ADVANCED RECOVERY FOR ATHLETES

LEDBOOTS

MANUAL DO USUÁRIO
USER MANUAL

INTRODUCTION

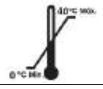
Dear customer, congratulations!

You have just acquired a product developed and manufactured with high technological and quality standards, designed for use in photobiomodulation physiotherapy. Our product, combined with your professional expertise, will contribute to achieving the desired results in the treatments performed with your patients.

Before starting to use the equipment, we strongly recommend that you carefully read the instructions and information contained in this manual. This will help you make the most of its features and functionalities, while also ensuring safer and more efficient use for both the operator and the patient. Should you have any questions, suggestions, or complaints, please contact us. AVA has a team of highly qualified professionals in the health and wellness market and is at the forefront of technological solutions and project development, ready to provide you with all the information you may need.

We hope to meet all your expectations with your new acquisition, and we thank you for your preference and trust in choosing our product.

Sincerely,
AVA - ADVANCED RECOVERY FOR ATHLETES.

SYMBOL	DESCRIPTION
	Standard symbol of attention.
	Consult the documents that accompany the product
IPX0	Equipment without protection against harmful water ingress
	Need for protection against humidity and any other type of liquid that could contaminate the product, during transport and storage.
	Be careful when transporting and storing (fragile).
	Transport and storage positioning symbol (upward direction)
	Temperature limit symbol for storage and transportation. [0 to 40°C]
	Pressure limit symbol for storage and transport. [80 kPa to 102 kPa]
	Relative humidity limit symbol for storage and transport. [30% to 90%]
	Maximum permitted load symbol on a package (transport and storage).
	Symbol for the maximum number of identical packages that can be stacked on top of each other (transport and storage).
	Manufacturer identification
	Manufacturing Date
SN	Serial number
	Direct current.
	Standby Mode – to identify the switch or position thereof, through which part of the equipment is turned on, in order to place it in standby mode.
	Symbol of type B applied part according to the degree of protection against electric shock.
	CLASS II equipment
	Danger - Emission of Optical Radiation.

1.1 - PRODUCT IDENTIFICATION

Technical name: LED System for Therapy
Anvisa Code: 1331065
Trade name: Led Boots
Models: LEDBOOTS-M; LEDBOOTS-G

1.2 - PRODUCT DESCRIPTION

LEDBOOTS is a therapeutic photobiomodulation device (LED stimulation).
It is provided with 528 850nm (infrared) + 660nm (red) emitting LEDs.
Allows power control at 100% or 50%.
Once the power has been selected, it is possible to adjust the treatment time from 1 to 60 minutes.

Indication of Use.
Purpose of cellular biostimulation through the application of light, inducing the organism to self-recovery by stimulating cells to perform their function.

Working Principle.
The LEDBOOTS equipment is electronic equipment, based on the emission of light through a low-intensity LED semiconductor diode boot at a wavelength of 850nm ± 15nm and 660nm ± 15nm that will penetrate the tissues and interact with the body promoting cellular repair (biostimulation), causing analgesia, anti-inflammatory action, inducing the body to self-recovery.
The light generating source is controlled by an electronic circuit whose emission is selected via the keyboard, with its exposure time monitored via the display. The light beam is guided through the optical area, which is an area sufficient to guarantee restorative illumination for the patient.reparadora no paciente.

Check the packaging to see if the items and quantities were delivered correctly.

1.3 - ACCOMPANYING PARTS AND ACCESSORIES:

ITEM		AMOUNT	PHOTO OF THE ITEM
01	Backpack	**01**	
02	**Bota de LED** LEDBoots 3.0 - M / size M LEDBoots 3.0 - L / size L	**01**	
03	Power Supply - 12.5V x 5.7A	**01**	
04	Power Supply Cable	**01**	
05	Instructions for Use (User Manual)	**01**	

1.4 - SPECIFICATIONS AND TECHNICAL CHARACTERISTICS

PRODUCT CLASSIFICATIONS AND FEATURES	
Product type	Active medical product for therapy
Type of protection against electric shock (IEC 60601-1)	CLASS II
Degree of protection against electric shock (IEC 60601-1)	Type B Applied Part
Degree of protection against harmful penetration of water or particulate matter	IPX0 Degree of Protection
Sterilization method	Not applied
Suitability for use in an Oxygen Rich Environment	Not suitable
Operating mode (IEC 60601-1)	Continuous Operation

PRODUCT CLASSIFICATIONS AND FEATURES	
Classification regarding use in the presence of an anesthetic mixture	It should not be used in the presence of flammable anesthetic mixtures with air or nitrous oxide. Not suitable (Non AP / Non APG)
Service life	5 years
Mobility	STATIONARY Equipment
Usage Environment	Professional healthcare facility environments Not suitable for domestic environment
Net Weight	2.8 Kg (Boot + Power Supply)
Boot Size x Patient Height	Patient height below 1.70m Size M Patient height equal to or above 1.70m Size L
Product dimensions	Compression Boot: - Size M - linear length: 100cm - Size L - linear length: 110cm
Pressure (Compressor)	Nominal working capacity: 260 mmHg
Compression modes:	1 Mode
Pressure Adjustment (air)	Not Applied

ELECTRICAL CHARACTERISTICS	
Equipment Supply Voltage	110-220 Vac (voltage range)
Power Frequency	50-60 Hz
Means for insulating the electrical supply network	Disconnect the power plug from the mains
Power Supply	Source output: 12 VDC x 4.0A)
Maximum Input Power	100VA
Software Version	AVA800 Version: V.1.0.0

TECHNICAL CLASSIFICATIONS ACCORDING TO NBR IEC 60601-2-57	
Equipment Classification (Risk Group)	Exempt Group (no photobiological HAZARD)
Operating mode with an Optical Radiation output	Continuous operation (continuous emission of optical radiation)
Wave-length	660nm ± 15nm (red) 850nm ± 15nm (infrared)
Emitter quantity (LED)	528 emitters (660nm + 850nm)
Maximum optical radiation output	660nm > 30 mW x emitter > 15.840 mW 850nm > 30 mW x emitterr > 15.840 mW Grand total > 31.680 mW
Maximum output variation optical radiation over the treatment area	Maximum variation (660nm) > ± 1,6 W (± 10%) Maximum variation (850nm) > ± 1,6 W (± 10%) Maximum variation Grand total > ± 3,2 W (± 10%)
Optical irradiation area	4.000 cm^2
Exposure Time (single pulse duration	1 to 60 minutes (1 minute step) Maximum exposure time variation: ± 10%

TECHNICAL CLASSIFICATIONS ACCORDING TO NBR IEC 60601-2-57	
Spectral Irradiance (660nm emitter)	**Intensity > 90% in the range 650 to 670 nm** **Spectral Irradiance (mW/cm2)** 660nm > 30 mW x emitter Power (mW): 15,840 mW (full power at 660nm) Surface area: 4,000 cm2 **>** 4,0 mW/cm² **Power per unit wavelength (mW/nm) Potência (mW): 15.840 mW** Power (mW): 15,840 mW (full power for 660 nm) Spectral Bandwidth (nm): 20 nm **>** 792 mW/nm **Spectral Power Density (mW/cm² /nm)** Radiant power (mW): 15,840 mW Surface area: 4,000 cm² Spectral Bandwidth (nm): 20 nm **>** 0.2 mW/cm² /nm
Spectral Irradiance (50nm emitter)	**Intensity > 90% in the range 840 to 860 nm** **Spectral Irradiance (mW/cm2)** 850nm > 30 mW x emitter Power (mW): 15,840 mW (full power at 660nm) Surface area: 4,000 cm2 **>** 4,0 mW/cm² **Power per unit wavelength (mW/nm) Potência (mW): 15.840 mW** Power (mW): 15,840 mW (full power for 660 nm) Spectral Bandwidth (nm): 20 nm **>** 792 mW/nm **Spectral Power Density (mW/cm² /nm)** Radiant power (mW): 15,840 mW Surface area: 4,000 cm² Spectral Bandwidth (nm): 20 nm **>** 0.2 mW/cm² /nm

1.5 - EMISSION APERTURES

1.6 - OPTIONS, CONSUMABLES AND SUPPORT MATERIALS

Options: Not applied
Consumables: Not applied
Support materials: Instructions for Use

1.7 - APPLIED PARTS

- The applied part of this Equipment is the internal part of the " Boot ".

2 - SPECIAL CONDITIONS FOR STORAGE, CONSERVATION AND HANDLING OF THE PRODUCT:

Storage:

- Store the product in its original packaging, protected from moisture and any other type of liquid that could contaminate it, away from direct sunlight, in a clean place.
- Store at temperatures between 0°C and +40°C, relative humidity between 30% and 90% (non-condensing) and atmospheric pressure between 80kPa and 102kPa .

Transport:

- Transport the product in its original packaging, protected from moisture and any other type of liquid that could contaminate it, away from direct sunlight.
- During transport, avoid vibrations and impacts on the equipment. Do not drop it on the floor.
- Transport at temperatures between 0°C and +40°C, relative humidity between 30% and 90% (non-condensing) and atmospheric pressure between 80kPa and 102kPa .

Conservation and Handling:

- After installation, keep the equipment in a clean place, away from dust, protected from rain and direct sun.
- Use at temperatures between 0°C and +32°C and relative humidity between 30% and 90% (non-condensing) and atmospheric pressure between 80kPa and 102kPa .

3 - SYSTEM OPERATION

3.1 CONTROL PANEL AND ITS FEATURES

KEY	FUNCTION/ADJUSTMENT
ON/OFF	Turn the equipment on and off Press for 3 seconds to turn ON/OFF Note: when turned off, the equipment remains on standby
PRESSURE	Key to start compression Note 1: No adjustment. Note 2 As soon as it fits snugly against the leg, it automatically stops inflating.
PLAY/PAUSE	Play/Pause optical emission Key off = equipment turned off (on/off) Red key = equipment on (pause) Green key = equipment on (working)
	Select power level (50% / 100%)
	Increases Operating Time (optical exposure) Maximum : 60 minutes Step: 1 minute
	Reduces Operating Time (optical exposure) Minimum: 1 minute Step: 1 minute

INDICATOR	FUNCTION
50%	When lit, it indicates that the selected power is 50%
100%	When lit, it indicates that the selected power is 100%
0.0 TIME	When lit, displays the remaining treatment time (minutes)

3. 2 – OPERATION PROCEDURE

STEP	DESCRIPTION
Preparation	Connect the Power Supply to the Control Panel and Power Supply Cable; Connect the Power Supply Cable to the electricity network; Place the Compression Boot on one of the legs, making sure the patient is in a comfortable position.
TURNING ON the Equipment	Press the key  **ON/OFF** por for 3 seconds for the equipment to turn on.
Select the Optical Radiation Output Power	Press the key  to switch between 50% and 100% LED power.
Optical Exposure TIME Adjustment	Press the key  to increase the optical exposure time Press the key  to decrease optical exposure time Note: the adjustment is from 1 to 60 minutes, with a 1-minute interval.
START OPERATION	 Press the key **PLAY/PAUSE** momentarily to start the treatment (part of the LEDs) Note: when the selected time ends, the operation stops automatically. Key off = equipment turned off (on/off) Red key = equipment on (pause) Green key = equipment on (working)
Start compression	 Press the key **PRESSURE** to start boot compression. Note: Compression stops when the pressure stabilizes. Note 2: if you press the key again, compression stops.
Pause OPERATION	 Press the key **PLAY/PAUSE** momentarily to pause treatment if necessary Note: during the "pause" the time count is interrupted
Turn OFF the Equipment	 Press the key **ON/OFF** for a few seconds for the equipment to turn off.
Finishing	Remove the Patient's Boot Clean and sanitize all parts; Store the LED Boot in a suitable place.

Caution – Using control or adjustment keys or performing procedures other than those specified herein may result in hazardous radiation exposure.

4 - ADVERTÊNCIAS E PRECAUÇÕES

This item has a list of recommendations (warnings and precautions) for the safe use of this equipment.

Safety information

- It is recommended that the healthcare professional be properly trained in photobiostimulation techniques, contraindications and other precautions related to the use of this type of equipment.
- LEDBOOTS equipment should be protected against unauthorized use, for example, kept in a protected location with restricted access.
- The use of command or adjustment keys or the performance of procedures other than those specified herein may result in dangerous exposure to radiation.

Warnings and/or precautions regarding Fire Risk

- There is a Risk of Fire if LEDBOOTS is used in the presence of flammable materials, solutions or gases, or in an oxygen-enriched environment.

Note: Some materials, for example dark-colored or cotton wool clothing, when saturated with oxygen, may catch fire due to the high temperatures produced in normal use of the LEDBOOTS

Warnings and/or precautions about Optical Risk

Avoid eye exposure. The light emitted by this device may cause eye damage.
It is recommended to protect the eyes and skin of the user and the PATIENT when using this equipment

Use protective glasses on the patient (item not supplied with the equipment), in order to avoid possible exposure to optical radiation;

Maintenance:

- The user must carry out a visual inspection of the protective glasses before each use to avoid possible exposure to radiation, checking that the lens is not cracked or chipped.
- Also check your frame.
- Do not place weight on the glasses.
- Do not use the glasses for purposes other than those recommended;

Even when using protective glasses, it is not advisable to directly see the light beam emitted by the equipment;

We recommend that professionals guide their patient or other people with access to the equipment (assistants) on precautions when handling the equipment.

Note: The equipment is completely safe as long as care and precautions regarding its use are followed in all procedures performed.

Warnings and/or precautions regarding Biocompatibility of Materials

LEDBOOTS is designed to contact the patient directly.

The Applied Part is biocompatible and meets the ISO 10993-1:2018 standard

Warnings and/or precautions about ELECTRICAL CARE

- Check the equipment's supply voltage indication. Do not use outside of specifications.
- Connection to Earth potential is mandatory, to guarantee PROTECTION and SAFETY for users and the patient. If in doubt, request the correct information for a good connection to Earth. Connecting this equipment to Earth potential helps eliminate interference that could cause it to malfunction.
- Do not use extension cords or adapter plugs to connect the equipment. This procedure is often the cause of interference and equipment malfunction.
- Do not use a Power Supply that is not supplied by AVANUTRI. Use of other Power Supplies may result in electric shock and will void the LEDBOOTS warranty.
- To avoid electrical shock, product malfunction, or damage, never operate the system with a damaged Power Cord , or other mechanical damage, or if the Control Panel is not fully operational.
- Do not bend or twist the Power Cord to avoid fire or electric shock.
- NEVER drop water on the Control Panel , or place the product in water or in a humid environment. To do this, take the following precautions:

Note: Potential damage due to water entering the cabinet (internal part where the electronic circuits are located): Risk of internal short circuit resulting in:

- cabinet flames, as well as the emission of dangerous substances resulting from the flame;
- deformation of the cabinet resulting from the flame;
- heating of the cabinet resulting from the flame, causing the parts that are or can be touched to have a temperature that exceeds the permitted values and consequently may result in burns;
- loss of electrical insulation, causing voltage (electrical energy) in accessible parts and consequently electric shock with the possibility of burns.

To avoid the RISK of loss or degradation of performance, as well as safety, use only original replacement parts (manufactured and/or supplied by AVA).

Means of electrically isolating the circuits of the Electrical Supply Network Equipment

To electrically isolate the circuits of the Equipment from the Power Supply Network, remove the Power Supply from the power socket when the equipment is charging the battery.

Attention : Do not position the LEDBOOTS in a way that makes it difficult to disconnect the Power Supply from the power socket. Keep the Control Panel at least 50 cm from the electrical outlet.

Patient warnings and precautions

- Patient safety depends mainly on well-trained professionals.
- Do not use this device without the patient's specific medical recommendation regarding the frequency and duration of sessions.
- When using LEDBOOTS , care should be taken to maintain a lying/sitting and relaxed position as much as possible.
- To reduce unwanted Optical Radiation, do not remove the LED Boot from the patient while it is still in use. is in operation. If it is necessary to remove the LED Boot before the end of the programmed time, always pause or turn off the equipment before removing the LED Boot from the patient .

Warnings and precautions for using the equipment

- Operators must read this User Manual completely before using the device.
- Follow your healthcare professional's recommendations regarding frequency and duration of use. Improper placement or prolonged use may result in tissue damage.
- Always check that the equipment in general is in good condition. The Control Panel, Boot with LEDs, Power Supply and Power Cable are in perfect condition.
- It is prohibited to insert sharp metallic objects such as paper clips, staplers, needles or food into the equipment.

Warnings and/or precautions for users /operators

- The equipment was designed for use by a qualified professional (physiotherapist or doctor).
- LEDBOOTS should not be used directly by the patient .
- It is essential that all equipment operators carefully read this User Manual, to ensure correct use/handling, avoiding possible damage to users/patients or to the equipment itself.
- If the instructions in this manual and the instructions provided by your physical therapist are not followed properly, proper therapy may be affected.
- Operators must keep this manual in an easily accessible place for quick consultation by the operator himself or by technical personnel authorized for maintenance;
- The operator must always be attentive, in accordance with the manual, and take the necessary protective measures.

Environmental warnings and precautions

- Keep flammable and explosive liquids and gases (including alcohol, ether, nitrous oxide and oxygen) away from the equipment. The equipment should not be used in places with flammable gases and liquids.t
- The use of anesthetics or flammable gases such as nitrous oxide (N20) and oxygen should be avoided. Adhesive solvents and flammable solutions used for cleaning and disinfection must be evaporated before the equipment is used. Also pay attention to the danger of combustion of endogenous gases.

Warnings and/or precautions outside of use

- Always turn off the system and unplug the Power Supply from its electrical outlet when not in use or being charged, to avoid the risk of electric shock.
- Keep the system, including the Power Supply and Power Cord, away from children and pets to avoid possible accidents (strangulation).

Warnings and precautions during transportation and storage

- Do not leave the Control Panel in direct sunlight. UV light may damage or discolor the Control Panel .
- Store the equipment in its original packaging or in another safe place.
- It is recommended to store in low places to avoid falls that could damage the equipment.
- To maintain the accuracy of internal components, when transporting, installing or operating, avoid impacts, jolts and damage from rain or excessive heat.
- Make sure that too much pressure is not placed on the device when it is transported to avoid damaging its components.
- Do not place the equipment near sources of water or moisture.
- Store the equipment and various accessories in a closed, clean and dry place to avoid direct exposure to moisture, dust and sunlight. When you do not use the device for a long time, it is recommended to place it in the original packaging.
- Your equipment must be protected from any rollover, fall, violent impact, vibration, strong sunlight, rain or snow water during travel. Avoid mixing with flammable, explosive and corrosive substances, as specified in this manual.

Warning during Corrective Maintenance

- While the equipment is in use with a patient, no part of the equipment may be repaired or maintained.
- During maintenance procedures, a warning must be placed next to the equipment prohibiting its use.
- To avoid the risk of electric shock, do not remove any components of the equipment.
- Only Technicians authorized by Ava can have access to the internal components of the equipment. Do not attempt to carry out maintenance or repair work on the equipment.

- All interventions must be carried out exclusively by Avanutri technicians or by technicians trained and authorized by Ava.
- No modifications to this equipment are permitted.
  HAZARDS that may result from unauthorized modification of the EQUIPMENT: - Loss or degradation of performance - Loss of electrical insulation, causing voltage (electrical energy) in accessible parts and consequently electric shock with the possibility of burns

Warning during Preventive Maintenance
- Periodically carry out scheduled preventive maintenance to ensure the operation and safety of the equipment.

Warnings and precautions when cleaning and disinfecting equipment
- Do not carry out cleaning/disinfection with the equipment switched on and/or connected to the power supply. Turn off the equipment to clean/disinfect.
- Do not use oil, benzine, alcohol, gasoline, or other chemicals to clean the device. This will damage the plastics and void your warranty.
- Do not use abrasive materials to clean the Control Panel and other parts. This will damage the plastics and other parts.
- The Control Panel is not a waterproof device. Do not apply a direct current of any liquid. Do not submerge or allow any liquid to accumulate on the panel surface.
- Do not machine wash. Do not machine dry.
- All accessories must be cleaned before storage to ensure that no failure occurs during the next use.

Contraindications for using the equipment, related to optical radiation:
- People with photosensitivity or allergy to light;
- Pregnant women;
- People with photosensitive epilepsy;
- People with cancer,
- People who are undergoing treatments that make their skin sensitive to light;
- People with sensitive eye conditions such as diabetic retinopathy, glaucoma or cataracts;
- Neoplastic masses or by patients with neoplasms;

Contraindications for using the equipment, related to compression:
- Acute pulmonary edema;
- Hypertension;
- Erysipelas;
- Acute thrombophlebitis;
- Acute heart failure;
- Acute infections;
- Deep vein thrombosis;
- Episodes of pulmonary embolism;
- Open wounds, irritations, infections, surgical points, lesions or tumors close to where the boots were used;
- Peripheral neuropathy;
- Lymphatic obstruction;
- Bone fractures or joint dislocations where the boots are used;

5 - USE SPECIFICATION

INTENDED MEDICAL INDICATION	
Intended medical indication	Purpose of cellular biostimulation through the application of light, inducing the organism to self-recovery by stimulating cells to perform their function.

INTENDED PATIENT POPULATION	
REFERENCE	FEATURE
Age	From adolescence
Weight	No relevant
Health	No relevant
Nationality	Multiple
State of Patient	Mentally capable. Not agitated
Contraindication (type of patient)	- People with photosensitivity or allergy to light; - Pregnant women; - People with photosensitive epilepsy; - People with cancer, - People who are undergoing treatments that make their skin sensitive to light; - People with sensitive eye conditions such as diabetic retinopathy, glaucoma or cataracts; - Neoplastic masses or in patients with neoplasms; - Acute pulmonary edema; - Hypertension; - Erysipelas; - Acute thrombophlebitis; - Acute heart failure; - Acute infections; - Deep vein thrombosis; - Episodes of pulmonary embolism; - Open wounds, irritations, infections, surgical points, lesions or tumors close to where the boots - were used; - Peripheral neuropathy; - Lymphatic obstruction; - Bone fractures or joint dislocations where the boots are used;

PART OF THE BODY WHERE THE EQUIPMENT INTERACTS	
Part of the body where the equipment interacts	The most common parts of the body that the equipment can interact with are: - Leg skin/muscles and joints

INTENDED USER PROFILE		
PROFILE		
Education	Minimum	Technician or higher with qualification in physiotherapy
	Maximum	There is no maximum
Knowledge	Minimum	Knowledge of photobiomodulation treatment (LED stimulation)
	Maximum	There is no maximum
Understanding of language	Minimum	Technical language for use in photobiomodulation systems
	Maximum	There is no maximum
Experience	Minimum	In physiotherapy
	Maximum	There is no maximum
Disabilities permissible	Minimum	Not applicable
	Maximum	Slight visual imperfection for reading or corrected vision

CONDITIONS OF USE		
Usage Environment	General	Common usage environments include: - Physiotherapy and Rehabilitation Clinics - Sports Training Centers Note: Not suitable for domestic environment
	Conditions of visibility	Ambient luminance range: minimum 60 lux
	Physical	- Electrical requirement: Single phase 100-240 Vac , 50/60Hz; - System runtime ambient temperature: 0° ~ 40° and the equipment protected from direct sunlight; - Relative humidity: between 30% and 90% (non-condensing) - Atmospheric pressure range: 80kPa to 102kPa. - Ambient sound pressure level: none
Frequency of use	They can be used several times a week (as advised by the healthcare professional responsible for the treatment).	
Mobility	Stationary Equipment	
PHYSICAL PRINCIPLE AND FUNDAMENTALS OF THE PRODUCT'S TECHNOLOGY, APPLIED TO ITS OPERATION AND ACTION		
Operating principle	The LEDBOOTS equipment is electronic equipment, based on the emission of light through a low intensity LED semiconductor diode boot at a wavelength of 660nm ± 15nm that will penetrate the tissues and interact with the body promoting cellular repair (biostimulation), causing analgesia, anti-inflammatory action, inducing the body to self-recovery. The light generating source is controlled by an electronic circuit whose emission is selected via the keyboard, with its exposure time monitored via the display. The light beam is guided through the optical area, which has a sufficient area to guarantee restorative illumination for the patient.t	
FREQUENTLY USED FUNCTIONS		
Frequently used functions	- Remove all parts (device and its accessories) from the Transport Box - Connect the Power Supply to the electrical network using the Power Supply Cable - Connect the Power Supply to the Control Panel. - Position the Boot with LEDs on the patient, at the treatment site - Activate the control keys (select power and treatment time) - Clean the device and accessories - Place all parts in the shipping box - Transport	
SIDE EFFECTS		
Adverse reactions:	- Not applied.	

6 - INSTALLATION AND CONNECTION TO OTHER PRODUCTS

The use of any part, accessory or material not specified or provided for in these Instructions for Use is thesole responsibility of the user.

6.1 - Connection to Other Products

THE LEDBOOTS It is not intended or used for direct connection with other equipment.

6.2 - Product Installation

ABefore installing the equipment, carefully read the instructions contained in this manual, regarding unpacking, assembly, configuration parameters and installation of the system, which will be the responsibility of a qualified professional, operator/user.

To install the equipment, familiarize yourself with the items and follow the instructions:

1- Remove the equipment from the transport box.
2 - Remove the parts from the Transport Case.
3 - Clean and sanitize all equipment (Boot with LEDs, Power Supply and Power Cable).
4 - Connect the Power Cable to the Power Supply and then to the mains. Then connect the Power Supply to the Control Panel.

Note: Only the equipment's Power Cable must be connected to the electricity network.

Attention:

- The electrical installation must comply with current standards for healthcare establishments – Safety requirements.
- Connection to the electrical network is via a 10 A Brazilian standard socket with a nominal voltage of 127 Vac or 220 Vac.
- Use only original cable, supplied by Avanutri.
- Correct grounding and a power outlet in good condition are essential for the safe operation of the equipment.

7 - MAINTENANCE AND SERVICES

7.1 - Corrective Maintenance

When equipment failures occur during use, the user can resolve simple failures by following the instructions below and contained in the user manual. If the problem is not resolved, request support from SAC – Customer Service to consult about the problem.

PROBLEM	SOLUTION
The equipment does not turn on	Press the "On/OFF" key for at least 3 seconds to turn on the equipment. If the equipment does not turn on, check that the power supply is connected to the equipment, and that the power cable is connected to the electrical supply network.
The equipment does not allow control of the power of the LEDs or the treatment time.	If the equipment does not allow control of power or treatment time, turn off the Control Panel and turn it on again after 1 minute. If the problem still persists, send the equipment to Authorized Technical Assistance.

PROBLEM	SOLUTION
Air compression failure.	Check whether the equipment is connected to the electricity network; Check if the button  is on. Check if the buttor  is activated. If the problem still persists, send the equipment to Authorized Technical Assistance.
Air leak	Check if there is any leak in the Boot with LEDs . If there is an air leak, send the equipment to Authorized Technical Assistance.
Difficulty inflating or deflating the Compression Boot	If a problem occurs when inflating or deflating, send the equipment to Authorized Technical Assistance.

7.2 - Preventive Maintenance and Conservation (maintenance of basic safety)

The user is responsible for the following maintenance and upkeep activities:

- External cleaning/disinfection of equipment.
- Checks in general, provided for in this item of the Manual.

Apparent damage

Check equipment and accessories regularly (before each use). Check for cracks, damage, deformation or poor connection of the Control Panel, Power Cord and Power Supply . If you identify a problem, contact Authorized Technical Assistance.

Equipment Output Check

The output of the LEDBOOTS equipment emitted in the treatment area must be checked each time the LEDBOOTS is turned on.

To do this, the user must turn on the Control Panel, select 100% power, select a time of 30 minutes and press the “Play/Pause” button. The Equipment Output must emit “visible” optical radiation for this verification to be validated.

Once validated, press the “Play/Pause” key again to stop validation. Adjust the treatment parameters (power and treatment time) and then follow the procedure described in item 3.2 – Operation Procedure

Authorized Technical Assistance is responsible for the following activities:

- General operational review (electrical circuit check)
- Checking the light intensity.
- Checking the pressure generated by the compressor.
- Any repairs to the internal parts of the equipment..

Preventative maintenance of this equipment must be carried out in accordance with the tables below:

DESCRIPTION	PERIODICITY
General operational review (electrical/electronic circuit)	Annual
Checking the light intensity	Annual
Checking the air system pressure	Annual

Authorized Technical Assistance

Contact the factory to indicate the nearest Authorized Technical Assistance.
AVA sac@ava.cr7.com.

To avoid the RISK of loss or degradation of performance, as well as safety, use only original replacement parts (manufactured and/or supplied by AVANUTRI).
The use of any part, accessory or material not specified or provided for in these Instructions for Use is the sole responsibility of the user.

Circuit diagrams, component list etc.

Ava will make available upon request circuit diagrams, component lists, descriptions, calibration instructions or other information that will assist Service Personnel (Authorized Service Personnel) in repairing those parts of the equipment that are designated by Avanutri as repairable by Service Personnel. Service (Authorized Technical Assistance).

7.3 - Product Lifespan

The useful life of the complete equipment is five years. At the end of the equipment's effective useful life, check that the device's functions are normal before using it. If there is any wear or abnormal noise, contact Authorized Technical Assistance personnel or stop using it.

8 – CLEANING AND ASEPSY OF THE EQUIPMENT

Attention:

- Usual or regular cleaning and asepsis must be carried out before the first use and at the end of each session.
- Before starting the asepsis and cleaning process, make sure that the Power Supply is disconnected from the electricity network.
- Never allow any type of liquid to enter the equipment, as this could cause damage and risk of electric shocks and accidents.
- Never use abrasive substances such as sapodilla or solvents such as liquid alcohol, alcohol gel, isopropyl alcohol, paint thinner or white spirit which damage the product, especially the acrylic light exposure opening part.
- Before storing the equipment, completely dry each item of the product.

Control Panel cleaning procedure :

- For external cleaning, use water and neutral detergent or enzymatic detergent, removing excess water with a clean cloth.
- Apply the selected cleaning product to a soft cloth and rub all Control Panel surfaces.
- Follow the manufacturer's instructions and precautions for the cleaning agent you select.

Cleaning procedure for the Boot with LEDs

- Manually wash the LED Boot in cold water, using a neutral detergent or antibacterial soap. Do not use fabric softener or bleach.
- Dry with a dry cloth. Do not use a clothes dryer.

Attention:

- Before starting the asepsis and cleaning process, make sure that the equipment's Power Cable and Power Supply are disconnected from the electrical network;
- Never allow any type of liquid to enter the equipment, as this could cause damage and risk of electric shocks and accidents.

9-PRECAUTIONS IN CASE OF CHANGES IN THE OPERATION OF THE PRODUCT

If the equipment presents abnormal heating or any other abnormality, check whether the problem is related to any of the items listed in item 7.1. If the problem cannot be resolved, request authorized technical assistance. In this case, turn off the equipment, remove the power cord from the socket, identify and segregate the equipment. Request technical assistance services through AVA ou do e-mail sac@ava.cr7.com

10-PRODUCT DISPOSAL

The following risks are identified, associated with the disposal of equipment, accessories, disposable products, waste, etc., at the end of their useful lives:

- Environmental contamination;
- Improper reuse or use after its useful life and consequently malfunction of the equipment and accessories, causing injuries to the user or patient.

To avoid environmental contamination or misuse of the product, it must be destroyed at the end of its useful life in the following ways:

- Segregated, packaged and identified;
- Discarded in accordance with the requirements of RDC No. 222, of March 28, 2018 and other legislation in force at the federal, state and municipal level;
- Disposed of through a specialized company or;
- Sent at the customer's expense and risk to the Avanutri factory for safe disposal.

Note 1: For more information on proper disposal, contact local or national legislative and environmental authorities.

Note 2: The equipment and/or its parts must be sent in clean and aseptic conditions.

Note 3: Failure to comply with these conditions exempts Avanutri from liability for possible impacts on the environment and/or people.

11 – SENSITIVITY TO PREDICTABLE ENVIRONMENTAL CONDITIONS UNDER NORMAL USE SITUATIONS

Description of electrical and electromagnetic interference

Compatibility refers to the ability of an equipment and/or system to continue performing all its primary functions, withstanding electromagnetic interference produced by any other emission sources and not emitting any type of harmful interference in the environment in which it is installed.

Medical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the limits established for each type of product.

LEDBOOTS is not suitable for installation in buildings, including domestic ones , and those directly connected to the public low voltage network, but only in buildings such as hospitals with a dedicated power supply system.

Portable and mobile radio frequency communications equipment may affect medical electrical products.

"**WARNING**: Use of this equipment adjacent to or on top of other equipment should be avoided as it may result in improper operation . If this use is necessary, this and other equipment should be observed to ensure that they are operating normally."

"**WARNING**: The use of accessories, transducers and cables other than those specified or supplied by the MANUFACTURER of this equipment could result in elevated electromagnetic emissions or reduced electromagnetic immunity of this equipment and result in improper operation. inadequate. "

"**WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm to any part of the LEDBOOTS, including specified cables by the MANUFACTURER. Otherwise , degradation of the performance of this equipment may occur . "

Note: The EMISSION characteristics of this equipment make it suitable for use in industrial areas and hospitals (ABNT NBR IEC/CISPR 11 class A). If used in a residential environment (for which ABNT NBR IEC/CISPR 11 class B is normally required), this equipment may not offer adequate protection for radio frequency communication services . The user may need to take mitigation measures , such as relocating or reorienting equipment.

Strong disturbances will not change the characteristics of the Output Current.

This equipment was developed using the highest technology available on the market, designed and tested to provide maximum performance, quality and safety to the user and operator according to the standards and safety levels as described in the tables below:

11.1 - Electromagnetic Emission

Guidance and manufacturer's declaration

LEDBOOTS is intended for use in the electromagnetic environment specified in Table 1 below.

Note: The customer or user of the LEDBOOTS must ensure that it is used in such an environment.

TABLE 1 - Electromagnetic Emission according to IEC 60601-1-2:2014

EMISSIONS TESTS	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - ORIENTATION
CISPR 11 RF Emissions	Group 1	The LEDBOOTS uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment. (CISPR 11:2015 +A1:2016, Annex A)
CISPR 11 RF Emissions	Class A	The LEDBOOTS is not suitable for installation in buildings, including domestic ones, and those directly connected to the public low voltage network, but only in buildings such as hospitals with a dedicated power supply system.
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations / Flicker Emissions IEC 61000-3-3	Not applicable	

11.2 - ELECTROMAGNETIC IMMUNITY

LEDBOOTS is intended for use in the electromagnetic environment specified in Table 2 below.

Note: Customers or users of this equipment must ensure that it is used in this type of environment.

TABLE 2 – Electromagnetic immunity according to IEC 60601-1-2:2014

IMMUNITY ASSAYS	TESTING AND COMPLIANCE LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	By contact: ± 8 kV Through the air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	By contact: ± 8 kV Through the air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	The floor must be wood, concrete or ceramic. If the floor is covered with synthetic material, the humidity ratio must be at least 30%.
Electrical fast transient/bursts IEC 61000-4-4	For power supply lines: ± 2 KV / 100 KHz For input/output lines: ± 1 KV / 100 KHz	For power supply lines: ± 2 KV For input/output lines: ±1 KV	The quality of the electrical current should be similar to that of a hospital or typical commercial environment.
Surges IEC 61000-4-5	Line-to-Line: ± 0,5 kV, ± 1 kV Line-to-Ground: Not applicable to Class II Equipment	Line-to-Line: ± 1 kV Line-to-Ground: Not applicable to Class II Equipment	The quality of electrical current should be similar to that of a typical hospital or commercial environment with surge protection.
Voltage dips Voltage interruptions IEC 61000-4-11	Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruption: 0 % UT; 250/300 cycle	Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruption: 0 % UT; 250/300 cycle	The quality of the electrical current should be similar to that of a hospital or typical commercial environment. If the LEDBOOTS user requires continued operation during power outages, it is recommended that the LEDBOOTS be powered by an uninterruptible power supply or battery. In the event of interruptions, drops or variations in voltage in the electrical network, the equipment can turn off and return to normal operation, without reducing the level of safety.
RATED power frequency magnetic fields (50/60 Hz) IEC 61000-4-8	30 A/m 50 or 60Hz	30 A/m 50 or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial environment or hospital environment.
Magnetic fields in proximity ABNT NBR IEC 61000-4-39	Not applicable	Not applicable	

IMMUNITY ASSAYS	TESTING AND COMPLIANCE LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V r.m.s. 0,15 MHz - 80MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	3 V r.m.s. 0,15 MHz - 80MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	Portable and mobile RF communications equipment should not be used close to any part of the LEDBOOTS, including cables, with a separation distance less than the recommended one, calculated from the equation applicable to the transmitter frequency. Recommended Separation Distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz Modulation: 80 % AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz Modulation: 80 % AM at 1 kHz	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz até 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 80 MHz até 2,7 GHz
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	385MHz to 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (see table 9).	385MHz to 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (see table 9).	where P is the maximum transmitter power in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, determined by electromagnetic site inspection (a), must be less than the compliance level in each frequency band (b). Interference may occur in areas close to equipment marked with the following symbol: 
U_T is the a.c. supply voltage. before applying the test level			

IMMUNITY ASSAYS	TESTING AND COMPLIANCE LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile radio systems, amateur radio, AM and FM radio broadcasts, and TV broadcasts, cannot be predicted theoretically with precision. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site assessment must be performed. If the measured field strength in the location where LEDBOOTS is used exceeds the applicable RF compliance level above, it should be noted that LEDBOOTS is operating normally. If abnormal performance is observed, additional measures may need to be taken, such as reorienting or repositioning the LEDBOOTS. (b) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66 MHz to 40.70 MHz. The ham radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5 .4MHz, 7MHz to 7.3MHz, 10.1MHz to 10.15MHz, 14MHz to 14.2MHz, 18.07MHz to 18.17MHz, 21.0MHz to 21.4MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz. (c) Over the frequency range of 150 kHz to 80 MHz, field strengths must be less than 3 V/m.			

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

FREQ.	BAND (MHz)	SERVICE	MODULATION	POWER MAXIMUM (W)	DISTANCE (M)	TESTE LEVEL	COMPLIANCE LEVEL
385	380-390	Tetra 400	Pulse, 18 Hz	1,8	0,3	27 V/m	27 V/m
450	430 - 470	Gmrs 460, Frs 460	FM, 1KHz, deviation ± 5Hz	2	0,3	28 V/m	28 V/m
710 745 780	704 - 787	Bana LTE 13,17	Pulse, 217 Hz	0,2	0,3	9 V/m	9 V/m
810 870 930	800 - 960	GSM 800-900; Tetra 800; iDEN 820 CDMA 850; Banda LTE 5	Pulse, 18 Hz	2	0,3	28 V/m	28 V/m
1720 1845 1970	1700 - 1990	Gsm 1800; CDMA 1900; GSM 1900; DECT; Band LTE 1,2,3,4 UMTS	Pulse, 217 Hz	2	0,3	28 V/m	28 V/m
2450	2400 - 2570	Bluetooth, WLAN 802.11b/g/n rfid 2450, Band LTE 7	Pulse, 217 Hz	2	0,3	28 V/m	28 V/m
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse, 217 Hz	0,2	0,3	9 V/m	9 V/m

11.3 - RECOMMENDED SEPARATION DISTANCES

Between portable and mobile RF communications equipment and LEDBOOTS.

LEDBOOTS is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or LEDBOOTS user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and LEDBOOTS, as recommended above, in accordance with the maximum output power of the communications equipment.

MAXIMUM TRANSMITTER OUTPUT CALCULATION (W)	SEPARATION DISTANCE ACCORDING TO TRANSMITTER FREQUENCY (M)			
	150 KHz to 80 MHz Outside the ISM and ham radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 KHz to 80 MHz Outside the ISM and ham radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0,12	0,23
0.1	0.38	0.63	0,38	0,73
1	1.2	2.00	1,2	2,3
10	3.8	6.32	3,8	7,3
100	12	20.00	12	23

NOTE

For transmitters rated at a maximum output power not listed above, the recommended separation distance d 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.

Note 1: Between 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Conformity levels lower than those specified by IEC 60601-1-2:2014 indicate that in cases of surges, drops or variations in voltage, or interruptions in the electrical network, the equipment remains in perfect working order when operated following the instructions for use, without reducing safety levels.

12- WARRANTY TERM

AVA guarantees this product for a period of 1 year. As long as it has been installed and used in accordance with the guidelines contained in the Instruction Manual and has been intended exclusively for its intended use.

1. The warranty will be valid for the period specified above, counting from the date of purchase by the first buyer/consumer.

2. During the stipulated period, the warranty fully covers labor and parts in the repair of defects duly found to be manufacturing defects. Only a technician from the AVA Technical Assistance Service is qualified to repair defects covered by the warranty, upon presentation of the original sales invoice to the first buyer/consumer.

3. The consumer has a period of 90 days to complain about apparent irregularities (deficiencies), which can be easily and immediately observed in the product, such as the items that make up the external part and any other part accessible to the user. Parts subject to natural wear, appearance parts and accessories in general have a warranty restricted to the legal period of 90 days..

THE WARRANTY LOSES ITS EFFECT IF:

a) The installation or use of the product does not comply with the recommendations in the Instruction Manual;
b) The product suffers any damage caused by accident, fall, acts of nature, mistreatment or even alterations and repairs carried out by people not authorized by the manufacturer. As a precaution, it is recommended to unplug the product from the socket when not using it for a long period of time;
c) The invoice and/or serial number of the product is tampered with, erased or damaged;
d) Defects and unsatisfactory performance are caused by the use of accessories that do not comply with the technical specifications of AVA or official technical standards, by the use of an improper electrical network or subject to excessive fluctuations;

THE WARRANTY DOES NOT COVER:

a) Transport and removal of products for repair/installation. If the consumer wishes to be served at the location where the product is installed, it will be at the discretion of the AVA Technical Assistance Service whether or not to charge the visit fee, and the customer must consult in advance when requesting the service;
b) Consumer service, free or paid, in cities that do not have the AVA Technical Assistance Service, with the costs and risks of transporting the device to and from the Technical Assistance Service being the sole responsibility of the consumer ;
c) Transport and removal of products that are installed in risky locations to the AVA Technical Assistance Service;
d) Elimination of external interference to the product, which could harm its performance;
e) Installation, external adjustments and cleaning services, as this information is contained in the Instruction Manual.

Considerations:

AVA is obliged, under the terms of this certificate, to only repair products with proven manufacturing defects, exempting itself from any responsibilities and other unforeseen obligations.

AVA does not grant any form and/or type of guarantee for products not accompanied by a consumer sales invoice, or products whose invoice is filled out incorrectly.

ADVANCED RECOVERY FOR ATHLETES

Informações | Informations

AVA - BRASIL

AVA - PORTUGAL

Green Fit Recovery, lda.
Avenida Engenheiro Duarte Pacheco, Torre 2, 8 andar,
Sala 10, Zip Code: 1070-102, city Lisboa, Portugal;
ID number: 518 096 700;
Resp. Técnico: Rodrigo Santana.

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