

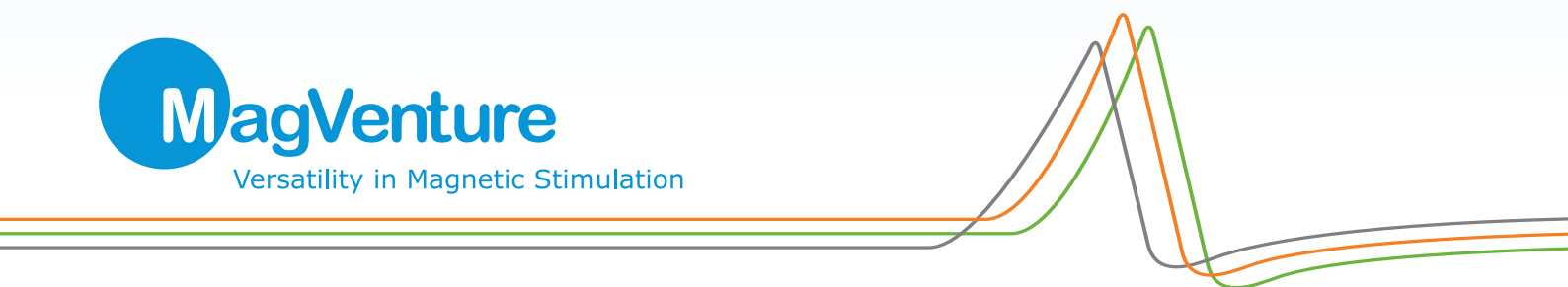
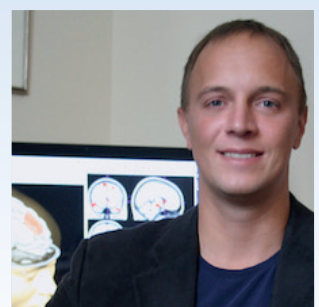
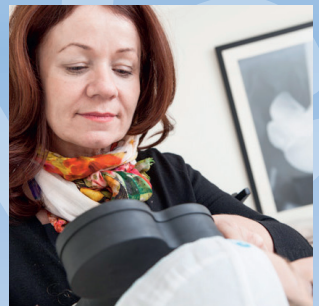
# MagVenture *NEWS*

*London Psychiatry Centre:*  
rTMS treatment for depression has exceeded our expectations

*University of Antwerp:*  
MagVenture and University of Antwerp develop world's first rTMS coil for rodents.

*The French Institute of Health and Medical Research:*  
New rTMS rat coil allows a translational approach towards treating Post Traumatic Stress Disorder

*University of Toronto:*  
10 quick questions for Jonathan Downar at the Department of Psychiatry



# Taking the “bench to bedside” approach – from basic science to practical application

In recent years there has been quite a drastic development within the field of Transcranial Magnetic Stimulation. This is not only with regards to the technology itself; there also seems to be a rapidly growing interest among researchers, healthcare practitioners, and the general public. In that respect, it seems only natural that we must now take a step backward in order to move forward!

Before we can optimize current treatment methods or find new ones, supported by the results from clinical trials, we need to fully understand the basics by undertaking a translational approach.

With MagVenture's recent development of the world's first coil specifically designed for performing rTMS on rodents, we hope we have made a small contribution towards this particular research approach.

In this issue of MagVenture News you can read about what sort of possibili-

ties this new coil will provide, according to leading researchers within the field who have already adopted this concept.

Professor Wissam El-Hage from The French Institute of Health and Medical Research is one of many researchers who have chosen a translational approach. He is also among the first to order the new rat coil and his reason for doing so is clearly defined: “We hope and believe that the results will lay the grounds for new and refined TMS therapies within the spectra of affective disorders, as we might be able to understand the mechanisms of TMS better and actually find strong pre-clinical evidence for them.”

Or, as Professor Steven Staelens from the University of Antwerp puts it: “In spite of the positive results in patients we still lack a basic understanding of the molecular mechanisms underlying the therapeutic effects of TMS.” The researchers at



the University's Molecular Imaging Center took the consequence of this realization and contacted MagVenture to ask us to help develop a coil for the stimulation of rat brains. Read much more about this unique and fruitful collaboration on page 8-10.

We eagerly anticipate the results from the translational research which can hopefully unravel more of the mechanisms of action of TMS. This will also help us in providing our customers with even better and more optimized solutions in both the research and clinical field.

**Stig Wanding Andersen**  
CEO, MagVenture

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*The views and opinions expressed in MagVenture News do not necessarily reflect the official policy or position of MagVenture or any of its affiliates.*

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# First mover London Psychiatry Centre: rTMS treatment for depression has exceeded our expectations

*The London Psychiatry Centre has offered rTMS treatment for depression to its patients since 2012. It is so far the only clinic in the UK to offer this alternative to antidepressants. In spite of the challenges of being a “first mover” and creating public awareness, the clinic is fully booked almost every day and its popularity does not seem to be slowing down. On the contrary.*

– We assess treatment-resistant patients who in many cases have struggled with their depression for years, explains Dr Rafael Euba, Consultant Psychiatrist at the London Psychiatry Centre.

– So our patients are delighted to hear that there is an effective treatment which could improve their symptoms. We have had several patients who were suffering enormously with a depressive illness. They had not responded to any treatments and it is very satisfying to see them get better.

## Improvement after 3-4 weeks

When asked how long it takes before patients typically begin to feel a change, Dr Euba explains that it



*Dr Rafael Euba and the rest of the staff from the London Psychiatry Centre have, since the beginning in 2012, treated more than 50 patients suffering from depression.*

varies enormously. Some will start to feel better almost immediately, whereas others will need several weeks of treatment before they start improving. Most, however, feel the benefits of the treatment after three or four weeks.

So far, more than 50 patients have already been treated by the London Psychiatry Centre's specially trained rTMS nurses and psychiatrists. Some of the patients have insurance cover,

but most do not. They are, however, willing to pay for the treatment themselves.

## Convincing results dispelled initial skepticism

Dr Rafael Euba himself first heard of Transcranial Magnetic Stimulation years ago and was particularly interested in techniques for the treatment of depression. At the time the evidence base for its efficacy was not as strong as it is today. – Ini

## The London Psychiatry Centre

The Centre was founded in 2011 and is a private psychiatric care clinic that provides innovative cutting-edge treatments for various mental health problems like depression, bipolar disorder, ADHD and trauma.

The Centre is also the first and only practice in the UK that is able to offer patients repetitive Transcranial Magnetic Stimulation (rTMS).



See London Psychiatry Centre's short film about TMS.



More information at [www.psychiatrycentre.co.uk/](http://www.psychiatrycentre.co.uk/)



The Centre is located on  
72 Harley Street, London W1G 7HG  
Telephone: 020 7580 4224  
E-mail: [Info@PsychiatryCentre.co.uk](mailto:Info@PsychiatryCentre.co.uk)

*– Initially it was a little difficult to accept that a non-invasive procedure with such a benign safety and side-effect profile should be so effective in treatment-resistant depression. Seeing the positive results however is the best way to dispel the doubts.*

Dr Rafael Euba

tially it was a little difficult to accept that a non-invasive procedure with such a benign safety and side-effect profile should be so effective in treatment-resistant depression. Seeing the positive results however is the best way to dispel the doubts, he explains.

#### **Challenging and rewarding to be a first mover**

– We are proud to be the first clinic in the UK to offer this treatment. It has of course been a challenge to develop the Clinic, says Dr. Euba.

He further explains that being the first and only agency to offer this treatment to the public has also presented the clinic with some difficulties in terms of managing and confronting the skepticism of others.

#### **Public healthcare reimbursement: yes please**

A public healthcare reimbursement for TMS, which for instance is today offered in Canada and is also accepted by an increasing number of German insurance companies, would certainly be welcomed by the

London Psychiatry Centre. The fact that there is currently no public reimbursement does not, however, seem to deter patients from knocking on the door at Harley Street.

#### **Promising future for TMS**

If one asks Dr Euba, the future of TMS in the field of psychiatry is looking bright:

– I suspect that in 10 years from now, we will have developed TMS protocols that can deliver higher amounts of energy. We will also be able to choose between stimulating large portions of the brain and more finely focused, or perhaps deeper, points in its geography. I also think the treatment will gradually become more time-efficient. Hopefully our TMS practice will also be much bigger, says Dr. Euba with a smile.

## **MagVita TMS Therapy™ – Depression treatment without medication**

MagVenture's depression treatment MagVita TMS Therapy™ based on rTMS (repetitive transcranial magnetic stimulation) allows psychiatrists to treat the large number of patients not responding to medications or who cannot tolerate side effects such as weight gain and sleep disorder.

A full depression treatment for patients who have been properly diagnosed by a psychiatrist and found suitable for rTMS depression treatment includes 5 treatment sessions per week during a period of normally 3-6 weeks.

The treatment has been CE approved for "Treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from two prior antidepressant medications, at or above the minimal effective dose and duration in the current episode".

## **Want to run tougher and longer protocols? With the new cooling solution from MagVenture you can!**

With the new **high-performance cooling system** from MagVenture, your number of available stimuli will be increased so that you can perform tougher, longer, and more continuous protocols.

The system **revolutionizes the cooling solutions** for TMS coils available on the market.

The MagVenture High-Performance Cooling system can be **integrated** in any existing MagVenture cooling system for Cool coils.



**+** More information at  
[www.magventure.com](http://www.magventure.com)

# University of Toronto:

## 10 questions for Jonathan Downar at the Department of Psychiatry

*Dr. Jonathan Downar from the University of Toronto and Co-Director of the United Health Network MRI-Guided rTMS Clinic is working to increase the efficacy of rTMS in treating depression, drawing on recent advances in functional neuroimaging.*

### 1) What is your main area of interest?

— At the moment our main focus is to develop techniques for predicting rTMS treatment outcome and optimal treatment parameters in individual subjects by using pre-treatment functional neuroimaging.

### 2) What is your main motivation for working with rTMS?

— Although medications and therapy are helpful for many people, a large percentage of patients with major depression, PTSD, OCD, and eating

**— Since there are few other effective treatments for refractory PTSD, we believe that rTMS could find a special niche in the treatment of PTSD in many patients.**

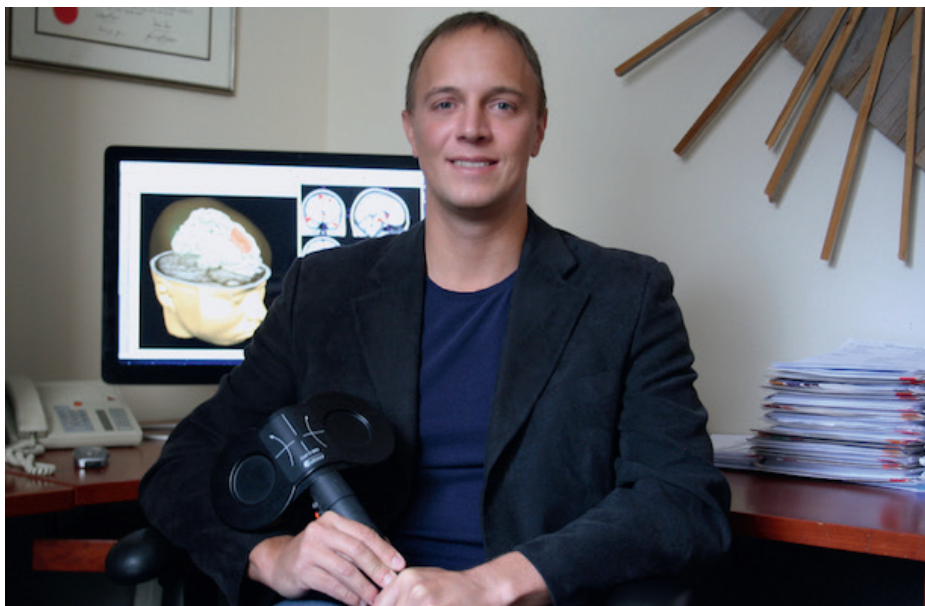
**Dr Jonathan Downar**

disorders do not respond to conventional treatment.

Over the last 20 years, there have been tremendous advances in our understanding of the neuroanatomy of these psychiatric disorders. However, this knowledge is most useful in guiding therapies that are anatomically specific in their effects.

As a neuroimaging scientist by my original pre-medical training, I tend to think of psychiatric disorders in terms of the underlying neural circuitry. rTMS is a natural fit to this kind of approach, because it can be used to precisely target specific regions and circuits within the brain. The hope is that, by judicious choice of stimulation targets and stimulation parameters, we can address the underlying pathology of these psychiatric disorders directly using rTMS.

### 3) What is the #1 challenge you are currently facing with rTMS?



*Dr Jonathan Downar with a Cool D-B80 Butterfly Coil, one of the coils used for treating patients at the UHN MRI-Guided rTMS Clinic in Toronto.*

— At the moment, our major challenge lies in identifying the best candidates for treatment.

We have found that the response to rTMS is sharply bimodal, with individual patients showing either marked or minimal response to treatment. If we can learn how to identify the responders ahead of time, perhaps via pre-treatment neuroimaging, we should be able to spare the majority of patients from futile treatment and boost the effective remission rates two-fold.

## The University Health Network rTMS Clinic at Toronto Western Hospital

The clinic was founded in 2011 and is affiliated with the Faculty of Medicine at the University of Toronto. It explores three different ways of using neuroimaging to improve rTMS efficacy:

- 1) Use MRI-guided frameless stereotaxic methods to ensure accurate placement of the rTMS coil over the target brain region.
- 2) Draw on the wealth of recent neuroimaging studies of emotion regulation to identify new and more effective targets for rTMS.
- 3) Develop fMRI biomarkers that can predict the optimal stimulation target and the optimal stimulation frequency in each individual patient presenting for treatment.

The ultimate goal of the Clinic is to achieve an rTMS efficacy that is comparable to that of more invasive neurostimulation techniques, such as electroconvulsive therapy (ECT) or deep brain stimulation (DBS).



More information at [www.rtmsclinic.ca](http://www.rtmsclinic.ca)

#### 4) Which possibilities do you see in using rTMS for the treatment of eating disorders?

– Binge eating and purging seem to show the most improvement with our current rTMS techniques, which target the dorsomedial prefrontal cortex.

Patients with binge eating disorder and bulimia nervosa have seen the most benefit. So far, we've had much less success with the restricting symptoms of anorexia nervosa. There are some interesting potential targets for anorexia that are emerging from the recent studies of deep brain stimulation (DBS) for this condition. Some of the potential targets are superficial enough to be reached with current rTMS coils. We hope to explore these targets in the near future.

#### 5) ...and for Post Traumatic Stress Disorder (PTSD)?

– A significant fraction of patients with PTSD show very little response to medications or therapy, and remain severely ill and disabled decades after the initial trauma.

For example, we have treated veterans of the early 1990s war in Bosnia, who still have severe and disabling symptoms more than 20 years later. We have seen some of these patients show dramatic improvement with rTMS of medial prefrontal cortex, and other research groups are seeing the same effect. The improvement is actually greater and longer-lasting than what we see for depression.

Since there are few other effective treatments for refractory PTSD, we believe that rTMS could find a special niche in the treatment of PTSD in many patients. With the large numbers of veterans and refugees now emerging from conflicts in Afghanistan, Iraq, and Syria, new treatments are certainly going to be needed.

#### 6) What has been the biggest eye-opener in connection with rTMS?

– I would say that the dramatic improvements in certain patients with severe PTSD and severe eating disorders are the most compelling cases we've seen so far. These patients have already maximized all existing therapies, so the fact that they are

achieving major improvement and even remission with rTMS implies that we may have a genuinely new treatment option available – something that comes along in medicine very rarely!

#### 7) What has been your biggest achievement so far?

– Most of our best outcomes have been serendipitous. When we started delivering dorsomedial prefrontal rTMS, we had hopes that it would prove to be markedly more powerful than the conventional dorsolateral target in treating depression. In reality, the biggest advantages of this approach now seem to be in treating eating disorders and PTSD – discoveries we were only able to make by offering treatment to a variety of

**– These patients have already maximized all existing therapies, so the fact that they are achieving major improvement and even remission with rTMS implies that we may have a genuinely new treatment option available – something that comes along in medicine very rarely!**

**Dr Jonathan Downar**

patients and taking careful observations of the outcomes. Although hypothesis-driven research is certainly crucial for advancing medical knowledge, we sometimes underestimate the equally important role of careful observation and exploration of hypothesis-generating, serendipitous outcomes.

#### 8) What are your thoughts on government funded rTMS for patients?

– Certain provinces in Canada are now funding rTMS, which is a great step forward.

There is no question that this treatment helps patients to overcome a disabling and debilitating illness. From a health systems perspective, though, we need to make sure that this treatment is as cost-effective as possible.

Public health-care systems around the world are encountering a crisis of funding, brought on in part by treatment costs that are inflating faster than our economies can grow. We can help to address this by

devising more cost-effective rTMS techniques: treatments that require shorter sessions, thus allowing more patients per day to be treated in each clinic, at a lower cost per patient.

As the costs come down, the economic argument for adding rTMS to our formularies will become stronger and stronger.

#### 9) Could you give an example of a person who received rTMS treatment and whose condition subsequently was improved due to this treatment?

– One of our published case reports concerns a 42 year old woman, trained as a pharmacist, with a 20 year history of completely treatment-refractory bulimia nervosa. Her

symptoms were severe enough to occupy up to 10 hours per day, and led to the loss of her job and her marriage. We treated her for depression, not expecting any improvement in eating symptoms.

The surprising outcome was that her binge and purge behaviors completely remitted early in treatment, and remained in remission for months after the end of treatment. This outcome led to our subsequent successful case series on the use of rTMS for binge and purge behaviors – an application we had not previously considered.

#### 10) If you were free to choose it, what headline should we read about you in 5 years from now?

– I'd rather not be in the headline at all! The focus should be on the discoveries, not the discoverers.

The headline I would like to see is "Prevalence of depression drops 50% in last decade – new treatments credited with the improvement." I think it's going to be a bit longer than 5 years before we get there, though.



# MagVenture and University of Antwerp develop world's first rTMS coil for rodents

*Applying rTMS on rats is not a new concept. In fact, experiments have been conducted since the early 90's. However, performance has until now been somewhat challenged by the lack of a coil which has been tailor made for the purpose of performing rTMS on small rodents.*

*A fruitful cooperation between MagVenture and the University of Antwerp has now led to the development of such a coil and the first test results look very promising. MagVenture News has interviewed Professor Steven Staelens (MICA) and biologist Joke Parthoens of the Molecular Imaging Center at the University of Antwerp, Belgium, about this venture.*

tions) where promising results have been achieved.

In spite of these positive results in patients we still lack a basic understanding of the molecular mechanisms underlying the therapeutic effects of TMS. This means that setting up TMS protocols in patients will still often involve a trial-and-error approach.

We are a molecular imaging laboratory and in vivo molecular imaging is a highly sensitive tool to study in vivo neuroreceptor kinetics and to visualize entire brain network dynamics in human patients as well as in small laboratory animals. We wanted to exploit molecular imaging to unravel

populations and has less human ethical boundary conditions to test new paradigms.

**What is your previous experience on working with rTMS on rats? How does this coil compare to previous?**

– The small dimensions of the rat brain compared to the human brain makes it very challenging to provide efficient TMS stimulation using human coils, as they largely out-limit the dimensions of the rat's head and hence typically lack focus of the magnetic fields, says neurobiologist Joke Parthoens.

Also, the smaller coils that are currently available do not induce electrical fields in the brain that are comparable to the electrical fields elicited with human coils in the patient's brain.

This is because the windings of a smaller coil will more easily heat up during stimulation. These features have made it almost impossible to translate the clinical findings back into preclinical laboratory practice.

– The Cool-40 Rat Coil, however, is smaller than most available coils and it allows currents up to 6.600A with a time derivative reaching 190 A/μs and a peak magnetic field of 5.6 Tesla near the surface of the coil. Even 5 mm below the surface, the intensity reaches 3.2 Tesla with a field gradient of 80kT/s. Moreover, its shape is also specifically designed so that it bends around the rat's head, explains Joke Parthoens.

– Thanks to the circulating flow of compressor cooled liquid in the casing surrounding the windings, a



*Professor Steven Staelens from the the Molecular Imaging Center Antwerp has for several years wanted to investigate the action mechanisms of rTMS as he is seeking to optimize this non-invasive alternative treatment for Obsessive Compulsive Disorder (OCD). With the new Cool-40 Rat Coil, the possibilities for doing just that are much better, he says.*

**What is your main motivation for wanting to work with rTMS on rats?**

– rTMS has been successfully applied in clinics to treat therapy-resistant forms of depression, says Professor Steven Staelens. – This is also the case in other areas such as addiction, anxiety, OCD, pain, schizophrenia (auditory hallucina-

the mechanism of action of rTMS. Using small animals offers the opportunity of large uniform drug naive

***The Cool-40 Rat coil is smaller than most available coils [...] Moreover, its shape is also specifically designed so that it bends around the rat's head.***

**Neurobiologist Joke Parthoens**



very large number of pulses can be administered at high intensities (e.g. 1 Hz, 70% mean output, continuously) and at high frequency bursts, up to 100 Hz!

#### **How did the cooperation with MagVenture come about?**

– Three and a half years ago we decided to set up small animal rTMS combined with molecular imaging to unravel the mechanism of action for rTMS, says Steven Staelens.

– First, we tried using human coils but quickly learned that these dimensions would never be suited for focal stimulation in rodents.

Further, we attempted to use the smallest available TMS peripheral nerve coils to use for stimulation of the rat's brain. Here we found out that the intensities were too low as we each time evaluated our experimental set up using in vivo molecular neuroimaging in rats.

***Within a month [...] MagVenture had already built a first prototype which fully met the initial specifications requested by MICA. The coil could elicit finger twitching upon providing a TMS stimulus when positioned on the forearm.***

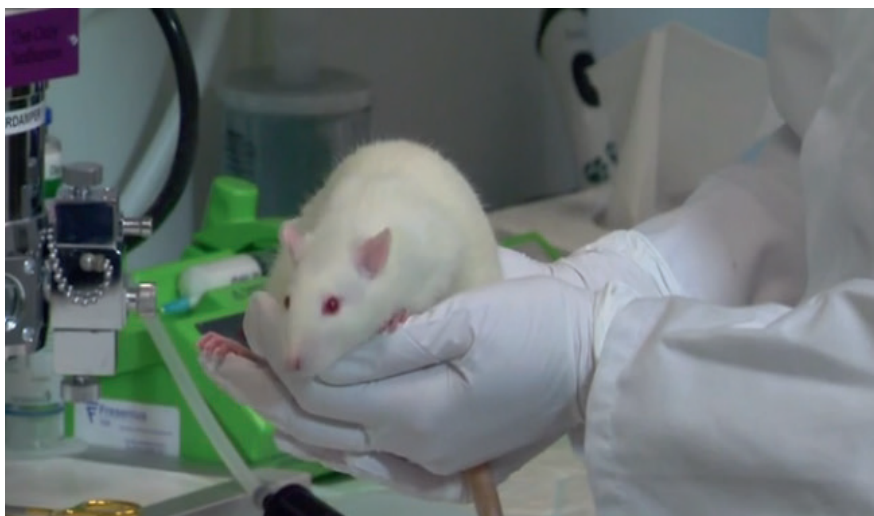
**Professor Steven Staelens**

Next, we decided to develop and build our own small coil in-house. Although promising at first, we encountered a major heating problem of our prototype upon repeated stimulation and one of our prototype coils literally exploded in the laboratory. At that point, we contacted a local engineering company to profession-

ally design a pre-clinical TMS coil according to our specifications. After an initial study with simulations the company delivered an expensive report stating that building a TMS coil with our specifications was technically not feasible.

Frustrated by this news, Professor Steven Staelens contacted Harm-Jan Wieringa from the local distributor MedCat, who he knew from ballistocardiographic EEG-fMRI experiments in his previous lab back in 2008. HJ Wieringa advised Professor Staelens to contact MagVenture because of their strong reputation on TMS-coil engineering combined with the flex-

**Click on image to see video about the rat coil**



ibility of their medium sized company to cooperate with scientists.

– Within a month after the first contact, MagVenture had already built a first prototype which fully met the initial specifications requested by MICA. The coil could elicit finger twitching upon providing a TMS stimulus when positioned on the forearm, says Professor Steven Staelens.

– Based on this proof-of-feasibility, MICA and MagVenture started a collaboration to develop an optimized coil for pre-clinical research based on a 'no cure no pay' principle. This cooperation turned out to be a boost for research.

Multiple iterations which involved a re-engineering of the coil based on biological test results were performed and within a period of 6 months, a final product which fulfilled all our user requirements was delivered.

## **Molecular Imaging Center Antwerp (MICA) – University of Antwerp**

MICA was founded in 2010 as a joint effort by the University of Antwerp and the University Hospital Antwerp. The research group consists of a molecular probe development team as well a preclinical imaging laboratory and a clinical department.

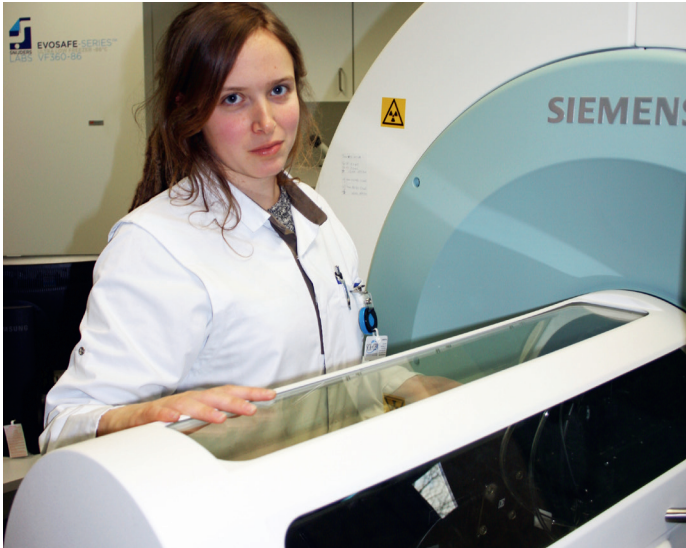
MICA is led by Professor S. Stroobants and has a team of internationally recruited imaging experts and a state-of-the-art infrastructure. Over the past 3 years, MICA realized a turnover of up to 10 million euro research grants.

One of MICA's research missions is to increase the basic understanding of the mechanism of action of TMS. Via pre-clinical TMS-neuro-imaging research MICA hopes to unravel the molecular mechanisms involved in TMS therapy in order to eventually optimize clinical TMS protocols.

The Cool-40 Rat Coil from MagVenture has been developed in close collaboration with the research group Molecular Imaging Center Antwerp (MICA) of the University of Antwerp.

 **More information at**  
[www.uantwerp.be/en/rg/mica/](http://www.uantwerp.be/en/rg/mica/)

 **Universiteit Antwerpen**



Neurobiologist Joke Parthoens, PhD student at the Molecular Imaging Center Antwerp, in front of the pre-clinical PET-CT scanner of Siemens which she uses to study the mechanism of action of rTMS in rats.

### Can you perhaps reveal some of your key findings so far? What has surprised you the most?

What surprised us the most was the focality of the stimulation: as we were searching for the optimal position on the rat's head to stimulate the right motor cortex while measuring Motor Evoked Potentials – MEPs – in the left hind limb, we noticed that even the slightest deviation from the optimal position to measure the highest MEPs already had an enormous impact on the size of the MEPs.

Since then, we have used the coil intensively in our research.

Furthermore, the reproducibility of the rat TMS coil in eliciting activation of the motor cortex has been fully documented.

### Can you describe some of the tests/protocols you have conducted with the rat coil?

– First we have optimized and validated the experimental procedures, explains Joke Parthoens.

– The electromyography (EMG) recordings from the hind limb upon stimulation of the motor cortex have shown to be remarkably stable. Motor threshold determinations were consistently produced at a threshold of around 25-30% of total machine output. This is ideal for our next experiments as it allows for a large dynamic range.

We have now built an entire administration suite so that animals can be stimulated awake and can also be injected with a radiotracer without the need for anesthesia. This way we get an entire image of the brain network dynamics during stimulation. We are also setting up animal models in addiction and in OCD.

### Which perspectives do you see in this field of research? How can the Cool-40 Rat coil in your opinion make the most valuable contribution to society?

– We strongly believe that unraveling the method of action of rTMS could assist in designing and selecting the appropriate treatments for

**Now that we finally have access to a pre-clinical TMS device, we have the ambition to combine it with in vivo molecular imaging to help unravel the molecular mechanisms underlying rTMS.**

Neurobiologist Joke Parthoens

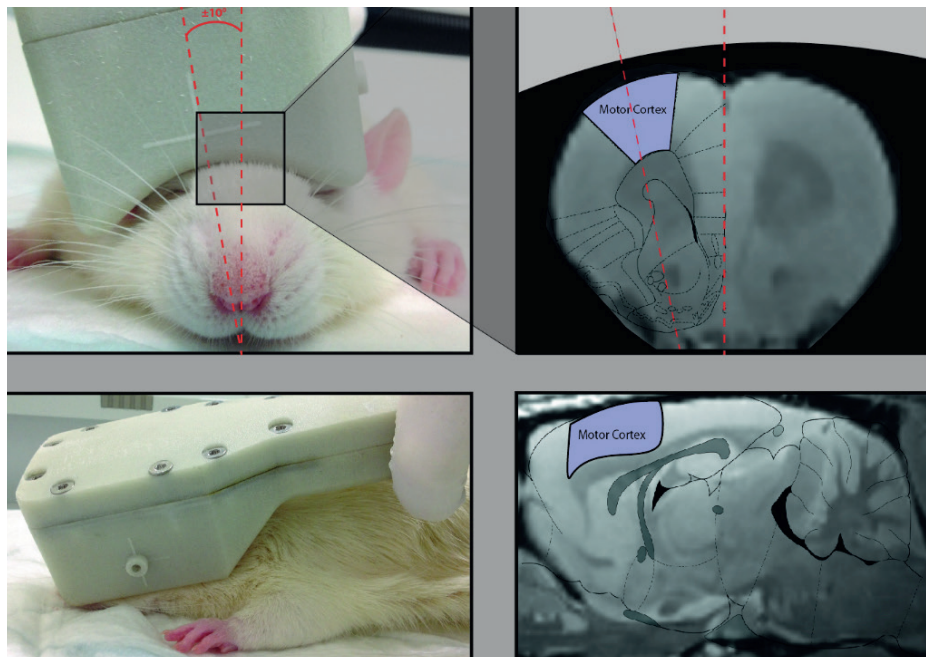
human patients, says Joke Parthoens.

With the Rat Coil, neurologists, psychiatrists and experimental psychologists will now have a basic scientific tool in their hands which will allow them to explore treatment solutions faster, more robust and with less human ethical boundary conditions.

Molecular imaging can bridge the gap between the neurobiological effect of rTMS and the neuropathophysiology of a CNS disease.

### Have you noticed any behavioral changes in the rats due to the magnetic stimulation performed?

In all our experiments with the Cool-40 rat coil until today not a single abnormal behavior was noticed during or following application of rTMS or sham stimulation. At this moment we are setting up our animal models for the first CNS pathologies and we are building a dedicated behavioral assessment arena to correlate our neuro-imaging results with specific behavioral readouts.



The Cool-40 Rat Coil prototype applied to a rat to determine the motor threshold in the rat hind limb upon stimulation of the left motor cortex.

Right: MRI template of the rat brain with atlas overlay. The motor cortex is delineated.

## Courses and product news

### Course in Clinical Use of TMS

Maastricht Brain imaging Center at Maastricht University offers a two-day workshop with focus on the clinical applications of TMS. There will be academic sessions in the morning and hands-on training in the afternoon. Further, there will be time for individual feedback sessions to discuss intended protocols or procedures.

During the workshops, speakers from the psychiatric and neurological fields will give short presentations on their work with TMS for psychiatric disorders and for rehabilitation purposes.

**Number of participants:** 20 maximum

**Place:** MBIC/Scannexus Research site, Maastricht Brain imaging Center, Maastricht University, The Netherlands.

**Date:** September 25-26, 2014

**Further information and registration:** Contact MagVenture at [info@magventure.com](mailto:info@magventure.com)



### Course in Neuroscience Research with TMS

The Danish Research Center for Magnetic Resonance (DRCMR) offers a 4 day TMS course.

The course consists of two days of basic TMS training for new-comers in the field as well as a two day

advanced course for experienced TMS users. It is possible to participate in all four days or just the first two days or the last two days.

The topics covered are:  
The basics of TMS & rTMS, paired pulse TMS & dual site TMS, virtual lesion approach & cognitive intervention, multimodal TMS, application in clinical studies, TMS-EEG, TMS-fMRI, visual suppression, theta burst, PAS, neuro-navigation.

The course also includes hands-on training.

**Number of participants:** 20 maximum

**Place:** The course is held by the DRCMR, Hvidovre Hospital, University of Copenhagen, Denmark.

**Date:** Autumn 2014 – date to be announced soon.

**Further information and registration:** Susanne Steffensen, DRCMR: [susannes@drcmr.dk](mailto:susannes@drcmr.dk)

### Upgrade your Medtronic MagPro

MagVenture offers a full upgrade of older Medtronic stimulators to MagVenture MagPro stimulators.

The upgrade adds all existing features of the present MagPro machines and the machine will be fully tested regarding functionality, specifications, and safety.

These features include

- USB interfaces
- full remote
- latest software version
- support of all presently existing coils
- Optional Theta Burst without roll-off.

The unit will get new front- and back plate (MagVenture labeled). Typically the upgrade will also contain new

keyboard and dials and new silver contacts in the power switch in the MagVenture X models.

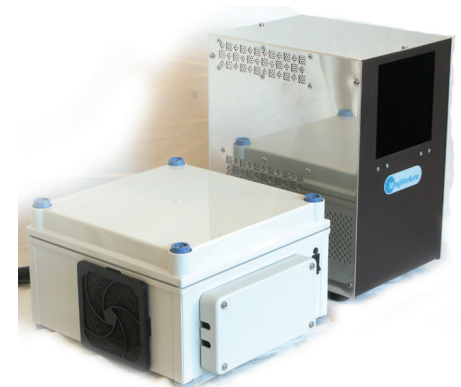
Finally, it will be fully tested regarding functionality, specifications, and safety.



### Run longer and more aggressive protocols without heating of the coil

The High-Performance Cooling-Option from MagVenture has been especially designed to increase cooling performance and allow for more aggressive protocols.

The High-Performance Option keeps the cooling temperature at 16°C (61°F) and thus prevents warm-up of the coil during high number of repetitions. The cooling time from 41°C (106°F) to 16°C (61°F) is approximately 10 minutes.



# 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 R30, R30 with MagOption, X100, and X100 with MagOption are all FDA 510(k) cleared (k061645, k091940). The intended use is stimulation of peripheral nerves for diagnostic purposes.

The use of devices for other than their FDA cleared intended use is considered as 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.

For further information please contact MagVenture.

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