# OSKO PULSE

**USER MANUAL** 



# **OSKO**

Technical Support and Customer Service:

Oska, Inc. support@oskawellness.com (+1) 844-630-9932

Contact a local distributor

www.oskawellness.com/pages/contact



#### Manufacturer:

Oska, Inc. DBA Oska Wellness 2725 Jefferson Street, #15A Carlsbad, CA 92008 USA EC REP

#### **European Representative:**

Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands



#### PLEASE READ ALL INSTRUCTIONS BEFORE USE

NOTE: You will need to charge your Oska® Pulse before use. Refer to CHARGING OSKA PULSE (Section 7) in this manual

Contact your local Oska customer care team if:

- If you need assistance in setting up, using, charging, or maintaining Oska® Pulse
- To report any unexpected event or operation to Oska, Inc. or your local distributor

Contact information is available at www.oskawellness.com/pages/contact.

#### SAVE THESE INSTRUCTIONS

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#### 1. INTRODUCTION

Oska Pulse is a wearable, portable, cordless, rechargeable, pre-programmed, and easy-to-use Pulsed Electromagnetic Field (PEMF) device.

Oska Pulse can be worn on or near the target area, under or over clothing. (Note: thick or multiple layers of clothing could obstruct the electromagnetic field). The device emits a PEMF that passes through all tissue types in the body, to work with your body for long-term recovery.

Individual response to therapy and recovery time may vary. Some may begin to feel relief within just two weeks, while for many it takes longer. Repeated and consistent use is required for best results. Those who are compliant with integrating Oska Pulse into their daily life will receive the most profound benefit.

With Oska Pulse you will not feel intense heat, pulsing or tingling. Some may notice a slight warming of the target area due to increased blood flow.

#### 2. INTENDED USE

Oska Pulse is a non-invasive pulsed electromagnetic therapy device intended for relief or reduction of all major types of pain, including back, shoulder, neck, knee, muscle, and joint.

# 3. CONTRAINDICATIONS 500

The Oska Pulse patient population includes adult men and women who do not have any of the following contraindications:

- Do not use if you have a heart pacemaker, defibrillator, or other implanted medical device, unless your doctor has first approved.
- Do not use if you have an implant made from magnetic or metallic materials.
   Ask your doctor first if you are unsure.
- Do not use if you received a corticosteroid injection. Consult your doctor prior to use.
- Do not use if you are pregnant or nursing.
- Do not use if you had cancer or are getting cancer treatment unless you have consulted your doctor and use is approved.
- Do not use if you feel pain but do not know the cause or origin of your pain. Consult your doctor prior to use.
- Do not use if you have a tendency for bleeding following acute injury or breaks in bones.
- Do not use if you or any other, including children, have reduced physical, sensory, or mental capabilities, or lack of experience and knowledge, unless given proper instruction and supervision.

# 4. WARNINGS 🔨

- Do not use Oska Pulse device near medical monitoring equipment (e.g., heart monitors, heart tracing, oxygen saturation devices), which may not operate properly when Oska Pulse is in use.
- Do not place Oska Pulse near operating MRI equipment as it may adversely affect Oska Pulse operation through electromagnetic interference as well as magnetic force.
- Do not use Oska Pulse near products that may have strong magnetic fields, such as microwaves or strong audio speakers. The device may not work properly around these products.
- The AC charging adapter supplied with Oska Pulse is a certified Medical Grade adaptor.
   If using another AC adaptor other than Oska supplied, please ensure a certified adaptor to medical device safety standard (IEC 60601-1) with an output marked Class 2 or meeting limited power source (LPS) requirements, and not to exceed 16V.
- Only use the USB charging cable supplied with Oska Pulse. Using cables not provided by Oska Inc. may damage or burn Oska Pulse device. Contact Oska Customer Service to obtain a replacement.
- Always store Oska Pulse out of reach of children to avoid the risk of choking resulting from a child swallowing or inhaling a small part that has broken off.

- Keep the charging cable and compression wrap out of the reach of children because strangulation could result from entanglement.
- Do not modify or repair the Oska Pulse device. Sharp edges or electrical components may cause injury or electrical shock. Return the device to Oska Inc. for examination if you believe the device is not working properly.
- The Oska Pulse device surface temperature is more than 41°C (105°F) when the device is charging.
- Do not use Oska Pulse while the device is charging or connected to a power source.
- Do not connect Oska Pulse to a high-power source.
- Do not use or discontinue use if the device surface becomes hot.
- Do not use Oska Pulse near heat or fire, such as fireplace, radiant heater, etc.
- Do not throw the device or battery in a fire.
- Do not use Oska Pulse in an oxygen-enriched environment or near oxygen equipment (e.g. oxygen cylinder, oxygen generator or concentrate, etc.).
- Dispose of the device and its battery in compliance with local regulations.
- Keep all electrical appliances (including Oska Pulse, charger, and power supply) away from liquid and water, including baths, showers, toilets, and sinks.
- Do not submerge or drop Oska Pulse in any liquid at any time, including while the device is in use, being charged, or powered off.

- Do not use or charge Oska Pulse if exposed to or submerged in liquid because exposure to liquids may cause irreparable damage to the electronic components.
- Do not use the device or compression strap between users without proper cleaning and disinfection due to risk of contamination, such as contact with body fluids and expired gases, etc. Use Oska Inc.'s recommended method of cleaning and disinfectant or follow your institution's instructions.
- The device is designed for a single user.

#### 5. PRECAUTIONS

- If you suspect that you have a negative reaction from using the electromagnetic field device, discontinue use and consult your doctor immediately.
- If you have recently had or are planning to have any surgery or laser/cosmetic procedure, please consult your doctor before using Oska Pulse.
- Do not apply the wrap too tightly as it may affect blood circulation.
- Do not use soap, cleanser, bleach, or any other cleaning agent not recommended by Oska Inc. that may potentially damage the device.
- Do not store Oska Pulse in direct sunlight or on a hot surface.

- Never store Oska Pulse or any of its parts in an automobile in cold or hot weather.
- If the device begins to generate heat, stop the session, or unplug the device immediately, and place the device in a cool place. Do not directly touch the overheated device.
- The device should be operated, transported, and stored in the manner specified in this
  manual in the SPECIFICATIONS section of this manual.
- Use caution prior to using the device if storing or not using Oska Pulse for long periods.
   Inspect the device and do not use the device if you see any signs of internal battery leaks.
- Always keep the device away from pets to avoid device damage, or risk from exposed wire, small and sharp objects.
- Oska Pulse is approved for air and ground transportation. However, if requested, please hand the device to designated authorities for inspection.
- Do not dispose of as household waste. Contact your local authorities to determine the proper method of disposal of electronic equipment.

#### 6. PACKAGE CONTENTS

Your Oska Pulse kit contains the following items:

- 1 Oska Pulse Device
- 1 Compression Wrap\*
- 1 USB Charging Cable\*
- 1 User Manual (not pictured)



Figure 1: Contents of the Oska Pulse kit.

<sup>\*</sup>May vary based on model of Oska Pulse

#### 7. CHARGING OSKA PULSE

Charging may be required before use. To charge your Oska Pulse, plug the charging cable into the USB port on your computer or an AC charging adapter and plug the other end into the docking port on the end of the Oska Pulse device.

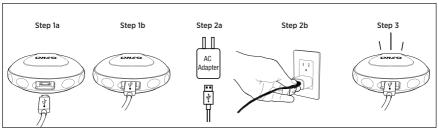


Figure 2: Charging your Oska Pulse



During the charging process, do not position the equipment in such a way that it is difficult to unplug the power supply.



Only use an AC power adapter certified to either UL60950, IEC60950-1, IEC60335-2-29, or IEC60601-1, with an output marked Class 2 or meeting limited power source (LPS) requirements, not to exceed 16V. Contact Oska, Inc. or your local Oska distributor for a replacement.

When the device is connected to a power source, LED lights will illuminate on the opposite end. If the battery is fully depleted then the LEDs may take a few minutes to illuminate. LEDs will remain lit (not pulse) while the device is charging, then go off when charging is complete. The battery may take three (3) or more hours to fully charge. Battery charge time may vary by environmental conditions.

A fully charged battery can provide ten (10) or more 90-minute sessions. Device run time can vary (+/-10%) due to operating conditions.

Battery life may decline following extended use. The battery is estimated to last between 200 and 500 charge cycles, but life may vary. Storing the device uncharged can reduce battery life. The battery is not user replaceable.

#### 8. OPERATING OSKA PULSE

#### POWER ON (

Press and release the button located on top of the device to power on your Oska Pulse. The device will emit a soft beep. LED lights will begin to pulse at the perimeter of the device to indicate PEMF is being emitted. The PEMF session starts as soon as the device is powered on. The device will start a new session each time it is powered on.

Note: Most individuals will not feel the electromagnetic field (PEMF) due to its low frequency range. This is normal and expected. Oska Pulse PEMF therapy is non-invasive.

#### POWER OFF

Oska Pulse is preset to run for 90 minutes without interruption, then automatically turn off when the duration completes. A session can be stopped early by quickly pressing and releasing the power button three (3) times. The device will beep and LED lights will turn off to indicate the device is powered off.

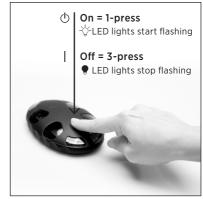


Figure 3: Turn on your Oska Pulse

#### LOW BATTERY

When the battery level is low, the device will beep multiple times while powering on. The extended beep sequence indicates that the device should be charged (see Section 7, CHARGING OSKA PULSE). Oska Pulse will turn off early, before the full 90-minute duration is completed, if a critical low battery level is reached during an active session.

#### **RECOMMENDED USE**

Generally, it is recommended to complete two (2) or more 90-minute sessions each day. Maintain or adjust use according to your body's response. Sessions may be broken up into 1-hour segments. However, consistent daily use is recommended for maximum results.

Appropriate use may vary by specific user condition. Consult your doctor to identify recommended use for your individual condition.



Drink plenty of water to maintain hydration and help your body maximize the benefits.

#### 9. USING A COMPRESSION WRAP



Figure 4: Compression Wrap

A compression wrap is included in the kit package. The wrap is elastic to help secure Oska Pulse on or near the target area.

**Step 1:** Slip the device in the loop located at the end of the wrap, Oska label and top of device positioned upward. Be sure the ends of the device are visible, the device is centered and secure.



**Step 2:** Position the device on or near the target area. Oska Pulse may be worn under or over clothing.

Note: The electromagnetic field extends approximately 11 inches from the device, in all directions. Optimal strength is within 8 inches. The further the distance from the device, the weaker the magnetic field strength.

**Step 3:** Attach the wrap around your limb, torso, or other target area and fasten it with the hook and loop.



The compression wrap contains natural rubber latex which may cause allergic reactions.



Do not apply the wrap too tightly as it may affect blood circulation, especially when used for a prolonged period.



Do not forget that you are wearing Oska Pulse and accidentally expose the device to water, liquid, or unsuitable environmental conditions. Should this occur, do not use, or charge the device. Exposure to liquids may cause irreparable damage to the electronic components.

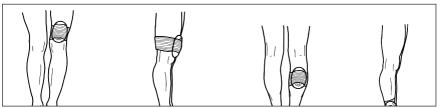


Figure 5: Examples of wearing a compression wrap on shoulder and back.

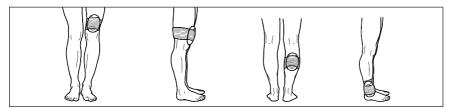


Figure 6: Examples of wearing a compression wrap on knee, calf, ankle, and foot.

#### 10. DEVICE CARE AND MAINTENANCE

- Clean the surface of Oska Pulse and the silicone skin with a slightly damp cloth only.
- We recommend disinfecting the device with 70% isopropyl alcohol dampened cloth or wipe periodically.
- Hand wash the compression wrap using warm water and household laundry detergent.
   Hang or lay flat to air dry.
- Always store Oska Pulse in a cool, dry place. Never keep it where the temperature is less than -10°C (14°F) or greater than 70°C (158°F).
- Never store Oska Pulse or any of its parts in an automobile in cold or hot weather.
- Use caution prior to using the device if storing or not using Oska Pulse for long periods.
   Inspect the device and do not use if you see any signs of internal battery leaks.
- Never store Oska Pulse for prolonged time with the battery charge depleted.
- Do not use or charge Oska Pulse after submerging or dropping it in any liquid because exposure to liquids may cause irreparable damage to the electronic components.
- Do not use soap, cleanser, bleach, or any other cleaning agent that may potentially damage the device.

#### 11. TROUBLESHOOTING

If you encounter any problem in the operation of the device, first turn the device OFF, then back ON again (see Section 8, OPERATING OSKA PULSE). This will allow the e-Tec programming to reboot and reset itself. Next, ensure the device is sufficiently charged (see Section 7, CHARGING OSKA PULSE).

If the problem persists, please contact Oska, Inc. or your local Oska distributor. Oska, Inc. can be reached at support@oskawellness.com or (+1) 844-630-9932. For distributor contact information visit www.oskawellness.com/pages/contact.

#### 12. TECHNICAL DESCRIPTION

Oska Pulse consists of a copper coil which generates a magnetic field. A frequency generator is used to energize the coil to create a pulsed electromagnetic field.

Pulsed Electromagnetic Field can influence the signal transduction pathway, ion binding and ion transport across the human cell membrane. It is capable of increasing Calcium (Ca++) ion transport resulting in tissue repair and regeneration.

### 13. SPECIFICATIONS

Manufacturer	Oska, Inc.
Device Name	Oska Pulse
Model/Variant Name	90-Minute
Model/Variant Part Number	CS011A
Operation Time	90 minutes
Operator	Patient or user
Operating Environment	Home care use
Operating Temperature	10°C (50°F) to 38°C (100°F)
Operating Atmospheric Pressure	700 hPa to 1060 hPA
Operating Humidity	Maximum 95% Relative Humidity, non- condensing
Storage & Transportation Temperature	-10°C (14°F) to 70°C (158°F)
Storage & Transportation Atmospheric Pressure	700 hPa to 1060 hPA
Storage & Transportation Humidity	Maximum 95% Relative Humidity, non- condensing
Protection from Solid Particle and Liquid Ingress	IP22
Weight	2.12 ounces (60 grams)
Dimensions	5.25 inches x 3.50 inches x 1.25 inches (13.3 cm x 8.9 cm x 3.2 cm)
Rechargeable Battery	3.7V Li-lon battery, rechargeable. The battery is not replaceable.
External Power Supply Charger	AC USB power adapter with Micro-USB cable. Adapter certified to either UL60950, IEC60950-1, IEC60335-2-29, or IEC60601-1, with an output marked Class 2 or meeting limited power source (LPS) requirements, not to exceed 16V.
Applied Part	Device surface area contacting treatment area(s).

## 14. SYMBOLS

Symbol	Descriptions
444	Manufacturer
₩	Country and Date of Manufacture
REF	Model Number or Part Number.
SN	Device Serial Number.
UDI	Unique Device Identification (UDI).
MD	Item is a medical device.
CE	European Conformity (CE) mark. Manufacturer declares that the product complies with applicable European regulations.
N	Nemko certified to comply with relevant electrical safety and EMC standards
C (UL) US LUSTED E402246	Electrical safety compliance to UL 1431 and CAN/CSA C22.2 No. 68.
	KC Certification for safety of electronic products in South Korea.
EC REP	Authorized Representative in the European Union
<u>i</u>	Refer to instruction manual/booklet.
H	Additional information available on website.
(1 <b>1</b> )	Medical device may be used multiple times on a single patient.

## 14. SYMBOLS (CONTINUED)

Symbol	Descriptions
$\triangle$	Warning or Caution, operator awareness required to avoid undesirable consequences.
LATEX	Contains natural rubber latex which may cause allergic reactions
IP22	Ingress of liquid and solid particle rank
	Entity importing the medical device into the locale.
À	BF Applied Part
1	Temperature Range
Ø	Humidity Range (non-condensing)
₹	Keep dry and away from moisture.
*	Keep away from direct sunlight and heat.
<u></u>	Atmospheric Pressure Range
夏	Waste of electrical and electronic equipment is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.
RoHS	European Directive 2011/65/EU Restriction of Hazardous Substances

#### 15. WARRANTY INFORMATION

#### MANUFACTURER WARRANTY

The Oska Pulse device is warranted to be free from manufacturer defect in materials and workmanship for a period of one (1) year from the date of purchase, subject to normal use of the device. Accessories are excluded from the manufacturer warranty. Oska Pulse lifetime is typically much longer than one year, depending on the frequency and duration of use.

The warranty period for Oska Pulse devices purchased in Germany (DEU) is two (2) years from date of purchase.

This manufacturer warranty only extends to the original device purchaser so long as purchased directly through Oska, Inc., or an authorized Oska Pulse affiliate, distributor, or retailer. If you believe your product is defective within the warranty period, or malfunctioning, then please contact a local distributor or Oska support representative. A Return Materials Authorization (RMA) is required as approval to initiate the warranty process.

Oska, Inc. reserves the right to determine if a product is defective and eligible for warranty replacement. Also, Oska reserves the right to change the method by which warranty service is provided, and a product's eligibility to receive a particular method of service. Please see the latest warranty policy available at www.oskawellness.com/pages/warranty, or contact Oska, Inc. directly at support@oskawellness.com or (+1) 844-630-9932.