

INTENSITY™ 5000

Hybrid

INSTRUCTION MANUAL



This manual is valid for the
InTENSity™ 5000 Hybrid TENS Stimulator

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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

Roscoe Medical, Inc. declares that the device complies with following normative documents:

**IEC60601-1, IEC60601-1-2, I EC60601-2-10, IEC60601-1-4,
ISO10993-5, ISO10993-10, ISO10993-1**

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1. SAFETY INFORMATION

1.1 General

The InTENSity™ 5000 Hybrid 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 Hybrid 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 shows the exact mode, time and intensity. Values of parameters are very convenient and easy to adjust according to the needs of the individual patient.

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.

Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until the 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 WORKS

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 patient, 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 wish to discuss this method of pain management treatment with your physician or therapist.

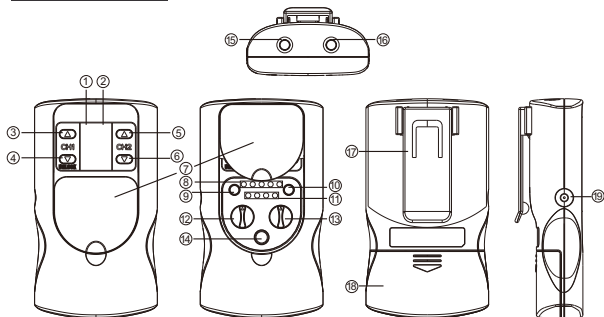
2. PARTS

About the InTENSity™ 5000 Hybrid

Your InTENSity Hybrid contains:

NO.	DESCRIPTION	QUANTITY
A	InTENSity™ 5000 Hybrid unit	1 PCS
B	Electrode pads	4 PCS
C	Cable	2 PCS
D	User Manual	1 PCS
E	9 V 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. Increases the output intensity of channel 1
4. Decreases the output intensity of channel 1
5. Increases the output intensity of channel 2
6. Decreases 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 and adjust the pulse width
13. Use to set and 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. Battery compartment cover
19. AC Adapter connection point

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 any of them are 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 under the care of a physician, consult with your physician before using this device.
2. If you have had any 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 your physician.
4. Do not apply stimulation over painful areas. 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 your 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 fatal.
7. This is a class II medical device and available only through a prescription from a physician.

8. Do not apply stimulation over, or in proximity to, cancerous lesions.
9. 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).
10. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), as they 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 for 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 this device, because stimulation may disrupt the healing process.
6. Use caution if stimulation is applied over the menstruating abdomen.
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 electrode pads supplied by the manufacturer or distributor.
10. Please stop using the device and consult your physician if you

experience any adverse reactions from this device, e.g. skin irritation.

Adverse Reactions

1. You may experience skin irritation and burns beneath 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 immediately and consult with your physician if you experience any adverse reactions.

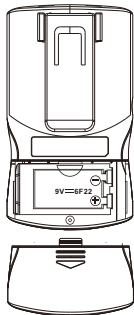
4. INSTRUCTIONS FOR USE

4.1 Battery

4.1.1 Check/Replace the battery

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

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

Dispose of used batteries according to the current federal, state and local regulations. As a consumer, you are obligated by law to discard spent batteries appropriately.

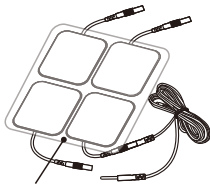


CAUTION:

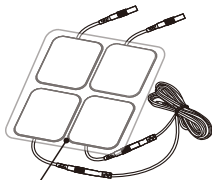
1. Swallowing a battery may be fatal. Keep the battery and the device out of the reach of children. If a battery is swallowed, consult a physician immediately.
2. If a battery has leaked, avoid contact with skin, eyes and mucus membranes. Rinse the affected areas with clear water immediately and contact a physician immediately.
3. Battery should not be charged, dismantled, thrown into fire or short-circuited.
4. Protect battery from excess heat.
5. Remove batteries from the unit if they are spent or if you are not using the unit for prolonged periods of time. This prevents damage caused by leaking battery.
6. Always replace with the same type battery.

4.2 Connect Electrode to Lead Wires

Insert the lead wire connector into electrode connector (standard 0.08 inch female connection). Make sure the connectors are completely pushed together showing no exposed metal of the pins.



Connection Cables



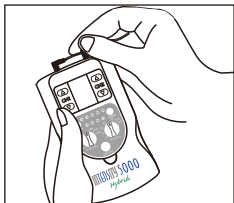
Transparent Film

CAUTION:

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

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

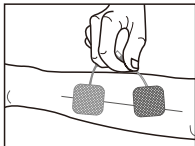
4.4.1 Electrode Options

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

4.4.2 Place Electrodes 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 cleaned 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 self-adhesive electrodes, it is recommended that you wash, degrease and dry the skin first.**
2. **Do not turn on the device when the self-adhesive electrodes are not positioned on the body.**
3. **Never remove the self-adhesive electrodes from the skin while the device is turned on. You will feel an uncomfortable electrical shock.**
4. **It is recommended that, at a minimum, 1.5" x 1.5" self-adhering, 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 this 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 on their own.

4.5 Turning On the Device

Before using the device for the first time, you are strongly advised to take careful note of the contraindications and safety measures detailed at the beginning of this manual (Safety information), as this powerful equipment is neither a toy nor a gadget!

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 therapeutic part program

InTENSity™ 5000 Hybrid supplies 5 therapeutic modes for you to select from. Press MODE button, the appropriate mode LED indicator will illuminate. 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). Stimulator with 10 pre-set programs, for details on how to program please refer to Section 5 "Programs". The therapeutic body part program can be selected by pressing the [S] button control.

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.

4.7 Select therapy time

There are 4 therapy times (15, 30, 60, C) for you to select. Press the [TIMER] button, the appropriate time LED indicator will be lit. Press [TIMER] 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 20.**
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 locks, 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 “D1” sound.

4.11 Turn the device off

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

5. PECIFICATIONS

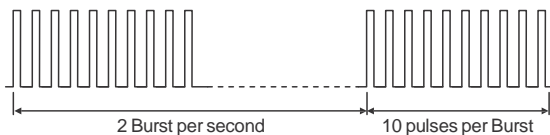
5.1 Technical information

	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.

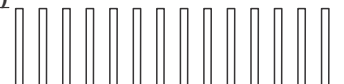
14	Modulation 2 mode (M2)	<p>Modulation 2 mode is a pulse rate modulation. The pulse rate is automatically varied in a cycle pattern over an interval of nominally 10 seconds. Pulse rate decreases over a period of 5 seconds from the control setting value to a value which is 40% less, then increase over a 5 seconds period to its original value. The cycle is then repeated.</p>
15	SD mode (SD)	<p>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 ~ 260μS) are fully adjustable.</p>

5.2 The waveforms of the stimulation programs

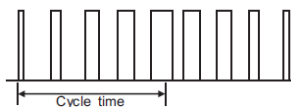
Burst(B)



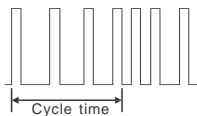
Normal (N)



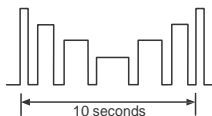
Pulse Width Modulation



Pulse Rate Modulation



SD (Strength-Duration)



6. PROGRAM

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

7. CLEANING AND CARE

7.1 Tips for Skin Care

Follow these suggestions to avoid skin irritation, especially if you have sensitive skin:

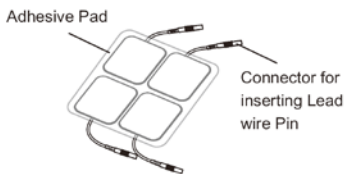
1. Wash the area of skin you will be placing the electrodes on with soap. Rinse thoroughly and dry the area completely before and after placing electrodes.
2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. 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 during treatment down time when you are not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

7.2 Cleaning the Device

1. Remove the battery from the device before you clean the device.
2. Clean the device after use with a soft, slightly moistened cloth. For hard to clean situations, 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 this 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, at minimum, 1.5" x 1.5" self-adhering electrodes be used at the treatment area.
3. Inspect your electrodes before every use. Replace electrodes as needed. Reusable electrodes can 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 can be 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 electrode application by spreading a few drops of cold water over the adhesive side and turn the surface up to air dry. Over saturation with water will reduce the adhesive properties.
3. Between uses, place the electrodes back onto the protective sleeve and insert them into the re-sealable bag and store 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 to the skin.**
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 the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10 and IEC/EN60601-1-2, such as with CE mark, or are legally marketed in the U.S. under 510(K) procedures.**

7.4 Cleaning the Electrode's Cords

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

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong.

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: <ul style="list-style-type: none"> • 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 ($4\text{cm} \times 4\text{cm}$).
	Mayn't operate the device according to the manual.	Please check the manual before use.
Intermittent output	Lead wires	1. Verify connection is secure. Ensure 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.

Should none of these measures correct the problem, the device should be serviced.

9. MAINTENANCE AND CAUTIONS

1. Do not immerse the device in water or any liquid. Do not drop or throw the device.
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 it to sunlight.
7. Keep the electrode pads clean.

10. STORAGE








1. Remove the batteries from the unit if you are not going to use it for a prolong period of time.
2. Leaking batteries can damage the unit.
3. Do not kink 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 a toxic waste collection point or through an electrical retailer. Please dispose of the device in accordance with the laws in your area..



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
	Type of protection against electric shock: Class II Equipment
	Refer to Instruction Manual

13. WARRANTY

Please contact your dealer in case of a claim under the warranty. If you have to send the unit back to your provider, enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1. The warranty period for device is one year from date of purchase. This product is guaranteed for a period of one year from the date of purchase against mechanical and electrical manufacturing defects. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. There are no user serviceable parts inside the instrument. Any attempted to repair by an unauthorized person(s) invalidates the warranty. This does not affect your statutory rights.
3. The following is excluded under the warranty:
 - All damage which has arisen due to improper treatment, e.g. non-observance of the user instruction.
 - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
 - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the retailer.
 - Accessories which are subject to normal wear and tear.



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