

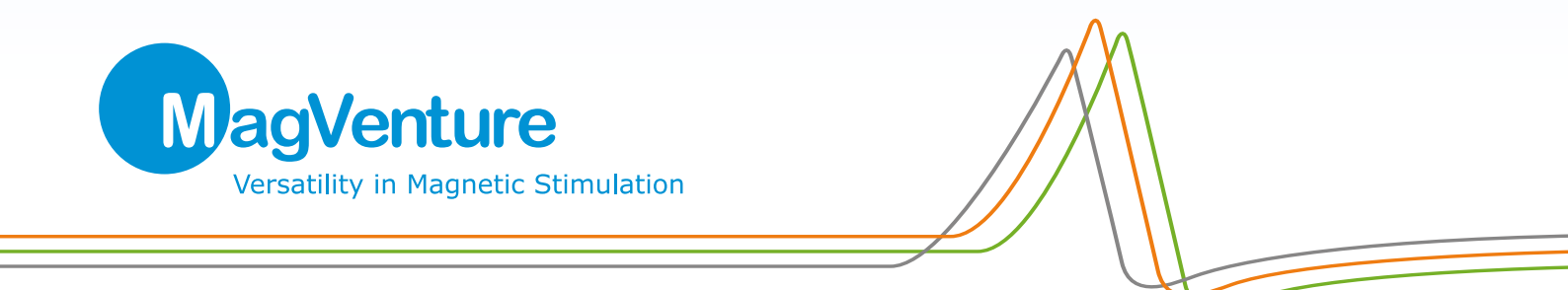
MagVenture *NEWS*

TMS of Knoxville, USA: TMS for the treatment of difficult depression has a very bright future

NIMHANS, India: One step closer to understanding schizophrenia

Skellefteå Hospital, Sweden: Swedish TMS pioneers experience a booming business

United Arab Emirates University:
10 questions for Professor Milos Ljubisavljevic,
College of Medicine and Health Sciences



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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.

Editor-in-Chief: Gunnar Hallsson.

Editor: Anne-Mette Damon.

Editorial Board: Lilja Astrup, Karina Haugaard Bech, Anne-Mette Damon, Jesper Groth, Sanne Jessen, Tomas Larsen, and Claus Mathiesen.

TMS of Knoxville, USA: TMS for the treatment of difficult depression has a very bright future

Since he first began to offer TMS in 2013, Dr. Lane Cook has helped a large number of patients beat their severe depression. By the time of their referral, they have already failed many antidepressants and/or psychotherapy. At the Knoxville-based clinic, however, the majority of these patients find new hope: 50% achieve full remission whereas 66-70% achieve response (at least a 50% reduction in depression rating scales).

“By the time our patients need TMS they are fairly discouraged and they meet us with a mixture of hopefulness and hopelessness,” says Dr. Cook. He gets half of his referrals from fellow local psychiatrists who have exhausted their medication and psychotherapy trials for treatment-resistant depressed patients.

The patients usually do not have any reservations about trying the treatment, except one big fear: that it won't work. An important part of the job for Dr. Cook and his staff is therefore to provide encouragement to the patients: “We tell them how easy the treatment is, that TMS will feel like a woodpecker on the head [from the tapping of the magnetic pulses on the head, ed.] but typically without any pain,” he says.

A 50% full remission and 66-70% response rate among these, until now, treatment-resistant severely depressed patients, would by many healthcare providers be seen as astounding results. To Dr. Cook, however, the numbers are not all that surprising, having been told “years ago” from a friend that her results with TMS were much better than what had previously been published. “The early studies of TMS were done in patients taken off antidepressants and the protocols were not fully maximized to their potential,” reports Dr. Cook.

Consumable costs top priority

Dr. Cook was among the first to offer MagVita TMS Therapy in the US shortly after it received FDA clearance in 2015. According to Dr. Cook, there are several issues to consider when choosing TMS equipment, with consumable costs ranking the top of his priority list. “High consumable costs are not cost-effective and in some states in the US, insurance reimbursement is actually less than the cost of consumables,” he explains. “We were paying as much to operate our first device to the manufacturer in one year as it cost to purchase the MagVita,” Dr. Cook explained. “In addition, the chair, the neck rest, and the cooled coil are

Dr. Cook's advice to healthcare providers who consider offering TMS in their clinical practice:

- Join the Clinical TMS Society (www.clinicaltmssociety.org)
- Establish your own peer/mentor network
- Consider consumable costs of treatment
- Make sure your TMS supplier provides technical support
- Make sure you have a good website
- Advertise locally
- Establish or join network of other TMS clinics in your area

And finally...

- Being well-known and respected helps.



Owner and Chief Medical Officer of TMS of Knoxville, Dr. Lane Cook (left), is here seen with TMS Coordinator Terry Chumley (right) who holds a B.A. in psychology and performs the daily TMS treatments at the clinic. In the treatment chair is Tessa Wilcox, TMS Technician and Research Associate at TMS of Knoxville.

Scan the code to see an interview with Dr. Lane Cook:



– Or find it on YouTube (search: “MagVenture”)



more comfortable, quieter and the experience for patients who have tried earlier TMS devices is much more acceptable.”

Easier to get reimbursement

Most insurance companies have specific criteria that the patient must meet before being eligible for TMS. Typically the patient must have failed 4 antidepressants with or without psychotherapy. However, problems of getting reimbursement from health insurance companies are now – more and more – a thing of the past, according to Dr. Cook, who finds it increasingly easy to obtain reimbursement, especially from companies he is already in network with. As far as the others, “you can always do single case agreements,” he says.

This change of tides among the insurance companies also makes it easier for the patients who no longer have to pay up front for the treatment. Most insurance companies require reasonable copay.

Spreading awareness of TMS

The advantage of having a TMS

practice as opposed to a typical psychiatric practice also pertains to the logistics: In a TMS practice, the psychiatrist only has to be present in the initial motor threshold or repeat MT, Dr. Cook explains. From there on, the technician/coordinator usually does the rest. His office manager handles the paper work, and has, for instance, solid expertise within insurance issues. This enables Dr. Cook to take time out of his busy work schedule to further spread awareness of TMS to help ensure that more people can get the help they need. It is, for instance, necessary that “more primary care physicians become aware of this excellent treatment resource,” he stresses.

Dr. Cook has given CME (Continuing Medical Education) talks on TMS, as well as several discussions for the public. He finds that both are good ways “to get the word out and help people grasp the concept of how this is different from psychotropic meds.”

Helpful peer and mentor network

Training as well as a peer and mentor network are also important

factors.

Dr. Lane Cook has participated in advanced TMS courses, something which is even a requirement by some insurance companies – and finds it extremely valuable to be able to get advice from renowned researchers at Duke or Harvard University. He completed advanced training at Medical University of South Carolina with Dr. Mark George who is widely considered as one of the founding fathers of TMS for depression. He enjoys being able to occasionally consult with Dr. George on TMS matters.

Hope for more indications

As for the future, Dr. Cook is confident that the future of TMS for the treatment of depression is “very bright” and furthermore hopes for an FDA clearance of Theta Burst TMS for rapid treatment of Major Depressive Disorder. Further down the line, Dr. Cook also hopes “that with research we can help more people, suffering for instance from Panic Disorder, Bipolar Depression, Generalized Anxiety Disorder, and PTSD.”

Dr. Lane M. Cook

Lane Cook, M.D., received his board-certification to practice psychiatry in 1981 and has been practicing in Knoxville, Tennessee, ever since. He is the owner as well as Chief Medical Officer of TMS of Knoxville, LCC. The clinic first began to offer TMS for the treatment of depression in 2013 and has since then treated more than 85 patients.

Lane Cook was appointed Assistant Professor of Psychiatry at both the Baylor College of Medicine as well as the University of Tennessee in 1981 and 1983, respectively.

Dr. Cook is a well-known clinician and a frequent lecturer around the Southeastern part of the US. He has given CME lectures as well as talks on TMS to the local National Association for Mental Illness and a mental health coalition group.



 **More information:** www.tmsofknoxville.com

NIMHANS, India: One step closer to understanding schizophrenia

At the National Institute of Mental Health and Neurosciences (NIMHANS) in Bangalore, India, Dr. Urvakhsh Mehta and his colleagues are using rTMS to modulate mirror neuron activity in schizophrenia and examine the association with social cognition performance.

“Schizophrenia has always been a difficult disorder to understand. While there is little doubt about its severely disabling nature, understanding its underlying brain dysfunction is something that has been extremely challenging,” says Dr. Urvakhsh Mehta of his fascination with schizophrenia. “As a clinician, schizophrenia gives me a good opportunity to combine my clinical knowledge and skills with advanced neuroscience investigations like TMS and MRI to further our understanding of this disabling disorder,” says Dr. Mehta who was first introduced to TMS in 2010 when he finished his residency in psychiatry and was looking out for cost-effective ways to study the human brain.

“My motivation for using TMS is how easy it is to manipulate brain activity in a non-invasive manner. This ability, when coupled with other investigational tools certainly yields unique information pertaining to brain functions. Also, there is not much ‘running cost’ of using TMS vis-à-vis many other investigations such as fMRI,” Urvakhsh Mehta explains.

My motivation for using TMS is how easy it is to manipulate brain activity in a non-invasive manner.

Urvakhsh Mehta

Social cognition is affected in schizophrenia patients

Dr. Mehta is currently pursuing leads he came across from his TMS study of assessing putative mirror neuron system activity in schizophrenia he did back in 2011. The study was funded by the Department of Biotechnology, Government of India

The mirror neuron system

The mirror neuron system was discovered in the early 1990s. Italian neurophysiologist Dr. Rizzolatti and his group found out that these dual-functioning neurons are active not only when we perform an action, but also when we observe someone perform the same action.

For instance, neurons in our premotor and inferior parietal cortices fire when we pick a pen and write a note. The same neurons also fire when we observe another individual perform the same task. These specialized nerve cells are called mirror neurons. This unique characteristic is thought to provide a neural template for understanding the intentions underlying actions and hence social cognition.

TMS when applied in single or paired pulses can be used to tap into the strength of this mirror neuron network. When applied repeatedly, it can be used to modulate (enhance or suppress) functions of this network.



involving 54 patients and 45 healthy volunteers. Single and paired pulse TMS were applied to record cortical reactivity during ‘static image’ and ‘action observation’ stimuli.

“We employed a combination of neuropsychological and TMS techniques and we were able to demonstrate that untreated schizophrenia patients had a reduced activity of the mirror neuron system and that the

gestures of the people that we interact with on a day-to-day basis – and for people suffering from schizophrenia, this is difficult,” Mehta explains.

Bipolar disorder research shows opposite findings

Although schizophrenia is an important area of research interest for Dr. Mehta, he has also conducted TMS research within other neuropsychiatric disorders. So far he has used single/paired pulse TMS and repetitive TMS as an investigational tool in patients with severe psychiatric disorders like schizophrenia and bipolar disorder.

“We studied the mirror neuron system activity in patients with manic bipolar disorder and found that they had an opposite finding when compared to schizophrenia. Their mirror neuron system activity was higher than observed in healthy volunteers. While this is an early (not replicated) finding, it has certainly given fodder for conceptualizing severe psychi-



TMS is becoming increasingly popular in India where both psychiatrists and neuroscientists are using it. Dr. Mehta has used the technology for 6 years.

There is not much 'running cost' of using TMS vis-à-vis many other investigations such as fMRI.

Urvakhsh Mehta

atric disorders as aberrations of the social brain”, says Dr. Mehta.

future, Dr. Mehta foresees that it may be possible to reach faster recovery for schizophrenia patients.

Schizophrenia gives me a good opportunity to combine my clinical knowledge and skills with advanced neuroscience investigations like TMS and MRI to further our understanding of this disabling disorder.

Urvakhsh Mehta

Faster recovery is possible
According to Dr. Mehta, rTMS has been used extensively in treating schizophrenia across the world. Persistent auditory hallucinations, negative symptoms and cognitive deficits are the three potential symptom targets of which the most studied is auditory hallucinations. In the

“The advent of patterned TMS techniques like Theta Burst stimulation has further kindled the imagination of clinicians in targeting faster recovery in a shorter period of time,” Dr. Mehta says.

The biggest achievement so far
When asked about his biggest

achievement within TMS so far, Dr. Mehta promptly replies: “Our successful use of TMS to explore the mirror neuron system and demonstration of its malleability using TMS.” As far as the future goes, Dr. Mehta still has research goals. “I would like to combine rTMS with other modalities like fMRI (functional magnetic resonance imaging), EEG (Electroencephalography) and fNIRS (functional near-infrared spectroscopy). I would also like to explore the physiological effects and the consistency of different patterned rTMS techniques in clinical populations with the aim to improve TMS stimulation parameters and better treatment outcomes,” Dr. Mehta says, stressing that he would also like to collaborate with engineers to be able to stimulate the brain even deeper without affecting intervening brain tissue.

Availability of rTMS
In India, an increasing number of psychiatrists and neuroscientists are using TMS for clinical and research applications. His team at NIMHANS in Bangalore is conducting workshops at other universities and clinicians and researchers are being

Continued on page 8 ▶▶



Skellefteå Hospital, Sweden: Swedish TMS pioneers experience a booming business

For 16 years, patients have been offered rTMS treatment for depression at Skellefteå Hospital in Sweden. That makes the hospital a first mover within TMS depression in the Nordic countries. Every day, 9-11 patients are treated by psychiatric nurse Christer Sundberg and his colleagues.

“I have treated at least 400 patients since I first joined the team at Skellefteå Hospital in 2007 and was introduced to TMS depression treatment. I found TMS interesting and innovative and became very fascinated by the treatment,” says Christer Sundberg who has since then treated adult patients of all ages with TMS.

“My patients have been between 18-90 years old and a large part benefit from the treatment. Some of them achieve remission and others get better with fewer depression symptoms,” he says and stresses that his main motivation for working with TMS is the chance to help otherwise treatment-resistant patients.

I am certain that even more people will be given a chance to get TMS treatment.

Christer Sundberg



Christer Sundberg (sitting in the TMS treatment chair), along with colleagues Barry Lundmark (left) and Göran Furberg (right) sees TMS as a great tool to help otherwise treatment-resistant patients out of a debilitating depression.

Cold to cool down coils

Having worked with rTMS depression treatment for 10 years, Christer Sundberg remembers how he used to go outside in the winter times to cool down the coils between treatments.

“That was the only way I could cool down the magnetic coil back then as the TMS equipment we had did not have a cooling system,” says Christer

Sundberg and emphasizes that it has been good for business to invest in a TMS system with active cooling.

“About a year ago, we invested in a MagVita TMS Therapy system with active cooling and that has made our business boom. Before we bought that system we were able to treat 5-6 patients per day, but with the active cooling system we are now able to



System with cooling of coils

The MagVita TMS Therapy system, MagVenture’s clinical platform for the treatment of depression, relies on an efficient liquid cooling system (see picture on left, red circle) to maintain the temperature of the coil.

This allows for a high patient throughput of 10 or more patients per day, as you do not have to wait for the coil to cool down between treatments.

I see great potential in the faster and more accelerated protocols which can bring down the time our patients have to spend in the hospital.

Christer Sundberg

help 9-11 patients every day. At the same time, we are constantly working on bringing down the waiting lists by thoroughly planning the day and looking at ways to optimize the treatment,” says Christer Sundberg who estimates that it is now possible to treat 70-100 patients every year.

Great potential in faster protocols

Currently the waiting time for TMS depression treatment at Skellefteå Hospital is up to 6 weeks for outpatients because patients admitted to the hospital are prioritized.

About a year ago, we invested in a MagVita TMS Therapy system with active cooling and that has made our business boom.

Christer Sundberg

“I see great potential in the faster and more accelerated protocols which can bring down the time our patients have to spend in the hospital,” says Christer Sundberg and adds that he also sees great possibilities for TMS in Sweden in the future. “I am certain that even more people will be given

TMS network

Christer Sundberg is part of a Swedish TMS network for both clinicians and researchers. The network was founded 2,5 years ago and gives the TMS clinicians from Skellefteå and Eksjö a chance to meet with researchers from the universities.



Skellefteå Hospital

Skellefteå Hospital is situated in the northern part of Sweden (red mark on map above). Each year, the Department of Psychiatry admits patients who are treated for depression, fatigue syndrome, and anxiety. The hospital has been administering TMS since year 2000. About 600 patients have received rTMS depression treatment since then.

“It is very fruitful for me to meet with them and hear their lectures. These great people give me an increased curiosity, energy and motivation to never give up hope that we can really beat depression with TMS,” ends Christer Sundberg.

► ► *Continued from page 6:*

NIMHANS, India....

trained in the application of TMS. That is great news, but also has its pitfalls, Dr. Mehta stresses.

“With increasing use, there comes a potential for misuse of TMS for commercial interests by using it indiscriminately without evidence. Stricter guidelines and monitoring of medical devices used for treatment purpose are the need of the hour along with the effort to make TMS available at lower price for its more widespread use in indications where there is evidence,” ends Dr. Mehta.

Dr. Urvakhsh Mehta

Dr. Urvakhsh's Mehta is Assistant Professor and Wellcome Trust / DBT India Alliance Early Career Fellow at the National Institute of Mental Health and Neuro Sciences in Bangalore, India.

From early on in his career, he wanted to work in a field that involves treatment and research of brain related disorders.

His main areas of research are social cognitive neuroscience with focus on mirror neuron dysfunction, phenomenology, neurobiology of schizophrenia and brain stimulation in psychiatry. He is the author of 31 articles.



United Arab Emirates University: 10 questions for Professor Milos Ljubisavljevic, College of Medicine and Health Sciences

Professor Milos Ljubisavljevic purchased his very first TMS device more than 20 years ago, while at the Clinical Neurophysiology Laboratory in Belgrade. Since then, he has worked intensively within many areas of TMS, ranging from movement disorders to animal models for the investigation of neuroplasticity within areas as diverse as stroke, obesity, and pain.

1) What initially made you interested in TMS?

I was attracted by the opportunity to influence ongoing brain activity painlessly. Before TMS I tried electrical brain stimulation. This is, however, unpleasant and painful, thus not widely applicable.

2) What is your main area of study?

I work in the broad field of use of non-invasive brain stimulation in the exploration of cortical plasticity and its applications in modulation or “tuning” of cortical plasticity in different neurological diseases.

As for obesity and craving, our recent study showed reduced craving in high-craving subjects one month after the last stimulation.

Milos Ljubisavljevic

3) What are your views on using TMS to explore the plasticity of the brain?

Simply put, plasticity relates to the brain’s potential to adapt to internal and external challenges.

TMS could not only temporarily aid but permanently improve this potential. This may hopefully include



With more than 25 years of experience, Professor Milos Ljubisavljevic is, in his own words, somewhat of a veteran within TMS, whose research covers a wide range of areas.

behavioral enhancements as well. What could be more exciting?!

4) What are you currently working on?

One line focuses on examining the mechanism of rTMS action in stroke and chronic pain, for which we use different animal models. Here we are interested in unraveling the molecular/cellular effects of rTMS. More specifically, we wish to examine how neurons versus glia cells respond to different rTMS protocols. Glia cells are supportive cells in the central nervous system, but unlike neurons, they do not conduct electrical impulses, thus they are differentially affected as compared to neurons.

Also, we believe that the stimulation may operate differently with regards to the physio-pathologic evolution of the disease i.e. it may exert different effects at different disease stages (acute vs chronic). If this hypothesis is true, different rTMS protocols/approaches may be required at different stages of the disease. We can call this the “rTMS sensitive time windows”. We wish to understand better which rTMS protocols should be “prescribed” depending on the disease stage to achieve the most optimal “tuning” of the brain.

The second line examines “signatures” of cortical plasticity in different neurological diseases like multiple sclerosis.

The main improvements and advancements in TMS applications will emerge from new devices that can offer multi-coil stimulation and variable magnetic pulse stimulation properties.

Milos Ljubisavljevic

And finally, we are interested in using the non-invasive brain stimulation to “tweak” the brain activity in conditions like obesity and craving, hoping to enhance/broaden the treatment.

5) Can you elaborate further on the role of glia cells within TMS research?

The last decades of research have made it clear that glia cells play an active role in neuronal signaling.

Furthermore, TMS has been shown to enhance neural stem production and to reduce apoptotic cell death [also known as programmed cell death] and inflammation after focal brain injury.

So, while we can assume that glia cells do play a role in TMS, we do not know yet exactly how TMS influences them. Therefore, we cannot reliably predict the role of TMS when it comes to different diseases.

Stroke and pain are relevant in a sense that animal models are reasonably well developed. They entail different physio-pathological processes which provide the opportunity to examine the effects of rTMS at sub/cellular level.

rTMS seems to affect/ enhance “beneficial” pathways of cellular repair in certain types of stroke. This is advantageous in the sense that the primary activity of these pathways promote recovery.

Milos Ljubisavljevic

6) What diseases does your research currently focus on?

The neuroplasticity laboratory is presently exploring TMS-induced biomarkers of normal and abnormal plasticity in multiple sclerosis patients as well as overweight/ obese subjects with high craving.

As for obesity and craving, our recent study showed reduced craving in high-craving subjects one month after the last stimulation. These find-

Plasticity relates to the brain’s potential to adapt to internal and external challenges. TMS could not only temporarily aid but permanently improve this potential. This may hopefully include behavioral enhancements as well.

Milos Ljubisavljevic

ings further underline the potential of noninvasive brain stimulation for the treatment of obesity.

7) Where do you see the most potential in the future?

Theta Burst stimulation is, without a doubt, by far the most effective rTMS protocol known today. While new protocols and stimulation patterns may also prove equally effective, I believe that the main improvements and advancements in TMS applications will emerge from new devices that can offer multi-coil stimulation and variable magnetic pulse stimulation properties, primarily the possibility to adjust the duration.

Development of such stimulators could significantly broaden the areas as well as indications of TMS application.

9) What, in your experience, is the biggest challenge when working with TMS?

With more than 25 years of experience already, I am somewhat a “veteran” within TMS and am therefore quite familiar with most challenges related to TMS use. One of the frustrating points is still the application of appropriate sham stimulation.

10) In your previous research within stroke rehabilitation, you explain how rTMS can enhance the brain’s potential to cope with the sustained injury and rewire itself. Can you elaborate on this?

Simply put, rTMS seems to affect/ enhance “beneficial” pathways of cellular repair in certain types of stroke. This is advantageous in the sense that the primary activity of these pathways promote recovery.

Nevertheless, we cannot assume that rTMS alone would be sufficient irrespective of the duration of its application and the duration of the effects. Rather, we believe that TMS needs to be coupled with other “plasticity” promoting interventions such as rehabilitation, behavioral therapy, etc.

Again, we would like to be able to provide better advice, based on future experiments, on what may be the optimal time window as well as the mode of application.

8) Which indications do you think would especially benefit from different TMS pulse durations and coil shapes?

If I knew the answer to this question, I would probably start my own company! The key, in my opinion, is to improve the focality, efficiency, and to enable the stimulation of deep i.e. subcortical brain structures by rTMS.

Events and product news



World-premiere: New high-performance MagPro stimulator

Theta Burst in combination with fMRI, advanced burst sequencing, and a 6 channel EEG/EMG may sound like a foreign language to some, but for researchers seeking to stretch the boundaries of TMS, these are highly desirable features. The 6th International Conference on Transcranial Brain Stimulation which took place in Göttingen, Germany, in September 2016, gathered some of the most prominent TMS researchers from around the world. They were offered a sneak preview of MagVenture's brand new high-performance TMS research device, the MagPro XP, which offers the aforementioned features and several others. The XP is an all-in-one rTMS device and will be MagVenture's latest edition to the growing family of MagPro stimulators.

The MagPro XP was furthermore on display at the International Brain Stimulation Conference in Barcelona, Spain, March 5-8, 2017, which MagVenture co-sponsored.

+ **More information:**
www.magventure.com

New MagVita TMS Therapy website

www.magvitatms.com is a website aimed at the US clinical market, offering both healthcare professionals as well as patients a chance to learn more about MagVenture's FDA

cleared treatment system for depression, the MagVita TMS Therapy. The website includes a map of MagVita TMS treatment providers across the US, as well as an extensive FAQ for healthcare professionals, and several videos and articles about rTMS from the clinical field.



+ **More information:**
www.magvitatms.com

Popular TMS course at Maastricht and Amsterdam

The increasingly popular Clinical TMS Certification Course at Maastricht University in the Netherlands, now in its third year of running, is now open for registration for the spring course taking place on April 20-21, 2017. The course is taught in English and combines academic lectures with intensive hands-on sessions in small groups – with a focus on the clinical application of TMS.

A course will furthermore be held in Amsterdam, 26-27 October 2017.

The number of seats is limited, and the University therefore recommends an early registration for the courses.

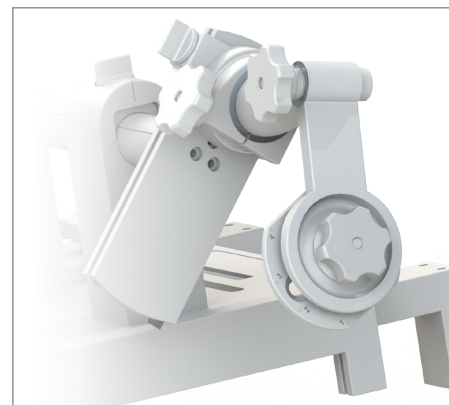
+ **More information and sign-up:** www.tmscourse.eu

TMS training in Pakistan

The Nari Clinic in Lahore, Pakistan recently invested in a MagPro X100 TMS system. Nine staff members at the hospital, which is owned and run by Meditech, received onsite



training by MagVenture's Application Expert Claus Mathiesen (also seen at the picture in the top left corner on this page) and are now certified TMS practitioners. Claus Mathiesen furthermore gave a well-attended lecture and Q&A session at the King Edvard Hospital psychiatric ward.



Quicker positioning of MRI coils inside the scanner

The holder for the MRi-B91 Butterfly Coil has been optimized with a ball joint in the front-end, ensuring easy and quick fine adjustment of the coil placement. This new front-end for the MRi coil holder has cut down the preparation and positioning time by up to 50%.

The new front-end is standard on all new MRI Coil Holders but can also be purchased to retrofit older version of the coil holder.

As there are more and more customers with other scanners than the Siemens Magnetom Trio scanner, MagVenture now also offers an MRI coil holder for Siemens Magnetom Prisma and Skyra scanners.

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

receive 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).

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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MagVenture A/S
Lucernemarken 15
3520 Farum
Denmark
Phone: +45 4499 8444
info@magventure.com

MagVenture, Inc
2300 Lakeview Parkway, Suite 700
Alpharetta, GA 30009
USA
Phone: +1 888-624-7764
infousa@magventure.com

MagVenture GmbH
Schmelzerstraße 25
47877 Willich
Germany
Phone: +49 (0) 2154 814 56 50
infodeutschland@magventure.com

 www.magventure.com