



Livia

USER'S MANUAL

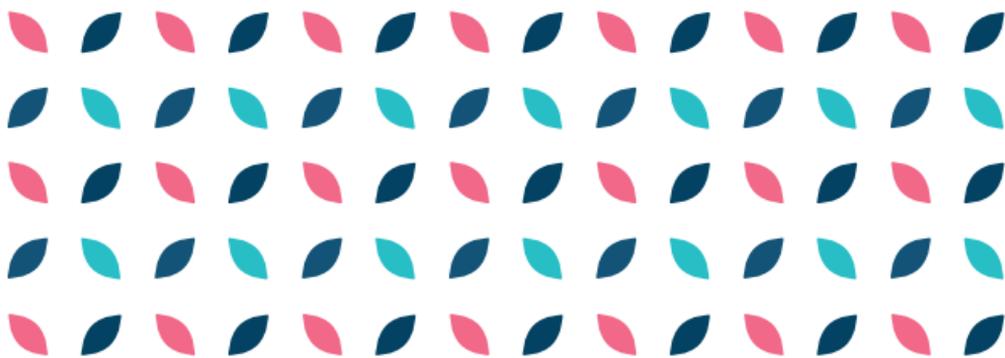


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CONVENTIONS AND GRAPHICAL SYMBOLS



Warnings indicate precautions and instructions which, if not followed, may result in personal injury or even death.



Cautions indicate instructions which, if not followed, may result in damage to the equipment or to the quality of treatment.



Notes provide information to aid in achieving optimal equipment performance.

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1. INTRODUCTION

1.1. INTENDED USE AND INDICATIONS FOR USE

Livia is designed to relieve menstrual pain and discomfort.

1.2. INTENDED USERS

Livia should be used only by women aged 16 and above.

1.3. PRINCIPAL OF OPERATION

Livia is a TENS (Transcutaneous Electrical Nerve Stimulator) device, which works as a pain treatment system through electrotherapy. The unit sends light electrical pulses into the body through the skin via electrodes which are placed over peripheral nerves. The TENS unit works by sending high-frequency electrical signals that are both continuous and mild to block out the pain signals being delivered to the brain. The Livia device was designed with specific pulse frequency and pulse length that are suitable for its intended use. When these pain signals are halted, pain is not felt by the reactive area and the patient gets relief. Low frequency bursts of mild electrotherapy also help activate the natural pain control response, releasing beta endorphins that ease the pain felt by the patient.

1.4. CONTRAINDICATIONS

TENS devices may affect the operation of a cardiac pacemaker and should therefore not be used by cardiac patients with cardiac pacemakers, implanted defibrillators, or other implanted metallic or electronic devices. Such use could cause electric shock, burns, electrical interference, or death.

1.5. ADVERSE REACTIONS

- Use of the device may cause irritation to the skin beneath the electrodes.
- Burns beneath the electrodes have also been reported in the literature.
- Application of electrodes near the thorax may increase the risk of

cardiac fibrillation.

- Allergic reactions to the tape or gel adhesive may be possible.
- Long-term stimulation of the same area may cause skin irritation.
- Users may experience headaches or other painful sensations during or following the application of electrical stimulation near the eyes or on the head and face.

2. WARNINGS

- Do not place electrodes over the neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- Do not place electrodes across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart which could be lethal.
- Do not place electrodes over open wounds, rashes, or over swollen, red, infected or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, and varicose veins).
- Do not place electrodes over, or in proximity to, cancerous lesions.
- Electrodes should be applied only to normal, intact, clean and healthy skin.
- The size, shape and type of electrodes may affect the safety and effectiveness of electrical stimulation.
- The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation.
- Using electrodes that are too small or incorrectly applied could result in discomfort or burning of the skin.
- For pre-gelled electrodes and other electrodes that cannot be fully cleaned or decontaminated between uses, we recommend that users not share electrodes with other persons because of the risks of adverse skin reactions and disease transmission.
- As Livia is a TENS device, it is intended for symptomatic treatment and has no curative effect.
- Electronic devices (such as an ECG and others) may not operate properly when TENS stimulation is in progress. CAUTION: Turn Livia off before applying or removing the electrodes.
- TENS is not recommended for patients with heart disease who have

not received a medical evaluation of possible adverse effects.

- TENS should not be used to alleviate an undiagnosed pain syndrome until the etiology has been well established.
- Livia should not be used for ovulation pain (mid-cycle pain).
- Livia should not be used while fertility problems are being evaluated, diagnosed, or treated.
- Livia should not be used during pregnancy, labor or breastfeeding.
- Batteries are rechargeable; batteries should not be replaced by unauthorized personnel.
- To avoid cross-contamination, electrodes are intended to be used by one person only.
- To avoid potential contamination, use the electrodes only on intact skin for no longer than 10 hours at a time.
- Keep Livia dry. Do not expose the device to a wet environment.

3. CAUTIONS

- Use caution while using Livia in tandem with any monitoring equipment with body-worn electrode pads. Livia may interfere with the signals being monitored.
- Strong electromagnetic fields may affect the correct operation of this device. If unusual phenomena are observed, move away from electromagnetic fields.
- Use caution following recent surgical procedures. Electrical stimulation may disrupt the healing process.
- The long-term effects of cutaneous electrodes for electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation electrodes should not be placed on opposite sides of the head.
- Keep electrodes out of the reach of children.
- Use caution if electrodes are applied over areas of skin that lack normal sensation.
- Replace self-adhesive electrodes if they no longer stick firmly to the skin.

Do not place electrodes:

- On broken skin.
- On skin which does not have normal sensation. If the skin is numb, too great a strength may be used in the Livia and this could result in skin inflammation.
- On the front of the neck. Doing so could cause the airway to close, affecting breathing, or causing a sudden drop in blood pressure (vasovagal response).
- Over the eyes. Doing so may affect eyesight or cause headaches.
- Across the front of the head. The effect on patients who have had strokes or seizures is unknown. The effects of stimulation of the brain are unknown.
- Over, or in proximity to, cancerous lesions.

Do not:

- Ignore any allergic reaction to the electrodes. If skin irritation develops, stop using the device and try a different type of electrode.
- Immerse your device unit in water or place it close to excessive heat – this may cause the device to cease operating correctly.
- Attempt to open up the device – there are no serviceable components.
- Use this device with electrodes other than those recommended by the manufacturer – performance may be compromised.

4. ADDITIONAL BENEFITS

- Livia relieves menstrual pain and discomfort.
- Livia increases feelings of well-being.
- Livia allows you to carry out your routine activities.
- Livia is easy to apply and to use.
- Livia is a compact, pocket-sized device that you can carry in your handbag when not in use and wear comfortably under your clothes when needed.
- Simply attach Livia to the area of your body where you go the most pain, switch it on to the desired amplitude and then go about your normal routine. You customize your level of treatment.
- Livia is not a medication and is non-invasive. It is the closest thing to a natural treatment for menstrual pain.

Note

- Use only as directed, and consult your doctor if pain or symptoms persist.
- Livia is a non-invasive treatment, and should be used only on uninjured skin.
- Livia is not a medication.

5. PACKAGE CONTENTS

Your Livia set contains:

- Livia device
- Electrode set +30 cm wire, ready to use
- Extra gel pads (replacement to those used in the Electrodes set)
- User manual
- Livia case
- USB charging cable, 50 cm

6. USING LIVIA

Livia is as simple to use as it is comforting.

Follow these easy steps to get started:

- Prior to first use, charge the Livia device for approximately 12 hours.
- Apply the electrodes to your skin.
- Connect the electrodes to Livia by plugging in the connector.
- Turn on Livia and adjust the level to your comfort.

6.1. ELECTRODE PLACEMENT

- The kit contains two multiple-use biocompatible gel electrodes. One side of each electrode is coated in white polymer and the other side has a sticky, adhesive gel. Remove the cover paper and place the sticky side of the electrode on your skin.
- The electrode should be placed on the area of your body where you have the most pain. Place the electrodes in such a way that one is located as close as possible to the center of your body and the

other, as far to the side as possible, while making sure that both of them are within your “field of pain.”

⚠ Caution

Use only the electrodes supplied with the device or supplied by an authorized Livia distributor.

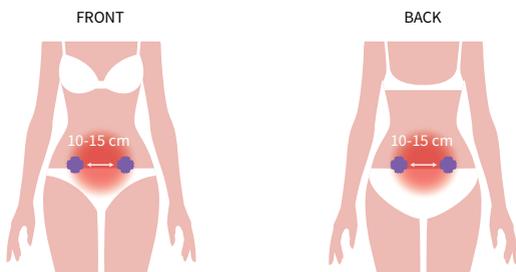


Figure 1: Electrode Positions

- Place the electrodes within this “field” at a distance of 10-15 cm apart from each other. Greater distances between the electrodes are not recommended; smaller distances are possible.
- Your skin does not have to be cleansed or treated in any special way. Make sure that good contact has been made over the entire adhesive surface of the electrode; properly placed electrodes should be attached to the skin, leaving no gaps, folds or air bubbles.
- Once placed properly, the electrodes should affix to your skin, remaining in place even when you move around freely.
- There is no need to remove the electrodes between treatment sessions, not even when you unplug the Livia unit. However, it is recommended that you change their placement, once in 24 hours, to avoid skin irritation. To remove the electrodes when your treatment is over, gently lift one of the edges and peel off toward the opposite side. The electrode will be detached quickly and painlessly.
- The same electrodes can be used several times (about 15 uses). At the end of your period, when you store the unit until its next use, we suggest that you cover the gelled (sticky) sides of the electrodes with their original cover and place them with Livia in their package in order to assist Livia efficacy over time.

📄 Note

The electrodes have been tested for bio-compatibility. In case of any allergic reaction, please seek medical attention.

6.2. Turning on Livia and Adjusting the Strength

- In the center of the front panel of Livia is a power button, which is easily operated by a light touch of the finger.
- Press “+” to increase the strength of the treatment; press “-” to reduce it.
- Hold Livia in one hand and, with the other, press the power button once. Gently press the “+” button several times until you feel a mild tickling sensation in the area between the two electrodes.



Figure 2: Livia operating buttons and LEDs

- If the sensation is pleasant, leave the setting as it is. Clip Livia on your clothing and go about your business as usual. If, on the other hand, the feeling is unpleasant, press the “-” button a few times until the sensation becomes pleasant and leave the setting as is. Livia is still working and treating you, even though you might not feel anything at this point.
- Whenever you turn the unit off, Livia automatically returns to its lowest operational level. In other words, each time your Livia device is turned on it will always start at the lowest strength setting – regardless of the level it was set to when you terminated the last session.
- Above the power switch, there is a set of green LEDs that blink whenever you increase or decrease the strength of the treatment (when you press the “+” or the “-” button.) A flashing red light will appear when the battery is low.
- Increasing the strength beyond the level of a tickle may cause muscle twitching and/or contractions. This is completely normal. To decrease the strength of Livia, press the “-” button a few times until the twitching contractions cease. Leave Livia to work at that level of stimulation.
- Once you turn Livia on, you’ll quickly feel the difference. Your pain will start to diminish approximately 10 minutes after beginning the treatment, and will be completely alleviated within 15 minutes of Livia application.

6.3. Duration of Livia treatment

- There is no limit to how long you can use Livia when you are experiencing menstrual pain. However, it is worth noting the benefits usually last for some time after your Livia device has been turned off.
- If your treatment session takes 30 minutes or more, you’ll have to keep adjusting the amplitude (the strength of the stimulation) in order to make the treatment effective.
- The more often you use Livia, the quicker you will be able reach the optimal amplitude and time for your particular needs.
- It is recommended not to leave the electrodes on the body for more than 10 hours.

7. CHARGING LIVIA

To charge your Livia device, use a phone or tablet charger, or the USB port of a computer. Once connected to a power source the charging process will begin. While Livia is being charged, the LED lights will flash slowly up and down. Once charging is completed, all LED lights stop flashing and remain steadily lit.

It is recommended to charge the Livia device for approximately 12 hours prior to first use.

⚠ Caution

- Do not charge the device while using it.
- Do not operate the device when electrodes are not connected. Make sure the device is off before removing or connecting the electrodes.

8. SPECIFICATIONS

Dimensions:	55 mm X 55 mm X 20 mm
Weight:	37 gr
Channel and Wave Form:	1 channel, Symmetric-Rectangular-Biphasic
Current Output:	0-60 mA into 1K ohms
Pulse Width:	100 micro sec., preset
Pulse Rate:	100 pps, preset
Amplitude Output Voltage:	0-60 mA into 1K ohms load, adjustable
Power Source:	3.7V Li-Ion rechargeable battery 380 mAh
Battery Life:	Approximately 3 years
Operation Environmental Conditions:	Temperature range: 5°C to +40°C Relative humidity range: 15% - 93%, non-condensing Ambient pressure range: 700 hPa to 1060 hPa
Transport and Storage Environmental Conditions:	Temperature range: -25°C to +70°C Relative humidity range: 15% - 93%, non-condensing

9. SYSTEM CONTROLS

 Minus button
Intensity reduction

 Plus button
Intensity increase

 Power button
Push button on/off

 LEDs

10. TROUBLESHOOTING

Problem	Probable Cause	Action
No indication lights.	Flat batteries.	Recharge battery.
Blinking red light when trying to turn Livia on.	Low batteries.	Recharge battery.
No sensation.	Incorrect connection.	<ol style="list-style-type: none"> 1. Make sure the wires are connected and are not damaged. 2. Verify that Livia is turned on. 3. Make sure both electrodes are attached to your body.
Sensation is too weak.	Setting is too low.	Press the "+" button to increase the setting.
Sensation is too strong.	Setting is too high.	Press the "-" button to decrease the setting.
Weak sensation, even on high setting.	Gel pads have been over-used, or are dry.	Replace gel pads.

For any unresolved issue please contact:

Manufacturer

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11. LABELS & SYMBOLS

The following table describes the symbols that appear on the system, its components, and packaging.

Symbol	Meaning
	Serial number
	Reference number
	Date of manufacture
	Manufacturer
	Refer to instruction manual/booklet.
	The system cannot be disposed of as unsorted municipal waste. Please contact your local distributor for unit disposal. Dispose of product at the end of its useful life according to local regulations.
	CE Mark
	Authorized representative in the European community.
	BF-type applied part.

12. CARE, CLEANING AND MAINTENANCE

12.1. System Lifespan

The system has an expected lifespan of approximately five years. At the end of its useful life, the device should be discarded according to local law for disposal of electrical and electronic devices.

12.2. Maintenance

The system should be serviced by the manufacturer only.



Note

The Livia battery is not replaceable. Do not attempt to replace the battery.

12.3. Cleaning of the External Parts of the System

- Use gloves when cleaning the system. Use an approved disinfectant wipe for medical use: one that is effective against viruses, bacteria spores, bacteria and fungi.
- Wipe all external surfaces of the device control unit and all cables.
- Care should be taken not to clean the cable connectors.
- All areas of the device should be cleansed with disinfectant wipes or equivalent anti-microbiological wipes.

13. SAFETY AND COMPLIANCE STANDARDS

The Livia system meets the safety and compliance standards and requirements listed below.

Standard No	Standard Title
IEC 60601-1:2005/ A1:2012 and EN 60601- 1:2006/A1:2013	Medical electrical equipment – Part 1: General requirements for safety and essential performance 3ed Ed. + AM1
IEC/EN 60601-1-11:2015	Medical electrical equipment – part 1-11 Collateral requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, 2nd Ed.
EN 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-2-10:2012/ A1:2012	Medical electrical equipment – part 2-10 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators, 2nd Ed.
EN 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 62366: 2015	Medical devices – Application of usability engineering to Medical devices
ISO 15223:2012	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 62304:2006 EN 62304:2006/AC: 2008	Medical device software – software life cycle processes
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 980:2008	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements

14. EMC AND ELECTRICAL STANDARDS REQUIREMENTS

Notes

- Livia requires special precautions with regard to electromagnetic compatibility.
- Livia must be installed and prepared for use as described in this manual.
- Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the operation of Livia, thus, the recommended separation distances marked in the table below should be complied with.
- Livia should not be used near or on top of another electronic device. If this cannot be avoided, check the Livia's operation prior to clinical use.
- The use of accessories other than those specified or sold by the manufacturer is not recommended. Replacement parts may increase emissions or decrease the immunity of the unit.

14.1. Electromagnetic Emissions

- Livia is intended for use in the electromagnetic environment specified in the following tables. This is not a life-sustaining device. The user and/or installer of the unit must ensure that Livia is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Livia is intended for use in the electromagnetic environment specified below. Livia users should ensure that it is used accordingly.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions Test: CISPR 11	Group 1	Livia 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	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

14.2. Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Livia is intended for use in the electromagnetic environment specified below. Livia users should ensure that it is used accordingly.			
Immunity Test	IEC 60601-1-2 test level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable Not Applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply lines. IEC 61000-4-11 For Charger only	<5 %UT (>95 %dip in UT)for 0.5 cycle 40 %UT (60 %dip in UT) for 5 cycles<5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Not Applicable Not Applicable Not Applicable Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public, low-voltage power supply network that supplies buildings used for domestic purposes in a commercial, hospital, or clinical environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Livia is intended for use in the electromagnetic environment specified below. Livia users should ensure that it is used accordingly.

Immunity Test	IEC 60601-1-2 test level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150kHz to 80MHz</p> <p>3 V/m 80MHz to 2.5GHz</p>	<p>Not Applicable</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Livia, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.17\sqrt{P}$</p> <p>$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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 meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.</p>			
<p>^aField 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 Livia is used exceeds the applicable RF compliance level above, the Livia device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Livia device.</p>			

14.3. Recommended Separation Distances

Recommended Portable and Mobile RF Communications Equipment and Livia		
<p>The Livia is intended for use in an electromagnetic environment in which radiated radiofrequency (RF) disturbances are controlled. The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (emitters) and the Livia, according to the maximum output power of the equipment, as recommended in the table below.</p>		
	Separation distance according to the frequency of transmitter (m)	
Rated maximum output power of transmitter (W)	80MHz to 800MHz $d = 1.17 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.73
1	1.17	2.3
10	3.7	7.3
100	11.7	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (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.</p> <p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>		

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WARRANTY

Livia is under warranty for two years from the date of purchase. This warranty refers to the unit only. It does not cover the electrode pads, lead wire, silicone skin or gel pads.

Livia's warranty applies only if the unit has been used for its intended purpose, has not been damaged through misuse, accident or neglect, and has not been modified or repaired by anyone other than LifeCare or its authorized agents. In case of a defect, return the unit to LifeCare or its authorized agents with your Proof of Purchase.