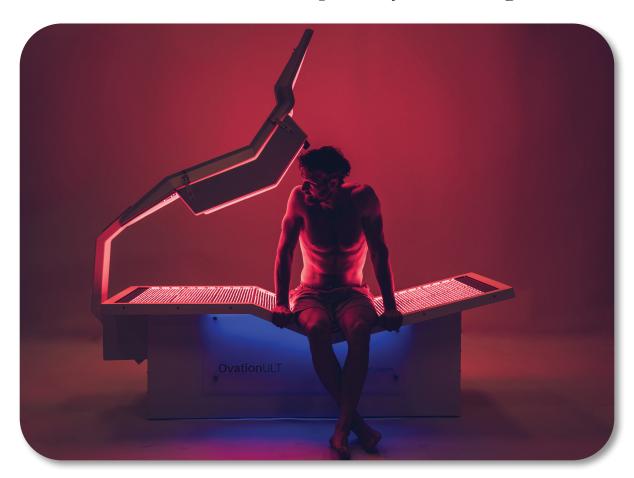


OvationULT

Red Light Therapy Bed with Vibrational Frequency Massage



Important Safeguards

When using electrical devices, basic safety precautions should always be followed, including the following:

Read all instructions within this manual carefully.

- 1. To protect against electrical shock, do not immerse the power cord in any liquid.
- 2. Power off bed when not in use and before cleaning.
- 3. Do not operate this device if the cord or plug is damaged. Notify Body Balance System at wecare@bodybalancesystem.com to coordinate a repair.
- 4. The use of accessory attachments not recommended or sold by Body Balance System may cause injuries.
- 5. Do not use this device outdoors.
- 6. To disconnect, ensure the power button is in the off position, then remove the plug from the surge protector. Grip plug and pull from the surge protector. Never pull on the cord.
- 7. Do not use the OvationULT for any other intended use without prior authorization from a medical professional.

SAVE THESE INSTRUCTIONS

Thank you for purchasing the OvationULT Zero Gravity Red Light Therapy Bed by Body Balance System, the industry's leading manufacturer of LED Red Light Technology.

The OvationULT red light therapy bed potential benefits are temporary relief of: minor muscle pain, minor joint pain, muscle stiffness, minor arthritis pain, muscle spasm, the temporary increase in local blood circulation, and relaxation of muscles. Further the system is Registered with the FDA as a Class II medical device, falls under the product code ILY, and may be used for therapeutic heating. The Body Balance System OvationULT Bed is a 100% non-invasive, LED Red & IR technology with no known side effects.

NO SURGERY | NO PAIN | NO DOWNTIME

Setup Instructions

- 1. Plug the power cord into a surge protector that is plugged into a grounded outlet.
- 2. Power the device on by pressing the "Power" button.
- 3. Press "Massage" button for frequency massage during the session (optional.)
- 4. Have client undress for session prior to entering the bed.
- 5. For comfort, users may want to wear eye protection prior to the lights on the bed being turning on.
- 6. Select desired session time button, there is then a 15-second delay to allow the user to enter the bed.
- 7. Have the client enter the bed, lie back, and relax.
- 8. Have the client pull down on the canopy (but never by the side panels) until the canopy touches the skin. (Note that the system will self-adjust based on the client's size.) Have client place arms outside of side panels.
- 9. When the session has ended the timer will expire and the lights will be turned off. The client may then push up on the canopy and exit.
- 10.To turn LED lights off at any time during a timed session simply push the "Power" button.
- 11. It is recommended in the OvationULT User Manual that the polycarbonate used on the OvationULT is cleaned* after **every use** using the following steps:
 - 1. Spray disinfectant directly onto a soft microfiber cloth.
 - 2. Wipe down all surfaces of the polycarbonate plastic with the cloth and solution.

Note: Disinfectant containing Hydrogen Peroxide or Isopropyl Alcohol are compatible with the polycarbonate sheet.

*Avoid using products containing aldehydes, phenols, hydroxides or amines as the active ingredient. Avoid disinfectants containing bleach or ammoniated chloride.

The polycarbonate is approved for medical use. Approved under ISO 10993-1 and USP VI

Recommended Protocol: 2-3 times per week for 3-4 weeks (10 treatments)

Contraindications:

- Epilepsy
- Pregnancy/Lactating/Breast Feeding
- Liver/Kidney Disorder
- Pacemakers
- Uncontrolled Hypertension
- · Severe Thyroid Gland Dysfunction
- Cancer
- Immunosuppressed
- · Heart Disease/Cardiac Arrhythmias
- Persons suffering from sunburn
- · Persons under medical care for diseases that involve photo sensitivity
- Persons receiving photo sensitizing medications

If your client has any of the above medical issues, or if they have questions about specific health issues, have them seek approval from a medical professional prior to treatment.

If there is any pain or discomfort during the treatment it should be discontinued immediately.

OvationULT Bed 3 Year Warranty

The OvationULT Bed by Body Balance System comes with a three-year warranty. Year one bed is fully covered from all manufacture defects, parts, repairs, and travel expenses for the technician. In years two and three all parts and labor are also covered there is just a fee for the cost of travel expenses to send a service technician to your facility for repairs. In some instances, we may seek out a local repair person in your area and hire them to make repairs for us. All warranty repairs will be conducted promptly to limit any downtime with your system. Because of the sheer number of electronic components on an OvationULT, we will ask you to supply us a picture of any issues if possible so we can determine the issue, if it is possible for us to just ship you a part of the level of urgency for the repair to be made. Bed diodes are good for an average of 40,000 hours which is equivalent to about 8-10 years of use. After this time Body Balance System can send a technician to your facility to replace all circuit boards and diodes on the bed. The cost for this will be determined at the time of service.

OvationULT Technical Information

Device Specifications:

- Unit Dimensions: 80" L x 31" W x 40 "H
- Weight of machine: 175lbs
- Supports up to 450lbs
- Power Input: 115/230 VAC
- Total Output: 24 VDC & 23.52 Amps
 - * Output Breakdown:
 - 24V DC-11.14 A (Canopy) @ 50/60 Hz
 - 24V DC-11.5 A (Base) @ 50/60 Hz
 - 12V DC-0.23A (Underlighting) @50/60 Hz
 - 24V DC- 0.65A (Timer) @ 50/60 Hz
- Number of Diodes: 9,481 Diodes (3 light sources per diode)
- Diode breakdown: 7,585 Red 1,896 Infrared
- Lenses: 9/16 from center
- Color Range: 635nm (Red) & 850nm (IR)
- Fits through standard 32" opening
- Plugs into standard 3 prong outlet

For your reference, our contact information can be found below:

Body Balance System, LLC 8840 W. Russell Rd. STE 245, Las Vegas, NV 89148 702-633-9040

For all service requests, contact BBS directly. No maintenance is to be done without authorization from the manufacturer.

When applicable, BBS will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of Medical Electrical Equipment that are designated as repairable by the manufacturer.

- The OvationULT emits non-ionizing electromagnetic radiation in the form of visible light (635nm) and infrared light (850nm) for therapeutic purposes.
- The Average Intensity: 65mWcm2
- Distribution: Lights are distributed across the full body of the patient.

Model Name:

OvationULT

Restrictions on Environments:

- Device is to be placed indoors only.
- The temp range of the room should be between 65° to 85° F.
- If facility is in a humid location: de-humidifiers are required to be placed in the same room as Medical Electrical Equipment.

Power Supply Specifications:

 The OvationULT operates off two 24V DC power supplies to bring power to the lights, a 24VDC power supply for the timer controls, and a 12VDC power supply for the cosmetic lighting of the bed. All power supplies are specified as part of the Medical Electrical Equipment.

Product Description:

• The OvationULT is an over-the-counter device intended to emit energy in the visible and IR spectrum in order to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, and the temporary relaxation of muscles.

How the Product Functions:

• The patient presses the power button and chooses a session time of 10, 15, or 20 minutes. Once they select the session, they have 15 seconds to lay down and pull the canopy down over themselves before the LEDs turn on, automatically. After the session time they choose concludes, the lights turn off automatically.

Temp Conditions:

- Indoor environments between 65-85° F with a humidity of less than 50%.
- If the system is in a clinical environment where humidity at higher levels is still present, a de-humidifier must be used in the room the OvationULT is stationed.

Number of Cycles the OvationULT Can Tolerate:

- LEDS-240,000 20 min. sessions. (80,000 HRS)
- Shock: 17,000 duty cycles before shock replacement is required.

Session Max On Time and Minimum Cool down Time:

- The OvationULT may continuously remain in standby mode.
- The max session time is 20 minutes in Power ON mode.
- The minimum break between sessions is 5 minutes.

Permissible environments for transport/storage:

- Transport: The OvationULT may be transported in weather conditions between 1-150° F with a humidity of up to 90%. (non-condensation)
- Storage: The OvationULT may be stored in environments between 65-85° F with a humidity of less than 50%.

Medical Electric Equipment Classification:

- The OvationULT is a Class I ME Device according to 60601-1.
- The applied parts of the OvationULT are tested as "BF" applied parts.
- The OvationULT does not require sterilization and is suitable for use in oxygen rich environments.
 - * The conformance testing of 60601-1 has been applied based on the classifications, above.

Harmonized Standards (Safety & Performance)

- 60601-1
- 60601-1-2
- 62471

Warnings:

- WARNING: Do not modify this equipment without authorization of the manufacturer.
- WARNING: The OvationULT must not be serviced or maintained while it is in use with a patient.
- WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- WARNING: To protect against electrical shock, do not immerse the power cord in any liquid.



Prop 65 WARNING: This product can expose you to chemicals including lead, which is known to the State of California to cause cancer and reproductive harm. For more information, go to www.P65Warnings.ca.gov.

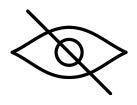
Label Symbols and Their Meaning:



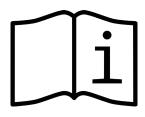
Max environmental temperature should be 85°.



Keep in a dry location. If humid, dehumidifier is required.



Eye protection is required.



Refer to instructions before operating the machine.



This internal component uses an AC current higher than 42.4V peak A.C. Do not touch this component if the ME Equipment is energized.