

User Manual

Mollii

Please read through the entire user manual prior to use.



User Manual (EN) 5

This user manual (version 1.55.1 EN) was produced by Inerventions and applies to Mollii.
The operating instructions are valid from 2017-04-01.
Software version: 1.2x

ENGLISH

Mollii consists of



Mollii - Garment unit (item number: 100-1)

1 jacket and 1 pair of trousers supplied with laundry bags.



Mollii - Control unit (item number: 100-2)

1 control unit. The control unit can be connected to the garment unit by means of 4 magnetic couplings. The control unit is secured around the waist with the belt supplied.

Item number

Note that every size of jacket and trousers has a unique item number. For a complete list of item numbers see: www.inventions.se

Intended use



















Mollii is a personal assistive device. Electrically stimulating the muscles relaxes spastic, tense and aching muscles and activates weak musculature.

Mollii is for use in the home environment.

Change of name

Mollii was previously called Elektrodress 100.

Symbols

	Button: ON/OFF. Turns the control unit on and off respectively.		Symbol: Declaration of conformity according to the Council Directive 93/42/EEC concerning medical devices. 0413 is the identification number for the notified body.
	Button: PLAY/PAUSE.		Symbol: Year of manufacture.
	Display: If this symbol is visible in the display, the control unit is in PLAY mode.		Symbol: Machine wash 40° C, delicate wash.
	Display: If this symbol is visible in the display, the control unit is in PAUSE mode.		Symbol: Dry flat.
	Display: Product defect – do not use the product! Contact Interventions AB if this symbol is displayed.		Symbol: Do not dry-clean.
	Display: Battery indicator.		Symbol: Do not tumble-dry.
	Symbol: This product is labelled according to EU Directive 2002/96/EC (WEEE). The symbol means that the product must not be disposed of as domestic waste, but in a dedicated site for recovery and reuse of electronics and electrical waste.		Symbol: Do not iron.
	Symbol: Patient connection is classified: BF.		Symbol: Do not bleach.
	Symbol: Read the entire user manual prior to using Mollii.		Symbol: Do not wring out when drying.

Safety instructions

CONTRA-INDICATIONS

Never use Mollii:

- If the user has implanted electronic medical devices or equipment which can be disrupted by magnets, for example, shunts.

- Together with electronic life-support equipment or high-frequency operation equipment.

- Together with EKG-equipment.

There is a risk of Mollii disturbing the function of the above-mentioned types of equipment.

All incorrect usage is at the user's own risk.

CAUTION

Do not use Mollii without consulting a doctor in connection with:

- Cardiovascular diseases
- Malignancy (cancer)
- Infectious diseases
- Fever
- Pregnancy
- Skin disease, rashes or other skin problems.
- Usage together with another medical device or medical treatment.

Usage in connection with the above can expose the user to unnecessary risk, and is therefore at the user's own risk. Always consult a doctor.

Mollii is for use solely by the user for whom it is adapted.

Magnetic couplings (couplings between control unit and garment) must not be lengthened or modified in any way.

Mollii may only be used by, or under the supervision of, a person who has read and understood the user manual.

Take care when children and pets are present.

- Ensure that the magnetic coupling (in garment and control unit) does not come into contact with devices that can be destroyed by magnets.

- Treatment with electrotherapy can make the user tired and drowsy.

Spilling liquid on Mollii can cause discomfort. The garment should consequently be turned off if it gets wet, and drinks and liquids should be avoided during use.

Jewellery/accessories should not be used together with Mollii.

SAFE USE

- Never insert objects or tools under the garment.
- Do not use Mollii if the control unit has visible marks or is damaged.
- Do not use Mollii in wet rooms, direct sunlight or in connection with flammable materials/liquids.
- Do not use Mollii if the garment or control unit is wet or damp.
- Ensure that the magnetic coupling is correctly positioned, instructions can be found on page 11.

SKIN CARE

Regular contact with electrodes can irritate or chafe the skin. It is therefore particularly important to maintain good hygiene and to ensure that you:

- wash the skin every day with soap and water.
- moisturise the skin frequently with unscented skin lotion.
- never use Mollii if there are sores on the skin or if it is irritated or injured.
- follow the instructions for cleaning.

BEAR IN MIND

Mollii is intended to be used for approx. 60 minutes every other day.

Take care when using Mollii. Bear in mind that, for example, the balance can be affected.

Do not undertake demanding or heavy physical exercise when using Mollii.

Mollii must not be used outdoors. Tip: use Mollii prior to outdoor activity

- the effect lasts for up to 72 hours.

CONTACT INTERVENTIONS

- If an accident, injury or incident occurs during normal use.

- If incorrect use results in an accident or injury.
- If this symbol comes up on the display:



Environment, Storage, Usage

ENVIRONMENT

Mollii should be used and stored indoors.

Temperature: 15 - 35 °C.

Atmospheric humidity:

Relative humidity 5% to 95%.

Atmospheric pressure:

approx. 1,013 hPa to 844 hPa (0 m to 2,000 m above sea level).

Keep the surrounding environment of Mollii clean and dry.

BEAR IN MIND

The flooring material can affect safety. Read the instructions on p. 16.

Maintain a minimum distance of 1 m to radio frequency equipment or therapeutic equipment that transmits micro-waves or short waves.

DISPOSAL

Please return Mollii to Inerventions AB for disposal. Please handle used batteries in accordance with the WEEE directive. See p. 7.

BEFORE USE

Ensure that the skin is clean and free of cracks

or rashes. Wash Mollii before it is used for the first time. Always check that Mollii is intact, dry and clean before use.

AFTER USE

Rinse the whole garment with cold water or wipe off the electrodes.

Use baby wipes for this as they are gentle on the skin.

REGULARLY

The garment can be machine washed in a laundry bag at 40° C, delicate wash. Wash regularly (about once a month) to keep fabric and electrodes clean. Clean control unit, leads and coupling by wiping off with a lightly dampened cloth with no detergent.

A poorly cleaned garment or dirty skin can result in eczema or a rash.

DURABILITY

Mollii should last for 25 washes, or 2 years of regular use. Use over and above this is not covered by the warranties of Inerventions.

STORAGE

Keep Mollii dry and at room temperature. Avoid dusty, damp and bright environments.

Store and transport Mollii in its original packaging.

Remove all batteries if Mollii is not going to be used for a period of 3 weeks or more.

TRANSPORT

Temperature:

-20 to 40 °C.

Atmospheric humidity:

Relative humidity 5% to 95%.

Atmospheric pressure:

approx. 1,013 hPa to 19 hPa (0 m to 12,000 m above sea level).

SPARE PARTS

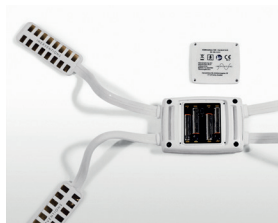
Repairs and servicing must be carried out by Inerventions AB. Faulty equipment must not be used. Contact Inerventions AB for service and support.

BATTERIES

Use a crosshead screwdriver to undo the 4 screws on the rear of the control unit.



Insert 4 x HR03/AAA batteries.



Check that no screws or similar have been left behind before replacing the battery cover.

Screw the cover on firmly using a screwdriver.

It is best to use rechargeable batteries.

Mollii has been tested with rechargeable batteries from GP (item number: 100AAHC).

DRESSING

Always check that Mollii is intact and clean before use.

Put on both parts of the garment (jacket and trousers) and then secure the belt with the control unit around the waist. Connect the magnetic couplings in accordance with the picture on the right. See the next page for dressing instructions.

The electrodes end up in the correct position if the right size is used and the zips are placed according to the instructions. Compare with the pictures on the next page.

CONNECTING THE CONTROL UNIT

Thread the belt through the loops on the back of the control unit. Secure the belt around the waist. Check that the magnetic couplings are intact. Check that the control unit is secured correctly and that nothing is protruding or has got caught between the magnetic coupling and the garment unit.

It is particularly important that the magnetic coupling which is located closest to the heart is correctly positioned.

Correct position:



Incorrect position which exposes the user to risk:



Dressing

1. Start with the trousers. Ensure that the lower zip ends up on the outside of the leg and forms a line between the ankle and the outside of the knee.



2. Check that the zips on the trousers form a straight line on the outside of the leg in accordance with the pictures below.



3. Pull the trousers right up before you do up the side zips and the fly.



4. Put the jacket on by inserting one arm at a time. Ensure that the side zips end up on the outside of the arm.



5. Check that the zips are positioned as in the picture on the left.



6. Thread the belt through the loops on the back of the control unit and secure the control unit and belt around the waist. Then secure the magnetic couplings on the garment in accordance with the picture above. Ensure that they are positioned correctly.



7. The shirt should be outside the trousers. Do up the zip on the stomach first, then the zips for the arms.

Check that the garment unit is positioned correctly on the body and the zips are straight.

START

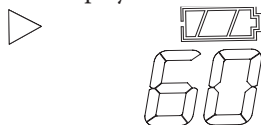
Ensure that the garment unit is dry. Start the control unit using the ON/OFF button.



Press "PLAY/PAUSE" once.



The display shows:



The figures on the display show the remaining time in minutes.

IF NECESSARY:

PAUSE by pressing "PLAY/PAUSE" once.

The display then shows:



Press PLAY/PAUSE again to continue.

FINISH

Turn off the control unit using the ON/OFF button. Remove the control unit before taking off the jacket and trousers. Clean and store Mollii according to the instructions.

DURING USE

Take the opportunity to move about while using the equipment and practise the movements that are hard to implement.

BEAR IN MIND

Mollii is intended to be used for approx. 60 minutes every other day. Always follow Interventions' instructions for safe use.

About electrical nerve and muscle stimulation

Mollii generates pulses with the following parameters (applies at 1,000 Ω):

- Pulse width: variable between 25 and 170 μ s.
- Length of period: 50 ms.
- Maximum amplitude: 20 V.

Each Mollii suit is customised when it is prescribed. Depending on diagnosis and manual examination of the patient, the prescriber decides which muscles are to be stimulated and with which pulse width. The user is not able to set pulse parameters or which muscles are to be stimulated.

On every start and continuation from pause mode, the pulse width is increased by up to 5 μ s every 5 seconds from 25 μ s until the preset pulse width is reached.

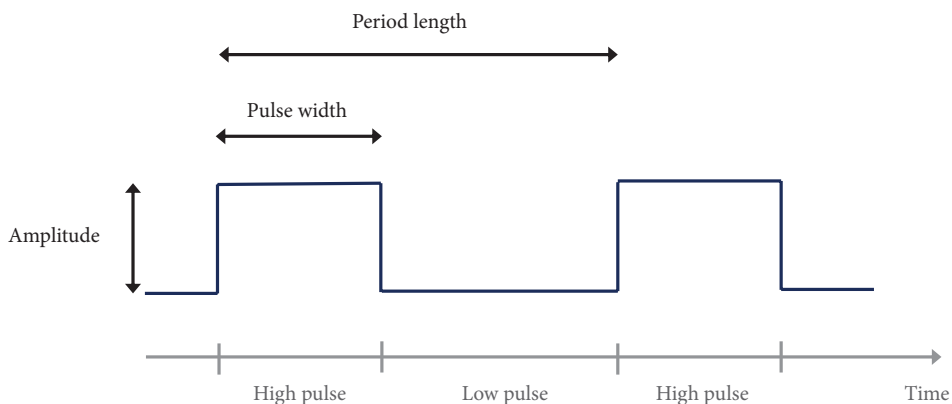


Table Data and Standards

Mollii is CE-labelled as a medical device, and thereby complies with the directive concerning medical devices (MDD 93/42/EEC) and the EMC directive.


In order to meet the requirements, Interventions has voluntarily chosen to fulfil

- EN ISO 14971 Application of risk management to medical devices
- IEC 60601-1, Safety of electrical medical devices
- EN ISO 10993 Biocompatibility
- EN ISO 13485 Quality management for medical device businesses

The tables below contain information from the EMC tests that Mollii has undergone. Please read the guidance therein regarding the environment and distance to other electronic equipment.

Guidance and the manufacturer’s declaration – electromagnetic radiation		
Mollii is intended to be used in an electromagnetic environment as below. It is the customer’s and the user’s responsibility to ensure that usage is limited to the environment described.		
Emissions test	Conformity	Electromagnetic environment – guidance
RF-emissions CISPR 11	Group 1	Mollii only uses radio frequency energy for internal functions. The amount of radio frequency radiation is therefore very low, and the likelihood of disrupting nearby equipment is low.
RF-emissions CISPR 11	Class B	Mollii is adapted for use in domestic environments and other environments connected to the generally available mains supply.
Harmonious emissions IEC 61000-3-2	N/A	
Voltage variations (flicker emissions) IEC 6100-3-3	N/A	

Guidance and the manufacturer's certification – electromagnetic immunity			
Mollii is intended to be used in an electromagnetic environment as below. It is the customer's and the user's responsibility to ensure that usage is limited to the environment described.			
Immunity test	IEC 60601 test level	Conformity	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered by synthetic material the relative atmospheric humidity should be at least 30 %
Electrical fast transient / Burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	N/A Not relevant in this case, Mollii is operated by an internal voltage source (batteries).	-
Overvoltage protection IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	N/A Not relevant in this case, Mollii is operated by an internal voltage source (batteries).	-
Voltage dips, failures and variations in current and voltage supply IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	N/A Not relevant in this case, Mollii is operated by an internal voltage source (batteries).	-
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	The magnetic field's mains frequency must be at levels that are typical for domestic or hospital environments.
NOTE UT is the value of the AC voltage source before testing.			

Guidance and the manufacturer's certification – electromagnetic immunity			
Mollii is intended to be used in an electromagnetic environment as below. It is the customer's and the user's responsibility to ensure that usage is limited to the environment described.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10Vrms	Portable- and mobile RF communication equipment with accompanying leads should be kept at the recommended distance from Mollii. The distance can be calculated using the equation below and the frequency of radiation from the radiation source. Recommended distance: 150 kHz - 80 MHz: $d = 1,2\sqrt{P}$ 80 MHz - 2.5 GHz: $d = 2,3\sqrt{P}$ Where P is the maximum outgoing output of the transmitter in watts (W) from the manufacturer of the equipment and d is the recommended distance in metres (m). The field strength from fixed radio frequency radioactive sources is determined by an electromagnetic site investigation a), but should be lower than the level for the respective frequency interval b). Interference can arise in the vicinity of equipment marked with the symbol below: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	10 V/m	
NOTE 1 The higher frequency interval applies at 80MHz and 800MHz. NOTE 2 This guidance does not apply in all situations and environments. The electromagnetic environment can be affected by absorption and reflection from objects, people and other environmental factors.			
a) Field strengths from fixed transmitters, such as base stations for radio (mobile or wireless) telephones, mobile radio, amateur radio, AM and FM transmissions and TV broadcasts cannot be predicted with theoretical accuracy. A site investigation should be considered to evaluate the electromagnetic environment on the basis of these factors. If the field strength measured in locations where Mollii is going to be used exceeds the above RF values, use of Mollii should be monitored and regulated so that normal function can be ensured. If variations in functionality are observed, further measurements, as well as moving and testing Mollii in other environments, should be implemented. b) The field strength for the 150 kHz -80MHz frequency interval must be less than 10 V/m. Recommended distance between portable and mobile RF communication equipment and Mollii			

Recommended distance between portable and mobile RF communication equipment and Mollii			
Mollii is intended for use in an electromagnetic environment where disturbances and radiation from RF equipment can be checked. The customer and user of Mollii can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitter) and Mollii according to the recommendations below. The distance depends on the maximum voltage of the RF communication equipment.			
Maximum output voltage of the transmitter W	The distance depends on the frequency of the transmitter (m)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with an output voltage that is not listed in the table above, the distance can be calculated using the equation in the table above. Where P is the maximum output power in watts (W) indicated by the manufacturer and d is the distance in metres (m)			
NOTE 1 The higher frequency interval applies at 80MHz and 800MHz.			
NOTE 2 This guidance does not apply in all situations and environments. The electromagnetic environment can be affected by absorption and reflection from objects, people and other environmental factors.			

Reporting faults and accidents

Contact Inventions AB immediately in the event of accidents or incidents. Use the contact details below:

Inventions AB
Ankdammsgatan 35
171 67 Solna
Tel: +46 (0)8 410 277 01
Mail: support@inventions.se

EN

If equipment is defective, contact Inventions using the contact details above for return instructions.

Inerventions AB, Ankdammsgatan 35, SE-171 67 Solna. Tel: +46 (0)8 410 277 01

