

REF UPC 200-A

Urgent[®] PC

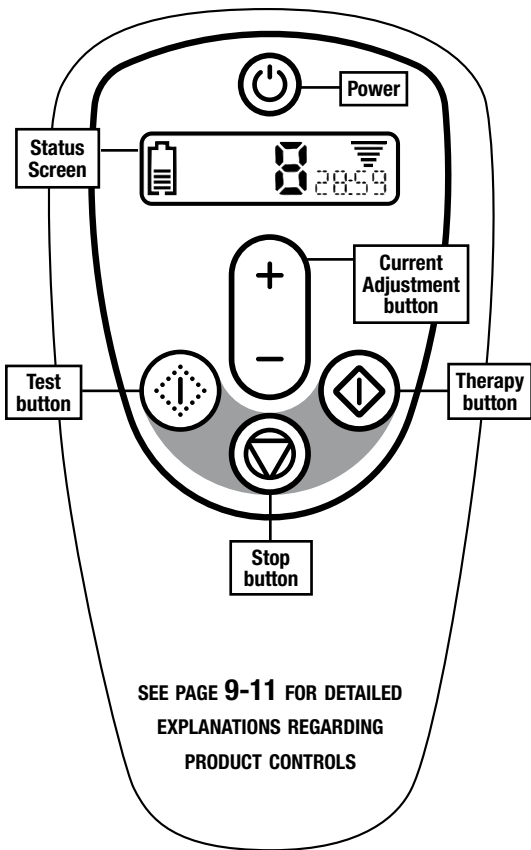
NEUROMODULATION SYSTEM

*For the treatment of Overactive Bladder (OAB)
and associated symptoms of urinary urgency,
urinary frequency, and urge incontinence.*

URGENT[®] PC STIMULATOR Instructions for Use

Description of Symbols	3
Indications	4
Description	4
Contraindications	4
Warnings	5
Precautions.....	6
Product Specifications	7
Procedure	12
Clinical Experience.....	17
Electromagnetic Compatibility.....	20
Warranty.....	23

Urgent® PC Stimulator



**SEE PAGE 9-11 FOR DETAILED
EXPLANATIONS REGARDING
PRODUCT CONTROLS**


DESCRIPTION OF SYMBOLS


Rx Only Prescription Use Only


 Product Reference Number


SN Serial Number

 Lot Number


 Consult Instructions for Use

 Temperature limitation of -20°C (-4°F) to 60°C (140°F)

 Relative humidity of 20% to 80%, non-condensing


 Atmospheric pressure of 500 hPa to 1060 hPa

 Type BF Applied Part

 Waste electrical and electronic equipment (WEEE) should not be disposed as unsorted municipal waste; WEEE should be collected separately.

 Direct Current

 9V Alkaline Battery

 Classified by Underwriters Laboratories Medical Equipment With Respect to Electric Shock, Fire, and Mechanical Hazards Only. In accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, EN 60601-1, IEC 60601-1, and IEC 60601-2-10.

 Manufacturer

 Authorized Representative in European Community

INDICATIONS

The Urgent® PC Neuromodulation System is intended to treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

DESCRIPTION

The Urgent PC Neuromodulation System is a minimally invasive neuromodulation system designed to deliver retrograde access to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve. The method of treatment is referred to as Percutaneous Tibial Nerve Stimulation (PTNS).

The Urgent PC Neuromodulation System is a combination of the Urgent PC Stimulator (Stimulator) and the Urgent PC Lead Set (Lead Set). The Stimulator and Lead Set are sold separately.

The Stimulator is a battery powered, external pulse generator and is designed, constructed, and manufactured for multiple use. The Stimulator is to be used only in conjunction with the Urgent PC single-use Lead Set. The Lead Set (comprised of the Lead Wire, Needle Electrode, and Alcohol Pad) transfers the electrical current from the Stimulator to the tibial nerve via the Needle Electrode. The only components of the Urgent PC Neuromodulation System provided sterile are the Needle Electrodes.

CONTRAINDICATIONS

1. In order for treatment to be effective and to avoid any possible problems or complications, the device is contraindicated for use on patients who have the following history or conditions:
 - » Patients with pacemakers or implantable defibrillators
 - » Patients prone to excessive bleeding
 - » Patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function
 - » Patients who are pregnant or planning to become pregnant while using this product.

2. The Stimulator is not intended for intra-cardiac or trans-thoracic use.
3. Concurrent use of medical monitoring equipment during stimulation is not recommended.
4. This device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

WARNINGS

1. This Instructions for Use is NOT a comprehensive reference to therapeutic techniques for the treatment indications noted for the Urgent PC.
2. Users should be familiar with appropriate application and techniques involved in the use of the Stimulator and the Lead Set.
3. Do not use the Stimulator in or around water.
4. Do not use the Stimulator or Lead Set if the skin in the area of use is inflamed, infected, or otherwise compromised. Monitor patients during treatment for pain or skin irritation/inflammation. Discontinue use of the Stimulator if the patient complains about these symptoms or any other discomfort.
5. Do not open battery cover while Stimulator is powered on or connected to the patient.
6. Patients should not spend more than 30 minutes in Therapy mode during a single treatment session.
7. The patient should remain comfortably seated, or in a supine position, for the duration of the treatment. The patient should not rise or walk until the treatment is complete, because mobility during treatment has not been assessed.
8. Do not use any Lead Set component (Lead Wire, Needle Electrode or Alcohol Pad) if the component is damaged.
9. Do not use the Needle Electrode or the Alcohol Pad if the packaging for either component has been opened or damaged.

10. Do not reuse the single-use Needle Electrode, Surface Electrode, or Lead Wire.
 11. Dispose of used Lead Set components in a bio-hazardous material disposal container.
 12. Remove battery if equipment is not likely to be used for some time.
 13. Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the Stimulator electrodes and possible damage to the Stimulator.
 14. Device operation in close proximity (e.g., 1 meter) to short wave or microwave therapy equipment may produce instability in the Stimulator output.
 15. The application of the electrodes near the thorax may increase the risk of cardiac fibrillation.
 16. Do not apply stimulation across or through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), chest, upper back or crossing over the heart.
 17. The Stimulator has electric shock protection, Type “Internally Powered Equipment.”
 18. The Stimulator enclosure is type IPX0 and does not protect against the ingress of water.
 19. Unauthorized modification of this equipment may cause injury to either the patient or the device operator
3. The following are potential health risks associated with this type of device and therapy:
 - » Discomfort and pain (including throbbing pain) at, or near, the stimulation site, including the patient’s lower leg and foot
 - » Bleeding at the needle site
 - » Redness/inflammation at, or near, the stimulation site
 - » Numbness of toes
 - » Stomach ache
 4. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and placed into service according to EMC guidelines provided (see page 19 for more information).
 - a. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.
 - b. The end user of this product should assure it is used in an appropriate environment.
 - i. Portable and mobile RF Communications equipment (i.e., cell phones) should not be used at close distances.
 - ii. Power frequency magnetic fields should be at levels characteristic of a typical commercial, hospital or clinic environment.

PRECAUTIONS

1. Prior to using the Urgent® PC Neuromodulation System, read and understand all instructions in the Urgent PC Stimulator Instructions for Use and Urgent PC Lead Set Instructions for Use.
2. Caution should be used for patients with suspected or diagnosed heart problems, especially those relating to the pacing or electrical functioning of the heart.

PRODUCT SPECIFICATIONS

Urgent PC Stimulator

1. Design Features:
 - » Lightweight, ergonomic, handheld design
 - » Electronic touch pad controls
 - » Raised and embossed buttons to provide tactile feedback
 - » LCD status screen to provide operational status
 - » One-way fit connection site for Lead Set

2. Electrical Current Settings:






Current Setting	Current (in mA)
0	0
1	0.15
2	0.5
3	1.0
4	1.5
5	2.0
6	2.5
7	3.0
8	3.5
9	4.0

Current Setting	Current (in mA)
10	4.5
11	5.0
12	5.5
13	6.0
14	6.5
15	7.0
16	7.5
17	8.0
18	8.5
19	9.0

- » Pulse characteristics:
 - Fixed pulse frequency of 20 Hz
 - Pulse width of 200 μ seconds
 - Square waveform
- » Resistance of 500-4000 Ohms.






Button Controls

The Stimulator is controlled by raised buttons on the device. These buttons are:

	<p>Power button – turns power on and off</p> <p><i>Note: To turn the power on or off, the user is required to press the Power button for approximately 2 seconds. This is designed to protect the Stimulator from inadvertent status changes.</i></p>
	<p>Test (yellow) button – begins Test mode</p> <p>Upon entering Test mode, the default current setting will be 0 (0mA). At the completion of the Test mode, the final current setting shall be the baseline setting in Therapy mode.</p> <p><i>Note: To activate Test mode, the user is required to press the Test mode button for approximately 2 seconds. This is designed to protect the Stimulator from inadvertent status changes.</i></p>
	<p>Therapy (green) button – begins Therapy mode</p> <p>The default current setting for Therapy mode will be the final current setting in Test mode. However, the Current Adjustment button may be used to increase or decrease the current level at any time.</p> <p><i>Note: To activate Therapy mode, the user is required to press the Therapy mode button for approximately 2 seconds. This is designed to protect the Stimulator from inadvertent status changes.</i></p>
	<p>Stop (red) button – stops flow of current in Test or Therapy mode</p> <p><i>Note: If treatment is stopped or interrupted during Therapy mode, the remaining Therapy mode time is displayed. Once stopped, the treatment session will need to be restarted, beginning with Test mode. Depending on when the session was interrupted, a new Lead Set may be required.</i></p>
	<p>Current Adjustment button – increases or decreases current</p> <p><i>Note: The current is adjustable in both Test and Therapy modes.</i></p>
<p><i>Note: if the Stimulator is not in Test or Therapy mode, and no button is pressed for 5 minutes, the Stimulator will power down.</i></p>	

Status Screen

Icons and alpha-numeric characters on the Status Screen provide operational feedback. These include:

	<p>Battery Level icon</p> <p>The number of horizontal lines displayed in the Battery Level icon represents the remaining battery life. Seven horizontal lines indicate a fully charged battery and one horizontal line indicates that the battery is nearly depleted. A flashing Battery Level icon signals that a replacement battery is needed. In addition, the Stimulator will emit a beep every 15 seconds when the battery is nearly depleted (only one line displayed in the Battery Level icon).</p> <p><i>Note: The system is designed to prohibit the start of Test mode if there is insufficient battery life remaining to complete the treatment.</i></p>
	<p>Lead Wire Status icon</p> <p>Indicates the functional status of the Lead Wire. The icon will flash if a new Lead Wire is required.</p>
	<p>Inactive Current icon</p> <p>Indicates that current is not flowing through the Lead Wire. Check the security of the Lead Connector, the adherence of the Surface Electrode, and the placement of the Needle Electrode Clip.</p>
	<p>Active Current icon</p> <p>Indicates that current is actively flowing through the Lead Set.</p>
	<p>Service Required icon</p> <p>If a fault is detected, Therapy mode will end and the Service Required icon will appear on the screen. Contact Cogentix Medical for further instructions.</p> <p><i>Note: Holding down more than one button at start-up may result in the Service Required icon appearing on the display. If this icon appears at start-up, use the Power button to turn the device off and on.</i></p>

	<p>Treatment Status (Lower right of screen)</p> <p>During Test Mode, the word "TEST" will appear on the screen.</p> <p>Once Therapy mode is started, a countdown timer will appear in the lower right of the display. This timer indicates how much time is left in the 30 minute Therapy session.</p> <p>Upon completion of Therapy, the word "END" will flash on the screen until shutdown.</p>
	<p>Current Setting (Center of screen)</p> <p>The selected current setting is displayed at all times in the center of the status screen. The current is adjustable in both Test and Therapy modes.</p>

Urgent PC Lead Set

The Lead Set transfers the electrical current from the Stimulator to the tibial nerve and includes:

- » Lead Wire: the components of the Lead Wire create the non-sterile circuit interface between the Simulator and the patient. A one-way fit Stimulator connector is attached to the proximal end of the Lead Wire. The distal end of the Lead Wire is split into individual wires. One wire is attached to an adhesive-backed Surface Electrode; the other is attached to the Needle Electrode Clip.
- » Needle Electrodes: two 34 Ga. solid stainless steel Needle Electrodes, each contained within a plastic guide tube with stop plug. Each Needle Electrode is supplied sterile (Ethylene Oxide) in an individual peel-open package (Manufacturer: Helio Medical Supplies, California, USA).
- » Alcohol Pad: a prepackaged alcohol pad to clean the Needle Electrode insertion site.

PROCEDURE

This therapy, percutaneous tibial nerve stimulation (PTNS), involves placing the Needle Electrode into the lower, inner aspect of either leg slightly cephalad to the medial malleolus. A Surface Electrode is placed over the medial aspect of the calcaneus on the same leg. The Lead Wire is first connected to the Stimulator, and then the Needle Electrode Clip is connected to the Needle Electrode. The Stimulator produces an adjustable electrical pulse that travels to the sacral nerve plexus via the tibial nerve. Among other functions, the sacral nerve plexus regulates bladder and pelvic floor function.

The patient is typically treated once per week for 30 minutes for a period of 12 weeks. No decision regarding treatment effectiveness should be made until the patient completes the 12 treatments. For patients responding to treatment, the time between treatment sessions may be slowly increased after the initial 12 treatments, with the patient closely monitored for the return of symptoms. If symptoms reappear or increase in severity, the patient's treatment schedule should revert to the last previously effective treatment schedule.

TREATMENT PROTOCOL FOR EACH TREATMENT SESSION

1. Check Battery Level

- » Before beginning any treatment session, it is advisable to check the battery level. To check the battery level, turn on the Stimulator by pressing and holding the Power Button for approximately 2 seconds. An audible tone will sound and icons will appear on the screen. Battery replacement is recommended when there is only one line remaining in the Battery Level icon. To conserve battery power, the Stimulator may be turned off during patient preparation.

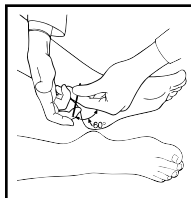
Note: The system is designed to prohibit the start of Test mode if there is insufficient battery life remaining to complete the treatment.

2. Insert the Needle Electrode



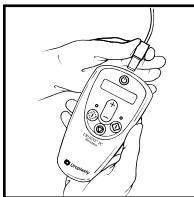
- » Locate the insertion site for the Needle Electrode by identifying the location on the lower inner aspect of either leg that is approximately three fingerbreadths (5 cm or 2") cephalad to the medial malleolus and approximately one fingerbreadth (2 cm or ¾") posterior to the tibia.

- » To prepare the Needle Electrode insertion site, open the Lead Set packaging. Remove and open the Alcohol Pad. Use the Alcohol Pad to clean the skin area surrounding the identified insertion site.
- » Place the patient in a comfortable position, supine or sitting, for easy access to the insertion site; for example, the patient may sit with the soles of the feet together and knees abducted and flexed. Open the sterile Needle Electrode package and remove the Needle Electrode/guide tube assembly.
- » Place the Needle Electrode/guide tube assembly over the identified and cleaned insertion site in a position that creates a 60-degree angle between the shaft of the Needle Electrode and the skin with the needle tip pointed cephalad. Remove the stop plug in the guide tube to release the Needle Electrode.
- » Gently tap the Needle Electrode head to pierce the skin. Once the Needle Electrode has penetrated the skin, remove



- the guide tube and advance the Needle Electrode using a rotating motion to facilitate entry. *Note: it is important to maintain a 60-degree angle with the Needle Electrode while advancing it in a path with the needle tip pointed cephalad. When appropriately inserted, approximately 2 cm (¾") of the Needle Electrode will be inserted in the leg.*

3. Connect Lead Wire to the Stimulator

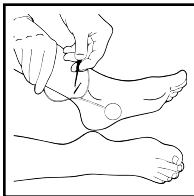


- » Plug the one-way fit connector of the Lead Wire into the Stimulator's connection site. Verify the narrow, slotted end of the blue lead wire connector is inserted all the way into the stimulator.

4. Attach the Surface Electrode

- » Remove the adhesive backing from the Surface Electrode.
- » Place the Surface Electrode near the medial aspect of the calcaneus on the same leg as the Needle Electrode insertion.

5. Attach Needle Electrode Clip



- » Depress the plunger on the Needle Electrode Clip to expose the connection hook at the tip. Loop the connection hook around the Needle Electrode and release.

6. Determine Current Setting for Therapy

- » Turn on the Stimulator by pressing and holding the Power button for approximately 2 seconds. An audible tone will sound and symbols will appear on the screen.

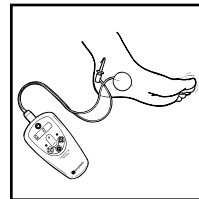
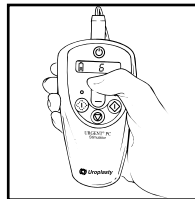
Note: If the Lead Wire Status icon is blinking, ensure that the Lead Wire connector is secure in the Stimulator's connection site.

- » Enter Test mode by pressing and holding the Test button for approximately 2 seconds. The default setting for Test mode is level 0 (0mA current).

Note: If the Inactive Current icon appears, current is not flowing through the Lead Set. Check the security of the Lead

Wire connector, the adherence of the Surface Electrode, and the placement of the Needle Electrode Clip.

- » Using the Current Adjustment button, slowly increase the current while monitoring the patient for a response. Patient response may be either motor or sensory. For some patients it is both. Motor response is typically a toe flex or fan, or an extension of the entire foot. Sensory response is generally described as a tingling sensation that travels away from the insertion site, towards the heel, arch, toes or up the leg.



- » Once a patient response is confirmed, reduce current setting by one level and begin Therapy mode.
- » If the incremental adjustment of amplitude fails to elicit either a motor or a sensory response, press the Stop button and reposition the Needle Electrode slightly. Re-enter Test mode using the preceding instructions.
- » If repositioning the Needle Electrode and repeating the current step-up procedure fails to elicit patient response, discard the Needle Electrode. Open the second Needle Electrode included in the Lead Set and repeat the procedure on the other leg.

7. Conduct therapy

- » After completing Test mode, Therapy mode can be entered by either:

- 1) Pressing the Stop button to end Test mode and then pressing the Therapy button to start Therapy mode.
- or 2) Pressing the Therapy button while the Test mode is still active.

Note: Test mode is a prerequisite to Therapy mode.

- » To ensure optimal treatment, the default current setting for Therapy mode will be the final current setting in Test mode. However, the Current Adjustment button can be used to increase or decrease the current level at any time during Therapy mode.
- » Therapy mode time is automatically set for 30 minutes.
- » When the therapy time has elapsed, Therapy mode will automatically end, the current will be inactive, and the Stimulator will emit a series of three beeps.

8. Complete Treatment Session

- » Turn off the Stimulator by holding down the Power button for approximately 2 seconds.
- » Remove the Needle Electrode Clip from the Needle Electrode.
- » Using a smooth, fluid motion, quickly remove the Needle Electrode from the leg. If bleeding occurs, apply slight pressure and bandage.
- » Disconnect the Lead Wire from the Stimulator and properly dispose of Lead Set components.
- » The treatment session is now complete.

TREATMENT FREQUENCY

- » Conduct 12 treatments, typically once per week.
- » After the initial 12 treatments, slowly increase the time between treatments, with the patient closely monitored for the return of symptoms.
- » If symptoms reappear or increase in severity, the patient's treatment schedule should revert to the last previously effective treatment schedule.

MAINTENANCE

After each treatment the surface of the Stimulator device should be wiped down with a soft cloth. The cloth may be slightly dampened, but not saturated, with water or with a mix of isopropyl alcohol (70%) and water (30%).

Use only a 9V alkaline battery to power the Stimulator. Never operate the Stimulator with any type of line-powered battery eliminator or other external power source. Battery life is dependent on the intensity of treatment; a new 9V battery will perform approximately 12 treatments at a current setting of 5mA (level 11). Recycle or dispose of batteries in compliance with applicable local and/or national regulations. Do not store Stimulator for long periods with battery in the device. If the Stimulator is not working properly, contact Cogentix Medical.

PERMISSIBLE OPERATING ENVIRONMENT

- » Ambient Temperature 10°C to 40°C
- » Relative humidity 30% to 75%
- » Atmospheric pressure 700 hPa to 1060 hPa

CLINICAL EXPERIENCE

A prior version of the Urgent PC Neuromodulation System (same stimulation waveform and treatment instructions) was evaluated for the treatment of patients with pelvic floor dysfunction with symptoms of urinary frequency, urgency or urge incontinence in: (1) a single-investigator study (Dr. Stoller/UCSF) involving 98 subjects, (2) and a subsequent, corroborative multicenter study involving 63 subjects. The 63 patients treated in the corroborative study consist of a primary cohort of 52 patients and a supplementary cohort of 11 patients. These 63 patients were treated using a uniform regimen (i.e., a single, 30-minute session/week for a total of 12 weeks). The primary data regarding the safety and effectiveness of the device came from the corroborative multicenter study (Govier et al., Journal of Urology, Vol. 165, pp. 1193-1198, 2001).

Safety

The safety of the Urgent PC Neuromodulation System is based on all 63 patients treated in the corroborative study. Of the 63 patients treated, 28 (44.4%) reported a total of 95 adverse events.

Of these 95 events, only 26 (27.4%) events in 9 patients were considered to be related to the device or the therapy. The adverse events included transient moderate pain at or near the stimulation site (n=3), transient mild pain or skin inflammation at or near the stimulation site (n=21), and transient mild bleeding at needle insertion site (n=2). No serious device related adverse events occurred in any patient.

NOTE: If your patient complains of any pain or discomfort following treatment, discontinue use of the stimulator and re-evaluate the case for continuation of treatment.

Effectiveness

In the single investigator-study, approximately 80% of patients were classified as a treatment success by the investigator. Success was defined as substantial subjective improvement whereby the initial complaint was no longer the central focus of the patient, or a greater than 50% improvement of the initial symptoms was seen. Failure was defined as minimal or no change in symptoms.

In the corroborative study, device effectiveness was based on primary cohort patients. Overall, 71% of patients were classified by the investigators as a treatment success. Success was defined by study design as at least a 25% reduction from baseline in daytime or nighttime frequency in those patients who presented at baseline with > 10 daytime micturitions and/or > 3 nighttime micturitions.

Detailed effectiveness results from the corroborative study are summarized in the following table:

Effectiveness results: 95% Confidence Intervals for the Mean Change, and the Median Percent Change from Baseline after 12 Weeks of Treatment							
Corroborative Study	Baseline Status		Mean Change From Baseline After 12 Weeks of Treatment				Median Percent Change
	N	Pre Treatment Mean	Mean	SD	95% Confidence Interval for Mean Change lb ub		
Daytime voiding frequency ^a	29	13.5	-3.5	3.7	-4.9	-2.1	-29.2%
Nighttime voiding frequency ^b	28	4.0	-1.0	1.7	-1.7	-0.3	-15.0%
24 hour voiding frequency	42	14.9	-3.6	4.2	-4.9	-2.3	-21.7%
Daytime incontinence episodes	39	4.4	-1.9	3.9	-3.2	-0.6	-40.0%
Nighttime incontinence episodes	40	1.3	-0.6	1.9	-1.2	0.0	-50.0%
Daytime urgency	42	8.3	-1.6	5.8	-3.4	0.2	-15.6%
Nighttime urgency	42	2.8	-0.3	1.6	-0.9	0.2	-9.5%
<p>Notes:</p> <p>^a This analysis was restricted to patients with at least 10 daytime voids per day prior to treatment.</p> <p>^b This analysis was restricted to patients with at least 3 nighttime voids per night prior to treatment.</p>							


MANUFACTURING

The Stimulator is manufactured in accordance with the safety norms set forth by the International Electrotechnical Commission and Underwriters Laboratory, IEC/UL 60601, including electromagnetic compatibility.

ELECTROMAGNETIC COMPATIBILITY

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Urgent PC Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Urgent PC Stimulator should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Urgent PC Stimulator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Urgent PC Stimulator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Urgent PC Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Urgent PC Stimulator should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV 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 IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1kV differential mode ± 2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (>95 % dip in U_T) for 5 cycles 70 % U_T (>95 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Urgent PC Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Urgent PC Stimulator should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RFIEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Urgent PC Stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RFIEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Urgent PC Stimulator is used exceeds the applicable RF compliance level above, the Urgent PC Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Urgent PC Stimulator			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Urgent PC Stimulator			
The Urgent PC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Urgent PC Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Urgent PC Stimulator as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.			

WARRANTY

Cogentix Medical warrants that reasonable care has been used to design and manufacture this product. Product will be replaced for up to 1 year from date of purchase if Cogentix Medical determines its material or workmanship is defective. This is Cogentix Medical's only warranty, and it excludes all other warranties (including those implied by operation of law). Cogentix Medical is not responsible for matters within the control of the user or others, such as product handling and storage, patient selection and diagnosis, and treatment procedures.

This Limited Warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, COGENTIX MEDICAL IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

(2) This Limited Warranty is made only to the purchaser of the Product. AS TO ALL OTHERS, COGENTIX MEDICAL MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

Any implied warranties of merchantability or fitness are specifically excluded. Statements and descriptions in marketing literature, while generally describing this product, do not constitute any warranties.

DISCLAIMER OF WARRANTIES

Cogentix Medical excludes all warranties and responsibilities for:

- » Improper use of or tampering with the product
- » Failure to follow instructions provided in this insert, and/or
- » Failure to follow the Instructions for Use for Urgent PC Stimulator and Urgent PC Lead Set.

Urgent is a registered trademark.

For additional information, please contact Customer Care.

Manufactured by:

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