

Dear Health Care Provider,

Thank you for taking the time to read this letter. My name is Dr. Sung Lee, and I am Director of Research at Brain State Technologies, the company that developed and is now distributing the BRAINtellekt 2[®] (B-2[™]). I am writing because your patient (or client) has expressed interest in becoming a user of the B-2. This letter is intended to help you have a conversation with them about the B-2, and how to make the most of its use.

The B-2 is a new tool for self-empowered health care, intended as an advanced approach to stress management, sleep enhancement, and mental acuity. It comes in the form of a headband with noninvasive sensors, a controller box, and a tablet computer. It applies advanced software algorithms to create audible tones based on real-time, dominant, changing frequencies of the brain's electrical frequency spectrum. This precision-guided self-updating is intended to permit fine-tuned adjustments to how the left and right hemispheres manage the autonomic nervous system response to stress.¹ The net result is to support the brain to optimize its unique activity patterns, on its own terms.

The B-2 is not a medical device. It does not stimulate the brain directly (as does transcranial direct current stimulation, for example), nor does it entrain the brain into any particular rhythm (as do binaural beat devices), nor does it attempt to reward the user for consciously learning to regulate their brainwaves (as is the goal with "neurofeedback").

The underlying technology of the B-2 has been studied in clinical trials at Wake Forest School of Medicine since 2011.² Engineering advances that enabled creation of the B-2 were supported in part by a research grant from the United States Army Research Office to Brain State Technologies.

We are recommending that B-2 users use their device for 4 to 15 minutes per session, at least 3 times weekly, or up to twice daily, as a regular practice for stress management. A great deal of data has accumulated about the effects of chronic stress and disturbed sleep on health and well-being. In my estimation, the negative effects of daily unmitigated stress, for the brain, are probably comparable to the effects of a daily diet of sugar, for the teeth.

We anticipate that for most individuals, regular use of the B-2 will entail enhancements in one or more of the following:

- ability to manage sleep
- mental clarity
- emotional well-being, including resilience to stressors

Based on our early experience, we also anticipate that for some individuals, use of the B-2 may be accompanied by shifts including:

- heightened sensitivity to the emotions or body sensations, as well as social and physical influences including medications (OTC and prescription), alcohol, and recreational substances
- temporary shifts in sleep including dreams, emotions, or energy levels that are in a direction opposite to what was desired or expected
- a temporary sensation of fullness in the head, which may be uncomfortable

¹ Tegeler et al. (2015). Rightward dominance in temporal high-frequency electrical asymmetry corresponds to higher resting heart rate and lower baroreflex sensitivity in a heterogeneous population. *Brain Behav* 5(6):e00343

² See www.wakehealth.edu/hirrem

For B-2 users who are taking prescription medications, we ask that their health care providers please do the following:

- 1) Please remind them about potential side effects of their medications. Again, we anticipate that in some cases, individuals may report sensitivities that they have previously not experienced.
- 2) If your patient is using benzodiazepines, anti-convulsants, muscle relaxants, or other sedative-hypnotics, anxiolytics, or GABA agonists; dopamine agonists or antagonists; anti-depressants or mood stabilizers; stimulants; opioids and other analgesics; and/or other neuropsychiatric medications, please consider re-evaluating their medication regimen with them, for the following reasons:
 - a. By virtue of their intended pharmacological purpose, these medications may act to clamp neural transmission³, possibly permitting less flexibility of brain rhythms and decreased satisfaction from use of the B-2.
 - b. Some individuals may be interested to explore whether use of the B-2 can help them reduce their use of psycho-active medications for stress-related conditions.

If your patient or client is generally sensitive to the effects of stress (e.g. those with psychological, neuropsychiatric, cardiovascular, immune conditions, or others), we recommend that they enlist their health care provider(s) for those conditions to agree to partner with them in use of the B-2, so they may help make adjustments to the care regimen, or make suggestions about their B-2 use, if potentially indicated. Here are examples of some considerations. If you have questions about these or other clinical scenarios, please email me.

- 1) Individuals with history of significant life stress, and especially if they are in a relative emotional “freeze” state, may experience heightened emotionality in association with using the B-2, for which additional psychosocial support may be helpful.
- 2) There may be value to timing the initiation of B-2 use, in a way that strategically integrates it within a larger therapeutic plan (e.g. in the context of a new or changed medication regimen, planned surgery, etc.)

Based on a history of using our core technology for purposes of relaxation and in clinical investigations, we have great optimism about the B-2 as a device for self-care and self-empowerment – and the empowered patient is a stronger partner for the therapeutic alliance.

On a separate, but related, note the developers of the B-2 are aware of the increasing and sometimes overwhelming demands on healthcare providers, and the increasing rates of burnout in the healing professions. We are developing a program for healthcare professionals who may be interested in the B-2 for their own well-being. Please email me if you would like information about that.

Sincerely,

Sung Lee, M.D., M.Sc., M.Phil.
Director of Research,
Brain State Technologies
Sung.Lee@brainstatetech.com

³ Sterling P (2015). Homeostasis vs allostasis: implications for brain function and mental disorders. *JAMA Psych.* 71(10): 1192-3.