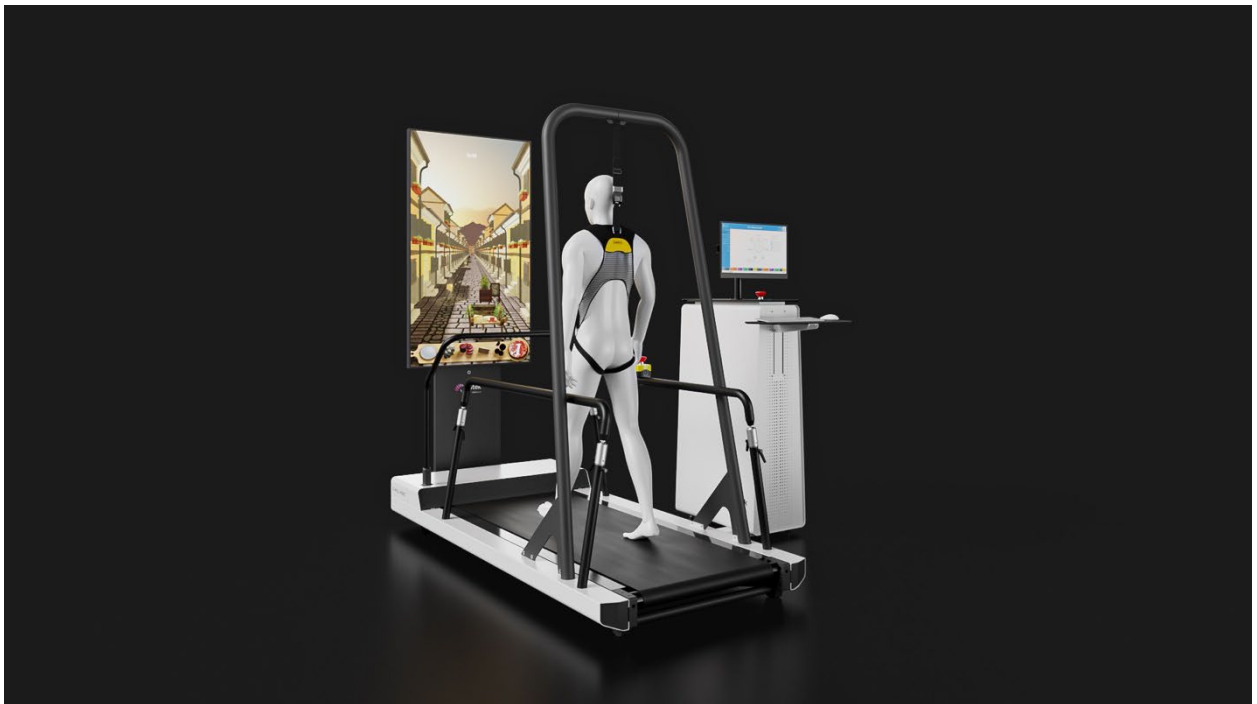


C-MILL HERO PRE-TRAINING MATERIAL



1 Background information

C-Mill Hero is part of HERO Solution. The HERO Solution consists of four hardware devices, synchronized by smart and user-friendly software: FysioRoadmap (Figure 1).



The C-Mill HERO encourages the patient to adjust their gait to the requirements of the environment. The ability to adjust gait may be related to reduced fall risk. To avoid falling and walk safely in daily life, we must be able to avoid a doorstep, puddle of water or other obstacles. The C-Mill HERO offers a unique therapy solution as a complete assessment and training tool, simulating everyday challenges in an engaging, effective, comfortable and safe environment.

The basis of a C-Mill (C' stands for Cueing and Context) is an instrumented treadmill allowing functional gait and balance training. By means of visual and acoustic cues, enhanced variation, motivation, parameter-adjustability and both real-time and after-session reports, therapy on the C-Mill brings the scientifically-based motor learning principles into clinical practice.

With its short setup time and applications that can be adjusted in during the session, the time spent on actual training for both patient and therapist can be greatly increased.

Training options

Various aspects of the walking pattern can be measured using the instrumented treadmill and the visual and acoustic cues can be used to encourage the patient to adapt their step length, step width, cadence and symmetry.

Incorporating repetitive, high-intensity and task-specific walking training, with direct feedback on performance, the C-Mill concept follows the latest evidence-based literature about gait training. (Hollands et al., 2015, Heeren et al. 2013, Fonteyn et al. 2014, van Ooijen et al. 2015, Houdijk et al. 2012, Papegaaij et al. 2017).

Objective evaluation

Monitoring training over time is important to identify the best course of action. The C-Mill provides highly reliable, objective and valid assessment data of all treatment sessions, so a patient's performance can be measured and saved for short- and long-term insights/ evaluation.

Fun

Besides these functional features, the C-Mill also delivers an enjoyable experience full of variety and rewarding moments, keeping the patient immersed and motivated. And, when it comes to patient therapy, nothing beats a motivated patient.

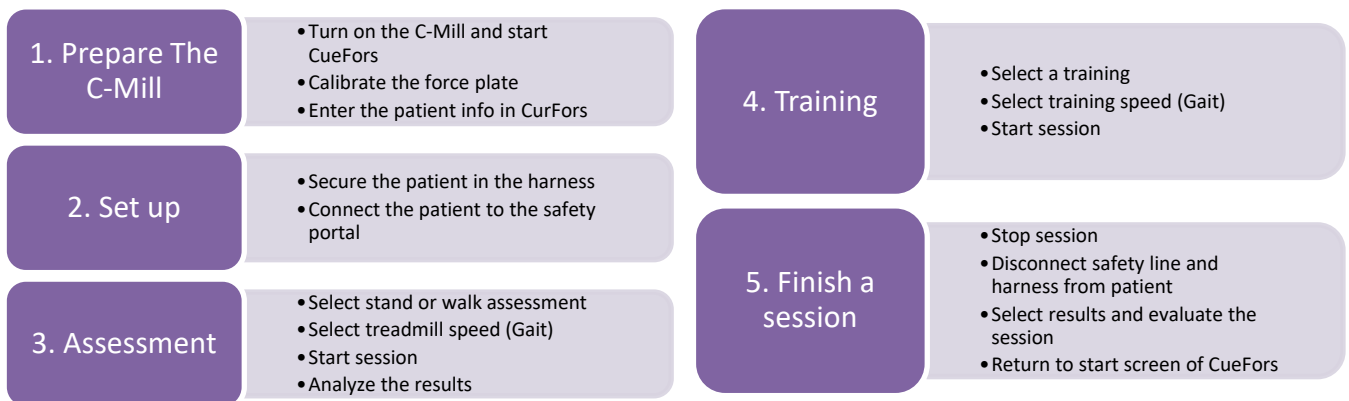
1.1 Intended use

The intended use of the C-Mill is to evaluate and train gait and balance of patients with balance and walking impairments (figure 2 and 3).



2 C-Mill Session Workflow

The following workflow is a *practical* guideline and can be used as a memory aid to standardize a training session on the C-Mill. The corresponding practical and theoretical information are thoroughly discussed during the User training. It is important to ensure the participants get as much hands on experience as possible.



3 C-Mill Therapy workflow

The C-Mill Therapy workflow is a clinical workflow and can be used to provide therapists a guidance for a complete C-Mill session, from intake to evaluation. The different phases are schematically presented in the figure below.



In this therapy phase the possible indications and contra-indications are discussed.

| |
|---|
| Indications |
| The C-Mill can be used for elderly with increased fall risk and patients with neurological, cardiovascular or orthopedic conditions affecting balance and gait. |

| Contraindications C-Mill |
|--|
| <ul style="list-style-type: none"> ▪ A severe cognitive, visual or hearing impairment where the patient is not able to follow the instructions of the operator. ▪ More than 135 kg total bodyweight or less than 25 kg* ▪ More than 2.00 meter body height ▪ Open skin lesion or bandage in the area of harness contact. ▪ < FAC 2** |
| Risk factors C-Mill |
| <ul style="list-style-type: none"> ▪ Severe reduced bone density ▪ Spinal instability or unstable fractures. ▪ Severe vascular disorders or cardiac abnormalities that affect the ability to exercise safely ▪ Running < FAC 5** |

* To ensure reliable force plate data

** FAC (Functional Ambulation Categories). See the FAC level explanation in paragraph 3.2 Intake.

3.2 Intake

| | Start level | Training goals |
|-------|---|--|
| Stand | FAC level \geq 1 (with BWS) FAC level 2 | - Dynamic balance - Weight shifting |
| Step | FAC level \geq 1 (with BWS) FAC level \geq 2 | - Stepping balance - One leg stance |
| Walk | FAC level \geq 1 (with BWS) FAC level \geq 3 | - Gait - Gait adaptability |

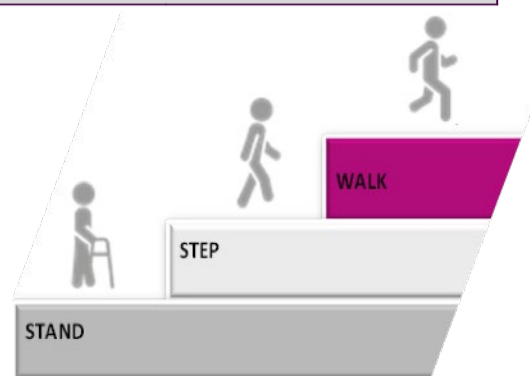
Categories

The three categories for the assessments and training with their corresponding therapy goals are:

Stand: Improve postural control while standing and shifting weight.

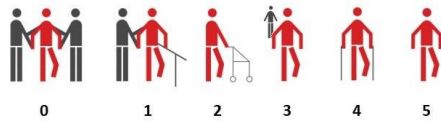
Step: Improve stepping balance, stepping ability and one-leg stance

Walk: Improve gait functionality and adaptability



Start level

Figure 4 provides the Functional Ambulation Categories (FAC) scores to determine the start level for Stand, Step and Walk.



- FAC 0: Patient cannot walk, or needs help from 2 or more persons
- FAC 1: Patients needs firm continuous support from 1 person who helps carrying weight and with balance
- FAC 2: Patient can walk with continuous or intermittent support of one person to help with balance and coordination.
- FAC 3: Patient can walk but requires verbal supervision/stand-by help from one person without physical contact
- FAC 4: Patient can walk independently on level ground, but requires help on stairs, slopes or uneven surfaces
- FAC 5: Patient can walk independently anywhere

3.3 Assessment

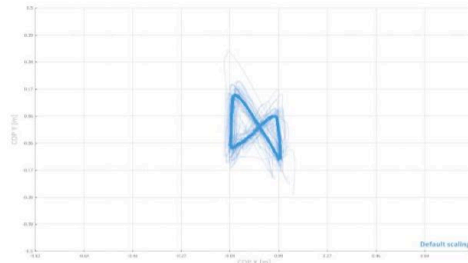
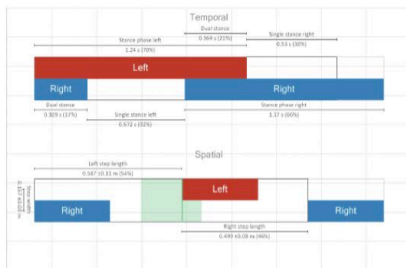
The assessments serve to measure the baseline level of the patient before setting the treatment goals

| Assessments | | | |
|---|---|---------------------|---|
| Category | Assessment goals | Assessment | Outcome measures |
| STAND | Static postural control | Postural stability | CoP velocity in cm/s |
| | Dynamic weight shifting in 4 directions | Limits of stability | CoP displacement in cm |
| WALK | Walking adaptability | C-Gait | C-Gait score |
| | Steady state gait | Walk assessment | Step length/Step width Stance duration / Step symmetry |
| Recording video is applicable during all sessions | | | |

Address the different outcome parameters of each assessment.

Spatial temporal

Butterfly



3.4 Training

In this phase the patient works on his/her specific treatment goals. These can be addressed in (custom) C-Mill protocols or by using manual control. Details of the training protocols will be explained during the training.

3.5 Re-assessment

This phase serves to monitor progression with another (the same) assessment to be able to compare the results with the previous assessment outcomes.

3.6 Evaluation

Re-evaluate the therapy with both patient and referring specialist.

References

- Fonteyn, E.M.R. et al., 2014. Gait adaptability training improves obstacle avoidance and dynamic stability in patients with cerebellar degeneration. *Gait & Posture*, 40(1), pp.247–251.
- Heeren, A. et al., 2013. Step by step: A proof of concept study of C-Mill gait adaptability training in the chronic phase after stroke. *Journal of Rehabilitation Medicine*, 45(7), pp.616–622.
- van Ooijen, M.W. et al., 2015. Improved gait adjustments after gait adaptability training are associated with reduced attentional demands in persons with stroke. *Experimental Brain Research*, 233(3), 1007- 1018.
- Hollands, K.L. et al., 2015. Feasibility and Preliminary Efficacy of Visual Cue Training to Improve Adaptability of Walking after Stroke: Multi-Centre, Single-Blind Randomised Control Pilot Trial. T. J. Quinn, ed. *PLoS one*, 10(10), p.e0139261.
- Houdijk, H. et al., 2012. Assessing Gait Adaptability in People With a Unilateral Amputation on an Instrumented Treadmill With a Projected Visual Context. *Physical Therapy*, 92(11), pp.1452–1460.
- Papegaaij, S. et al. 2017. Virtual and augmented reality based balance and gait training.