

strong application and scientific support, and supervision until the accepted paper. Building up new know-how, is the daily bread for our support force. By our quality assurance policy, we are obliged to monitor closely the scientific output generated with our amps and software. Over the years this filled a large application database.

After increasingly urging requests, we decided to provide the MRI application fraction of the application database to our customers and put a list of more than hundred NLM listed papers on BrainAmp MR based MRI applications online.

Version 1.0 of the reference list is available at [www.brainproducts.com/references.php](http://www.brainproducts.com/references.php)

The listed papers link via double click directly to PubMed and the full text. Inclusion criteria in this database were simple:

- BrainAmp MR based combined EEG/EMG/peripheral physiology application in MR  $\geq 1.5$ T
- Published in a NLM listed journal

We are fully aware, that many important papers are still missing. This is for sure not because we don't like them (we are happy with our users for each accepted paper!) but rather because it became a very hard work to monitor completely the increasing scientific output (Fig. 1) which is generated with our technology. Nevertheless, we are sure the list is helpful for our users to track the progress of the combined EEG/fMRI methodology and to find papers demonstrating what is currently feasible with the Brain Products BrainAmp/fMRI concept.

If your work is still missing, please notify us. We will be happy to add your papers. Join the community of the experts. ●

### Brain Products Inside

#### CE or not CE: That's the question!

by Alexander Svojanovsky, Brain Products General Manager

"EEG systems are medical devices" – for some people that goes without saying, some have an opponent position on that statement. Well, because there are differing opinions and nobody could answer this question clearly, well-founded and legally binding, we started the procedure to ascertain the truth. The only possibility to get a reliable answer to that question was to start a lawsuit against a company which is selling products without medical certificate. Of course this was not the best way to create a friendship with that company but obviously the only way to force a legally binding decision to the market. Creating international harmonized guidelines and laws is difficult. The initiators are aware of this and they know that creating mistakes are a human nature. Thus, some guidelines and laws are not perfectly formulated or misleading. The "market is motivated to adjust itself", that's what we did. Recently a German court has pronounced a judgment which can be summarized as following:

"Manufacturers assign the intended use to their products.

CE?

Advertisement must unmistakably reflect the intended use and exclude misunderstandings."

This means, if the medical use of a product is clearly excluded through advertisement, intended use and product characteristics, it is not a medical product. Biosemi excludes the medical purpose, advertises by excluding the

medical use and additionally claims that their products are objectively unsuitable to be used for medical purposes due to e.g. impossible impedance check or open source acquisition software. The German court confirms this behavior but unfortunately this is not legally binding for Europe. Other national courts may decide differently. In terms of harmonization we will intend on a legally binding decision for whole Europe – whatever it will be – at least finally clarifying the circumstances.

We understand the judgment as opener for new opportunities and we are already considering how to integrate them into our own structure to create benefits for our products and in the end for our customers. ●

### Brain Products Inside

#### Job Opportunity at Brain Products

by Alexander Svojanovsky, Brain Products General Manager

We are offering a position in our Sales/Support department. Requirements are:

- Academic Degree: Postdoc or higher
- Experienced user of our hard- & software
- Programming skills: Matlab Basic Skills
- Language: English (German optionally)

Please describe yourself and your profile as detailed as possible. In particular this should include a thorough description of your technical skills and relevant documents such as curriculum vitae,

exam certificates etc. In order to give your application a personal touch, please also include

a comprehensive cover letter. Please send your application documents by mail to: Brain Products GmbH, Alex Svojanovsky, Zeppelinstrasse 7, 82205 Gilching, Germany  
Or send an email to [as@brainproducts.com](mailto:as@brainproducts.com) Find more information on [www.brainproducts.com/jobs.php](http://www.brainproducts.com/jobs.php) ●

