User's manual

MYORK EQUIPMENT

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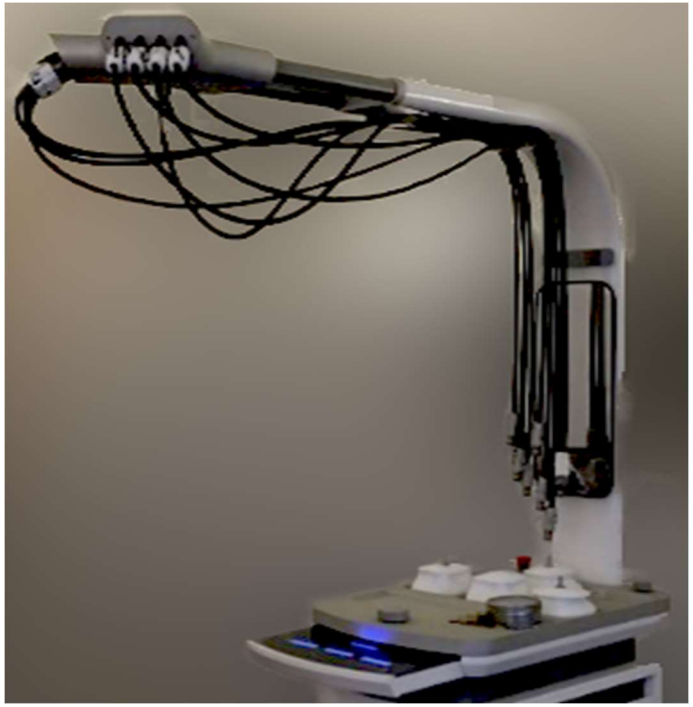
SIRET 83428848200021 GLN 3770018797014 SRN FR-MF-000028533

Premium version MRK 941PG Premium



Standard version MRK941PG

MRK521P

SOMMAIRE

1. INTRODUCTION

With the idea of developing equipment allowing to work without penibility and with increased efficiency, RK INNOV has developed an electromedical massage equipment MyoRK. It contains a vacuum pumping system allowing to perform a suction action with control of the applied vacuum pressure to the application heads. It is programable and operates automatically (hands- free) and also allows a manual use.

This manual is intended to introduce the MyoRK equipment and gives the instructions that must be followed to ensure the proper use with proper operation and maintenance in hygiene and safety conditions. The first edition date of this document is *June 2021*, the revision date is indicated in the document reference at the top right of the page (date codified upside YYMMDD).

This manual is completed by the instructions for the applications heads (or TACs) in the document referenced “TAC Notice” and by additional information given in the document provided during training. These documents need to be read before the first use, particularly the warnings and cautions given hereafter.

Moreover, the MRK training given by RK INNOV is mandatory before the use of the MyoRK equipment.

Intended purpose

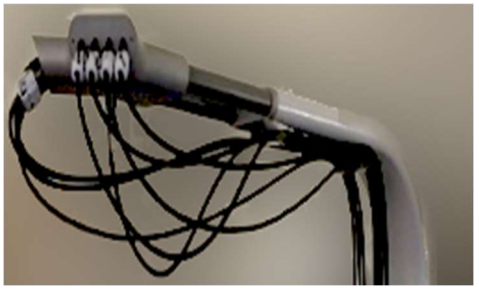
MyoRK equipment equipped with TACs is designed for the application of vacuum therapy to relieve musculoskeletal pain.
The target population and body parts, clinical benefits, indications, precaution, contraindications and TAC complementary information are given in the TAC notice.

MyoRK equipments and TACs are intended for Health professional use only, practitioners of manual therapies such as physicians, physiotherapists, osteopaths, after a specific training provided by RK INNOV. MyoRK equipment is placed under the responsibility of the person trained by RK INNOV and designated as the responsible user.

Description

The MyoRK equipment is an electroprogrammable vacuum system connected to the application heads (TACs) which are the applied parts on the patient. The operating principle is to generate negative pressure for TAC adhesion (cupping). The MyoRK equipment includes:

- A basic frame comprising electrical module (technical box) and equipped with
- a tray for holding TACs
- a keyboard for controlling the MyoRK integrated on tray or an optional sliding tablet
- an optional drawer for TAC storage …
- A Y-shaped part, called "Y-part", fixed on a gallows extending the basic frame (models with gallows) or directly on the basic frame (models without gallows), which provides up-to 9 outputs (1 central output and up-to 4 outputs on each side)
- Up-to 9 flexibles intended to be connected to the Y-part
- Up-to 9 TACs intended to be connected to the flexibles
- Replacement kit with 2 replacement TAC filters per flexible and a filter key
- The present manual and the notice of TACs



The tray is equipped with:

- A direct potentiometer on the proximal edge, for manually driving the vacuum pressure in the direct line (middle flexible
- A safety potentiometer on the on the right rear side, for adjusting the maximum vacuum pressure in programmable lines
- An emergency stop on the left rear side, for stopping the vacuum pump
- Two flexible racks on the sides for the standard versions, equipped with attachment brackets allowing to store the flexibles

For the Premium version, the flexibles are stored on the fixing hooks of the gallows along the gallows by hooks.

The Keyboard comprises an ON/OFF button and 4 navigation areas for the sequential management of 4 independent channels, each channel driving 2 pneumatic lines. Each navigation area includes:

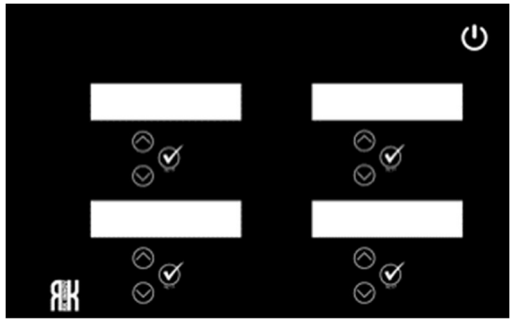
- A screen for displaying the program number, elapsing time ...
- Navigation buttons for selecting the program ….

Each flexible is equipped with an attachment system at both ends:

- One end allows the flexible to be attached to the Y-part
- The other end to be attached to the TAC

The TAC-side end of each flexible is equipped with two control buttons:

- The top button (white button) has a " ON/OFF " function for vacuuming
- The bottom button (black button) has a function for airing and moving or releasing TAC.



Technical characteristics

- Net mass (kg) 110 kg (with gallows) 95 kg (without gallows) 180 kg (premium version)
- Dimensions L x W x H (m) 0.79 x 0.50 x 2.02 (with gallows) 0.79 x 0.50 x 0.89 (without gallows)
  1.34 x 0.57 x 2.02 m (premium version with gallows extending 0.55)
- Power cord 2.50 m
- Electrical characteristics 120V (60 Hz) 3.5 A or 230 V (50 Hz) 2 A
- Nominal electrical Power 400 W
- Fuse 5 x 20 mm, Quick-Acting F, H, 250 VAC Manufacturer fuse reference indicated on the back of the MyoRK
- Sound intensity < 55 dB
- Maximum vacuum pressure -750 mbar absolute pressure 250 mbar
- Output number 5 to 9 separate pneumatic lines, 1 direct line and up-to 8 lines programmable
- Manual settings 2 graduated potentiometers to adjust the vacuum pressure
- Programming: 2 to 4 programming channels, up-to 20 programs
- Flexibles 5 to 9
- Flexible lengths Standard versions with gallows: 2.45 m without gallows: 1.65 m
  Premium version: 1.90 m (1) 1.85 m (4) 1.65 m (4)
- Application heads 5 to 9 (see TAC Notice)
- Made in France
- Warranty 2 years
- Lifetime 10 years

Classification and safety standards conformity

- Regulation (EU) 2017/745 on medical devices, annex I class IIa
- Electromedical equipment complying with EN60601-1 Stationary equipment class I Applied parts: BF-type (symbol, see §2)
- Electromedical equipment complying with EN60601-1-2
  - Conducted emission and radiated disturbances CISPR 11 group 1, class B
  - Harmonics current emission CEI 61000-3-2 class A
  - Voltage fluctuation and flicker CEI 61000-3-3
- Associated software complying with EN 62304 class A
- Protection against the penetration of foreign objects: IP2X

Performance requirements

- Variable vacuum pressure 0 to -750 mbar (direct line, manual use)
  -50 to -350 mbar (programmable lines)
- Pulse period 0.2, 2, 20 s (300, 30 or 3 pulses/min)
- % pulse / total time 25, 50, 75 % and 100 % (continuous mode)
- Session duration 5 to 15 min (continuous) and 20 to 45 min (pulsating mode) depending on the selected program

Use performance

- Up- to 9 separate pneumatic lines, 1 direct line and up-to 8 lines programmable
- Up- to 9 application heads working simultaneously
- Flexibility - Manual use on the direct line / automatic use on the other programmable lines
- Flexibility - Continuous mode for a passive work / pulsating mode for an active work

Manual settings

- Direct potentiometer for manually driving the vacuum pressure in the direct line (manual use) and for determination of the maximum vacuum pressure without pain for the patient (pressure pain threshold)
- Safety potentiometer for adjusting and locking the limit vacuum pressure in the programmable lines

Programming

- up to 4 simultaneous running programs
- 20 different programs (5 families of 4 programs) to automatically for different vacuum pressures and durations according to the pressure pain threshold, body area and pathology to be treated
- Display of the program name, number and remaining time

Application heads
TACs

- 4 models that are ergonomic for comfortable applications
- Large sizes allowing to work on large body surfaces and therefore to work quickly on the whole body, both the back and front sides
- Easy handling
  - quick and reliable connections to the flexibles
  - control buttons for vacuuming and venting, allowing easy movement, removal and change
  - washable
- Storage in a suitcase or in a lockable drawer (Premium version, maximum load of 10 kg)

Safety

Control of the vacuum pressure and session duration to limit side-effects

- Direct potentiometer for manual use and for determination of the pressure pain threshold
- Safety potentiometer for adjusting and locking the vacuum pressure to the pressure pain threshold
- Electronic regulation of the vacuum pressure in the entire pneumatic lines including the TAC inner space without exceeding the pre-set value of the pressure pain threshold
- Different programs limiting the vacuum pressure and session duration

TAC design for a safe application

- Different shapes and sizes fitting to different anatomical areas
- Wide edge and presence of pins allowing to reduce positive pressure on skin-contact surfaces and skin detachment
- Smooth and washable surfaces for ease of decontamination
- Biocompatible material to avoid any biological risks

Use limited to the health professionals with a preliminary training,
TAC use limited to dry cupping (non-invasive, without breaking the skin barrier)

2. MEANING OF SYMBOLS AND LABELS

MyoRK equipment is an electromedical equipment regulated as a class IIa medical device. It bears, under the regulation, the CE marking.

2.1 Used symbols

Name and address of the Manufacturer

Manufacturer's product name

Manufacturer's catalogue reference

Manufacturer's serial number

Unique Device Identifier

BF-type applied parts

0197 Medical device put on the market, complying with the regulation (EU) 2017/745 (superseding Directive 93/42/EC)

The equipment should not be treated as household waste, complying with the Directive 2012/19/EU (WEEE, Waste Electrical and Electronic Equipment)

Obligation to read instructions before first use

General warning pictogram

2.2 Affixed labels and marking on the equipment

Label located on the keyboard to prevent someone from putting anything on that part

Label located close to the keyboard or on the IHM tablet to prevent someone from sitting on that part

Label located on the gallows to prevent someone from pushing this part

Label located on the drawer sides to prevent an overload and to warn not to fill the drawer more than 10 kg.

2.3 Markings on the control areas

Symbol located around the red emergency button to indicate the “EMERGENCY STOP“ to press it and put the pump of the MyoRK OFF

TAC remote buttons, white button operates suction (ON/OFF commutation for vacuuming), black button for airing (air release).

3. WARNINGS AND CAUTIONS

Please, follow recommendations from training and read all safety information, contraindications, precautions, and warnings prior to use the equipment. The responsible user is responsible of the equipment and its use complying with instructions. Failure to follow these instructions can cause tissue damage, injury or pain to the patient. Improper use of the equipment can cause damage to the equipment. RK INNOV will not be liable for any inappropriate use of the equipment.

3.1 General

- Read all warnings and limits of use before the first use, including those of the TAC Notice, mainly the contraindications and precautions
- Have followed the training provided by RK INNOV
- Any serious incident that has occurred in relation to the equipment shall be reported to the ANSM or competent authority of the Member State of interest – Any serious incident or adverse effect, such as described in TAC Notice or not, shall be reported to the manufacturer.

It is prohibited to:

- use the equipment for purposes other than those recommended by RK INNOV
- remove the main frame and modify this equipment – Only RK INNOV is empowered to open access covers for maintenance
- use components and TACS non supplied by RK INNOV – Use of components or accessories, not provided by RK INNOV, could lead to reduce electromagnetic interference immunity or increase electromagnetic emission.
- When damaged or required, see the list of the spare parts in annex and request for RK INNOV.

3.2 Environment (see § 4 Installation requirements)

- Do not use the equipment in unsuitable environmental conditions, on a dusty, unstable floor or in a moist atmosphere
- Take care, use of the equipment requires aeration, do not cover or clutter the back and sides of the equipment to ensure proper ventilation
- Use the equipment in a normally ventilated room up to 10 h maximum.

3.3 Installation and configuration (see § 4 Installation requirements)

- Do not position the equipment so as to make it difficult to plug/unplug from the wall outlet
- Do no plug into a damaged, not grounded electrical outlet or not controlled
- Only connect the equipment to a functional grounded socket equipped with a protective earth to avoid the risk of electric shock
- Do not use any power cord, connectors, electrical fuse … other than supplied by RK INNOV and in case of degradation, request for RK INNOV
- Do not use any extension cords
- Route (fully unwind) the power cord and keep it away from warm surfaces and from user's path.

3.4 Operating and use (see § 5)

- Do not use other TACs and flexibles than those supplied by RK INNOV
- Except the TACs, do not touch the accessible parts and the patient simultaneously
- Respect the contraindications, precautions and warnings for the TACs (see TAC Notice)
- Respect the pain felt by the patient
- In emergency case (patient's pain), press the emergency button to stop the pump and disconnect the TACs immediately to prevent them from falling on their feet.

Take care of the moving parts

- Check by traction the effective connections to the TACs before to start program
- Avoid switching off the equipment while the programs are running - Before switching off the equipment, disconnect the TACs to avoid them falling out
- For the Premium version
- After using the drawer, check its proper closure - When not used, do not forget to fold down the tablet in its resting position - During its use, the tablet remains opened, be careful not to knock it.
- At the end of the session and before releasing the patient, disconnect the TACs and fix the flexibles on gallows.

Beware of mishandling

- Do not put anything on the TAC tray (except TACs) or keyboard, no containers with liquid ...
- Do not allow solid debris, liquid or other foreign bodies to fall or be sucked into the unit, as these could cause damage
- Do not store a load exceeding 10 kg in the optional drawer (maximum weight of storage)
- Do not lean, push, rest or sit on the equipment
- Do not use the gallows and flexibles as a guidance system when getting up from the massaging table
- Patient should not be able to reach flexibles and keyboard during treatment and requires to be guided to leave the massaging table.

Beware of misuse

- Except for TACs, do not handle flexibles when the equipment is under voltage, always stop and unplug the equipment from the electrical supply outlet before connect or disconnect flexible(s), handle the Y-part connections, filter change and other cleaning and maintenance
- Always keep the equipment and accessories in a clean and dry place protected from dust
- Clean and disinfect used TACs after each patient (see TAC Notice)
- Use and store only dry TACs (see TAC Notice) and moisture-free filters

Never use the equipment if it does not operate correctly, show a reduction of the pump power (clogged filters, ventilation ports obstructed), it has been exposed to excessive humidity or it is visibly damaged (power cord or outlet, keyboard, control buttons).

3.5 **Maintenance** (see § 8)

In order to maintain the performance over time and to ensure the safe and efficient operation, carry out cleaning and maintenance in accordance with the instructions in section Maintenance with the following warnings:

- Do not handle when the equipment is under voltage. Always switch off the equipment with the ON/OFF on the keyboard to disconnect flexible(s), handle the Y-part connections, change filters and others cleaning or maintenance operations
- Do not bend the flexibles to avoid deformation and pinching of the electrical wires
- Do not change the equipment, do not disassembly frame, only RK INNOV is empowered to open access covers for maintenance, request RK INNOV for examination and repair
- Do not use other components (cables, transducers …) other than those supplied by RK INNOV as replacement parts for maintenance purposes, that may result in electrical danger and increased emissions or decreased immunity of the equipment.
- Do not use detergents or other liquids

3.6 **Transport** (see § 7)

- Only RK INNOV is authorized to lift and transport equipment
- Do not use (hang, lean or push) gallows to move - Gallows is not intended to move equipment and strictly reserved for flexibles.
- Do not pull the equipment by the power supply cord.

4. INSTALLATION REQUIREMENTS

The installation is carried out only by specialized technicians under the responsibility of RK INNOV. To operate safely, the following conditions are required.

4.1 Environmental conditions

- Operating temperature: + 5 °C to + 40 °C (use) -25 to 70 °C (storage)
- Relative humidity: 30 % to 90 % HR
- Atmospheric pressure: 70 kPa to 106 kPa
- Electromagnetic environment: “Professional healthcare facility environment” and “Home healthcare environment”

For maintenance, the MyoRK equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. It is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes (see § 3.2).

4.2 Premises

- Use and store in a proper room, far away from polluants and contaminates
- Use in a normally ventilated room up-to 10 h maximum
- Secure space in order to be able to position the equipment for good ventilation and easy access for connections / disconnections
  Space requirement for use: 20 cm at the back, 70 cm at the front and 1 m on the sides
- if possible, install equipment in a dedicated room, locked in the absence of authorized and trained personnel.

4.3 Power supply

- Power supply according to the operating voltage indicated on the MyoRK marking
- Power socket reserved for equipment
  - functional grounded socket with neutral, phase and earth
  - not remotely controlled
  - positioned within 2,5 m of the equipment and at the rear of it in order to avoid any risk of snatching off and any human risk of falling.

5. USE

The equipment can be used hands-free, which allows the therapist to manage several treatment booths simultaneously and then to work more efficiently. The main instructions are given hereafter (Use warnings, see § 3). The practical use of TACs, potentiometers, keyboard keys, errors, ... is carried out during the training.

Power on the equipment

- Check that both potentiometers are set to position " 1 "
- Connect the equipment to the mains with its power cord.
- Press the 0/I switch (position I) on the power socket at the rear of the MyoRK to switch on the equipment
  The equipment under voltage is in standby mode, the power indicator of the keyboard lights up (red light).
- Press the ON/OFF button on the top right of the keyboard, the screens light up and display menu
- It can take up-to 20 s to start the equipment (ready state).

Place the massage table so that the patient's head is not below the flexibles.

Set the safety value for the patient in first before selection of the program

- Follow the instructions given in the TAC Notice
- Check that the 2 potentiometers are set on the graduation "1"
- With the TAC connected to the direct line, assess the patient's pain rising the intensity of the direct potentiometer
- Set the safety potentiometer at this value (pressure pain threshold) or below and lock it.
- Select the program.

Connect the TACs to the flexibles

- Follow the instructions given in TAC Notice
- Check the effective connection by traction to the TAC.

Select the treatment program

- Select the program level 1- SOFT 2- MODERATED 3- MEDIUM 4- HARD
- Keyboard on sliding tablet (optional) can be opened during session but if not used, it is strongly recommended to close it (see 3).
- In error case, the relevant screen displays the single fault message "vacuum fault, restart the equipment"
- Restart the equipment (switch off and on again), if the default remains, contact RK INNOV.

Application of the TACs

- Follow the instructions given in TAC Notice for the control buttons (top and bottom buttons) located on the flexible ends, TAC sides
- In case of patient's pain, according to the emergency, press the bottom button to release TACs, stop the program or press the emergency stop button
- For the ending the application, press the the bottom button to release TACs.

At the end of the session

- Stop all programs, put the potentiometers on the graduation “1”
- Disconnect TACs and place them in a case intended to receive the used TACs
- Store the flexibles on the flexible attachment brackets on the sides of the tray or on the fixing hooks of the gallows (Premium version)
- Clean, disinfect and dry TACs (see TAC Notice)

At the end of the use day, do not forget to:

- Switch off the power button on the keyboard
- Store the cleaned, disinfected and dried TACs (see 6)

Power off the MyoRK equipment when it is not used

- Switch off the unit on the back of the MyoRK (position 0) and unplug the unit from the power supply if it is not going to be used for a long period.

6. STORAGE

Always keep the equipment and accessories in a clean and dry place protected from dust and direct sunlight
After disconnection of the TACs, place the flexibles on the fixing hooks along the gallows
Store the cleaned, disinfected and dried TACs away from dust in a secured place under the responsibility of the responsible user trained in order to prevent any use by unauthorized personnel. If possible, lock the room (see TAC Notice).

7. TRANSPORT

For any small movement or repositioning of equipment in the same room, see 3.6
For any transport outside the room or transport requiring the lifting of equipment:

- Only RK INNOV is authorized to move and transport equipment
- Notify RK INNOV so that they can intervene (see After sales service)
- Plan lifting means (pallet truck) and other required means for applying handling good practice.

8. MAINTENANCE

Regularly maintenance by the User once a week by visual inspection to ensure :

- the cleanliness of the ventilation holes (air vents) of the metallic unit to avoid any obstruction
- the ventilation ports are kept clear of dust or other contaminants
- the flexible filters are not clogged in order to avoid a reduction of the power of the pump or its wear
- no signs of damage of the flexibles (are not intended to be changed as part of routine maintenance), … in case of degradation, request RK INNOV.

⚠ For any of the following operations, always turn off and unplug the equipment (see 3.5)

- Check filters of the flexibles once a week and change at least once a 2 months if daily use
- Clean the flexible sheaths, made of plastics, with a wipe soaked in disinfecting solution used for TACs (see TAC Notice)
- Clean the keyboard and button surfaces with a soft, slightly moistened fabric
- Clean the metallic surfaces and other accessible parts including the ventilation holes with a soft fabric to remove dust
- If the vacuum pressure slows down, contact RK INNOV

Regular maintenance operations by RK INNOV once a year

- Proper and effective functioning, flexibles …
- Cleaning the inside of the housing with a soft moistened fabric
- Control of the vacuum regulation
- Check of the pump filter and cleaning if necessary
- Pump revision, once every 3000 h

After Sales Service

For the previous interventions to request to RK INNOV, transport and any problem of usage, doubt, difficulty, incident or suggestion of improvement, thank you to note the serial number of your equipment and to contact RK INNOV SAS at contact@rkinnov.fr
In case of return of the TACs, clean them carefully as indicated in the instructions (see TAC Notice).

Warranty

MyoRK equipment is guaranteed 2 years from the date of delivery against any defect of manufacture and operation, resulting from a defect in material, workmanship or design. The RKINNOV guarantee does not cover damage caused as a result of:

- an intervention on the equipment that led to a design or surface coating change
- inappropriate use that does not comply with the instructions presented in this manual (lack of maintenance, overuse, etc.)
- an abnormal wear or a case of force majeure (accident,…)

Under the warranty and subject to the submission of a copy of the invoice, RK INNOV will repair or replace the defective components. This warranty covers labor and shipping costs after repair.

Disposal Ensure compliance with directive 2012/19/EU (WEEE) and local regulatory requirements for the disposal of electrical equipment.

ANNEX - LIST OF THE SPARE PARTS

Designation	Reference RK INNOV	Unit quantity
Small TAC	TACP	1
Medium TAC	TACJP	1
Long TAC	TACL	1
Round TAC	TACR	1
Power cable	MRK-Câble	1
Flexible standard	MRK-FLEX 245	1
Flexible of the direct line*	MRK-FLEX 190	1
Flexible long*	MRK-FLEX 185	1
Flexible short*	MRK-FLEX 165	1
Flexible recognition device	*MRK-FLEX mark*	*1*
TAC filter	MRK-FLEX-filter	1
Filter key	MRK-FLEX-key	1

** intended for the premium version*