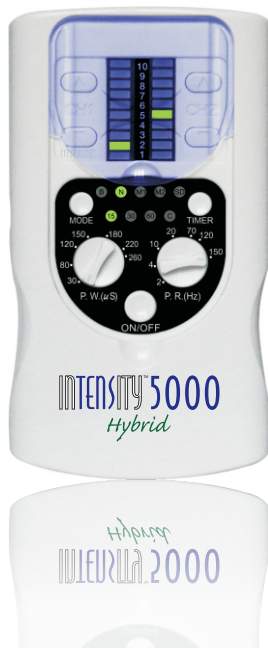


INTENSITY™ 5000

Hybrid

INSTRUCTION MANUAL



This manual is valid for the
In TENSity™ 5000 TENS Stimulator

This user manual is published by Current Solutions™, LLC

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: United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

Conformity to safety standards

Current Solutions™, LLC declares that the device complies with following normative documents:

**IEC60601-1, IEC60601-1-2, IEC60601-2-10, IEC60601-1-4,
ISO10993-5, ISO10993-10, ISO10993-1**

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1. INTRODUCTION

1.1 General

The InTENSity™ 5000 is a battery operated TENS device that sends electrical impulses through electrodes to the body and reaches the nerves causing pain. The device is provided with two controllable output channels, each independent of each other. A pair of electrodes can be connected to one output channel.

The electronics of the InTENSity™ 5000 create electrical impulses whose Intensity, duration, number per second and modulation may be altered with the controls/switches. These buttons are very easy to use and the LED display showing the exact mode, time and intensity. Values of parameters are very convenient adjusted for patients.

1.2 Medical background

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.

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 (TENS) 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 WORK

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulations (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 patients, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination 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.

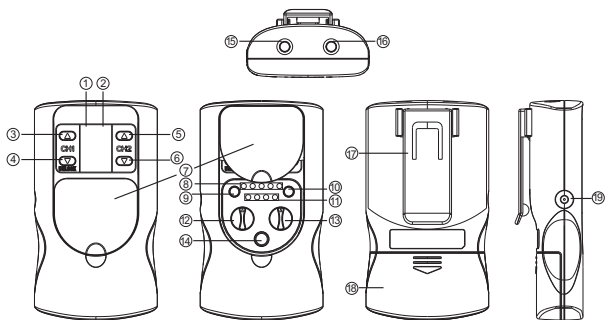
2. PARTS

About InTENSity™ 5000

Your InTENSity™ 5000 is containing:

No.	DESCRIPTION	QUANTITY
A	InTENSity 5000 Unit	1 PCS
B	Electrode pads (1.5" x1.5")	4 PCS
C	Cable	2 PCS
D	User manual	1 PCS
E	9V battery, type 6F22	1 PCS
F	Carrying case	1 PCS

Main Unit Parts



- 1) Intensity output indicator(channel 1)
- 2) Intensity output indicator(channel 2)
- 3) Increasing the output intensity of channel 1
- 4) Decreasing the output intensity of channel 1
- 5) Increasing the output intensity of channel 2
- 6) Decreasing the output intensity of channel 2
- 7) Key-press cover
- 8) Therapy mode LED indicator
- 9) Use to set the therapy mode
- 10) Use to set the therapy time
- 11) Therapy time LED indicator

- 12) Use to set adjust the pulse width
- 13) Use to set adjust the pulse rate
- 14) ON/OFF button
- 15) Output socket: electric signal output after connection of the cable with adhesive electrodes on channel 1
- 16) Output socket: electric signal output after connection of the cable with adhesive electrodes on channel 2
- 17) Belt Clip
- 18) The battery compartment cover
- 19) Adapter Receptacle

3. GENERAL WARNINGS AND SAFETY

Before you start

Please carefully read and understand the following warnings and cautions to ensure the safe and correct use of this device and to prevent injury.

- Make sure the batteries are installed correctly.
- Connect the cable to the electrode pads and then connect to the unit.
- Attach the electrode pads to the area of pain.
- Do not use the electrode pads if it is scratched or damaged in any way.

Contraindications

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

- 1) If you are in the care of a physician, consult with your physician before using this device;
- 2) If you have had medical or physical treatment for your pain, consult with your physician before using this device;
- 3) If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult with your physician;
- 4) Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device;
- 5) Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
- 6) Do not apply stimulation across your chest because the introduction of electrical current into the chest may

cause rhythm disturbances to your heart, which could be lethal;

- 7) This is class II medical device available only through a prescription from a physician.
- 8) Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- 9) Do not apply stimulation over, or in proximity to, cancerous lesions;
- 10) Do not apply stimulation 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;
- 11) Do not apply stimulation when in the bath or shower;
- 12) Do not apply stimulation while sleeping;
- 13) Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury;
- 14) Do not use the device on children. It has not been evaluated for pediatric use.
- 15) Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals;
- 16) Apply stimulation only to normal, intact, clean, healthy skin.

Precautions

- 1) You may experience skin irritation or hypersensitivity due to the electrode pads;
- 2) If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician;
- 3) If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- 4) Use caution if you have a tendency to bleed internally,

- such as following an injury or fracture;
- 5) Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;
 - 6) Use caution if stimulation is applied over the menstruating;
 - 7) Use caution if stimulation is applied over areas of skin that lack normal sensation.
 - 8) Keep this device out of the reach of children;
 - 9) Use this device only with the electrode pads supplied by the manufacturer or distributor.
 - 10) Please stop using the device and consult your physician if you experience adverse reactions from the device, e.g. skin irritation.

Adverse Reactions

- 1) You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
- 2) You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face;
- 3) You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

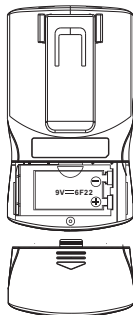
4. INSTRUCTIONS FOR USE

4.1 Battery

4.1.1 Check/Replace the battery

Over time, in order to ensure the functional safety of device, the battery must be periodically changed.

- 1) To remove the battery cover, press and pull down following the direction of the arrow indicated on the battery cover.
- 2) Remove the battery from the compartment
- 3) Insert the 9V HD battery into the battery compartment.
- 4) Ensure you are installing the battery properly. Be sure to match the positive (+) and negative (-) ends of the battery to the marking in the battery compartment of the device.
- 5) Replace the battery compartment cover and press to close.



4.1.2 Disposal of battery

Spent batteries do not belong in household waste. Dispose of the battery according to the current federal, state and local regulations.



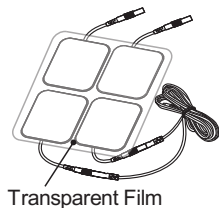
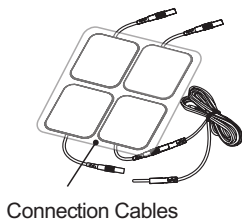
CAUTION:

- 1) **Battery may be fatal if swallowed. Therefore, keep the battery and the product out of the range of children, if a battery was swallowed, consult a physician immediately.**
- 2) **If a battery has leaked, avoid contact with skin, eyes and mucus membranes. Rinse the affected spots with clear water immediately and contact a physician right away.**

- 3) Battery may not be charged, dismantled, thrown into fire or short-circuited.
- 4) Protect battery from excess heat; Take the battery out of the product if they are spent or in case you no longer use the article. This prevents damage caused by leaking battery.
- 5) Always replace the same type battery.

4.2 Connect electrodes to lead wires

Insert the lead wire connector into electrode connector. Make sure there are no bare metal of the pins exposed.

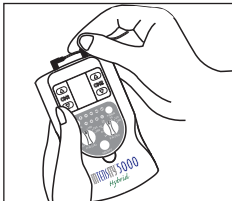


CAUTION:

Always use the electrodes with CE mark, or which are legally marketed in the US under 510(K) listing.

4.3 Connect lead wires to device

- 1) Before proceeding to this step, be sure the device is completely turned OFF.
- 2) Insert the wires provided with the system into the jack sockets located on top of the device.
- 3) 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.
- 4) This device has two output receptacles controlled by Channel 1 and Channel 2 at the top of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.



CAUTION:

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

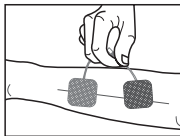
4.4 Electrode

4.4.1 Electrode options

The electrodes are disposable and should be routinely replaced when they start to lose their adhesive nature. If you are unsure of your electrodes adhesive properties, order replacement electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Follow application procedures outlined in electrode packing, to maintain optimal stimulation and to prevent skin irritation.

4.4.2 Place electrode pads on skin

Apply electrodes to the exact site indicated by your physician or therapist. Before applying electrodes, be sure the skin surface over which electrodes are placed is thoroughly clean and dry. Make sure the electrodes are pressed firmly to the skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly, and evenly.



CAUTION:

- 1) Before applying the electrode pads to the body, ensure the skin surface is clean and free from lotions or moisturizers.**
- 2) Do not switch the device on when self-adhesive electrode pads are not positioned on the body.**
- 3) Never remove the pads from the skin while the device is still switched on.**
- 4) For hygiene reasons we recommend that the electrode pads are replaced every 30 days.**
- 5) Please make sure the device is completely turned off before connecting.**
- 6) It is recommended that, at minimum, 1.5" x 1.5" self-adhering based, square electrodes are used at the treatment area**

4.4.3 Electrode placement

The placement of electrodes can be one of the most important parameters in achieving success with therapy. Of utmost importance is the willingness of the physician 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, speak to your physician about alternative stimulation settings and/or electrode placements. Once an acceptable location has been achieved, mark down the electrode sites and the device settings, so the patient can easily continue treatment.

4.5 Turn the device on

In order to turn on the device, press [ON/OFF] button, mode LED indicator and timer LED indicator will light up.

4.6 Select the therapy mode

The InTNSity 5000 supplies 5 therapeutic modes for you to select. Press the [MODE] button, the appropriate mode LED indicator will be light. Press [MODE] button to select the therapy mode circularly.

There are 5 therapeutic modes available: B (Burst), N (Normal), M1 (Pulse width modulation), M2 (Pulse rate modulation), SD (Strength Duration).

4.7 Adjust the pulse width and pulse rate

By turning the [P. W.] knob clockwise to select pulse width, the pulse width is adjustable from 30 μ s to 260 μ s.

By turning the [P. R.] knob clockwise to select pulse rate, the pulse rate is adjustable from 2 Hz to 150 Hz.

4.8 Select therapy time

There are 4 therapy time (15, 30, 60, C) for you to select. Press the [TIMER] button, the appropriate time LED indicator will be light. Press [MODE] button cycle to select the therapy time.

4.9 Adjust Channel intensity

Press the intensity control button [▲] and [▼] to control the intensity output and you will hear a “beep” sound. Slowly press the intensity button control until you reach the setting recommended by your physician or therapist. Repeat for the other channel, if both channels are used.

CAUTION:

- 1) The maximum output intensity level is 10.**
- 2) The therapy mode and therapy time LED indicator will flash in this state.**

4.10 Safety Lock Feature

The Safety Lock Feature automatically activates after there is no operation in the panel for 20 seconds by locking out the ability to press the buttons (except the pulse width and pulse rate knobs). This is a safety feature to prevent accidental changes to your settings and to prevent accidental increases to the intensity levels. After the device locked, you will hear three “beep” sounds when you press other buttons (except the [▼] button of channel 1). Press the [▼] button of channel 1 to unlock the device and you will hear a “DI” sound.

4.11 Turn the device off

Press the [ON/OFF] button to turn off the device.

5. SPECIFICATION

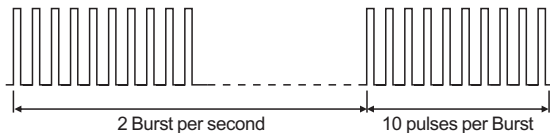
5.1 Technical information

	Mechanism	Technical description
01	Channel	Dual, isolated between channels
02	Power Supply	One 9 Volt Battery
03	Pulse Amplitude	Adjustable, 0-80 mA peak into 500 ohm load each channel
04	Pulse Rate	Adjustable, from 2 to 150 Hz Burst rate: 0.5Hz (Burst mode)
05	Pulse Width	Adjustable, from 30 to 260 microseconds
06	Voltage	0 to 40 V (Load : 500 ohm)
07	Wave Form	Mono-phase square pulse wave
08	Size	11.7cm(L) x 6.6cm(W) x 28.5cm(H)
09	Weight	94 g (without battery)
10	Timer	15, 30, 60 minutes or Continue
11	Burst (B)	Bursts occur twice very second. Pulse width (adjustable), pulse rate = 100 Hz, Burst rate = 0.5Hz
12	Normal Mode (N)	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
13	Modulation 1 mode (M1)	Modulation 1 mode is a pulse width modulation. The pulse width is automatically varied in a cycle pattern over an interval of nominally 10 Seconds. Pulse width increase over a period of 5 seconds from 30 us to the control setting value, then decreases over a 5 seconds period to its original value (30 us). The cycle is then repeated.

14	Modulation 2 mode (M2)	Modulation 2 mode is a pulse rate modulation. The pulse rate is automatically varied in a cycle pattern over an interval of nominally 10 Seconds. Pulse rate decreases over a period of 5 seconds from the control setting value to a value which is 40% less, then increase over a 5 seconds period to its original value. The cycle is then repeated.
15	SD mode (SD)	The SD (Strength-Duration) mode consists of automatic modulation intensity and pulse width in 70% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 70% while the pulse width is increased by 70% in 5 seconds. In the next 5 seconds, the intensity is increased by 70% while the pulse width is decreased by 70%. Total cycle time is 10 seconds. Pulse rate (2~150Hz) and pulse width (30 ~ 260 μ S) are fully adjustable.

5.2 The waveforms of the stimulation programs

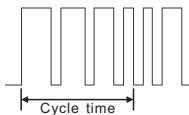
Burst(B)



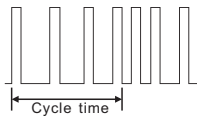
Normal (N)



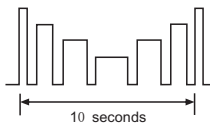
Pulse Width Modulation



Pulse Rate Modulation



SD (Strength-Duration)



6. PROGRAM

Mode	Program	Modulation Method	Frequency	Pulse Width	Treatment time
TENS	B	Burst	100Hz Burst:0.5Hz	30-260us	15,30,60min,continuous
	N	Continuous	2-150Hz	30-260us	15,30,60min,continuous
	M1	Pulse width modulation	2-150Hz	30-260us	15,30,60min,continuous
	M2	Pulse rate modulation	2-150Hz	30-260us	15,30,60min,continuous
	SD	Strength-Duration	2-150Hz	30-260us	15,30,60min,continuous

7. CLEANING AND CARE

7.1 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 center 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.

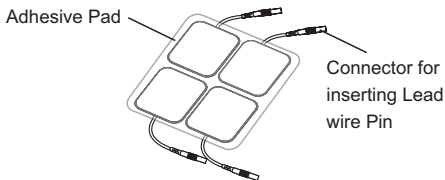
- 6) When removing electrodes, always remove by pulling in the direction of hair growth.
- 7) It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
- 8) Never apply electrodes over irritated or broken skin.

7.2 Cleaning the device

- 1) Remove the battery from the device every time when you clean the device.
- 2) Clean the device after use with a soft, slight moistened cloth. In case of more extreme soiling you can also moisten the cloth with mild soapy water.
- 3) Do not use any chemical cleaners or abrasive agents for cleaning.

7.3 Electrodes

- 1) Use the device only with the leads and electrodes provided by the manufacturer. Use only the electrode placements and stimulation settings prescribed by your physician or therapist.
- 2) It is recommended that, at minimum, 40mm x 40mm self-adhering electrodes should be used at the treatment area.
- 3) Inspect your electrodes before every use. Replace electrodes as needed. Reusable electrodes may cause slight skin irritation, lose adhesion properties and deliver less stimulation if overused.



Reusable, Self-adhering electrodes

To use these electrodes

- 1) Attach the electrode to the lead wire.
- 2) Remove the protective backing from the electrode surface. Do not throw away the protective backing because it is reused after the treatment session has been completed.
- 3) Place the tacky surface to the prescribed skin area by pressing the electrode firmly against the skin.

To remove your electrodes

- 1) Lift the corner of the electrode and gently remove it from the skin.
- 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.
- 3) Between uses, store the electrodes in the resealed bag in a cool dry place.

CAUTION:

- 1) **Do not pull on the electrode wire. Doing so may damage the wire and electrode.**
- 2) **Do not apply to broken skin.**
- 3) **The electrodes should be discarded when they are no longer adhering.**
- 4) **The electrodes are intended for single patient use only.**
- 5) **If irritation occurs, discontinue use and consult your clinician.**
- 6) **Read the instructions for use of self-adhesive electrodes before application.**
- 7) **Always use the electrodes with CE mark, or are legally marketed in the US under 510(K) procedure.**

7.4 Cleaning the Electrodes cords

Clean the electrode cords by wiping them with damp cloth. Coating them lightly with talcum powder will reduce tangles and prolong the life.

7.5 Maintenance

- 1) Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- 2) The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
- 4) Check the unit before each use for signs of wear and/or damage. Replace worn items as required.

8. TROUBLESHOOTING

Problem	Possible Cause	Solution
LED indicator fail to light up	Battery contact failure	1. Try fresh batteries.
		2. Ensure batteries are inserted correctly. Check the following contacts: • All contacts are in place. • All contacts are not broken.
Stimulation weak or cannot feel any stimulation	Electrodes 1. Dried out or contaminated 2. Placement	Replace and re-connect
	Lead wires Old/worn/damaged	Replace
Stimulation is uncomfortable	Intensity is too high	Decrease intensity.
	Electrodes are too close together	Reposition the electrodes.
	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 16.0cm ² (4cm*4cm).
	Mayn't operate the device according to the manual.	Please check the manual before use.
Intermittent output	Lead wires	1. Verify connection is secure. Insure firmly.
		2. Turn down the intensity. Rotate lead wires in socket 90°. If still intermittent, replace lead wire.
		3. If still intermittent after replacing lead wire, a component may have failed. Call the repair department.

		4. Some programs will seem intermittent. This is expected.
Stimulation is ineffective.	Improper electrode and applicator placement Unknown	Reposition electrode and applicator Contact clinician.
The skin becomes red and/or you feel a stabbing pain	Use the electrodes on the same site every time.	Re-position the electrodes. If at any time you feel pain or discomfort stop use immediately.
	The electrodes aren't stuck onto the skin properly.	Ensure the electrode is stuck securely on the skin.
	The electrodes are dirty.	Clean the electrode pads with a damp, lint free cloth or replace new electrode pads.
	The surface of the electrode was scratched.	Replace new electrode.
Output current stops during therapy	The electrode pads come off the skin.	Turn off the device and stick the electrode pad firmly to the skin.
	The cable is disconnected	Turn off the device and connect the cable
	The power of the batteries has been exhausted.	Please replace them with new batteries.

9. MAINTENANCE AND CAUTIONS

- 1) Do not immerse device in water or any liquid. Do not drop the device or throw it from a height.
- 2) After using the device, please remove the output plug from the output socket and re-attach the electrode pads to the protective transparent film.
- 3) Always use the protective film when the pads are not in use.
- 4) Do not twist or pull the output cable.
- 5) Do not use any chemical to clean the main unit or the electrodes. If you need to clean them, please wipe with a damp, lint free cloth.
- 6) Do not let the pad dry out or expose to sunlight.
- 7) Keep the electrode pad clean.

10. STORAGE

- 1) Remove the batteries from the unit if you are not going to use it for a long period of time.
- 2) Leaking batteries can damage the unit.
- 3) Do not make any sharp kinks in the connecting leads or electrodes.
- 4) After use, stick the electrode pad onto the protective plastic film.
- 5) Do not expose the device to direct sunlight and protect it against dirt and moisture.
- 6) Store the device in a cool, well- ventilated place.
- 7) Never place any heavy objects on the device.

11. DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly. Please dispose of the device in accordance with the legal obligation.



12. GLOSSARY OF SYMBOLS

	Batch code
	Serial number
	Attention: Read the operating instruction before use!
	Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.
	Type BF Applied Part

13. WARRANTY

This product is guaranteed for a period of one year from the date of purchase against mechanical and electrical manufacturing defects. There are no user serviceable parts inside the instrument. Any attempted repair by unauthorized persons invalidates the warranty. This does not affect your statutory rights.



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