

NeuroSphere™ Virtual Clinic

Category:

Best Digital Health Solution

Company Name:

Abbott

Number of employees:

> 1000

Turnover and/or Funding:

N/A

Product/Solution Name:

NeuroSphere™ Virtual Clinic

Corporate Name:

NeuroSphere™ Virtual Clinic

Date of Approval:

2021-03-08

Indications:

NeuroSphere™ Virtual Clinic is a first-of-its-kind application in the U.S. that is breaking down barriers to care - allowing people to get the healthcare they need, when they need it, regardless of their location.*

Approved by the FDA on March 8, 2021, Abbott's NeuroSphere Virtual Clinic allows a patient to both communicate with a physician and receive settings to their implanted neurostimulation systems in real time, even half a world away from their doctor's office. The neurostimulation therapies offered by Abbott are currently used to help reduce symptoms in people living with chronic pain and movement disorders, such as Parkinson's disease and essential tremor. This, in turn, can help people get back to the life they want to live while reducing or even eliminating the need for medications** that require regimented drug schedules to control their conditions or can cause severe side

effects.

Neuromodulation systems are cutting-edge medical platforms designed to deliver low-intensity electrical pulses to targeted nerve structures, such as the spinal cord, dorsal root ganglion or specific areas of the brain, to modulate neural activity and alleviate symptoms. Comprised of implanted leads that are connected to a pulse generator, the system allows doctors to personalize a patient's stimulation therapy and accommodate changes in the person's disease state over time through external programming tools. With NeuroSphere Virtual Clinic, a doctor can make these adjustments remotely without requiring a patient to step foot in the office.*

NeuroSphere Virtual Clinic continues to demonstrate its value by increasing access to optimal neuromodulation treatment for people with chronic pain and movement disorders who don't live close to a care provider, have difficulty accessing care or are unable to go to the doctor because their health conditions keep them from moving freely and easily. The application is a direct representation of how Abbott develops technology that puts people first, allowing them to lead more fulfilling lives while effortlessly managing their chronic conditions.

* Anywhere with a cellular or Wi-Fi connection and sufficiently charged patient controller.

** Follow your physician's guidance for your current medication regimen and do not make any changes to your medication usage without consulting with your health care provider.

For more background:

<https://abbott.mediaroom.com/2021-03-08-Abbott-Introduces-NeuroSphere-TM-Virtual-Clinic-First-of-its-Kind-Remote-Neuromodulation-Patient-Care-Technology-in-the-U-S>

Therapeutic Areas:

NeuroSphere Virtual Clinic is intended to optimize therapy with Abbott's neurostimulation devices, which include systems that provide therapeutic stimulation of the spinal cord, the dorsal root ganglion, and the brain to address chronic conditions, such as:

- o Chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery and intractable low back and leg pain
- o Moderate to severe chronic intractable pain of the lower limbs in adult patients with complex regional pain syndrome (CRPS) types I and II, considered the world's most painful chronic condition
- o Chronic back pain for those who have not had or are not eligible to receive back surgery (known as non-surgical back pain)
- o Painful diabetic peripheral neuropathy (DPN), a debilitating complication of diabetes

that can include symptoms, such as intense pain and numbness in the legs, feet and hands, which can lead to depression, anxiety and sleep issues

- o Movement disorders, such as Parkinson's disease and essential tremor

General Information File Document upload:

N/A

Background information and need for drug / device:

Approximately 51.6 million Americans suffer from chronic pain. Additionally, about 1.1 million live with Parkinson's disease, and an estimated 7 million live with essential tremor - movement disorders that tend to worsen over time. Patients with these often-debilitating disorders face significant hurdles not only to find physicians who specialize in the treatment of their conditions, but also in making the journey to and from the healthcare facilities to receive care. Nationwide, only 7,053 pain medicine and pain management specialists were available to help people manage their chronic pain symptoms as of 2023. Similarly, only 6,267 neurological surgeons were practicing in 2023.

Both of these conditions can make movement and travel difficult. As many as 60 percent of people with severe chronic back pain have reported that their condition makes it difficult to walk, and a quarter say that the pain can leave them unable to walk or climb stairs. Further, as many as 70 percent of people with chronic pain report that the condition limited their ability to drive and 56 percent of people who didn't drive said their pain kept them from getting behind the wheel.

Similarly, people with movement disorders can also find it hard to travel. Studies have shown that people with Parkinson's disease have more challenges with driving because of motor, cognitive and visual dysfunctions, and can be more likely to get into an accident. This often leaves people with movement disorders reliant on family members or friends to take them to and from doctor's appointments.

Simultaneously, because there are so few specialists who deal with these conditions, people often have to travel far to receive care, especially with neurostimulation devices, which have been shown to greatly reduce symptoms and improve patients overall quality of life. Research shows, for example, that patients who live with Parkinson's travel more than 60 miles and 15 hours, on average, to access specialists offering neuromodulation treatment and complete their treatment titration sessions. As a result, more than a third of patients with Parkinson's struggle to get to a clinic for care.

Craig Overman, an Abbott patient living with Parkinson's, shared that before

NeuroSphere Virtual Clinic was introduced, he traveled 11 hours round trip to his neurologist's office, requiring his wife to take off work and for the couple to factor in out-of-pocket costs to cover travel expenses. Similar to Craig, who lives in Wyoming, people who reside in more rural states tend to live further from medical centers and their physicians. But, because Craig and his surgeons chose an Abbott DBS system, he is now able to receive remote treatment adjustments from the comfort of his home with NeuroSphere Virtual Clinic.

For more background watch: <https://www.youtube.com/watch?v=ZaBXXedFIBk>

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<https://www.abbott.com/corpnewsroom/products-and-innovation/neurosphere-virtual-clinic-brings-relief-to-rural-town.html>

Background File Document upload:

N/A

History of the development of the solution/product:

Understanding the challenge around access to optimal neuromodulation treatment, Abbott embarked on a journey toward creating a seamless system for improved care access. Initial development for NeuroSphere Virtual Clinic began prior to the COVID-19 pandemic, but the project was expedited during the early stages of the pandemic to address the added burden of disease management and greater need for remote care.

The company didn't want to offer just another typical telehealth approach that only allowed patients and doctors to communicate by video conferencing. Instead, developers knew that to truly benefit patients, the solution had to help people engage with their healthcare providers on their terms and from the comfort of their homes. The Virtual Clinic platform would also need to allow people to receive new stimulation settings in a seamless manner, while simultaneously interfacing with their doctors.

This was an unprecedented plan that required the ability to create a secure and reliable connection between the doctor's programming device and the patient's neuromodulation device, which is implanted in the patient's body, regardless of how many miles apart they were at the time. This was accomplished through:

- o The development of a secure, extensible cloud infrastructure
- o Robust, multi-layered security controls compliant with state-of-the-art cybersecurity and data privacy standards

Following years of work, the company finally launched NeuroSphere Virtual Clinic in March 2021, marking the first time people with chronic pain and movement disorders could not only communicate with and be monitored by their doctors, but also receive stimulation therapy from their specialist anywhere in the world and in real-time via an

implanted Bluetooth-enabled device.

Most recently, Abbott also announced that NeuroSphere Virtual Clinic has been incorporated into Abbott's NeuroSphere™ Digital Health app, building on current connected care patient support capabilities to encompass the whole care journey - from early education to post-implant follow up. As part of this extended remote support system, the Digital Health app introduces a live assistance feature, which allows patients to request support from Abbott's patient education team when they have questions about their device.

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<https://abbott.mediaroom.com/2021-03-08-Abbott-Introduces-NeuroSphere-TM-Virtual-Clinic-First-of-its-Kind-Remote-Neuromodulation-Patient-Care-Technology-in-the-U-S>

o <https://abbott.mediaroom.com/press-releases?item=124687>

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

At the end of 2024, a woman traveled from Austin, Texas, to Kenya to visit family and take a safari. The Abbott spinal cord stimulation (SCS) system that helped quell her pain made it possible for her to make the trip. But while she was there, something went wrong - the stimulation from the SCS device was no longer adequate to alleviate her symptoms. Because she didn't have a doctor in Kenya and she wasn't scheduled to return to the U.S. for several months, she knew she could end up suffering without help.

The woman reached out to her doctor, who connected with Abbott. Between the two, they walked her through adding the NeuroSphere Virtual Clinic app to her phone and connecting it to her device. Then, using the application, they were able to check her SCS system and make adjustments to her therapy - all from almost 9,000 miles away.

She is just one of over 40,000 patients with chronic pain and movement disorders in more than 19 countries who have been positively impacted by NeuroSphere Virtual Clinic. But the benefits of the application do not end there.

A recent study demonstrated how NeuroSphere Virtual Clinic also greatly accelerated positive treatment outcomes for patients with Parkinson's compared to in-clinic care. The difference in outcomes between the two groups was remarkable - patients who worked with their doctors using NeuroSphere reported symptom improvement 15 days sooner than those who worked with their doctor in the clinic. People who used the

system also reported quality-of-life improvements at one-month - two full months before their counterparts - that were sustained throughout the three-month study. Additionally, people who used NeuroSphere to adjust their neuromodulation system following implant spent an average of just 48 minutes total to complete all their titration sessions and fully optimize their stimulation settings, compared to 15 hours for those who adjusted their systems at the doctor's office over the course of their titration sessions.

Ultimately, NeuroSphere Virtual Clinic has the potential to improve access to care for people who live in areas - both rural and urban - with inadequate access to medical services. This means more people can receive the critical therapies they need, improving adherence and reducing emergency visits, even if a person is unable to go to the doctor because of circumstances like personal economics, caregiver flexibility or a global pandemic.

While it was introduced in the U.S. in 2021, no other technology includes the capabilities and advancements that NeuroSphere Virtual Clinic provides to people, their caregivers and treating physicians.

- o <https://www.nature.com/articles/s43856-025-00744-7>

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- o <https://www.abbott.com/corpnewsroom/products-and-innovation/neurosphere-virtual-clinic-brings-relief-to-rural-town.html>

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- o <https://www.abbott.com/corpnewsroom/pain-and-movement/a-fathers-pain-eased-by-holding-his-child-safe.html>

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- o <https://www.nbcwashington.com/news/health/parkinsons-disease-patients-can-be-treated-by-specialists-remotely/2681650/>

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- o <https://www.fox32chicago.com/news/new-technology-allows-doctors-at-rush-to-treat-patients-remotely>

- o https://apnews.com/direct/?prx_t=aG8HAAAAAAniAPA&prx_ro=s

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

The references below support the messages within this submission.

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