

AGF-5X

Digital Transcutaneous Electrical
Nerve Stimulator

INSTRUCTION MANUAL



drive
MEDICAL DESIGN & MANUFACTURING

Port Washington, NY 11050

V1.1

drive
MEDICAL DESIGN & MANUFACTURING

INDEX

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Chapter 1 : INTRODUCTION

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies.

Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation is a non-invasive, drug-free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

HOW TENS WORKS

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to be used to relieve pain. The TENS unit sends comfortable impulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patient, mode selected for therapy, and the type of pain. In many patients, the reduction or elimina-

tion of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may discuss this with your physician or therapist.

Chapter 2: CAUTIONS

1. Precautions:

Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

2. Contradictions:

TENS devices can affect the operation of demand type cardiac pacemakers. TENS is not recommended for patients with known heart disease without physical evaluation of risk. Do not use TENS on the carotid sinus (neck) region. Do not apply TENS for undiagnosed pain syndromes until etiology is established. Do not stimulate on the site that may cause current to flow transcranially - (through the head).

3. Adverse Reactions

Possible allergic to gel, skin irritation and electrode burn are potential adverse reactions.

4. Read operation manual before use of TENS.

5. We emphasize that patient with an implanted electronic device (for example, a pacemaker) should not undergo TENS treatment without first consulting a doctor. The same applies to patients with any metallic implants.

6. If TENS therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is reevaluated by the physician or therapist.

7. Avoid adjusting controls while operating machinery or vehicles.

8. Turn the DIGITAL SD TENS off before applying or removing electrodes.

9. DIGITAL SD TENS devices have no AP/APG protection.

Do not use it in the presence of explosive atmosphere and flammable mixture.

Chapter 3 : WARNINGS

1. Caution should be used in applying TENS to patients suspected of having heart disease. Further clinical data is needed to show there are no adverse results.

2. The safety of TENS devices for use during pregnancy or birth has not been established.

Do not use TENS during pregnancy.

3. TENS is not effective for pain of central origin. (This includes headache.)

4. TENS devices should be used only under the continued supervision of a physician.

5. TENS devices have no curative value.

6. TENS is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.

7. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

8. There should be a prominently placed statement warning that stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

9. Do not place electrodes on the front of the throat as spasm of the Laryngeal and Pharyngeal muscle may occur.

10. Care should be taken so that when operating potentially dangerous machinery the stimulator controls are not changed abruptly.

6. Electrodes should not be placed over the eyes, in the mouth, or internally.

11. Keep this device out of the reach of children.

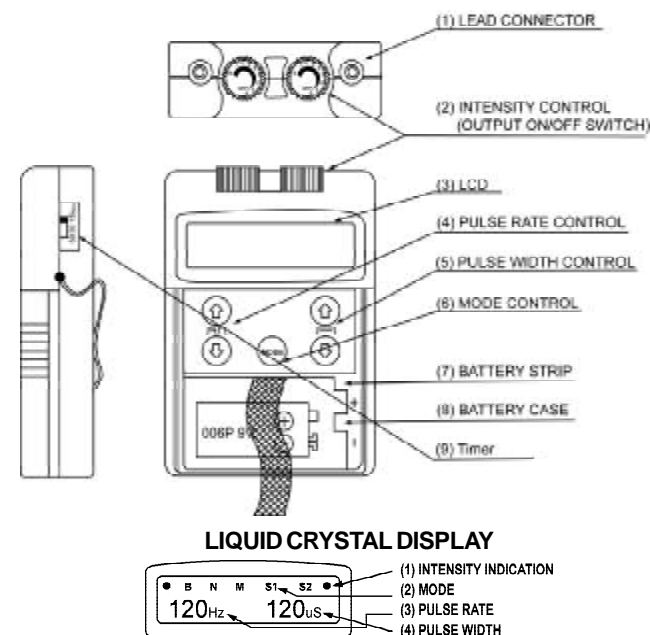
12. Caution: Federal law restricts this device to sale by or on the order of a physician.

Chapter 4: GENERAL DESCRIPTION

The AGF-5X DIGITAL SD TENS is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves causing pain. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel.

The electronics of the AGF-5X DIGITAL SD TENS create electrical impulses whose Intensity, duration, number per second and modulation may be altered with the controls/switches. Press buttons are very easy to use and the large liquid crystal display showing the exact mode and values of parameters are very convenient for patients.

Chapter 5 : CONSTRUCTION



Chapter 6 : TECHNICAL SPECIFICATIONS

The technical specification details of AGF-5X DIGITAL SD TENS are as follows.

	MECHANISM	TECHNICAL DESCRIPTION																				
01.	Channel	Dual, isolated between channels																				
02.	Pulse Ampulitude	Adjustable, 0-80 mA peak into 500 ohm load each channel.																				
03.	Wave Form	Asymmetrical Bi-Phasic Square Pulse																				
04.	Voltage	0 to 34V (Load: 500 ohm)																				
05.	Power source	One 9 Volt Battery. (Alkaline, or nickel-cadmium rechargeable)																				
06.	Size	100 (H) x 60(W) x 21 (T) mm																				
07.	Weight	120 grams with battery.																				
08.	Pulse Rate	Adjustable, from 1 Hz to 150 Hz.																				
09.	Pulse Width	Adjustable, from 30 to 260 microseconds.																				
10.	Timer	Selectable, 15, 30 and 60 minutes.																				
11.	Burst Mode	Pulse rate adjustable from 0.5 Hz to 5Hz. Pulse width (adjustable), frequency fixed=100 Hz, Max output voltage 5 V rms (13 mA rms) or 80 mA Peak to Peak into 500 ohm load.																				
12.	Modulation Mode	Pulse Width is automatically varied in cycle pattern. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Mode</th> <th>Amplitude (mA)</th> <th>Width (uS)</th> <th>Rate (Hz)</th> <th>Time</th> </tr> </thead> <tbody> <tr> <td>M</td> <td>Adj. (0-80)</td> <td>Setting (30-260)</td> <td>Adj. (-40%)</td> <td>10</td> </tr> <tr> <td>S1</td> <td>Setting (0-80)</td> <td>Setting (- 40%)</td> <td>Setting (1-150)</td> <td>10</td> </tr> <tr> <td>S2</td> <td>Setting (0-80)</td> <td>Setting (-70%)</td> <td>Setting (1-150)</td> <td>9</td> </tr> </tbody> </table>	Mode	Amplitude (mA)	Width (uS)	Rate (Hz)	Time	M	Adj. (0-80)	Setting (30-260)	Adj. (-40%)	10	S1	Setting (0-80)	Setting (- 40%)	Setting (1-150)	10	S2	Setting (0-80)	Setting (-70%)	Setting (1-150)	9
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13.	Max. Charge Per Pulse	20 micro-coulombs																				

Chapter 7 : REPLACABLE PARTS

The replaceable parts and accessories of DIGITAL SD TENS devices are as given below –

Except leads, electrodes and battery, battery case cover, please do not try to replace the other parts of a device.

	PARTS
01	ELECTRODES LEADS
02	ELECTRODES
03	9V BATTERY, TYPE 6F22
04	BELT CLIP
05	BATTERY CASE COVER
06	LEAD CONNECTOR
08	MAIN PCB
09	INTENSITY KNOB

Chapter 8 : ACCESSORIES

Each set AGF-5X TENS are completed with standard accessories and standard label as given below

I. Accessories

REF. NO.	DESCRIPTION	Q'TY
AGF-101	40 X 40 mm Adhesive Electrodes	4 pieces
AGF-111N	Electrodes Leads	2 pieces
	9 V Battery	1 piece
	Instruction Manual	1 piece
	Carrying Case	1 piece








II. LABEL



The label attached to the back of device contains important message about this device- model, serial number, supply voltage, CE number and classification.

Please do not remove.

Chapter 9 : GRAPHIC SYMBOLS

1.  Note Operating Instructions
2.  Degree of Electrical Protection BF
3.  Do not insert the plug into AC power supply socket.
4.  Pulse Rate
5.  Pulse Width
6.  Increase Parameter
7.  Decrease Parameter

Chapter 10 : PARAMETER CONTROLS

PULSE DURATION

Wider pulse duration settings will deliver stronger stimulation for any given intensity setting. As mentioned in the Controls section, by using a combination of intensity and pulse duration, it is felt that various pulse widths are capable of stimulating different groups of nerve fibres.

The choice of which pulse duration to use is partially dependent upon the Treatment Mode and Protocol selected (refer to the appropriate section).

PULSE RATE

The Pulse Rate (hertz or pulses per second) chosen depends greatly upon the type of electrode placement given to the patient.

When using contiguous and dermatome electrode placements (i.e. stimulating

directly through the area of pain or localized enervation), a quick pulse rate (setting greater than 80Hz on the Pulse Rate Control) is desired. The patient should not perceive individual pulses but rather have the sensation of steady continuous stimulation.

Despite above recommendations, these individual patients may require slight variations of the above settings, according to the nature of their condition.

TREATMENT MODE

Normal or Conventional TENS offers the practitioners complete control over all the various treatment parameters of the instrument.

Burst Mode is analogous to the Low Rate TENS technique except the low frequency individual pulses are replaced by individual "bursts" of 7-10 individual pulses. It is thus a combination of Conventional TENS and Low Rate TENS. In Burst Mode, the treatment frequency is fixed by the instrument and is not adjustable with the Frequency Rate control.

Modulated Mode attempts to prevent nerve accommodation by continuously cycling the treatment intensity. When using Modulated Mode increase the intensity only when the unit is at the maximum intensity of the modulation cycle. If the intensity is increased during a low intensity period of the cycle, the patient may turn up the control very slowly, so that they may feel the intensity any higher.

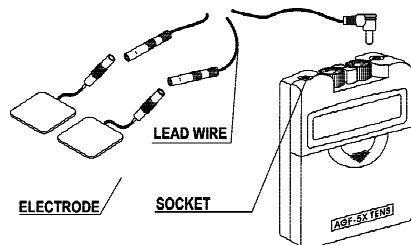
TIME DURATION

The onset of pain relief should occur shortly after the intensity setting has been determined. However, in some cases, pain relief may take as long as 30 minutes to achieve. TENS units are typically operated for long periods of time, with a minimum of 20 – 30 minutes and in some post-operation protocols, as long as 36 hours.

In general, pain relief will diminish within 30 minutes of the cessation of stimulation.

Chapter 11 : ATTACHMENT OF ELECTRODE LEAD WIRES

The wires provided with the system insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.



After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires. Jerking the wire instead of holding the insulated connector body may cause wire breakage.

CAUTION

Do not insert the plug of the patient lead wire into the AC power supply socket.

Chapter 12: LEAD WIRE MAINTENANCE

Clean the wires by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

Chapter 13 : ELECTRODE OPTIONS

Your clinician will decide which type of electrode is best for your condition. Follow application procedures outlined in electrode packing, to maintain stimulation and prevent skin irritation. Use the legally marketed TENS electrode is recommended. The device is completed with standard carbon film adhesive electrodes in size 5x5cm.

Chapter 14: ELECTRODE PLACEMENT

The placement of electrodes can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the clinician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, feel free to experiment. Once an acceptable placement has been achieved, mark down the electrodes sites and the settings on the patients reference sheet of this manual, so the patient can easily continue treatment at home.

CONTIGUOUS PLACEMENT

This is the most common placement technique. It involves placing the electrodes alongside the area of localized pain site, in such a way as to direct the flow of current through or around the area of pain.

In a single channel application, this would involve placing each pad on either side of the pain site if the pain is localized on a limb and deep within the tissue. Pad placement on the posterior and anterior aspects of the affected limb will allow the current to flow completely through the limb and thus through the endogenous pain site.

With a two channels application, the clinician may either direct the current flow to cross through the pain site or, in what is called the "bracket" method allowing the current flow on either side of the painful area, generally through the nerve branches that feed into the pain site.

Chapter 15: TIPS FOR SKIN CARE

To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.

2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the “pulling stress” from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from centre outward; avoid stretching over the skin.
5. To minimize “pulling stress”, tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

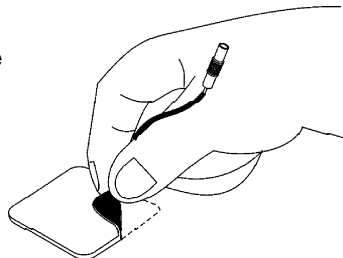
Chapter 16 : APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES

Application

1. Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site.

Removal

1. Lift at the edge of electrodes and peel; do not pull on the lead wires because it may damage the electrodes.
2. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



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Care and Storage

1. Between uses, store the electrodes in the resealed bag in a cool dry place.
2. It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.

Important

1. Do not apply to broken skin.
2. The electrodes should be discarded when they are no longer adhering.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your clinician.
5. Read the instruction for use of self-adhesive electrodes before application.

Chapter 17 : ADJUSTING THE CONTROLS

1. Slide Cover

A slide-on panel covers the buttons controlling pulse width, pulse rate and mode. Your medical professional may wish to set these controls for you and request that you leave the cover in place.

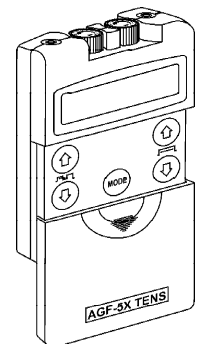
2. Power On/Off Switch and Intensity Control

If both controls are in the off-position, device is switched off.

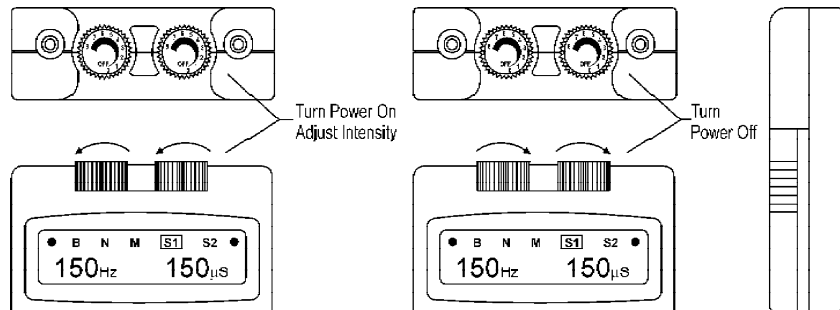
By turning the controls clockwise, the power will be switched on. A black dot will be revealed on the LCD as soon as the stimulation is commenced.

The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise.

To reduce the current strength or switch the device off, turn the control counter clockwise to the required setting or off-position, respectively.

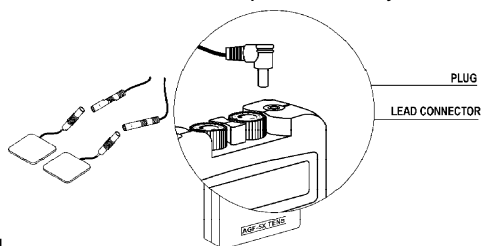


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3. Lead Connector

Connection of the electrodes is made with two-lead connector. The device must be switched off before connecting the cables. Both intensity controls must be at the Off position. Electrodes must be pressed firmly on the skin.



4. Mode Control

Expose the controls by sliding front cover down from top of unit. This button controlling 5 modes: B for burst stimulation, N for constant stimulation, and M for pulse width modulation stimulation, S1 for intensity and pulse rate modulation, S2 for intensity and pulse width modulation. Press the button until engaged in mode desired.



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5. Pulse Rate Control

Pulse rate is adjustable from 2Hz to 150 Hz . Its value is visible on the LCD. This buttons determine how many electrical impulses are applied through the skin each second. By pressing these controls, the number of current impulses per second (Hz) for both channels can be continually adjusted. Unless otherwise instructed, turn the pulse rate control to the 70-120 Hz range.



A. Increase

When pressing this button, the pulse rate will increase gradually.



B. Decrease

When pressing this button, the pulse rate will decrease gradually.



6. Pulse Width Control

Pulse Width is adjustable from 30 uS to 260 uS. Its value is visible on the LCD. These buttons adjust the length of time each electrical signal is applied through the skin, which controls the strength and sensation of the stimulation. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 uS setting.

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Chapter 18: BATTERY INFORMATION

AGF-5X TENS can be used with a rechargeable battery when necessary. If you use rechargeable batteries, please follow the instructions.

RECHARGEABLE BATTERIES:

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this instruction manual.

After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

BATTERY CHARGING

- (1) Plug the charger into any working 110 or 220/240v mains electrical outlet. The use of any attachment not supplied with the charger may result in the risk of fire, electric shock, or injury to persons.
- (2) Follow the battery manufacturer's instructions for charging time.
- (3) After the battery manufacturer's recommended charging time has been completed, unplug the charger and remove the battery.
- (4) Batteries should always be stored in a fully charged state.
To ensure optimum battery performance, follow these guidelines:
 - (a) Although overcharging the batteries for up to 24 hours will not damage them, repeated overcharging may decrease useful battery life.
 - (b) Always store batteries in their charged condition. After a battery has been discharged, recharge it as soon as possible. If the battery is stored more than 60 days, it may need to be recharged.
 - (c) Do not short the terminals of the battery. This will cause the battery to get hot and can cause permanent damage. Avoid storing the batteries in your pocket or purse where the terminals may accidentally come into contact with coins, keys or any metal objects.



A. Increase

When pressing this button, the pulse width will increase gradually.



B. Decrease

When pressing this button, the pulse rate will decrease gradually.



7. The device will store the mode that is used before it is switched off automatically.

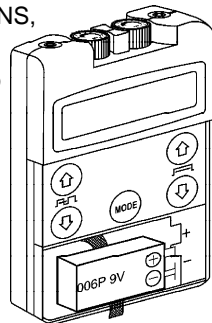
8. Timer

There is a timer on the right side of unit. The treatment time is selectable at 15, 30 and 60 minutes. Push the switch when the desired position is reached. Output will be shut off when time is up. Turn off the power when output is terminated.

9. Check / Replace the Battery:

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary.

1. Make sure that both intensity controls are switched to off position.
2. Slide the battery compartment cover and open.
3. Remove the battery from the compartment.
4. Insert the battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and press to close.



(d) WARNINGS:

1. Do not attempt to charge any other types of batteries in your charger, other than the nickel-cadmium rechargeable batteries. Other types of batteries may leak or burst.
2. Do not incinerate the rechargeable battery as it may explode!

Chapter 19: MAINTENANCE, TRANSPORTATION AND STORAGE OF TENS DEVICE

1. Non-flammable cleaning solution is suitable for cleaning the device.
Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accessories in carrying box and keep it in cool dry place.
6. The packed TENS device should be stored and transported under the temperature range of $-20^{\circ}\text{C} \sim +60^{\circ}\text{C}$, relative humidity 20% ~ 95%, atmosphere pressure 500 hPa ~ 1060 hPa.

Chapter 20: SAFETY-TECHNICAL CONTROLS

For safety reasons, check your AGF-5X DIGITAL SD TENS each week based on the following checklist.

1. Check the device for external damage.
 - deformation of the housing.
 - damaged or defective output sockets.
2. Check the device for defective operating elements.
 - legibility of inscriptions and labels.

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- make sure the inscriptions and labels are not distorted.

3. Check the usability of accessories.

- patient cable undamaged.
- electrodes undamaged.

Please consult your distributor if there are any problems with device and accessories.

Chapter 21 : MALFUNCTIONS

Should any malfunctions occur while using the AGF-5X DIGITAL SD TENS, check

- whether the parameters are set to the appropriate form of therapy. Adjust the control correctly.
 - whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
 - whether the LCD reveal the menu. If necessary, insert a new battery.
 - for possible damage to the cable. Change the cable if any damage is detected.
- * If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

Chapter 22 Conformity to Safety Standards

STATEMENT OF EMC

The AGF-5X TENS devices are in compliance with IEC 60601-1-2: 1993.

CONFORMITY TO MDD REQUIREMENTS

The AGF-5X TENS devices are in compliance with IEC60601-1 safety standard.

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Chapter 23 : WARRANTY

All AGF-5X SD TENS models carry a warranty of three year from the date of delivery. The warranty applies to the stimulator only and covers both parts and labour relating thereto.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.

Manufacturer:

Drive Medical Design & Manufacturing
99 Seaview Boulevard
Port Washington, NY 11050
Phone #: 516-998-4600

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