Peritron™ data displayed simultaneously.

You may wish to monitor gluteal or abdominal muscles with the EMG while the patients pelvic floor muscles are also being monitored with the pressure sensor. Alternatively, you may wish to use an EMG electrode vaginal sensor and transmit that data to PhysioLog software

Reliability

Recent studies confirm that the Peritron™ is a reliable tool when used correctly. Please see "Reliability of Pelvic Floor Muscle Strength Assessment using Different Test Position and Tools", Vol. 25, No. 3 2006, Neurourology and Urodynamics, Frawley, Galea et al. and "A comparison of Perineometer to Brink Score for Assessment of pelvic floor muscle strength", American Journal of Obstetrics and Gynecology (2005) 192, 1583–91, Hundley, Wu , Visco.

Q. Can I use the sensors on more than one patient?

- A. Multi-patient use of sensors is not recommended. We recommend one patient-one sensor to eliminate any risk of cross contamination. Being such a personal item, ALL users prefer their own sensor which is available at a modest cost. Cleaning it becomes the responsibility of the user.

Q. My patients tend to push out the vaginal sensor...

- A. During a contraction both the abdominal muscles and the muscles of the pelvic floor act on the sensor. The pelvic floor muscles push on the side of the sensor. The abdominals push down and in doing so, attempt to push it out. When the pelvic floor is weak it is not unusual for the push created by the abdominals to be dominant. The tendency to push out the sensor will lessen when the patient has learned to reduce the action of her abdominals and increase the action of her pelvic floor.

Your aim is to see your patient's pelvic floor making an ever increasing contribution to the readings on the Peritron.

Q. What is a normal reading for vaginal measurements?

- A. As readings are influenced by the geometry of the vagina, oestrogen status, time since intercourse, and stage of the menstrual cycle there is no such thing as a 'normal' reading. For these reasons, session to session readings will vary also.

However, by way of a guide, the reading after insertion is usually 20-40. A satisfactory zero-based contraction will register 20-30. A really strong one is 60. It is the session-to-session improvements that matter.

Q. What is a Normal reading for anal measurements?

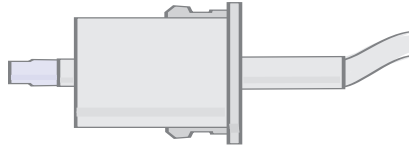
- A. A resting pressure of about 50 and a contraction of 100-150 is normal. A really strong contraction will be about 250.

Q. The sensor has gone flat – There seems to be an air leak.

- A. Did you click the sensor/tube/monitor together USING A SLIGHT TWIST. Twisting helps make a good airtight seal. If the sensor still goes flat then check that the short length of soft rubber tube on the male connectors and the mating surface of the female connectors are free of particles. Wipe them with a soft cloth/cotton bud.

The short length of soft tube makes an air-tight seal against the:

1. socket inside the vaginal sensor
2. female connector of the connecting tube of the vaginal sensor



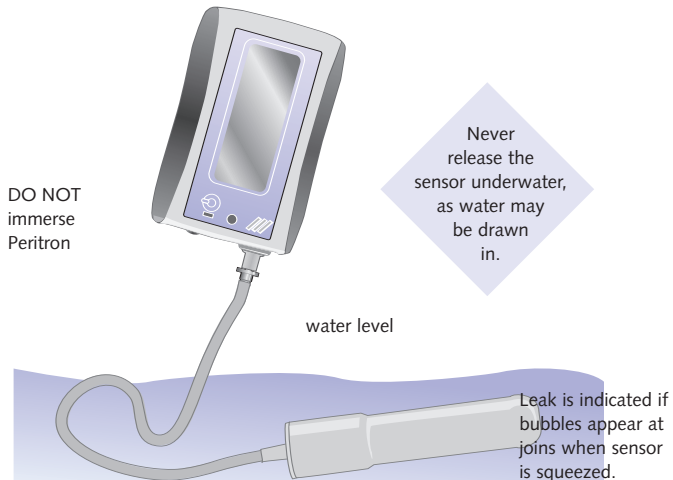
Connector on connecting tube of vaginal sensor

Water immersion leak test Join together the sensor, tube and monitor using a slight twisting action and immerse the sensor and part of the tube under water. Squeeze the sensor firmly and look for bubbles escaping. If there is a hole in the sensor it should be replaced. If no bubbles escape and the sensor still goes flat then there must be an air leak in the monitor unit. Return it to your distributor for repair. NEVER IMMERSE ANY PART OF THE MONITOR UNIT NOR ALLOW WATER TO ENTER THE TUBE as it will damage the electronics.

IEC60601-1 (Clause 5) Classification:

The Peritron is an INTERNALLY POWERED DEVICE with Type BF Applied Part for SHORT-TIME OPERATION.

The Peritron is NOT WATER RESISTANT. There is no protection against ingress of water (IPX0)



This leak test is detailed more fully on protocol sheet PI 21 which is available on request.

Q. Sometimes the reading changes when it is not being used

A. Peritron™ is adjusting to a new or changing room temperature. Click the button to reset the Display to zero.

Q. What do I do when 'LOBAT' appears in the Display?

A. Every time the Zero button is pressed, for example when turning the Peritron™ on or zeroing the unit, the Battery Power is tested; if the Battery is getting low, the LO BATTERY indicator message appears briefly – this is a warning that the batteries are low and should be changed soon. At this point the device is still accurate - the message is a warning. When the batteries become critically low, and the accuracy of the device may be jeopardized, the LOW BATTERY sign will appear during normal usage, and may remain on.

Modern batteries have many different chemistries, e.g. Alkaline, Lithium, Rechargeable, etc. and as such it is impossible to predict battery life remaining; some batteries, for example lithium batteries remain at full power until almost the end of their life, then suddenly expire.

For best practice, replace the batteries as soon as the LOW BATTERY indicator first appears.

Access to the battery compartment is via the rear hatch.

Replace it with 2 standard AA 1.5 volt alkaline batteries, or 1.2 rechargeable, or preferably AA Li-Ion batteries.

Q. How can I check the accuracy of the reading?

A. With the tube connecting the vaginal sensor to the Monitor, immerse the sensor in water, zero the Display and then immerse it an additional known depth, say 30 cm. The reading on the Display should be 28 or 29.

Technical note: *The sensor requires 3-4 cm water pressure to cause it to start to deform. After the initial deformation the resistance to further deformation is 1.0-2.0 cm water pressure. Thus, once zeroed, the reading on Peritron™ will lag the true pressure in the sensor by 1-2 cm water.*

Q. How can I change the units displayed?

A. Units of measurement can only be changed by authorised personnel. Please contact Cardio Design customer support for more information.

Q. How can I view the raw data from a session?

A. With the upgrade to PhysioLog™ Software for PC or PDA and the Bluetooth module* added to the Peritron? you are able to view the raw data file (an XML file). Please ask your distributor or visit www.cardiodesign.com.au to purchase this upgrade.

* Not available in some markets

Q. How can I give the client better bio-feedback?

A. With the upgrade to PhysioLog™ Software for PC or PDA and the Bluetooth module* added to the Peritron™ you are able to give the client visual and audio biofeedback to enhance muscle training. Please ask your distributor or visit www.cardiodesign.com.au to purchase this upgrade.

Q. Can I save the data on the Peritron™ and analyze it later?

A. With the upgrade to PhysioLog™ Software for PC or PDA and the Bluetooth module* added to the Peritron™ you can save data by pushing the 3WTS down to start and up to finish saving data. This data can later be uploaded via Bluetooth to another Bluetooth enabled device.

* Not available in some markets

TARGET DEVICE

The Target Device is used to provide audio and visual feedback to a maintained level of target pressure. When using the Target device, and additional menu option becomes available called Target. Within this option, a specified Target pressure level can be indicated, for example 54 cm H₂O. The users role is to achieve this target pressure, and maintain it. Audio and Visual bar chart displays are used to indicate to the user if they are above or below the target level. When using the Target Device, the bar chart display varies from the standard format, as below.

The bar chart is a series of lines that indicate proximity to the target activity. If the current activity level is the same as the target, the display changes to a series of hyphens:

- - - -

At this point audio feedback will also beep intermittently with a second long tone to indicate the user is achieving the correct level.

As the pressure level drops below the target level, vertical lines appear to the left of the display – the lower the drop, the more lines appear. As pressure goes above the target, vertical lines appear to the right of the display, for example:

Far below target

|||| - -

Medium below target

|| - -

On target

- - - -

Medium above target

- - ||

Very far above target

-- ||||

If the user prefers you can use the numerical display in Target mode.

When the user pressure level is within 10% of the Level Range, the audio tone starts to beep with 1 second intermittent tones. When the pressure level is outside of this 10% target zone, the audio feedback is a continuous pitched tone. Using the audio tones alone, users can learn to adjust their feedback levels of pressure – this allows the user to assume a more natural position without needing to see the visual display.

ADC BLUE

In ADC Blue mode, the Peritron™ simply becomes a wireless analog to digital converter and transmitter. This is useful if you need to transmit data from an analog source such as an EMG device to PhysioLog™ software.

The ADC Blue input jack takes an input voltage of 0-5 Volts, and displays it in millivolts on the screen, i.e. 2.5Volts will display as 2500 milliVolts.

When using a Bar chart or logarithmic display for the ADC Blue it is important to remember that the maximum value is 5 Volts. Each LEVEL step is therefore worth approximately 50.5 millivolts. (i.e. 5000mVolts max / 99 levels)... for example, the default LEVEL setting is 10, this means that a full scale deflection is equivalent to 0 to 505millivolts of input.

With an EMG that may only put out a maximum of 2 volts, you would need to increase the level to approximately 40 to see a response on the Bar display.

When in ADC Blue mode, the Peritron™ will turn off after 3 minutes of a zero reading.

CHANGING UNITS OF MEASURE

By default the units of pressure measured in the Peritron™ are centimeters of water (cmH₂O). Many peer journals use the cmH₂O unit for studies involving pelvic floor pressure. It is possible to change the Units of the Peritron™ to one of several pressure standard units. The pressure unit options are:

Centimeters of Water
Inches of Water
milliBars
Pounds Per Square Inch
Kilopascals
Inches of Mercury
Millimeters of Mercury

The switch to allow the change of units is hidden within the case.

Procedure for calibration/changing Units:

1. Turn Device Off
2. Take out batteries
3. Unscrew case
4. Put 'Calibrating pin' in,

5. Replace cover
6. Replace batteries
7. Turn device on and follow procedure for changing the calibration/units
8. Repeat process to remove the 'Calibrating pin'

The process for calibrating the unit or changing the units requires opening the case of the Peritron; this process should only be undertaken by qualified authorised personnel. If required, Cardio Design can provide this service, please contact Cardio Design customer support for more information.

For purpose of maintenance, repair, or calibration, Cardio Design will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the owner's appropriately qualified technical personnel to repair or calibrate the Peritron™. Cardio Design can provide maintenance, repair and calibration services, please contact Cardio design customer support for more information.

When the unit is not used for a long period, be sure to remove the batteries. If using rechargeable batteries, follow the manufacturer's instructions. Ensure discharged batteries are disposed of according to the manufacturer's instructions.

Do not use the equipment near other equipment or device which may interfere with its operation.

Important note:

Values stored to memory during a saved session and values transmitted via the Bluetooth transmitter are always in cmH2O. This is to ensure consistency between PhysioLog™ Software and the device, i.e. to ensure values transmitted/stored are always in the same common unit.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Perineometer Model 9300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Perineometer Model 9300 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Perineometer Model 9300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause interference in nearby equipment.
RF emissions CISPR 11	Class B	The Perineometer Model 9300 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuation / flicker emissions IIEC 61000-3-3	Not applicable	

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PERINEOMETER

The Perineometer Model 9300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Perineometer Model 9300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Perineometer Model 9300 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 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

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 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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Perineometer Model 9300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Perineometer Model 9300 should assure that it is used in such an environment.

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%
Electrical fast transient/burst	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 cycle 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 s	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3/Am	Not applicable	

Note: U_T is the a.c. mains voltage prior to the application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Perineometer Model 9300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Perineometer Model 9300 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Perineometer Model 9300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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 metres (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 the Perineometer Model 9300 is used exceeds the applicable RF compliance level above, the Perineometer Model 9300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the contour a 380.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

SPECIFICATIONS

Peritron™ is a microprocessor-based perineometer that measures the strength of pelvic floor muscle contractions by sensing the pressure of air in a vaginal or anal sensor. The pressure is displayed either numerically in centimetres water pressure or as a multi range analogue bar-graph.

Peritron™ requires no user adjustments or calibration.

Operating Range 0-300 cm water pressure.

Environmental conditions for operation: Humidity: <80%RH

Temperature: 10 to 30 Degrees Celcius

Pressure (on sensor) < 75KPa

Display Resolution 0.1 cm water.

Accuracy Max Error < 0.7 cm H₂O full scale (within operating temperature range)

Battery Life Greater than 40 hours (No Audio, No Bluetooth - tested with Lithium, Alkaline and rechargeable NiMH batteries)

Approx. 10 hours (Bluetooth on - with Lithium and rechargeable NiMH batteries)

Approx. 10 hours (Audio on - with Lithium batteries)

Monitor Numerical: Liquid Crystal 4 digits 18 mm high with indicator for battery low. Reading updated every 0.6 seconds.

Analogue: Bar graph Display of 8 elements. Reading updated 10 times/second.

Peak, Average, Duration, Gradient, Recall, Area Under Curve

When 3WTS is pressed upwards the Display shows sequentially the readings of the most recent contraction.

Vaginal Sensor of 9300V 26-28 mm dia. 55 mm long active surface, 108 mm overall with thin wall, precision molded medical grade silicone rubber sheath suitable for inflation up to 100cm water pressure

Anal Sensor of 9300A 15-19 mm dia. 30 mm long active area, 30 mm dia flange, 80 mm overall with medical grade silicone rubber sheath

Sensor Connecting Tube 80 cm PVC tube with connectors. Vaginal sensor has inflation 'T' and one way valve .

Auto-off function operates after 3 minutes of no activity

Battery 2 x 1.2 to 1.5V AA lithium cells accessible to user. Life >40 hrs – no audio, 10 hours continual audio

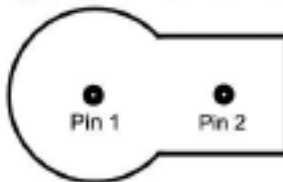
Carry case 23 x 17.5 x 5 cm, molded with insert .

Warranty Peritron™ is warranted to be free of defects for 12 months.

Peritron™ is a totally lead free product, and voluntarily complies with RoHS (Restriction of Substances Hazardous to Health) standards.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Analogue Signal Input Connection



Pin 1 - 0 to 5 Volt DC Analogue Signal Input

Pin 2 - Analogue Signal Input Ground Reference

Important - *The Analogue Signal Input is a 0 to 5 V DC analogue signal input. Any device attached to this analogue input port should comply with Medical Standard IEC60601-1. Placing a voltage over 5 Volts onto the signal input may permanently damage the Peritron and/or any other equipment attached. The Analogue Signal Input has over input protection circuitry, however care should be taken to not allow voltages over 5 Volts from entering the system, in particular care should be taken to avoid static electric shocks to any part of the Peritron. No warranty is undertaken for any damage caused to equipment attached via the Analogue Signal Input connection to the Peritron™.*

ORDERING INFORMATION

AUTHORISED ACCESSORIES

- 9300 V** Peritron™+ kit with vaginal sensor and connecting tube in case.
If anal capability required also, order anal sensor 3010 and tube 3020.
- 2005** Vaginal Sensor with inflation capability (suits PFX™ & Peritron™)
- 2041** 80 cm tube with inflation 'T' for Vaginal Sensor.
- 2011** Collar for Vaginal Sensor to control depth of insertion.
- 2141** 80 cm tube for Vaginal Sensor.
- 9300A** Peritron™+ kit with anal sensor and connecting tube in case.
- 3010** Anal sensor.
- 3040** 80 cm tube with connectors for Anal sensor.
- 9310** Physiolog Pro software*
- 9320** Physiolog Regular, Workout or Mobile Software*

*Not available in all markets

Transportation/storage limitation for Peritron are as follows:

Humidity: <80%RH (No dew condensation)

Temperature: -20 to 70 Degrees Celcius

The Peritron has been tested to the following standards by EMC Technologies Pty Ltd (Australia):

EMC - EN 60601-1-2

Radiated Emission - EN55011 / AS/NZS CISPR11

Radiated Immunity - EN61000-4-3

ESD - 61000-4-2

RS101 part of the military standard Mil Std 462D

The following have been undertaken by TCA Australia

AS/NZS 3200.1.0:1998 / IEC 60601-1:88+A1:1991+A2:1995

Test Reports are available upon request



Type BF
applied
part



CE
approval
certificate



FCC Part15
Subpart B

PCB is from an UL approved supplier. NOT FOR CONNECTION TO MAINS POWER OUTLET.

Designed and manufactured by:

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