Российская Академия Наук

Russian Academy of Sciences

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Of the Russian Academy of Sciences,
Chief Medical Officer

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Test Report

 # 8/13 of December 30, 2013

Clinical test on Corden medical unit, a spinal and paravertebral muscle correction unit manufactured by Corden LLC, Chelyabinsk, Russia

1. Between October 10, 2013 to December 30, 2013, the Physical Therapy Department in the RAS Hospital conducted test on Corden medical unit, a spinal and paravertebral muscle correction unit manufactured by Corden LLC, Chelyabinsk, Russia (hereinafter referred to as "Corden").

2. It was the aim of the test to estimate the applicability of the said unit to practices of healthcare institutions across the Russian Federation. The test included the following:

- Declared purpose compliance evaluation;
- Declared technical parameter compliance evaluation;
- Usability and performance evaluation;
- Operation safety evaluation;
- Results and efficiency evaluation;
- Complications evaluation in patients who undergo Corden therapy;
- Time it takes to master Corden;
- Comparative evaluation with analogs;
- User guide informativity.

3. Reason for test:

Registration with the Federal Supervision Service for Healthcare.

4. Grounds for test:

Medical unit test approval # 202/2013 issued on September 17, 2013 subject to Order #5068-Пр/13 issued by the Federal Supervision Service for Healthcare on September 17, 2013.

5. The following units were submitted for test:

- Corden spine and paravertebral muscle correction units of the following models:

- Acute cerebral and cerebrospinal circulatory disorders, including spinal cord infarctions, spinal artery occlusions, or thrombosis etc).
- Advanced scoliosis.
- Spinal disc herniations with ruptured fibrous rings.
- Ankylosis (stiffness of a joint).
- Pronounced advanced instability in spinal segments, accompanied with spondylolysthesis.
- Acute or grave organic diseases.

7. Medical test findings were as follows:

The unit was tested in the Physical Therapy Department on 21 patients (9 male patients and 12 female patients) aged between 28 and 66.

Prior to the test, physical therapists were instructed on the properties, the operation, and the proper usage of the unit. Therapeutical sessions were conducted on a daily basis, 5 to 7 sessions a day.

Patients selected for the test were interviewed and their informed consents were obtained.

Patient #	Gender and age	Diagnosis	Application and clinical effect
1	F, 56	Lower back pains	Pain syndrome relief
2	M, 48	Shoulder epicondylitis	Pain syndrome relief
3	F, 45	Scapulohumeral periarthritis	Pain syndrome relief and improved joint mobility
4	M,62	Scapulohumeral periarthritis	Improved joint mobility
5	F, 47	Tension headaches	No effect
6	M, 43	Neck pains	Pain syndrome relief
7	F, 37	Lower back pains	Pain syndrome relief
8	F, 49	Tension headaches	Pain syndrome relief
9	F, 32	Degenerative disc disease accompanied with lower back radicular pains	No pronounced effect
10	M, 38	Degenerative disc disease accompanied with lower back radicular pains	Pain syndrome relief
11	F, 28	Kyphoscoliosis and thoracic pains	Pain syndrome relief
12	F, 39	Scoliosis and thoracic pains	Pain syndrome relief
13	F, 40	Lower back pains	Pain syndrome relief
14	M, 54	Thoracic pains	No pronounced effect
15	F, 45	Degenerative disc disease accompanied with lower back radicular pains	Pain syndrome relief
16	M, 47	Degenerative disc disease accompanied with lower back radicular pains	Pain syndrome relief
18	F, 66	Stroke rehabilitation; right arm paresis	Improved mobility of arm
19	M, 65	Neck pains and backaches caused by occupational muscle tension	Weakly positive effect
20	F, 33	Asthenic syndrome	Improved overall health

21	F, 30	Asthenic syndrome	Improved overall health

The following **conclusions** were made from the test conducted:

- The unit is compliant with its intended medical purpose in terms of its operational properties;
- Corden spine and paravertebral muscle correction unit (models: Corden spine and paravertebral muscle correction unit and Corden Magic spine and paravertebral muscle correction unit are compliant with their declared technical parameters;
- High therapeutic efficiency of the unit in therapy and rehabilitation of patients with various profiles was established;
- The unit is easy to operate and therapeutic procedures are simple and require no specialized environments. The unit is small in size and weight and environment friendly, which makes it easy to use in hospital, outpatient, and household environments;
- The unit is a device for non-invasive physical therapy; it is easy to clean and to disinfect.
- No complications or side effects were discovered during the test as long as the unit was used in compliance with the user guide, no adverse effects to the course of primary diseases or comorbidities were discovered.
- No malfunctions or breakdowns of the unit were discovered in the course of the test.
- It takes very little time to master operation of the unit;
- The user guide is quite informative;
- The unit can be used in physical therapy departments of clinics, sanitariums, and other healthcare institutions on patients of various age groups or individually in household environment on medical prescription;
- The effect of Corden spine and paravertebral muscle correction units is as good as that of the analog below:
  ARMOS 2, a swinging base polymer unit for mobilization massage and acupressure for therapeutic spinal relief, manufactured by Armos LLC, holds RU #29/06010203/5424-03 issued on August 15, 2003.
- The unit test results are true for the both of the models specified in the technical requirement and submitted for registration, namely
  -Corden spine and paravertebral muscle correction unit; and
  -Corden Magic spine and paravertebral muscle correction unit.

Conclusion

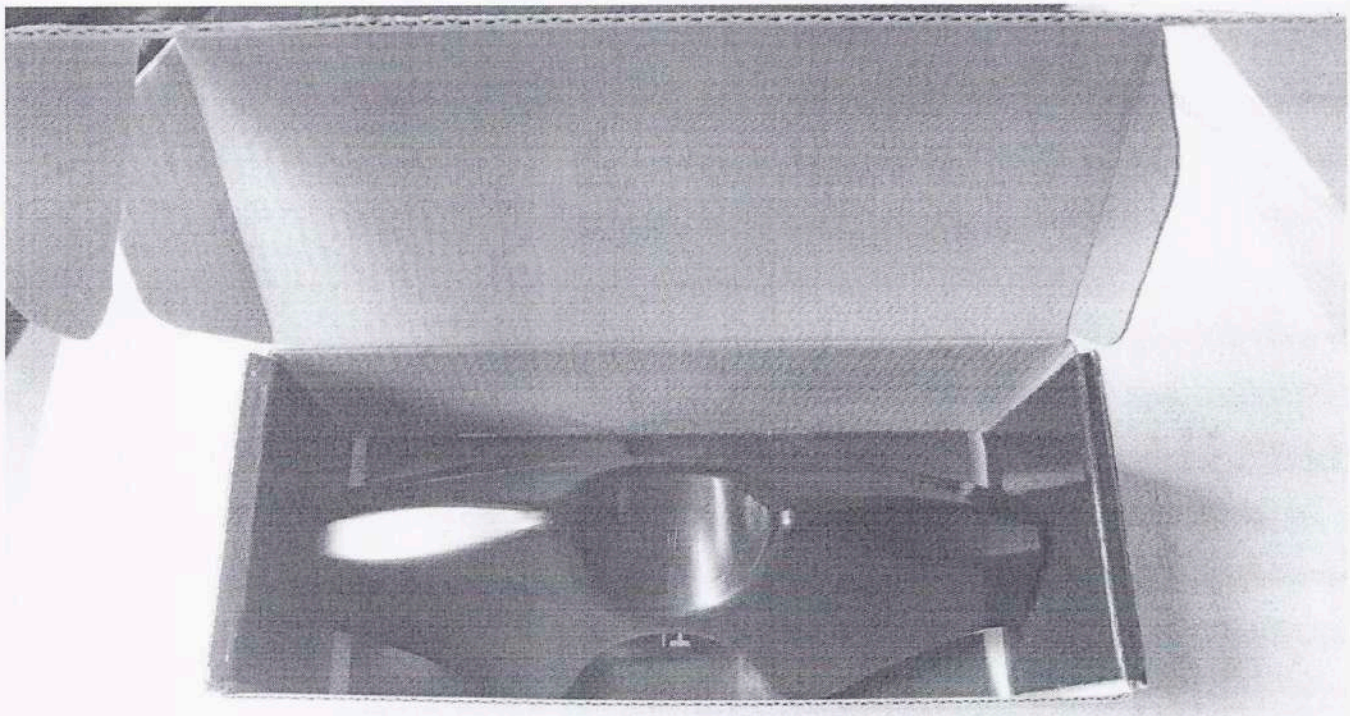
The results of the clinical test conducted suggest that Corden spine and paravertebral muscle correction unit, Chelyabinsk, Russia, may be recommended for wide clinical use across the Russian Federation.

Board Chairperson: F. M. Ballyuzek, Doctor of Medicine, Professor

Board members:

Physical Therapy Department Chief: D. F. Kapakaskalidi

Appendix 1 to Report # 8/13 – pictures of a sample unit



Board Chairperson M. F. Ballyuzek, Doctor of Medicine, Professor