

**Clinical Evaluation Report**

(in accordance with the requirements of MEDDEV.2.7.1, Appendix E)

**Evaluation object (hereinafter devices):****Vibroacoustic device:**



- Vitafon
- Vitafon -T
- Vitafon -5

**Vibroacoustic and infrared devices:**

- Vitafon-IR
- Vitafon -2

**Evaluation method:**

Clinical Evaluation of the consolidated data on clinical trials and research.

Action	Function	Name	Date	Signature
Made by	Quality Assurance Manager	V.P. Mozhuga	25.08.2016	
Approved	General manager	V.A. Fedorov	29.08.2016	

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## 1 General details in regard to the devices

### • Identification of the devices:

Type	Model
Vibroacoustic apparatus	VITAFON
	VITAFON-T
	VITAFON -5
Vibroacoustic and infrared apparatus	VITAFON -IR
	VITAFON -2

### • Manufacturer: "VITAFON" Co. Ltd

## 2 Description of the device and its intended application

### 2.1 General information

The devices are the articles of medical equipment. The devices are manufactured as per the requirements of *GOST R 50444-92 «Medical devices, apparatuses and equipment. General performance specification»* and are certified in accordance with the established procedure. As to its safety, the devices meet the requirements of *GOST R 50267.0-92* and *EN60601-1 «General requirements for basic safety and essential performance»* for the articles of II class, BF type with the casing without protection against water ingress.

According to Directive 93/42/EEC, the devices are referred to active therapeutic non-invasive medical products of IIa class intended for short-term use.

The devices do not contain any pharmaceutical substances, tissues and blood components. The devices are intended for multiple, short-term use. The exposure time is no more than 60 minutes daily. The contact with the body is indirect, superficial, through hygienic cloth. The service life of the devices are 5 years.

### 2.2 Specifications

Lower frequency of the 1 <sup>st</sup> subband, Hz, within the range of .....	30-60
Upper frequency of the 1 <sup>st</sup> subband, Hz, within the range of .....	1500 - 4500
Lower frequency of the 2 <sup>nd</sup> subband, Hz, within the range of .....	200 - 1000
Upper frequency of the 2 <sup>nd</sup> subband, Hz, within the range of .....	9000-18000
Pulse modulation period, within the range of .....	0.5-1.2
Duration of one microvibration frequency change cycle, s, within the range of .....	70-120
Amplitude of membrane microvibration at the lower frequency of the 1 <sup>st</sup> subband, µm, within the range of:	
Mode for minimal amplitude.....	2,8-5,4
Mode for maximum amplitude, not more.....	28,0
Power of infrared emission done by the infrared emission transducer:	
minimal, mWt, not more than .....	3,0
maximum, mWt, within the range of .....	20,0 – 40,0
Infrared emission wave length, micron .....	0,95 ±0,04

### 2.3 Purpose of the devices

The devices are used for prophylaxis and treatment of the diseases associated with disturbance and insufficiency of the capillary blood flow and lymph flow. Microvibrations generated by the devices promote the improvement of blood and lymph flow in the exposed region.

The exposure of the tissues and organs to low intensity modulated mechanical oscillations (microvibrations) in the acoustic frequency band makes it possible to achieve the pronounced therapeutic effect. When the vibroacoustic transducer (vibrophone) directly contacts with the superficial skin layers, microvibrations penetrate into the tissues (in the radius of and to the depth of down to 7-10 cm) and influence selectively different biological structures and also microvibration deficit is compensated in the tissues and organs of the human organism.

The devices have anti-inflammatory, anti-edematous, analgesic, trophic and regenerative effects. They are used for treatment of functional disorders caused by disturbed innervation of the organs and tissues and also for enhancement of the immunity and general strengthening of the organism, for securing the therapeutic effect after recovery and with the purpose of prophylaxis.

The infrared emission applied in the devices of "Vitafon-IR" and "Vitafon-2" in combination with vibroacoustic treatment allows to improve the results of vibriacoustic effect for inflammatory diseases.

### 2.4 Hygienic rules

Wipe the operating surface of the vibroacoustic transducer (vibrophone) using a cloth moistened with 3% hydrogen peroxide solution within 30 seconds with the purpose of disinfection before application of the device.

Apply the vibrophones and infrared transducers with their membranes to the body surface through a gauze, paper or cotton cloth.

## 3 Indications

The vibroacoustic devices are intended for use in the complex treatment of the diseases for the more successful therapy of which it is required or advisable to improve the capillary blood flow and lymph flow or to compensate microvibration deficit.

Indication	Applicable for apparatuses:	Grounds for inclusion in the list of indications of the User Manual
<b>Joint diseases: Gonarthrosis, "Heel spur", Dupuytren's contracture</b>	Vitafon-T, Vitafon-2, Vitafon-5	Annex I
<b>Spine diseases: Low-back pain Osteoarthritis of the lumbar spine</b>	Vitafon-T, Vitafon-2, Vitafon-5	Annex II

#### 4 Contraindications for use

The use of the device is contraindicated:

- Abdominal aortic aneurysm
- Bleeding ulcers
- Crohn's disease
- Hemorrhoids
- Menstrual period
- in the region of malignant neoplasms;
- during pregnancy;
- in the region of thrombophlebitis;
- in the region of pronounced atherosclerosis;
- in patients with acute infectious diseases;
- in case of elevated body temperature;
- in the region of action of implanted pacemakers.

If the exposure region covers organs, in which concrements are revealed (gall bladder, urinary tract etc.), the procedures should be administered only on recommendation and under supervision of the physician.

#### 5 Evaluation of treatment effect and choice of clinical data types

##### 5.1 Context for development of the devices

The devices have been developed basing on the new clinical use of the available technology and additional changes in the existing technology.

The therapeutic exposure to mechanical microvibration of acoustic frequency underlies this technology. The devices implementing this exposure technology have the general name "vibroacoustic apparatuses" and this therapy type is called vibroacoustic therapy.

His technology was used for the first time in the devices of the "Intrafon" series developed jointly by the All-Russian Research and Testing Institute of Medical Equipment (VNIIMT) and Central Military Research Aviation Hospital (CVNIAG).

The works of Russian scientists, in particular academician D.N. Nasonov and his school, served as the theoretical and experimental substantiation for this method. In 40-70s of the last century, D.N. Nasonov and his colleagues established that the audible sound with certain resonance frequency and intensity could be a physiologic stimulus, which was able to cause activation of the nervous, muscular and renal tissues [3,5,8]. Later experimental morphologic studies were performed at the CVNIAG, which allowed to determine the threshold and maximum permissible sound intensities which can be used for

stimulation of the kidneys and upper urinary tract in the clinical practice [6,10]. Just these studies determined the parameters and safe exposure levels used in the devices “Intrafon”.

Since 1986 the devices of the “Intrafon” series have been used for treatment of some urologic diseases, diseases of the gastrointestinal and cardiovascular systems, in particular, for normalization of the arterial blood pressure in the patients with hypertension syndrome caused by renal diseases, at the hospitals and physiotherapeutic rooms at outpatient clinics [7].

The mechanical microvibration of acoustic frequency generated by the transmitter of special design underlies the therapeutic action of the “Intrafon” devices.

The “Vita fon” device was developed in 1994 on the base of this device. The mechanical microvibration of acoustic frequency also was the base of its therapeutic action but it was intended not only for clinical but also for home use.

When developing the device, the designers took into account the findings of the renowned physiologist N.I. Arinchin who investigated microvibrations and revealed that “their ‘micropump performance has a certain correlation with frequency and amplitude of the phonomyogram” [1,2]. The pump function of microvibration occurs due to availability of the valves in the venous and lymphatic vessels.

In order to ensure the safe use at home, the vibroacoustic apparatuses use only microvibration frequency range and amplitudes, which are natural for the organism and which do not exceed the microvibration frequency and amplitude range observed in case of the maximum muscle strain and vibration of vocal cords [4].

Difference of the “Vita fon” device from the “Intrafon” device:

- The “Vita fon” devices has smaller dimensions, lesser weight and more compact working parts
- The “Vita fon” device uses the whole safe acoustic microvibration frequency range (see para 2.2) while the “Intrafon” device uses only one fixed frequency of 2.7 kHz.

The following vibroacoustic devices have been developed by the company “Vita fon” to increase effectiveness and improve number of the consumer functions:

Device	The difference with the device “Vita fon”
Vita fon-IR	The additional infrared transducer to improve the results of vibroacoustic therapy in treatment of inflammatory diseases.
Vita fon-2	Additional removable vibroacoustic transducers and infrared transducer that allow shorten the time of the procedure.
Vita fon-T	The presence of timer for the time of the procedure.
Vita fon-5	The possibility to connect additional vibroacoustic transducers to shorten the time of the procedure. The independent power supply that allows to undergo procedure in any time and in any place.

All these devices have specifications of vibroacoustic exposure (see para 2.2), which are absolutely similar to those of the “Vita fon”.

Taking into account the nature of the difference in the specifications of the devices of the series "Vita fon" and their analogue, the "Intra fon" device, the clinical data used for assessment of the "Intra fon" device, may be applied to estimation of safety and performance of the technology. At the same time, the availability of differences requires more precise assessment of performance and confirmation of the safe use. The clinical studies were performed with this purpose.

## 5.2 Definition of similar devices used in the clinical trials

The "Vita fon" company manufactures three vibroacoustic apparatuses:

- Vita fon
- Vita fon -T
- Vita fon-5

and two vibroacoustic and infrared apparatuses:

- Vita fon-2
- Vita fon-IR

All manufactured devices have identical exposure specifications and the clinical data obtained for one device may be applied to another device and when we use another device, we shall obtain the similar clinical picture, respectively.

**Table 1 – Correspondence of the exposure specifications of different devices**

«Vita fom»	«Vita fon-T»	«Vita fon-2»	«Vita fon – 5»
Mode 1	Mode 1	Transducer: double vibrophone, mode 2, energy 2	Transducer: double vibrophone of B1 type, mode 0
Mode 2	Mode 2	Transducer: double vibrophone, mode 2, energy 3	Transducer: double vibrophone of B2 type, mode 0
Mode 3	Mode 3	Transducer: double vibrophone, mode 4, energy 2	Transducer: double vibrophone of B1 type, mode 9
Mode 4	Mode 4	Transducer: double vibrophone, mode 4, energy 3	Transducer: double vibrophone of B2 type, mode 9

The output specifications of the "Vita fon-IR" device are similar to those of the "Vita fon-2" device with connected single vibrophone and IR-transmitter.

## 5.3 The main requirements to the device which are to be assessed in the clinical trials

Table 2 presents the main requirements to the device which are important from viewpoint of safe use.

**Table 2 – The main requirement to ensure safe use**

Hazard subgroup	Hazard name	Requirement to controlled parameters	Severity of consequences
Mechanical energy	Vibration	Microvibration amplitude at the frequency of 40 Hz should not exceed 30 µm, microvibration frequency is 30 – 18000 Hz	Insignificant
Biochemical	Allergenicity	The materials of the working part should not cause skin irritation and allergic reactions	Insignificant

The parts of the devices and packing contact directly with the patients in the process of operation, therefore, preclinical assessment is regularly performed to estimate the toxicity and allergenicity of the materials used in the manufacture of the device. The allergenicity and toxicity of the materials are assessed at specialized toxicological laboratories.

The microvibration of acoustic frequencies is the main therapeutic factor. Therefore, when selecting the types of clinical data, complications and side effects are assessed by this factor.

### References to the literature for Part 5

- 1 **N.I. Arinchin, G.F. Borisevich.** Micropump activity of skeletal muscles in case of their stretching .- Minsk, Science and engineering, 1986. – 112 p.
- 2 **N.I. Arinchin.** Human peripheral “hearts”. – Minsk: Science and engineering. 1988. – 64 p.
- 3 **D.N. Basonov, K.S. Ravdonik.** Response of isolated striated muscles of the frog to audible sounds // Physiologic Journal of the USSR.- 1947. – Vol. XXXIII. - No 5. - P. 569-580.
- 4 **A.E. Vasiliev, A.Yu. Kovelonov, D.V. Kovlen, F.N. Ryabchuk, V.A. Fedorov.** Organism resources: immunity, health, longevity. – Saint Petersburg: “Vita Nova” Ltd., 2004. - 416 p.: fig.
- 5 **V.M. Grigorieva, L.P. Lebedeva.** Comparative study of the effect exerted by sonic and ultrasonic oscillations on the living tissue at insonation through air. – Proceedings of the scientific session on the problem “Modern state of the teaching on industrial noise and ultrasound, their influence on the organism and occupational adverse effect”.- Leningrad, November 12-14, 1968. - P. 40-41.
- 6 **A.R. Guskov.** Direct electrical and sonic stimulation of the upper urinary tract in the patients with concrements in urethers. – Ph.D. thesis. – Moscow, 1985. - 189 p.
- 7 Instruction for medical use of the “INTRAFON-1” sonic stimulator.
- 8 **D.N. Nasonov, K.S. Ravdonik.** Direct effect of audible sounds on the nerve cells in isolated spinal ganglia of rabbits: Report of the Academy of Sciences of the USSR, new series. - 1960. - Vol. 71. - No 5. - P. 985-987.
- 9 **D.N. Nasonov, D.L. Rosental.** Direct effect of audible sounds on renal tubular epithelium of the frog: Report of the Academy of Sciences of the USSR, new series. - 1950. - Vol. 71. - No 6. - P. 1163-1166.
- 10 **V.S. Ryabinsky, A.R. Guskov.** Stimulation of the upper urinary tract with sonic waves in the patients with concrements in urethers. //Urology and nephrology - 1984. - No. - P. 45-49.



## 6 Evaluation of the benefit of use of the apparatus series "Vitaфон"

Consideration of the results of clinical trials on the use of indications of apparatus series "Vitaфон" (Annex I - Annex II), leads to the conclusion about the benefits of the use of apparatus series "Vitaфон" in physiotherapy and rehabilitation medicine practice.

## 7 Evaluation of safety of use of the apparatus series "Vitaфон"

### 7.1 Risk Analysis

The evaluation the safe use of apparatus series "Vitaфон" in accordance with the procedure: QMS PR 09 Design and development, Risk Analysis is performed. For all product series "Vitaфон" in the result of the Risk Analysis:

- *Risk Analysis\_Vitaфон-T\_23.03.2015*
- *Risk Analysis\_Vitaфон-2\_12.03.2015*
- *Risk Analysis\_Vitaфон-5\_16.03.2015*
- *Risk Analysis\_Vitaфон-IR\_18.03.2015*

, the level of residual risk - low.

### 7.2 Customer Feedback

Since 1996, up to the present time, the company "Vitaфон" constantly analyzes the data received from the customer. Table №3 is a list of sources of feedback to the user:

**Table 3 – List of feedback sources**

Source	Audience
Calls to the Center of business service (CBS)	Buyers and users of the devices
Mail letters, coming to e-mail: <a href="mailto:info@vsegdazdorov.ru">info@vsegdazdorov.ru</a>	Visitors of the site <a href="http://www.vsegdazdorov.ru">www.vsegdazdorov.ru</a> via tool "Write a letter"
Mail letters, coming to e-mail: <a href="mailto:info@vitaфон.ru">info@vitaфон.ru</a>	Visitors of the site <a href="http://www.vitaфон.ru">www.vitaфон.ru</a> and users of the devices
Processing questionnaires	People who have responded to The Questionnaire sent from e-mail <a href="mailto:feedback@vitaфон.ru">feedback@vitaфон.ru</a>

The Center of Business Service continuously records all requests of consumers, circulation recorded in the DataBase of the company.

The data for various diseases derived from customer feedback are sorted by disease group and are recorded in a special log DataBase. By analyzing this data, the company together with leading specialists of medical institutions to draw conclusions on the effectiveness of the use of devices in the treatment and prevention of various diseases.

Annually, the Center of business service is preparing a report on the treatment of consumers of all sources of feedback and analysis of questionnaires. Analysis of questionnaires and requests of consumers show a high therapeutic effect of apparatus "Vitaфон" series, both in treatment and in prevention of diseases.

As a result of analysis of the data from 1996 to the present, did not reveal any incident.

**8 Evaluation scientific literature**

To confirm the safety of the method of vibroacoustic effects company "Vitaфон" annually conducts a search of the scientific literature on clinical studies with the use of vibroacoustic therapy. The analysis found the scientific literature conducted by a doctor, a specialist in the field of vibroacoustic therapy.

For each scientific work being assessed by the criterion of benefit / risk. The analysis formed a general annual report: QMS.RC.20 / 05 Protocol of the literature search

As a result, since 2013 the data analysis is currently not found a single case of the risk of using the method of vibroacoustic effects.

**CONCLUSIONS**

The critical evaluation of the consolidated data on clinical testing and studies, and scientific literature allows make the following conclusions

- The application of the considered devices is effective and is usefeul.
- The negative effects the happened due to application of the devices were not revealed.
- The risks named in the documentation on Risk management did not result in negative occurrences.
- In the scientific literature no risks of application vibroacoustic therapy were revealed.

Therefore, the devices are effective and conform with requirements on safety and effectiveness of application in medical practice.

The Clinical Evaluation Report was reviewed and approved by the competent specialists (Annex VIII).

## Annex I

<b>INDICATION:</b>	Joint diseases: Dupuytren's contracture, "Heel spur", Gonarthrosis
<b>Applicable for apparatuses:</b>	Vitafon-T, Vitafon-2, Vitafon-5

**GROUND FOR INCLUSION IN THE LIST OF INDICATIONS OF THE USER MANUAL:**

Clinical trials	Clinical trial/ Poland: The use of vibroacoustic therapy in patients after surgical treatment of Dupuytren's contracture.
	Clinical trial/ Poland: Evaluation of the effectiveness of vibroacoustic therapy treatment of patients with so-called "Heel Spur". A preliminary report
	Clinical trial/ Poland: The influence of vibroacoustic therapy on the functional status of patients with gonarthrosis. A preliminary report
Risk Analysis in accordance with the standard: EN ISO14971:2012	<u>Technical File Documents:</u> Risk Analysis_Vitafon-T_23.03.2015 Risk Analysis_Vitafon-2_12.03.2015 Risk Analysis_Vitafon-5_16.03.2015

**DETAILED INFORMATION ON CLINICAL TRIALS:****THE USE OF VIBROACOUSTIC THERAPY IN PATIENTS AFTER SURGICAL TREATMENT OF DUPUYTREN'S CONTRACTURE**

Acceptance for publication	11.2012
Publication	Fizioterapia Polska 2012; 4(4); Vol. 12, 355-362
Medical institution	University Clinical Hospital No2 of the Military Medical University, Lodz, Poland
Report name	The use of vibroacoustic therapy in patients after surgical treatment of Dupuytren's contracture
Apparatus, which was used in the study	Vitafon-T
Design of Clinical trial	Comparison of results in parallel groups: Group 1 (10people): Postoperative laser treatment combined with vibroacoustic therapy Group 2 (10people): Vibroacoustic therapy only
Evaluation method	<ul style="list-style-type: none"> <li>• Measurement of range of motion in the joints of the fingers</li> <li>• Laitinen questionnaire</li> <li>• VAS scale</li> </ul>
Number of patients	10/10

**Competence of the personnel conducting clinical trial:**

Function	Name	Medical specialization
Physiotherapist Rehabilitation Division, Private Medical Center. Saint Family Hospital, Lodz	Magdalena Stepien	Physiotherapist
Doctor of Medical Sciences, Physiotherapist Department of Rehabilitation, University Hospital, Lodz	Pawel Piatkowski	Physiotherapist
Doctor of Medical Sciences, Orthopedist, Department of Hand Surgery, University Hospital, Lodz	Robert Rokicki	Sports medicine

**Results from clinical trial:****Reference to the Clinical Report, Conclusions:**

"1.Vibroacoustic therapy significantly reduced postoperative pain in patients with Dupuytren's contractures (by about 70% in each group).

2. The range of movements in the operated fingers, and MCP and PIP joints significantly improved after vibroacoustic therapy.

3. Laser treatment combined with vibroacoustic therapy enhances the favourable effect involving improvement of the range of movement in the operated joints (MCP and PIP), however it does not significantly affect pain sensation"

### EVALUATION OF THE EFFECTIVENESS OF VIBROACOUSTIC THERAPY TREATMENT OF PATIENTS WITH SO-CALLED "HEEL SPUR". A PRELIMINARY REPORT

Acceptance for publication	01.2013
Publication	Ortopedia Traumatologia Rehabilitacja 2013; 1(6); Vol. 15, 77-87
Medical institution	"Vital" Rehabilitation Centre, Warsaw, Poland
Report name	Evaluation of the effectiveness of vibroacoustic therapy treatment of patients with so-called "Heel Spur". A preliminary report
Apparatus, which was used in the study	Vitafon-2
Design of Clinical trial	Comparison of results in parallel groups: Group 1 (40people): Vibroacoustic therapy only Group 2 (20people): Ultrasound and laser therapy
Evaluation method	<ul style="list-style-type: none"> <li>Modified short-form McGill Pain Questionnaire</li> <li>VAS scale</li> </ul>
Number of patients	40/20

#### Competence of the personnel conducting clinical trial:

Function	Name	Medical specialization
Doctor of Medical Sciences Department of Rehabilitation and Physical Medicine, Military Medical University Hospital, Lodz, Poland	Adam Lukasiak	Doctor of rehabilitation medicine
Physiotherapist "Vital" Rehabilitation Centre, Warsaw, Poland	Monika Krystosiak	Physiotherapist
Doctor of Medical Sciences Department of Rehabilitation and Physical Medicine, Military Medical University Hospital, Lodz, Poland	Patrycja Widlak	Doctor of rehabilitation medicine
Associate professor Department of Rehabilitation and Physical Medicine, Military Medical University Hospital, Lodz, Poland	Marta Woldanska-Okonska	Head of clinic, Rehabilitation and Physiotherapy

#### Results from clinical trial:

##### Reference to the Clinical Report, Conclusions:

"1. The results of the present study confirm analgesic effectiveness of the vibroacoustic method in musculoskeletal overload conditions.

2. In order to confirm its effectiveness, it is necessary to conduct further prospective randomized studies with blinding and evaluate the long-term results."

### THE INFLUENCE OF VIBROACOUSTIC THERAPY ON THE FUNCTIONAL STATUS OF PATIENTS WITH GONARTHROSIS. A PRELIMINARY REPORT

Acceptance for publication	05.2014
Publication	Reumatologia 2014; 52, 5: 292–298
Medical institution	Institute and Faculty of Laser Therapy and Physiotherapy, <i>Collegium Medicum</i> in Bydgoszcz, Nicolaus Copernicus in Toruń
Report name	The influence of vibroacoustic therapy on the functional status of patients with gonarthrosis. A preliminary report
Apparatus, which was used in the study	Vitafon-T
Design of Clinical trial	Single group – 44 patients (20 men and 24 women)
Evaluation method	Double measurements (before and after therapy): <ul style="list-style-type: none"> <li>• VAS scale</li> <li>• The circumferences of the knee joints (5 cm above the joint space) and the functions of the lower limbs</li> <li>• The mobility and the risk of fall assessment test “Timed Up and Go” (TUG)</li> <li>• The test of the number of knee bends done without experiencing discomfort and/or pain</li> <li>• Laitinen questionnaire</li> </ul>
Number of patients	44

#### Competence of the personnel conducting clinical trial:

Function	Name	Medical specialization
Doctor of Health Sciences Institute and Faculty of Laser Therapy and Physiotherapy, <i>Collegium Medicum</i> in Bydgoszcz, Nicolaus Copernicus in Toruń	Agnieszka Skopowska	Balneologist
Therapist Institute and Faculty of Laser Therapy and Physiotherapy, <i>Collegium Medicum</i> in Bydgoszcz, Nicolaus Copernicus in Toruń	Maciej Biernacki	Therapist
Doctor of Medical Sciences Institute of Psychology, Kazimierz Wielki University in Bydgoszcz	Monika Dekowska	Therapist
Student “Physical Medicine” Student’s Scientific Circle, Institute and Faculty of Laser Therapy and Physiotherapy	Piotr Ozog	Student
Student “Physical Medicine” Student’s Scientific Circle, Institute and Faculty of Laser Therapy and Physiotherapy	Anna Grochowska	Student

#### Results from clinical trial:

##### Reference to the Clinical Report, Conclusions:

"Vibroacoustic therapy has brought positive healing effects of an analgesic and anti-swelling character among patients with gonarthrosis which, eventually, enhanced the general mobility. Due to the positive effect of vibroacoustic therapy in patients with gonarthrosis, it may become one of the elements of the healing process of degenerative changes in the knee joints. The intentionally changed vibroacoustic therapy procedure, adapted to the National Health Fund treatment system, provides opportunities of application in a broader group of patients – which does not exclude the use of the producer’s recommendations. It is advisable to extend the sample group to other groups of patients with diverse disease aetiology, according to evidence-based medicine."

## Annex III

<b>INDICATION:</b>	Spine diseases: Low-back pain, Osteoarthritis of the lumbar spine
<b>Applicable for apparatuses:</b>	Vitafon-T, Vitafon-2, Vitafon-5

**GROUNDINGS FOR INCLUSION IN THE LIST OF INDICATIONS OF THE USER MANUAL:**

Clinical trials	Clinical trial/ Poland: Evaluation of the effectiveness of combined magnetostimulation and vibroacoustic therapy treatment in low back pain and range of motion of the lumbar spine in professional drivers with low-back pain
	Clinical trial/ Poland: An assessment of analgesic effects of vibroacoustic therapy in treating pains of umbosacral spine in office workers
	Clinical trial/ Poland: Comparison of effectiveness of the acoustic wave therapy and ion cyclotron resonance in degenerative vertebral freed column disease
Risk Analysis in accordance with the standard: EN ISO14971:2012	<u>Technical File Documents:</u> Risk Analysis_Vitafon-T_23.03.2015 Risk Analysis_Vitafon-2_12.03.2015 Risk Analysis_Vitafon-5_16.03.2015

**DETAILED INFORMATION ON CLINICAL TRIALS:****EVALUATION OF THE EFFECTIVENESS OF COMBINED MAGNETOSTIMULATION AND VIBROACOUSTIC THERAPY TREATMENT IN LOW BACK PAIN AND RANGE OF MOTION OF THE LUMBAR SPINE IN PROFESSIONAL DRIVERS WITH LOW-BACK PAIN**

Acceptance for publication	03.2013
Publication	Medycyna Sportowa / Polish J Sport Med 2013; 3(4); Vol. 29, 187-196
Medical institution	Specialised Hospital No2 in Bytom, Poland
Report name	Evaluation of the effectiveness of combined magnetostimulation and vibroacoustic therapy treatment in low back pain and range of motion of the lumbar spine in professional drivers with low-back pain
Apparatus, which was used in the study	Vitafon-2
Design of Clinical trial	Comparison of results in parallel groups: Group A (10people): Vibroacoustic therapy+ magnetostimulation Group B (10people): Double magnetostimulation Group C (10people): Double Vibroacoustic therapy Group D (10people): Double vibroacoustic therapy with an infrared radiator
Evaluation method	<ul style="list-style-type: none"> <li>• VAS scale</li> <li>• Lumbar spine mobility range measurements using Schober's and Moll &amp; Wright's tests</li> <li>• Quality of life questionnaire EQ5D</li> </ul>
Number of patients	10/10/10/10

**Competence of the personnel conducting clinical trial:**

Function	Name	Medical specialization
Doctor of Medical Sciences, Physiotherapist Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom	Monika Mucha-Janota	Physiotherapist
Associate professor Department of Health Sciences, The Jan Kochanowski University of Humanities and Sciences, Kielce	Zbigniew Sliwinski	Physiotherapist
Doctor of Medical Sciences, Physiotherapist Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom Specialised Hospital No 2 in Bytom	Romualda Mucha	Physiotherapist
Therapist Silesian Medical University in Katowice	Jan Budziosz	Therapist
Professor Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom Department of Health Sciences, The Jan Kochanowski University of Humanities and Sciences, Kielce Silesian Medical University in Katowice	Aleksander Sieron	Head of Department

**Results from clinical trial:****Reference to the Clinical Report, Conclusions:**

"1. The application of vibroacoustic therapy and magnetic stimulation in the studied occupational group contributed to a decrease in pain indicators as well as the improvement of spine mobility and the quality of life.

2. Combination of vibroacoustic therapy and magnetic stimulation is characterized by the highest effectiveness of treatment in the studied group of professional drivers with lumbar pain syndrome."

**AN ASSESSMENT OF ANALGESIC EFFECTS OF VIBROACOUSTIC THERAPY IN TREATING PAINS OF UMBOSACRAL SPINE IN OFFICE WORKERS**

Acceptance for publication	06.2013
Publication	Fizioterapia polska/ nauka study 3/2013(13), 8-13
Medical institution	Specialised Hospital No2 in Bytom, Poland
Report name	An assessment of analgesic effects of vibroacoustic therapy in treating pains of umbosacral spine in office workers
Apparatus, which was used in the study	Vitafon-T
Design of Clinical trial	Single group – 52 patients (women)
Evaluation method	Double measurements (before and after therapy): <ul style="list-style-type: none"> <li>• VAS scale</li> <li>• Laitinen questionnaire</li> </ul>
Number of patients	52

**Competence of the personnel conducting clinical trial:**

Function	Name	Medical specialization
Physiotherapist The Jan Kochanowski University of Humanities and Sciences, Kielce	Marlena Drezewska	Physiotherapist
Professor Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom Department of Health Sciences, The Jan Kochanowski University of Humanities and Sciences, Kielce Silesian Medical University in Katowice	Aleksander Sieron	Head of Department
Associate professor Department of Health Sciences, The Jan Kochanowski University of Humanities and Sciences, Kielce	Zbigniew Sliwinski	Physiotherapist

**Results from clinical trial:****Reference to the Clinical Report, Conclusions:**

"Application of vibroacoustic therapy to office workers reduces complaints of pain of the lumbar spine, reducing their frequency and reduces mobility limitations.

Individual factors such as age and length of service does not affect the efficacy of therapy in the treatment of pain of the vibro-acoustic sacral spine in patients with sedentary work."

### **COMPARISON OF EFFECTIVENESS OF THE ACOUSTIC WAVE THERAPY AND ION CYCLOTRON RESONANCE IN DEGENERATIVE VERTEBRAL FREED COLUMN DISEASE**

Acceptance for publication	03.2014
Publication	Fizioterapia polska 3/2014(14), 8-11 Part1 Fizioterapia polska 4/2014(14), 6-13 Part2
Medical institution	Specialised Hospital No2 in Bytom, Poland
Report name	Comparison of effectiveness of the acoustic wave therapy and ion cyclotron resonance in degenerative vertebral freed column disease
Apparatus, which was used in the study	Vitafon-2
Design of Clinical trial	Comparison of results in parallel groups: Group K (20people): Simulated acoustic wave and kinesitherapy according to modified Mein's exercises Group FA (20people): Acoustic wave (AW) and kinesitherapy according to modified Mein's exercises Group JCR (20people): Ion cyclotron resonance (ICR) and kinesitherapy according to modified Mein's exercises Group FA+ JCR (20people): Acoustic wave and ion cyclotron resonance
Evaluation method	Double measurements (before and after therapy): <ul style="list-style-type: none"> <li>• VAS scale</li> <li>• Lumbar spine mobility range measurements using Schober's and Moll &amp; Wright's tests</li> <li>• Laitinen questionnaire</li> <li>• Quality of life questionnaire EQ5D</li> </ul>
Number of patients	20/20/20/20



**Competence of the personnel conducting clinical trial:**

Function	Name	Medical specialization
Doctor of Medical Sciences, Physiotherapist Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom	Monika Mucha-Janota	Physiotherapist
Doctor of Medical Sciences, Physiotherapist Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom Specialised Hospital No 2 in Bytom	Romualda Mucha	Physiotherapist
Professor Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom Department of Health Sciences, The Jan Kochanowski University of Humanities and Sciences, Kielce Silesian Medical University in Katowice	Aleksander Sieron	Head of Department
Therapist Clinical Ward of Internal Diseases, Angiology and Physical Medicine of the Chair of Internal Diseases and The Centre of Diagnostics and Laser Therapy, Bytom	Karolina Sieron-Stoltny	Therapist

**Results from clinical trial:****Reference to the Clinical Report, Conclusions:**

- "1. Ion cyclotron resonance and acoustic wave combined with ion cyclotron resonance reduce the perception of pain and increase the range of motion within the lumbar spine. Combined application of ICR and AW exerts a stronger analgesic effect as compared to other treatments of patients with lumbar OA.
2. In the quality of life assessments, combination of ion cyclotron resonance and kinesitherapy is comparable to the combination of cyclotron resonance, acoustic wave and kinesitherapy.
3. The use of ion cyclotron resonance as well as the use of the combination of acoustic wave and ion cyclotron resonance reduces the demand for non-steroidal anti-inflammatory drugs.
4. Combination of acoustic wave and ion cyclotron resonance in lumbar OA treatment has a synergistic effect of maximizing therapeutic benefits"

## Annex III

## Approval of the results of clinical evaluation

After review of the Clinical Evaluation Report in regard to the vibroacoustic devices "Vitafon", "Vitafon-T", "Vitafon-5" and the vibroacoustic and infrared devices: "Vitafon-IR", "Vitafon-2" we approve its results and conclusions:

Action	Function	Name	Qualification and employment period	Date	Signature
Approved	Chief physician of State Public Institution of Healthcare of Leningrad Region "Center of Preventive Care and Struggle with AIDS and contagious diseases", Doctor of Medical Science	A.Yu. Kovelonov	<b>Basic qualification:</b> infectious diseases doctor, total employment period 31 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 16 yrs.	26.08.2016	
Approved	Candidate of Medical Science, Associate Professor, S.M. Kirov Military Medical Academy	A.I. Kurtov	<b>Basic qualification:</b> urologist, total employment period 47 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 14 yrs.	29.08.2016	
Approved	Associate Professor, I. I. Mechnikov North-Western State Medical University, candidate of Medical Science	G. N. Loginov	<b>Basic qualification:</b> ophthalmologist, total employment period 44 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 14 yrs.	26.08.2016	
Approved	Chief of the Department on internal diseases and nephrology in I. I. Mechnikov North-Western State Medical University, Doctor of Medical Science, Professor	V.G. Radchenko	<b>Basic qualification:</b> therapist, total employment period 38 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 17 yrs.	26.08.2016	
Approved	Associate Professor, I. I. Mechnikov North-Western State Medical University, candidate of Medical Science	F.N. Ryabchuk	<b>Basic qualification:</b> pediatrics, gastroenterology, total employment period 49 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 14 yrs.	29.08.2016	
Approved	Associate Professor, I. I. Mechnikov North-Western State Medical University, candidate of Medical Science	P. V. Seliverstov	<b>Basic qualification:</b> therapist, total employment period 15 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 14 yrs.	29.08.2016	
Approved	Chief of the Department on therapy in the Hospital of Peter the Great, candidate of Medical Science	D.B. Tsursumia	<b>Basic qualification:</b> therapist, total employment period 23 yrs; <b>Length of time worked with vibroacoustic apparatuses:</b> 16 yrs.	29.08.2016	