CRYO SPORT

USER MANUAL

ADVANCED RECOVERY FOR ATHLETES

INTRODUCTION

Dear customer, congratulations!

You have just purchased a product developed and produced with high technological and quality standards, with application in the area of physiotherapy using cryotherapy combined with compression.

Our product combined with your professional knowledge will help you, together with your patient, to achieve the desired results in the treatments performed.

Before starting to use the equipment, we insist that you carefully read the instructions and information contained in this manual, to make better use of its characteristics and functionalities, in addition to using it with greater safety and efficiency, both for the operator and the patient.

If you have any questions, suggestions or complaints, please contact us. AVANUTRI has a team of highly qualified and qualified professionals in the health and quality of life market, as well as being at the forefront of technological solutions and project development and able to provide all the information you need.

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

Yours sincerely,

AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA.

1- SYMBOLOGY USED

Symbols, graphics and conventions that can be found in these Instructions for Use, on the product and on its packaging.

SYMBOL	DESCRIPTION
	Standard symbol of attention
	Consult User Manual
	Consult the documents that accompany the product
IPX0	Equipment to protect against harmful water ingress
	Need for protection from direct sunlight.
	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 (direction upwards)
	Temperature limit symbol for storage and transport.[1 to 5 ºC]
	Pressure limit symbol for storage and transportation. [80 kPa to 102 kPa]
	Relative humidity limit symbol for storage and transportation.[30% to 90%]
	Maximum permitted load symbol on a package (transport and storage).
	Symbol of maximum number of identical packages that can be stacked one on top of the other (transport and storage).
	Manufacturer identification
	Manufacturing date

SYMBOL	DESCRIPTION
SN	Serial number
	Disposal in common trash is prohibited
	Alternating current
	Type B applied part symbol according to the degree of protection against electric shock
	CLASS II equipment
	Non-ionizing radiation

1.1 – Product identification

Technical name: Physiotherapy Device
Trade name: CRYO SPORT
Model: AVA500

1.2 - Product Description

Cryo Sport is equipment that combines cold and compression therapy. It has adjustment of compression (air), flow (water circulation) and treatment time, through a control panel on the top of the cabinet.
Allows the placement of water and ice, which results in cooling of the applied part.

Water Circulation Unit, Connection Hose and Wrap.

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

1.3 - Accompanying parts and accessories:

ITEM	DESCRIPTION	AMOUNT	IMAGE
01	Carrying Bag	1	
02	Water Circulation Unit	1	
03	Wrap	1	
04	Connection Hose	1	
05	Power cable	1	
06	12V 4A Power Supply	1	
07	User manual	1	

1.4 - Specifications and Technical Characteristics

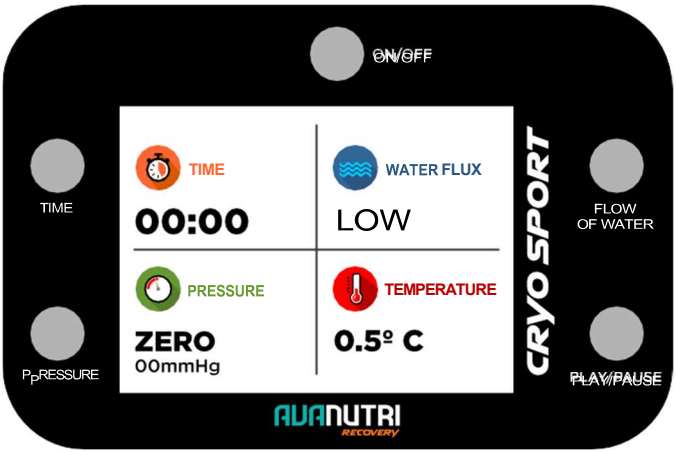
Product Classifications and Features	
Product Type	Active medical product for therapy
Type of protection against electric shock (IEC 60601-1)	CLASS II
Degree of protection against electric shock (IEC 60601-1)	Type B Applied Part Note: Applied part without electrical parts
Degree of protection against harmful penetration of water or particulate matter	IPX0 Degree of Protection
Sterilization method	Not applied
Suitability for use in an ENVIRONMENT RICH IN OXYGEN	Not suitable
Operation mode	Continuous operation
Classification regarding use in the presence of anesthetic mixture	Should not be used in the presence of flammable anesthetic mixtures with air or nitrous oxide. Not suitable (Non AP / Non APG)
Lifespan	5 years
Mobility	STATIONARY health product
Electrical Characteristics	
Supply Voltage	110 - 220 Vac (voltage range)
Power Frequency	60 Hz
Means of isolation from the power supply network electrical	Disconnect the power plug from the mains
Power supply	Source output: 12 VDC x4.0A
Maximum Input Power	42VA
Firmware Version	AVA500 -01
Physical Characteristics of the Product	
Net Weight (without water/ice)	5,0 kg (Water circulation unit + Wrap + Connection Hose + 12V 4A Power Supply + Power Cable
Dimensions of the Water Circulation Unit	• Length: 17.6772 Inch • Width: 4.01575 Inch • Width: 8.46457 Inch Note: Dimensions not including travel bag
Control Panel	
Display	
Screen type	• Screen type
Activation Keys	Push button type: • ON/OFF • Time • Pressão • Water flux • Play/pause

Control Panel	
Timer	
Operating time adjustment	• Maximum adjustment time: 120 minutes • Pre-configured working range: 0 to 120 minutes • Resolution (adjustment): 5 minutes • Accuracy: ±30 seconds
Pressure	
Compressor (ar)	• Nominal working capacity: 150 mmHg • Pre-configured working range: 0 to 75 mmHg • Resolution (adjustment): 25 mmHg • Accuracy: ± 25% of the set value Note 1: The value indicated on the display (configured) is equal to the average value of operation since the system acts with the ffset, turning on and automatically turning off the compressor around the value configured. Note 2: The adjusted (configured) air pressure is only valid after stabilization of the air/water circuit, which occurs after 1 minute and 30 seconds of equipment operation for the parameters adjusted on the control panel.
Pressure Adjustment (air)	• No pressure - 0 mmHg • Low (continuous) - 25 mmHg • Average (continuous) - 50 mmHg • High (continuous) - 75 mmHg • Low (intermittent) - 30 sec. 25 mmHg x 30 sec. 12.5 mmHg • Average (intermittent) - 30 sec. 50 mmHg x 30 sec. 25 mmHg • High (intermittent) - 30 sec. 75 mmHg x 30 sec. 37.5 mmHg
Water flux	
Type of water	Filtered or distilled water
Water pump (flow)	• Nominal working capacity: 360L/h • Pre-configured working range: 53 to 64 L/h • Resolution (adjustment): Low / Medium / High • Accuracy: ± 25% of the set value
Water Flow Adjustment	• Low (53 L/h) • Average (56 L/h) • High (64 L/h) Note: the water flow (flow rate) specified above is only valid afterthe stabilization of the air/water circuit, whichoccurs after 1 minute and 30 seconds of operation of the equipment to the parameters set on the control panel.
Temperature indicator	
Thermometer	Reading range: 1°C to 40°C Resolution: 0.5°C Accuracy: ± 2°C

1.5 – Options, consumables and support materials

Options: Not applicable
Consumables: Water and Ice
Support materials: Instructions for Use

1.6 Display and its features



Button / Indicator	Function / Adjustment
ON/OFF	Button Turns the equipment on and off Note: when turned off, the equipment remains on standby
TIME	Operating Time Button Adjustable from 0 to 120 minutes, with a 5-minute interval. Note: the start (after turning on the equipment) is programmed for time = 30 minutes.
WATER FLUX	Water flow button This parameter reflects the flow rate (water circulation) within the circuit. • Available settings: • Low • Average • High
PRESSURE	**Pressure Button** This parameter reflects compression (pressure to be exerted on the Wrap). This parameter has the main objective of adjusting and approximating the Envelope to the body so that the temperature can be changed effectively. Available settings: • No pressure - 0 mmHg • (continuous) - 25 mmHg • Average (continuous) - 50 mmHg • High (continuous) - 75 mmHg • Low (intermittent) - 30 sec. 25 mmHg x 30 sec. 12.5 mmHg • Average (intermittent) - 30 sec. 50 mmHg x 30 sec. 25 mmHg • High (intermittent) - 30 sec. 75 mmHg x 30 sec. 37.5 mmHg
TEMPERATURE	Water temperature **indicator** inside the tank, which can be adjusted accordingly with the water/ice ratio.
PLAY/PAUSE	Play/Pause button Starts or pauses operation (water circulation and compression).

1. 7 - APPLIED PARTS

· The applied part of this Equipment is the “Envelope”

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 1°C and +50°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 transportation, avoid vibrations and impacts on the equipment. Do not drop it on the floor.
• Transport at temperatures between 1°C and +50°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 +40°C and relative humidity between 30% and 90% (non-condensing) and atmospheric pressure between 80kPa and 102kPa.

3 - SYSTEM OPERATION

To operate the system, you will need:
• The Water Circulation Unit filled with ice and water as indicated by the fill line labels inside the reservoir. Optimal performance is achieved by first adding 1.5 liters of water and then filling the reservoir to the top with ice.
• 12V 4A Power Supply and Power Cable
• Connection Hose.
• Wrap

Comments:
• The Envelope consists of an internal heat exchanger and an external sleeve. The sleeve and heat exchanger combination is referred to throughout this manual as the “Shell”.
• To ensure proper performance the control unit must be placed on a stable surface (such as the floor or a table) during use.
• Note that using the system in a hot location may affect the ability to provide adequate cooling, or may limit the duration of ice.
• Before starting the usage cycle, ensure that the unit has been recharged.

PRIMARY OPERATION FUNCTIONS

1- Press the door release button to open the ice box door.
2- Add water up to the fill line indicated on the label inside the reservoir.
3- Add ice to the reservoir, observing the ice fill line
4- Close the ice box door. Make sure you hear the click.
5- Position the user in a comfortable position following the instructions of the physiotherapist or specialist.
6- Place the Water Circulation Unit in the place where you intend to use it (stable surface).
7- Press the power button (ON/OFF). Do not press the Play/Pause button at this time.
8- The control panel will start the process and immediately make adjustment options available.
9- Press the adjustment buttons on the Control Panel, according to the options below:
a) **STOPWATCH** (Time) - Select the usage time.
Adjustable from 0 to 120 minutes, with a 5-minute interval.
Note: the start (after turning on the equipment) is programmed for time = 30 minutes.
b) WATER FLOW - Select one of the available water flows (low, medium and high).
This parameter only reflects the flow rate (water circulation) within the circuit.
Available settings: Low, Medium and High
c) **ADJUSTMENT AND ACCOMMODATION PRESSURE** – Select the degree of adjustment / pressure to be exerted on the wrap, this parameter has the main objective of adjusting and bringing the wrap closer to the body so that the temperature can be changed effectively.
Available settings:
• No pressure – 0 mmHg
• Low (continuous) – 25 mmHg
• Average (continuous) – 50 mmHg
• High (continuous) – 75 mmHg
• Low (intermittent) – 30 sec. 25 mmHg x 30 sec. 12.5 mmHg
• Average (intermittent) – 30 sec. 50 mmHg x 30 sec. 25 mmHg
• High (intermittent) – 30 sec. 75 mmHg x 30 sec. 37.5 mmHg
Note: The Water Circulation Unit must be turned on before connecting a wrap.

10- Connect the Connection Hose to the Water Circulation Unit.
11- Apply the selected Wrap to the treatment site, making sure the patient is in a comfortable position.
12- Connect the other end of the Connection Hose to the selected Wrap already adjusted to the treatment site.
13- Press the PLAY/PAUSE button to start the session and make sure the circuit is working and heat exchange is taking place.
Note: If you need to correct or adjust any parameter, press the PLAY/PAUSE button. Perform the correction and press the PLAY/PAUSE button again.
14- When the timer reaches the programmed time, an audible warning will be emitted and the circuit will enter standby mode, then press the ON/OFF button to turn off the equipment;
15- Disconnect the hoses both at the end of the Water Circulation Unit and at the end of the Wrap;
16- Remove the wrap from the patient;
17- Press the water tank lid release button;
18- Take the Water Circulation Unit to a sink or appropriate place to dispose of the water/ice;
19- Carefully drain the water/ice;
20- Wipe off excess water;
21- Store the equipment and its accessories in a safe place.

4 - WARNINGS AND PRECAUTIONS

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

Warnings for the safe and correct use or application of the equipment:
• Operators/users must read this User Manual completely before using the device.
• Do not use this device without the patient's specific medical recommendation regarding the frequency and duration of sessions.
• The prescription usually indicated in the medical literature is to use cold therapy at least 4 times a day, for approximately 30 minutes each time, with at least a 30-minute break between sessions, observing the peculiarities of each patient's treatment.
• Although the temperature is adjustable (proportion of water and ice), medical literature indicates that the greatest benefit of cold therapy (cryotherapy) is in the temperature range of 4.5 °C to 15.5 °C, adapting to the type of “injury” of each patient and the prescribed medical recommendation;

• Generally reported recommendations for compression are to set pressure from “none” to “low” during the first 24 to 48 hours after surgery or injury, gradually increasing to “medium” or “high” depending on the patient's response and if it is comfortable after the first 48 hours;
• The literature never recommends that “high” pressure be applied if the patient is in bed.
• If the session needs to be interrupted due to any dangerous incident with the patient, press the pause button then OFF and immediately remove the wrap from the patient.

Care and contraindications for using the equipment

Cold therapy sessions (cryotherapy) combined with compression are contraindicated for patients with the restrictions listed below due to associated risks and/or undesirable side effects that may cause harm/risk to the patient's health:
• Acute stage of inflammatory phlebitis in the affected region.
• Any current clinical signs suggestive of deep vein thrombosis in the affected region.
• Significant arteriosclerosis or other ischemic vascular disease in the affected region.
• Any significant risk factors or current clinical signs of embolism (e.g., pulmonary embolism, cerebral ischemia, atrial fibrillation, endocarditis, myocardial infarction, or atheromatous plaque embolism).
• Who have a condition in which increased venous or lymphatic return is not desired in the affected extremity (eg, carcinoma).
• Decompensated hypertonia in the affected region.
· With significant vascular debilitation in the affected region (e.g. from previous frostbite, diabetes, arteriosclerosis or ischemia).
• With hematological dyscrasia affecting thrombosis (eg, paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle cell anemia, serum cold agglutinin).

Note:
1. The Wrap is not sterile. Do not place directly on open wounds, irritations, infections or surgical points. The Wrap can be applied over clothing or dressing;
2. Frequently monitor the skin receiving cold therapy and stop the session if increased redness and discoloration occurs and remove the Wrap from the patient.
3. In cases not listed or foreseen above, consult a specialist doctor.

Warnings and precautions for using the equipment

• Follow your healthcare professional's recommendations regarding frequency and duration of use. Improper placement or prolonged use may result in tissue damage.

• To avoid damage to your product, do not operate the system without water in the Water Circulation Unit reservoir.

• Do not use anything other than ice and water in the Water Circulation Unit reservoir.

• Danger of overflow NEVER let water or ice fall outside the Water Circulation Unit reservoir, especially on the control panel, or add water and ice above the limit. To do this, take the following precautions:

• Protect the Control Panel with a dry cloth, to ensure that no amount of water or ice falls on it, which could result in electrical damage and loss of equipment functionality;

- When placing water and ice in the reservoir, place it in the center of the reservoir;
- Pour slowly.
- Only add water to the limit indicated on the label inside the tank. Do not exceed this limit.

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

- flames from the cabinet, 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 reach 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 an electric shock with the possibility of burns.

• To avoid potential damage to your product, do not place hot water in the Water Circulation Unit reservoir. The system is not designed to operate and has not been tested with hot water.

• To avoid potential damage to your product, do not use Wraps from another manufacturer with the CRYO SPORT system.

• To avoid damage to your product, do not operate the Water Circulation Unit without the Connection Hose connected.

• Monitor the arrangement of the Connection Hose and cable during use to avoid accidents.

• To ensure the best fit, ensure the Wrap is completely empty before each application.

Electrical care warnings and/or precautions

• Check the indication of the equipment's supply voltage range. Do not use outside the specified range.
• 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 CRYO SPORT.
• Use of other Power Supplies may result in electric shock and will void the CRYO SPORT warranty
• To avoid electrical shock, product malfunction or damage, never operate the system with damaged Power Cord or Connection Hoses, or other mechanical damage, or if the Water Circulation Unit is not fully operational.
• To avoid RISKS of loss or degradation of performance, as well as safety, use only original replacement parts (manufactured and supplied by AVANUTRI).

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 Network Plug (power cable) from the power socket.
Attention: Do not position the Cryo Sport Equipment in a way that makes it difficult to disconnect the Mains Plug (power cable) from the power socket. Keep the Water Circulation Unit at least 50 cm from the electrical outlet.

Warnings and/or precautions outside of use

• Always turn off the system and unplug the power cord from its electrical outlet when not in use or before adding or emptying ice and water, to avoid the risk of electrical shock.
• Keep the system, including hoses and cables, away from children and pets, to avoid possible accidents (strangulation).

Warnings and/or precautions for users/operators

• The equipment was designed for use by a qualified professional (physiotherapist or doctor).
• It is essential that all users of the equipment carefully read this User Manual, to ensure correct use/handling, avoiding possible damage to users/patients or to the equipment itself.
• Monitor to make sure that the programmed parameters are being executed correctly;
• If the instructions in this manual and the instructions provided by your physical therapist are not followed properly, proper therapy may be affected.
• The user must keep this manual in an easily accessible place for quick consultation, either by the user or by technical personnel authorized for maintenance;
• The operator must always be attentive, in accordance with the manual, and take the necessary protective measures.
• Position the equipment to avoid injuries, be careful not to trip over the power wire and the system Connection Hose.

Patient warnings and precautions

• Patient safety depends mainly on well-trained professionals.
• Immediately discontinue use if you experience burning, itching, or increased pain and swelling.
• Frequently monitor the skin receiving cold therapy and discontinue use if increased redness or discoloration occurs.

Environmental warnings and precautions

• Set the equipment to standby mode or turn off the power supply during the treatment interval.
• 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.
• The use of anesthetics or flammable gases such as nitrous oxide (N2O) 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 precautions during transportation and storage

• Do not leave the Water Circulation Unit directly in sunlight. UV light may damage or discolor the control unit.
• Store the Water Circulation Unit with the lid fully open to allow the interior to dry and preserve the reservoir seal.
• Store the Water Circulation Unit in its Carrying Bag or other safe place.
• It is recommended to store in low places to avoid falls that could damage the equipment
• Do not place the 12V Power Supply 4Inside the reservoir of the Water Circulation Unit for storage or transport.
• To avoid damage to your product, do not carry the Water Circulation Unit by the lid. Carry it using only the handle.
• To maintain the accuracy of internal components, when transporting, installing or operating, avoid impacts, jolts and damage from rain or excessive heat.
• Avoid transporting the equipment with water in the tank. Drain it before transport.

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 panels from the unit.
• Only Technicians authorized by Avanutri 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 Avanutri.
• No modifications to this equipment are permitted.

Warning during Preventive Maintenance

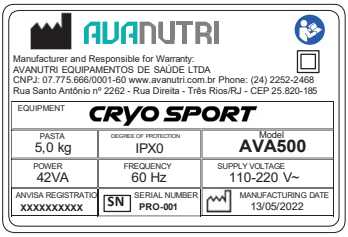
• Periodically carry out scheduled preventive maintenance to ensure the operation and safety of the equipment.
• To change the water in the Water Circulation Unit reservoir, always use distilled or filtered water. Otherwise, it could compromise the effectiveness of the cooling system, in addition to damaging the hydraulic system.

• Under no circumstances can the equipment operate without water, as it is essential for cooling the Wrap, and consequently, for the safety of the operator and patient.
• Monitor whether the temperature sensor is working correctly. If there is any inconsistency in the information, replace it.

Warnings and precautions when cleaning and disinfecting equipment

• Do not carry out cleaning/disinfection with the equipment in standby mode. Turn off the equipment to clean/disinfect.
• Do not use any solvent-based cleaning product on the Water Circulation Unit, rubber or plastic parts. This will damage the plastics and void your warranty.
• Do not use abrasive materials to clean the Water Circulation Unit and other parts. This will damage plastics and rubbers.
• The water circulation unit 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 surface of the front panel and display.
• Do not wash the machine.
• Do not machine dry.

Warnings and/or precautions labeled on the equipment

Equipment Serial Label	Type B applied part	Consult the Manual
		

Note: *All labeling is available for product rebranding and may be provided by Avanutri, as long as they are necessary for the maintenance equipment technique.*

5 – INDICATION FOR USE

5.1 - Usage specification

Intended medical indication	
Intended medical indication	The CRYO SPORT system combines cold and compression therapy, assisting in the treatment of **acute injuries reducing edema**, **swelling** and pain where cold and compression are recommended. Scientific studies prove that local therapy with ice or low temperature and Compression brings benefits and accelerates post-injury treatment. It is also used in the recovery of athletes between training sessions/ competitions.

Intended patient population	
Reference	**Feature**
Age	From adolescence
Weight	Not relevant
Health	Patients with musculoskeletal injuries (observing contraindications)
Nationality	Multiple
State of Patient	Not relevant
Contraindicated For people with	• Acute stage of inflammatory phlebitis in the affected region. • Any current clinical signs suggestive of deep vein thrombosis in the affected region. • Significant arteriosclerosis or other ischemic vascular disease in the affected region. • Any significant risk factors or current clinical signs of embolism (e.g. pulmonary embolism, ischemia, cerebral, atrial fibrillation, endocarditis, myocardial infarction or atheromatous plaque embolism) • Who have a condition in which increased venous or lymphatic return is not desired in the affected extremity (e.g. carcinoma) • Decompensated hypertonia in the affected region • With significant vascular debilitation in the affected region (e.g. from burns colds, diabetes, arteriosclerosis or ischemia) • With hematological dyscrasia affecting thrombosis (e.g. cold hemoglobinuria paroxysmal, cryoglobulinemia, sickle cell anemia, cold serum agglutinin).

Part of the body where the equipment interacts	
Parte do corpo em que o equipamento interage	Lower limbs (Places where there is musculoskeletal injury)

Intended User Profile		
Profile	**Minimum**	**Maximum**
Education	Technician or higher with physiotherapy qualification	There is no maximum
Knowledge	Qualification in Physiotherapy	There is no maximum
Language understanding	Technical language as specified in the project for use in project for use in physiotherapy system with temperature and compression	
Experience	In physiotherapy	There is no maximum
Permissible deficiencies	Not applicable	• Slight visual imperfection for reading or corrected vision • Arms and hands to manipulate the Circulation Unit reservoir of Water and Wrap
Terms of use		
Usage environment	General	• Professional and clinical use for hospitals, outpatient clinics and health center sports training • Not suitable for domestic environment
	Visibility conditions	Ambient luminance range: minimum 60lux
	Physicist	• Requisito elétrico: Monofásico 110-220 Vac, 60Hz; • Ambient temperature of system execution: 0º ~ 40º and the equipment protected from sunlight direct; • Relative humidity: between 30% and 90% (non-condensing); • Atmospheric pressure range: 80kPa to 102kPa; • Ambient sound pressure level: none.
Frequency of use	The most common indication in specialized literature is to use cold therapy at least 4 times a day, for approximately 30 minutes per session, with a break of at least 30 minutes between each one.	
Mobility	STATIONARY health product to be used on the patient in rest sitting or lying down. ***Note:*** *The product must be connected to an electrical network as per specified in its manual and positioned in a flat and stable place.*	

Physical Principle and fundamentals of product technology, applied to its operation and action	
Operating principle	Constituído por uma Unidade de Circulação de Água (ciclo de troca de frio) e Envoltórios para cada parte do corpo. O Equipamento tem uma bomba de circulação de água, e um reservatório para colocar água e gelo, também possui um pequeno compressor para inflar a bolsa de ar (envoltório) que será colocada na parte do corpo lesionada. Em resumo o sistema é composto por uma Unidade de Circulação de Água e um Envoltório em um determinado local para que juntos através da circulação de água gelada e compressão trazem
Frequently used functions	
Functions used frequently	• Remove all parts (device and its accessories) from the Storage Bag. Transport • Connect the Connection Hose to the Enclosure and the Unit Water Circulation • Connect the 12V 4A Power Supply to the Power Unit Water Circulation • Place water and ice in the Reservoir of the Circulation Unit. Water • Place the Wrap on the leg • Activate the control keys • Read message in menu • Select a menu option • Clean the device and accessories • Dismantle the Water Circulation Unit accessories • Place all parts in the Carrying Bag • Carry

5.2 - Secundary effects

Adverse reactions:
• Burning, itching, or increased pain and swelling may occur.
• Increased redness, discoloration may occur.

6 - INSTALLATION OR CONNECTION TO OTHER PRODUCTS

CRYO SPORT is not intended or used for direct connection with other equipment.
Attention:*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.*

7 - MAINTENANCE AND SERVICES

7.1 - Electrical Connection

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.
Only the equipment's power cable must be connected to the network.

Note:

- *Use somente cabo original, fornecido pela Avanutri.*
- *Um correto aterramento e uma tomada de alimentação em boas condições são fundamentais para o funcionamento seguro do equipamento.*

7.2 - Product Installation

Before 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.

Water Circulation Unit, Connection Hose and Wrap.

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 Bag.
3- Clean and sanitize all equipment (Water Circulation Unit, Connection Hose and Envelope).
4- Connect the Connection Hose to the Water Circulation Unit.
5- Connect the Connection Hose to the Wrap.
6- Pour water into the tank up to the fill line inside the tank (1.5 liters of water).
7- Add ice to the reservoir up to the upper limit.
8- Connect the 12V 4A Power Supply to the Water Circulation Unit.
9- Make the electrical connection, as provided in the “Electrical Connection” item of this topic.

Water placement and ice (see label)

Power Source Connection 12V 4A power supply

7.3 - 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, in order to resolve it as quickly as possible.

Problem	Solution
Display issues on the LCD screen	Check that the Power Cable is correctly connected to the electrical network and 12V 4A Power Supply; Check if the 12V 4A Power Supply plug is connected to the Unit of Water Circulation. Verificar se o botão On/Off está desligado. Turn off the 12V 4A Power Supply and turn the equipment on again after 2 min.
Circulation failure water and compression of air.	Check whether the equipment is connected to the electricity network; Check if the On/Off button is off. Check that the Play/Pause button is not activated
Circulation failure water.	Check if there is water in the Water Circulation Unit reservoir. Check that the water filter is not blocked. Clean the Filter as below • Remove the filter by disconnecting it from the reservoir hose. • Enxugar a tela externa do filtro, logo após certificar de que não exista nenhum sinal de sujeira que possa obstruir a passagem de água. ***Note:*** *Replace the filter if necessary with an original part.*

7.4 - Preventive Maintenance and Conservation (maintaining basic security)

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

• External cleaning/disinfection of equipment

• Replacement of water in the Water Circulation Unit reservoir

• Checks in general, provided for in this item of the Manual

Authorized Technical Assistance is responsible for the following activities:

• General operational review (check for internal leaks, check the hydraulic circuit, pneumatic circuit and electrical circuit, etc.)

• Calibration of pressure and flow indicators.

• Qualquer reparo nas partes internas do equipamento.

Preventative maintenance of this equipment must be carried out in accordance with the tables below:
General review of operation (hydraulic circuit and electrical/electronic circuit, pneumatic circuit).

Descrição	Periodicidade
General review of operation (hydraulic circuit and electrical/electronic circuit, pneumatic circuit)	Anual
Calibration of pressure and flow indicators	Anual

Authorized Technical Assistance
Contact the factory to indicate the nearest Authorized Technical Assistance.

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

7.5 - 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 – EQUIPMENT CLEANING AND ASEPSY

Usual or regular cleaning and asepsis must be carried out before the first use and at the end of each session.
To clean the external equipment, use water and neutral detergent or enzymatic detergent, removing excess water with a clean cloth.
Follow the manufacturer's instructions and precautions for the cleaning agent you select.
Optionally, the system (water circulation unit, hoses and wraps) can be sanitized using a cloth with a mixture of isopropyl alcohol and water. **Never use solvents.**

Cleaning procedure for Water Circulation Unit:

• Apply the selected cleaning product to a soft cloth and rub all surfaces of the water circulation unit.

• Allow the water circulation unit to dry completely before storing it in the bag.

• The control unit must be cleaned as necessary.

Cleaning procedure for connectors and hoses:

• Apply the selected cleaning product to a soft cloth and rub all surfaces of the connectors and hoses.

• Dry completely before storing in the bag.

Wrap cleaning procedure:

• Carefully remove the heat exchanger (wrap) and its outer cover.

• Hand wash the cover and heat exchanger (Wrap) in cold water, using a neutral detergent or antibacterial soap. Do not use fabric softener or bleach.

• Hang to dry naturally. Do not use a clothes dryer.

Attention:

• Before starting the asepsis and cleaning process, make sure that the equipment's Power Cable and 12V 4A Power Supply are disconnected from the electrical network;

• Never allow any type of liquid to infiltrate 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 7.3. 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 Avanutri customer service or email sac@avanutri.com.br or telephone (24) 2252-2468.**

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.
CRYO SPORT 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 1:** 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 becomes necessary, this and other equipment should be observed to ensure that they are operating normally."*

***"WARNING 2:** 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."*

***"WARNING 3:** Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm to any part of the CRYO SPORT, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment may occur."*

***Note:** The EMISSIONS 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 alter the water circulation or compression characteristics of the treatment bag.
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
CRYO SPORT is intended for use in the electromagnetic environment specified in Table 1 below.
***Note:** The customer or user of CRYO SPORT must ensure that it is used in such an environment.*

TABLE 1 - Electromagnetic Emission according to NBR IEC 60601-1-2:2017

Emissions Tests	Conformity	Electromagnetic environment - orientation
CISPR 11 RF Emissions	Group 1	CRYO SPORT uses RF energy only to its internal functioning. Therefore, its emissions RF are very low and are not likely to cause any interference with electronic equipment Upcoming.
CISPR 11 RF Emissions	Class A	CRYO SPORT is not suitable for installation in buildings, including domestic ones, and those directly connected to the public low voltage network, but only in buildings like hospitals with the dedicated power system.
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker Emissions IEC 61000-3-3	Not applicable	

11.2 - Electromagnetic immunity

CRYO SPORT 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 being used in this type of environment.*

TABLE 2 - Electromagnetic immunity according to NBR IEC 60601-1-2:2017

Immunity assays	Test Level and of Compliance	Compliance Level	Environment Orientation electromagnetic
Electrostatic discharge (ESD) IEC 61000-4-2	**By contact:** ±8kV **Through the air:** ± 15 kV	**By contact:** ±8kV **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
Electrical transients rapid/Pulse train ("Burst") IEC 61000-4-4	**Provides:** ± 2 KV / 100 KHz **Communication:** ± 1 KV / 100 Khz	**Provides:** ± 2 KV **Communication:** ±1 KV	The quality of the electrical current should be similar to that of a hospital or typical commercial environment.
AC Outbreaks IEC 61000-4-5	**Line by Line:** ± 0,5 kV, ± 1 kV **Line to Earth:** Not applicable to Equipment Class II	**Line by Line:** ± 1 kV **Line to Earth:** Not applicable to Equipment Class II	The quality of the electrical current should be similar to that of a hospital or typical commercial environment with surge protection.

Immunity assays	Test Level and of Compliance	Compliance Level	Environment Orientation electromagnetic
Voltage drops, short interruptions and voltage variations in Source input line feed IEC 61000-4-11	**Voltage drop:** 100% (0% UT) by 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100% (0% UT) for 1 cycle 30% (70% UT) for 25/30 cycles **Voltage interruption:** 0%UT; 250/300 cycles **Note:** UT is the voltage of AC power before application of the level of rehearsal.	**Voltage drop:** 100% (0% UT) by 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100% (0% UT) for 1 cycle 30% (70% UT) for 25/30 cycles **Voltage interruption:** 0%UT; 250/300 cycles	The quality of the electrical current should be similar to that of a hospital or typical commercial environment. If the CRYO SPORT user requires continued operation during power outages, it is recommended that the CRYO SPORT 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.
magnetic field in power frequency declared(60Hz) IEC 61000-4-8	30A/m 60Hz	30A/m 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial environment or hospital environment.
Conducted disturbances field-induced of RF IEC 61000-4-6	3 V r.m.s. 0.15MHz up to 80MHz 6 V r.m.s. in ISM bands and amateur radio 0.15MHz up to 80MHz Modulation: 80% AM at 1 kHz	3 V r.m.s. 0.15MHz up to 80MHz 6 V r.m.s. in ISM bands and amateur radio 0.15MHz up to 80MHz Modulation: 80% AM at 1 kHz	Portable and mobile RF communications equipment should not be used for any part of the CRYO SPORT, including cables, than the calculated separation distance recommended from the equation applicable to the transmitter frequency. Recommended Separation Distance
RF EM Fields Irradiated IEC 61000-4-3	3V/m 80 MHz up to 2.7 GHz Modulation: 80% AM at 1 kHz	3V/m 80 MHz up to 2.7 GHz Modulation: 80% AM at 1 kHz	$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$
Fields nearby of equipment for wireless communication by RF IEC 61000-4-3	385MHz to 5785MHz Assay Specifications for IMMUNITY CABINET INTERFACE to equipment for wireless communications by RF (see table 3).	385MHz to 5785MHz Assay Specifications for IMMUNITY CABINET INTERFACE to equipment for wireless communications by RF (see table 3).	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 Mhz $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz up to 2.7Ghz

Ensaios de imunidade	Nível de Ensaio e de Conformidade	Nível de conformidade	Orientação de ambiente eletromagnético
			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: 

UT is the a.c. supply voltage. before applying the test level

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 absorption and reflection of 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 accurately. To assess the electromagnetic environment due to fixed RF transmitters, a electromagnetic assessment of the site. If the measured field strength in the location where CRYO SPORT is used exceeds the applicable RF compliance above, it must be observed that the CRYO SPORT is operating normally. If a abnormal performance, it may be necessary to take additional measures such as reorienting or repositioning the CRYO SPORT.

(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; 26.957 MHz to 27.283 MHz; 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 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 Mhz, 18.07 MHz at 18.17 MHz, 21.0 Mhz to 21.4 MHz, 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.

TABLE 3: IMMUNITY to fields in the vicinity of equipment RF wireless communication

Freq.	Band (MHz)	Service	Modulation	Power Maximum (W)	Distance (m)	Level of rehearsal	Level of conformity
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 5KHz	2	0,3	28 V/m	28 V/m
710 745 780	704 -787	Banda 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; Band 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; Banda LTE 1,3,4,25; 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 802.11a/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 CRYO SPORT.
CRYO SPORT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the CRYO SPORT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CRYO SPORT, as recommended above, in accordance with the maximum output power of the RF communications equipment. communications.

Calculation of Maximum output of transmitter (W)	Separation distance according to transmitter frequency (m)			
	150KHza80 MZ Outside the bands of the ISM and amateur radio $d = [\frac{3.5}{V_1}]\sqrt{P}$	150KHza80 MZ Inside the ISM bands and amateur radio $d = [\frac{12}{V_2}]\sqrt{P}$	80MHza800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHza2.7GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	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

Note1: *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 2: *Between 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note 3: *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 NBR IEC 60601-1-2:2017 indicate that in cases of voltage surges, drops or variations, 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

AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA guarantees this product for a period of 2 years. 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 guarantee will be valid for the period specified above, counting from the date of acquisition 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 AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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 product serial number is tampered with, erased or damaged;

d) Defects or unsatisfactory performance are caused by the use of accessories that do not comply with the technical specifications of AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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 AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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 AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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 AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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:
AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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.
AVANUTRI EQUIPAMENTOS DE SAÚDE LTDA 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

MADE IN CHINA

Green Fit Recovery, Lda.
Avenida Engenheiro Duarte Pacheco, Torre 2, 8 andar, Sala 10, Zip Code: 1070-102 Lisboa, Portugal;
ID number: 518096700
Resp. Técnico: Rodrigo Santana