



DRACO

Ankle joint rehabilitation device

USER GUIDE

V.2.0.R2

Basic UDI-DI 5903918WDDRA-0001QN



USER GUIDE
V.2.0.R2







1. INTRODUCTION

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

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

This manual provides all the needed information concerning DRACO 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:

Terma Sp. z o.o.
80-298 Gdansk
Czaple 100
Poland
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F: +48 58 695 05 06
email: termamed@termamed.pl
www.termamed.pl

Exclusive distributor:

MEDEN-INMED Sp.z o.o.
75-847 Koszalin
Wenedów 2
Poland
T: +48 94 347 10 40
F: +48 94 347 10 41
email: meden@meden.com.pl
www.meden.com.pl

Service:

MEDEN-INMED Sp.z o.o.
T: +48 94 344 90 48 / +48 600 693 741
F: +48 94 347 10 41
email: murbanowicz@meden.com.pl



2. EXPLANATIONS OF SYMBOLS

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

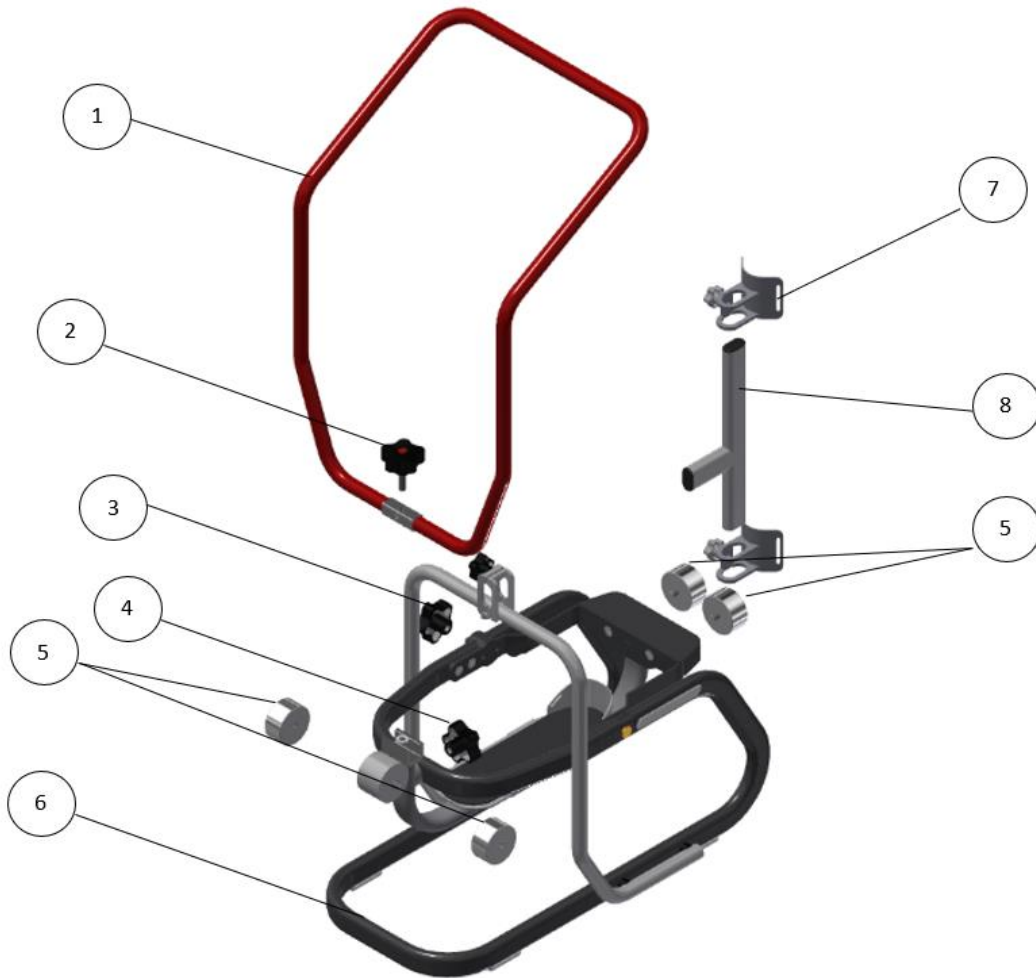


Safety warnings and essential usage details.



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

3. DESCRIPTION OF THE DEVICE STRUCTURE





The list of components:

No.	Element	Description	Amount
1	Lever	Adaptive element that enables to perform self-assisted exercised of the crurotalar joint. The lever can be separated through unscrewing the knob (2).	1
2	Knob V.1	A knob enabling the lever installation (1) in the structure of the device.	1
3	Knob H.1	A knob that locks/unlocks the option of flexion and extension of the crurotalar joint exercises.	1
4	Knob H.2	A knob that locks/unlocks the option of abduction and adduction of the crurotalar joint exercises.	1
5	Weight	Weight can be attached in one of four sockets in the structure of the main frame of the device. Weight is dedicated to resistance exercises performance.	4
6	Main frame	Retainer enabling the attachment of any other components of the device.	1
7	Shin stabilization	A component enabling to stabilize the shin in the structure of the device while performing exercises of the crurotalar joint.	2
8	Shin stabilization arm	A component setting the position of the shin stabilization (7).	1
9	Foot knob	A knob enabling to change the height of the foot in the structure of the device.	1

4. INDICATIONS

DRACO Ankle joint rehabilitation device is dedicated for adults. It is dedicated for kinesiotherapy post traumatic injuries

Indications:

- 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

in the ankle joint.

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.

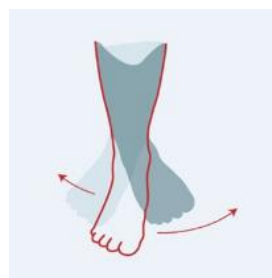
5. ADVISED FORMS OF THERAPY

The device is delivered to the customer folded. It needs to connect the lever (1) to the base frame (6) using the knob (2). Preparing for exploitation does not require using any tools.

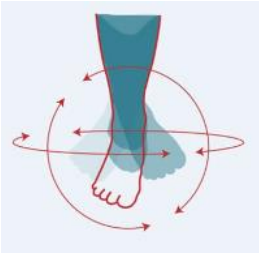
The device enables to perform the following exercises:



Flexion and extension of the ankle



Pronation and supination of the ankle



Multidimensional exercises

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.

Możliwe jest wykonywanie ćwiczeń w podanych poniżej zakresach:

47 degrees - dorsiflexion

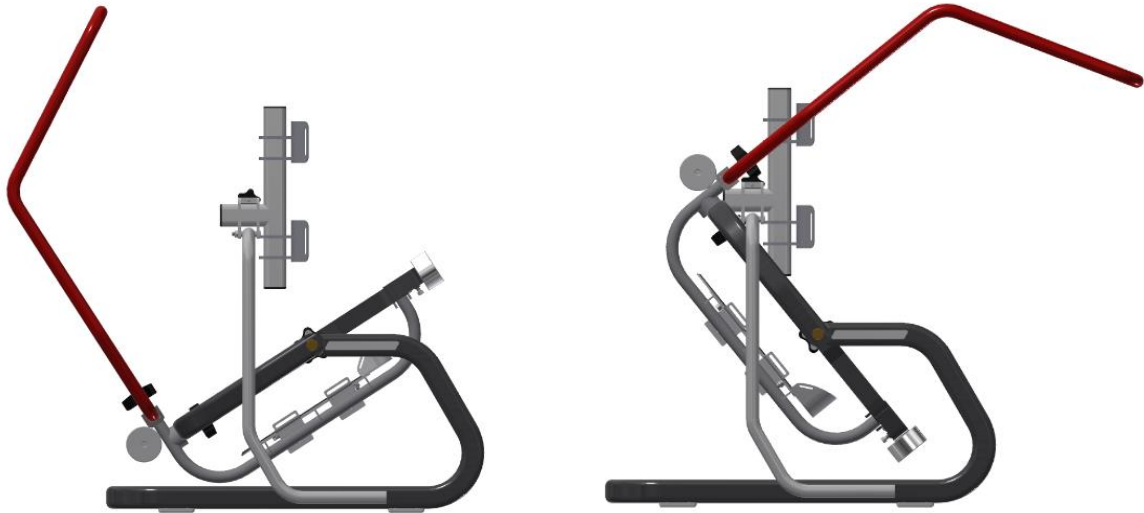
40 degrees - plantarflexion

34 degrees – pronation and supination

47, 40, 34 degrees – multidimensional exercises.

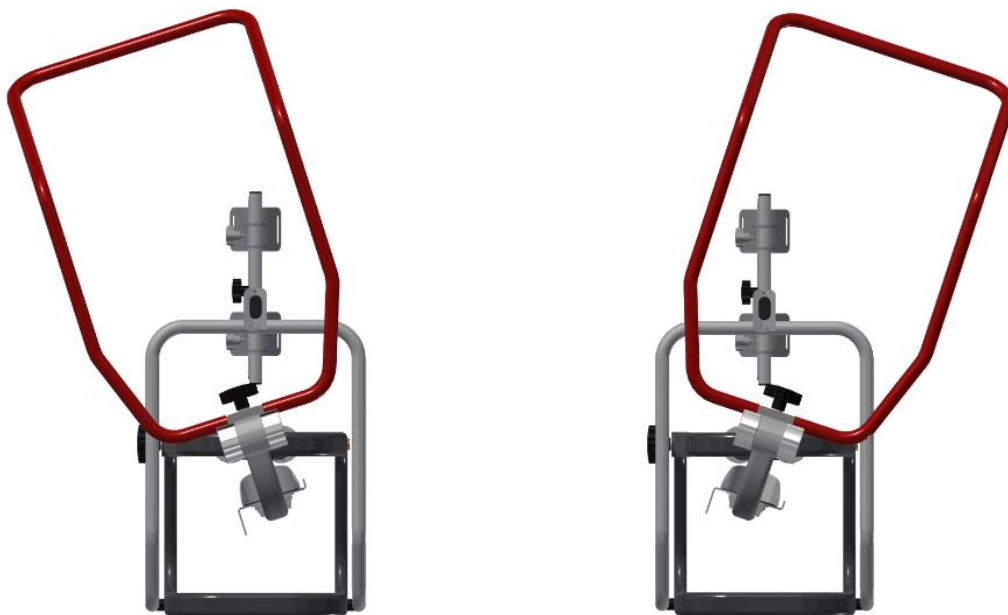
Plantarflexion and dorsiflexion:

- A knob H.1 (3) unlocked.
- A knob H.2 (4) locked.
- Weight (5) placed in the sockets according to the therapist indications (to support the resistance exercises).
- Lever (1) installed according to the therapist indications (used to perform self-assisted exercises).
- Shin stabilization according to the therapist indications (advised to perform isolated exercises in the crurotalar joint).



Pronation and supination:

- A knob H.1 (3) locked.
- A knob H.2 (4) unlocked.
- Weight (5) placed in the sockets according to the therapist indications (to support the resistance exercises).
- Lever (1) installed according to the therapist indications (used to perform self-assisted exercises).
- Shin stabilization according to the therapist indications (advised to perform isolated exercises in the crurotalar joint).





Unlocking knobs H.1 and H.2 together enables to perform multidimensional exercises.

Resistance installation

To realize the resistance exercises the weight must be attached to the main frame.



Instalacja ciężarków przy ruchu zginania i prostowania stawu skokowego/ pronacji i supinacji:

W zestawie znajdują się 4 ciężarki ważące blisko $\frac{3}{4}$ kg każdy. Ciężarki posiadają gniazda, za sprawą których, istnieje możliwość ich połączenia (progresja obciążenia).

Ciężarki mogą zostać zaimplementowane w czterech gniazdach w strukturze ramy bazowej (dwa z przodu urządzenia oraz dwa z tyłu).





Therapeutic process realized with usage of DRACO 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 application 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 DRACO 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.

DRACO Ankle and 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:

DRACO

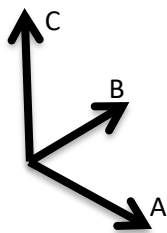
Version:

V.2.0

Class:

Class I, rule I

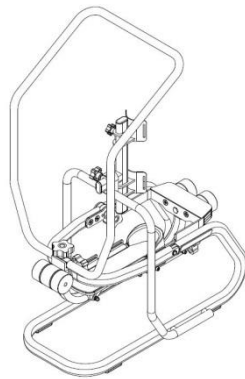
Dimensions:



A = 400 mm

B = 640 mm

C = 960 mm



Ranges:

Plantarflexion

47 stopni

Dorsiflexion

40 stopni

Pronation and supination

34 stopnie

Weight:

16 kg (including 4 weight, 0,67 kg each)



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. Defective 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 be 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:

Address:

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:

