

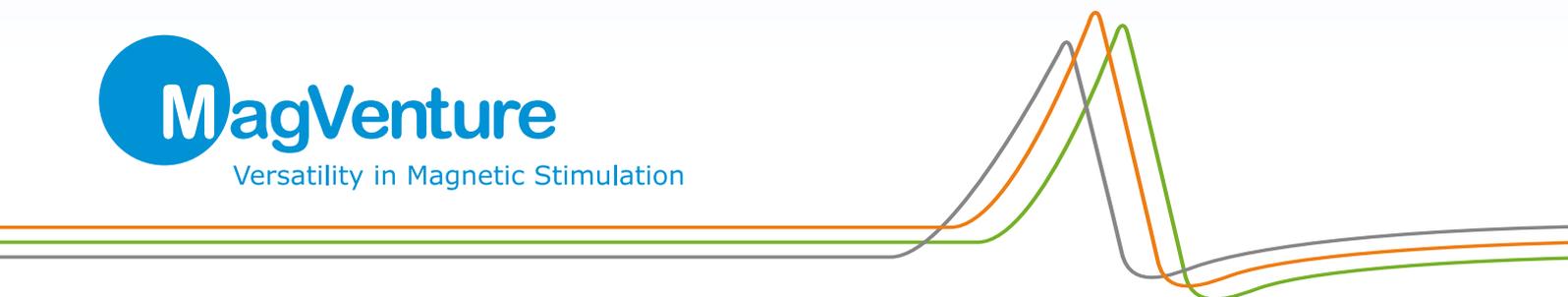
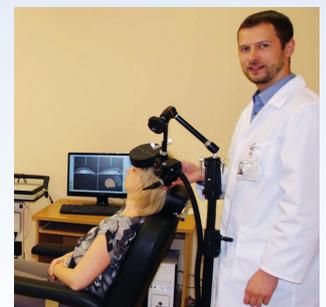
# MagVenture **NEWS**

*University of São Paulo, Brazil:*  
10 questions for Dr. Andre Brunoni

*Hospital Wilhelmshaven, Germany:*  
More patients are now treated with TMS than ECT

*University of Auckland, New Zealand:* TMS is an important tool both in the assessment and rehabilitation of central nervous system injuries

*Republican Vilnius Psychiatric Hospital, Lithuania:*  
State of the art rTMS is a way to help otherwise treatment-resistant patients



## From humble beginnings...

Just over 25 years ago in the city of Copenhagen, Denmark, in what used to be a greengrocery store, we built our first magnetic stimulator. This prototype of ours would soon after go on to become the first MagPro. Since then, a lot has happened, both here at MagVenture, but also when it comes to TMS in general. TMS for the treatment of severe depression is, most importantly, becoming more and more common, although globally, the adaptation of the technology is far from evenly distributed.

The earliest “TMS adopter” is by far the US. The treatment was FDA cleared for the treatment of major depressive disorder in 2008 and today there are hundreds of clinics in the US offering rTMS.

The treatment is also becoming increasingly accessible in several other countries. Furthermore, an impressive amount of research has already been conducted or is currently ongoing – from small pilot studies to large-scale multi-center, sham-controlled trials. All this work is being led by dedicated researchers and their pioneering work will undoubtedly help pave the way for new treatment protocols.

For MagVenture in 2016, the future is looking bright and exciting: our “MagPro Family” now consists of 7 different stimulators, 33 different coils, a large variety of accessories, not to mention several collaborative partnerships. Our engineers are reputedly known in the market as being “insane” when it comes to defining



the performance standards. They are currently developing several new products which will hopefully help push forward both the technology and the possibilities, for researchers as well as for clinicians.

**Stig Wanding Andersen**  
CEO, MagVenture

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*The usage of rTMS for any other purpose than the cleared indication, in the country in which the product is intended to be used, is considered investigational.*

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# 10 questions for Dr. Andre Brunoni, University of São Paulo, Brazil

When it comes to research within TMS, Brazil is considered the leading force of South America, with several trials already conducted and more on the way. MagVenture NEWS spoke with Dr. Andre Brunoni from the University of São Paulo who is one of the major contributors to this development.

## 1) How did you first become interested in TMS?

During my first year as a resident in psychiatry, I did a one-month fellowship in the Berenson-Allen Center for Non-Invasive Brain Stimulation at the Beth Israel Deaconess Medical Center, in Boston, under the supervision of Prof. Felipe Fregni who was then working there. I was fascinated with the possibility of non-invasively treating patients using TMS and also with the versatility of TMS, a tool that can also be used in research settings to probe brain activity.

## 2) How would you describe the “landscape of TMS” in Brazil?

It is certainly improving. 10 years ago, TMS was seen as a very “exotic” technique and even psychiatrists and researchers were very sceptic about it. At the present time, non-invasive brain stimulation, particularly TMS, is better known by physicians and psychiatrists, especially the younger ones. However, Brazil is a very big country, and TMS is still largely unknown outside the major state capitals.

## 3) What is the status of rTMS in the public health system in Brazil?

TMS was “officially” introduced in clinical practice in Brazil in 2012, after its regulation by the Brazilian Medical Board. From then onwards, we see more and more psychiatrists using TMS in their clinical practices, outside of research centers. Unfortunately, TMS has not yet been recognized as a treatment by our national public health system; also because of that, some private insurance companies still refuse to reimburse the patients for the treatment.



*Dr. Andre Brunoni of the University of São Paulo, here seen with MagVenture’s MagPro R20 stimulator, has been a driving force in raising awareness of non-invasive brain stimulation in Brazil. Besides numerous research projects the University also offers a semiannual TMS course which is fully booked every time.*

## 4) Are patients in Brazil who receive rTMS treatment for their depression typically eligible for insurance coverage?

This varies a lot according to the region of Brazil. In the city of São Paulo, for instance, around 50% of the population has a private insurance and thus would be theoretically eligible to receive rTMS for depression treatment. Unfortunately, many insurance companies refuse to reimburse or pay for rTMS on the grounds that rTMS is still not covered by our “SUS” [Sistema Unico de Saude, the national public health system in Brazil]. Some companies also say that there is not enough evidence

## Recent TMS studies from the University of São Paulo

Several trials have been conducted within recent years at the University of São Paulo, including:

- The efficacy of TMS combined to amitriptyline to accelerate antidepressant response (Rumi et al., 2005)
- TMS as a treatment for depressive symptoms in Parkinson’s disease (Fregni et al., 2004)
- Relative efficacy of TMS vs. ECT in unipolar depression (Rosa et al., 2006)
- Efficacy of TMS to treat auditory hallucinations in clozapine-resistant schizophrenia (Rosa et al., 2007)
- Investigation of TMS effects in obsessive-compulsive disorder (Mansur et al, 2011).

that rTMS is effective. In such cases, the patients usually have to sue their insurance company in order to receive the treatment – fortunately; in most cases they are successful.

## 5) Can you describe some of the most significant TMS studies (including results) conducted in Brazil?

Non-invasive brain stimulation research has been very fruitful in Brazil for a long time. In the past 15 years, important studies were conducted at many centers, includ-

***Non-invasive brain stimulation research has been very fruitful in Brazil for a long time. In the past 15 years, important studies were conducted at many centers, including the TMS service in the Institute of Psychiatry at the University of São Paulo.***

**Andre Brunoni**

ing the TMS service at the Institute of Psychiatry at the University of São Paulo, of which I have been the head since 2013. We have published several clinical trials showing the efficacy of TMS [see box on the previous page].

**6) Theta Burst Stimulation (TBS), the patterned form of rTMS, is currently emerging in several new studies within depression treatment. What is your view on TBS?**

TBS is a TMS modality that is particularly advantageous to induce neuroplasticity. This is important because several lines of evidence showed that depression is a disorder associated with decreased neuroplasticity in some brain areas, such as the prefrontal cortex. Therefore, neuroplasticity increasing might directly ameliorate depressive symptoms. TBS has another advantage: the treatment protocol is very short, lasting 5 minutes or less.

For these reasons, TBS is being intensively investigated in the treatment of major depression. Initial results are showing that TBS might be as effective as the standard high-frequency rTMS protocol, which lasts about 40 minutes. We plan to investigate the use of TBS in our TMS service at the University's Institute of Psychiatry.

**7) Can you tell us about the TMS course you are currently offering at the University of São Paulo?**

We offer a TMS course twice a year where the use of TMS in psychiatric disorders is covered. We always get full attendance, showing the growing

**Initial results are showing that TBS might be as effective as the standard high-frequency rTMS protocol, which lasts about 40 minutes. We plan to investigate the use of TBS in our TMS service at the University's Institute of Psychiatry.**

**Andre Brunoni**

interest of clinicians in using TMS. The participants are mainly psychiatrists and physicians from all over Brazil with little or no expertise in TMS who want to know more about the technique or start using it in their private practices or public hospitals. We also receive graduate students and medical residents who are interested in the research aspects of neuromodulation. In this course we also offer training in using rTMS. This is usually complemented by a practical course where the student stays in our service for one week. Students also enjoy this practical course because we run a busy service, performing around 20 TMS sessions per day.

**8) What would you say has been the most remarkable achievement of your department so far?**

My research has focused in the past years in the investigation of another technique of non-invasive brain stimulation called transcranial direct current stimulation (tDCS). tDCS has the same advantage as rTMS of being a non-pharmacological treatment with benign adverse effects and virtually no contraindications. We are at the present time carrying on several tDCS trials investigating its efficacy in unipolar depression, bipolar

depression, schizophrenia and OCD.

**9) What is your experience of rTMS vs. tDCS for the treatment of depression?**

The pros of tDCS are affordability and portability as well as ease of use. The main con is that tDCS efficacy is still unclear: some results have been positive, although other studies showed negative or mixed findings. Also, it seems that tDCS is less effective in refractory samples.

**10) In your opinion, what is the biggest future challenge of rTMS?**

I think that rTMS – as well as other brain stimulation techniques – still have some important challenges such as parameter optimization and better understanding of its mechanisms of action. Particularly in Brazil, I believe that the biggest challenge is its incorporation as a treatment modality in our public health service.

We need more cost-effectiveness studies in Brazil of comparing rTMS to other pharmacological treatments, some of them very expensive, which are fully covered by the SUS. Of course, the challenge here is not only scientific, but also political.

## Doctor Andre Brunoni

Dr. Brunoni graduated in Medicine in 2004 from the University of São Paulo and specialized in Internal Medicine and Psychiatry. This included research at the Spaulding Rehabilitation Hospital in Boston, USA as well as the Department of Physical Medicine and Rehabilitation at Harvard Medical School, before completing a PhD in Non-Invasive Brain Stimulation in 2012.

Dr. Brunoni is currently the Director of two clinical and research centers at the University of São Paulo: the Institute of Psychiatry in the Clinics Hospital and the University Hospital. His research involves the use of non-invasive brain stimulation techniques for the treatment of mental disorders, such as mood disorders, obsessive-compulsive disorder and schizophrenia. He has published more than 100 articles in PubMed peer reviewed journals.



## Hospital Wilhelmshaven, Germany: More patients are now treated with TMS than ECT

*20 years have passed by since Professor Dr. med. Here Folkerts began to offer rTMS depression treatment at the University of Münster. He is now the medical director at the Hospital Wilhelmshaven in Germany where 150 people annually undergo rTMS treatment.*

ECT used to be the main treatment option for depression at the Hospital Wilhelmshaven, but recent years have witnessed a shift in the number of rTMS patients and ECT patients.

“For the past 6 years, we have treated about 150 people with rTMS every year compared to 100 ECT patients. Until 6 years ago, we only treated 20 patients with rTMS a year so we have seen a significant increase in the number of rTMS patients,” says Prof. Dr. med. Here Folkerts who is responsible for both the ECT as well as the rTMS treatments



*150 patients annually receive rTMS treatment for their depression at Hospital Wilhelmshaven. The number of patients receiving rTMS have now surpassed the number of patients getting ECT treatment, according to Professor Folkerts.*

According to Dr. Folkerts, the reason for the higher number of rTMS patients is that the knowledge about TMS in general has increased. The

### **TMS is usually used in combination with medication**

Even though the number of TMS patients has increased, ECT is still the chosen treatment for severely ill patients.

“For people suffering from severe depression, we usually start with ECT treatment and sometimes we use rTMS as maintenance therapy. For other patients who are not as ill with depression, we start with TMS Therapy in combination with pharmacotherapy, and then we add ECT if we do not see sufficient results,” Dr. Folkerts says and continues:

***The fact that I am able to help my patients get better with a quite new and innovative treatment is my main motivation for working with rTMS.***

**Here W. Folkerts**

at the hospital. He stresses that Hospital Wilhelmshaven has good results with TMS for their patients with treatment-resistant depression.

practitioners also know more about how to perform and target TMS.

### **Professor Dr. med. Here Folkerts**

Prof. Dr. med. Here Folkerts is head of the clinic for Psychiatry, Psychotherapy and Psychosomatics at Hospital Wilhelmshaven.

In addition he is the medical director of the Hospital in Wilhelmshaven. Each year, 1800 adult patients are treated by Dr. Folkerts and his colleagues. Treatment of depression disorders, post-traumatic stress disorder and anxiety disorders are at the focus of attention. Both inpatients and outpatients are treated.

Dr. Folkerts holds a Master Degree from the University of Münster and he is member of the faculty from the university of Goettingen. Since 1976, the Hospital Wilhelmshaven is an academic teaching hospital of the University of Göttingen. The main academic interest of Prof Folkerts is the field of neurostimulation.



“We see good results with TMS in combination with pharmacotherapy. The remission rate is 40-50 percent. Most of our patients receive TMS and antidepressants in combination – only a small part of our patients receive TMS without medication, and most of these patients are patients

***Most of our patients love TMS because there are no side effects. I don't know of anybody who has wanted to quit the treatment because of side effects.***

**Here Folkerts**



*TMS treatment at the Hospital Wilhelmshaven of a depressive breastfeeding patient. The treatment is administered by an employee of Professor Folkerts.*

who do not want to take medication at all – for example women who are pregnant or breastfeeding.”

### **Both inpatients and outpatients are treated**

A typical patient at the hospital has suffered from a treatment resistant depression for ½-1 year with a mild degree of depression (HAM-D score 15-25). The majority of patients receive rTMS treatment 5 times a week for at least 4 weeks – often longer.

“Most of our patients are admitted to the hospital, but we also have patients on an ambulatory basis. These patients are usually referred to the hospital from their own general practitioner or psychiatrist who knows that we offer rTMS depression treatment,” says Dr. Folkerts.

At Hospital Wilhelmshaven, rTMS treatment is free for inpatients, whereas outpatients are usually covered by private health insurances.

### **Patients love TMS**

The patients are quite happy about receiving TMS depression treatment. “Most of our patients love TMS because there are no side effects. I don't know of anybody who has wanted to quit the treatment because of side effects. Usually the patients say that they go to the “*Tackern*,”” says Dr. Folkerts. [Tackern is the German word for the tapping sound that the MagPro makes during stimulation].

### **Possible to help complicated patients**

The patients are not the only ones who are happy about TMS. Dr. Folkerts is very glad that he is able to help people out of their depression. 20 years down the road, the ability to help his patients remains the driving force for Dr. Folkerts.

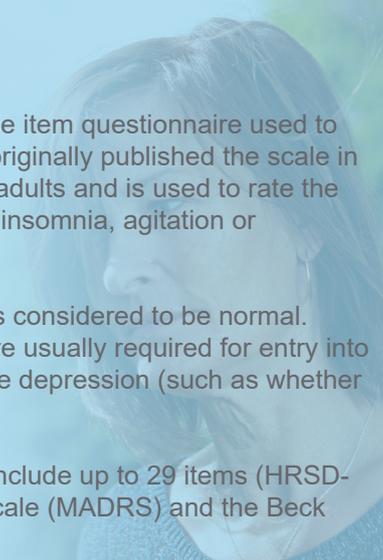
“It is a good day at the office when I am able to successfully treat complicated patients. It is sometimes an academic puzzle to find the right treatment, but the fact that I am able to help my patients get better with a quite new and innovative treatment is my main motivation for working with rTMS,” Dr. Folkerts ends.

## **Hamilton Rating Scale for Depression (HAM-D)**

The Hamilton Rating Scale for Depression (HRSD), abbreviated HAM-D, is a multiple item questionnaire used to provide an indication of depression, and as a guide to evaluate recovery. Hamilton originally published the scale in 1960 and revised it several times over the years. The questionnaire is designed for adults and is used to rate the severity of their depression by investigative mood, feelings of guilt, suicide ideation, insomnia, agitation or retardation, anxiety, weight loss, and somatic symptoms.

The original 1960 version contains 17 items to be rated (HRSD-17). A score of 0-7 is considered to be normal. Scores of 20 or higher indicate moderate, severe, or very severe depression, and are usually required for entry into a clinical trial. Questions 18-20 may be recorded to give further information about the depression (such as whether diurnal variation or paranoid symptoms are present), but are not part of the scale.

Although Hamilton's original scale had 17 items, other versions were developed to include up to 29 items (HRSD-29). Other much used scales include the Montgomery-Åsberg Depression Rating Scale (MADRS) and the Beck Depression Inventory (BDI)

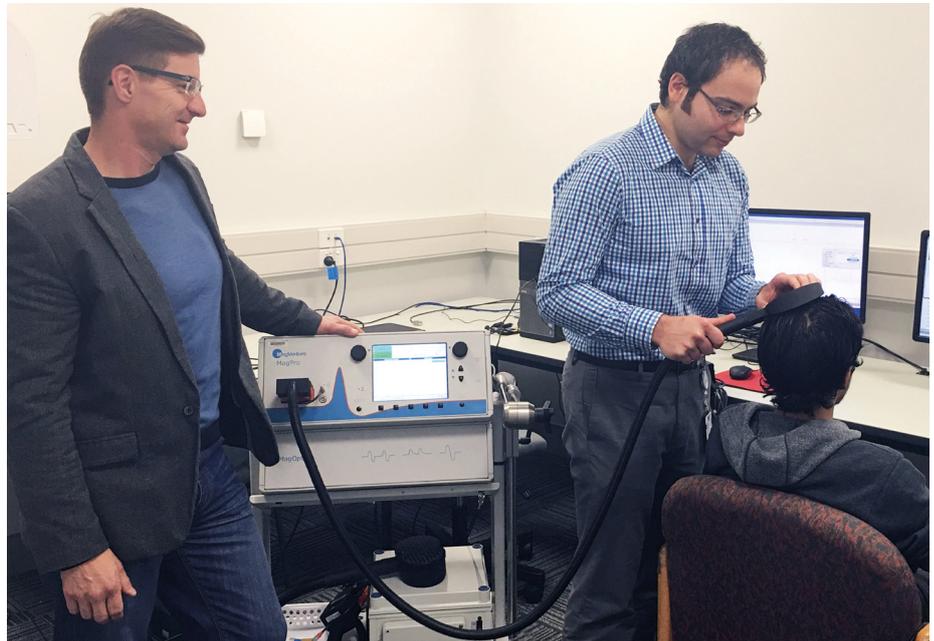


# University of Auckland, New Zealand: TMS is an important tool both in the assessment and rehabilitation of central nervous system injuries

Understanding how cortical mechanisms function and how to control and learn voluntary movements are extremely important factors in helping patients with neurological injuries or impairments. According to Dr. John Cirillo, a postdoctoral research fellow from the University of Auckland, New Zealand, TMS can play a key role in the rapidly growing field of neurorehabilitation, both when it comes to predicting the possible outcomes of treatment and when identifying the prognosis/diagnosis.

## TMS induces neuroplasticity

“Neuroplasticity is important in learning and memory and therefore crucial when it comes to the recovery from various central nervous system injuries,” says Dr. Cirillo. “By combining TMS and motor training protocols it is possible to promote a more favorable environment in motor cortex to induce plasticity and investigate mechanisms of neuroplasticity in humans”, explains Dr. Cirillo. “TMS is



Dr. John Cirillo standing on the right, assisted by Professor Byblow on the left, is here demonstrating paired pulse TMS with threshold tracking. This particular technique has the potential to be used to diagnose neurological disorders which the MagPro X100 has the capacity to handle.

**[TMS] gives the researchers a clear and objective assessment of whether there is communication between the brain and affected limbs.**

**John Cirillo**

a non-invasive and painless technique which allows us to indirectly assess the human motor cortex activity by electromyography recordings.”

## TMS tool can predict recovery potential

“Our general focus is improving the patient’s recovery of motor function after stroke, especially the ability to

live independently after stroke”, says Dr. Cirillo. Research on stroke rehabilitation at the university over the last years, led by Associate Professor Cathy Stinear and Professor Winston Byblow, has seen the development of an efficient and economical test tool called PREP (Predicting REcovery Potential). “The first step in the PREP algorithm uses standardized arm movements scored by clinicians. A prediction can typically be made for around half of patients using this first

## PREP - Algorithm for Stroke Recovery

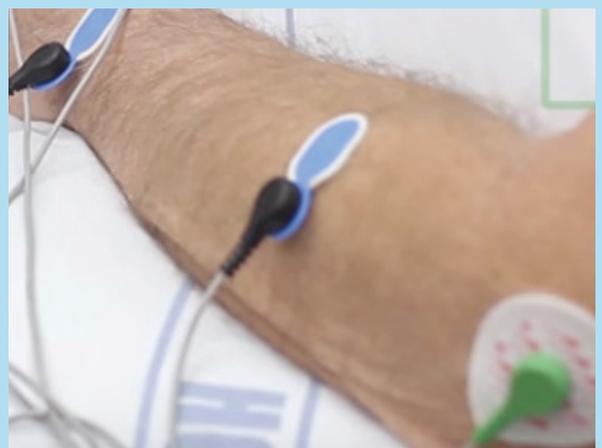
The PREP test (Predicting REcovery Potential for the hand and arm ) is developed by researchers at the University of Auckland and involves the following three steps:

**Step 1:** Standardised arm movements scored by clinicians

**Step 2:** Testing the motor pathways to the affected arm (TMS, see image)

**Step 3:** Detailed imaging of the brain (MRI scan)

**+** More information: <http://prepforstrokerehab.wikispaces>.



step. However, the true potential for recovery in remaining patients remains uncertain,” explains Dr. Cirillo. By applying TMS over the motor cortex hand and arm representations, the researchers can help predict the recovery potential for these patients based on whether a signal (motor evoked potential, MEP) is recorded in the muscle sent from the brain (step two of the PREP algorithm). “PREP is particularly useful for identifying patients with potential for recovery that might otherwise go unrecognized, and it enables us to distinguish between individuals with limited or essentially no potential for recovery of the affected limb,” he explains.

### TMS allows for various techniques

Well-established functional neuroimaging techniques involving magnetic resonance and encephalography may provide excellent spatial and temporal resolution used in connection with the diagnosis as well as prognosis. They do, however, pose some limitations, according to Dr. Cirillo: Mainly their inability to assess the neurophysiological mechanisms of brain function. “The problem lies in the fact that they only observe the neuronal activity, they do not differentiate between excitatory or inhibitory inputs,” explains Dr. Cirillo.

**Larger scale studies would more than anything impact how we implement a therapeutic strategy.**

**John Cirillo**

These mechanisms can, however, be assessed by using TMS, which activates inhibitory and excitatory processes that project onto the corticospinal neuron.” This critical neuronal activation pattern of TMS allows various techniques, particularly paired-pulse TMS, to target and assess inhibitory or excitatory projections within the cortex.

The research team at the University of Auckland therefore uses both single and paired pulse TMS.

### Determining communication between brain and limbs

“Single pulse TMS makes it possible for us to examine the brain’s output

to the spinal cord and muscle. This information can be extremely helpful very early after stroke because it gives the researchers a clear and objective assessment of whether there is communication between the brain and affected limbs, as also evident in the PREP test,” explains Dr. Cirillo.

### Understanding the underlying mechanisms

Paired pulse TMS, on the other hand, delivers two distinct stimuli through the same coil, which allows the researchers to examine circuits within the brain that influence that output. “Ultimately this will increase the understanding of the underlying mechanisms that occur during spontaneous recovery after injury and will allow us to optimize and/or accelerate motor recovery after a neurological insult, particularly stroke,” says Dr. Cirillo.

### In the pipeline: Threshold tracking TMS

Dr. Cirillo and his colleagues are currently also using paired pulse TMS with threshold tracking. This TMS technique differs from traditional TMS protocols, as it tracks a target motor response elicited by TMS. An important feature of this technique is its ability to reduce limitations that may

underestimate the true value of inhibition with traditional protocols.

This may have implications for assessment of inhibitory function diagnostically with TMS, where small changes in inhibition are not apparent or highly variable with traditional protocols.

The effectiveness of threshold tracking TMS as a diagnostic tool to investigate neurological disorders may also depend on the induced current direction in the brain. This has previously been a challenge, mainly due to limitations in the TMS stimulators but is possible with the MagPro X100 with MagOption stimulator.

### Goal: a universal rehabilitative standard

According to Dr. Cirillo, a well-known and constant challenge is the recruitment of patients. No two strokes or spinal cord injuries are ever the same, and there is considerable variability both within and between individuals and techniques applied.



*The career goal of Dr. John Cirillo, Auckland University, is to help establish a universal rehabilitative standard based on the work and findings of both researchers and clinicians.*

“TMS and magnetic resonance imaging help reduce this variability but larger scale studies would more than anything impact how we implement a therapeutic strategy. This could ultimately lead to establishing a universal rehabilitative standard, as well as closely link therapeutic strategies developed by both researchers and clinicians, which would also be a fulfilment of my career goal,” ends Dr. John Cirillo.

# Republican Vilnius Psychiatric Hospital, Lithuania: State of the art rTMS is a way to help otherwise treatment-resistant patients

*Pharmacology is not always the best choice when it comes to treating severe depression. That is also the case at Republican Vilnius Psychiatric Hospital where the neurophysiology department headed by Dr. Kastytis Dapsys introduced rTMS treatment 7 years ago. Since then, 260 patients aged 18-78 years old have been treated for major depression.*

“The typical patient is a patient who has experienced recurrent depressive episodes with a resistance to pharmacology,” says Dr. Dapsys who first heard about rTMS during the 5th World Congress of Biological Psychiatry in Berlin in 2001 and since then got more interested in rTMS depression treatment from reading the scientific literature.

“I have always been fascinated by the possibility of using the latest state of the art non-invasive physiological treatment methods in the psychiatric field. The ability to help otherwise treatment-resistant patients to improve provides a satisfaction on not just the professional level, but also on the personal level,” says Dr. Dapsys.

## Searching for the best treatment

Being a leading psychiatric hospital in Lithuania, Republican Vilnius Psychiatric Hospital is always looking for ways to improve treatment methods and provide patients with the latest scientific developments. “That is why we invested in rTMS



*Psychiatrist Giedrius Gerulskis is both involved in rTMS depression treatment and rTMS research at Republican Vilnius Psychiatric Hospital where 260 patients have so far been treated for major depressive disorder.*

equipment in the first place and began to offer rTMS depression treatment. And that is why we are also researching various electrophysiological changes in EEG, induced by rTMS treatment, in the hope of finding possible therapeutic efficacy markers and contributing to the exploration of the rTMS mechanism in depression treatment,” Dr. Dapsys says. The results of the rTMS research, carried out with Dr. Vladas Valiulis and psychiatrist Giedrius Gerulskis, suggest an electrophysi-

times milder and without adverse cognitive side effects while providing a similar clinical outcome.

## Convincing study results

Judging from the results of a 2013-study conducted at the hospital, the decision to implement rTMS was the right one: around 80 percent of the patients showed a considerable improvement with a more than 50 per cent decrease in MADRS test scores. 25 percent achieved remission. These positive results have

***The ability to help otherwise treatment resistant patients to improve provides a satisfaction on not just the professional level, but also on the personal level.***

**Kastytis Dapsys**

ological profile similar to electroconvulsive therapy (ECT) yet several

led to satisfied patients who are not afraid to undergo rTMS depression treatment again if depressive episodes should reoccur.

## The MADRS test score

The Montgomery Asberg Depression Rating Scale (MADRS) is a diagnostic questionnaire which is used by psychiatrists to measure the severity of depressive episodes in patients with mood disorders. The scale was designed in 1979 by British and Swedish researchers as an adjunct to the Hamilton Rating Scale for Depression (HAMD).

The questionnaire includes questions on 10 symptoms: apparent sadness, reported sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic thoughts and suicidal thoughts. The overall score ranges from 0-60 as each item yields score of 0 to 6. A high MADRS score indicates a more severe depression.

“The majority of our patients are positive towards the treatment and remain positive throughout the treatment sessions,” says Dr. Dapsys and stresses that previous ineffective pharmacological treatment is continued at steady doses during the course of rTMS. This is done in order to eliminate a possible effect of drug withdrawal on physiological processes during rTMS treatment.

### TMS still not for everybody

At Republican Vilnius Psychiatric Hospital the treatment is only available for inpatients of the hospital.

“We only admit adult patients who are diagnosed with treatment resistant depression. Before we offer rTMS treatment, the patient is evaluated by a council of psychiatrists for the suitability of TMS treatment,” says Dr Dapsys and explains what it would take to make TMS depression treatment available for more patients: “In my mind, it would take a change of admission criteria to allow the treatment of adolescents just as TMS treatment coverage for outpatients should be made available in Lithuania. Being able to treat outpatients would open up possibilities to carry out maintenance therapy on patients with a tendency to relapse. That is presently not the case,” Dr. Dapsys ends.



### Republican Vilnius Psychiatric Hospital

The hospital is a specialized mental health care institution for delivering services for diagnostics and treatment of mental disorders. The hospital was the first psychiatric facility in Lithuania to offer transcranial magnetic stimulation. Recently the psychiatry department of Klaipėda Republican Hospital has also invested in rTMS equipment and has started treating patients. Chief of the neurophysiology department Dr. Kastytis Dapsys holds a Ph.D. degree in biophysics from Vilnius University.

 [More information at: www.rvpl.lt](http://www.rvpl.lt)

## Highly integrable TMS solutions

Meet our preferred partners

### Robotics

Robot-assisted TMS offered by **Axilum Robotics**.

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- Holding the TMS coil at a predefined target
- Controlled movement of the TMS coil along complex trajectories in the brain

### Neuronavigation

Navigated stimulation offered by **Localite TMS Navigator**

- Directly integratable with the MagPro stimulator
- Configurable to customer needs and wishes
- Plan stimulation areas and monitor and record the correct positioning of coil

### EEG

EEG Recordings offered by **Brain Products**.

- Support in the determination of cognitive processes
- A large range of amplifiers, electrodes and caps with custom or standard montages
- Various accessories

 [www.magventure.com](http://www.magventure.com)

## Events and product news

### Coil lifetime increased by 50%

The number of available pulses for MagVenture's liquid-cooled coils has now been raised by 50%. This means that one coil can now perform more than 2,250 depression sessions compared to 1,500 before, depending on stimulation intensity. This lowers the cost per treatment dramatically, which is excellent news for the many TMS clinics.

Changes in both production materials and production methods have led to these more robust coils and the benefits are now passed on to the market.



The Cool-B65 coil now has a 50% longer lifespan.

### Video about the MagVita TMS Therapy® system

It is easy to use, has low operating costs, provides high power stimulation, and is suitable for both small and large clinics. Get a quick overview of MagVenture's FDA cleared and CE approved TMS treatment system for Major Depressive Disorder: The MagVita TMS Therapy® system. Scan the code or go to YouTube: "MagVenture MagVita." Here you can also find a step-by-step guide which shows the whole MagVita TMS Therapy procedure.



Clinical TMS workshop in London: Chris Morden, co-owner of ECTRON Ltd., demonstrates MagVenture's TMS coil for depression treatment to some of the many workshop participants. The event was hosted by ECTRON, MagVenture's TMS distributor in the UK, and took place at the Royal College of Psychiatrists, June 8, 2016.

### Successful TMS workshop in London

"Excellent learning environment", "Good day. Helpful and productive", "Excellent combination of lectures, practical demonstrations and networking". Those were among the comments from participants at the June 8<sup>th</sup> Clinical TMS workshop at the Royal College of Psychiatrists (see photo above). The well-attended event, which was hosted by ECTRON, MagVenture's distributor in the UK, included a guest lecture by professor Alexander Sack from Maastricht University. He is also the organizer of the University's Clinical TMS Courses which have been offered since 2014.

"We are currently seeing a growing interest in rTMS here in the UK", says Alex Jones, director at ECTRON. In 2015, the National Institute for Health and Care Excellence (NICE) in the UK approved rTMS as an effective and safe method of treating depression for patients in the UK.

### Easy location of DLPFC – one size fits all

A TMS device is often used for multiple different research studies at the same time, each with different rules for targeting the DLPFC both left and right. MagVenture's new marking plate is adjustable and therefore accommodates these various rules.

The new marking plate may not only be used for studies involving both the right and the left side of the brain, it can also easily be adjusted for various location rules (from 5 to 7cm with 0.5 cm intervals). Customers using the TMS device for studies targeting both the right and left DLPFC or for differing target rules (such as 5 and 6.5 or cm) will therefore now only need one marking plate.



# About MagVenture

MagVenture is a medical device company, established in 2007, specializing in non-invasive magnetic stimulation systems for depression treatment as well as for clinical examination and research in the areas of neurophysiology, neurology, cognitive neuroscience, rehabilitation, and psychiatry.

From its headquarters in Denmark, MagVenture develops and markets advanced medical equipment based on the use of pulsating magnetic fields.

MagPro magnetic stimulators are sold on the world market through direct sales subsidiaries in Germany and the USA, and through a global network of distributors in Europe, Asia, Middle East, and the Americas.

## Regulations in the USA

In the USA federal law regulates the sale of Medical Devices through the US Food and Drug Administration (FDA). This is done to ensure safety and effectiveness. Devices which are permitted to be marketed for their intended use must either have a 510(k) or PMA clearance.

MagPro® stimulators R20, R30, R30 with MagOption, X100, and X100 with MagOption are all FDA 510(k) cleared (k160280, k061645, k091940 and k150641).

k150641: The intended use is treatment of Major Depressive Disorder in adult patients who have failed to re-

ceive satisfactory improvement from prior antidepressant medication in the current episode.

k160280, k061645, k091940: The intended use is for stimulation of peripheral nerves for diagnostic purposes.

The use of devices for other than their FDA cleared intended use is considered investigational. Such use is only permitted if the Investigational Device Exemption (IDE) guidelines have been followed. For full information on this procedure, please consult FDA's website ([www.fda.gov](http://www.fda.gov)).

All investigational devices must be labeled in accordance with the labeling provisions of the IDE regulation (§ 812.5) and must bear a label with this statement:

“CAUTION Investigational Device. Limited by Federal (or United States) law to investigational use.”

Please note that transcranial magnetic stimulation (TMS, rTMS) with MagPro stimulators is considered investigational in the USA (except the above cleared intended use).

For further information please contact MagVenture.

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