Vitberg

Vitberg Recovery System **2**

Operation Manual

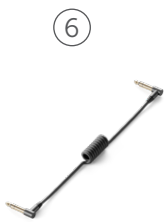
Certified medical device class IIa

CE 0197 MD Medical Device

TÜVRheinland CERTIFIED
Management System EN ISO 13485:2016
www.tuv.com ID 9000013500

View of the left side of the RS2 Base Device

View of the right side of the RS2 Base Device



Construction of the RS2 Base Device:

1. RS2 controler
2. Power socket
3. S.K.O.T. socket
4. Remote control pocket
5. Vitberg AC Adapter
6. Vitberg Connector

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Before you start using the device, read this Operation Manual carefully and keep it for future reference. Follow the advice in all "ATTENTION" and "WARNING" labels in the Manual and on the units and accessories.

version IFU SiO VRS2 3/08/2023/EN

Certified medical devices

The RS2 Base Device and Expansion Modules meet all legal requirements for medical devices. Vitberg RS2 was submitted to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Warsaw.

Vitberg's devices have received medical EC TÜV Rheinland certification for vibration therapy devices.

Management System EN ISO 13485:2016

Design and development, manufacture, distribution and service of vibration therapy equipment

Registration number: SX 1497948-1

The certificate holder's management system refers to the EN ISO 13485:2016 standard.

Vitberg is a member of EUDAMED – the European database of medical devices.

SRN PL-MF-000010936

General information

Vitberg RS2 is an active medical device for oscillatory-cycloid vibrotherapy. It was designed for physiotherapy, massage, treatment or supporting therapeutic and physiotherapy processes.

Vitberg RS2 may be used in nursing homes, physiotherapy centres, hospitals, sanatoriums, hospices, sports clubs, beauty parlours, by professional users and also at home. It is recommended for patients over 12 years of age, weighing less than 160 kg. Therapy is allowed for people under the age of 12 in the presence of an adult or guardian.

Vitberg RS2 is particularly recommended for post-traumatic physiotherapy, locomotor system strengthening, alleviating complaint symptoms (including pain), metabolism improvement, tissue relaxation and circulatory system stimulation.

Vitberg RS2 combines its general activity, based on the WBV – Whole Body Vibration (generalised vibrations) with a local one (using extra Expansion Modules).

Depending on the programme and the Expansion Module used, the Vitberg RS2 can impact the human body by:

- Changing blood vessel flexibility;
- Improving blood circulation and local improvement of the skin blood supply;
- Facilitating lymph circulation;
- Alleviating pain;
- Increasing tendon and fascia flexibility;
- Improving the range of motion in people with locomotor deficit;
- Increasing the maximum strength and flexibility of muscles;
- Stimulating bone formation processes;
- Reducing contractures;
- Alleviating the symptoms of stress urinary incontinence;
- Improving bowel movements;
- Relaxation of the whole body;
- Facilitating some metabolic processes.

The Vitberg Recovery System 2 basic kit includes:
RS2 Base Device with Vitberg Power adapter and Connector, RS2 Wedge 1 and RS2 Wedge 2

RS2 Base Device

Active medical device class IIa

Length	960 mm ± 10 mm
Width	500 mm ± 10 mm
Height	120 mm ± 5 mm
Weight	3 kg ± 0.1 kg

Vitberg AC Adapter

Vitberg RS2 equipment

Power consumption	25 W
Power supply	~230 V; 50 Hz
Output	11.3 ± 5% VDC
Weight	0.4 kg ± 0.05 kg

Vitberg Connector

Vitberg RS2 equipment

cable for connecting Vitberg RS2 active modules

RS2 Positioning Wedge 1

Inactive medical device class I

Length	490 mm ± 10 mm
Width	500 mm ± 10 mm
Height	190 mm ± 5 mm
Weight	1.6 kg ± 0.05 kg

RS2 Positioning Wedge 2

Inactive medical device class I

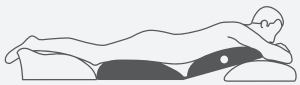
Length	370 mm ± 10 mm
Width	500 mm ± 10 mm
Height	120 mm ± 5 mm
Weight	0.8 kg ± 0.05 kg

Available programs and indications

Programs and indications for the RS2 Base Device (without Expansion Modules)

The RS2 Base Device is equipped with Cardio, Neuro and Oxy programs, which are activated by appropriate selection on the remote control. In order to activate the mentioned three programs, it is not required to connect the Expansion Module. All you need is the RS2 Base Device.

treatment duration: approx. **30 min**.

Programme	Position	Indications for use
CARDIO		deterioration of exercise tolerance, abnormal chest pain, feeling of rapid heartbeat, deterioration of cardiovascular performance, conducting extensive recovery, psychotherapy treatments, exhaustion, overwork, haemorrhoidal disease, cellulite, improving skin tone and firmness
NEURO		pain complaints in the lumbar spine (e.g. discopathies), balance disorders, pain in the joint and muscle system (including hips and thighs), improvement after hip replacement surgery, limited mobility in the pelvis, nervousness, slowing down cognitive processes, difficulty thinking, memory and concentration problems, sleep disorders, feelings of anxiety, aggression, stress, malaise, burnout, irritable bowel syndrome, stress urinary incontinence
OXY		fatigue, shortness of breath, hoarseness, respiratory wheezes, shortness of breath, a feeling of heaviness in the chest, support for the treatment of chronic obstructive pulmonary disease, asthma, cystic fibrosis and other disorders of the respiratory system (supports the removal of lung secretions, improves blood saturation – oxygen saturation of the blood)

Available programs, activated in the RS2 Base Device, after connecting Expansion Modules

When the Expansion Module is connected, the assigned, relevant program is automatically activated: Legs, Knees, Stomach, Hands or Back (see page 23). Correct connection of the Expansion Module blocks the possibility of changing the program. Only disconnecting the Expansion Module allows you to choose again between Cardio, Neuro or Oxy programs.

How to use Vitberg RS2

Vitberg RS2 oscillating-cycloidal vibrotherapy can be used in home and office settings. In order to optimize the effects of therapy, it is advisable to combine oscillatory-cycloidal vibrotherapy with other therapeutic, rehabilitative, cosmetic and dietary measures. The reinforced design of the Vitberg RS2 allows to exercise directly on the device during vibrotherapy treatments (while maintaining the recommended position). It is recommended to use corrective, strengthening, breathing, loosening and relaxation exercises. Guided and self-assisted exercises, isometric, active, passive and active-passive limb exercises as well as synergistic exercises can also be used, which, through functional combinations, help to effectively activate individual muscle groups.

Vitberg RS2 vibrotherapy has anti-inflammatory effects, improves circulation, warms up muscles, increases mobility, relieves pain and facilitates exercise, relieves stress on joints, relaxes and protects against injury. Performing exercises during vibrotherapy increases its effectiveness.

It is possible to use Vitberg RS2 vibrotherapy as a warm-up immediately before general therapeutic exercises. It is also used in the form of preparation for manual therapy, massage and cosmetic procedures. Just 30 minutes of vibrotherapy can double the effectiveness of other therapies.

Vitberg RS2 oscillatory-cycloidal vibrotherapy can be used as a complete therapy: pain relief, anti-inflammatory, improvement, cardiovascular, metabolic, pulmonary and cosmetological. It is also widely used in supporting weight loss and fighting obesity.

Unless the doctor or physiotherapist recommends otherwise, the procedures should be administered until the symptoms subside.

It is not recommended to apply more than two procedures a day.

If you suffer from circulatory problems, do the procedures based on the following principle: one procedure before noon and the other in the evening.

If you suffer from lower limb problems, it is recommended to administer the procedure immediately before you go to bed.

To maintain the therapeutic effect and for prevention, it is recommended to apply the therapy at least twice a week.

Children should not receive more than one procedure a day.

Children under the age of 12 can use massages only under the supervision of an adult.

It is not recommended to apply procedures with an empty stomach.

It is absolutely prohibited to use the RS2 Base Device and Expansion Modules when driving vehicles.

The intensity of the treatments should be adjusted according to the subjective perception of the user.

Always start a series of treatments at the lowest intensity.

Expansion Modules must not be used unless connected with the RS2 Base Device.

Do not use the RS2 Base Device and Expansions Modules for any other purposes than they are designed for, as described in the manual. If you use positions and select programmes incompliant with the manual, the therapy may turn out unsuccessful.

Remember to always lie down with your feet towards the power socket and the remote control pockets to your right.

For Oxy and Stomach positions – the pockets will be on the left side.

How to use Vitberg RS2

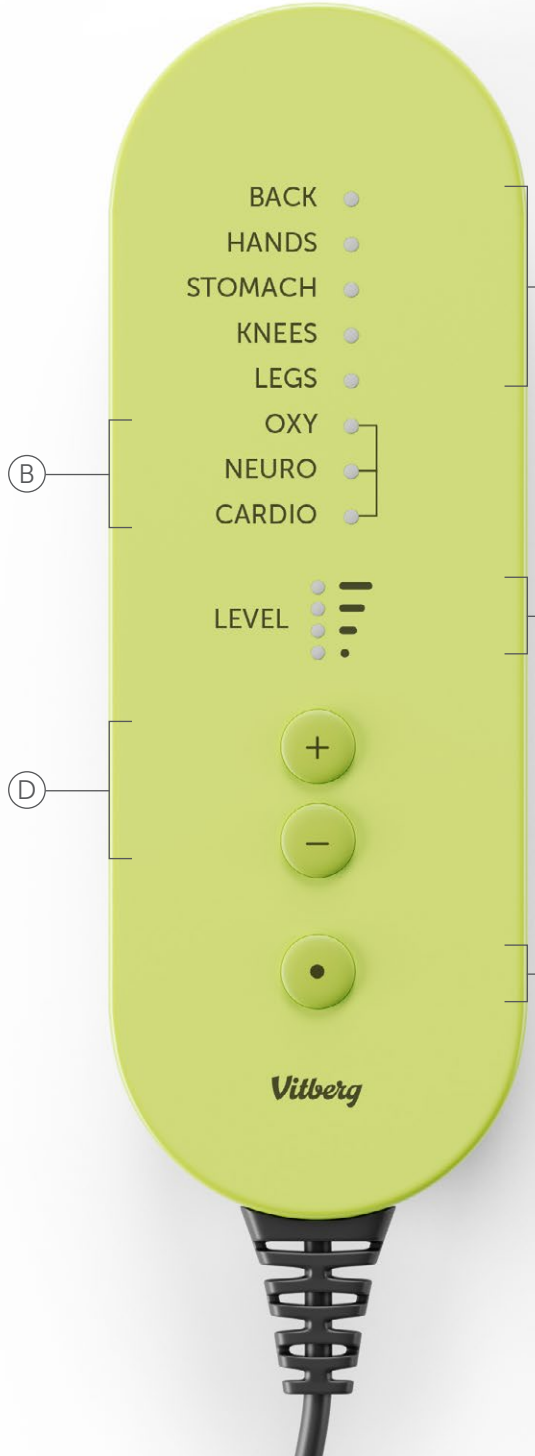
We have divided the intensity of Vitberg RS2 vibrotherapy into 4 levels, which are adjusted according to the user's health, physique, physical activity and age. The intensity level assigned to each user group, should not be exceeded. The change in intensity from less to more, and vice versa (within the range allowed for the group) depends on the patient's subjective perception. New users are advised to start all treatments on the Vitberg RS2 device at intensity one, for a minimum of 3 days. Similar recommendations apply to those who have a minimum of 3 weeks of interruption in vibrotherapy treatments on Vitberg RS2.

Recommended maximum treatment intensities based on patient's body shape and age

	Underweight	Normal weight	Overweight/ Obesity	Sports (fit, active patient)
Over 70 y.o.	1	2 1	3 2 1	3 2 1
50–70 y.o.	2 1	3 2 1	4 3 2 1	4 3 2 1
Under 50 y.o.	3 2 1	4 3 2 1	4 3 2 1	4 3 2 1

Vibrotherapy treatments are recommended in 10-day cycles. The maximum dose of oscillatory-cycloidal vibrotherapy should not exceed 2 treatments per day (about 60 minutes). It is not recommended to cool down the body immediately after the treatments and to get up quickly from the device. Treatments can be performed around the clock. After 10 treatment days, there should be a break from treatments, at least for one day.

RS2 controler



RS2 Base Device Programs

Green LEDs indicate the selected programme in the RS2 Base Device: Cardio, Neuro lub Oxy.

Cardio/Neuro/Oxy program selection and intensity level change

The plus and minus buttons are used to change the intensity of the massage, but also to change the programs on the RS2 Base Device (selectable: Cardio, Neuro and Oxy programs).

A Automatically activated programs of RS2 Expansion Modules

Green LEDs indicate the selected program specific to the connected RS2 Extension Module (Legs, Knees, Stomach, Hands or Back).

C Intensity level

Orange LEDs indicate massage intensity. During the first treatment, we recommend the first level of intensity. The intensity level is adjusted when the program is approved.

E Start/stop program

The button with a dot is used to confirm and switch off the programme. If you want to switch the device off during the procedure, press and hold this button for 3 seconds.

Switching on and off and error indications

Switching on

The RS2 Base Device is ready for operation immediately after connecting the power supply. Connecting the RS2 Base Device to the power supply will be signalled by lighting the “Cardio” program LED. At the same time, the Device performs testing for proper operation.

Switching off

After the program finishes, the RS2 Base Device will switch off automatically and will switch to the standby mode which is signalled by the lit “Cardio” program LED. When it is necessary to switch the device off during the procedure, press and hold for 3 seconds the lower (E) button. The device will switch off automatically and will switch to the standby mode which is signalled by the lit “Cardio” program LED.

Power supply error

If a defective or improper power supply is plugged into the RS2 Base Device, the RS2 Remote Control will begin to signal an error with a sound.

Solution: check if the power supply is connected correctly. If the problem persists, contact the Vitberg maintenance service team.

Expansion Modules error

If a Vitberg module/connector is incorrectly connected to the S.K.O.T. socket or the module is damaged/incompatible, RS2 controler will begin to signal the error with a sound.

Solution: check the correct connection of Expansion Modules. If the problem persists, contact the Vitberg maintenance service team.

Please note! Any changes or modifications of the medical device shall result in annulling the user’s guarantee rights. Such modifications can also constitute direct health and life hazard.

If the device is damaged in any way, it should be taken to the qualified service technicians of Vitberg for repair.

Vitberg maintenance service
tel.: +48 531 791 500
Mon-Fri: 7:00 AM-3:00 PM
serwis@vitberg.com

Connecting and starting the device in 4 steps

STEP 1 Connect

On the lower left side of the Base Device you will find a power socket. (2).

Connect the Vitberg Power adapter to this socket. (5).

STEP 2 Arrange your device and lie down

Arrange the Base Device according to the selected program. If the program requires the connection of an Expansion Module, connect it with the Vitberg Connector (6).

At the bottom of each module you will find a diagram of the arrangement of a given position.

Make yourself comfortable.

Connecting and starting the device in 4 steps

STEP 3 Select a program

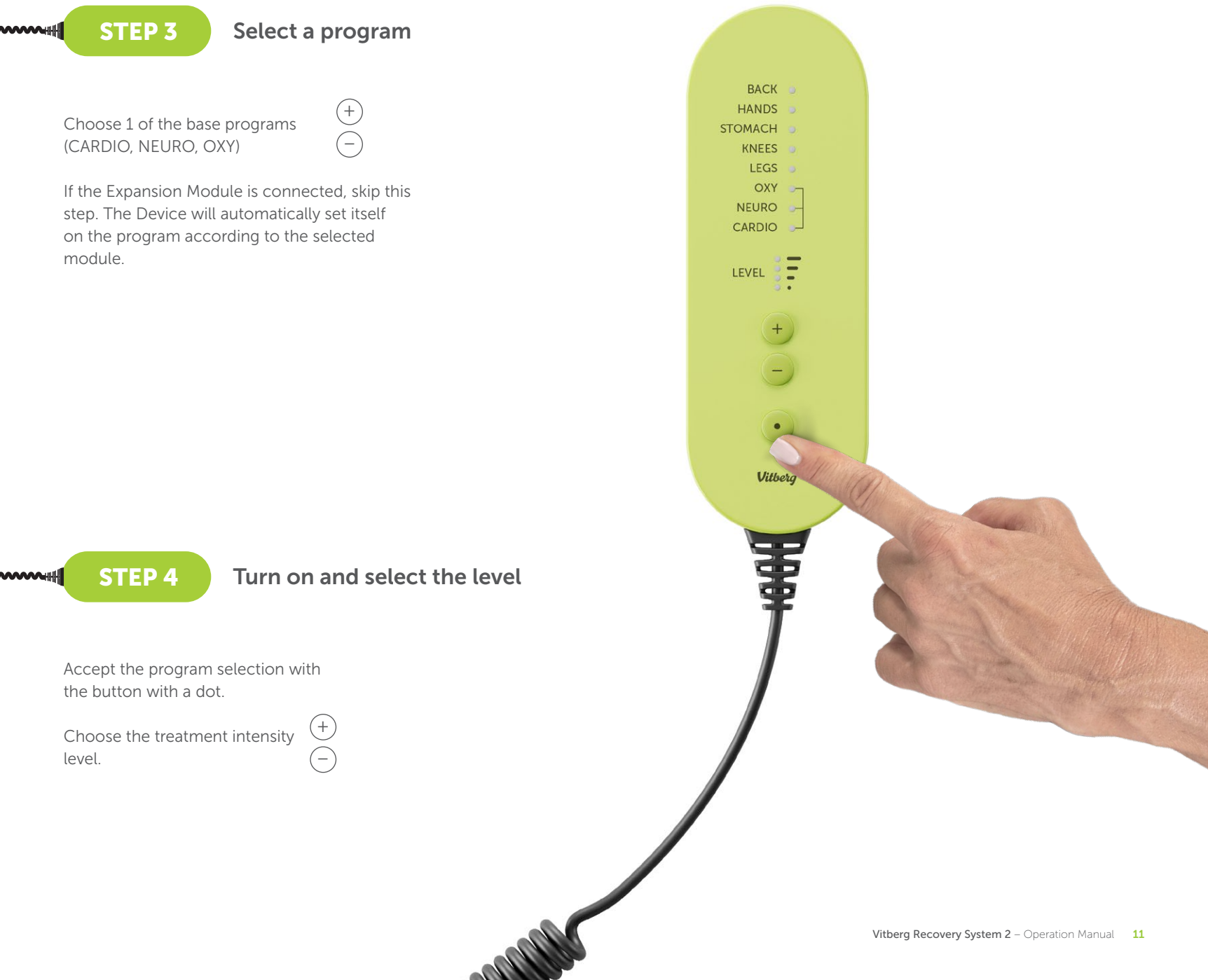
Choose 1 of the base programs (CARDIO, NEURO, OXY)

If the Expansion Module is connected, skip this step. The Device will automatically set itself on the program according to the selected module.

STEP 4 Turn on and select the level

Accept the program selection with the button with a dot.

Choose the treatment intensity level.



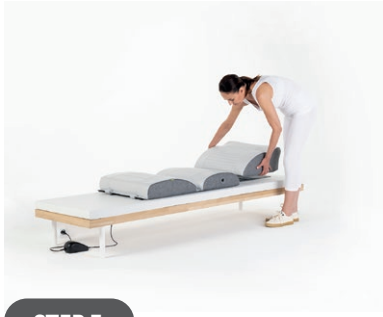
Preparation and arrangement of Cardio and Neuro

STEP 1

Place the RS2 Base Device on a flat surface. Separate the fastening Velcro from.

STEP 2

Place the mounting Velcro under the RS2 Base.



STEP 3

Connect the RS2 Base Device with Velcro to the Wedge 1.

STEP 4

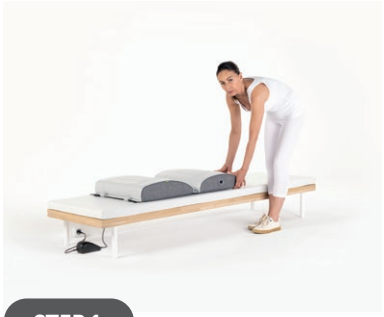
In the Cardio program, slide Wedge 2 under RS2 Base Device so that the lower part of RS2 Base Device is raised up and rests on Wedge 2.

In the Neuro program, lay the whole thing flat.

Correct Cardio position with RS2 Positioning Wedge 1 and 2.

Correct Neuro position with RS2 Positioning Wedge 1 and 2.

Preparation and positioning of Oxy position



STEP 1

Place the RS2 Base Device on a flat surface.

STEP 2

Place Wedge 2 under the top of the RS2 Base Device so that it is raised slightly upward.

STEP 3

Separate the fastening Velcro from Wedge 1 and lay it under the lower part of the RS2 Base Device.

STEP 4

Connect the RS2 Base Device with Velcro to the Wedge 1.

Correct position of Oxy with RS2 Positioning Wedge 1 and 2.

Daily use

Cleaning and disinfecting

Before you start cleaning the external surface of the device or any accessory, inspect it visually in detail. If you notice any damage, take the device to the maintenance service team.

Before you start cleaning the RS2 Base Device and the Expansion Modules, ensure the power adapter is disconnected from the mains. The Vitberg power adapter disconnected from the mains should be cleaned dry.

Clean the applied surface with a soft cloth moistened with water or a mild cleaning agent, e.g. soft soap. The use of disinfectants is permitted. The use of protective sheets is recommended. Do not use any abrasive cloths, scrubbing powder or solvents, e.g. spirit or petrol as they can damage the applied surface of the device or the remote controller housing. If the device is used by more than one user, disinfect the applied surface before every procedure.

Wipe the excessive cleaning liquid away thoroughly. Prevent the cleaning liquid from penetrating or accumulating in connector openings, latches or slots.

The RS2 Base Device and Expansions Modules can be disinfected with neutral disinfectant solutions, designed for disinfecting artificial leather surfaces, including dentist's chairs, couches etc.
Please note! Incorrect cleaning can result in malfunction of the RS2 Base Device and Expansions Modules.

Storage and transport

The RS2 Base Device and Expansions Modules should be stored in clean, dry conditions at temperatures: -25°C to +70°C and humidity of 30%–75%. They should be transported in original packaging. If you transport the device in temperatures other than -25°C to +70°C, remember to use the transport packaging offering extra thermal insulation. Before the device is switched on again after it has been unpacked, leave it until it reaches the operating temperature of +10 to +40°C.

The RS Base Device and Expansion Modules may not meet the technical requirements if they are stored, transported or used in a way contrary to the specified conditions of storage and use.

The time of leaving the RS2 Base Device and Expansion to heat from the minimum storage temperature (-25°C) to the ambient temperature (+20°C) should be at least 2 hours.

The time of leaving the RS2 Base Device and Expansion Modules to cool from the maximum storage temperature (+70°C) to the ambient temperature (+20°C) should be at least 2 hours.

Life cycle

The anticipated life cycle of the device is 5 years after the purchase date. After that, to guarantee safe operation of the device to the user, it is recommended to perform technical inspection regularly, every two years, in the Vitberg maintenance service.
This is a reusable product.

Operating conditions of the Vitberg RS2 system:

Noise level	below 75 dB(A)
Permissible relative humidity	30-75%
Atmospheric pressure	700 to 1.060 hPa
Vibration frequency (idle):	25-52 Hz ± 5%
Permissible patient weight	30-160 kg
Device operating temperature	from +10 to +40°C
Storage temperature	from -25 to +70°C

Precautions

It is prohibited to use any power supply other than indicated. It can damage the device or change its operating parameters. The RS2 Base Device is equipped with a dedicated power adapter called Vitberg Power Adapter (manufactured by Vitberg).

It is prohibited to use the RS2 Base Device if you are under the influence of alcohol or other substances/drugs.

It is prohibited to interfere with any component of the RS2 Base Device and the Vitberg Power Adapter mechanically yourself. Any repair activities must be carried out by qualified service technicians of Vitberg.

It is prohibited to insert any foreign objects into the Vitberg Power Adapter plug, to pull the power supply from the mains socket using the supply cable or to connect to any extension cables. It is prohibited to use the RS2 Base Device if any cable or unit is damaged.

It is prohibited to connect any accessories not recommended by the manufacturer or to use any original RS2 Base Device components for purposes other than indicated in this Operation Manual. If you detect any damage or malfunction of the device, contact the service technicians of Vitberg.

Keep the packaging of the RS2 Base Device and Expansion Modules components away from children, people with insufficient mental abilities and animals. Playing with a plastic bag or cover can be dangerous, as it can result in suffocation or choking.

Because of the risk of strangling with the power supply cable, keep the cable away from children and animals.

Do not immerse the RS2 Base Device or Expansion Module, the Vitberg Power Adapter, power supply cables or the Vitberg Connector in liquids, do not expose them to water or other liquid substances. If the Vitberg RS2 system modules were immersed in any liquid or if any condensation can be seen on the device, do not use it.

The Vitberg power adapter immersed in any liquid should not be used and should be taken to be inspected by Vitberg maintenance service. To avoid electric shock, do not place any objects filled with liquid, including glasses with drinks, on the device.

Do not cover the RS2 Base Device and Expansions Modules, as well as the Vitberg Power Adapter with blankets etc. Use away from open flame (e.g. candles, incenses, cigarettes, cigars, pipes etc.) and high temperature (e.g. light bulbs, radiators, dryers, ovens, heaters). It is prohibited to use any electrical cushions and/or blankets during the procedure.

Use the recommended positions and avoid changing them throughout the entire programme duration.

Use the RS2 Base Device and Expansions Modules on surfaces ensuring stable support and user safety.

Do not situate the RS2 Base Device in a way hampering its disconnection.

Environmental protection

Correct product disposal — waste electrical and electronic equipment.

The marking placed on the product or texts referring to it indicates the product should not be disposed of with other waste after its life cycle expires.
To obtain information on the place and method of this product's recycling safe for the environment, the household users should contact the retailer whom they bought the product from or the local government body. The corporate users should contact their supplier and check the purchase agreements terms and conditions.

Contraindications with remarks

1. **Advanced pathological changes of blood vessels (e.g. aneurisms, thrombosis, arteriosclerosis) and conditions following newly treated myocardial infarctions and brain strokes**.
   » It is recommended to use no earlier than 6 months after the event (heart attack/stroke) or consult a doctor, physiotherapist or specialist.
   After consultation with a doctor, physiotherapist or specialist – a minimum of 4 weeks after the event.
2. **Massage of the area where pacemakers were implanted.**
   » Does not apply to the Legs, Knees and Cardio, Neuro and Hands programs at intensities 1 and 2.
3. **Following the procedures of endoprosthesis implantation, implantation, reconstruction and other surgical procedures until the areas are fully healed.**
   » For endoprostheses, implants, reconstructions after achieving osteointegration (minimum 3 months after surgery).
   For other surgical procedures, it is recommended to use no earlier than 1 week after surgery (proliferation and remodelling phase excluding the inflammatory phase).
4. **Acute inflammations caused by pathogenic microbes (bacteria, fungi, viruses), including skin inflammation and abscesses**.
   » Applies only to acute inflammatory conditions with fever.
5. **Unregulated high blood pressure.**
   » Applies to patients with untreated hypertension, with frequent fluctuations in blood pressure without control of medication taken.
6. **Acute multiple sclerosis relapse.**
   » Until remission (partial or complete resolution of symptoms).
7. **Epilepsy.**
   » Not applicable to patients with no observed incidents in the past year.
8. **Diseases entailing dizziness.**
   » In the case of dizziness that lasts more than 1 minute with a change of body position and in the case of dizziness accompanied by nausea, vomiting, sensation of fullness in the ear, hearing disorders. Dizziness can also result from side effects of diuretics, vasodilators, sedatives and antidepressants, antiepileptics, sleeping pills and analgesics.
9. **Insufficient mental ability.**
   » Constant supervision of a supervisor required.
10. **Syringomyelia.**
11. **Conditions following bone fracture until the bone has fully recovered.**
12. **Conditions following any broken tendons, ligaments and muscles, until fully recovered.**
13. **Advanced kidney and gall bladder stones.**
    » Do not use for urinary stones larger than 5 mm in diameter.
14. **Haemorrhagic conditions, haemorrhages.**
15. **Active cancer process.**
    » You should wait five years after completing cancer treatment, unless your doctor gives you permission to use vibrotherapy treatments earlier. The exception to this is mastectomy – safe use of vibrotherapy treatments after mastectomy is possible after a 12 month recovery period.
16. **Increased temperature/fever.**
17. **Skin lesions/wounds.**
    » Does not apply to the case of healing wounds.
18. **Pregnancy and childbed.**

Adverse reactions

Currently, the only identifiable side effects of vibrotherapy are described as temporary and quickly passing. These include dizziness, drowsiness, nausea, a feeling of fatigue, and redness and itching of the skin in the treated area. These effects pass with the cessation of the treatment or shortly after (they rarely last longer than 2–3 hours after the treatment). They should not be a cause for concern. This is the body's natural response to a new stimulus. During the treatments, make sure to check for other side effects.

Similar symptoms may be more frequent in patients who spend a lot of time seating or lying and whose physical activity is low.

The treatment can result in transient systolic and asystolic blood pressure growth.

The material used for the sheathing of the RS2 Base Device and Expansion Modules is hygienically certified by the National Institute of Public Health - National Institute of Hygiene.

However, in rare cases, skin contact with the cover can cause allergic reactions. It is not recommended to apply the procedures with the RS2 Base Device and Expansion Modules in a direct skin contact. For hygiene reasons, it is recommended to massage in light, loose clothes made from natural materials, e.g. cotton.

⚠ If you have any doubts concerning your health, consult your specialist doctor before you start the therapeutic massage.

⚠ Any serious incident related to the device should be reported to the manufacturer Vitberg Sikora Jacek and to the competent authority of the Member State where the user or patient resides.

⚠ Vitberg Sikora Jacek shall not be held liable for any injuries resulting from the incorrect use of the product, failure to follow any instructions, comments, warnings or recommendations concerning the product use.

Declaration of Conformity of the Base Device

CE 0197

MD Medical Device

EU DECLARATION OF CONFORMITY

Manufacturer:

Vitberg Sikora Jacek
ul. Borelowskiego 29
33-300 Nowy Sącz
POLAND, EU
SRN PL-MF-000010936

I declare, under my sole responsibility, the medical device:

Vitberg Recovery System
(other names Vitberg, Base Device)
Models, types: RS, RS2, Med Home

Basic UDI-DI 590470340V2RSDE

Product qualified as:
MD 1108 Active rehabilitation devices and active prostheses

Description: Device for medical vibrotherapy and active physiotherapy. Recommended for post-traumatic rehabilitation, strengthening the locomotor system, alleviating the symptoms of diseases (including pain), improving metabolism, relaxing tissues, stimulating the circulatory system, facilitating movement, relieving joints, relaxing and protecting against injuries. Performing exercises during vibrotherapy increases its effectiveness. It is recommended to perform corrective, strengthening, breathing, loosening and relaxation exercises during the treatments. You can also use guided and self-assisted exercises, isometric exercises, active, passive and active-passive limbs, as well as synergistic exercises, which help to effectively activate individual muscle groups through functional connections.

In accordance with the Regulation of the Minister of Health of November 5, 2010 on the methods of medical device classification (Journal of Laws of 2010, no. 215, item 1416) is classified as class IIa under rule 9.

The device meets the applicable requirements of the Medical Devices Act of April 7, 2022 (Journal of Laws of 2022, item 974) and Directive 93/42/EEC.

The conformity assessment procedure conducted in accordance with the Annex 2.3 of the Regulation of the Minister of Health of February 17, 2016 on essential requirements and conformity assessment procedures of medical devices as amended (Journal of Laws of 2016, item 211). The list of standards and legal regulations used for conformity assessment can be found in the technical documentation. The market release is carried out based on the provisions of the quality control protocol in the TD2.

The Notified Body participating in the conformity assessment:

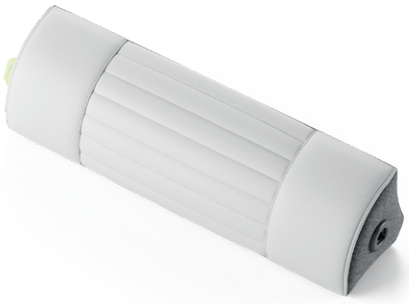
TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany

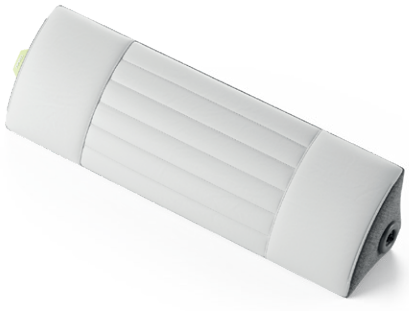
Jacek Sikora
CEO

Nowy Sącz, Poland, EU 20.12.2022

Vitberg

Version 3/05/2023 EN





MD Medical Device

CE

Vitberg Recovery System **2**

RS2 Expansion Modules

Operation Manual

Medical devices class I

RS2 Expansion Modules

RS2 Legs Module

Active medical device class I

MD Medical Device CE

IP22

Length	340 mm	± 10 mm
Width	500 mm	± 10 mm
Height	110 mm	± 5 mm
Weight	1.1 kg	± 0.05 kg

RS2 Knees Module

Active medical device class I

MD Medical Device CE

IP22

Length	210 mm	± 10 mm
Width	500 mm	± 10 mm
Height	155 mm	± 5 mm
Weight	0.8 kg	± 0.05 kg

RS2 Stomach Module

Active medical device class I

MD Medical Device CE

IP22

Length	200 mm	± 10 mm
Width	500 mm	± 10 mm
Height	110 mm	± 5 mm
Weight	0.7 kg	± 0.05 kg

RS2 Hands Module

Active medical device class I

MD Medical Device CE

IP22

Length	410 mm	± 10 mm
Width	500 mm	± 10 mm
Height	130 mm	± 5 mm
Weight	1.2 kg	± 0.05 kg

RS2 Back Module

Active medical device class I

MD Medical Device CE

IP22

Length	140 mm	± 10 mm
Width	500 mm	± 10 mm
Height	130 mm	± 5 mm
Weight	0.7 kg	± 0.05 kg

Connecting a RS2 expansion module

Vitberg Connector is used to connect Expansion Modules to the RS2 Base Device, via the S.K.O.T. socket. The S.K.O.T. socket is located on the side of the RS2 Base Device and each active Expansion Module (both S.K.O.T. sockets must always be on the same side).
A longer Vitberg Connector is added to the Hand Module for the comfort of the procedure.

Connecting RS2 Base Device with Expansion Modules using Vitberg Connector

Connect the RS2 Base Device to the Expansion Module using the Vitberg Connector. Firmly push the plugs into the S.K.O.T. sockets. The correct connection of the RS2 Base Device with an Expansion Module will be confirmed by a characteristic “clicking” sound.

Device configuration

1

Select the appropriate RS2 Expansion Module.

RS2 Legs Module

RS2 Knees Module

RS2 Stomach Module

RS2 Hands Module

RS2 Back Module

2

Connecting an Expansion Module with the RS2 Base Device activates the programme ascribed to it automatically.

3

Assume the therapeutic position ascribed to particular units.

Legs position

Knees position

Stomach position

Hands position

Back position

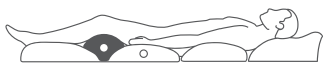
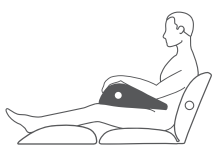
4

Confirm the program with the dot button and set the massage intensity level with the plus (+) and minus (-) buttons.

Available programs and indications

Programs and indications available on the RS2 Base Device after activating Expansion Modules.

treatment duration: approx. **30 min.**

Programme	Position	Indications for use
LEGS		circulatory insufficiency, ulcers, diabetic wounds, swelling, heaviness, calf cramps, varicose and spider veins (telangiectasia), muscular pain and neuralgia in the leg area, spasticity, contractures and paresis (cerebral palsy, stroke, ataxia), sensory problems, cold feet, multiple sclerosis, osteoporosis, post-traumatic rehabilitation, sports massage
KNEES		movement disorders, degenerative diseases of the knee joint (e.g. gonarthrosis, arthrosis), internal joint damage, contractures, stiffness, general knee and Achilles tendon rehabilitation (analgesic effect, relaxation, reducing stiffness, increasing mobility and tissue regeneration), impaired postural and locomotor functions, knee joint instability, patellofemoral band syndrome, ligamentous rupture, joint pain, muscle and neuralgia, multiple sclerosis, post-traumatic rehabilitation, post-traumatic recovery, cellulite, sports massage, sports training, regenerative massage
STOMACH		functional constipation, chronic bowel problems, overweight and obesity, intestinal peristalsis problems, pre-diabetic conditions and diabetes, pain and mobility restrictions in the trunk, sexual dysfunction, stress incontinence, cellulite, improving skin tone and firmness, post-traumatic rehabilitation and sports massage
HANDS		circulatory insufficiency, numbness or tingling of the hands, feeling of cold hands, muscle pain and neuralgia in the area of hands and arms, spasticity, contractures and paresis (cerebral palsy, stroke, ataxia), Parkinson's disease, arthroses, arthritis, rheumatoid arthritis, multiple sclerosis, osteoporosis, osteopenia, post-traumatic rehabilitation, oedema, sports massage
BACK		blood pressure problems, conditions related to blood flow in the carotid arteries, prophylaxis in cerebral ischemic diseases, restrictions of mobility in the neck and shoulder girdle, spinal pain in the neck and thoracic region, neck numbness, headaches, migraines, tinnitus, occupational dysphonia, apnoea, post-stroke rehabilitation, prevention of discopathy, spinal instability, sciatica, root and pseudo-root pain, post-traumatic rehabilitation, sports massage

Declaration of Conformity of active and inactive modules

CE MD Medical Device

EU DECLARATION OF CONFORMITY

Manufacturer::

Vitberg Sikora Jacek
ul. Borelowskiego 29
33-300 Nowy Sącz
POLAND, EU
SRN PL-MF-000010936

I declare, under my sole responsibility, the medical device:

RS2 Legs Module
RS2 Knees Module
RS2 Stomach Module
RS2 Back Module
RS2 Hands Module

Basic UDI-DI 590470340V2MABT

In accordance with REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/ EEC, Annex VIII is classified, as Class I under Rule 13.

The device meets, the applicable requirements of REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices.

The list of standards and legal regulations used for the conformity assessment can be found in the technical documentation. The market release is carried out based on the provisions of the quality control protocol in the TD4 technical documentation [TD4].

Jacek Sikora
CEO

Vitberg

Nowy Sącz, Poland, EU 20.12.2022

Version 3/05/2023 EN

CE MD Medical Device

EU DECLARATION OF CONFORMITY

Manufacturer:

Vitberg Sikora Jacek
ul. Borelowskiego 29
33-300 Nowy Sącz
POLAND, EU
SRN PL-MF-000010936

I declare, under my sole responsibility, the medical device:

RS2 Positioning Wedge 1
RS2 Positioning Wedge 2
RS2 Positioning Wedge 3
RS2 Armrests
Med Home Wedge 1
Med Home Wedge 2

Basic UDI-DI 590470340V2MNCM

In accordance with REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/ EEC, Annex VIII is classified, as Class I under Rule 1.

The device meets, the applicable requirements of REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices.

The list of standards and legal regulations used for the conformity assessment can be found in the technical documentation. The market release is carried out based on the provisions of the quality control protocol in the TD5 technical documentation [TD5].

Jacek Sikora
CEO

Vitberg

Nowy Sącz, Poland, EU 20.12.2022

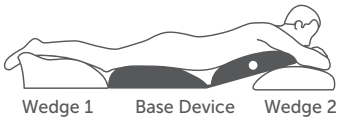
Version 3/05/2023 EN

All programs available in Vitberg RS2

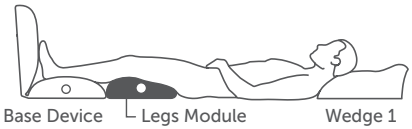
Cardio

Neuro

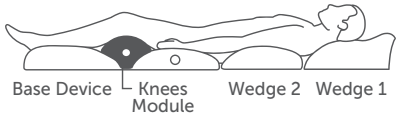
Oxy



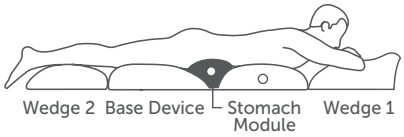
Legs



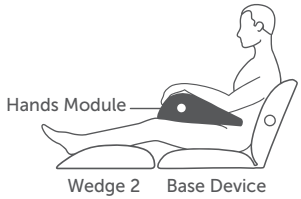
Knees



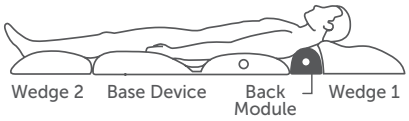
Stomach



Hands



Back



Additional comfort modules

also try the **RS2 Positioning Wedge 3**
and **RS2 Armrests**

RS2 Positioning Wedge 3

Inactive medical device class I

RS2 Armrests

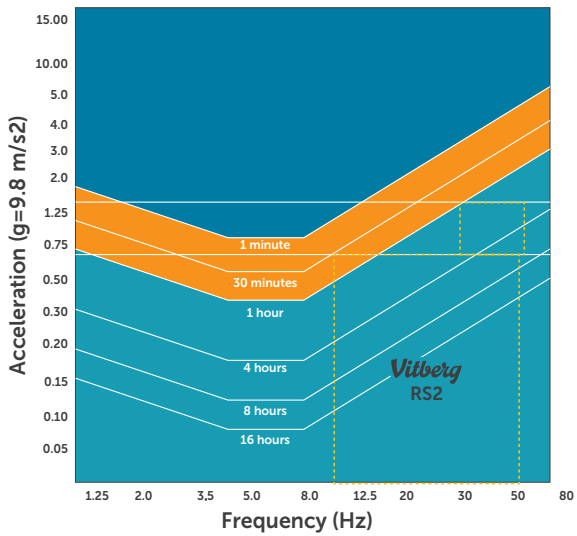
Inactive medical device class I

Safety of vibrotherapy and Vitberg RS2 devices

Vibrotherapy is a form of therapeutic and preventive therapy, categorized as a physical therapy procedure. The treatment takes advantage of natural vibrations that are ubiquitous in the environment. Nowadays, vibration massage is popular among doctors and professionals around the world. Vibrotherapy is not one of the treatments in the electrotherapy or electrotherapy group. The therapeutic stimulus is a mechanical stimulus and is indicated as one of the safest in physical therapy.

Vitberg RS2 devices use unique software based on oscillatory-cycloidal vibrotherapy. The product software is owned by Vitberg. The software is protected by the laws of the Republic of Poland and by international copyright law.

Emission performance tests	Conformity	Electromagnetic environment
RF emission according to CISPR 11	Group I	The DEVICE generates the RF energy solely as a result of internal functions. Thanks to that, the RF emission is negligible and unlikely to cause any interference in its immediate vicinity.
RF emission according to CISPR 11	Class B	The DEVICE is appropriate for operation in any institution, including residential premises and premises connected directly to the low-voltage grid which supplies residential buildings.



The average acceleration throughout the program does not exceed 0.7g. The recommended 2 treatments per day do not exceed the time sum of the acceleration ranges indicated as safe in accordance with the requirements of ISO-2631-1 and the Decree of the Minister of Family, Labour and Social Policy of June 12, 2018 (Journal of Laws of 2018, item 1286).

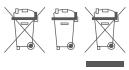
Vitberg RS2 does not use the magnetic field to generate therapeutic stimulus

If the RS2 Base Device is not used for further massage during consecutive 30 minutes, disconnect the Vitberg power adapter from the mains socket and remove the power adapter plug from the RS2 Base Device power supply port.

It is prohibited to plug any plugs other than Vitberg Connector to the S.K.O.T. socket. This entails the risk of the device damage or electrical shock.

The device meets all requirements in accordance with standards on electromagnetic compatibility (EMC) of medical devices. Including conducted disturbance, radiated disturbance, discharge immunity and magnetic field immunity. The voltage level of the emitted disturbance and the intensity of the emitted field do not exceed the permissible levels specified by EN 55011 for group 1, class B.

Explanation of symbols and abbreviations

CE 0197	Means meeting the requirements of the Medical Device Directive 93/42/EEC
CE	Means meeting the Regulation of the European Parliament and of the Council (EU) 2017/745 on medical devices (MDR)
MD	Medical device
	Warning. See attached documents
	See the operation manual, the operation manual is also available at www.vitberg.com
	Type BF applied part
IP22	Class of protection provided by the electrical device housing
	Read the rules of disposal of this waste type
 20XX	Manufacturer, date of production
UDI	UDI (01)xxxxxxxxxxxxxx GTIN product code (11)xxxxxx manufacture date (10)xxxxxxxxxxxxxxx lot number (21)xxx serial number
	For indoor use

	Class II device (protection class)
	Important information
	Manufactured in Poland
	Top, don't roll over
	Protect from moisture
	Packaging is 100% recyclable
	Do not throw
	Careful, fragile
	Store a maximum of 4 in a column
Vitberg RS2 VRS2	Vitberg Recovery System 2
S.K.O.T.	Directed Therapeutic Oscillations System

Ver. IFU SIO VRS2 3/08/2023/EN

5 904703 400486 >

Vitberg

www.vitberg.com

Contact and technical support

To obtain information on the products, starting them and to report medical incidents, contact the company:

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Maintenance: +48 18 442 32 31 serwis@vitberg.com