

Intended purpose of using the medical device including indication:

SunBall is a medical device that is used as an interactive rehabilitation tool that works on the principle of biological feedback and can be part of compensatory exercises for afflicted and healthy people. This medical device is used for treatment in physiotherapy, ergotherapy including specialized neurorehabilitation. It offers a way of exercise that improves patient's motivation and attention through interactive gaming tasks, which supports neuroplastic brain changes and helps the processes of motoric learning.

It can be used by patient with orthopedic diagnoses (bone damage injuries, ligaments, tendons and muscles, entezopathy, tendon sculpture, muscles and ligaments – hand surgery etc.), neurological diagnoses (peripheral paresis – after injuries, in degenerative disease cases, central paresis - after spinal and spinal cord injuries, after stroke, cerebral palsy, multiple sclerosis and other neurodegenerative and demyelinating diseases; some cognitive malfunctions, etc.). Patients are not limited by age when using this medical device (both child and geriatric patient are cooperating). As an activating and compensatory element, the device can also be used by healthy population of various ages.

b) Device evaluation

Objectives and justification:

For the medical device, a clinical evaluation has been done at the provider's working facility. During the assessment, the purpose was to assess the functionality and declared efficiency and its purpose of use given by the creator of this medical device.

Properties of the medical device:

The properties of this product meet the basic requirements of Government Decree No. 54/2015 Coll. about technical requirements for medical devices and the specified technical standards and regulations in accordance with Directive 93/42 EEC about medical devices, as amended.

The manufacturer declares that the medical device is safe under the conditions of the manufacturer's intended use. The properties, type, character, and parameters of the medical device are consistent with the intended use of the manufacturer and are in accordance with current clinical and scientific findings.

The assessment was carried out based on the latest scientific findings and literature. The manufacturer also provided several samples. (In the attachment).

Principle and purpose of the device:

SunBall is a medical device that is used as an interactive rehabilitation tool that works on the principle of biological feedback and can be part of compensatory exercises for afflicted and healthy people within physiotherapy, ergotherapy including specialized neurorehabilitation. It offers a way of exercise that improves patient's motivation and attention with various diagnosis mentioned above through interactive gaming tasks, which supports neuroplastic brain changes and helps the processes of motoric learning.

The exercise is designed to improve overall postural stability, coordination of focused and automated movements and muscle development. Desired motoric expression is a solution to the game task, so the system also uses and connects motoric, psychical and cognitive functions.

SunBall maintains constant pressure in the ball, processes sensor data and communicates with computer. The analytical data obtained offers the opportunity of objectivization patient's state improvement within the therapy.

Comparison of SunBall with other medical devices with the same or similar intended purpose of use:

SunBall has the same purpose and use as other comparable products, such as **PAB®-pressure air biofeedback** from TOGU GmbH located at Atzinger Str. 1, 83209 Prien am Chiemsee, Germany or **Tyrostation (PABLO, TYMO)** from Tyromotion GmbH, located at Bahnhofgürtel 59, 8020 Graz, Austria. The non-invasive therapy medical devices visualize the pressure, monitor the data, analyze them and display them in graph. The **SunBall** medical device uses air-filled therapeutic tool for exercise. Unlike **PAB®-pressure air biofeedback**, it also allows interactive games and simple single-axis balancing exercises and games and cognitive functions training. After training, as with compared devices, the assistance of another person, with the exception of patients with severe tetraplegia, is not necessary. **SunBall** is preferably used for the treatment of motoric disorders in the upper limbs and the hand, however, depending on the severity of the injury, it is useful for the treatment of whole-body movement disorders and possibly for simple balance exercises. Like **PAB®-pressure air biofeedback**, it is easy to move (a ball connected to a laptop), instead of **Tyrostation (PABLO, TYMO)**, which is more of a work and training place with a preinstalled device for specific exercises for the upper limbs. The undisputed advantage of **SunBall's** medical device against compared devices is its significantly lower purchase costs.

The table compares the properties of the **SunBall** evaluated device with the following devices:

	SunBall	<u>PAB® – pressure air biofeedback</u>	<u>Tyrostation (PABLO, TYMO)</u>
pressure visualization	✓	✓	✓
data monitoring	✓	✓	✓
interactive games	✓	x	✓
3D motion sensor	x	x	✓
hand therapy	✓	✓	✓
whole-body therapy	✓	✓	x
balance exercise	single-axis	x	dual-axis
invasive	x	x	x
other person's assistance needed	x	x	x

cognitive functions training	✓	only pressure measurement visualization	✓
data analysis, graph	✓	✓	✓
air-filled therapeutical resources	✓	✓	not found

Clinical findings:

In any therapies with therapeutic intent, it is necessary to ideally build on neurophysiological findings - for any movement it is important firstly to inform about system setup, then information processing and evaluation so that the instructions for the intended movement are as efficient as possible and eventually sufficiently stimulate functional motion system, as an effector of intended motion. The central nervous system, in physiological circumstances, initially obtains sufficient information from proprioceptors, but for various reasons this information may not be sufficient (one-sided exercise, hypokinesia, diseases, gradual function decline by age). Internal feedback mechanisms can then be supported with information from the exo-receptor (optical and acoustic feedback).

Over the last decade, tools and devices using virtual reality have been increasingly used in rehabilitation practice. The basic concept is based on visualization of activity and enabling feedback. This can be used practically by patients with various diagnoses with disorders in the motion apparatus (Stein et al., 2011, Burdea and Coiffet, 2003) and patients with cognitive function disorders (Anton et al., 2009).

The causes of movement disorders are very different from injuries through cardiovascular diseases to neurological disease. Clinical images vary from patient to patient, but there is a collective need for a complex approach to therapy. In medical rehabilitation during reeducation and improvement of movement it makes it very beneficial to use therapeutic procedures that can be rehabilitated by the patient separately, and it is therefore desirable to allow feedback for control and eventual correction of exercise. To do this, it is advantageous to use tools containing sensors that, after interfacing with the appropriate software, evaluate sensor information and then visualize them in a virtual reality environment. In practice, the 2D screen is the most commonly used.

Because the traditional rehabilitation concept is often insufficiently motivating for patients, virtual reality has begun to become increasingly used not only to provide plain information about the action done. Playfulness and competition are human qualities that are very useful for improving the efforts of both therapies and auto-therapy. In this respect, the link between rehabilitation and patient play is a major activation and motivation element. According to Borghes et al. (2013) are games with therapies that are key to achieving rehabilitation goals. The games can be used to quantify the activity (force used and number of movements), as well as to improve the movement performed (combination of force change, motion focusing, etc.) and general improvement of cognitive functions (Vinas-Diz et al., 2015). For game-based devices within the virtual reality, the study clearly demonstrated increased patient motivation during exercise (Swanson et al., 2015). A playful and motivational approach in these applications has unquestionable benefits for patients and, ultimately, for therapists, which makes it easier to involve the patient in therapy. Lee provided the

same results et al. (2016), which showed the use of virtual reality by patients after a knee joint surgery, and that in very painful conditions this therapy is advantageously used, although some common types of therapy cannot be used just for the patient's great pain.

Nowadays, the rehabilitation of patients with disorders of cognitive function is already a standard. Therapies of these patients are more difficult due to memory problems, attention and concentration, speed of information processing, executive functions including emotional self-regulation, speech and expressing ability or spatial orientation. In these cases, the use of virtual reality offers significant enrichment and therapy improvement. For example, Anton et al. (2009) has shown its widespread use and inclusion in the daily life of children with ADHD („Attention Deficit Hyperactivity Disorder“ – hyperkinetical disorder (HKP), *behavioral disorder with hyperactivity*), where good potential of virtual reality as an effective and scalable attention measurements was proved. Aresti-Bartolome provided comparable information and Garcia-Zapirain (2015) in a study focused on children with autistic spectrum disorders - the use of avatars has improved the response time and visual interaction of children with the therapist. When used by patients after central stroke injuries, the use of interactive hand-play games has also been tested with good effect, and it has been shown that patients want to play these games, and rehabilitation in this form is highly motivating (Seo et al., 2016). The use of virtual reality by post-stroke patients was also investigated by Corbett, Imeri and Gatti (2015), comparing 15 studies with a total of 341 participants. Although there has been a clear contribution to improving patient mobility, the fact remains that most consoles and programs are still expensive and therefore unusable in medical practice. Affordable medical facilities that allow progress visualization and the course of therapy would definitely be a benefit to patients in normal rehabilitation practice.

Device rating:

SunBall is a medical device that makes rehabilitation by patients of various ages easier, from childhood to the elderly, with a wide range of diagnoses. Children can be affected both by motion system diseases and neurological diseases (for example bad body posture, scoliosis, post-traumatic states, central and peripheral nervous system diseases such as cerebral palsy or various types of peripheral paralysis). The tool can also be used when working with children with behavioral or autistic spectrum disorders. Regarding adults, the tool can be used in various neurological and orthopedic diagnoses such as stroke, neurodegenerative and demyelinating diseases, brain injuries, spinal cord or peripheral nerve injuries, stability and coordination disorders, and the ability to perform movements that have been caused by various other causes, such as traumatic injuries of the motion system. For seniors, **SunBall** is an ideal activation and motivation element that helps keep them in both physical and mental fitness.

SunBall works with the possibility of replacing some of the deficiencies in the system's detection and adjustment system by optical feedback. Thanks to the transfer of pressure from the ball to the image (*or audio signal*), it is possible to create not only optical feedback within the software but also to improve the motivation and emotional adjustment of the patient. When using **SunBall**, it is possible to save the results in the memory of the device and thus to further motivate the patient not only for one specific exercise but also for a longer period of time.

The basic offer of exercises in **SunBall** software is only indicative, because exercises should primarily perform basic assessment of the ability of the patient (physical and cognitive) and the selection of exercises or modify them individually according to the results of the examination and the expected goal of the exercise. This examination should be performed by patients by a trained therapist (ideally physiotherapist or ergotherapist).

Risk analysis:

It was performed according to ISO 14971 (idt ISO 14971: 2012). Medical devices - Application of risk management to medical devices and analysis of defects and their consequences (FMEA - Failure Mode and Effect Analysis). The manufacturer stores the documentation.

Based on a risk analysis, we can conclude that after the initial briefing on working with **SunBall** rehabilitation balls, we found no risk of using the device by trained people, and we have not noticed any adverse events arising from the use of this medical device.

c) Summary and conclusion

SunBall has proven to be suitable for the treatment of patients of various ages from childhood to the elderly, and can be used to treat patients with a wide range of diagnoses. Children can be affected both by motion system diseases and neurological diseases (for example bad body posture, scoliosis, post-traumatic states, central and peripheral nervous system diseases such as cerebral palsy or various types of peripheral paralysis). The **SunBall** medical device can also be used when working with children with behavioral or autistic disorders. Regarding adults, SunBall can be used by patients with various neurological and orthopedic diagnoses such as stroke, neurodegenerative and demyelinating diseases, brain injuries, spinal cord or peripheral nerve injuries, and stability and coordination disorders, as well as the ability to perform movements that originated from various other causes, such as traumatic injuries to the motion system. For seniors, **Sunball** is an ideal activation and motivation element that helps keep them in both physical and mental fitness.

In conclusion, **SunBall** medical device can also be an add-on to the exercise of healthy people (compensation for one-sided overloading of work, sport, and relaxation in psychologically demanding occupations).

The properties of these products meet the basic requirements of Government Decree No. 54/2015 Coll. about the technical requirements for medical devices and the specified technical standards and regulations in accordance with directive 93/42 EEC about medical devices, as amended.

The assessor considers the evaluated medical device in accordance with act No. 268/2014 Coll. about medical devices and on amendment of certain related acts, to be **safe for users and third parties**.