

NOTICE

MANUAL MASSAGING DEVICE MyoDK



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INTRODUCTION

In musculoskeletal system disorders, a strong neuromuscular component leads to muscle dysfunction with articular hypomobility, poor loco-regional vascularization and musculoskeletal overwork. Hence the interest of massage techniques aiming the neuromuscular relaxation.

In daily practice, we can note:

1. Patient intolerance to some of these techniques, leading to a poor compliance,
2. The tiredness and relative drudgery for the therapist leading to tendino-muscular pathologies, thus the difficulty to have an homogeneous practice,
3. The patient's dissatisfaction over time because it is always painful.

The pain measurement is subjective and patients often forget the pain they had at the treatment beginning. Hence, the idea of developing a device that relieves practitioners in their daily repetitive actions has an action on all tissues including deep muscles and information on the applied force on the patient's body.

1 GENERAL INFORMATION

The MyoDK device has been patented by Dr. David KHORASSANI and was developed by DAVKOR. The new version was developed by RK INNOV. It is a class 1 medical device which bears the EC marking (see chapter 2).

It helps to assist practitioners in their daily repetitive actions and thus to relieve and limit work-related fatigue. It allows therapists to work faster without drudgery, to control the applied pressure with clinical results more interesting in practice. It allows a controlled and effective therapeutic action.

This operating manual is in order to introduce the MyoDK device. It describes each component to understand the operating principles and contains the instructions to ensure proper use with correct functioning and keeping of the health and safety conditions.

It must be read before the first use, especially the warnings and restrictions given in chapter 3. Additional information on manual massage techniques is given in chapter 7.

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Destination

The MyoDK device is restricted for professional use and is intended for therapists (physicians, physiotherapists, osteopaths, etc.) practicing manual massage therapy.

It is specifically designed for the PCPTherapy technique. It is marketed under an exploitation license with obligation of preliminary training. Only practitioners who have followed the "PCPTherapy" training can practice the technique according to the conditions given in the operating license.

It can also be used for manual massage techniques by point pressure also aimed at tendon-muscle relaxation, such as the Transverse Deep Massage (TDM), Cyriax method, Trigger point, etc.

The MyoDK device equipped with heads, named TAMs, is intended for the application of PCPTherapy to relieve musculoskeletal pain, for the following indications:

- Back pain, including lumbar and neck pain and joint pain
- Prevention, support and/or treatment of musculoskeletal pathologies
 - o Tendinopathies,
 - o Rachialgia (cervicalgia, dorsalgia, lumbalgia),
 - o Posture disorders
 - o Fibromyalgia
- Sport

with the main clinical benefits :

- Reduction in myofascial and tendon tension (general relaxation)
- Relaxation of muscles, including deep muscles
- Reduction in joint stress
- Increased joint flexibility and mobility
- Reduced pain (increased pain threshold under pressure)
- Improved posture
- Improved quality of life

Technical characteristics

- Portable device, compact and lightweight
- Weight of the device without head: 1090 g
- Dimensions without head: 17.5 x 12.5 x 36.5 cm
- Base allowing the transfer of the weight of the body on the body of the patient
- Piston for applying force
- Applied force: up-to 250 N
- 1 dial graduated to indicate the level of force applied
- 3 interchangeable application heads
- Made in France
- Guaranteed 2 years
- Service life 10 years, TAM 5 years.

Use performance

- Portable device, storage in a lockable case
- Simple manual use, no setting
- Comfortable use:
 - Support base, allowing to use body weight and thus relieve his upper limbs
 - Protective cover over the support base for comfortable working over time
- Flexibility: different positions and application methods allowing multiple uses for personalized and adapted treatments
- 3 interchangeable application heads
 - Quick and reliable connection
 - Ergonomics for a comfortable application
 - multiple pins working simultaneously for quick work on the whole body
- *Possibility to combine PCPTtherapy with the MyoDK device and vacuum therapy with the MyoRK equipment (see MRK Brochure)*

Design safety

- Mechanical device offering most of the advantages of manual techniques
- Indicator displaying the level of the applied force allowing to determine the pressure pain threshold and to control the applied pressure

Application heads

- Different ergonomic shapes and sizes allowing to respect the different anatomical areas
- Equipped with several and wide pins allowing to both have multiple application points and a lower pressure on skin-contact surfaces and then to reduce the pain felt at the pressure
- Smooth surfaces for ease of decontamination
- Biocompatible material to avoid any biological risk

Package contents, 1 storage case including:

- A manual massage device referenced MyoDK
- A protective cover of the base
- 3 adaptable heads referenced TAM8, TAM4 and TAM2
- This instruction notice.

Working and storage conditions

- Temperature limits : -25 to +70 °C
- When not in use, store the device carefully in its case with the heads thoroughly cleaned and dried as described in section 6.

2 MEANING OF LABELING AND MARKING SYMBOLS

The MyoDKdevice is a regulated health product as class I medical device. Under this regulation, it bears the CE mark. The marking of the device is behind the central part (back of the dial). It includes the following symbols :



Device placed on the market in compliance with the requirements of applicable Regulation (EU) 2017/745

REF

Device reference

SN

Serial number



Consult instructions before the first use

3 RESTRICTIONS AND WARNINGS

Contraindications

- Generalized cancer
- Acute infectious, tumor and neurological diseases
- Locally, at the level
 - skin rash, injured, infected, cancerous areas
 - acne, cutaneous herpes, wart, suspicious mole...
 - hematoma, erythema, dermatosis
 - deep varicose veins and for 2 months after vein surgery
 - recent trauma, fracture, ...

Precautions

The MyoDK device should not be used on injured skin. The practitioner will take precautions (low level of pressure exerted) in case of:

- Pregnancy
- Coagulation disorders or anticoagulant treatment in progress
- Osteoarticular fragility.

Others to ensure safety and a minimum of pain for the patient

- observe the above contraindications and precautions
- only apply to healthy skin
- always carry out a preliminary test before treatment to assess the patient's pain threshold (see § 5)

- perform the treatment with a pressure below the pain threshold
- apply while keeping the handle with the application head at a right angle to the surface being treated to avoid slipping
- If necessary, place your fingers inside the head to block the head and prevent it from slipping while maintaining the vertical position of the handle.

General use

- restricted to specialist healthcare professionals (see §1 "Intended use")
- Observe the precautions given during prior training.
- Use only the application heads (TAMs) supplied by RK INNOV.
- To avoid falls with risk of material damage:
 - o Check that the head is correctly connected to the pestle.
 - o Do not hold the MyoDK by the head and handle it carefully without sudden movements.
 - o Between 2 uses, place the MyoDK in its case. Do not stand it upright but lay it flat, as its protective cover makes it unstable, with the risk of it falling and hitting the dial.
 - o When not in use, store and transport it in its case.

Cleanliness

- Clean and disinfect the application heads before the first use, after each patient and each session in accordance with § 6.
- When not in use, replace the cleaned and dried heads* in the suitcase.
- Use and store in a clean, dry, dust-free place away from pollutants, contaminants, etc.

Ageing

- Check that TAMs are in good surface condition
- Clean and store them correctly
- Follow § 7 and contact RK INNOV if you have any problems or doubts.

Lifetime depends mainly on the absence of shocks, ... For daily use in normal conditions, the lifetime of the MyoDK is estimated at 10 years and that of the TAMs at 5 years.

Disposal, follow § 6

4 DESCRIPTION

The MyoDK device consists of a pestle with a base and interchangeable heads that apply to the patient's body. The following picture presents the MyoDK and its application heads, the 8 fingers (TAM8), 4 fingers (TAM4) and 2 fingers (TAM2).



The ergonomically shaped **base**, with its protective cover, allows an adapted application on the body of the therapist. It can be placed at the level of the arm, the shoulder, the thorax, the abdomen... depending on the place to be treated. It allows to apply a force on the body of the patient with less penibility for the therapist.

The **handle or pestle**, fixed in the center of the base, operates by a piston mechanism. It allows the transmission of the force applied from the base to the head. It is equipped with a graduated dial. The indication allows to control the force applied and thus to control, reproduce or modulate the pressure exerted.

The **application heads** are interchangeable and fixed to the end of the pestle. They have different sizes and ergonomic shapes that can be applied to different parts of the body depending on the protocol used (see chapter 5).

TAM8 (8 fingers) **TAM4** (4 fingers) **TAM2** (2 fingers)



5 OPERATING INSTRUCTION

The technical manipulation of the MyoDK Device is very simple. It must be applied perpendicular to the treated body surface.

Head choice according to the area to be treated

According to the treated area of the body, use the appropriate head (see the following table):

Reference	Application example
TAM8	General
TAM4	Trapeze , TFL (Tensor Fasciae Latae)...
TAM2	Spine, tendons

Positioning

The photos below show two examples of using position. The base of the MyoDK can be placed on different parts of the body of the therapist (the arm, the shoulder, the thorax, the abdomen...).

Objective evaluation of pressure pain

The MyoDK allows evaluating the pain threshold in an objective way. The therapist will thus be able to assess the intensity of the pain in the area to be treated at the beginning and in each session in order to follow the progress of the pain and the progress and thus reassure the patient about the improvement observed (feedback effect).

Role of hands released from the support function

The ergonomics of the device allows the therapist to apply the necessary force with less difficulty, so a better care for the patient over time. The hands released from the support function allow to appreciate the muscular relaxation and to seek the other contractions to be treated.

Examples of therapist / patient positioning

Thorax / trapezius



Lower limb / TFL



6. CLEANING AND DISINFECTION

Comply with the Good Clinical Practice

Clean and disinfect the application heads after each patient and each session with an alcohol-based solution* designed for disinfecting medical equipment*. Do not soak the heads, use a spray. Dry with absorbent paper.

* Except diluted alcohol, do not use organic solvents

Recommended cleaning and disinfecting product: solution SURFANIOS PREMIUM diluted to 0,3 % in water (25 ml in 8 L of water), ANIOS spray or any other disinfecting cleaning solution with CE marking

Hand wash or machine wash at 30°C the protective cover and leave to air dry.

7. MAINTENANCE

Storage

Place the clean and dry heads away from dust in the supplied case and store in a clean, dry area.

Service check

- Check at the beginning of the session, the needle position reset to "0"
- If not, test the correct operation of the piston by pressing as far as possible and checking the return of the needle to zero. In case of zero shift, contact RK INNOV
- Make a visual examination to check the integrity of the TAMs, the good surface state, ...
- check the pestle axis in case of impact, do not use and contact RK INNOV in case of doubt

Post-sale customer service

For any possible problem of use and safety, doubt, difficulty or suggestion of improvement, please note the serial number of your device and contact RK INNOV SAS contact@rkinnov.fr

Guarantee

The MyoDK device is warranted for 2 years against any defect in manufacturing and operation, arising from defects in material, manufacturing or design, in accordance with the contractual warranty conditions specified in the operating license. The guarantee is excluded in the following cases:

- Misuse not following the instructions in this notice
- Intervention on the MyoDK device that led to the opening and / or modification of the components
- Normal wear, negligence or lack of maintenance;
- Damage due to force majeure.

As part of the warranty, RK INNOV will replace parts found to be defective by its technical services. This warranty covers labor and shipping costs to the purchaser after repair or replacement.

Disposal

- Clean and disinfect TAMs
- Discard in accordance with local regulations in force for waste disposal.

8 FURTHER INFORMATION

8.1 - Side effects and adverse events

Undesirable events include those associated with all massage techniques:

- dizziness at the end of the session due to prolonged lying on the stomach
- headaches due to mobilisation of toxins.

Adverse events, which may be felt mainly after the first few sessions, are mild to moderate in severity, resolving within 2 days. They include

- muscle weakness, muscle soreness
- occasional increase in pain
- bruising leaving skin marks.

Strong ecchymosis with skin marks may last for up to 5 days with no side effects, In exceptional cases (patients with fragile vessels and/or application of excessive pressure and/or duration), application may cause hematoma.

8.2 Information to be given to patients

Prolonged lying on the stomach with general relaxation may cause dizziness at the end of the session. To avoid any discomfort, patients are advised to bend their legs to one side, rise slowly to a sitting position and remain seated for about 1 min before getting up.

Relaxation gives a sensation of lightness, which may even lead to muscle weakness. Aches and pains and a feeling of tiredness may be felt after the first few sessions. It is advisable to avoid physical exercise for 24 to 48 h after the session and to follow the specific recommendations.

As with all skin mobilisation techniques, the session has a drainage effect. It is advisable to drink plenty of water after the sessions to encourage and compensate for the urinary elimination of toxins. In the event of pain, an analgic may be taken after the session for 24 to 48 h.

The compression effect may cause marks (ecchymosis) on the skin which may last for a few days without any side effects, but you should avoid exposure to the sun in the following days.

8.3 Manual massage techniques applying force

Manual massage techniques applying force allow to generate a local vasodilatation, which promotes blood circulation and veno-lymphatic drainage. The treatment has analgesic action and promotes healing. Depending on its effectiveness, it relieves the pain of patients (acute and chronic), reduce joint constraints (improve joint mobility and flexibility) and improve muscle recovery and posture.

8.4 Comparison of PCPTtherapy and DTM technique from Cyriax

The deep transverse massages (DTM) of Cyriax consist in mobilizing the tendons in certain pathological circumstances:

- Recent or old post-traumatic inflammation
- Sequellar lesions in the absence of intra-tendinous calcification .

The DTM are performed at the pain area, perpendicular to the direction of the tendon, at a rate of 2 to 3 sessions per week for a total of fifteen sessions if the first are effective. It is essential to warn patients that pain may occur at the beginning of the session but should be reduced after a few minutes.

In the PCPTtherapy technique, the applied force maintained below the pain threshold and the application is generally done on several points simultaneously, it is more diffuse and therefore less painful. It can even be comfortable since it often allows relaxation of the patient.

By using the MyoDK, the hands are released from the manipulation function and can appreciate the muscle relaxation and seek the other contractions to be treated. It is possible to evaluate the pain threshold in an objective way and thus to have a follow-up of the evolution of the pain, to be able to objectify the results and the progress in the time and thus to facilitate the communication with the patient.