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Company profile

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Equistasi is a wearable, registered (class 1, ministerial code n. 342577 on 05/08/2010) medical device, an innovation resulting from a science-based project. It is composed of a rectangular plate measuring 10×20×0.5 mm with a weight of 0.17 gr.

This medical device is exclusively composed of nanotechnology fibers that transform body temperature into mechanical vibration energy. It self-produces a mechanical focal vibration with a non-constant frequency of about 9000 Hz that helps coordinate movements in patients affected by diseases such as Parkinson's, Multiple Sclerosis, and Friedreich's Ataxia.
A medical device
Equistasi is exclusively composed of nanotechnology fibers that transform body temperature into mechanical vibration energy.

- Equisasi is not a medicine; rather, it is a medical device, which means that it has no contraindications and no electrical or electronic base, and that it can be reapplied many times and has no expiration date. It can be applied during daily physical activities as well as during rehabilitation treatment.

- Equistasi is highly innovative and has six main characteristics that should be highlighted: it is wearable, lightweight (less than a quarter of a gram: 0.15 gr.), it doesn't have any electrical or electronic base, it's reusable, and it never expires.

TREATMENT USING THE MEDICAL DEVICE INVOLVES THE CREATION OF A STRONG RELATIONSHIP BETWEEN THE DOCTOR OR THERAPIST AND THE PATIENT

[Image of the device]
A disruptive innovation
Equistasi is appropriate for the treatment of both adults and children. The medical device may also be used in the rehabilitation treatment of animals.
The mission of Equistasi is to produce innovative medical devices and to do so with an awareness that these devices should improve the lives of patients.

Equistasi promotes collaborations with the most prestigious research centers (IRCCS) and places a high value on the exchange of skills. It has defined a code of conduct in line with the framework of action outlined by the European Union aimed at promoting Corporate Social Responsibility.

Equistasi’s industrial and financial strategies are aimed at realizing its chief goal of always meeting the expectations of its customers, partners, and employees.

In order to achieve its objectives, the company adheres to certain principles of behavior, including respect for law and for ethical principles such as transparency, fairness, and loyalty. Equistasi condemns and will not have recourse to illegal or unethical behavior in order to achieve economic objectives, and it ensures that its actions in the market and in the community at large are fully transparent, which promotes fair competition.

The company pursues excellence and competitiveness, offering its customers quality services that respond in an efficient manner to their needs. It protects and develops its human resources following principles of sustainable development and respect for the environment, principles that protect the rights of future generations.
Equistasi offers support for patients' rehabilitative therapy. It is composed exclusively of applied nanotechnology fibers and does not contain any pharmacological elements.

The focal mechanical vibration applied to affected muscular regions interacts with mechanoreceptors, the Golgi tendon organs, and neuromuscular spindles. Stimulation produced by the vibrations transmits information to the central nervous system: the higher motor centers, stimulated by the vibrations, act to improve the proprioceptive information that underlies motor control.
For all these reasons, Equistasi is an innovative and particularly interesting rehabilitative therapy.

The role of the physiotherapist in this innovative rehabilitation method is fundamental: he or she must possess multidisciplinary knowledge in biomechanics, anatomy, physiology, and neurophysiology and must be ready to predict the effects of the interaction between the Equistasi device and the anatomical regions to which it is applied.

- Equistasi can be used during orthopedic rehabilitation, to strengthen motor control and normalize muscle tone, to ameliorate chronic and acute pathologies, and to address dysmorphism and paramorphism.

- The medical device is indicated as an instrument suitable for the modulation of the proprioceptive circuits that are the basis of motor activities, regardless of the type of lesion affecting these circuits. For this reason, the application of Equistasi in neurological rehabilitation (for example, for Parkinson’s Disease or Multiple Sclerosis) can optimize a patient’s neuromuscular function by enhancing his or her residual abilities and improving postural control.

- Equistasi also carries antalgic properties, whose effects can be perceived within minutes following treatment. These can help correct a patient’s postural patterns and assist with recovery of a correct alignment.

- The medical device is indicated as a support, accessible to all and non-invasive, for caregivers who want to see an improvement in impaired proprioceptive skills and in the general quality of life.
**OUR FIELD OF APPLICATION**

**Pain**

Equistasi® is a medical device with antalgic properties, whose effects are perceived within minutes after application. The antalgic effect of focal vibration is due to the afferent barrage along the amyelinated pathways [The Gate Control Theory, Melzack and Wall (1965). See the complete publication at this link].

Specifically, Equistasi FV enhances presynaptic inhibition, and inputs originating from peripheral nociceptive afferents can be inhibited by effectively reducing the pain sensation. These vibrations were also tested in a controlled and randomized electrophysiological trial, performed by Dr. Enrico Alfonsi of the IRCCS Casimiro Mondino Neurological Institute Hospital of Pavia, in which the amount of presynaptic inhibition that the device can amplify—and how much the same focal vibrations—affect the spinal circuit of the soleus muscle.

**Multiple Sclerosis**

The effects of local mechanical vibrations of the Equistasi device have been tested in clinical trials, including on patients with MS. First results indicate an improvement in patients’ ambulation/gait and a modulation of muscular tone, especially in mainly spastic patients. After the results of this study, published in Restorative Neurology and Neuroscience, Equistasi is proceeding with a multicentric to validate the results obtained. The results point out, in continuity with other scientific studies, the existence of an inverse correlation between years of illness and the improvements that can be obtained with the vibrational method of the Equistasi device. This supports the fact that rehabilitative therapies and also vibrational therapy should be administered as soon as possible in patients with MS in order to optimize the obtainable results.
Parkinson’s

The studies conducted on Parkinson’s patients with a high instability rate, resistant to conventional pharmacological therapy, show that the application of the Equistasi wearable proprioceptive stabilizer, in an intense physiotherapy program, seems to be effective in improving patients’ balance; and this is in terms of instrumental results, on the clinical variables and the rate of falls.

The scientific rationale at the basis of points of application and defined posology has a wide validation in scientific literature with appreciable results in balance and postural stability. This last feature, common in Parkinson’s patients that usually manifests itself in the most advanced stages of the disease, represents a highly disabling symptom — not very responsive to the therapy — and it also interferes with the ability to maintain balance, predisposing to the loss of the same and, consequently, resulting in unexpected falls.

Ataxia

At the end of 2016, the effect of the Equistasi device on patients with Ataxia has been verified. The Federico II University of Naples and the La Sapienza University of Rome have completed and published a pilot study on 11 patients (five Friedrich and six SCA) in open field. Even with caution due to the small sample and the absence of placebo in the trial, the results are very encouraging and indicate a good improvement in the balance and ambulation of the treated patients. The procedure to start a multicenter double-blind Equistasi vs Placebo study has begun. The results obtained by applying four Equistasi devices on the skin of the patients, go in the direction of the improvement of the motor aspects, and also those of the upper limbs, and are well described in the article in the bibliography.
Involvement in sports activities often has a beneficial impact on the body, although sports subject the body to biomechanical stresses and traumatic events that can affect not only our ability to perform them optimally, but also our general health and well-being.

The device is designed to be highly resistant to wear, and therefore can be used for sports that involve contact with water.
A non-invasive device
The medical device is designed to be highly resistant to wear, and therefore can be used for sports that involve contact with water.

Equistasi is an important ally to patient participation in sports:

1. It improves the speed of motor recovery from traumatic events that may occur during sports activities.
2. It enhances motor control and postural stability. Lower energy dispersion guarantees better performance.
3. It has been certified as a non-doping medical device. The technical analysis carried out in the Chemical Analysis / Toxicological Laboratory of the Department of Pharmaceutical Sciences at the University of Milan found that the application of Equistasi does not regulate the absorption of substances by means of a pharmacological action and is therefore not toxic.
Improving the lives of patients requires world-class clinical studies and evidence.

The mission of Equistasi is to discover, develop, and produce innovative medical solutions. The company is dedicated to scientific integrity and ethical principles in the design, conduct and reporting of research.

Abstract
This study in healthy subjects examined the effects of a system delivering focal microvibrations at high frequency (Equistasi®) on tonic vibration stimulus (TVS)-induced inhibition of the soleus muscle H reflex. High-frequency microvibrations significantly increased the inhibitory effect of TVS on the H reflex for up to three minutes. Moreover, Equistasi® also significantly reduced alpha-motoneuron excitability, as indicated by the changes in the ratio between the maximum-amplitude H reflex (Hmax reflex) and the maximum-amplitude muscle response (Mmax response); this effect was due to reduction of the amplitude of the H reflex because the amplitude of muscle response remained unchanged. The present findings indicate that Equistasi® has a modulatory effect on proprioceptive reflex circuits. Therefore, Equistasi® might interfere with some mechanisms involved in both physiological and pathophysiological control of movement and of posture.

Keywords: H reflex, high-frequency microvibrations, tonic vibratory stimulation

Leonardi L1, Aceto MG2, Marcotulli C3, Arcuria G1, Serrao M1, Pierelli F1, Paone P3, Filla A2, Roca A2, Casali C3.

A wearable proprioceptive stabilizer for rehabilitation of limb and gait ataxia in hereditary cerebellar ataxias: a pilot open-labeled study
Available at https://link.springer.com/article/10.1007%2Fs10072-016-2800-x

Abstract
The aim of this pilot study is to test the feasibility and effectiveness of a wearable proprioceptive stabilizer that emits focal mechanical vibrations in patients affected by hereditary cerebellar ataxias. Eleven adult patients with a confirmed genetic diagnosis of autosomal dominant spinocerebellar ataxia or Friedreich’s ataxia were asked to wear an active device for 3 weeks. Assessments were performed at baseline, after the device use (T1), and 3 weeks after (T2). SARA, 9-HPT, PATA, 6MWT, and spatial and temporal gait parameters, measured with a BTS-G-Walk inertial sensor, were used as study endpoints. As expected, no adverse effects were reported. Statistically significant improvements in SARA, 9HPT dominant hand, PATA test, 6MWT, cadence, length cycle, support right/cycle, support left/cycle, flight right/cycle, flight left/cycle, double support right/cycle, double support left/cycle, single support right/cycle, and single support left/cycle were observed between T0 and T1. All parameters improved at T1 did not show statistically significant differences a T2, with the exception of length of cycle. This small open-labeled study shows preliminary evidence that focal mechanical vibration exerted by a wearable proprioceptive stabilizer might improve limb and gait ataxia in patients affected by hereditary cerebellar ataxias.

Keywords: Focal mechanical vibrations; Gait ataxia; Hereditary cerebellar ataxias; Neurorehabilitation
The effects of mechanical focal vibration on walking impairment in multiple sclerosis patients: A randomized, double-blinded vs placebo study

Abstract

Background: Multiple Sclerosis is a heterogeneous disorders involving in early stage gait and balance. Together with immunomodulating therapies, rehabilitation had a crucial role in improving motor tasks and quality of life. Between the emerging techniques, Focal Vibrations (FV) could play a role, but they have been used in MS only to reduce muscle tone and fatigue alone or together with botulinum toxin. Objective: To assess whether FV is effective on walking impairment in a cohort of MS patients. Methods: We performed a single-centre randomized, double-blind, sham-controlled study to investigate efficacy of FV vs sham vibration in 20 RR MS patients. Ten patients received treatment with the active device and ten patients sham treatment. Demographical, clinical and gait instrumental data analysis have been collected for each patient at baseline (T0), after treatment (T1) and after three weeks of wash out (T2). Results: Both groups were clinically and demographically comparable. Treated patients showed significant improvements during the first right step (FRS) (p = 0.007), average stride length (ASL) (p = 0.012), double support right (DSRT) (p = 0.016) and left (DSLT) (p = 0.003) time. Non-treated patients didn’t show any significance for any dynamic variables. Moreover, on posturographic measurements we registered only a trend towards significance in swing area with eyes open (SAEO) (p = 0.087). We also found in treated group significant improvements in FRT (p = 0.018); BBS (p = 0.037) and FSS scales (p = 0.038) between T1 and T0. Lastly, we found a significant inverse correlation in the treated group between disease duration and percentage of improvement for DSLT (r = –0.775; p = 0.014) in T1 vs T0 and percentage of improvement of FSS, with an inverse correlation with both disease duration (r = –0.775; p = 0.014) and AGE (r = –0.733, p = 0.025) in T1 vs T0. Conclusion: Our results suggest a beneficial effect of FV on walking impairment in MS patients suffering from spasticity and/or postural instability, which partially lasted until follow up.

Keywords: Multiple sclerosis, neurorehabilitation, focal vibrations, gait analysis
Abstract
Muscle spindles endings are extremely sensitive to externally applied vibrations, and under such circumstances they convey proprioceptive inflows to the central nervous system that modulate the spinal reflexes excitability or the muscle responses elicited by postural perturbations. The aim of this pilot study is to test the feasibility and effectiveness of a balance training program in association with a wearable proprioceptive stabilizer (Equistasi) that emits focal mechanical vibrations in patients with PD. Forty patients with PD were randomly divided in two groups wearing an active or inactive device. All the patients received a 2-month intensive program of balance training. Assessments were performed at baseline, after the rehabilitation period (T1), and two more months after (T2). Posturographic measures were used as primary endpoint; secondary measures of outcome included the number of falls and several clinical scales for balance and quality of life. Both groups improved at the end of the rehabilitation period and we did not find significant between-group differences in any of the principal posturographic measures with the exception of higher sway area and limit of stability on the instrumental functional reach test during visual deprivation at T1 in the Equistasi group. As for the secondary outcome, we found an overall better outcome in patients enrolled in the Equistasi group: 1) significant improvement at T1 on Berg Balance Scale (+45.0%, p = .026), Activities-specific Balance Confidence (+83.7, p = .004), Falls Efficacy Scale (−33.3%, p = .026) and PDQ-39 (−48.8%, p = .004); 2) sustained improvement at T2 in terms of UPDRS-III, Berg Balance Scales, Time Up and Go and PDQ-39; 3) significant and sustained reduction of the falls rate. This pilot trial shows that a physiotherapy program for training balance in association with focal mechanical vibration exerted by a wearable proprioceptive stabilizer might be superior than rehabilitation alone in improving patients’ balance.

Abstract
This study in healthy subjects examined the effects of a system delivering focal microvibrations at high frequency (Equistasi®) on tonic vibration stimulus (TVS)-induced inhibition of the soleus muscle H reflex. High-frequency microvibrations significantly increased the inhibitory effect of TVS on the H reflex for up to three minutes. Moreover, Equistasi® also significantly reduced alpha-motoneuron excitability, as indicated by the changes in the ratio between the maximum-amplitude H reflex (Hmax reflex) and the maximum-amplitude muscle response (Mmax response); this effect was due to reduction of the amplitude of the H reflex because the amplitude of muscle response remained unchanged. The present findings indicate that Equistasi® has a modulatory effect on propioceptive reflex circuits. Therefore, Equistasi® might interfere with some mechanisms involved in both physiological and pathophysiological control of movement and of posture.

Keywords: H reflex, high-frequency microvibrations, tonic vibratory stimulation
PATIENTS’ EXPERIENCES

All experiences matter. Equistasi provides opportunities for patients and staff to freely share, in their own words, what matters most to them, no matter how difficult or sensitive the topic may be.

We listen and learn from patients’ insights, which can be used alongside other important data sources, to better understand the significant impact of this medical device.
Videos on YouTube

Imbalance (user-generated content)
- [https://www.youtube.com/watch?v=cydr4UoVDbE](https://www.youtube.com/watch?v=cydr4UoVDbE) (before using Equistasi)
- [https://www.youtube.com/watch?v=hxiD9jRnNGM](https://www.youtube.com/watch?v=hxiD9jRnNGM) (twenty minutes after using Equistasi)

Multiple sclerosis (user-generated content)
- [https://www.youtube.com/watch?v=Z9dkSrizHnY](https://www.youtube.com/watch?v=Z9dkSrizHnY) (twenty minutes after using Equistasi)

Double hernia (user-generated content)
- [https://www.youtube.com/watch?v=as_hjgTQi4A](https://www.youtube.com/watch?v=as_hjgTQi4A)

Motor neuron disease (user-generated content)
- [https://www.youtube.com/watch?v=SDdaPxlo9Fo](https://www.youtube.com/watch?v=SDdaPxlo9Fo) (forty-five minutes after using Equistasi)

Parkinson’s
- [https://www.youtube.com/watch?v=mQ5YJkl6tE4](https://www.youtube.com/watch?v=mQ5YJkl6tE4)

Two months after application (user-generated content)
- [https://www.facebook.com/nmura1/videos/10207781026437610/](https://www.facebook.com/nmura1/videos/10207781026437610/)

One month after application (user-generated content)
- [https://www.facebook.com/nmura1/videos/10207493081319162/](https://www.facebook.com/nmura1/videos/10207493081319162/)

Videos on Facebook

Atypical parkinsonism (user-generated content)
- [https://www.facebook.com/francesco.serio.14/videos/g.390807518032913/1715861931814040/?type=2&theater&ifg=1](https://www.facebook.com/francesco.serio.14/videos/g.390807518032913/1715861931814040/?type=2&theater&ifg=1)

Parkinson’s (user-generated content)
- [https://www.facebook.com/groups/390807518032913/permalink/397851310661867/](https://www.facebook.com/groups/390807518032913/permalink/397851310661867/)

Multiple sclerosis (user-generated content)
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Parkinson’s (user-generated content)
- [https://www.facebook.com/groups/390807518032913/permalink/397849537328711/](https://www.facebook.com/groups/390807518032913/permalink/397849537328711/)

Twenty minutes after application (user-generated content)