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CLEVEMED LAUNCHES CLINICAL STUDY MONITORING PARKINSON'S DISEASE MOTOR SYMPTOMS IN THE CLINIC AND AT HOME USING KINESIA™

CLEVELAND, Ohio (January 28, 2009) - Cleveland Medical Devices Inc. (CleveMed) has launched a large scale multicenter clinical study to continue development and validation of [Kinesia™](#), a compact wireless system for monitoring severity of Parkinson's disease (PD) motor symptoms. Kinesia uses miniature motion sensors worn on the hand and wirelessly transmits motor symptom information to a PC. Data is collected while patients follow computer based video instructions which guide them through various arm and hand movements. In the study, Kinesia will be used to quantify symptoms including tremor, bradykinesia (slowed movements) and dyskinesias (wild involuntary movements) in the clinic and at patients' homes. Data collected during the study will be used to validate existing Kinesia algorithms for automated tremor scoring as well as aid in development of new algorithms for automated bradykinesia and dyskinesia scoring. Results will be compared to the current clinical standard in PD evaluation, the Unified Parkinson's Disease Rating Scale (UPDRS), a qualitative system that rates symptoms on a 0-4 scale.

"Objective quantification of tremor, bradykinesia, and dyskinesias is important in light of new pharmaceutical trials and novel therapies such as deep brain stimulation," said Dr. Alberto Espay, Neurologist at the University of Cincinnati Movement Disorders Center, one of three participating clinical sites. "Kinesia should prove useful both for quantifying Parkinson's disease symptoms in the clinic and tracking symptoms during on and off times in patients' homes. This may ultimately improve quality of life for individuals with Parkinson's disease."

In 2008, a pilot study was completed in which sixty PD subjects were evaluated using a subset of the UPDRS motor exam while wearing Kinesia. Automated algorithms for scoring rest, postural and kinetic tremor developed during the study showed good correlation to clinician UPDRS scores. Based on the success of this initial study, CleveMed is expanding to a multicenter study with three locations and one hundred fifty subjects with PD to validate the system on a larger Parkinson's population with wide ranging motor symptoms and severity levels.

CleveMed is collaborating with neurologists at the Cleveland Clinic Foundation (Cleveland, OH), the University of Cincinnati Movement Disorders Center (Cincinnati, OH), and the Henry Ford Health System (Detroit, MI). Fifty subjects will be recruited from each site and evaluated wearing the Kinesia device in the clinic. After the initial evaluation, the device will be sent home with each subject for one week to evaluate the efficacy of home use.

"The traditional UPDRS exam must be performed during an office visit," said Dustin A. Heldman, Ph.D., Senior Biomedical Engineering Researcher in CleveMed's Division of Movement Disorders. "Home

monitoring will allow clinicians to monitor complex motor symptom fluctuations that cannot be captured during an office visit." Involving multiple clinical sites and a large number of subjects will provide a rich data set for CleveMed to improve existing automated scoring for tremor and expand automated scoring to include bradykinesia and dyskinesias. The algorithms will be incorporated into the current Kinesia platform providing a system that will objectively rate PD motor symptoms on a consistent and continuous basis.

About CleveMed

CleveMed was founded with the goal of developing innovative telemetry devices for a variety of medical applications. Today, CleveMed is developing and pioneering the use of novel wireless monitoring systems for high growth neurology and rehabilitation applications, including [movement disorders](#) and [sleep disorders](#). Through these innovations, CleveMed has developed a growing range of products that address the needs of the medical, research and academic communities. For more information, please visit www.CleveMed.com

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