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ADAMO ROBOT - V 1.0

Instruction For Use



Document Code: IFU ADM-001 Version: 03 Date: 01/10/2024

Page **2** de **44**

Table of contents

INTRODUCTION	5
ADMINISTRATIVE DATA	6
Product identification	6
Manufacturer data	6
STATEMENS AND TESTING	7
Statement of delivery of the Instruction manual	7
Testing and Commissioning Certificate	8
STATEMENT AND MEDICAL DEVICE	11
GENERAL	12
Symbols	12
Importance of this manual	12
State "Machine Off"	13
Specification of Expected Clinical Benefits	13
Indications, Contraindications and Warnings	14
Indications	14
Contraindications	15
Warnings	16
Authorized operators	18
Intended Purpose	18
Intended Users	18
Intended Patient Population	18
Operator in charge of handling	18
Mechanical/Electrical/Pneumatic maintenance technician	18
Safety representative	18
Manufacturer's technician	19
All rights reserved	19
Warranty	19
TECHNICAL DESCRIPTION	21
Name of parts	21
Dimensions of the machine	23
Technical data	23



Document Code:	
IFU ADM-001	

Version: 03

Date: 01/10/2024

Page **3** de **44**

	Intended use of the machine	. 24
	Environmental Conditions	. 24
	Energy supply	. 24
	Products used for the operation	. 24
TI	RANSPORTATION AND HANDLING	. 25
	Transportation of the machine	. 25
	Packaging	. 25
	Handling of packaging with a forklift or trans pallet	. 27
	Unpacking	. 27
	Manual handling of the machine	. 27
	Positioning of the machine	. 27
IN	ISTALLATION	. 29
	General warnings	. 29
	Electric connection	. 29
SA	AFETY	. 30
	Safety devices	. 30
	Personal Protective Equipment (PPE)	. 31
	Electro Magnetic Compatibility (EMC)	. 31
	Residual Risks	. 32
	Safety Signs	. 33
U	SE AND OPERATION	. 34
	Places occupied by authorized operators	. 34
	Prior to Ignition	. 34
	Installation and Connection. Operational Requirements	. 35
	Turning on the machine	. 35
	Use of the Machine	. 35
0	N SCREEN MESSAGES	. 38
	Collision	. 38
	Activating motors	. 38
	Robot in Fail (rearm needed)	. 39
	Internal Temperature Level	. 39
	Repeat the point	. 40
	Communication error	. 41



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 4 de 44

Violation error	41
Security error	
MAINTENANCE	
Cleaning	43
Every week	
Every year	43
Extraordinary maintenance	44
DECOMMISSIONNIG	45
Storage	45
Demolition	45
SPARE PARTS	45
HISTORY OF MODIFICATIONS	46



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 5 de 44

INTRODUCTION

Dear Customer, first of all, we wish you to thank you for the confidence you gave us by purchasing your new world of an automated physiotherapy system ADAMO ROBOT.

We are sure that your expectations will be met given the level of technology achieved by our products with a continued commitment to improve on a daily basis and encourages us to grow and to implement constant improvements on the technology, manufacturing and sales.

We feel that your purchase will give you the meet the requirements you expect and please feel free to contact us whenever you need assistance, or you think you're not getting the best of your ADAMO robot. We will be happy to offer you all our experience and knowledge to answer any question you may have.

INFORMATION TO THE CUSTOMER			
DOCUMENT	PAGE	TO DO	
STATEMENT OF DELIVERY OF THE INSTRUCTION MANUAL	7	The authorized operators must complete and sign to confirm the delivery and reading of instruction manual	
TEST AND COMMISSIONING CERTIFICATE	8	Give to the test technician of the Manufacturer or the Authorized Dealer a copy of page 6 Completed in all its parts.	
PRODUCT REGRISTATION FOR WARRANTY VALIDATION	19	See paragraph "WARRANTY"	



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 6 de 44

ADMINISTRATIVE DATA

Product identification

Brand name	ADAMO ROBOT®		
EMDN code	Z120602- Physiotherapy equipment		
UDI-DI	843702389701		
Risk class	Class IIa	Rule/s	9, 11

Manufacturer data

ADAMO ROBOT S.L. SRN: ES-MF-000028921 Tel (+34) 914 170 457 sales@adamorobot.com

Fiscal address

C/ Miguel Villanueva 2, 2D 26001 Logroño -Spain

Main office

C/ Manuel Tovar 49, 28034 Madrid -Spain

Contact person regarding this document

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Document Code:	
IFU ADM-001	
Version: 03	
Date: 01/10/2024	
Page 7 de 44	

STATEMENS AND TESTING

Statement of delivery of the Instruction manual

The employer, to the extend required by applicable law on safety and health of workers at work, herby declares it has delivered to the authorized operators this Instructions For Use for the correct information and training on use and maintenance of the machine.

AUTHORIZED OPERATORS	DATE	SIGNATURE FOR RECIEPT



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 8 de 44

Before filling in the table, make a copy for future reference.

Testing and Commissioning Certificate	DATE:		
Designation: ADAMO Robot	Name:		
Model:	Street:		
Serial No:	City:		
Manufacture Year:	State:		
This is to certify that the machine in question was tested by: Test technician of the manufacturer or authorized dealer: Name:			
At the presence of the entrusted operator: Name: At the presence of the entrusted operator and Sa Name:	fety Representative:		
Check for proper installation of the machine			
☐ Verification of the correct setting of all the wo	orking parameters.		
☐ Verification of correct operation and interven	tion of all the safety devices.		
Commissioning and performance of a work cy	cle.		
Possible optimization of the working paramet	ers.		
Machine Stop.			
☐ Delivery of the instruction manual.			
SIGNATURE Test Technician of the Manufacturer or Authorized Dealer	Safety Representative		



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 11 de 44

STATEMENT AND MEDICAL DEVICE

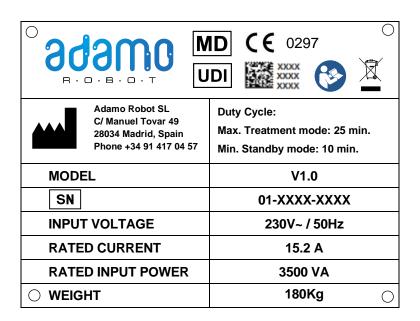
The CE marking of the machine indicates compliance with the essential occupational health and safety rules set forth by the European Directives listed in the Declaration of CE Conformity.

The label is laser printed on a stainless-steel sheet and has the following dimensions:

Length = 104 mm - Height = 180 mm - Width = 1 mm

It is applied externally on one side of the machine indicated in Fig. 1 and states the following data, in a legible manner:

- ADAMO ROBOT LOGO, MD, CE, UDI, CE,
- NAME, ADDRESS OF MANUFACTURER
- DESIGNATION OF THE MACHINE (MODEL)
- SERIAL NUMBER (model-mmyy-unit)
- INPUT VOLTAGE / Frequency (V~/Hz)
- RATED CURRENT (A)
- RATED INPUT POWER (VA)
- WEIGHT (Kg)



For any inquiries, assistance, or technical support, please feel free to reach out to us using this previous contact details.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 12 de 44

GENERAL

Symbols

SYMBOL	TITLE	STANDARD
C € 0297	CE Mark – Notified Body	MDR 2017/745
MD	Medical device	N/A
UDI	Unique device identifier	N/A
SN	Serial number	ISO 7000-2498
	Manufacturer	ISO 7000-3082
	Refer to IFU	ISO 7010-M002
	Generic warning	ISO 7010:2003-W001
	WEEE label	Directive 2012/19/EU
Ţ	Fragile, handle with care	ISO 7000-0621
*	Keep dry	ISO 7000-0626
<i>X</i>	Temperature Limit	ISO 7000-0632
XXXX XXXX XXXX	UDI-DI GS1 DataMatrix	EAN-13
	Hot Surface	ISO 7010-W017
0	Signal of Generic obligation	N/A
	User or operator in charge	N/A
Θ	General Forbidden symbol	N/A

Importance of this manual



Before using the machine, the Intended Users and Authorized Operators are obliged to read and thoroughly understand this manual in all its parts.

This instruction for use has been prepared in accordance with the directions provided by the European Directives in order to ensure an easy and correct understanding of the topics covered by the authorized operators operating and maintaining the machine in question. If, despite the attention being paid by the manufacturer while drafting this document, such operators should not fully understand this text while reading, they are requested to ask the manufacturer for the correct explanations and information in order to avoid incorrect personal interpretations that



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 13 de 44

may jeopardize safety. Before using the involved machine, the authorized operators are obliged to read and understand all parts of this manual and adhere strictly to the rules herein described in order to assure their own and others' safety, the best performance of the machine and ensure the maximum efficiency and durability of all its components. This manual shall be available at any time for the authorized operators and shall be well protected and preserved, always close to the machine.



This manual should always be available for Intended Users and Authorized Operators and located in the vicinity of the machine well protected and preserved.

This manual must compulsorily be delivered together with the machine when it is transferred to another user.

The manufacturer disclaims all liability for injury to persons, animals and/or property caused by ignoring the rules and warnings described in this manual.

This manual reflects the state of the art of technique at the time of the machine marketing and cannot be considered improper just because, according to new experience, it may be updated later on.

In case of loss or damage of the manual request a copy to the manufacturer, specifying the identification data of the document: code, issuance and review.

State "Machine Off"

Before performing any type of maintenance and/or setting on the machine, disconnect the power supply ensuring that the power switch (18) is in position "OFF (0)", the plug of the power cable (15) is unplugged and placed near the machine and the tank has been drained from residual compressed air by opening the drain valve (12).

Specification of Expected Clinical Benefits

ADAMO ROBOT® intended purpose is to support users in alleviating musculoskeletal pain and enhancing movement and daily function in patients, through physiological effects on muscle tension and neural signalling.

This medical device is intended to be a tool to alleviate pain caused by musculoskeletal diseases applying continuous compressed air pressure mixed with an additional jet of hot air. Clinical studies promoted by ADAMO ROBOT S.L. are demonstrated that patients treated with ADAMO ROBOT® experienced a significant relief after their 10th session:

- 26% of improvement according to ODI (Oswestry Disability Index) questionnaire for Back
 Pain Assessment Scale
- 40% of improvement according to VAS (Visual Analogue Scale) scale.

These scales are internationally used for researchers to measure the level of patient's disabilities and are considered the golden standard of low back functional outcome tools.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 14 de 44

Indications, Contraindications and Warnings Indications

The ADAMO ROBOT® indications are:

- a) Regarding patient clinical conditions, the use of ADAMO ROBOT® is adequate in the following cases:
 - Myofascial pain syndrome: Supports the reduction of muscle tension and alleviates discomfort linked to myofascial pain, a condition commonly associated with chronic pain syndromes.
 - Trigger points: Assists in deactivating trigger points and alleviating localized muscle pain in areas of chronic muscle stiffness.
 - Cervical, dorsal, and low back pain: Suitable for managing pain in the neck, upper back, and lower back that is related to muscular tension, stiffness, or myofascial restrictions.
 - Tendinopathies: Applicable in cases of tendon inflammation and discomfort (such as rotator cuff or patellar tendinopathy), aiding in pain reduction and functional recovery.
 - Chronic muscular tension: Effective in reducing persistent muscle tension and spasms, as seen in conditions like tension headaches or stress-related muscle pain.
 - Soft tissue stiffness: Indicated for improving flexibility and movement in soft tissues with restricted range of motion due to scarring, fibrosis, or chronic stiffness.
 - Postural dysfunctions: Beneficial for managing muscular discomfort associated with postural imbalances (e.g., forward head posture, rounded shoulders), where prolonged tension and muscular imbalances contribute to pain.
 - General musculoskeletal discomfort and overuse syndromes: Suitable for alleviating discomfort in conditions arising from repetitive strain or overuse (e.g., office-related muscle pain, sports overuse injuries).
 - Age and ability to cooperate: ADAMO ROBOT® is primarily indicated for adults between 18 and 60 years of age who can cooperate during treatment and remain in the appropriate position throughout the session.
- b) Regarding the environmental conditions:
 - ADAMO ROBOT® is exclusively designed for use indoor, in hospitals, physiotherapy clinics, rehabilitation centers, and other authorized medical facilities. It is not intended for home use, outdoor use, or non-clinical settings.
 - ADAMO ROBOT® shall be placed on a flat surface that ensures stability in relation to the overall dimensions and weight respecting the minimum position referred in of the instructions for use.
 - ADAMO ROBOT® is intended to be used in the following environmental conditions:

Temperature	Relative	Atmospheric	Electronic
	Humidity	Pressure	Disturbances
20-28°C	70%	70-100 KPa	According EMC ISO standards

ADAMO ROBOT® indications regarding environment



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 15 de 44

c) Regarding type of movement

As described in section 2.3.16.1 Configurations, the robotic arm has five different type of movements, one for each mode. In the table below, it is described the indications for each type of movement.

Manual mode	Point by point mode	On arch mode	Lineal mode	Pendular mode
The user moves the arm by himself. When a free movement is required		When continuous air pressure is applied to specific points. Heat may be added or not.	Continuous air pressure with optional heat is applied along a pre- established points maintaining pressure in both directions for the set of number of cycles	Continuous air pressure, with optional heat is applied back and forth along pre-established points, maintaining pressure in both directions for the set number of cycles

ADAMO ROBOT® indications regarding robotic arm movement

Contraindications

The use of ADAMO ROBOT is contraindicated in the following situations

a. General contraindications:

- Its use is contraindicated in patients under 18 years or over 60 due to the lack of safety data in these populations.
- Open skin lesions or dermal involvement: Treatment should not be applied to areas with open wounds, burns, dermatitis, eczema, or any other active skin condition, as compressed air could penetrate tissues and lead to complications such as the formation of air bubbles in the body.
- Fever and systemic infections: Patients with fever or systemic infections should not undergo treatments with Adamo Robot, as the application of pressure or heat could exacerbate the underlying condition.
- Severe circulatory disorders: Treatment is contraindicated in patients with severe vascular diseases such as deep vein thrombosis or chronic venous insufficiency, where pressure could increase the risk of complications.
- Recent surgeries: Patients who have undergone recent surgeries in the treatment areas should avoid using the device until healing is complete and the physician approves it.
- Severe skin allergies: Patients with allergic skin conditions should avoid treatment on affected areas, as the pressure could aggravate the reaction.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 16 de 44

- Bleeding disorders: Patients with bleeding disorders, such as haemophilia, or who are taking blood thinners, should avoid applying pressure, as it could increase the risk of bleeding or bruising.
- Pregnancy: Although massage therapy may be safe during pregnancy in certain circumstances, the application of pressure and heat to the abdominal or lumbar area during pregnancy should be avoided.
- Sensitive areas and body orifices: Compressed air should not be applied near the eyes, ears, nose, mouth, or other orifices of the body. Air pressure in these areas can cause serious injuries, such as eye damage, perforation of the eardrum, or the introduction of air into cavities where it can lead to infections or embolisms.

b. Specific contraindications related to the use of hot air

- Acute inflammatory diseases: Although the air emitted does not reach dangerous temperatures, patients with acute inflammatory diseases (such as acute rheumatoid arthritis) may still experience an exacerbation of symptoms due to the application of moderate heat.
- Severe neurological alterations or altered sensitivity to heat: Patients with peripheral neuropathies, multiple sclerosis or diabetes with neuropathy should be closely monitored, as they may not correctly perceive temperature changes, even if they are minor.
- Cancer: Heat is not recommended near areas with tumours or where radiation therapy has been given, because of the risk of affecting the tissues involved.
- Metal implants or electronic devices: Although the maximum temperature does not exceed normal body temperature highly, heat applied near metal implants or electronic devices could affect the patient's perception or interfere with these devices.
- Heat sensitivity: Patients with conditions such as Raynaud's disease or other diseases that respond negatively to heat should avoid applying any type of heat, even moderate.

c. Specific contraindications related to the use of air at room temperature

 Cold sensitivity: Patients with conditions such as cryoglobulinemia or cold urticaria should not be treated with room temperature air, as the sensation of decompression cooling could exacerbate these disorders.

Warnings

Users of ADAMO ROBOT® shall observe the following warnings when using the device

• For a thorough understanding of device functionality, the user shall read the instructions for use in its entirety before starting to use the device.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 17 de 44

- Before using the equipment, users are required to be trained. Do not use ADAMO ROBOT® if you are not trained for it.
- The user shall verify that the patient remains immobile during the treatment to ensure its correct application.
- The ADAMO ROBOT® User Manual should always be available for authorized operators and be located close to the device, well protected and preserved.
- ADAMO ROBOT® generate loud noise during use. The use of hearing protection is required for users when a continuous use is made.
- Some patients (around 5% of the population) may experience physical urticaria related to stimuli such as heat or changes due to a decrease in temperature caused by heat dissipation, potentially causing an itching sensation, which is generally temporary and minor. This itching sensation can create discomfort for sensitive patients. For first-time use, patients should be appropriately monitored.
- During treatment, some dispersed air outside the target area may cause a mild cooling sensation for the patient. To ensure comfort, it is recommended to inform the patient about this possibility and cover non-treated areas to minimize unintended cooling.
- ADAMO ROBOT® is intended to be used during a maximum of 25 minutes/session. If several sessions are performed, a rest time of 10 minutes among sessions shall be observed. Other conditions of use can lead to equipment overheating.
- ADAMO ROBOT® complies with requirements regarding EMC safety; however, even though the device is compliant at the levels of immunity specified in the standards, certain devices (as magnetic resonance imaging, MRI) emits interferences that can affect its performance if it is placed too close to these equipment or electrical power sources. Users shall be aware of this possibility and do not use the device close to this devices.
- Keep the device away from water and humidity to avoid electrical hazards.
- These devices shall be conserved and checked as outlined in the instructions for use.
- Do not use the device if defective and contact the manufacturer as soon as possible. Only authorized and qualified personnel can make maintenance or modifications in the device. The user shall have sole responsibility for any malfunction due to maintenance operations performed by anyone not trained by ADAMO ROBOT S.L.
- Each user has a user name and password to access to ADAMO ROBOT®. User name and password ensure privacy and confidentiality of patient data. Do not share with other persons.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 18 de 44

Authorized operators



THE OPERATORS ARE AUTHORIZED TO MAKE ON THE MACHINE ONLY SPECIFIC **ACTIONS OF THEIR COMPETENCE.**

THE AUTHORIZED OPERATORS, BEFORE PERFORMING ANY WORK ON THE MACHINE MUST BE SURE TO BE IN POSSESSION OF FULL PSYCHO-PHYSICAL CAPACITIES, SUCH AS TO ENSURE COMPLIANCE WITH THE SAFETY CONDITIONS.

This technical manual is intended for Users according to specific technical and professional skills required for the type of use or intervention and for Authorized Operators for the maintenance of machine. The symbols below are arranged at the beginning of a chapter and/or paragraph, to indicate which is the operator concerned with the subject matter.

Intended Purpose



ADAMO ROBOT® is intended to support users in alleviating musculoskeletal pain and enhancing movement and daily function in patients, through physiological effects on muscle tension and neural signalling.

Intended Users



ADAMO ROBOT® intended users are rehabilitation healthcare professionals trained by the manufacturer in the device use.

Intended Patient Population



ADAMO ROBOT® is intended to be used in adult patients, according to intended indications (see Section 2.3.10.1 Indications of this document) and who are not involved in the contraindications (see Section 2.3.10.2 Contraindications) of this document, and

who can benefit from pressure and temperature-based therapies, under the supervision of a trained rehabilitation healthcare professionals.

Operator in charge of handling



It is a professionally trained operator, authorized to perform only the ignition, use, setup, tuning (with the mandatory protection enabled and the machine turned off) and the turning off the machine and in total respect of the instructions in this manual, equipped with personal protective equipment (PPD) specified and occupying the places (see

related paragraph).

Mechanical/Electrical/Pneumatic maintenance technician

It is a qualified technician, authorized to perform actions only on the mechanical/electric/ pneumatic parts to make adjustments, and maintenance and/or repairs, even with the protections disabled (upon consent of the Supervisor) in strict compliance with the instructions in this manual or other document specifically provided exclusively by the manufacturer, equipped with personal protective equipment (PPD) specified and occupying the places described (see related paragraph).

Safety representative

It is a qualified engineer appointed by the customer in possession of technical and professional qualifications required by the regulations on safety and health of workers in the workplace.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 19 de 44

Manufacturer's technician

It is a qualified technician made available by the manufacturer and/or authorized dealer to perform the required technical assistance, routine work and extraordinary maintenance and/or operations not mentioned in this manual that require specific knowledge of the machine, equipped with personal protective equipment (PPD) specified (see related paragraph).

All rights reserved

The reserved rights related to this instruction manual (IFU) are in the possession of the manufacturer. All information (text, drawings, diagrams, etc.) given here is confidential. No part of this manual may be reproduced and distributed (in whole or in part) by any means of reproduction (photocopy, microfilm or otherwise) without the written consent of the Manufacturer.

All trademarks are property of their respective owners.

Warranty

- 1) WARRANTY DECLARATION: The Manufacturer gives an undertaking to the End-User to replace, repair or otherwise intervene in the machine, if it has conformity defects that compromise its correct use and operation, but only if such defects are attributable to the actual liability of the Manufacturer. The Manufacturer reserves the right to adopt the optimal solution to restore the conformity of the machine within a reasonable period. The warranty does not cover parts of the Products subject to normal wear and tear and/or deterioration or defects resulting from inappropriate transport.
- **2) END-USER:** The End-User is the person who buys the machine to use it directly. The End-User who buys the machine as a natural person for purposes that do not fall within the scope of commercial or professional activity is defined as a "consumer". The End-User is defined as a "professional or company" when the purchase is made by a professional or by a company acting for purposes which fall within the scope of its commercial or professional activity.
- **3) TERMS:** The Manufacturer is liable to the End-User when the lack of conformity occurs within the following terms from the date of purchase:
 - 24 months if the purchase was made by a 'consumer' as described in point 2).
 - 12 months if the purchase was made by a "professional or company" as described in point 2).

All End-Users have the right to extend the warranty (Extended Warranty) for up to three years from the date of purchase of the machine if they: (a) have registered their purchase with the Sales department of ADAMO Robot and (b) have completed the registration form completely and accurately, filling in the required fields with exact, complete and true information and have kept the registration code to be mentioned in the event of problems. Replaced parts or products will remain under warranty until the original product warranty expires.

4) VALIDITY: The warranty is valid if the End-User notifies the Manufacturer of the conformity defect within 2 months from the date on which he has discovered it, but within the final term



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 20 de 44

indicated in point 3) above. The above report must be accompanied by a regular purchase document (tax receipt or invoice). In the case of an Extended Warranty, the declaration must also indicate the registration code.

- **5) FORFEIT:** The warranty will be void if the purchaser uses the machine improperly and/or not in accordance with the provisions of this "Instruction Manual" provided by the Manufacturer, or if the lack of conformity was caused by inexperience on the part of the purchaser or by chance. The use of the products after the discovery of defects releases the Manufacturer from any warranty commitment or liability.
- **6) LIABILITY:** The Manufacturer is released from any liability resulting from any damage sustained by the purchaser, resulting from loss or diminution of production which derives from any lack of conformity.
- **7) COSTS:** The End-User has the right to the restoration of the conformity of the machine under warranty without any costs for labor or materials. The shipping methods must be agreed with the authorized dealer or with the Manufacturer. If the non-conformity is only apparent, or the complaint arrives after the deadline, the Manufacturer may charge the cost of both transport and any repair that is indicated by the authorized dealer or the Manufacturer.



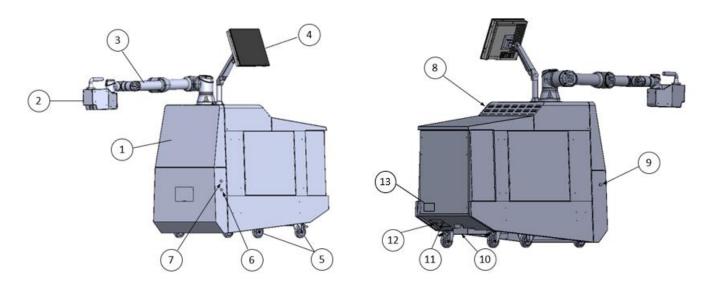
Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 21 de 44

TECHNICAL DESCRIPTION

All the specifications shown in this section corresponds to the **ADAMO ROBOT V1.0**:

Name of parts

The medical device ADAMO ROBOT® is composed of the key functional elements laid down:



DAMO ROBOT® key functional components

Code	Element	Description	Supplier
1	Metal enclosure	Painted galvanized sheet metal chassis	SAPEMI
2	End effector	Painted aluminium enclosure	SAPEMI
3	Robotic Arm	Collaborative Robot UR5e for programmable treatment positioning	Universal Robots
4	Panel PC Screen	User interface Touch Screen Panel PC	Advantech
5	Rear rotating wheels	Swivel castor with wheel brake	Tente
6	Temperature selector	Three position (low, med and high) manual temperature selector	Eaton
7	Temperature button	Temperature selection confirmation button	Eaton
8	Cooling Fan	Air extraction fans for internal enclosure cooling	Sunon
9	Detention button	Treatment detention button	Eaton
10	Condensation water container	Compressed air condensation humidity collector	SAPEMI

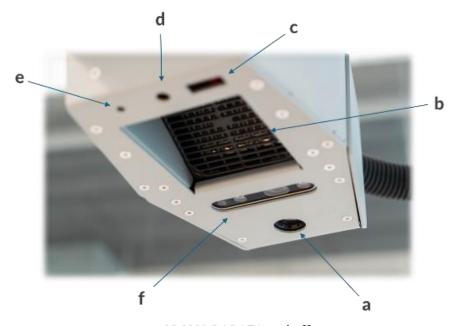


Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 22 de 44

11	Electric power supply plug	Panel mounted power male connector	Schurter
12	Main power switch	Green illuminated green power switch	Arcoelectric
13	Label	Inox sheet CE Label	Graincas

ADAMO ROBOT® list of key functional components

On the other hand, inside the end-effector there are the following main components:



ADAMO ROBOT® end-effector

Code	Element	Description	Supplier
a	Thermal camera	High resolution thermographic camera	Teledyne Flir
b	Air Heater	Compresses air heater	Stego
С	Safety proximity sensor	Near patient detection sensor	Pepperl+Fuchs
d	Compressed air outlet nozzle	Treatment air precision output nozzle	Silvent
е	Laser cross indicator	Treatment point laser indicator	Laserfuchs
f	3D volumetric and colour camera	Patient body contour measurement	Intel RealSense

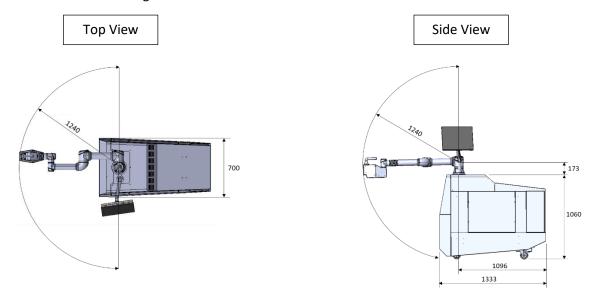
ADAMO ROBOT® end-effector list of components



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 23 de 44

Dimensions of the machine

The following figure shows the clearances of the machine and for the movements of the robotic arm. Al dimensions are given in mm.



Technical data

ADAMO ROBOT V1.0		
Power Supply (VAC / Hz)	230 / 50	
Electric Consumption (A)	15,2	
Input Power (VA)	3500	
Max. Air Pressure (Bar)	6	
Air flow output (I/min)	230	
Air flow intake (I/min)	415	
Noise Level (dB)	78	
Weight (kg)	180	



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 24 de 44

Intended use of the machine

The machine was designed and built for the use described in the next table.

FIELD OF USE	MEANING	
PLACE OF USE	Places indoors with sufficient lightning, ventilation and contract temperature conditions having the characteristics referred in "Tech Data" appropriate to the laws in force in the country of use for safety health in the workplace. The machine must be placed on a surface ensures stability in relation to the overall dimensions and weight, respet the minimum position shown in "POSITIONING THE MACHINE". YOU MUST KEEP THE MACHINE OUT OF REACH UNAUTHORIZED PERSONS.	
INTENDED USE	ADAMO ROBOT® is intended to support users in alleviating musculoskeletal pain and enhancing movement and daily function in patients, through physiological effects on muscle tension and neural signalling.	
OPERATORS IN CHARGE OF USE	ADAMO ROBOT® intended users are rehabilitation healthcare professionals trained by the manufacturer in the device use.	
NON- CONTINUOUS OPERATION		

Environmental Conditions

ENVIRONMENTAL CONDI	TIONS
Min – Max ambient Temperature (°C)	20 - 28
Max. Relative Humidity (%)	70
Atmospheric Pressure (kPa)	70-100

Energy supply

ENERGY SOURCE	POWER SUPPLY	
ELECTRIC	Connection via plug on electrical switchboard (see "Technical Data").	

Products used for the operation

PRODUCT USE FOR OPERATION	
Ambient "clean" air, free of pollutants harmful to health.	



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 25 de 44

TRANSPORTATION AND HANDLING

Transportation of the machine

The machine is delivered to the customer through a "specialized transportation company" or by the manufacturer who, through its own personnel and appropriate means, in compliance with the regulations, shall ensure the operations of packaging, lifting, loading, transport and unloading in relation to the type of transport (land, sea or air).



ALL OPERATIONS OF LIFTING, LOADING, TRANSPORT AND UNLOADING OF THE MACHINE REQUIRE TO BE PERFORMED BY A "SPECIALIZED TRANSPORT COMPANY" OR BY THE MANUFACTURER WITH PERSONNEL AND MEANS SUITABLE FOR USE.

Packaging

The packaging is a wooden box supported by a pellet and it has been specifically designed to fit the machine inside of it.

The packaging contains:

- The ADAMO Robot
- An electric power cable
- Two (2) front wheel blocks
- The instruction manual
- A supplementary ramp

The characteristics of the packaging are indicated in the following table.

SPECIFICATION	VALUE
Packaging Weight	375 Kg
Pack Measurement	137 x 72 x 163 cm (Length x Width x Hight)

The packaging is labelled on the lateral sides as following:



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 26 de 44

(€ ▲		
SN 01-XXXX-00XX	MD	Physiotherapy Robot
Protect from rain.	0°C	ADAMO Robot SL C/ Manuel Tovar 49 28034 Madrid, Spain Phone +34 91 417 04 57

Preparin g the Device for Transportation

Before transporting the device, it is essential to follow a series of preparation steps to ensure the safety of the components during the journey. The main tasks involve releasing the compressor pressure and disconnecting the automatic compression motor. Follow the steps below to properly prepare the device for transport.

Steps for preparing the device for transport:

- 1. Turn off the device, ensuring that the robotic arm is in resting mode (the head and arm should be retracted into their standard position, as shown in the following image).
- 2. Disconnect the power cable.
- 3. Open the rear cover (use an Allen key for M5 screws) and remove the four screws on the cover where the label is located.
- 4. Disconnect the automatic switch as shown in the image.
- 5. Reattach the rear cover by securing the screws.
- 6. Open the side cover on the same side as the PC panel.
- 7. Locate the compressor tank drain valve and open it. Wait a few minutes until the tank is completely empty (check the pressure gauges located on the right side of the side opening).
- 8. Close the drain valve.
- 9. Close the side cover and reattach the two screws.

BEFORE ANY TRANSPORT BY LAND, SEA, OR AIR, IT IS ESSENTIAL TO FOLLOW THE PREPARATION STEPS, INCLUDING RELEASING THE REMAINING COMPRESSOR PRESSURE AND DISCONNECTING THE AUTOMATIC AIR COMPRESSOR SYSTEM. Failure to do so may result in damage to the device during transportation.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 27 de 44

Handling of packaging with a forklift or trans pallet

IT IS MANDATORY THAT, IN THE RANGE OF HANDLING OPERATIONS, THERE ARE NO PEOPLE, ANIMALS AND/OR THINGS WEHOSE SAFETY CAN BE COMPROMISED ACCIDENTALLY.

THE HANDLING OF THE PACKAGE CAN BE PERFORMED ONLY BY THE USE OF A TRANSPALLET OR FORKLIFT SUITABLE FOR USE.



IT IS MANDATORY, DURING THE LIFTING OPERATIONS (UP/DOWN), NOT TOMAKE SUDDEN MANOUVERS AFFETING THE STABILITY OF THE LOAD.

- 1) Insert the forks under the pallet, keeping them at the center of the latter.
- 2) Raise the packaging a few centimeters to make sure the load is actually centered in the forks.
- 3) Carefully move the package to the positioning area expected, therefore lowering the load until full stability is reached.

Unpacking

THE MANUAL HANDLING OF THE MACHINE MUST BE DONE BY AT LEAST TWO OPERATORS IN CHARGE, OR USING A SUITABLE MEAN, IN ACCORDANCE WITH THE REGULATIONS OF THE "MANUAL HANDLING OF LOADS", IN ORDER TO AVOID ADVERSE CONDITIONS THAT INVOLVE RISK OF ERGONOMIC INJURIES TO THE BACK OR OTHER PARTS OF THE BODY.

After laying the packaging on the ground do the unpackaging as follows:

- 1) Unlock the toggle latch catch clamp haps.
- 2) Carefully open the lateral door down until the ramp touches the floor.
- 3) Put the supplementary ramp following the slope of the ramp of the door.
- 4) Unlock the brakes of the back wheels below the machine.
- 5) Pull the machine out of the box through the slope until the four wheels touches the ground.

Manual handling of the machine

THE MANUAL HANDLING OF THE MACHINE MUST BE DONE BY AT LEAST TWO (2) OPERATORS IN CHARGE, OR USING A SUITABLE MEAN, IN ACCORDANCE WITH THE REGULATIONS OF THE "MANUAL HANDLING OF LOADS", IN ORDER TO AVOID ADVERSE CONDITIONS THAT INVOLVE RISK OF ERGONOMIC INJURIES TO THE BACK OR OTHER PARTS OF THE BODY.

Positioning of the machine

Once on the ground, the machine can be moved freely to avoid collision with any object or uneven floors. Once the machine is in its final location the brakes of the back-side wheels must be locked (see section "Name of parts").

To avoid undesired movements during operation, the front wheels should be blocked with the wheel blocks supplied with the machine as shown in the following picture.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 28 de 44



The blocks are approximately the same length of the machine so the blocks must be placed manually such that both wheels are blocked from each side.

IN ORDER TO ENSURE THAT THE AUTHORIZED OPERATORS OCCUPY THE WORK POSITIONS EXPECTED, IT IS MANDATORY TO ENSURE MINIMUM MEASURES OF POSITIONING AS SHOWN IN SECTION "DIMENSIONS OF THE MACHINE".



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 29 de 44

INSTALLATION

General warnings



IT IS COMPULSORY TO COMPLY WITH THE CORRECT PROCEDURES ASSEMBLY/DISASSEMBLY AND CONNECTION OF COMPONENTS DESCRIBED IN THIS CHAPTER.

THE MANUAL HANDLING MUST BE IN COMPLIANCE WITH THE REGULATIONS ON THE "MANUAL HANDLING OF LOADS" IN ORDER TO AVOID ADVERSE CONDITIONS THAT INVOLVE RISK OF INJURIES TO THE BACK.

ALL OPERATIONS DESCRIBED BELOW ARE DONE TO PREPARE THE MACHINE READY FOR THE OPERAT ION.

Electric connection



THE MANUFACTURER HAS NO LIABILITY FOR FAILURE OR MALFUNCTIONS OF OPERATION TO THE MACHINE CAUSED BY VOLTAGE DROPS EXCEEDING THE TOLERANCES PROVIDED BY THE DISTRIBUTING BODY (\pm 10% POWER - FREQUENCY \pm 2%).

THE MAINS TO WHICH THE MACHINE IS CONNECTED MUST BE IN ACCORDANCE WITH THE REQUIREMENTS OF THE LAWS OF THE COUNTRY OF USE, MEET THE SPECIFICATIONS CONTAINED IN "TECHNICAL DATA" (p.17) AND BE PROVIDED WITH A SUITABLE GROUNDING SYSTEM.

IT IS COMPULSORY TO INSTALL THE UPSTREAM OF THE POWER SUPPLY LINE AN ELECTRIC CUTTING DEVICE WITH A SUITABLE DISCONNECTING PROTECTION COORDINATED WITH THE GROUNDING PLANT.

IF NECESSARY, IT IS COMPULSORY TO CONNECT THE MACHINE ONLY TO GENERATORS OF ELECTRICITY WITH A POWER GREATER THAN THE POWER SUPPLY INSTALLED, TO SUPPORT THE ABSORPTION CURRENT UPON STARTUP.

FAILURE TO FOLLOW THE WARNINGS ABOVE MAY CAUSE IRREVERSIBLE DAMAGE TO THE ELECTRIC EQUIPMENT OF THE MACHINE AND THE SUBSEQUENT VOID OF THE WARRANTY.

THE ELECTRIC CONNECTION MUST HAVE A PROTECTIVE EARTH FOR A PROPPER OPERATION.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 30 de 44

SAFETY



IN THE EVENT OF ANY SERIOUS INCIDENT RELATED TO THE USE OF THIS PRODUCT, THE USER OR PATIENT MUST IMMEDIATELY INFORM THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE WHERE THEY ARE LOCATED.

Safety devices

The Safety Devices adopted are as follows (for the references on the drawings, please see section "Name of Parts"):

REF.	DESCRIPTION	FUNCTION
1	UR5e cobot overload detection system.	While operating, the robotic manipulator has the capability to stop when it detects a certain amount of force applied to it. This prevents any harmful damage to itself and to the users that could block the robot's movement or push it unintentionally.
2	End-effector proximity detection system.	The lower plane of the end-effector has a proximity sensor which, during the treatment, stops the compressed air output whenever an object or gets to less than 5mm from it. This would prevent any blockage or harmful damage to the end-tool and to the user <i>e.g.</i> , in case of sudden movement of the patient during the treatment.
3	Cooling fans protection grids (8).	It is a fix guard that consists of a metal grid at the top of the machine's cabinet. It prevents accidental contact with the cooling fans. IT IS COMPULSORY NOT TO COVER THE COOLING FANS PROTECTION GRIDS.
4	Internal overheating thermal protection	In case of internal overheating caused by the malfunctioning to the elements or because the cooling fan protection grids have been covered unintentionally, the system will stop automatically if temperature reaches 50°C and reset when it reaches a safe working temperature.
5	Treatment Stop button (9)	This button stops the treatment and returns the cobot to its initial position. It avoids any contact of the cobot with the user in case he decides to stand up during the course of a treatment.



IT IS COMPULSORY TO CONSTANLY CHECK THE GOOD FUNCTIONING AND EFFICEINCY OF ALL THE SAFETY DEVICES IN THIS MACHINE.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 31 de 44

IT IS COMPULSORY TO REPLACE ANY SAFETY DEVICES MALFUNCTIONING AND/DAMAGED.



IT IS FORBIDDEN TO MANIPULATE, EXCLUDE, REMOVE AND/OR REPLACE ANY SAFETY DEVICE IN THIS MACHINE.

IT IS ABSOLUTELY FORBIDDEN TO REPLACE ANY SAFETY DEVICE OF COMPONENET WITH NON-ORIGINAL SPARE PARTS.

Personal Protective Equipment (PPE)

The use of Personal Protective Equipment (PPE) is mandatory, in accordance with the legislation on safety and health in the workplace regulations of the country of use of the machine.

SIGN	PPE REQUIRED	TYPE OF APPLICATION
	Protection of hands (protective gloves against thermal hazards)	During installation, handling and
	Protection of feet (shoes with reinforced toe).	maintenance.
	Ear Protection Required.	During treatment mode and in normal use.



IT IS COMPULSORY TO USE THE PPE SUGGESTED BY THE MANUFACTURER ACCORDING TO THE TABLE ABOVE.

Electro Magnetic Compatibility (EMC)

ADAMO Robot conform to the EN60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be considered:

- The use of accessories and cables other than those supplied or specified by ADAMO ROBOT, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- During use (or measurement), portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by ADAMO ROBOT. Otherwise, degradation of the performance of the device could result.
- The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 32 de 44

The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- In certain occasions, when short voltage interruptions happen a protection magnetothermic circuit braker in the air compressor inside the machine cuts off. It doesn't represent any risk to the user but prevents to keep the pressure of the treatment air.

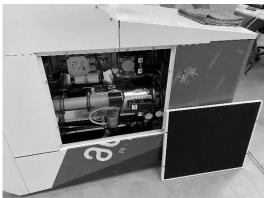


ONLY FOR QUALIFIED MAINTENANCE TECHNITIAN CONTACT SUPPORT INTERNAL COMPONENTS MAY BE HOT



In this case circuit braker should be rearmed manually following the next steps.

- 1) Turn off the machine following the steps described in "Turning off the machine".
- 2) Remove the side cover



3) Push the rearm button of the circuit breaker



4) Install again the side cover and turn on the machine again

Residual Risks

The authorized operator must remark that, although the manufacturer has taken every precaution technically possible to make the machine safe, in order not to compromise the functionality and productivity of the machine, there are several residual risks related with the use of the device. All of them are addressed in this document as CONTRAINDICATIONS and



	Document Code:
	IFU ADM-001
ĺ	Version: 03
ĺ	Date: 01/10/2024
ĺ	Page 33 de 44

WARNINGS. Please, review carefully all CONTRAINDICATIONS and WARNINGS and follow instructions laid down in this document and shared with you during the user training. If you have any doubt about the use of the medical device, or the device is not working properly, DON`T USE IT and contact the manufacturer for complementary instructions.

Safety Signs

The safety signs used are constituted by an adhesive label, applied externally to the machine.



IT IS FORBIDDEN TO MANIPULATE, DAMAGE OR REMOVE THE SAFETY SIGNS APPLIED ON THE MACHINE.



IT IS COMPULSORY TO KEEP WELL CLEAN THE SIGNS IN ORDER TO ENSURE A GOOD VISIBILITY.

IT IS COMPULSORY TO REPLACE THE SAFETY SIGNS DETERIORATED, BY REQUESTING THEM TO THE MANUFACTURER AND/OR AUTHORIZED DEALER.

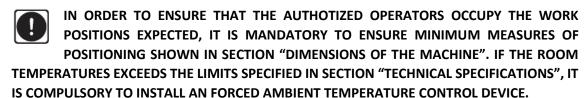


Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 34 de 44

USE AND OPERATION

Places occupied by authorized operators

The machine should be placed with the characteristics described in section "Intended use of the Machine", placed on a flat floor that ensures stability in relation to the overall dimensions and to the weight (see section "TECHNICAL DESCRIPTION").



Prior to Ignition



BEFORE TURNING ON THE MACHINE THE OPERATOR IN CHARGE MUST CHECK THE CONTROLS INDICATED IN THE FOLLOWING TABLE. ALL THE OBJECT ARE REFENCED ACCORDING TO THE IMAGES SHOWN IN SECTION "NAME OF PARTS".



No.	CHECK CONTROL	
1	Make sure that no unauthorized persons are near the machine.	
2	Make sure that the machine is properly positioned, and the brakes of the back wheels blocked (5) and the wheel blocks of the front wheel in their position.	
3	Make sure all connections are properly made.	
4	Make sure that to clean the lenses of the cameras placed at the lower plane of the end-effector (2) of the cobot (3).	
5	Ensure that switch (12) is in "OFF (0)" position.	
6	Use the Personal Protective Equipment (PPE) required.	
7	Make sure you have read and understood all parts of this "Instruction Manual".	
8	Make sure that after last use routine maintenance has been made.	



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 35 de 44

Installation and Connection. Operational Requirements

This product includes software that can only be executed on the ADAMO ROBOT® device and under no circumstances on external or third-party devices.

- **Device dimensions**: 0.7 m (width) x 1.38 m (length) x 1.55 m (height); 180 kg.
- **Minimum room dimensions**: 3 m x 4 m (preferably with some type of acoustic isolation).
- Connectivity: Ethernet, WIFI (2.4 GHz)*.
- **Power supply**: 230 VAC 3.5 KW 50 Hz.
- **Structure**: Movable structure (supported on wheels).
- Ambient temperature: Range of 20-28 °C (ventilated room).

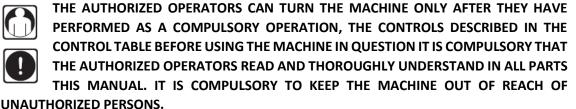
Internet availability and use is not essential for device operation, but it is highly recommended* to access all available features.



ADAMO ROBOT® HAS UNDERGONE RIGOROUS VULNERABILITY AND PENETRATION TESTING, THEREBY VALIDATING THE DEVICE'S SECURITY AGAINST UNAUTHORIZED ACCESS. IT IS ESSENTIAL THAT EACH USER CAREFULLY MANAGES THEIR ACCESS CREDENTIALS, USING SECURE AND UNIQUE PASSWORDS, AND LIMITS ACCESS STRICTLY TO AUTHORIZED PERSONNEL. ANY UNAUTHORIZED ACCESS CAN COMPROMISE SYSTEM SECURITY AND DATA PRIVACY.

Turning on the machine





Turn on the machine by setting the switch (12) in "ON (I)" position and the machine will automatically start running all the internal component checking procedures. Wait until the initial login image is shown in the screen (4) and follow the instructions.

If after 15 min the login input does not appears the screen contact the maintenance technician.

Use of the Machine



ONLY THE AUTHORIZED OPERATORS CAN MAKE USE OF THE MACHINE AND ONLY AFTER THEY HAVE PERFORMED THE COMPULSORY TRAINING SESSIONS PROVIDED BY THE MANUFACTURER OR THE SUTHORIZED DEALERS. IT IS COMPULSORY TO KEEP THE MACHINE OUT OF REACH OF UNAUTHORIZED PERSONS.

The authorized operator must use the machine following the instructions shown on the screen.

Before starting a treatment, the operator must check that the cobot is in its initial safe position which avoids any contact with the patient. The treatment must always be made with a stretcher and the patient must always be laying head down. The following image shows the cobot in its initial safe position and the recommended position of the stretcher.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 36 de 44

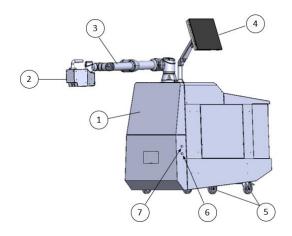


The stretcher must be placed in front of the machine and once checked that the robot is in its initial position the patient can lay down on the stretcher. It is recommended to use a stretcher with adjustable height.

The patient must always be completely still and must not move during the whole treatment.

If by any circumstance the patient wants to stop the treatment it must push the "STOP" button. The "STOP" button pauses the treatment and the cobot returns automatically to its initial safe position. The Authorized operator can resume or stop the treatment following the instructions on the screen.

The temperature of the compressed air is initially set by the authorized operator during the configuration of the treatment. The user can also modify the temperature of the compressed air by turning the nob (7) to the required position and pressing the manual control temperature button (6). The machine will keep the manually selected temperature until the end of the treatment.





Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 37 de 44

After the treatment is finished the robot always returns to its initial safe position.

In any case, the authorized operator must check that the cobot is in its initial safe position before the patient could move.

Even though the machine can be turned "On" permanently if a treatment last for more than 25 minutes it is recommended to wait 10 minutes before starting a new treatment.4



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 38 de 44

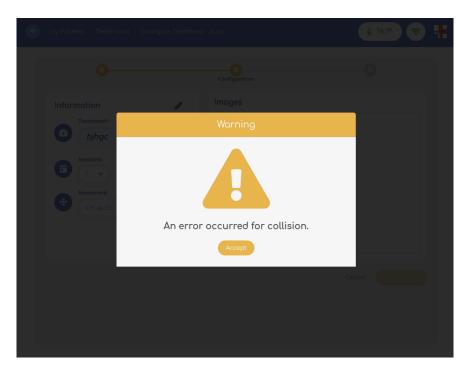
ON SCREEN MESSAGES

List of errors:

- Collision
- Activating motors
- Robot in Fail (rearm needed)
- Internal Temperature Level
- Repeat the point
- Communication error
- Violation error
- Security error

Collision

When the robot detects that the end-effector (2) of the robot is closer to patient that the appropriate treatment distance the robot will stop and show the following message in the screen.



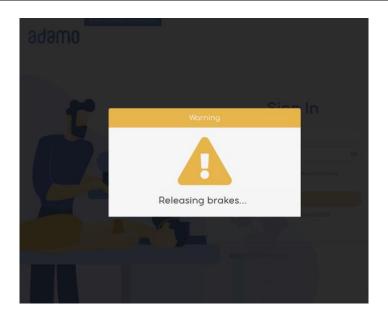
In this case the user must select the Accept button on the screen to continue.

Activating motors

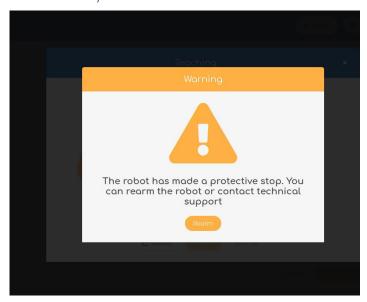
The robot's motors are currently being activated. It is essential to wait until the activation process is complete before proceeding with any tasks or operations involving the robot.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 39 de 44



Robot in Fail (rearm needed)



The different assumptions in which the robot will adopt security positions are explained below:

- If during a treatment session the patient or the staff touch the robot
- If during the "Teaching" stage (definition of the myofascial points when creating a new treatment) the robot detects a sudden and abrupt movement
- If the robot tries to reach a position out of its range

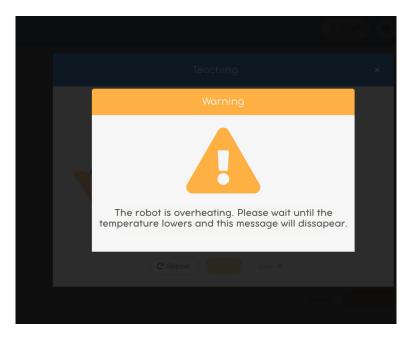
Click rearm to proceed.

Internal Temperature Level

If the internal temperature of the machine reaches up to 50°C, the machine will stop, and the following warning message will show on screen. When the temperature lowers down to 40°C the treatment machine will go back to operation.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 40 de 44



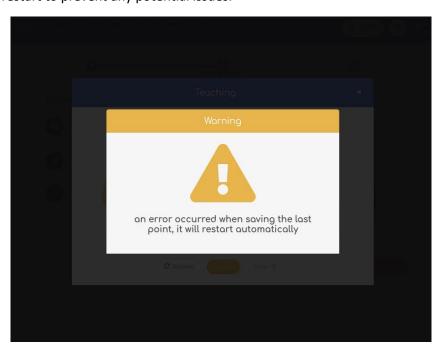
If the error temperature doesn't decrease the following conditions should be checked:

- The ambient temperature of the room should comply with technical specifications.
- The cooling fans protection grids are not covered.

If these conditions are met and the machine continues to overheat contact technical support.

Repeat the point

It has been implemented a screen that triggers an error message in the event of attempting to save the same points as the previous ones during the Teaching step. This error prompts an automatic restart to prevent any potential issues.

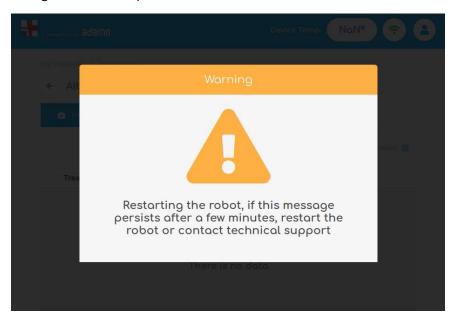




Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 41 de 44

Communication error

There is an error message indicating a communication failure between the PC panel and the PLC. This issue may arise due to a malfunction or disruption in the communication link between the control panel and the programmable logic controller (PLC) responsible for coordinating the robot's operations.

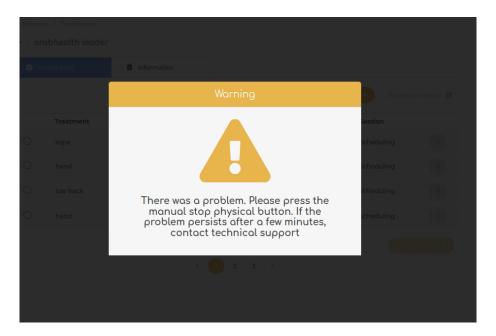


Violation error

There is also a critical error message indicating a violation in the robot's controller due to a misalignment or improper positioning of the robot. This error arises when the robot's movements deviate from the designated path or when it encounters an obstacle, causing a breach in its operational parameters. Such violations pose a significant risk to the safety and integrity of the robot system, potentially leading to equipment damage or hazardous situations in the treatment environment.

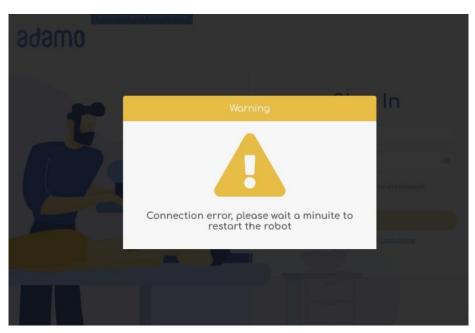


Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 42 de 44



Security error

A security error has been detected within the robot controller system. To ensure the safety and integrity of the system, it is recommended to restart the robot controller after a minute of waiting.





Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 43 de 44

MAINTENANCE

This is the set of activities designed to maintain the conditions of use and operation of the machine, through various types of intervention (adjustments, visual inspection, recovery levels, etc.) performed by the maintenance technician or by the manufacturer's technician at the frequency forecast.



THE AUTHORIZED OPERATORS SHOULD PERFORM ONLY THE MAINTENANCE WORKS REQUIRED IN ACCORDANCE WITH THEIR SPECIFIC PROFESSIONAL COMPETENCE AND UPON CONSENT OF THE SUPERVISOR IN CHARGE.



IT IS FORBIDDEN TO AUTHORIZED OPERATORS TO LEAVE THE MACHINE WITHOUT SUPERVISION DURING THE MAINTENANCE WORKS. THEY SHOULD ALSO PROTECT THE PLACE OF WORK WITH ADEQUATE NOTICE OF DANGER AND PROHIBITION FOR **WORKS IN PROGRESS.**

All maintenance operations must be performed when the machine is turned off according to the steps described in "Turning off the Machine"

Cleaning

All the surfaces of the machine can be cleaned with water, isopropyl alcohol or alcohol with 10% of ethanol.

To clean any trace of dirt of the surface of all components of the machine use a soft cloth avoiding getting moisture through the openings.



Do not use harsh chemicals, strong detergents nor bleach.



Do not rub or hit the surface with anything hard or sharp as this may permanently damage the surface of its components.

Every week

At the end of the workday, dispose the condensation liquid from the collection container (10).

- Turn off the machine following the steps described in "Turning off the machine".
- 2) Remove the water collection container (10) pulling it from the back side of the machine.
- 3) Dispose the liquid.
- 4) From the back side of the machine, push the container again to its position ensuring that the draining hose stays inside the container.



You must dispose of the condensation liquid in compliance with the regulations of the country of use.

Every year

Only made by the Manufacturer's Technician the machine must be subjected to annual maintenance process keep the optimum working conditions.



Document Code:	
IFU ADM-001	
Version: 03	
Date: 01/10/2024	
Page 44 de 44	

To maintain the compressor in optimum conditions it must have the following maintenance using only manufacture's spare parts:

- Replacement of air sterilization filter
- Replacement of humidity filter

Extraordinary maintenance

This is the set of activities designed to maintain the conditions of use and operation of the machine, through various types of intervention (adjustments, changes, etc.) performed by qualified technicians in the event of failure or wear.



FOR ANY INTERVENTION OF EXTRAORDINARY MAINTENANCE IT IS COMPULSORY TO REQUIRE THE TECHNICAL ASSISTANCE TO THE MANUFACTURER OR AUTHORIZED DEALER.



Document Code:
IFU ADM-001
Version: 03
Date: 01/10/2024
Page 45 de 44

DECOMMISSIONNIG

Storage

In the event that the machine should be stored for some time, you must place it in a safe environment, with a proper degree of temperature, humidity and protected from dust.

Demolition

Upon demolition of the machine, strictly follow the requirements in force in the country of demolition.

Proceed to the differentiation of the parts that make up the machine according to the different types of construction materials (plastics, copper, iron, etc.).

These products must be considered pollutants and hazardous charging licensed contractors and disposed of by appointing specialized companies for different types of products.



ALL PART S OF THE MACHINE MUST BE IDENTIFIED ACCORDING TO THE DEFINITIONS OF "CER CODES" (EUROPEAN WASTE CATALOGUE) AND DISPOSED OF BY **INSTRUCTING AUTHORIZED AND SPECIALIZED COMPANIES, IN STRICT COMPLIANCE** WITH THE REGULATIONS IN FORCE IN THE COUNTRY OF DEMOLITION OF THE MACHINE.



WASTES OF ELECTRICAL AND ELECTRONIC EQUIPMENT (RAEE) MUST BE DISPOSED OF IN STRICT COMPLIANCE WITH THE REGULAT IONS IN FORCE IN THE COUNTRY FOR THE **DEMOLITION OF THE MACHINE.**

SPARE PARTS



GENUINE PARTS FOR ANY SUBSTITUTIONS MUST BE REQUIRED ONLY TO THE MANUFACTURER.

IT IS STRICTLY PROHIBITED THE USE OF NON-ORIGINAL SPARE PARTS.



Document Code:	
IFU ADM-001	
Version: 03	
Date: 01/10/2024	1
Page 46 de 44	

HISTORY OF MODIFICATIONS

	MODIFICATION HISTORY		
Edition No.	Date	Change made	
1	02/03/2024	Initial edition	
2	19/09/2024	Updated Technical description section. Header, sign, sterilization aclaration, adress	
3	01/10/2024	ID name Administrative Data Indications, Contraindications and Warnings Installation and Connection. Operational Requirements	