

AVIOR

Ankle and knee joints rehabilitation device

USER GUIDE

V.2.0.R2

Basic UDI-DI 5903918WDAVI-0001U9





1. INTRODUCTION

Wishing you satisfaction of AVIOR usage, we thank you for your choice.

AVIOR device is a response for the patients who are suffering from crurotalar and knee joint disfunctions Due to its adaptavity it enables to perform independent movements: flexion, extension, abduction, adduction and multidimensional movement of the foot and also flexion and extension of the knee. Construction of AVIOR device enables the complex crurotalar and knee joint rehabilitation based on self-assisted, active and resistance exercises.

This manual provides all the needed information concerning AVIOR device proper functioning.

The manufacturer is entitled to change the content of the manual when it's needed. The updated version of the manual will be available to download from the manufacturer's website www.termamed.pl from the "Downloads" section.

Manufacturer:

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2. EXPLANATIONS OF SYMBOLS

It is mandatory to read the safety statements before using the device. The safety statements are classified as follows:



Safety warnings and essential usage details.



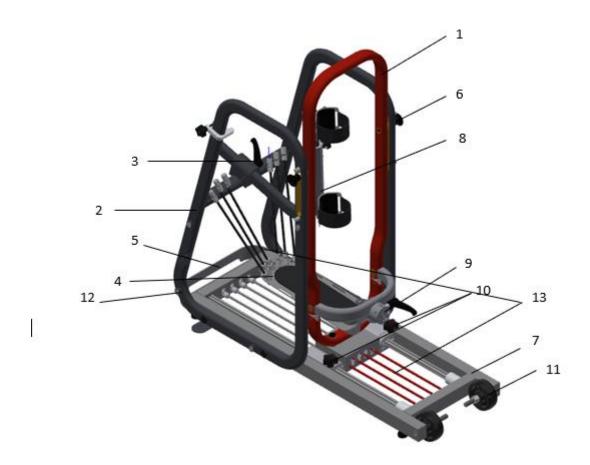
Safety of exploitation warnings. Unless followed, may result in minor personal injury and/or product/property damage.



Mark of the active part of the device described on the illustrated scheme and explained in table.

3. DESCTIPTION OF THE DEVICE STRUCTURE

Versatility of AVIOR possible settings enables to perform the therapy of various disfunctions of crurotalar joint. The structure of the device is explained on the model below.



The list of components:

1	Lever	Adaptive element that enables to perform self-assisted exercised of the crurotalar and knee joint.
2	External frame	Base element enabling to attach other components.
3	Clamp lever 1,2,3	Clamp elements enabling to define the position of the shin stabilization (6).
4	Foot platform	Foot positioning element.
5	Transport handle	Handle that enables safe and comfortable transportation of the device info needed room.
6	Mounting pin	Adaptive element which installed in the lever (1) or external frame (2) enables to perform exercises of the knee joint. When the mointing pin is removed, exercises of the crurotalar joint can be performed.
7	Main frame	Base element that enables to attach other components.
8	Shin stabilization	Shin stabilisation positioning element.
9	Abduction and adduction knob	Clamps defining the position of the foot platform against the saggital axis of the device.
10	Reciprocating movement lock	Clamps defining the position of the foot platform against the rail.
11	Wheel	Element that enables safe and comfortable transportation of the device info needed room.
12	Adjustable mounting element	Positioning element with possibility to adjust the height of the shin stabilization in the structure of the device. This element is compatible with the shin stabilization (8).
13	Expanders	Weight defining elements enabling to perform resistance exercises (not mentioned on the model).

4. Indications

AVIOR device is dedicated for adults. It is dedicated for kinesiotherapy post traumatic injuries.

- Injuries to ligaments and cartilage,
- Muscle and ligament strains,
- Twists of the crurotalar joint,
- Dislocations in the area of crurotalar joint,
- Breaks of the crurotalar joint,
- After knee joint arthroscopy.

The device is dedicated to be used in rehabilitation facilities and at home on the basis of a loan from the facility. The condition for safe and effective use is the constant supervision of a physiotherapist over the course of exercises, ranges of motion and the applied resistance.

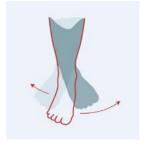
ADVISED FORMS OF THERAPY

The device is delivered to the customer in the form of the device that does not require any adaptation to start operation.

The device enables to perform the following exercises:



Flexion and extension of the ankle



Pronation and supination of the ankle



Flexion and extension in the knee

Exercises can be performed in a following manner:

- Plantar flexion and dorsiflexion of the ankle self assisted, active and resistance,
- Pronation and supination of the ankle active and resistance,
- Flexion and extension of the knee self assisted and resistance.

Ranges of motion

- 40 degrees dorsiflexion
- 35 degrees plantarflexion,
- 31 degrees pronation and supination,
- 40 degrees extension of the knee,
- 30 degrees flexion of the knee.

Flexion and extension of the knee

Performing exercises of flexion and extension of the knee needs the following settings od the device:

- Abduction and adduction knob locked (9),
- Reciprocating movement knob (10) unocked,
- Mounting pins (6) installed,
- Shin stabilization (8) removed.

The device is equipped with a set of expander rubbers dedicated to resistance exercises at the last stage of therapy. The manufacturer provides one set of rubber bands in the set for the exercise. Rubbers are delivered in 3 different colors, depending on the place of installation in the device and therapeutic purpose.

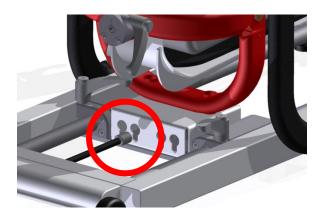
- black ankle exercises,
- red flexion of the knee,
- gray extension of the knee.





To perform the resistant exercises of the flexion and extension of the knee the set of expanders is needed to be installed according to the picture below:





Expanders installation to perform flexion and extension of the knee joint:

Expanders need to be installed in the dedicated sockets in the main frame (7). Pay attention to the proper location of the expanders, which should slide into the space of the smaller hole.

Dorsiflexion and plantarflexion of the ankle:

Performing exercises of dorsiflexion and plantarflexion of the ankle needs the following settings od the device:

- Abduction and adduction knob (9) locked,
- Reciprocating movement knob (10) locked,
- Mounting pins (6) off,
- Shin stabilization (8) installed (clamp levers (3) closed).





To perform the resistant exercises of the dorsiflexion and plantarflexion of the ankle the set of expanders is needed to be installed according to the picture below:







<u>Expanders installation to perform</u> <u>dorsiflexion and plantarflexion of the ankle</u> <u>joint:</u>

Expanders need to be installed in the dedicated sockets in the foot platform (4). The sleeve at the end of the expander must fit the wider hole. Slide the sleeve to the space of the smaller hole.

Pronation and supination of the ankle joint:

Performing exercises of pronation and supination of the ankle needs the following settings od the device:

- Abduction and adduction knob (9) unlocked,
- Reciprocating movement knob (10) locked,
- Mounting pins (6) installed,
- Shin stabilization (8) installed (clamp levers (3) closed).





To perform the resistant exercises of the dorsiflexion and plantarflexion of the ankle the set of expanders is needed to be installed according to the picture below:







Expanders installation to perform dorsiflexion and plantarflexion of the ankle joint:

Expanders need to be installed in the dedicated sockets in the foot platform (4). The sleeve at the end of the expander must fit the wider hole. Slide the sleeve to the space of the smaller hole.



Therapeutic process realized with usage of AVIOR device is performed in sitting. The patient must be comforted while seated, with possibility to adjust the height of the seat.



It is advised that the angle between a thigh and shin was nearly 90° while the thigh is placed in parallel to the ground.



The platform of the foot and shin stabilization are equipped with belts fastening the foot in the structure of the device. Before the exercises are performed, the foot must be stabilized in the device.

6. WARNINGS

To ensure the highest safety of user's health it is necessary to read and follow the warnings below.



Before usage it is necessary to read the user guide first and definitely follow the terms, advices and warnings.



User guide is also available at www.termamed.pl where tutorial videos are also uploaded.



The only entity allowed to service and technical reviews is a manufacturer TERMA Sp. z o.o. of a service pointed by a manufacturer. The manufacturer is not responsible for any improvement or repairs made by other parties.



In case of any incidents which causes damage on the patient's health, it must be reported immediately to the manufacturer. Additionally, it's advised to fill in such case "Incident aplication form" and send it by post or e-mail to the manufacturer. The form is a part of a user guide available also at www.termamed.pl in the "Downloads" section.

7. CONTRAINDICATIONS AND RECOMMENDATIONS

In order to ensure the highest comfort and safety during AVIOR device exploitation, please mention the contraindications to the therapy listed below:

- 1. Changes in the skeletal system, such as: unfused bones, injuries which do not allow for the implementation of the training.
- 2. If the patient anthropometric conditions do not allow for adjustment of the structure of the device.

It is recommended to use sportswear made of cotton for full range of motion.

AVIOR Ankle and knee rehabilitation device is a reusable device.

The elements of the device, with which the patient comes into contact, require disinfection each time after the end of the therapeutic session by each patient.

Cleaning the device should be performed with the use of soft, dry fabrics, or with the addition of clean water. For all products, it is forbidden to use abrasive materials that could damage the coating. Recommended disinfectants for delicate surfaces, containing alcohol.

8. TECHNICAL DETAILS

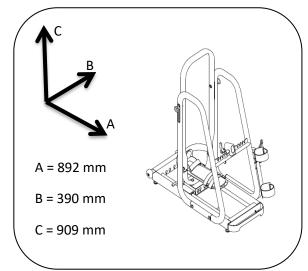
Manufacturer:

Terma Sp. z o.o. Model: **AVIOR** Version: V.2.0

Class:

Class I, Rule I

Dimensions:



Ranges:

Pronation and supination:

40°

Dorsiflexion and plantarflexion:

35°

Flexion and extension of the knee:

30/40°

Weight:

25 kg

9. WARRANTY

Terma Sp. z o.o. guarantees good condition and efficient operation of the device mentioned in the Warranty Card, hereinafter referred to as Product, according to the technical and exploitation details described in the user guide. Warranty confirms the responsibility of the entity who introduced the product to the market to free of charge removal of any faults of the product that was sold. The warranty does not limit or suspend buyer's rights resulting from nonconformity of the goods with the contract.

- 1. The warranty period starts on the day of receipt of the Product and is 24 months for the main structure of the device.
- 2. The free warranty repair shall be understood as the performance by the Guarantor during the warranty period of the specific activity appropriate for removing the defect covered by the warranty. This warranty covers Product defects caused by defective parts or defects in production. Warranty liability covers only defects caused by the underlying causes of the sale.
- **3.** The condition for the Buyer to use the rights given by warranty is to present at the time of the service request a total of:
- a. Deffective product,
- b. A proof of purchase.
 - **4.** The warranty will be done by the service during 14 working days from the date of acceptance the product to be repaired or from delivering it to the manufacturer's service to the address:

Terma Sp. z o.o.

Czaple 100, 80-298 Gdańsk, Poland 58 694 06 04, serwis-medyczne@termagroup.pl

5. The scope of warranty service does not cover the installation, commission and maintenance activities which, in accordance with the user guide, is required to performed by the user of the Product on his own.

Warranty repairs do not include periodic maintenance and product reviews, and in particular: cleaning, regulation, performance control, correction of operating errors or parameter programming, and other actions that the user is responsible for.

The warranty excludes cases of random damage independent of operating conditions (for example: thefts, accidents, fires, floods) and mechanical damage caused by improper use.

- 6. The Buyer, by submitting the Product to the Service, and in particular by sending it to third parties, shall provide him with a secure package. Any damage or damage to the Product resulting from its improper packaging shall be covered by the Buyer. Along with the Product, the Buyer shall include the exact description of the defect that causes the need of repair. The person submitting the complaint should provide his / her personal details: name, address, telephone number.
- 7. Guarantor chooses the best way to remove the defect. The Guarantor undertakes to remove physical defects free of charge by repair or replacement of the Product free of defects. Regardless of how defects are removed, the warranty continues.
- 8. Any faulty Products or parts exchanged under the guarantee become the property of Terma Sp. o.o.
- **9.** If only a part of the Product is defective and can be detached from the Product in accordance with the technical and operating conditions described in the user guide, the Buyer's right under these Warranty Terms shall be limited to the repair of the defective part of the Product only.
- 10. The Buyer has the right to exchange the Product for the new one, free from defects, if:
 - a. During the warranty period referred to in Section 1, the Service will carry out five warranty repairs and the Product will still reveal defects that prevent it from being used for its intended purpose, or
 - b. The service will confirm in writing that removal of the defect is impossible.
- **11.** User loses warranty rights in case of:
 - a. Statements of unauthorized alerts or corrections in the Guarantee Card made by unauthorized entities.
 - b. Statements made in the Product by unauthorized modifications or adjustments not expressly provided in the operating instructions.
 - c. Statements of attempted repairs and interventions by third parties.

- d. Statements of use of parts and materials not recommended by the Manufacturer and the Guarantor.
- **12.** The warranty does not support:
 - a. Damages caused by improper storage, transportation, failure to perform maintenance, periodic inspection.
 - b. Damages resulting from maintenance and repair work performed by the user in contravention of the user guide.
 - c. Damages caused by the user's fault or ignorance.
 - d. Product damages resulting from natural usage resulting from its use.
 - e. Damage caused by the user's fault or ignorance.
 - f. Damages caused by non-original spare parts or use of materials not intended for use with the Product.
 - g. Products whose Warranty Card or serial numbers have been altered, blurred or removed in any way.
 - 13. Warranty does not cover parts and materials whose consumption is a natural consequence of work, and these are, in particular, consumable items that are clearly consumed during the operation of the Product. Warranty rights do not include the buyer's right to demand the return of the lost profits in connection with the failure and repair of the Product.

INCIDENT APPLICATION FORM

In the event of an incident that results in damage to the equipment or injury to the patient, manufacturer must be immediately reported. After filling the "Incident application form," given below, it should be provided to the manufacturer by e-mail termamed@termamed.pl or posted and also to the service: murbanowicz@meden.com.pl.

Name of institution:
Adress:
Institution contact details:
Contact details of the patient involved in the incident:
Contact person name, surname, e-mail and phone number:
Date of the incident:
Date of the notification:
Description of the incident:

Inc	sident effects:	
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