Performa™ Professional Series

USER MANUAL

Operation Instructions For:
Performa™ Combin8 Quattro
Performa™ Combin8 Duo
Performa™ Stimul8
Performa™ Gener8

PERFORMANCE HEALTH®

Performa™

THIS USER MANUAL IS VALID FOR THE PERFORMA™ PROFESSIONAL SERIES DEVICES

This user manual is published by Performance Health®

Performance Health® 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.

Conformity to safety standards

Performance Health® declares that the Performa™ Professional Series comply with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2-10, IEC60601-2-5, ISO7010
IEC61689, ISO14971, ISO10993-1, ISO10993-5, ISO10993-10

Complies with MDD 93/42/EEC and Amended by directive 2007/47/EC requirements

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INTENDED USER/OPERATOR

This manual has been written for the users of the Performa™ Professional Series medical devices. It contains general information on the operation, precautionary practices, and maintenance information. In order to maximize its use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

These devices are designed to only be used by or under the supervision of persons using the medical device in the course of their work and in the framework of a professional healthcare activity, who understand the benefits and limitations of electrotherapy and ultrasound therapy.

WARNING (USA ONLY):

U.S.A. Federal Law restricts these devices to sale by, or on the order of a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.

These devices have been thoroughly tested and inspected to assure proper Performance and operation.

Specifications put forth in this manual were in effect at the time of publication. However, to ensure continual improvement measures, changes to these specifications may be made at any time without obligation on the part of manufacturer.

IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

It is important that you read all the warnings and precautions included in this manual because they are intended to keep the patient safe, prevent injury and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL	
DANGER	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.

⚠ DANGER

THIS STIMULATOR MUST NOT BE USED IN COMBINATION WITH THE FOLLOWING MEDICAL DEVICES:

1. Internally transplanted electronic medical devices, such as a pacemaker.
2. Electronic life support equipment, such as respirators.
3. Electronic medical devices attached to the body, such as electrocardiographs.

Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.

Do not use other RF equipment near the Performa™ Professional Series.

Do not use RFID systems near the Performa™ Professional Series.

Do not use electrical stimulation in conjunction with high frequency surgical equipment or microwave or shortwave therapy systems. This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided on pages 57 – 59.

These devices are contraindicated for use in an MRI environment and should be removed prior to an MRI exam or MRI exposure. Keep the device away from strong magnetic fields. **These devices are MR unsafe.**

⚠ WARNING

DO NOT USE THIS DEVICE UNDER THESE CONDITIONS:

- If a patient has a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Together with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- In the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- On open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- Over areas of skin that lack normal sensation.
- Do not use while patient is in bath or shower.
- Do not use while patient is sleeping.
- Patients with arterial or venous thrombosis or thrombophlebitis are at risk of developing embolisms when electrical stimulation is applied over or adjacent to the vessels containing the thrombus. If a patient has a history of deep vein thrombosis, even many years past, the affected area should not be stimulated.
- Fresh fractures should not be stimulated in order to avoid unwanted motion.
- Stimulation should not be applied immediately following trauma or to tissues susceptible to hemorrhage.

⚠ WARNING (cont.)

DO NOT USE ON THESE INDIVIDUALS:

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because the device has not been evaluated for pediatric use.
- Persons incapable of expressing their thoughts or intentions.

NEVER APPLY THE ELECTRODES TO:

- The head or any area of the face. The effects of stimulation of the brain are unknown.

- Any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

- Both sides of the thorax simultaneously (lateral or front and back), or across the patient's chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

WARNINGS AND PRECAUTIONS REGARDING THE ELECTRODES:

- Apply electrodes to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
- If the patient experiences any skin irritation or redness after a session, do not continue stimulation in that area of the skin. Do not bend or fold the electrode because it may not function properly. Place the self-adhesive electrodes onto the plastic film and then store into the sealed package when not in use.
- Do not apply ointment or any solvent to the electrodes or to the patient's skin because it will disrupt the electrodes from functioning properly.

⚠ WARNING (cont.)

- The electrodes are already pre-gelled and will adhere to clean skin.
- To avoid damage to the adhesive surface of the electrodes, put them only on the skin or on the plastic film provided.
- Make sure the components are connected well and the electrodes are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE ELECTRODES THIS WAY:

- **Self-adhesive electrodes are for single-patient use only. Do not use electrodes on several different patients to avoid transferring any contamination.**
- Electrodes should not touch each other when placed onto patient's skin. Keep them at least 1½" apart (and no more than 6" apart) during treatment. Electrodes too close together or touching could result in improper stimulation or skin burns.
- Do not place on patient's spine or backbone.
- Electrodes should not touch any metal object, such as a belt buckle or necklace.
- Electrodes should not be placed simultaneously on the soles of both feet.
- Electrodes should not be placed simultaneously on the calves of both legs.
- Do not place or relocate the electrodes while the device is on.
- Always turn the power off before removing or changing the electrode location.
- Do not leave electrodes attached to the skin after treatment.
- Do not lean against or lay on electrodes while administering electrotherapy as this could cause an increase in stimulation.

⚠ WARNING (cont.)

GENERAL WARNINGS:

- Make certain the unit is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- To avoid the risk of electric shock, this equipment must only be connected to a grounded outlet.
- The Performa™ Professional Series devices are not suitable for use in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
- These devices should be kept out of the reach of children.
- Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- Before administering any treatment to a patient you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the application of electrotherapy and ultrasound.
- To prevent electrical shock, disconnect the unit from the power source before attempting any maintenance procedures.
- The use of accessories, transducers and cables than those specified, with the exception of transducers and cables sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the device.
- Make certain there are no cracks or damage to any wires attached to the device.

⚠ WARNING (cont.)

ELECTROTHERAPY WARNINGS

- TENS therapy has not been established for pain of central origin.
- This device is to be used as a symptomatic treatment for pain and has no curative value. Patients should be cautioned and their activities regulated if pain that would otherwise serve as a protective mechanism is suppressed.
- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of therapeutic electrical stimulation during pregnancy.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.).

ULTRASOUND WARNINGS

- Precaution should be taken when using therapeutic ultrasound on patients with hemorrhagic diathesis.
- Ultrasound treatment presents a potential safety hazard in patients whose pain response has been decreased because of disease, previous surgery, ionizing radiation therapy, chemotherapy, general or regional anesthesia. It may cause burns. Do not use on insensitive areas or in the presence of poor circulation.
- Large thermal doses may result in regions of thermal aseptic necrosis which may not be apparent on inspection of the skin.
- Patients who have cardiac pacemakers should be protected from direct ultrasound exposure over the thorax to protect the lead wires and pacemaker from such exposure.
- If a patient complains of periosteal pain (deep, achy pain) during ultrasonic treatment, intensity should be reduced to a comfortable level.

⚠ WARNING (cont.)

ULTRASOUND WARNINGS (CONT.)

- Moving technique of the applicator should be used when applying therapeutic ultrasound at intensities greater than 0.5 W/cm² to assure even exposure of tissues to ultrasound.
- Heating of the joint capsule in acute or subacute arthritis should be avoided.
- Additional precautions should be used when ultrasound is used on patients with the following conditions:
  1. Laminectomy, i.e., when major covering tissues have been removed
  2. Over anesthetic areas
  3. On patients with hemorrhagic diathesis
- Ultrasound should be routinely checked before each use to determine that all controls function normally. Especially if the intensity control does properly adjust the ultrasonic power output in a stable manner. Also, determine that the treatment time control does actually terminate ultrasonic power output when the timer reaches zero.
- Use the ultrasound applicator with care. Inappropriate handling of the ultrasound applicator may adversely affect its characteristics.
- Before each use, inspect the ultrasound applicator for cracks, which may allow conductive fluid to seep through.
- Ultrasound therapy is not designed to be water tight. Entrance of water or liquid could cause malfunction of internal components and therefore create risk of severe injury to the patient.
- Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic ultrasound who have hemorrhagic diathesis or bleeding disorders.
- Do not use a conductive medium with an alcohol based content.

⚠ CAUTION

CAUTION WHILE USING THE STIMULATOR:

- If the stimulator is not functioning properly or the patient feels discomfort, immediately stop using the device.
- Do not use for any other purpose except for what it is intended for.
- Do not pull on the electrodes or lead wires during treatment.
- Patients should remove all metal accessories (i.e. necklace, watch, ring(s), etc.) prior to administering therapy as these items may cause damage to the device.
- Do not use near a cell phone as this may cause the stimulator to malfunction.
- Do not bend or pull the end of the cord.
- When pulling out the cord from the device, hold the plug and pull.
- Replace the lead wires when broken or damaged.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- The size, shape and type of electrodes may affect the safety and effectiveness of electrical stimulation. Please read instructions for which electrodes should be used (specifically for combination therapy and High Volt).
- The electrical Performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation.
- Using electrodes that are too small or incorrectly applied, could result in discomfort or skin burns.
- Keep yourself informed of the contraindications.
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner.

⚠CAUTION

CAUTION WHILE USING THE STIMULATOR (CONT.)

- Inspect applicator cables and associated connectors before each use.
- This device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

GENERAL PRECAUTIONS

- The long-term effects of electrical stimulation are unknown.
- Apply stimulation to only normal, intact, clean, dry, and healthy skin.
- Electrotherapy is not effective in treating the original source or cause of the pain, including headache.
- Electrotherapy is not a substitute for pain medications and other pain management therapies.
- Electrotherapy devices do not cure disease or injuries.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain.
- Patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If patients have suspected or diagnosed epilepsy, proceed with caution.
- Use caution if patient has a tendency to bleed internally, such as following an injury or fracture.
- Using the device after a recent surgical procedure may disrupt the healing process.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.

GENERAL PRECAUTIONS

- **Keep unit out of the reach of young children**. The unit contains small pieces that may be swallowed. The electrode cord can cause strangulation. Immediately **DIAL 911** should any of these things occur.
- It is highly recommended that only clinical grade electrodes be used with these devices. Economic electrodes used with other portable electrotherapy devices could cause uneven dispersion and/or cause shocking sensation or possible burns to the area being treated.
- If a patient is injured during treatment, discontinue use immediately and contact your dealer about the injury.

ELECTROTHERAPY INDICATIONS* & CONTRAINDICATIONS

Indications for **TENS, EMS, NMS, NMS Burst, Russian (RUSS), High Voltage Pulsed Current (HVPC), Interferential, Pre-modulated Interferential and Microcurrent** waveforms:

- Pain relief of chronic intractable pain
- Pain associated with post-traumatic or postoperative conditions
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis (do not stimulate calf muscle simultaneously)

* Electrotherapy Indications are only applicable to the Performa™ Stimul8, Combin8 Quattro & Duo only.

CONTRAINDICATIONS

- This device should not be used for symptomatic pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- This device should not be used on patients with demand-type cardiac pacemakers.
- This device should not be used over cancerous lesions.
- Electrode placements that apply current to the carotid sinus region (anterior neck) must be avoided.
- Electrode placements that apply current transcerebrally (through the head) must be avoided.
- Electrode placements that apply current transthoracically (the introduction of electrical current into the heart may cause cardiac arrhythmias) must be avoided.
- Stimulation should not be applied over swollen, infected, inflamed area or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
- Other contraindications are patients suspected of carrying serious infectious disease and/or disease where it is advisable, for general medical purposes, to suppress heat or fevers.
- Safety has not been established for the use of therapeutic electrical stimulation during pregnancy.

ULTRASOUND INDICATIONS* & CONTRAINDICATIONS

INDICATIONS FOR ULTRASOUND

- Relief of pain, muscle spasms and joint contractures that may be associated with:
  1. Adhesive capsulitis
  2. Bursitis with slight calcification
  3. Myositis
  4. Soft tissue injuries
  5. Shortened tendons due to past injuries and scar tissues
  6. Ligament sprains
- Relief of sub-chronic, chronic pain and joint contractures resulting from:
  1. Capsular tightness
  2. Capsular scarring

* Ultrasound Indications are only applicable to the Performa™ Stimul8 and Combin8 devices only.

CONTRAINDICATIONS

The established contraindications to heat therapy itself, for example:

- In an area of the body where a malignancy is known to be present
- Over or near bone growth centers until bone growth is complete
- Over the thoracic area at all
- This device should not be used over a healing fracture
- In the presence of metal implants of any type
- Patients with sensory loss on the area to be treated
- Therapeutic ultrasound should not be applied over the pregnant or potentially pregnant uterus. Therefore, therapeutic ultrasound should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant.
- Areas of thrombophlebitis should not be treated with therapeutic ultrasound due to the increased possibility of clotting or dislodging a thrombus. Conditions where this might occur are deep vein thrombosis, emboli and severe atherosclerosis.
- Tissues previously treated by deep x–ray or other radiation should not be exposed to therapeutic ultrasound.
- Ultrasonic treatment over the stellate ganglion, the spinal cord after laminectomy, subcutaneous major nerves and the cranium should be avoided.
- This device should not be used over the gonads/testicles or to the developing fetus.
- This device should not be used over the heart.
- This device should not be used on the brains.
- This device should not be used on ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
- This device should not be used over or applied to the eyes.
- This device should not be use on the facial sinus as this exposes the eyes to the same hazards.
- Ultrasound should not be used on unconscious patients or over anesthetic areas.
- On the head or near the pharynx or larynx.

APPLICATOR MOVEMENT OF ULTRASOUND

If movement of the applicator is too slow, the patient may feel periosteal pain characterized by a deep ache or pain. If motion is too fast, or if the applicator does not maintain good contact with the skin, the therapeutic effect of the sound waves will be reduced and the applicator may overheat.

POTENTIAL ADVERSE EFFECTS OF ULTRASOUND

- Cataracts
- Male Sterility
- Enhanced Drug Activity
- Thermal Stress

PATIENT SUSCEPTIBILITY

Some patients are more sensitive to ultrasound output and may experience a reaction similar to a heat rash. Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction does occur.

COUPLING

Coupling is described as contact between the applicator and the treatment site and may be accomplished through the use of a coupling agent, such as gel or lotion. Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves. **DO NOT** use a conductive medium with an alcohol based content or that is not approved specifically for ultrasound conductivity.

PARAMETER DEFINITIONS

C.C.	Constant Current Output Mode
C.V.	Constant Voltage Output Mode
F.M.	Frequency Modulation
Freq.	Frequency
C.F.	Carrier Frequency
Duty	Duty Cycle
Beat H.	Sweep High Beat Frequency
Beat L.	Sweep Low Beat Frequency
A.M.	Amplitude Modulation
P. Dur.	Phase Duration
Cycle	Cycle Time
Ramp	Ramp Time

ELECTROTHERAPY

(Applicable to the Performa™ Stimul8, Combin8 Quattro & Duo only.)

IF-4P: IFC (Interferential) Traditional (4 Pole)

Interferential Current is a medium frequency waveform distributed through two channels (four electrodes)*. The currents cross each other in the body at the area requiring treatment. The two currents interfere with each other at this crossing point, resulting in a modulation of the intensity (the current intensity increases and decreases at a regular frequency).

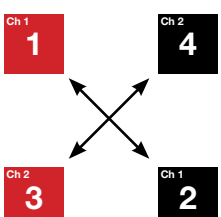
PARAMETERS:

Carrier Frequency	Carrier frequency is the base frequency of the alternating current.
Beat Frequency (High & Low)	Occurs when two waveforms are in and out of phases. The difference between the two frequencies produces the modulated effect (i.e. Beat H. of 4000 and Beat L. of 4150 will yield a 150 pps beat frequency).
Vector-Auto	Vector-Auto is a form of **amplitude** modulation and is a percentage of the set interferential amplitude (intensity) and will decrease from its maximum level over 6 seconds.
Vector-Manual	Vector-Manual is a form of **amplitude** modulation. When Vector-Manual is set to a different angle, the output intensities of two channels are different. The rhythmical change in position of the interference pattern, results in the modulation of the amplitude of one or both input currents.

Stimulator Output Parameters

Waveform Type	Sinewave
Output Mode	Electrodes
Mode Selection	CC (Constant Current) or CV (Constant Voltage)
Vector Scan	Auto: 20% – 100%, Stepping 20%; Manual: 0° – 90°, Stepping 15°
Carrier Frequency	2 – 10 KHz, Stepping 0.5 KHz
Beat High	(Beat L.) – 200 Hz, Stepping 1Hz
Beat Low	1 – (Beat H.) Hz, Stepping 1Hz
Intensity	CC: 0 – 100mA, Stepping 0.5mA; CV: 0 – 100V, Stepping 0.5V
Treatment Time	1 – 60 Minutes

* IF-4P requires the use of at least four (4) electrodes at all times, as well as criss-crossing the electrodes as indicated below.



IFC (Interferential) Premodulated (2 Pole)

Premodulated Current is a medium frequency waveform. Current comes out of one channel (two electrodes). A bipolar technique in which the two frequencies are “mixed” inside the machine prior to tissue delivery.

PARAMETERS:

Carrier Frequency	Carrier frequency is the base frequency of the alternating current.
Beat Frequency	Occurs when two waveforms are in and out of phases. The difference between the two frequencies produces the modulated effect (i.e. Beat H. of 4000 and Beat L. of 4150 will yield a 150 pps beat frequency).
Cycle Time	Cycle time refers to the time that the current is On and Off (in seconds). Example: For a cycle time of 10/50, the current will be flowing for 10 seconds and resting for 50 seconds.
Ramp Time	Ramp time is used to set a gradual increase in intensity during the “on-time”. Ramps occur at the beginning and ending of a cycle.

Stimulator Output Parameters

Waveform Type	Sinewave
Output Mode	Electrodes
Mode Selection	CC (Constant Current) or CV (Constant Voltage)
Carrier Frequency	2 – 10 KHz, Stepping 0.5KHz
Beat High	(Beat L.) – 200 Hz, Stepping 1Hz
Beat Low	1 – (Beat H.) Hz, Stepping 1Hz
Intensity	CC: 0 – 100mA, Stepping 0.5mA; CV: 0 – 100V, Stepping 0.5V
Treatment Time	1 – 60 Minutes
Ramp	2s

BIPHASIC (TENS)

The Asymmetrical Biphasic and the Symmetrical Biphasic waveforms are often used in TENS (Transcutaneous Electrical Nerve Stimulation) applications. TENS is low frequency waveform and has a short pulse duration. The Alternating Rectangular waveform is an interrupted biphasic current with a rectangular pulse shape. This waveform is commonly used as a pain management application.

PARAMETERS:

Phase Duration	Expressed in µs, is the time it takes to complete one phase of a pulse. The length affects the type of nerve recruited.
Frequency	In a pulsed current, the Frequency refers to the number of pulses that occur in a one second period of time and is denoted in (Hz) or Pulses Per Second (pps).
Frequency Modulation	Expressed in Hz, varies the frequency to reduce accommodation. Example: When the pulse frequency is set to 80 Hz and the frequency modulation is set to 40 Hz, the final frequency will vary from 80 – 120 Hz.
Amplitude Modulation	Amplitude Modulation is rhythmical fluctuation of the intensity to prevent accommodation.

Stimulator Output Parameters

TENS Asymmetrical Biphasic

Output Mode	Electrodes
Mode selection	CC (Constant Current) or CV (Constant voltage)
Intensity	CC: 0 – 200mA, Stepping 0.5mA; CV: 0 – 200V, Stepping 0.5V
Phase Duration	20µs – 1,000µs, Stepping 5µs
Frequency	1 – 250 Hz, Stepping 1 Hz
Cycle Time	Continuous, 10/10, 10/20, 10/30, 10/50, Custom
Ramp	1s, 2s, 5s
Treatment Time	1 – 60 Minutes

TENS Symmetrical Biphasic

Output Mode	Electrodes
Mode selection	CC (Constant Current) or CV (Constant voltage)
Intensity	CC: 0 – 200mA, Stepping 0.5mA; CV: 0 – 200V, Stepping 0.5V
Phase Duration	20µs – 1,000µs, Stepping 5µs
Frequency	1 – 250 Hz, Stepping 1 Hz
Cycle Time	Continuous, 10/10, 10/20, 10/30, 10/50, Custom
Ramp	1s, 2s, 5s
Treatment Time	1 – 60 Minutes

BIPHASIC (RAAS)

Rapid Agonist Antagonist Sequencing (RAAS) is proposed to mimic muscle-firing patterns of healthy individuals. It uses the electrical stimulation of sensory and motor nerves to achieve a skeletal muscle contraction using an electromyogram — derived functional pattern. It is used extensively for neuromuscular reeducation and treatment of muscle disuse atrophy.

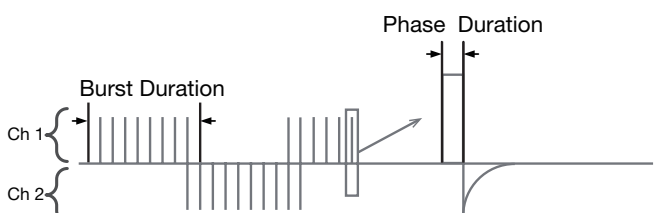
PARAMETERS:

Phase Duration	Expressed in µs, is the time it takes to complete one phase of a pulse. The length affects the type of nerve recruited.
Frequency	In a pulsed current, the Frequency refers to the number of pulses that occur in a one second period of time and is denoted in (Hz) or Pulses Per Second (pps).
Burst Duration	The time elapsed from the beginning to the end of one burst, and is denoted in (ms)
Pattern Frequency	The Pattern Frequency refers to the number of the sequential pulse train pattern be repeated in a one second period of time and is denoted in (Hz).

Stimulator Output Parameters

RAAS Asymmetrical/Symmetrical Biphasic

Output Mode	Electrodes
Mode selection	CC (Constant Current) or CV (Constant voltage)
Intensity	CC: 0 – 200mA, Stepping 0.5mA; CV: 0 – 200V, Stepping 0.5V
Phase Duration	20µs – 1,000µs, Stepping 5µs
Frequency	1 – 250 Hz, Stepping 1 Hz
Burst Duration	100ms – 5,000ms, Stepping Adaptive
Pattern Frequency	0.7 Hz (Burst Duration 100ms-500ms) 0.3 Hz (Burst Duration 500ms-1,000ms) 0.15 Hz (Burst Duration 1,000ms-2,000ms) 0.07 Hz (Burst Duration 2,000ms-5,000ms)
Treatment Time	1 – 60 Minutes



RUSSIAN STIMULATION

Russian Current is a medium frequency rectangle waveform, delivered in bursts or series of pulses. This method was claimed by its author (Kots) to produce maximal muscle strengthening effects without significant discomfort to the patient.

PARAMETERS:

Carrier Frequency	Carrier frequency is the base frequency of the alternating current.
Frequency	In a pulsed current the Frequency refers to the number of pulses that occur in a one second period of time and is denoted in (Hz) or Pulses Per Second (pps).
Duty	Duty is the percentage of the total treatment time that the current is actually flowing.
Cycle Time	Cycle time refers to the time that the current is On and Off (in seconds). Example: for a Cycle Time of 10/50, the current will be flowing for 10 seconds and resting for 50 seconds.
Ramp	Ramp is used to set a gradual increase in intensity during the “on-time”. Ramps occur at the beginning and ending of a cycle.

Stimulator Output Parameters

Carrier Frequency	2.5 KHz
Frequency	20 – 100 Hz, Stepping 5 Hz
Duty cycle	10% – 50%, Stepping 10%
Mode selection	CC (Constant Current) or CV (Constant voltage)
Intensity	CC: 0 – 100mA, Stepping 0.5mA; CV: 0 – 100V, Stepping 0.5V
Treatment Time	1 – 60 Minutes
Cycle time	Continuous, 10/10, 10/20, 10/30, 10/50, Custom
Ramp	1s, 2s, 5s

HIGH VOLT

The High Volt waveform has a very brief pulse duration characterized by 2 distinct peaks delivered at high voltage. High voltage causes a decreased skin resistance making the current comfortable and easy to tolerate. A monophasic twin-peaked waveform, with a short phase duration and a long interpulse interval, eliminates the formation of any appreciable chemical or thermal effects in the tissue.

PARAMETERS:

Frequency	In a pulsed current, the Frequency refers to the number of pulses that occur in a one second period of time and is denoted in (Hz) or Pulses Per Second (pps).
Polarity	This refers to the polarity (**+/-**) of the red lead wire; connect the lead wire to the active electrode.
Cycle Time	Cycle Time refers to the time that the current is on and off (in seconds). Example: for a Cycle Time of 10/50, the current will be flowing for 10 seconds and resting for 50 seconds.
Ramp	Ramp is used to set a gradual increase in intensity during the “on-time”. Ramps occur at the beginning and ending of a timed on cycle.

NOTE: When administering High Volt Therapy (whether in combination or only electrotherapy stim) you should use the large dispersive electrode measuring 3" x 5" at the least. This will reduce adverse reactions to the skin as well as evenly distribute the stimulation.

Stimulator Output Parameters

Frequency	1 – 120 Hz, Stepping 1 Hz
Polarity	Positive, or Negative,
Phase Duration.	100µs
Intensity	CV: 0 – 500V, Stepping 5V
Treatment Time	1 – 60 Minutes
Ramp	1s, 2s, 5s

MICROCURRENT

Microcurrent is a monophasic waveform of very low intensity which replicates the body's use of natural frequencies when repairing or growing its new cells. It creates a physiological electric modality that increases ATP (energy) production in the cells of your body. The physiological working mechanism of this effect is not clearly understood yet, but has previously been shown to help with reduction in healing time.

PARAMETERS:

Frequency	In a pulsed current, the Frequency refers to the number of pulses that occur in a one second period of time and is denoted in (Hz) or Pulses Per Second (pps).
Polarity	This refers to the polarity (**+/-**) of the red lead wire; connect the lead wire to the active electrode.

Stimulator Output Parameters

Frequency	0.1 – 1,000 Hz, Stepping 0.1 Hz/1 Hz
Polarity	Positive, Negative, Alternating
Intensity	CC: 0 – 1,000μA, Stepping 5μA
Treatment Time	1 – 60 Minutes
Cycle (Fixed)	50%
Ramp (Fixed)	1s

NMS

NMS is a symmetrical biphasic waveform with a 120 µs interphase interval. Because the pulse is relatively short, it is suitable for applications requiring high intensities, such as in muscle strengthening protocols.

PARAMETERS:

Frequency	In a pulsed current the Frequency refers to the number of pulses that occur in a one second period of time and is denoted in (Hz) or Pulses Per Second (pps).
Phase Duration	Expressed in µs, is the time it takes to complete one phase of a pulse. The length affects the type of nerve recruited.
Cycle Time	Cycle time refers to the time that the current is on and off (in seconds). Example: for a Cycle Time of 10/50, the current will be flowing for 10 seconds and resting for 50 seconds.
Ramp	Ramp time is used to set a gradual increase in intensity during the “on-time”. Ramps occur at the beginning and ending of a timed on cycle.

Stimulator Output Parameters

Output Mode	Electrodes
Mode selection	CC (Constant Current) or CV (Constant Voltage)
Intensity	CC: 0 – 200mA, Stepping 0.5mA; CV: 0 – 200V, Stepping 0.5V
Phase Duration	20µs – 400µs, Stepping 20µs
Interphase Interval	120µs
Frequency	1 – 200Hz, Stepping 1Hz
Ramp	1s, 2s, 5s
Cycle Time	Continuous, 10/10, 10/20, 10/30, 10/50, Custom
Treatment Time	1 – 60 Minutes

ULTRASOUND THERAPY

(Applicable to the Performa™ Stimul8 and Combin8 devices only.

PARAMETERS:

Ultrasound Frequency	Expressed in MHz, it is the frequency of the ultrasound waves. The ultrasound frequency determines the penetration depth, which has the largest value at 1 MHz and the lowest value at 3 MHz.
Duty Cycle	Expressed in %, defines the ratio of the pulse duration to the pulse repetition time. Ultrasound can be applied in pulsed or in continuous mode. When the Duty Cycle is set to 100%, the apparatus operates in continuous mode.
Effective Radiation Area (ERA)	Expressed in cm^2, defines the cross-sectional area of the ultrasound beam (see technical specifications for details). The Effective Radiation Area is fixed and defined by the size of the ultrasound applicator.
Ultrasound Amplitude	Expressed in Watt/cm^2, is the quotient of Ultrasound Power and Effective Radiation Area. The ultrasound output display can be toggled between Watt and Watt/cm^2. In pulsed mode, the Amplitude during the pulse is displayed. The time-averaged Amplitude can be obtained by multiplying this value by the Duty Cycle.

Ultrasound Parameters	
Frequency	1 MHz*, 3 MHz*
Duty Cycles	10% – 100%,Continuous, Stepping 10%
Pulse duration	1 – 9 ms* (set by Duty Cycle)
Pulse Frequency	100 Hz
Output Power	
Duty Factor ≥80% for 5 cm^2	0.5W – 10.0W
Duty Factor ≤70% for 5 cm^2	0.5W – 15.0W
Duty Factor ≥80% for 1 cm^2	0.1W – 2.0W
Duty Factor ≤70% for 1 cm^2	0.1W – 3.0W
Output Accuracy	± 20% (for any level above 10% of maximum)
Amplitude	
Duty Factor ≥ 80%	2.0W/cm^2
Duty Factor ≤ 70%	3.0W/cm^2
Treatment Timer	0 – 30 min ± 0.1 min
5 cm^2 Applicator	
ERA (Effective Radiation Area)	5 cm^2
1 cm^2 Applicator	
ERA (Effective Radiation Area)	1 cm^2
Beam Type for 1 cm^2 & 5 cm^2 Applicators	
1 MHz	Collimating
3 MHz	Collimating
BNR (Beam Non-Uniformity Ratio)	5:1 Maximum

* ± 10%

ULTRASOUND THERAPY (cont.)

Parameter Limit

For security, the device has some limitations for electrotherapy. The maximum intensity has a relationship with the frequency and pulse duration following below table:

Pulse Frequency	Phase Duration	Max Current Output
<100	<300µs	200mA
<100	300 – 500µs	150mA
100 – 250	<500µs	100mA
<100	500 – 1000µs	100mA
100 – 250	500 – 1000µs	70mA

Technical Data	
Power Supply	100V – 240V, 50 Hz – 60 Hz, 1A
Power Output	15V, 4A Max
Dimensions	10" x 7" x 5" (L x W x H)
Operating Environmental	
Temperature	-10°C (14°F) to 55°C (131°F)
Relative Humidity	10% – 90%
Atmosphere Pressure	700hPa – 1,060hPa

Transportation and Storage Environment	
Temperature	-20°C (-4°F) to 55°C (131°F)
Relative Humidity	20% – 90%
Atmosphere Pressure	700hPa – 1,060hPa

CONNECTION TO AC POWER

Insert the power cable into the socket on the back of the device and plug it into a grounded wall outlet.

⚠ CAUTION

- Do not place the device in a location where the power cord could be tripped over or pulled out during treatment.
- Do not attempt to use the device if it is not properly grounded. Make certain that the device is electrically grounded by connecting it only to a grounded electrical service receptacle conformable with the applicable national and local electrical codes regarding medical environments.
- Set power switch to “On”. 
- Power LED indicator is lit green indicating that the device is connected to the power supply.
- The device will initialize and perform a self test. This may take a while.
- At the end of the self test, the device enters the Home Menu and is ready for use.

DISCONNECTION FROM POWER

- When you have finished treatments, turn the device off by setting the power switch on the back of the device to “Off”. When the green power LED turns off, the device is now disconnected from the power supply.

Performa™ Stimul8

Description	SKU#	Qty.
Performa™ Stimul8 Electrotherapy Device	081716356	1
Printed Manual	N/A	1
Quick Start Guide	N/A	1
Medical Grade Power Cord	PH8000X	1
Patient Stop Switch	7000766	1
Performa™ Cloth 2” Square (4/pk)	081067438	1
Performa™ Cloth 2” x 3.5” Rectangle (4/pk)	081067461	1
ValuTrode Cloth 3” x 5” Rectangle (2/pk)	081071612	1
110” Lead wires (2/bag)	7000767	2
CD with Electronic Manual	N/A	1

Optional Accessories:

Performa™ Series Therapy Cart	081716364	1
1 cm Sound Head	7000764	1

Performa™ Combin8 Quattro

Description	SKU#	Qty.
Performa™ Combin8 Quattro 4-channel Electrotherapy/Ultrasound Combo Device	081716349	1
Printed Manual	N/A	1
Quick Start Guide	N/A	1
Medical Grade Power Cord	PH8000X	1
Patient Stop Switch	7000766	1
5 cm Sound Head	7000765	1
Performa™ Cloth 2” Square (4/pk)	081067438	1
Performa™ Cloth 2” x 3.5” Rectangle (4/pk)	081067461	1
ValuTrode Cloth 3” x 5” Rectangle (2/pk)	081071612	1
Performa™ Sonishield Antimicrobial Ultrasound Gel, 8.5 oz.	081710748	1
110" Lead Wires (2/bag)	7000767	2
110" Combination Lead Wire, Green (1/bag)	7000768	1
CD with Electronic Manual	N/A	1

Performa™ Gener8

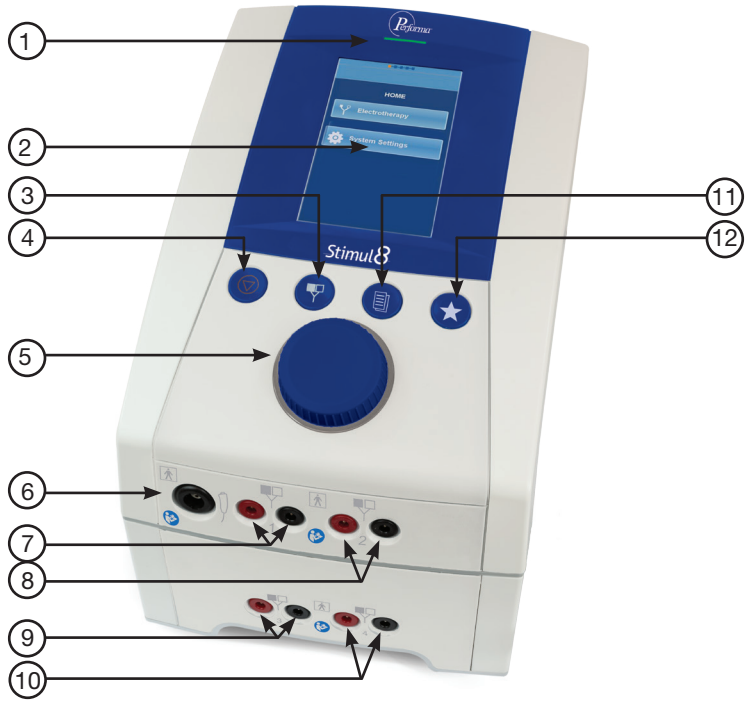
Description	SKU#	Qty.
Performa™ Gener8 Dual Soundhead Ultrasound	081716380	1
Printed Manual	N/A	1
Quick Start Guide	N/A	1
Medical Grade Power Cord	PH8000X	
5cm Sound Head	7000765	1
1cm Sound Head	7000764	1
Performa™ Sonishield Antimicrobial Ultrasound Gel, 8.5 oz.	081710748	1
CD with Electronic Manual	N/A	1

Performa™ Combin8 Duo

Description	SKU#	Qty.
Performa™ Combin8 Duo 2-channel Electrotherapy/Ultrasound Combination Device	081716372	1
Printed Manual	N/A	1
Quick Start Guide	N/A	1
Medical Grade Power Cord	PH8000X	1
5cm Sound Head	7000765	1
Performa™ Sonishield Antimicrobial Ultrasound Gel, 8.5 oz.	081710748	1
Patient Stop Switch	7000766	1
Performa™ Cloth 2” Square (4/pk)	081067438	1
Performa™ Cloth 2” x 3.5” Rectangle (4/pk)	081067461	1
ValuTrode Cloth 3” x 5” Rectangle (2/pk)	081071612	1
110" Lead Wires (2/bag)	7000767	1
110" Combination Lead Wire, Green (1/bag)	7000768	1
CD with Electronic Manual	N/A	1

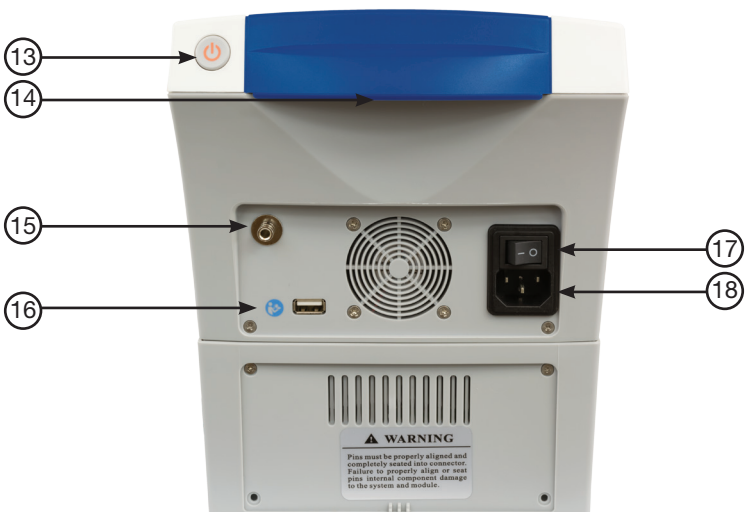
PERFORMA™ STIMUL8

1. Power LED Indicator
2. Touch Screen Display
3. Electrotherapy Button
4. Patient Stop Switch Button
5. Central Control Dial with Light Ring
6. Patient Stop Switch Connection
7. Channel 1 Lead Wire Connections
8. Channel 2 Lead Wire Connections
9. Channel 3 Lead Wire Connections
10. Channel 4 Lead Wire Connections
11. Clinical Protocol Button
12. Favorites Button



OPERATOR CONTROLS (CONT.)

13. Power Button
14. Carry Handle
15. Grounding Test Post
16. USB Diagnostic Port*
17. On/Off Switch
18. Power Cord Connection



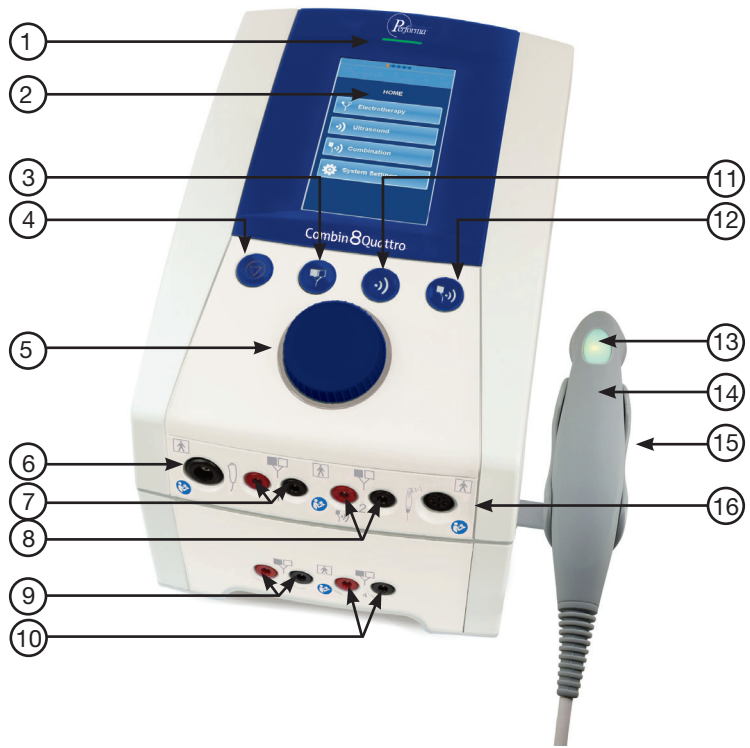
DEVICE SYMBOLS

Symbol	Meaning
	Electrode Cable Connection
	BF Application Part
	Patient Stop Button Connection
	Please refer to the manual for detailed instructions

* USB Diagnostic Port is used for repairs and/or maintenance issues and should only be used by a certified technician.

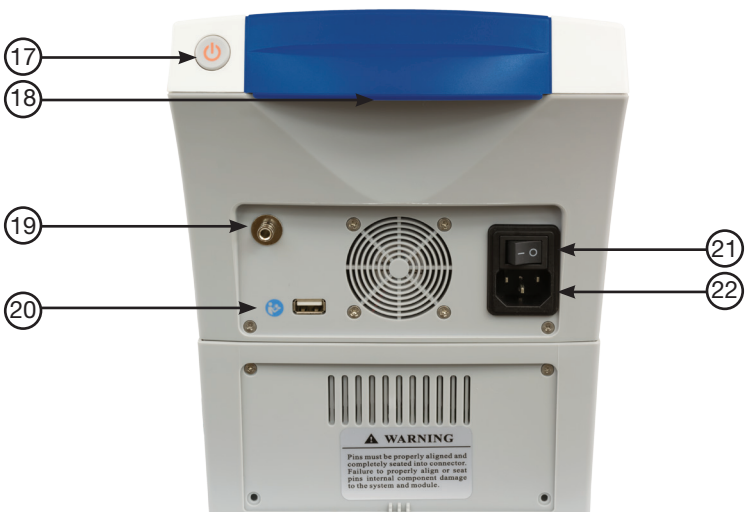
PERFORMA™ COMBIN8 QUATTRO

1. Power LED Indicator
2. Touch Screen Display
3. Electrotherapy Therapy Button
4. Patient Stop Switch Button
5. Central Control Dial with Light Ring
6. Patient Stop Switch Connection
7. Channel 1 Lead Wire Connections
8. Channel 2 Lead Wire Connections
9. Channel 3 Lead Wire Connections
10. Channel 4 Lead Wire Connections
11. Ultrasound Therapy Button
12. Combination Therapy button
13. Ultrasound Indicator Light
14. 5 cm Ultrasound Head
15. Ultrasound Head Cradle
16. Ultrasound Head Connection



OPERATOR CONTROLS (CONT.)

17. Power Button
18. Carry Handle
19. Grounding Test Post
20. USB Diagnostic Port*
21. On/Off Switch
22. Power Cord Connection



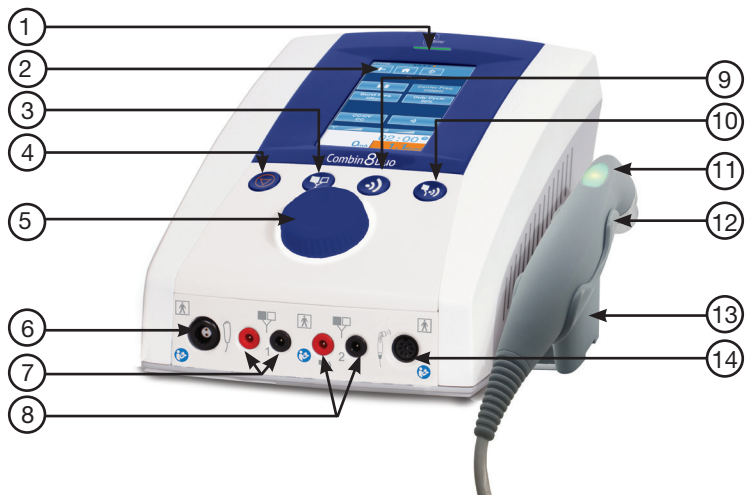
DEVICE SYMBOLS

Symbol	Meaning
	Electrode Cable Connection
	BF Application Part
	Ultrasound Applicator Connection
	Patient Interrupt Button Connection
	Please refer to the manual for detailed instructions

* USB Diagnostic Port is used for repairs and/or maintenance issues and should only be used by a certified technician.

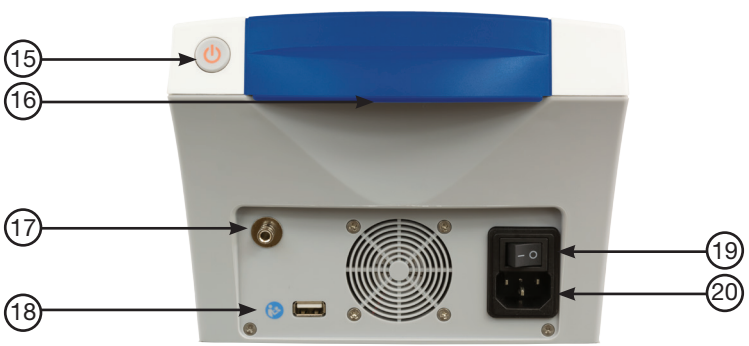
PERFORMA™ COMBIN8 DUO

1. Power LED Indicator
2. Touch Screen Display
3. Electrotherapy Therapy Button
4. Patient Stop Switch Button
5. Central Control Dial with Light Ring
6. Patient Stop Switch Connection
7. Channel 1 Lead Wire Connections
8. Channel 2 Lead Wire Connections
9. Ultrasound Therapy Button
10. Combination Therapy button
11. Ultrasound Indicator Light
12. 5 cm Ultrasound Head
13. Ultrasound Head Cradle
14. Ultrasound Head Connection



OPERATOR CONTROLS (CONT.)

15. Power Button
16. Carry Handle
17. Grounding Test Post
18. USB Diagnostic Port*
19. On/Off Switch
20. Power Cord Connection



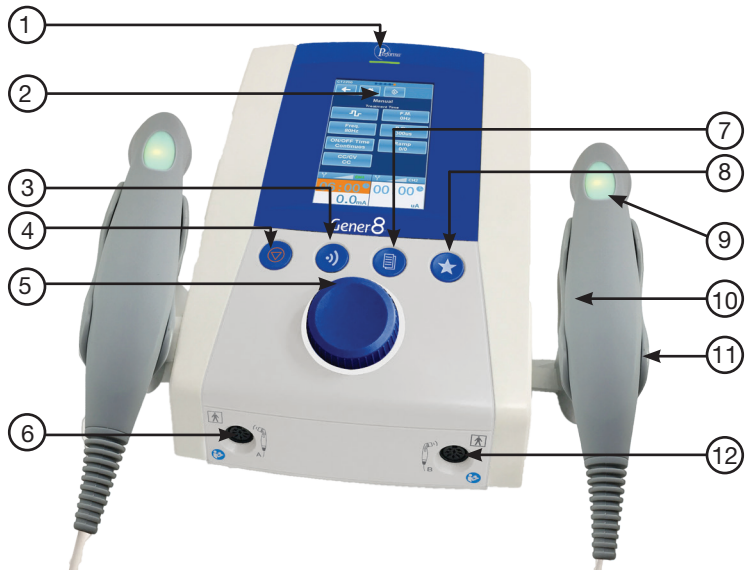
DEVICE SYMBOLS

Symbol	Meaning
	Electrode Cable Connection
	BF Application Part
	Ultrasound Applicator Connection
	Patient Interrupt Button Connection
	Please refer to the manual for detailed instructions

* USB Diagnostic Port is used for repairs and/or maintenance issues and should only be used by a certified technician.

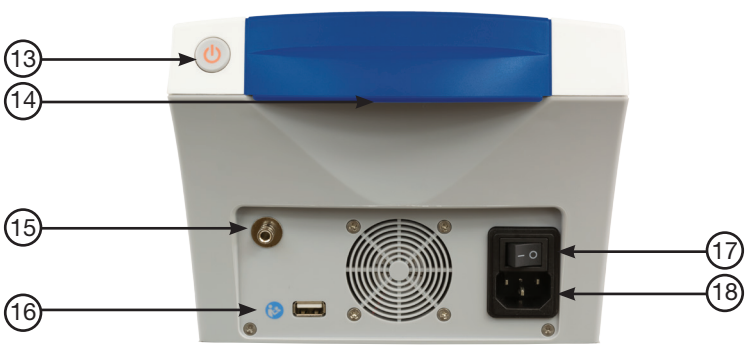
PERFORMA™ GENER8

1. Power LED Indicator
2. Touch Screen Display
3. Ultrasound Therapy Button
4. Patient Stop Switch Button
5. Central Control Dial with Light Ring
6. Channel 1 Ultrasound Head Connection
7. Clinical Protocol Button
8. Favorites Button
9. Ultrasound Indicator Light (Same on Both)
10. Ultrasound Head (5cm or 1cm on Either Channel)
11. Ultrasound Head Cradle (Same on Both Sides)
12. Channel 2 Ultrasound Head Connection



OPERATOR CONTROLS (CONT.)

13. Power Button
14. Carry Handle
15. Grounding Test Post
16. USB Diagnostic Port*
17. On/Off Switch
18. Power Cord Connection



DEVICE SYMBOLS

Symbol	Meaning
	BF Application Part
	Ultrasound Applicator Connection
	Please refer to the manual for detailed instructions

* USB Diagnostic Port is used for repairs and/or maintenance issues and should only be used by a certified technician.

The Performa™ Professional Series is a family of clinical therapy devices which offers the practitioner a wide range of treatment options. These devices share an identical control panel equipped with a full color screen making treatment set-up easier than ever. A few simple key presses are all you need to quick-start a treatment. The User Interface intuitively groups and displays all the options for a modality setup on the large touch screen to ensure that treatment parameters can easily be selected and adjusted.

PERFORMA™ STIMUL8

The Performa™ Stimul8 is equipped with two or four completely identical electrotherapy channels. The electrotherapy channels can be used in combination (linked) or totally independent. A comprehensive set of current waveforms, to include TENS/EMS/IF/Russian/High Volt and Microcurrent, are available, targeting both pain management and muscle stimulation applications.

Protocols can run on linked or independent channels. With independent channels, two or four different protocols can be performed simultaneously.

PERFORMA™ COMBIN8 QUATTRO

The Performa™ Combin8 Quattro is a combination device, combining the functions of the Performa™ Stimul8 and the Ultrasound Therapy in a single device. With the Performa™ Combin8 Quattro, the simultaneous application of ultrasound and electrotherapy (combination therapy) helps to reduce treatment times by applying two therapies at once. The remaining electrotherapy channel can then be used independently.

PERFORMA™ COMBIN8 DUO

The Performa™ Combin8 Duo is a combination device, with the same functionality as the Performa™ Combin8 Quattro but with just 2-channel capabilities. The Performa™ Combin8 Duo can apply electrotherapy or ultrasound independently, or combined.

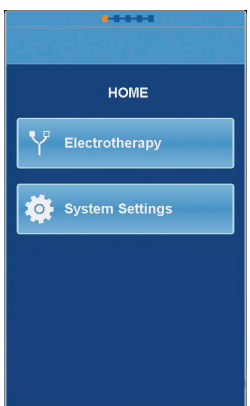
PERFORMA™ GENER8

The Performa™ Gener8 is a dual sound head clinical ultrasound device equipped with a both a 5cm and 1cm sound head. The sound heads sit on either side of the device and do not require switching one for the other to customize patient therapy. With the press of a button, you choose to use either the 5cm or 1cm sound head.

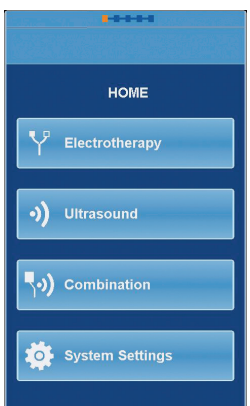
HOME SCREEN DISPLAY

When you turn on the unit, you will first enter the Home Menu. In the Home Menu, none of the channels are selected. The Home Menu provides structured access to all therapies available within the unit, with appropriate parameter defaults. Just select a menu item by touching the button to navigate to the next screen. You can navigate back to the previous screen by touching the back arrow at the top of the screen. Anywhere in the navigation, you can jump back to the Home Menu by touching the home button.

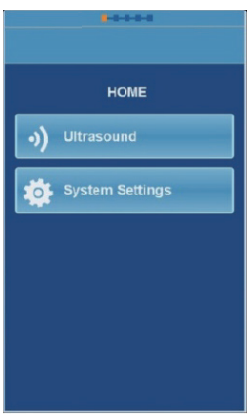
Performa™ Stimul8



Performa™ Combin8 Quattro & Duo



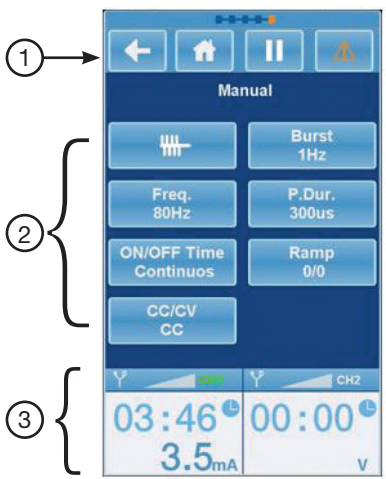
Performa™ Gener8



MAIN THERAPY DISPLAY

After navigating from the Home Menu, the below screen will be the main therapy display (content subject to change). This display is organized in three (3) sections with information relating to the therapy selected for intended use:

1. Navigation Bar
2. Selected Parameters
3. Channel Tab Information



TOUCHSCREEN DISPLAY — NAVIGATION BAR

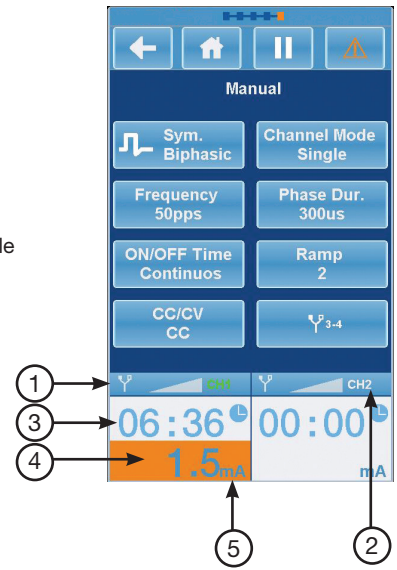
Icon	Name	Function
	Back	Return to previous screen.
	Home	Return to Home screen.
page 1/2	Page Number	The number of pages in multi-page menu screens or treatment step number.
	Favorite	Store therapy settings or a programmed sequential protocol in a favorite.
	Delete	Delete a favorite.
	Pause	Pause treatment. The output current decreases to 0 and the treatment timer suspends counting down.
	Start/ Continue	Start/Continue treatment. The output current increases to the previous value and the treatment timer resumes counting down.
	Accept	Accept the selected option.
	Stop	Stop the treatment, reset the treatment time and intensity.

ELECTROTHERAPY TREATMENT SCREEN

(Applies to the Performa™ Stimul8 & Combin8 Devices.)

1. Electrode Output Indicator
2. Channel Indicator (Channel 1, 2, 3 or 4)*
3. Remaining Treatment Time
4. Output Value
5. Unit of Output Value (mA)

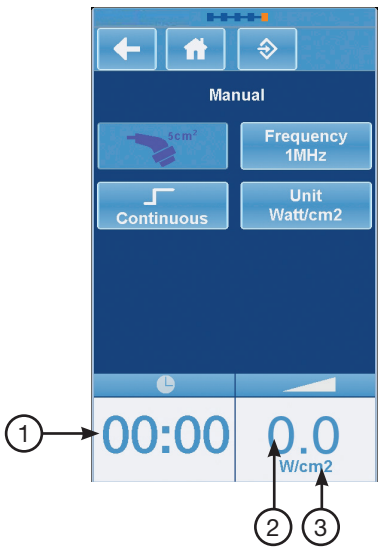
* For the Performa™ Combin8 Duo, only Channels 1 or 2 will be available



ULTRASOUND TREATMENT SCREEN

(Applies to the Performa™ Gener8 and Ultrasound portion of the Performa™ Combin8 Quattro & Duo.)

1. Remaining Treatment Time
2. Output Value
3. Unit of Output Value (w/cm²)



COMBINATION THERAPY SCREEN

(Applies to the Performa™ Combin8 Quattro & Duo.)

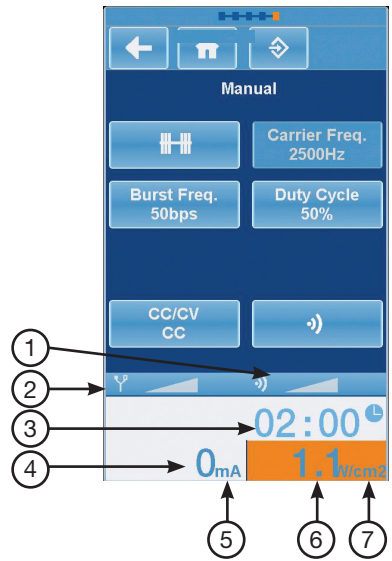
1. Ultrasound Output Indicator
2. Electrode Output Indicator
3. Remaining Treatment Time

Electrotherapy

4. Output Value
5. Unit of Output Value (mA)

Ultrasound

6. Output Value
7. Unit of Output Value (w/cm²)



ELECTROTHERAPY

(Applies to Performa™ Stimul8, Quattro & Duo.)

⚠CAUTION

- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.
- To prevent infection, electrodes should not be used on broken skin.

Before Treatment

- Check the patient for contraindications and warnings as described on page 11.
- Test the heat sensitivity of the treatment area.
- Clean the treatment area. Any areas with excess hair should be clipped or shaved to ensure good conductivity.

Self-Adhesive Electrodes

Self-adhesive electrodes have higher series impedance than flexible rubber electrodes. This can cause the stimulator to terminate treatment at higher current amplitudes. When this occurs it is recommended to continue the treatment with flexible rubber electrodes, properly moistened with a conductive medium.

Self-adhesive electrodes are not recommended for use with currents that contain a DC component.

Connection and Disconnection Reactions

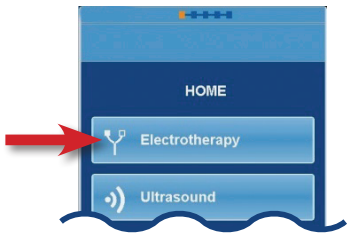
Constant Current (CC) output characteristics may cause unpleasant connection and disconnection reactions if the electrodes are not securely placed or lose contact with the skin. Make sure the current amplitude is set to 0 mA when you apply or remove the electrodes.

This manual contains instructions for the Performa™ Professional Series Gener8, Stimul8, Combin8 Quattro & Duo.

Electrotherapy Set-Up* — Clinical Protocols

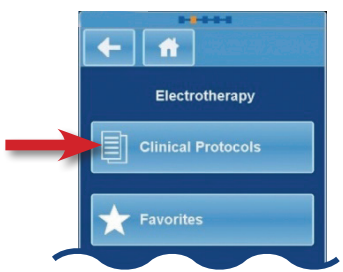
1. Home

- The Home Menu gives access to all functions of the unit.
- Select the Electrotherapy button.



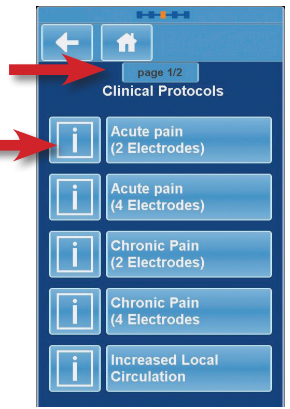
2. Clinical Protocols

- The Electrotherapy Menu gives you access to the following functions:
  1. Clinical Protocols
  2. Favorites
  3. Manual Operation
- Select Clinical Protocols button.

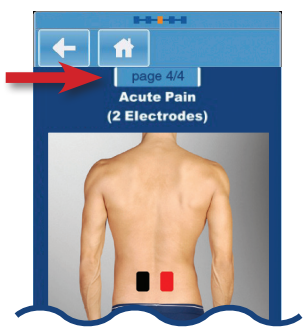


2. Clinical Protocols (cont.)

- Use the central control dial to scroll through the pages, then select the desired clinical protocol button.
- For more information about the clinical protocol, press the [i] button next to the desired protocol.



- Use the central control dial to scroll through the information. The last page will show suggested electrode placement.



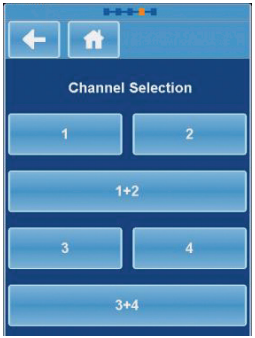
* This function does not apply to the Performa™ Gener8.

Electrotherapy Set-Up — Clinical Protocols (cont.)

3. Channel Selection*

- Select the channels for desired treatment.
- When channel 1 is selected, channels 2, 3 and 4 are still available for another therapy.
- When channels 1+2 or 3+4 are selected, both channels have the same parameters. Only the intensity can be set differently.

* For the Combin8 Duo, only Channel 1, 2 or 1+2 will be an available option



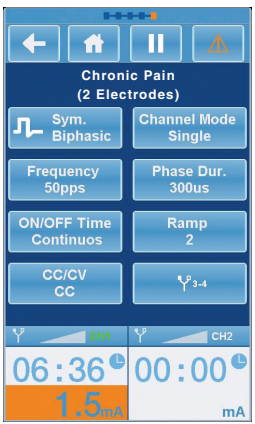
4. Parameters

Adjust the parameters by touching the desired parameter button.

- Change the value by rotating the central control dial.
- **NOTE:** Some parameters have more options to choose from and on the next screen, another list appears from which to choose from.
- Touch the 

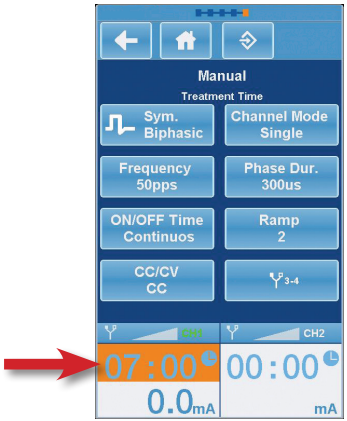
button if you want to switch to parameters of channels 3 & 4*.

* Only Available on the Combin8 Quattro & Stimul8.



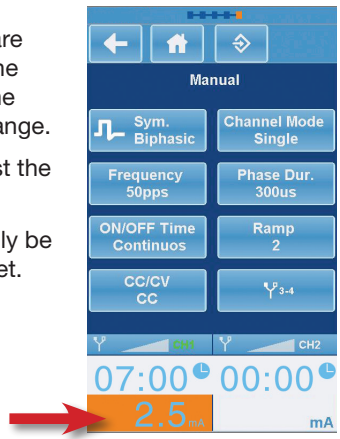
5. Treatment Time Adjustment

- Touch the timer. The color will change to orange. Adjust the treatment time with the central control dial.



6. Start Therapy

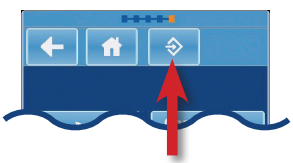
- Once your parameters and timers are set, start the therapy by touching the output intensity on the bottom of the screen. The color will change to orange.
- Use the central control dial to adjust the output level.
- **NOTE:** The current intensity can only be adjusted after the timer has been set.



6. Start Therapy (cont.)

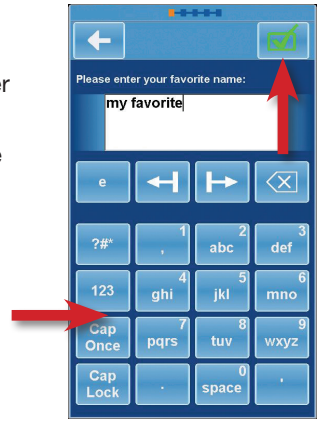
- To pause the treatment, touch the pause button in the navigation bar.
- To continue the treatment touch, the run button in the navigation bar.
- To stop the treatment, touch the STOP button in the navigation bar.
- **NOTE:** To restart after pressing stop, you will need to re-enter the treatment time first.

7. Storing Your Favorite Settings



- When a treatment screen is completely set as required, you can save those settings as a favorite for later use.
- As long as the treatment has not been started, a store button will be available on the navigation bar.
- To store your settings to Favorites, touch the store button.

- Enter the name of your favorite using the keyboard.
- Press to store your favorite under the name just entered.
- **NOTE:** Once saved, Favorites can be retrieved from the Electrotherapy, Ultrasound and Combination Menus.
- **NOTE:** 4-polar treatments are automatically saved and loaded as a dual channel treatment.



Electrotherapy Set-Up* — Manual Operation

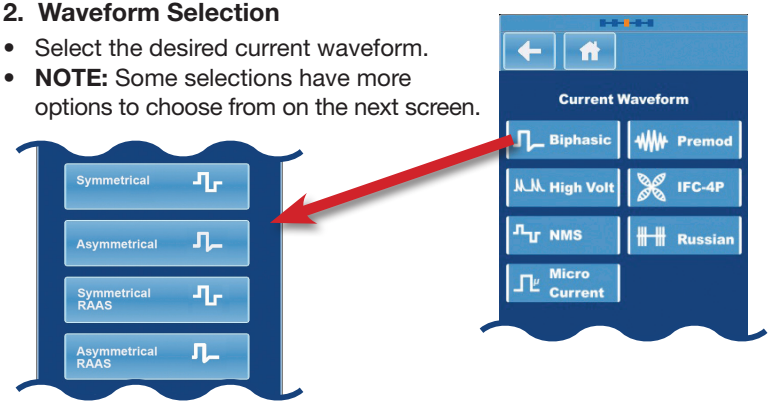
1. Manual Operation

- The electrotherapy menu provides access to the following functions:
  1. Clinical Protocols
  2. Favorites
  3. Manual Operation
- Select Manual Operation.

* This function does not apply to the Performa™ Gener8.

2. Waveform Selection

- Select the desired current waveform.
- **NOTE:** Some selections have more options to choose from on the next screen.



3. Channel Selection*

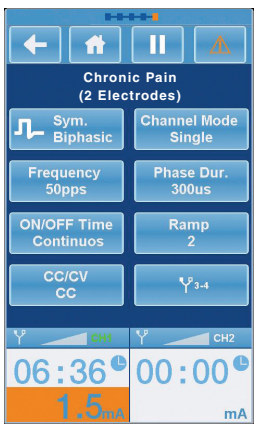
- Select the channels for electrotherapy.
- When channel 1 is selected, channels 2, 3 and 4 are still available for another therapy.
- When channels 1+2 or 3+4 are selected, both channels have the same parameters. Only the intensity can be set differently.

* For the Combin8 Duo, only Channel 1, 2 or 1+2 will be an available option

4. Parameters

- Adjust the parameters by touching the desired parameter button and change the value with the central control dial.
- **NOTE:** Some parameters have more options to choose from and on the next screen, another list appears from which to choose from.
- Touch the 3-4 button if you want to switch to parameters of channels 3 & 4**.

** Applies only to Performa™ Combin8 Quattro and Stimul8.

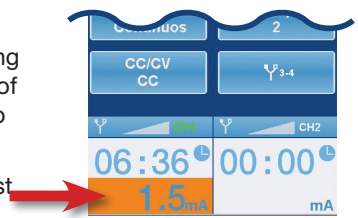


5. Treatment Time Adjustment

- Touch the timer. The color will change to orange. Adjust the treatment time with the central control dial.

6. Start Therapy

- Once your parameters and timers are set, start the therapy by touching the output intensity on the bottom of the screen. The color will change to orange.
- Use the central control dial to adjust the output level.

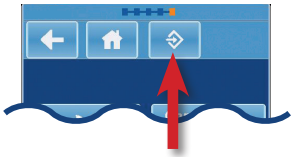


- **NOTE:** The current intensity can only be adjusted after the timer has been set.
- To pause the treatment, touch the pause button in the navigation bar.

- To continue the treatment, touch the run button in the navigation bar.
- To stop the treatment, touch the STOP button in the navigation bar.
- **NOTE:** To restart after pressing stop, you will need to re-enter the treatment time first.

7. Storing Your Favorite Settings

- When a treatment screen is completely set as required, you can save those settings as a Favorite for later use.
- As long as the treatment has not been started, a store button will be available on the navigation bar.



- To store your settings to Favorites, touch the store button.
- Enter the name of your favorite using the keyboard.
- Press to store your favorite under the name just entered.

- **NOTE:** Once saved, favorites can be retrieved from the Electrotherapy, Ultrasound and Combination menus.
- **NOTE:** 4-polar treatments are automatically saved and loaded as a dual channel treatment.

Ultrasound Therapy — Application
(Performa™ Gener8, Combin8 Quattro & Duo only.)

Contact Control

The ultrasound applicator has a contact control function that suspends treatment when the acoustical contact with the body drops below a certain level. The indicator light on the applicator will turn on to signal this situation, while the ultrasound amplitude display will start blinking and the treatment timer will stop counting down. During this situation, the applicator emits a small amount of energy to sense restoration of acoustical contact. You may experience this when the applicator only partially contacts the body. When contact restoration is sensed, the treatment is resumed at the set amplitude. The contact control function does not work at amplitudes below 0.2 Watt/cm².

The Contact Medium

To ensure efficient transfer of energy, a contact medium is required between the ultrasound applicator and the body. Air causes virtually total reflection of the ultrasound energy. The best medium for the transfer of ultrasound energy is a gel.

- The gel should be applied to the part of the body to be treated and then spread out with the ultrasound applicator.
- Never apply the gel to the ultrasound applicator. The applicator will register this as acoustical contact and may emit ultrasound energy, which could damage the applicator.

If the body surface is very irregular, making it difficult to obtain good contact between the ultrasound applicator and the body, or if direct contact must be avoided (e.g. due to pain), the affected area may be treated under water (subaqual method). The water should be degassed (by previous boiling) in order to prevent air bubbles arising on the ultrasound applicator and the body.

Before Treatment

- Check the patient for contraindications. See page 12 for details.
- Test the warmth sensitivity of the treatment area.
- To optimize ultrasound transmission, clean the skin of the treatment area with soap or a 70% alcohol solution.
- Any areas with excess hair should be clipped or shaved to ensure good conductivity.

During Treatment

- The ultrasound applicator has to be moved constantly, with the semi-static method. During treatment, the displayed ultrasound amplitude can vary around the set value, caused by fluctuations in acoustical coupling.
- Ask the patient regularly for his/her findings. If necessary, the treatment will have to be adapted. The amplitude can be reduced or the continuous mode can be changed to pulsed mode or vice versa.
- When there are signs that the ultrasound transmission is bad, add more contact gel or spread it with the applicator.

After Treatment

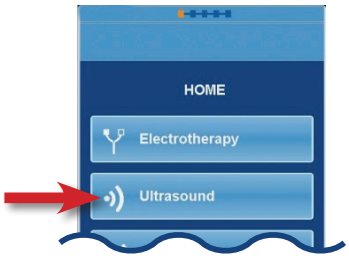
- Clean the skin of the patient and the ultrasound applicator with a towel or tissue. Clean the applicator with a 70% alcohol solution.
- Check for the effects that can be expected (for example pain, circulation and mobility).
- Ask the patient to inform the therapist of any reactions.

Ultrasound Therapy Set-Up — Clinical Protocols

(Performa™ Stimul8 and Combin8 devices only)

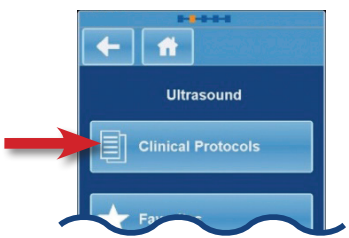
1. Home

- The Home Menu gives access to all functions of the unit.
- Select the Ultrasound button.



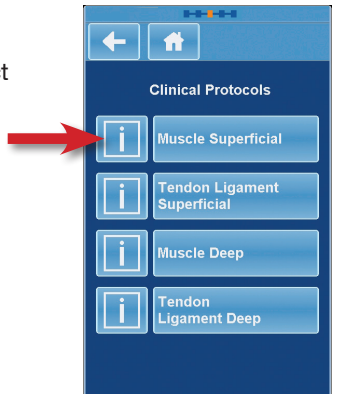
2. Clinical Protocols

- The Ultrasound Menu gives you access to the following functions:
  1. Clinical Protocols
  2. Favorites
  3. Manual Operation
- Select Clinical Protocols button.

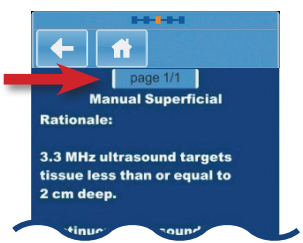


2. Clinical Protocols (cont.)

- Use the central control dial to scroll through the pages, then select the desired clinical protocol button.
- For more information about the clinical protocol, press the [i] button next to the desired protocol.



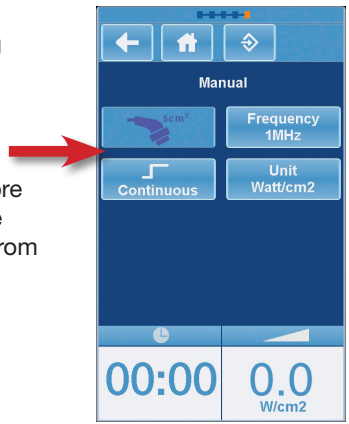
- Use the central control dial to scroll through the information.



Ultrasound Therapy Set-Up — Clinical Protocols (cont.)

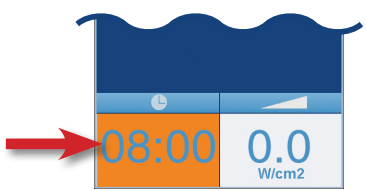
3. Parameters

- Adjust the parameters by touching the desired parameter button and change the value with the central control dial.
- **NOTE:** Some parameters have more options to choose from and on the next screen, another list appears from which to choose from.



4. Treatment Time Adjustment

- Touch the timer. The color will change to orange. Adjust the treatment time with the central control dial.



To ensure efficient transfer of energy, a contact medium is required between the ultrasound applicator and the body. The best medium for the transfer of ultrasound energy is a gel.

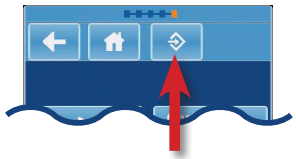
5. Start Therapy

- Once your parameters and timer are set, make contact with the treatment area. Then start the therapy by touching the output intensity on the bottom of the screen. The color will change to orange.
- Use the central control dial to adjust the output level.
- **Note:** The current intensity can only be adjusted after the timer has been set. The count-down starts when contact is activated.

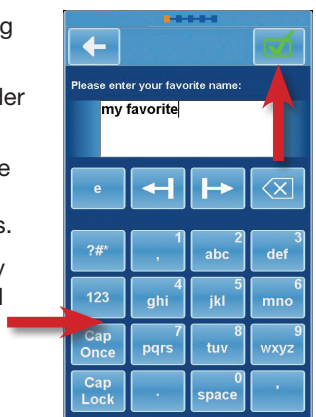
- To pause the treatment, touch the pause button in the navigation bar.
- To continue the treatment, touch the run button in the navigation bar.
- To stop the treatment, touch the STOP button in the navigation bar.
- **NOTE:** To restart after pressing stop, you will need to re-enter the treatment time first.

Ultrasound Therapy Set-Up — Clinical Protocols (cont.)

6. Storing Your Favorite Settings



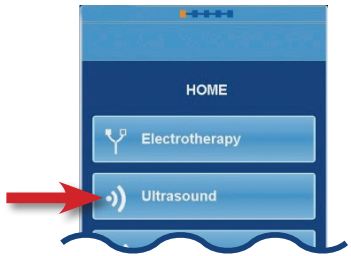
- When a treatment screen is completely set as required, you can save those settings as a favorite for later use.
- As long as the treatment has not been started, a store button will be available on the navigation bar.
- To store your settings to Favorites, touch the store button.



- Enter the name of your favorite using the keyboard.
- Press to store your favorite under the name just entered.
- **NOTE:** Once saved, favorites can be retrieved from the Electrotherapy, Ultrasound and Combination menus.
- 4-polar treatments are automatically saved and loaded as a dual channel treatments.

Ultrasound Therapy Set-Up — Manual Operation

1. Home



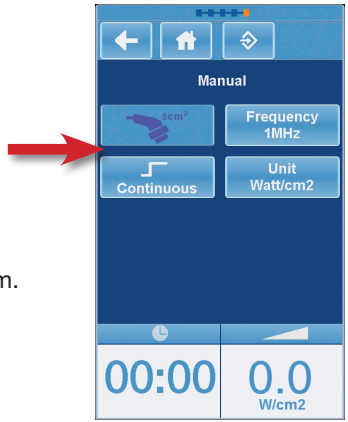
- The Home Menu gives access to all functions of the unit.
- Select the Ultrasound button.

2. Manual Operation

- The Ultrasound menu provides access to the following functions:
  1. Clinical Protocols
  2. Favorites
  3. Manual Operation
- Select Manual Operation button.

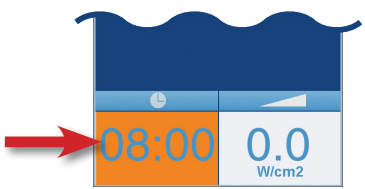
3. Parameters

- Adjust the parameters by touching the desired parameter button and change the value with the central control dial.
- **NOTE:** Some parameters have more options to choose from and on the next screen, another list appears from which to choose from.



4. Treatment Time Adjustment

- Touch the timer. The color will change to orange. Adjust the treatment time with the central control dial.



To ensure efficient transfer of energy, a contact medium is required between the ultrasound applicator and the body. The best medium for the transfer of ultrasound energy is a gel.

5. Start Therapy

- Once your parameters and timer are set, make contact with the treatment area. Then start the therapy by touching the output intensity on the bottom of the screen. The color will change to orange.
- Use the central control dial to adjust the output level.
- **NOTE:** The current intensity can only be adjusted after the timer has been set.

  The count-down starts when contact is activated.

- To pause the treatment, touch the pause button in the navigation bar.
- To continue the treatment, touch the run button in the navigation bar.
- To stop the treatment, touch the STOP button in the navigation bar.
- **NOTE:** To restart after pressing stop, you will need to re-enter the treatment time first.

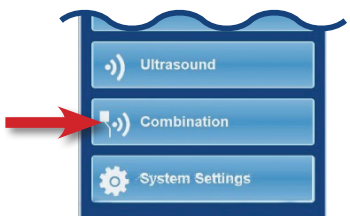
Combination Therapy Set-Up — Manual Operation
(Performa™ Combin8 and Duo Only)

PLEASE NOTE: Combination Therapy combines ultrasound & electrotherapy through the sound head. In order for combination therapy to be active, you **MUST** use the dark green combination lead wire plugged into channel #2 receptacle. All other lead wires should be unplugged.

To ensure efficient transfer of energy, a contact medium is required between the ultrasound applicator and the body. The best medium for the transfer of ultrasound energy is a gel.

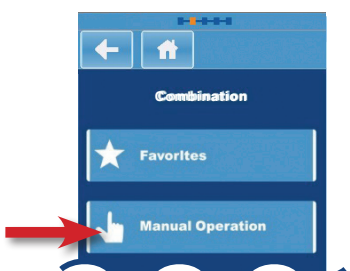
1. Home

- The Home Menu gives access to all functions of the unit.
- Select the Combination button.



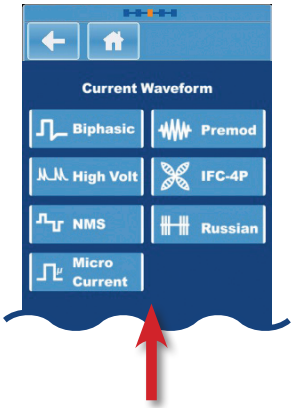
2. Manual Operation

- The Combination Menu provides access to the following functions:
  1. Favorites
  2. Manual Operation
- Select Manual Operation button.



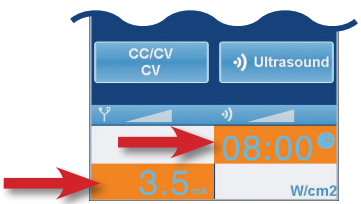
3. Setting Electrotherapy Parameters

- The first parameter screen that is shown is for electrotherapy parameters. Select the desired electrotherapy waveform by pressing the button.
- **NOTE:** Some selections have more options to choose from and on the next screen, another list appears from which the current waveform can be selected.



4. Treatment Time and Parameter Adjustment

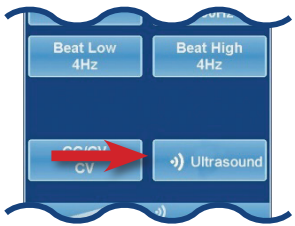
- Touch the timer. The color will change to orange. Adjust the treatment time with the central control dial.
- Adjust the parameters by touching the desired parameter button and change the value with the central control dial.



Combination Therapy Set-Up — Manual Operation (cont.)

5. Setting Ultrasound Parameters

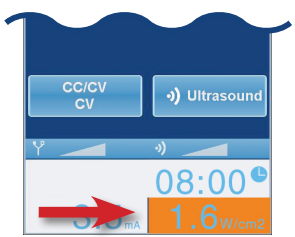
- Once you are finished setting the electrotherapy parameters, press the Ultrasound button.
- Select the desired ultrasound frequency by pressing the buttons



- **NOTE:** Some parameters have more options to choose from and on the next screen, another list appears from which to choose from.

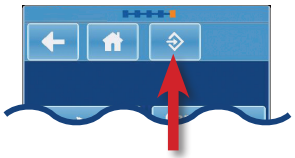
6. Treatment Time Adjustment

- Touch the Timer button if you need to change the treatment time set in step 4. The color will change to orange. Adjust the treatment time with the central control dial.
- Adjust the parameters by touching the desired parameter button and change the value with the central control dial.



7. Storing Your Favorite Settings

- When a treatment screen is completely set as required, you can save those settings as a favorite for later use.
- As long as the treatment has not been started, a store button will be available on the navigation bar.
- To store your settings to Favorites, touch the store button.

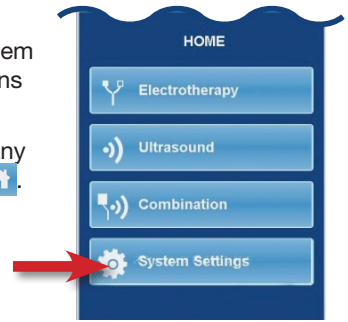


- Enter the name of your favorite using the keyboard.
- Press to store your favorite under the name just entered.
- **NOTE:** Once saved, favorites can be retrieved from the Electrotherapy, Ultrasound and Combination menus.
- **NOTE:** 4-polar treatments are automatically saved and loaded as a dual channel treatment.

System Settings

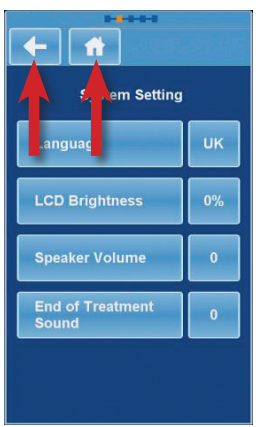
1. Home Screen

- From the Home Menu, choose “System Settings” to access to all the functions of the unit.
- **NOTE:** You can reach this menu at any time by pressing the Home button .



2. Settings Adjustment

- Here you can personalize the unit. Several settings can be changed or adjusted by touching the desired option and using the central control dial to navigate through the options.
- Touch the back arrow or Home button to return to the Home Menu.



Adjusting Current Amplitude

The unity of the displayed current amplitude depends on the previously selected current waveform and can be expressed in mA or V by pressing the CC/CV button.

CC/CV Mode

Depending on the selected current waveform, the electrotherapy channels can be used in the Constant Current or Constant Voltage mode. In CV mode, the output current depends on the electrical contact with the patient and can therefore vary. You can change the CC/CV setting in the parameter menu.

Current Polarity

When monophasic currents are used, the red connection is the positive connection and the black is the negative connection.

Cleaning

Cleaning of the Device

- Switch off the device and disconnect it from the power supply.
- The device can be cleaned with a damp cloth.
- Use lukewarm water and a non-abrasive liquid household cleaner (non-abrasive, non-alcohol content solution).
- If a more sterile cleaning is needed, use a cloth moistened with an Antimicrobial cleaner.

⚠CAUTION

Do not submerse the device in liquids. Should the unit accidentally become submersed, contact the dealer or authorized service center immediately. Do not attempt to use a system that has been wet inside until inspected and tested by a certified service technician. Do not allow liquids to enter the ventilation holes.

Cleaning of Display Panel

Use a soft and dry cotton or micro fiber cloth to clean the panel. To remove fingerprints or grease, use a non-abrasive glass cleaning agent. Apply a small amount of the cleaning agent to a soft cotton cloth and carefully clean the panel.

⚠CAUTION

- Do not spray the cleaning agent directly on the glass panel.
- Do not use cleaning agents that contain strong alkali, lye, acid, detergents with fluoride or detergents with ammonia.

Care and Storage of Electrodes

(Performa™ Stimul8 and Combin8 devices only.)

- The life of the electrodes varies depending on skin conditions, storage temperature,the amount of use, type of stimulation and stimulation site.
- If electrodes begin losing adhesion, gently rub one or two drops of water onto the gel surface and allow them to quickly air-dry. Over saturation with water will reduce the adhesive properties.
- Then place them back on the protective liner and in the original resealable bag sealing tightly to prevent air from drying out the electrodes.
- Between uses, store in a cool dry place.

⚠CAUTION

- **The electrodes are intended for single patient use only.**
- If irritation occurs, discontinue use and consult your clinician.
- Always use the electrodes with CE mark, or are legally marketed in the US under 510(K) procedure.

Cleaning the Lead Wires and Cables
(Performa™ Stimul8 and Combin8 devices only.)

Periodically wipe the lead wires clean with a cloth dampened in a mild soap solution, and then gently wipe them dry. Use of rubbing alcohol on the lead wires will damage the insulation and dramatically shorten their life.

Ultrasound Applicator
(Performa™ Stimul8 and Combin8 devices only.)

To prevent corrosion, clean and dry the contact surface immediately after use. Make sure that no ultrasound gel remains on the applicator. We further recommend cleaning the applicator and cable daily, using lukewarm water. The applicator can be disinfected using a cloth moistened with a 70% alcohol solution. Check the applicator and cable regularly for damage.

Error Codes

Error Code	Reason for Tone	Solution	Problem Still Exists?
101	There is no electrode load detected. The connection of pads or lead wires is not secure	Check the electrode pads and lead wires. Change lead wires or pads.	Contact manufacturer tech support.
102			
103			
104			
105	The ultrasound applicator is not connected well.	Check the connection of the ultrasound applicator.	Contact manufacturer tech support.
107	The output current exceeds the setting current value.	Restart the device	Contact manufacturer tech support.
108			
109			
110			
111	The pulse duration of the output waveform exceeds the setting pulse duration value.	Restart the device	Contact manufacturer tech support.
112			
113			
114			
117	The self check has failed.	Restart the device	Contact manufacturer tech support.
118	External stim board self check has failed.		
119	Stim board may be defective		

Error Code	Reason for Tone	Solution	Problem Still Exists?
120	The storage for favorites is full.	Delete some of the favorite programmings.	
121	The password is wrong.	Contact manufacturer.	
122	The SD socket is broken or the SD card falls off the socket.	Restart the device	Contact manufacturer tech support.
123	The communication between the boards is bad.		
124	Start screen will not display		
125	The device does not follow the setting parameters.	Stop the electrotherapy, and then restart the device.	Contact manufacturer tech support.
126	The device cannot read the SD contents.	Restart the device	Contact manufacturer tech support.
127	Only exists in combination mode.		
128	Improper operation of the ultrasound head. Ensure you are using enough ultrasound gel on applicator and moving around as indicated in the manual instructions.	Let applicator cool off and then try again.	Contact manufacturer tech support.

TECHNICAL MAINTENANCE

⚠CAUTION

- Electrical safety of the device relies on a properly grounded electrical connection via the power cord.
- To ensure continued compliance with the 21 CFR 1050.10 standard, this unit should be adjusted and safety tested once each year. Procedures specified in the service manual should be followed. This may be carried out by your supplier, or by another agency, authorized by the manufacturer. It is also recommended that a service history record be maintained. In some countries this is even obligatory.
- Use of controls or adjustments or Performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

⚠WARNING

- This unit operates with high voltages. No attempt should be made to disassemble the unit. Maintenance and repair should be carried out by authorized personnel only. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- All other technical maintenance is restricted to authorized manufacturer maintenance personnel.

- Replace lead wires annually. (Performa™ Stimul8, Combin8 and Duo only)
- Please follow the directions on the electrode packaging for the care of the electrodes. The life of an electrode varies, depending on skin conditions, skin preparation, storage and climate. Replace electrodes that no longer stick.
- **NOTE:** If the following measures fail to alleviate the problem, please call the authorized agency or your supplier.

Problem	Possible cause	Solution
Displays fail to light up	Adapter contact failure	Ensure adapter is connect. Check the following contacts: • All contacts are in place. • All contacts are not broken. • Ensure that adapter is connected.
Stimulation weak	Electrodes 1. Dried out or contaminated 2. Placement	1. Replace. 2. Electrodes must be a minimum of 1.5 inches apart.
	Lead wires: old/worn/damaged	Replace.
Stimulation stops	Poor electrode contact	Reapply electrodes, secure firmly.
	Damaged or worn electrodes or lead wires	Replace.

Stimulation is Uncomfortable.	Intensity is too high.	Decrease intensity.
	Electrodes are too close together.	Reposition the electrodes.
		Electrodes must be a minimum of 1.5 inches apart.
	Damaged or worn electrodes or lead wires.	Replace.
	Electrode active area size is too small.	Replace electrodes with ones that have an active area no less than 2 inches.
Stimulation is Ineffective.	Improper electrode.	Reposition electrode.
	Unknown.	Contact clinician.

End of life

The Performa™ Professional Series contains materials that can be recycled and/or are noxious to the environment. Specialized companies can dismantle the unit and sort out these materials. When you dispose of the unit, find out about local regulations concerning waste management.

Safety and Performance Standards

IEC 60601-1

General requirements for the safety of electrical medical systems, including Annex 1, national differences for Australia, Canada and the United States.

Safety Class According to IEC 60601-1

Class I type BF

IEC 60601-2-5

Particular requirements for the safety of ultrasonic therapy equipment.

IEC 60601-2-10

Particular requirements for the safety of nerve and muscle stimulators.

This equipment complies with all requirements of the Medical Device Directive (93/42/EEC).

Medical Device Classification

21 CFR 1050.10

This equipment complies with all requirements of 21 CFR1050.10, Performance Standard for Ultrasonic Therapy devices.

21 CFR 898

This equipment complies with all requirements of 21 CFR 898, Performance Standard for electrode lead wires and patient leads.

EMC Details

Medical electrical devices such as the Performa™ Professional Series are subject to special precautions with regard to electromagnetic compatibility (EMC) and must be installed and commissioned in accordance with the EMC advice given in the instructions for use and accompanying documents.

Portable and mobile RF communication systems (e.g. mobile phones) may cause interference with the Performa™ Professional Series.

The Performa™ Professional Series should only be operated with the original power cord specified in the list of contents delivered.

Operating the device with any other power cord can lead to increased emissions or reduced interference immunity of the device.

Guidelines And Manufacturer's Declaration – Electromagnetic Interference		
The Performa™ Professional Series device is intended for operation in an electromagnetic environment as indicated below. The customer or user of the Performa™ Professional Series unit should ensure that it is operated in such an environment.		
Interference Tests	**Conformity**	**Electromagnetic Environment Guideline**
RF emissions according to CISPR 11	Group 1	The Performa™ Professional Series device uses RF energy solely for its internal functioning. Its RF emission is therefore very low and it is unlikely that this will cause interference to neighboring electronic Performa™ Professional Series.
RF emissions according to CISPR 11	Class A	The Performa™ Combin8 Quattro device is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuation emissions and flicker according to IEC 61000-3-3	Conforms	

The device should not be used when placed immediately next to or stacked on top of other devices. If operation is necessary when immediately next to or stacked on top of other devices, the device should be monitored to ensure it is operating as intended in this arrangement.

Guidance And Manufacturer's Declaration – Electromagnetic Immunity			
The Performa™ Professional Series device is intended for use in the electromagnetic environment specified below. The customer or the user of the Performa™ Professional Series device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) to 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 to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines not applicable	Power Outlet quality should be that of a typical commercial or hospital environment.

Surge IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Power outlet quality should be that of a typical commercial or hospital environment.
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 seconds)	<5% UT (>95% dip in UT for 0.5 cycle) 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT for 25 cycles) <5% UT (>95% dip in UT for 5 seconds)	Power outlet quality should be that of a typical commercial or hospital environment. If the use of the Performa™ Professional Series device requires continued operation during power outlet interruptions, it is recommended to install a battery*.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

The main features of the Performa™ Professional Series devices are as follows: interference-free delivery of shockwaves, interference-free control of all functions. Uninterrupted operation is not required with the use intended.

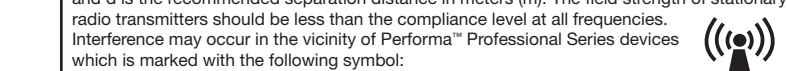
Guidelines and Manufacturer's Declaration – Electromagnetic Interference Immunity

The Performa™ Professional Series device is intended for operation in the electromagnetic environment specified below. The customer or user of the Performa™ Professional Series should ensure that it is used in such an environment.

Interference Immunity Tests	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment-Guidelines
Conducted RF disturbance variables according to IEC 61000-4-6 Radiated RF disturbance variables according to IEC 61000-4-3	3V effective value 150 kHz to 80MHz 3 V/m 80 MHz to 2.5GHz	3V effective value 150 kHz to 80MHz 3 V/m 80 MHz to 2.5GHz	Portable and mobile radio should not be used any closer to the Performa™ Professional Series devices, including cables, than the recommended separation distance calculated from the equation applicable to the transmission frequency.

Recommended Separation Distance:

d= 1.2 √P d= 0.35 √P for 80 MHz to 800 MHz d= 0,7 √P for 800 MHz to 2.5 GHz Where P is the rated power of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strength of stationary radio transmitters should be less than the compliance level at all frequencies. Interference may occur in the vicinity of Performa™ Professional Series devices which is marked with the following symbol:



NOTE 1: At 80 MHz and 800 MHz, the higher frequency range is applicable.
NOTE 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Theoretically, it is not possible to exactly predict the field strengths of fixed transmitters such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasting. To determine the electromagnetic environment in relation to the fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Performa™ Professional Series device is to be used exceeds the above compliance levels, the Performa™ Professional Series device should be monitored in order to ensure that it is functioning as intended. If unusual features are noticed, additional measures may be necessary such as re-orienting or relocating the Performa™ Professional Series device.

Above the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF telecommunications 4-series and the Performa™ Professional Series device are in the following table.

The Performa™ Professional Series device is intended for operation in an electromagnetic environment where RF disturbances are monitored. The customer or user of the Performa™ Professional Series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications 4-series (transmitters) and the Performa™ Professional Series device – according to the output power of the communications device, as indicated in the following table.

Rated Output of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d= 0.35 √P	800 MHz to 2.5 GHz d= 0.7 √P
0.01	0.12	0.035	0.07
0.1	.038	0.11	0.22
1	1.2	.035	0.70
10	3.8	1.1	2.2
100	12	3.5	7

For transmitters rated at a maximum output which is not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the respective column, whereby P is the maximum rated output of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range is applicable.
NOTE 2 :These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARRANTY

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

1) Performance Health® sole obligation in the case of any breach of its warranties set forth in the manual shall be, at Performance Health's option, to replace the Product with a new or factory certified refurbished product without charge to the Purchaser or to refund the purchase price of the Product. If the product is unopened/unused it can be returned minus a 25% restock fee. The warranty period for the Performa™ Professional Series device is three years from date of purchase and does not include accessories.
2) For defective products, please contact your distributor or Performance Health® directly at 800-323-5547. If product cannot be remedied over the phone, a prepaid shipping label will be sent to you with the authorized RMA number (if product is within warranty). **Any product sent back without an authorized RMA number will be returned to the sender.** Performance Health® will not be responsible for damage due to improper packaging or shipment. If Performance Health® determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Performance Health® will replace the product with a new or factory certified refurbished product at Performance Health®'s expense or refund the purchase price to the original purchaser for the price of the defective product (minus shipping costs).
   If Performance Health® determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Performance Health® will inform the Purchaser and return the product, freight billed to the purchaser.
3) Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
4) The following is excluded under the warranty:
   - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
   - Any device that has been opened or has a damaged warranty seal, automatically voids the warranty and no refund or warranty replacement will be provided.
   - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
   - Accessories which are subject to normal wear and tear.
5) Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

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Manufactured for:
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42-PH8000-MAN_00