

## BETA TEST DATA REPORT

To ensure product functionality, Helicor performed a beta test with 76 persons in July 2005. Beta testing is essentially product testing by intended users in their home generally designed to examine every aspect of the product from hardware to usability. The primary goals of the StressEraser beta test were designed to examine hardware/software functionality (did buttons break, could the finger sensor detect a pulse on different age, sex, and racial groups, were there software bugs, etc.), usability, durability, physical features, instructions, technical accuracy, generalizability across populations, and to receive qualitative feedback on the effectiveness of the device.

Beta tests rely on general prompts, such as "What did you think of the User Guide or "Have you been able to consistently generate waves on the screen." Because the StressEraser is a clinical tool, testers were also asked questions like "did the stress eraser make you feel calmer during the day" An interactive webpage forum was created for users to log their comments and receive feedback.

Because we received numerous comments on the clinical utility of the device and side-effects, we decided to include a list of quantitative questions across several general domains about whether the StressEraser helped, made no change, or made things worse. Prior to this, testers were also asked to identify problem areas in their life.

The purpose of the following brief report is to highlight some of the unprompted user comments how the StressEraser helped them relax and report on some of the quantitative data that corresponds to these domains. It is important to note that testers were not given any information about possible the clinical utility of the device aside from simple stress reduction. This was to ensure that findings could not be attributable to an expectation or placebo effect.

Testers were selected from a pool of 9000 persons enrolled in the Centercode beta-testing program. These possible testers are located country-wide, and cover every demographic. Our goal was to have a participant pool that satisfied the following criteria: a gender ratio of approximately 60% female/40% male; a range of ages, skin tones, and nail polish users (for generalizability of the infrared finger sensor); a mix of computer skill level; approximately 10 testers who have worked with Centercode before on beta tests to ensure some persons have device bug finding experience; approximately 25% of persons employed in a health related field; and testers who self-reported have stress in some area of their life. None of the testers were informed of the product prior to enrolling in the beta test.

Procedures: Testers were chosen and informed by Centercode that they had been selected to participate in the StressEraser beta test. Once testers filled out a Non-disclosure Agreement and consent form, they were asked to log-on to the website to fill out an initial survey which included questions such as, "On a scale of 1 to 10, with 1 being very relaxed and 10 being extremely stressed, please rate your current stress level." Testers were then shipped the devices and manuals and were instructed to start using the device. In addition, they were to check in to the Centercode website to log feedback, in the form of bug reports (mechanical problems with the device), enhancement requests and suggestions (product improvement), open forum entries (posting questions and comments), and daily journal entries (allow users to track progress). Testers were required to fill out surveys posted every other day. Once posted, the survey had to be filled out before the user was able to log additional entries.

## **Results**

76 persons were enrolled in the beta test and 7 dropped out prior to completing the initial survey. Drop-out occurred for several reasons including device on-off malfunction (4 persons) and inability to comply with test requirements. Of the remaining 69, 3 persons were removed from analyses for the following: one said the device helped with all domains, one said the device made nearly every area of his life worse and another had inconsistent response patterns (see side-effects section for an explanation of the latter two persons). Data presented is on the 66 persons who had at least one follow-up period so the sample size ranges from 51-64. All data collected is included following this report. Of this group of 66 persons, 54.5% were female and the average age was 37.25 (SD=10.24; Range 19-64). 72.1% were employed (4.5% part-time), 4.5% were retired, 12.1% were stay at home parents, and 6.1% were students. All participants spoke English.

Compliance: Of the testers analyzed, they reported using the device an average of 10.75/14 days (SD= 2.63; Range = 3-14) and averaged 77.10 (SD=29.89; Range = 15-120) points per day. This translated into about 59.2% compliance (days x points/1400). 64.3% reported consistently getting 100 points a day and 73.2% reported being able to consistently get three dot waves or points.

## **Validation:**

Overall 76.7% of the sample reported that the StressEraser makes them feel calmer. Below is a table which highlights what percentage of the sample reported having a problem in an area (i.e. irritability), what percentage of

the total sample reported improvement in an area, and what percentage of those reporting a problem, also reported improvement in that area.

*Table 1. Problem Areas and Percentage of Persons Reporting Improvement.*

	Percent of Sample considering domain problematic (n=55-58)	Percent of the Total Sample Reporting Improvement in Area (n=57-60)	Percent of those who considered domain problematic reporting improvement in Area (n=48-56)
<b>Irritability</b>	80.7	61.0	69.6
<b>Patience Level</b>	84.2	61.0	64.6
<b>Anger Level</b>	50.9	46.4	62.1
<b>Ability to Cope</b>	52.7	55.2	72.4
<b>Mood Swings</b>	63.2	40.4	62.9
<b>Work Stress</b>	64.0	46.3	64.5
<b>Home Stress</b>	66.0	46.3	62.2

There is a clear trend for persons to report improvement in all areas associated with relaxation and those who reported a domain to be problematic, were more likely to report improvement. This does not appear to be a placebo-effect because we added questions that might be unrelated to increasing relaxation such as financial improvement. Since only 3.5% of persons reported financial improvement, we can reasonably infer that these results were not due to acquiescence (saying yes to everything).

The most interesting and important outcome is that there is a **significant linear relationship** between the amount of days x points per day (compliance) and improvement in these areas. We performed one-way ANOVA's to see if those who reported improvement differed in how much they used the device as compared to those did not report improvement. Results are presented in Table 2. Overall, results reveal that there was a significant dose effect relationship with improvement in nearly all relaxation domains. As noted earlier, this is also does not appear to be a placebo response in that the amount someone used the StressEraser had a non-significant impact on things like ones financial situation or eating habits.

Table 2. Differences in Total Number of Points (Compliance) and Improvement.

	Improvement	No Improvement	df	F	p
<b>Calmer</b>	928.83 (341.96)	543.63 (400.81)	53	10.41	.002
<b>Irritability</b>	989.58 (306.09)	631.25 (406.69)	52	13.49	.001
<b>Patience</b>	960.18 (365.85)	694.52 (364.87)	52	6.78	.012
<b>Anger</b>	995.04 (327.74)	712.22 (400.62)	49	7.50	.009
<b>Ability to Cope</b>	941.56 (354.26)	692.43 (392.89)	51	5.75	.020
<b>Mood Swings</b>	1037.72 (323.30)	736.37 (386.57)	50	8.83	.005
<b>Work Stress</b>	947.13 (317.33)	730.40 (416.82)	47	4.17	.047
<b>Home Stress</b>	960.52 (306.04)	710.63 (431.55)	47	6.31	.015

Note: The N's for Column three vary depending on whether we had data on both number of points and improvement in each domain.

Side-effects: To ensure that we were not biasing results, we asked if any of the domains measured caused problems (see general data report for all domains measured). None of the testers reported that the device made it more difficult to relax or caused increased anxiety. The same tester indicated that the StressEraser made almost all the problems in our assessment worse. When we received the device back, our tracking code revealed he only used the device for 7 minutes out of an entire 2 week period yet reported using it everyday for 90 minutes a day. Another reported that it helped with many aspects such as anger level, energy level, stress level, eating habits and reported improvement in his level of happiness from pre-test to post test. Yet he also reported that several overlapping constructs got worse such as depression level, ability to cope, mood swings and tobacco use. We believe that this data is invalid due to random responding. We have presented this data in the frequencies section but believe that this participant's data is not valid. Similarly, we excluded one participant who reported improvement in nearly all areas of functioning. Other than this tester, 3 reported that using the StressEraser made their headaches worse, 1 reported jaw pain, 1 reported increased tobacco use, 1 reported it made their eating habits worse, 1 reported that relationships with family worsened, and 1 reported GI problems. Also numerous participants reported the device made them sleepy which was only captured in the qualitative quotes section below. To put this in perspective, 19 reported reduced headaches, 6 improved jaw pain, 5 reduced tobacco use, 5 improved eating habits, 26 improved relations with family members, and 4 improved GI problems.

We also used the State-Trait Anxiety Interview (STAI) to assess overall changes in anxiety levels. The STAI has been validated across 100's of studies. The Trait Anxiety Interview was given at the beginning and end of the beta test while the State Anxiety Interview was given while a tester was stressed and then immediately after completing a StressEraser session. Overall the group made significant changes on both scales. Results are presented below in Table 3.

TABLE 3. Pre-Post State-Trait Anxiety Scores.

	<b>BL</b>	<b>EOT</b>	<i>df</i>	<b>t</b>	<i>p</i>
State Anxiety	60.01 (10.72)	39.69 (11.59)	39	9.90	.000
Trait Anxiety	51.10 (10.22)	43.10 (10.49)	51	6.82	.000

### **Qualitative Validation:**

Below are numerous qualitative quotes from beta testers who found benefit from using the device and those reporting side-effects. The quotes are separated into 2 sections. The first is general improvement and the second is where we inquired qualitatively about side effects. Please note that there is overlap between the qualitative and quantitative data where some people reported the same type of improvement or side-effects in both sections. The entire side-effect journal entry is included in this report. It is important to note that Helicor did not ask tester for these comments directly- but rather asked open ended questions like- please describe your experience using the StressEraser.

Quotes regarding improvement from testers:

"I feel an unbelievable calmness that I haven't felt for a long time, and continue to feel that way for quite some time after using it. I'm really, really impressed by this device! I have spent years trying to find ways to calm my nerves, and this is exactly what I've been looking for. What a wonderful, innovative product!...Thanks for making me feel better and be a better person!"

"I used it for the first time a few minutes ago, and WOW! I DO feel much more relaxed; almost euphoric. I like the product's sleek design. You can take it anywhere."

"I must say the after using the StressEraser in any situation I feel so much better. Whether I'm feeling very stressed, or I just want to relax in general, I love the results I get from the StressEraser....The thing that makes the

StressEraser such a pleasure to use is the fact that it is non-invasive and it is really easy to use once you get the hang of it. For me there is nothing complicated in using the StressEraser. I just slip my finger in and all is well."

"It is for me a meditation for dummies device. I love it....I have found heaven in this device. I am calmer more and more during the day....The device has become a true friend."

"This morning at 2:30 AM I still hadn't been able to fall asleep, so I decided to use my Stress Eraser....It was a GREAT way to help me slow down and relax."

"The device has made a impact on my life".

"[The StressEraser] makes me fall into a sort of meditative state....it is comforting to know that it is there when I do need it."

"I LOVE this device....I carry mine everywhere....Thanks to Helicor, I really feel I have more control over my life again.

"I actually fell asleep with it on my finger."

"I can feel the difference in my stress levels....This is a wonderful device!"

"It really helps me relax right before bed which is greatly helping me."

"I can't remember the last time I've been so relaxed. It's a refreshing feeling for once."

"I just can't say enough good things about this device....I love this device. It's so easy to adjust my breathing to relax when I can see immediate feedback on how my breathing changes when I get stressed and how that affects my waves."

The past four days have been highly stressful with a death of a close loved one. Even in the trauma of the event, the stress eraser has done it's job well, calming me whenever I feel really upset."

I've noticed myself dozing off after about 10 minutes of each session."

"It is actually been hard to part with around the house. I like the feeling of knowing it is there."

Getting rid of stress really helps, and the StressEraser is a great tool to get rid of the stress!...I commend you for developing this device."

"It really does cause me to relax."

"The thing that really appeals to me over other bio-feedback is the simplicity of just sticking your finger in and breathing....This unit fits in my pocket and can be pulled out and used easily."

"It does help me to feel more relaxed - which is what I really need."

"Just taking a few minutes to get my mind clear is a benefit. Without the StressEraser I would keep going and be stressed and burned out by the end of the day."

"I found myself starting to nod off during my lunch time session with the Eraser. Wonderful to be so relaxed."

"Every time I look and hold this thing I can't even imagine how many countless hours went into design and fabrication. Man, this thing is SLICK! Everything down to the smallest details, like the battery direction icons, is simply genius!"

"I took mine to the dentist yesterday and while the hygienist was working on me, I used it and actually it was my calmest dental visit yet. I have been in several wars, flown over 10,000 hours in combat jets, visited New York City, and one Worlds Fair, but I have always been more stressed in dental visits than anything else."

I became so relaxed after using it for about 5-10 minutes that I could hardly keep my eyes open!"

Today my aunt told me that I looked perky and alert. That was the first time in years that anyone has said that I look "perky" or "alert"....Other people are apparently noticing. It felt good to hear my family say that I look good, instead of asking what's wrong."

"I'm loving this thing and its really working for me! I feel more relaxed this morning. Calmer - not stressed out....I never gave 'breathing exercises' as a means for stress reduction/relaxation, much credit...but I am being proven quite wrong by my own experiences and success so far with this device."

"I have also been noticing that my recovery time when exposed to stressful situations has become much shorter and recovery in general seems to be

more complete and longer lasting. I find myself obsessing over specific situations a little less than normal."

"The device has helped me to make a much cleaner "break" between my day and when I start trying to sleep."

"I am totally amazed at how much better I feel. I have more energy, I am more alert and even optimistic. It really shocks me at how great it worked.... I am totally impressed with what breathing does. It helped me so much. I have tried doing it before, but this little biofeedback stress eraser is really teaching me how to do it right."

"Now that I finally have the hang of it I'm in love!!"

**Below is the list of side-effects journal entries reported by users during the beta test.**

Topic: "Side effects"

I was trying mine out this afternoon and I became so relaxed that I couldn't keep my eyes open anymore! lol Has anyone else had this happen to them? I know that the information that came with the device states that we could get sleepy or lightheaded but it should pass - well mine passed all right, it passed right after my 2 hour nap! :) I'm just curious if anyone else was effected so much.

I also felt very sleepy as I started to use it...maybe the fact that I was laying in bed had something to do with it!! no seriously, just concentrating on your breathing and watching the waves is almost hypnotic...i could really see someone who has panic attacks using this to destress in public as a way to take their mind off of the panic that they are feeling

"Do not use while operating heavy machinery"

:)

I found my self falling asleep (or at least getting very drowsy) as well. Your score takes a real hit when you do that (at least mine did).

I found no mention in the manual of what to do if you were getting sleepy (other than don't operate machinery).

I remember reading somewhere in the booklet (I think.) that we might feel sleepy or lightheaded after using the device but that it would wear off. Well I

wasn't awake long enough to determine when it wore off. lol

I took the AFTER using the device literally and didn't think it applied to WHILE using the device. I think they need to put in some words about falling asleep while using it. :)

I have to say that this definitely made me sleepy. I have GAD (Generalized Anxiety Disorder) and so far I haven't had a panic attack since using this, and I feel that it's really been a big help. I can't say I love being sleepy so much, but it's worth it to me! :)

See I had that same problem! I was fighting to keep my eyes open while I was still using it. So I shut it off half way through and went to sleep for 2 hours. lol :o)

i did not get sleepy...i think i was too stressed out trying to work on my breathing!hahaha

lol! SAME HERE!! I kept closing my eyes, because I was so relaxed! I too, took a nap after that, but I normally do anyways-though today's nap WAS longer and I was able to fall asleep faster than usual...so time will tell. lol

I found out that I can't NOT use the device with my TENS unit or even with my breathing unit.

Seems the current messes with the device. I got a false reading. I am redoing it without the other devices and out of my wheelchair.

I have to admit that this device would be a little difficult to use with a CPAP machine -- though I could really see this integrated into a CPAP. I had to stop using my CPAP because I couldn't sleep with the mask on...so I had to pick between No sleep (but well oxygenated) or cruddy sleep (no CPAP).

But this might be helpful with relaxing with all that equipment on....hmmm.

Nathan -- I guess I can blame my falling asleep at work on the device now? ;)

I did find the "method" to relax and allow my body to want to sleep.

I am going to try this with relaxing music tomorrow to see what happens.

i have the same problem..stopped using it long ago for that very reason..and i was thinking the same thing..that it could be used with a CPAP machine,

since the breathing method is the same

Challenges with the xPAP can be met and overcome if you have the right help and guidance. It sounds like you didn't. Drop me an email privately. Maybe I can help with the xPAP issues -- it's what I do when I am not beta testing. :)