SPECIAL GYRO MANUFACTURER

PRZEDSIĘBIORSTWO WIELOBRANŻOWE
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BPPV Medical Treatment Gyroscope
User Manual

MD CE

This User Manual applies to medical device – BPPV Medical Treatment Gyroscope manufactured by:

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MD CE

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1. Indications for use

The device is intended to treat benign paroxysmal positional vertigo (BPPV).

2. Target group

People with vertigo and balance disorders requiring diagnosis and treatment based on diagnostic and therapeutic manoeuvre techniques.
Maximum patient weight: 130 kg.
Professional user/operator – physician.

3. Contraindications

The device may be unsuitable for persons with cardiac problems, epilepsy, pregnancy, people with diseases of the nervous system, unusual headaches, significant pathologies in the cervical spine, uncontrolled elevated blood pressure, some associated neurological symptoms or other unusual symptoms.

4. Information on any special storage or handling conditions

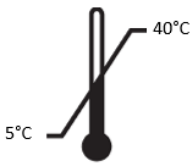
Use of the device is allowed only after learning the user rules, which must be presented to the patient in an accessible manner, in an easily accessible place, e.g. on a board outside the space where the device is located. Only a trained attendant/operator and a patient may be in the room when the device is used. It is forbidden for any other persons to remain in the gyroscope station area. It is recommended that the device station be placed in a separate room, such as a diagnostic room. Only the attendant/operator may allow patients to enter the device station.
Do not allow patients to enter the space around the device until the rings are securely locked. The device must be set up on the steel beams that are provided with the device as a standard.

It is forbidden to use the device while it is placed on the wheels integral to the base.

Transport, storage and operation conditions:

The device should only be used in a space suitable for medical examinations.

Temperature: from 5° C to 40° C.



Protect from excessive humidity.

5. Product Characteristics

The BPPV medical treatment gyroscope is designed to diagnose and treat benign paroxysmal positional vertigo (BPPV). The device is operated manually by a healthcare professional specializing in vertigo and other balance disorders.

The treatment of benign paroxysmal positional vertigo (BPPV) is most often performed using the traditional method – the classical method, i.e. the method of "diagnostic and therapeutic manoeuvres" performed on a conventional treatment table. In the Dix-Hallpike manoeuvre, the doctor places the patient from a semi-sitting to a lying position with the head twisted at an angle of 45 degrees and observes the patient's emerging nystagmus. The method has significant limitations. It offers only a limited number of available positions, little precision in maintaining the correct plane of motion, and limited acceleration that can be achieved safely for the patient. It is unsuitable for use in patients with a variety of spinal conditions. For this reason, the effectiveness of manoeuvres performed in the classical manner is very limited in medical practice, and there is a risk of remission.

6. Product Description and Key Components

The device consists of a primary structure, i.e. a base and two steel rings. Attached to the base is a control cabinet with pedals that control electromagnets connected to it and a power supply. An arm with bouncers is also attached to the base. Inside the smallest ring, there is a seat equipped with a patient security system.

7. Precautions

The product can only be used under the specified pressure, humidity and temperature conditions. The product can only be used by trained personnel. If the product or any of its components are damaged, it must be repaired before further use. Clean the device after each use. After/before each use, the operator must clean all the parts which come in contact with the patient using appropriate cleaning agents. To operate the device, use only the components designed for this purpose.

The patient must keep their hands on the handles provided.
The device should not be used in patients weighing more than 130 kg.
No modification of the product is allowed without prior authorization from the manufacturer.
No parts of the product can be serviced or maintained during use.
All movable elements of the patient's clothing or jewellery must be taken off. Patients are required to take off jewellery and glasses, empty their pockets of all items, e.g. cell phone, keys, and change. They must remove all foreign objects from their mouth, e.g., chewing gum, dentures, etc. Persons with longer hair – should pin/braid it.
It is forbidden to stretch arms and legs beyond the perimeter of the smallest ring while using the product.
Before starting the device, check that the fastened patient is not able to touch the larger ring with their outstretched legs or hands – if they can touch it, they must not use the device.
If the patient asks to stop the procedure, the staff must immediately stop the device.

The staff must remain in constant visual and verbal contact with the patient, so that they can immediately respond to any emergency by stopping the device.

8. Side effects/adverse reactions

- Intensive and prolonged use of the product may result in minor raptures of the capillary blood vessels.
- Some components of the device may be allergenic or cause an allergic reaction in the patient or user.
- Patients with moderate headaches may experience temporary deterioration immediately after treatment.
- Patients with nausea may vomit during diagnosis and treatment procedures. They must be asked to notify the operator as early as possible if they are going to vomit so the operator can interrupt the procedure.

9. Specifications necessary for the user/operator

Patients are secured by:

(a) fastening the seat belts
(b) closing the seat gates
(c) doublechecking the integrity of the safeguards used.

The patient may be allowed to enter the device seat only when all the rings are locked with a brake and the lock security is checked by the staff. Only persons trained in the use of the BPPV Medical Treatment Gyroscope may operate the device.
The device must be blocked when the patient is getting into or out of the device
.
The attending staff assists each patient in getting into and off the device.
When the device is not in operation, it must be protected against access by unauthorized persons.
It is strictly forbidden for persons under the influence of alcohol and other intoxicants to enter the device.

Each device owner, whether operating the device or letting it be used by other persons, is

required to purchase liability insurance.

10. Detailed information on the initial handling of the product

The operator's responsibilities include: checking all structural components of the BPPV Medical Treatment Gyroscope, tightening all bolts, checking for play on bearings and at all the points where parts are bolted together. All welds must also be checked for cracks. If any of the above irregularities have been found, it is prohibited to start the device, and the owner/operator is obliged to inform the manufacturer.

The device is delivered with its Technical and Operating Documentation which provides detailed guidelines for the operation and maintenance of the device. The operator must check the product before each use to ensure that it meets the guidelines provided by the manufacturer. If the product functions incorrectly, contact the manufacturer's technical support immediately. It is the responsibility of the operator to control the expiration date of the technical assessment certificate. The use of the device without possessing a valid technical certificate is prohibited. The period of use – the expiration date of the technical assessment certificate.

Technical Support:

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11. Special training of the product user.

Before putting the device into operation, the user/operator must become familiar with all the information provided in the User Manual and be trained by the designated persons who deliver the product.

Patients must be informed of possible side effects and precautions.

12. Starting the device

Starting the device (setting the gyro's rings in motion) – after fastening the patient with belts and securing with the swinging gates, the operator steps back and outside of the rings' operating area. If a step stool has been used, remove it from the operating space.
Standing outside the device, the medical professional checks that there is no one in the device's working space. The operator then manually releases the mechanical brake of he ring. The rings are driven solely by human muscle power. The rings must not be allowed to rotate inertly and without control. While maintaining control of the rings, unlock the electromagnet of the smaller ring with the pedal. It is put in the desired position and then locked again. With the smaller ring positioned as required, unlock the electromagnet of the larger ring.

THE RINGS MUST NEVER ROTATE INERTLY WITHOUT CONTROL WHILE THE DEVICE IS OPERATING!!!

13. Stopping the device

Stop the device (stop the ring of the device) – in the following order:

1. Remember never to put the ring of the device into inertial rotation.

- Emergency situation: when the rings rotate inertly, we allow the rings to rotate until they come to a complete stop.

2. Lock the largest ring with the electromagnet's pedal so that it remains in the upright position. The position is set manually. The rings must not move relative to each other when the electromagnet is locked.
3. When the largest ring is locked in the upright position, it is at rest (it does not rotate) – manually set the lock with the handbrake.
4. The smaller ring should be locked with an electromagnet – it should never rotate without control.

- Emergency situation: when the rings rotate inertly, allow them to rotate until they come to a complete stop.

5. When the smaller ring is aligned with the larger ring, manually lock the rings with the hand brake by locking both rings at the same time.

6. If the smaller ring is not aligned with the larger ring, unlock the electromagnet with the control pedal, align them and then lock them with the electromagnet again.
7. Manually lock both rings with the hand brake.
8. Check that all the rings are locked.
9. If the patient's height or health condition requires so, provide a step stool.
10. Unfasten the patient from the device seat.
11. The operator of the device always helps the patient get off the device.

14. Information for users and patients

Any serious incident related to the device must be reported to the manufacturer and the competent authority of the Member State where the user or patient resides. In Poland, this is Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (Al. Jerozolimskie 181 C, 02-222 Warszawa).

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