

## REAL™ Immersive System

### Background and Evidence for Use of a Virtual Reality Therapeutic Medium for Upper Body Rehab

Stroke is among the most debilitating and costly diseases faced by the global healthcare system. While stroke is only the fifth leading cause of death in the United States, it is the leading cause of long-term adult disability.<sup>1,2</sup> In the United States, there are over 795,000 new strokes per year, and over 3.3% of all Americans live with the consequences of stroke – a figure expected to increase by 20% by 2030.<sup>3</sup> The burden on public healthcare systems from stroke is extremely high. The United States spends an estimated \$34 billion per year on stroke treatment, rehabilitation, and lost productivity. By the year 2030, the U.S. is projected to spend an estimated \$56.5 billion.<sup>3</sup> In addition to more effective preventative and acute stroke care, the AHA/ASA cites the need for more effective rehabilitative services.

Many rehabilitation experts agree that the most important element in any rehabilitation program is carefully directed, well-focused, repetitive practice. Patients who engage in rehabilitation with more intensity and frequency over longer time periods tend to have better outcomes.<sup>4</sup> However, the US Centers for Disease Control and Prevention reports that less than a third of discharged stroke patients receive any inpatient or outpatient rehab,<sup>5</sup> and, of those who do, frequency of use is low despite clear evidence that it is effective.<sup>6</sup> There are numerous possible reasons for this. Stroke rehab needs to be performed intensively, repeatedly, and for up to a year following onset to be most effective.<sup>7</sup> Following a stroke incident, patients are often depressed, cognitively impaired, and unmotivated due to their new disability. Feedback mechanisms to help the patient relearn correct movement patterns are labor intensive and lack stimulation. To the patient, clear indications of progress are hard to visualize and slow to develop, further reducing motivation.<sup>5</sup> Data on patient progress, needed to justify continued treatment to healthcare providers and payors, can be inaccurate and labor intensive to track and produce. Despite these barriers, extensive research shows that neurorehabilitation technology can dramatically enhance neuroplasticity and drive the relearning of skills impacted by damage from stroke, better than conventional therapy alone.<sup>7</sup>

Neuroplasticity is the term for physical changes that the brain undergoes when learning new things. This is a well-understood mechanism<sup>8</sup> involving a balance of new synaptic growth, synaptic pruning, and strengthening of neurotransmitter-mediated synaptic connections.<sup>9</sup> These mechanisms are at play whether the uninjured brain is learning a new skill, or the brain needs to relearn a skill due to neurological damage, such as infarction from ischemic stroke. Virtual Reality (VR) is a hardware and software technology that can induce neuroplastic change.<sup>10</sup> VR can deliver immersive, interactive auditory and visual experiences that give the user a sensation of truly being in and interacting with a different environment, where anything is possible. Virtual embodiment is the concept of a full-presence virtual avatar, which tracks and reflects the patient's real-time movements, enabling the patient's brain to accept that avatar as their own body.<sup>11</sup> This deepens the sense of immersion and provides a direct link to controlled stimulation of neuroplasticity.

With VR, the rehabilitation environment can be safe, encouraging, efficient, and supportive. Interactions can be tailored to the patient's individual needs, therefore enhancing the potential improvement within a given session. With accurate body-position tracking in real time, a new bio-feedback loop can be established using intuitive auditory and visual cues to allow the patient to self-correct their posture and limb movements for maximum exercise efficiency. Progress can be documented movement-to-movement, session-to-session and week-to-week to expose tangible improvement to the patient, caregiver, and payors, supporting ongoing rehabilitation when the patient has not yet plateaued. "Addictive" qualities of gaming can be exploited to encourage and reinforce compliance with a rehab plan<sup>12</sup>—one of the single largest barriers to successful recovery. Yet beyond these benefits, research shows that VR can provide links to drive neuroplasticity not otherwise obtainable in the real world.<sup>13</sup> Accelerated motor learning occurs when the patient "sees" their affected limb for instance, moving in a healthy, intact way. The affected side of the patient's avatar can be set by the clinician to mirror, or scale to the normal side during bi-lateral movement. The brain is triggered by



the “intention-action-observation”<sup>14</sup> effect, creating new synaptic connections in response to experiencing this “correct” movement, even if the patient’s limb in the real world is exhibiting motor impairment. The virtual world itself can be programmed with functional, yet engaging games that are necessary to relearn activities of daily living, while also including reward-driven cognitive puzzles. The motor tasks and cognitive puzzles can automatically adapt to the patient’s recovery state so that their complexity increases in step with the patient’s improvement. In summary, research supports the use of VR in rehabilitation, although more data is needed. That’s where the REAL System has a role.

## **Introducing the REAL™ Immersive System**

Prior to use, please refer to the User Manual for complete information, product indications, warnings, precautions, and potential adverse events.

Penumbra has combined forces with Sixense Enterprises, Inc., a tech company in Silicon Valley specializing in motion tracking technology to develop virtual reality technology for healthcare. Sixense specializes in immersive and full presence VR. In immersive VR, the user wears a headset and is transported to a virtual world. In full presence VR, the device tracks user motion, and allows the user to see their body in this VR environment as it moves.

Using our knowledge of stroke and the deficiencies that occur after a stroke, we developed a set of proprietary activities that are targeted for upper body rehab. Penumbra’s REAL Immersive System has been designed by engineers with decades of experience in electronics, medical device design, software development, 3D art, and game development. Evidence-based, effective therapies utilized by clinical rehabilitation experts were used to build therapy experiences within REAL. The REAL System is one, simple, portable rehabilitation tool that can easily be brought to the patient at the bedside, in a rehab center, or mobile health location. The system is wireless, tetherless, mobile, and accurately tracks the body without line-of-sight dependencies.

The three main components of our system include a VR Headset, a set of six sensors, and a tablet with TherapyView™ app that allows the clinician to administer and monitor the therapy session. Every aspect of the system has been tailored with the healthcare system in mind. Upon powering on, the patient is immediately immersed in VR, engaging in visual challenges guided by their therapist. Body sensors are attached with soft neoprene bands, and in less than two minutes of set-up time, the patient is working in a virtual world with their full-presence avatar. The therapist can see what the patient sees on an included tablet interface, which the therapist uses to select various activities, adjust activity parameters, and monitor the patient’s experience at the tap of a button. Data from the patient’s movement and accomplishments is securely saved so that documentation is easy to produce, and long-term trending can guide the patient’s recovery. We are developing a new way of engaging the patient and offer a tool to extend the clinician’s skills.

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Product availability varies by country. Rx only. Prior to use, please see User Manual for complete information, product indications, warnings, precautions, and potential adverse events. The product is intended to be used in a clinical environment and prescribed and supervised by a medical professional trained in rehabilitation therapy. A medical professional must be present at all times to provide direct supervision of the use of the product. Copyright ©2019-2020 Penumbra, Inc. All rights reserved. The REAL Hero logo, REAL, and TherapyView are registered trademarks or trademarks of Penumbra, Inc. in the USA and other countries. All other trademarks are the property of their respective owners.

## About Penumbra

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in the United States, most of Europe, Canada and Australia, and through distributors in select international markets.

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