



Health Technology Review

Technology Ref.:	HTA22043
Technology Name:	Exsurgo – Axon
Approvals by International Bodies:	device is listed (listing does mean that it is approved by FDA)
Company name:	Exsurgo Ltd
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Short Description of the Technology:	<p>Treatment is structured around the Axon Brain Computer Interface, an Electroencephalogram (EEG) device, a mobile computing device such as a tablet or smart phone and Exsurgo Connect, a cloud-based clinical analytics platform which can record, interpret and report on the electrical brain activities read by the Axon headset and information related to the patient's condition, reported by them through the app.</p> <p>EEG Neurofeedback works by monitoring brain activity and through “operant conditioning” (positive reinforcement) helps the patient ‘retrain’ how their brain responds to nerve signals from the body. Axon harnesses the latest science and AI technology to make EEG neurofeedback therapy faster, better and much cheaper.</p>
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Health Technology Assessment Team Recommendation:	Approve with limitation
Summary of Review:	
<p>It's a Disruptive AI-driven neuroscience platform, the technology combines a miniaturized headset, Cloud-based AI for analytics, and a consumer-friendly app, its neurofeedback intervention to treat the primary and secondary symptoms of chronic pain. Electroencephalography (EEG) Neurofeedback is an established, medically-proven process used to evaluate electrical activity in the brain. Based on the proven science that people learn by positive (and negative) reinforcement, patients can ‘retrain’ their brains to respond to pain signals in a different way. Neurofeedback (NFB) as part of a Brain Computer Interface can help some patients manage chronic pain by normalizing maladaptive brain activity measured with electroencephalography (EEG). As per the evidence's availability, there is a lack of full scientific evidences for the efficacy for the use of this technology in routine clinical practice which would be proven in a controlled clinical trial with good number of participants. Nevertheless, preliminary results are very promising and the potential of this technology to replace currently used pain medication could be significant</p>	
Advantages	Disadvantages
Non-pharmacological intervention , Non-invasive & easy-to-use	Neurofeedback treatment requires a personalized training program in order to be safe and effective



Enhance Patient quality of life; reduce and manage the pain level.	Efficacy; The evidence on the efficacy of NFB in alleviating the pain is limited (Research on it is still in early stage)
Sustainability; EEG neurofeedback therapy can deliver sustainable benefits to chronic pain sufferers.	People with complex chronic pain can be difficult to assess and treat by this technology
Accessibility; Remote solution for Pain management, the patient can use the device from the comfort of their house after obtaining specialized training based on their condition.	Patient data safety; As case for all cloud-based application, the system could be hijacked & the risk for patient data leak.
Efficacy; As per current studies, the results of neurofeedback so far have been very promising not only in terms of improvement in chronic pain but also in terms of improvement in pain associated symptoms such as fatigue, depression, anxiety and sleep.	Possible side effects as stated in relevant studies that some people report feeling fatigued, disoriented, anxious, agitated or irritable. Others have experienced stronger side effects, such as headaches or trouble falling asleep
Self-therapy; The goal of neurofeedback is to train the brain to regulate itself, and to help the person training to understand when their brain is in the desired state.	Neurofeedback training requires training by a certified medical professional; Serious side effects can occur if neurofeedback training is not overseen by a certified medical professional
Safety; Generally, neurofeedback treatment is considered a safe practice and is associated with minimal risk.	Evidence such as randomized control trials with good number of participants is required to substantiate the use in clinical practice

We recommend an **approval with limitation of using this technology** with the following conditions:

1. To conduct a local Trial in one or more of the authorized facilities for research in Abu Dhabi to further demonstrate efficacy of the treatment / device.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image





Population, setting and intended user for Technology “Exsurgo – Axon”

- **Population/ Intended User;**
 - Management of Chronic pain from any neurological or musculoskeletal cause, of which examples could be, post herpetic (or post-shingles) neuralgia, complex regional pain syndrome (CRPS), lower back pain, neck pain, major joint pain, spinal cord injury, phantom limb pain, brachial plexus injury related pain, traumatic peripheral nerve injury pain and post-cancer treatment pain, it may have potential on Mental health as well such as anxiety.
- **To be performed by:**
 - By certified medical professional.
- **Clinical Setting:**
 - It is a prescription device that could be used in both clinic and home.
- **Condition of use:**
 - As per the manufacturer instructions for use.
- **Exclusion criteria:**
 - Other conflicting medical issues.