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|---|---|
| **Study Title:** | Evaluating the Indego Exoskeleton for Persons with Hemiplegia Due to CVA |
| **Study Number:** | PHIND_CVA01 |
| **Product Name:** | Indego® |
| **Study Phase:** | 510 K |
| **Indication:** | Current FDA approval for persons with Spinal Cord Injury (T4 and lower).<br>This study to provide safety results to the FDA for potential approval for persons with hemiplegia due to CVA (Cerebral Vascular Accident) |
| **Investigators:** | Multi-center: Shepherd Center (GA), Cedar Sinai Medical Center (CA), Rusk Rehabilitation (NY), Sheltering Arms (VA), St Charles Hospital (NY), Craig Hospital (CO), Kessler Foundation (NJ), Rehabilitation Institute of Chicago (Shirley Ryan AbilityLab, IL) and TIRR Memorial Hermann (TX) |
| **Sponsor and Monitor** | Parker Hannifin Corporation<br>Human Motion and Control<br>1390 E. Highland Rd<br>Macedonia OH 44056-2310 |
| **Sponsor Contact:** | Achilleas Dorotheou<br>Parker Hannifin<br>VP Business Development<br>Head, Human Motion & Control<br>Office (216) 896 2044<br>Email: adorotheou@parker.com |
| **Shepherd Center Principal Investigator** | Donald Peck Leslie, MD<br>Medical Director, Shepherd Center<br>2020 Peachtree RD, NW<br>Atlanta, GA 30309<br>Email: donald_leslie@shepherd.org |
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| **Original Protocol:** | 25 October 2016 |
| **Revisions:** | NA |

PHIND_CVA01
Parker Hannifin Corporation
Protocol Date: Oct 25, 2016
Revision: NA

## SPONSOR SIGNATURES

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**INDEGO (Figure 1. Page 8)**
The Indego exoskeleton was approved for use by the FDA in February of 2016 with individuals with spinal cord injury (SCI) at levels T4 and below for rehabilitation use, and for T7 and below for personal use in the home and community. Shepherd Center was instrumental in leading the multi-site clinical trials that led to the Indego FDA approval for persons with SCI.

Shepherd Center, in collaboration with Vanderbilt University and Parker Hannifin Corporation, has also led the clinical research efforts for use of Indego for persons with hemiparesis resulting from cerebrovascular accident (CVA) since 2012.

A publication from our earliest work using Indego with persons with CVA (Shepherd RRC project #510) can be found here: S. A. Murray, K. H. Ha, C. Hartigan, and M. Goldfarb, "An assistive control approach for a lower-limb exoskeleton to facilitate recovery of walking following stroke," Neural Systems and Rehabilitation Engineering, IEEE Transactions on, vol. 23, pp. 441-449, 2015. Shepherd Center Principal Investigator was Donald Peck Leslie, MD

A second manuscript from an Indego trial for persons with CVA conducted in 2015 and 2016 as a collaborative effort between Shepherd Center, Vanderbilt University and Parker Hannifin Corporation (Shepherd RRC Project #660) has been submitted but not yet accepted for publication. A full copy of the manuscript is attached in this IRB submission: Spencer A. Murray, Student Member, IEEE, Clare Hartigan, Casey Kandilakis, Elizabeth Sasso, and Michael Goldfarb, Member, IEEE "A Preliminary Crossover Study of Exoskeleton Control Methodologies for Gait Rehabilitation Post-Stroke". Shepherd Center Principal Investigator was Donald Peck Leslie, MD

The Indego User Mauual is attached in this submission. In addition, videos and other Indego information can be found at www.Indego.com

## STUDY SYNOPSIS

**Primary Objective:**

- To demonstrate that the Indego® device is safe to use as a gait training intervention for persons with hemiplegia due to CVA.

*Results of this multi-site study to include 40 subjects will be submitted to the FDA as part of a 510K Parker Hannifin submission to seek FDA approval for Indego use with persons following stroke.*

**Hypothesis:**

- Indego can be safely used as a gait training intervention for persons with hemiplegia due to CVA for persons with mild, moderate or severe stroke.
- Indego can be safely used as a gait training intervention for persons with hemiplegia due to CVA for persons with acute (less than 2months), sub- acute (2-6 months) and chronic (greater than 6 months) onset.
- Following six Indego sessions, persons with hemiplegia due to CVA may show improvements in mobility when comparing pre- training measurements to post-training measurements.

**Study Design:**

Forty subjects in total will be enrolled across nine clinical sites: Shepherd Center (GA), Cedar Sinai Medical Center (CA), Rusk Rehabilitation (NY), Sheltering Arms (VA), St Charles Hospital (NY), Craig Hospital (CO), Kessler Foundation (NJ), Rehabilitation Institute of Chicago (Shirley Ryan AbilityLab, IL) and TIRR Memorial Hermann (TX). Subjects will be seen three times per week for two weeks.

Up to five subjects are expected to be enrolled at Shepherd Center.

<table>
<tr><th></th><th>Session Content</th><th>Session Duration</th></tr>
<tr><td>Session 1</td><td>Consent<br>Initial Evaluation and Fit</td><td>2 hours</td></tr>
<tr><td>Session 2</td><td rowspan="4">Indego Training Sessions</td><td rowspan="4">1 hour</td></tr>
<tr><td>Session 3</td></tr>
<tr><td>Session 4</td></tr>
<tr><td>Session 5</td></tr>
<tr><td>Session 6</td><td>Indego Training Session<br>Final Evaluation</td><td>2 hours</td></tr>
</table>

Study duration for each individual enrolled is two weeks. If a session is missed, attempts must be made to reschedule within the same week. The maximum amount of time the protocol may be interrupted or extended (due to illness, weather, other) is two weeks. The number of study visits remains the same.

Shepherd Center will be provided with an Indego® kit for the duration of the trial. This kit will include small (short), medium and large (tall) hardware components, all necessary padding options, and 2 hand held IPod touch operator controllers. Parker will provide “on call” engineering support.

Enrollment for PHIND_CVA01 will be on a rolling basis so that each site can enroll any number of subjects until the total subject number across sites reaches forty. Should a subject not complete all study sessions, an additional subject will be added to replace the person who did not complete the study. Data for persons who did not complete all sessions for the study will be analyzed separately.

Subjects may be enrolled from inpatient, day program, outpatient, post rehabilitation programs, or from home. Researchers will not attempt to have an equal representation among “programs” of when the subject was enrolled. However, the sponsor will attempt to have a mix of acute, sub acute and chronic conditions.

In addition, enrollment will be monitored based on severity of motor involvement using the Fugl-Meyer Motor Assessment (FMA). The maximum FMA score is 100 (Upper Extremity maximum score = 66 and Lower Extremity maximum score =34). The FMA will be scored by the physical therapist at the time of the Initial Evaluation.

- Mild = FMA Total Motor Score greater than 79
- Moderate = FMA Total Motor Score 56-79
- Severe = FMA Total Motor Score 36-55
- *Very Severe = FMA Total Motor Score 0-35.

(Duncan, Goldstein, Horner, Landsman, Samsa and Matchar 1994)

*Sponsor does not anticipate enrolling persons in the Very Severe FMA Category; subjects must be able to walk 14 meters or 46 feet with the assistance of one to two persons to qualify for study participation.

Study subjects will serve as their own control. This will be accomplished by gathering baseline historical data from the medical record. In addition, multiple baseline assessments will be done during session one to establish each subject's current strength, functional status and mobility at the time of enrollment.

**INCLUSION CRITERIA**

- 18 years and older
- Height 5'1" to 6'3" (acceptable height may vary depending on femur length)
- Weight 250 lbs. or less
- History of one sided ischemic or hemorrhagic stroke with resultant hemiparesis
- Ability to walk 14 meters or 46 feet with the assist of 1-2 persons
- Manual Muscle Test (MMT) 4/5 in at least one Upper Extremity (UE)
- No restrictions on time since stroke (acuity), but all subjects need to be cleared by MD for locomotor training
- No other known brain abnormalities or neurological diseases /disorders
- Has never been treated for a stroke in the past
- Passive range of motion (PROM) at shoulders, trunk, hips, knees and ankles within functional limits for safe gait.
- Skin intact where interfaces with the Indego device
- Modified Ashworth Scale for spasticity 3 or less in the lower extremities
- Absence of complicating physical or mental conditions as determined by MD that would preclude the individual from safely participating in gait training
- Must be able to follow directions and communicate basic needs, demonstrated by a MMSE (Mini Mental Status Exam) score of 18 or greater

**EXCLUSION CRITERIA**

- Failure to meet all inclusion criteria
- Pregnancy
- Colostomy bag
- Uncontrolled / untreated hyper- or hypotension

**MEASURES**

- **Function**
    - Mini Mental Status Exam (MMSE)
    - Fugl – Meyer Assessment *(to be assessed during PT evaluation only, for stratifying severity of stroke)*
    - Spasticity: Modified Ashworth Scale (MAS)
        - Bilateral upper and lower extremities
    - Strength
        - Manual Muscle Test (MMT) of upper and lower extremities
            - Strength will be tested even if the subject presents with MAS 0-3. The potential influence or limitation of the MAS score will be reflected in session notes

- **Activity (to be assessed WITHOUT Indego; Indego will be used during gait training only, not during mobility measures)**
    - Functional Ambulation Category (FAC)
    - Fast Gait speed (as measured during the 10 Meter Walk Test with 14 Meter Track)

**SESSION DATA**

**Within each of the six sessions, the following parameters will be also monitored and recorded:**

- Medications
- Skin Integrity – Pre/Post each session
- Vital signs – Pre/Post each session
- Pain – FLACC scale (Face, Legs, Activity, Cry, Consolability scale with pictorial images)
- Functional Ambulation Category (FAC)
- Adverse Events
    - Subject
    - Device
    - Falls
- Comments on Spasticity (Formal MAS only during sessions one and six)

**SESSION GUIDELINES**

- Therapists will make all attempts not to affect the subject's functional performances on mobility measures, however patient safety is priority. Levels of assistance provided to the subject will be recorded.
- Indego sessions should be scheduled to avoid fatigue and to work in collaboration with other inpatient or outpatient therapies.
- One study session allowed per day
- Concurrent therapies are allowed, but therapists should take into account adequate rest for the subject in the event they have other appointments the same day.
- A fall is defined as "An unintentional change in position coming to rest on the ground, floor, or onto the next lower surface (e.g. onto a bed, chair or bedside mat). The fall may be witnessed, reported by another person, or identified when the user is found on the ground. Falls include any fall whether it occurred at home or out in the community. Falls are not a result of an overwhelming external force (e.g., the user is pushed by another person). An intercepted fall occurs when the user would have fallen if he or she had not caught him or herself, or had not been intercepted by another person—this is still considered a fall " Definition provided by FDA to Parker Hannifin on July 20, 2016 based on Centers for Medicare and Medicaid Service guidelines.

**EXPECTED TIMELINE TO COMPLETE 40 SUBJECTS ACROSS SIX SITES:**

- 40 subjects for 2 week intervention = 80 weeks/6 sites = 13 weeks per site (3.25 months)
- Depending on site enrollment, total study duration should last roughly 8 months.

**EFICACY ENDPOINTS**

**Primary Endpoint:**

- To show that the Indego® device is safe and potentially effective at providing gait training intervention for persons with hemiplegia due to CVA.

**Supportive and Exploratory:**

- Assess vital sign and skin
- Assess pain
- Assess impact of Indego training related to mobility measures.
- Assess changes in spasticity

**SAFETY MEASURES**

- Subjects must meet all inclusion criteria and posses none of the exclusion criteria
- Subjects must have medical clearance to participate prior to consenting process.
- Vital signs will be taken before and after each session

- Skin checks will take place before and after each session
- An Indego® certified PT will be present for all sessions.
- Sponsor will provide "on call" engineering support for the duration of the study.
- The six clinical sites chosen for the study are all experts in the field of neurological rehabilitation.
- All Subject Adverse Events and Serious Adverse Events will be documented, reported and followed to resolution.
- All device related adverse events to include device malfunctions pertaining to the device hardware, software or hand held controller interface will be documented, reported and followed to resolution.

## STATISTICAL MEASURES

Forty subjects must complete all sessions for the study to be concluded. If any subject is unable to complete all sessions, their data will be analyzed separately and reported as a sub set to the main report.

A total sample size of 40 participants and over 200 Indego training sessions for this study will yield reasonable statistical power in determining the safety of the device and potential differences between pre- and post-test values, one-sample means tests, and Pearson correlation coefficients. When conducting matched pairs t-tests for pre- and post-test differences, 40 participants will yield a power of 0.87, with an alpha level of 0.05 and an effect size of 0.50, an effect size value that falls within the medium range according to Cohen (1998).

Cohen, Jacob. Statistical Power Analysis for the Behavioral Sciences. Hillsdale (NJ): Lawrence Erlbaum Associates, Inc.; 1998.

Descriptive analyses will also be reported for medical history, severity and onset of CVA, subject evaluation measures, gait characteristics and subject/device adverse events.

## RATIONALE

The following is paraphrased from S.A. Murray's dissertation "Development and assessment of a control approach for a lower-limb exoskeleton for use in gait rehabilitation post stroke." Vanderbilt University, 2016:[1]

CVA is one of the leading causes of chronic disability in the United Stated. There are an estimated 6.6 million people having survived a cerebrovascular accident (CVA) and an estimated 610,000 first-incident CVAs occurring each year in the United States[1]. Restoration of gait functionality is often a high priority during rehabilitation in patients with lower-limb hemiparesis [2, 3]. This has thereby caused many to develop robotically-assisted gait-training devices in recent years.

While results vary in the highly-heterogeneous population of stroke patients, a recent meta-analysis found that electromechanically-assisted rehabilitation devices may improve the likelihood that a patient will recover the ability to walk independently [4]. Many control approaches have been proposed and described for the control of these robotic devices [5-15]. These control strategies can be roughly categorized as either a "trajectory-based controlled" or "non-trajectory-based controlled" type. Trajectory-based controllers dictate the spatiotemporal nature of joint movement; non-trajectory based controllers do not. Examples of the latter include force tunnels around the desired trajectory [8, 12, 14], teach-and-replay impedance based control strategies to generate subject-specific trajectories [16], and model-based strategies to target specific portions of the gait cycle [9, 17].

The following is paraphrased from S.A. Murray et. al 2019, currently in preparation for publication[1]

A trajectory control approach can offer functional advantages relative to a non-trajectory control approach, such as the ability to consistently reproduce healthy gait kinematics, provide full movement assistance, and provide

[1] Note: These points of clarification added on April 17, 2019.

early therapy to subjects who may otherwise be non-ambulatory. Despite these potential advantages, researchers hypothesize that a trajectory-based control approach may allow patients to assume a *passive* role within the device, since the device is, in essence, providing full coordination and effort associated with movement. It is well-known that increased patient participation results in improved outcomes [18, 19], and therefore recovery is more likely if the machine promotes active rather than passive patient participation.

Thus, despite the advantages of a trajectory-based controller, researchers hypothesize that a non-trajectory-based control approach would place increased responsibility for coordination and movement on the patient, and would therefore require greater engagement, and thus presumably result in improved functional outcomes.

Use of Indego for the proposed study is a non-trajectory based controller approach. Use of the Indego controller for persons with stroke has been safely utilized in the following studies, previously approved by Shepherd Center Research Review Committee:

- Project #510: i-Step Long-Leg Orthosis (3 subjects with CVA enrolled. Study has been closed)
- Project #660: Engineering Assessment of the Indego® Software Controllers – Parker #ENG1 (8 subjects with CVA currently enrolled. Study remains active)

In previous Shepherd RRC approved studies, gait parameters were controlled and manipulated by Vanderbilt or Parker Engineers thought a tethered cord from the Indego device to a laptop computer. For the proposed study, the gait parameters will be manipulated by the physical therapist through an IPod controller connected wirelessly to Indego using Bluetooth.

To date there have been no serious adverse events of falls using the Indego with persons with. No sites other than Shepherd Center have completed research using the Therapy Mode controller that was designed for persons with stroke and other neurological disorders.

The proposed study will allow a greater number of subjects and participating sites to evaluate the safety of the Therapy Mode Indego controller and assist in data collection for potential approval through the Parker 510 K submission by the FDA to use the Indego as a gait training tool for persons with hemiplegia due to stroke.

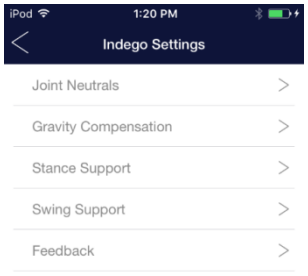
**(Figure 1) Indego® ; total weight 26 pounds, 5 modular components, powered assist at the hip and knee joints, carbon fiber ankle foot orthoses is passive.**

**(Figure 2) Subject training in the Indego with PT assist and tethered control cord. In the proposed study the tethered cord will not be present, rather an Ipod touch will be used to communicate the subject settings to the Indego device through wireless Bluetooth.**

Clinicians will have the option to modify 5 different groups of subject settings through the wireless Bluetooth Ipod touch controller:

1. Joint Neutrals,
2. Gravity Compensation
3. Stance Support
4. Swing Support
5. Feedback.

Each of these 5 main categories is adjustable for the right and/or left sides of the body.




**Joint Neutrals**: Pressing the "Reset Neutrals" buttons will cause Indego to capture the current position of each joint and treat this stored angle as the joint's neutral position (i.e. Indego will treat the stored position as though it were zero degrees of flexion or extension at each joint). This permits Indego to automatically calibrate itself to adjust for slight misalignment between the user and the Indego, or to adjust for users who walk with joint angles that differ from the anticipated.

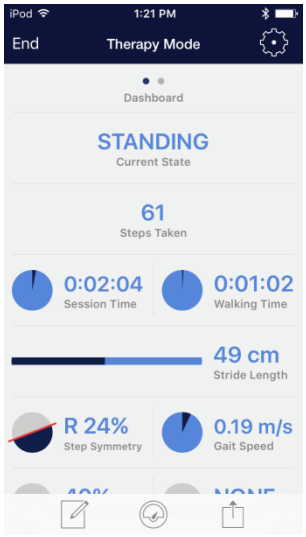
**Gravity Compensation:** Reduces the weight of the user's leg (i.e. making the user's limb seem lighter during gait). The percentage of the user's limb weight to be accounted for may be varied independently for each leg by adjusting the position of the Left Leg Support and Right Leg Support sliders. The amount of compensation is represented on a scale of 0 to 100 percent in 10 percent increments. Changing the support level adjusts the support for both upper- and lower leg compensation.

**Stance Support:** Stabilizes the stance limb by providing resistance to excessive knee flexion or hyperextension.

**Swing Support:** Provides an additional push at the hip or knee joints when gravity compensation is insufficient to achieve the desired joint excursion during swing. Flexion assistance becomes active as soon as the Indego detects that the user is attempting to take a step, and remains active until either the duration of the flexion assistance passes, or the user begins to extend the knee. Extension assistance is provided once the knee begins to extend, and lasts until the knee achieves adequate extension or until heel strike is detected.

**Feedback:** Provides audio feedback in order to signal to the user and clinician that the user achieved a desired step length. When heel strike is detected, Indego calculates the length of the step. If the step met or exceeded the goal step length the iPod will produce an audible chime.

**The Indego Dashboard provides objective information during and following each therapy session, including:** the current state, the number of steps taken, total session time, walking time, battery level, power limiting level, stride length, step symmetry, and gait speed during a session.

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