

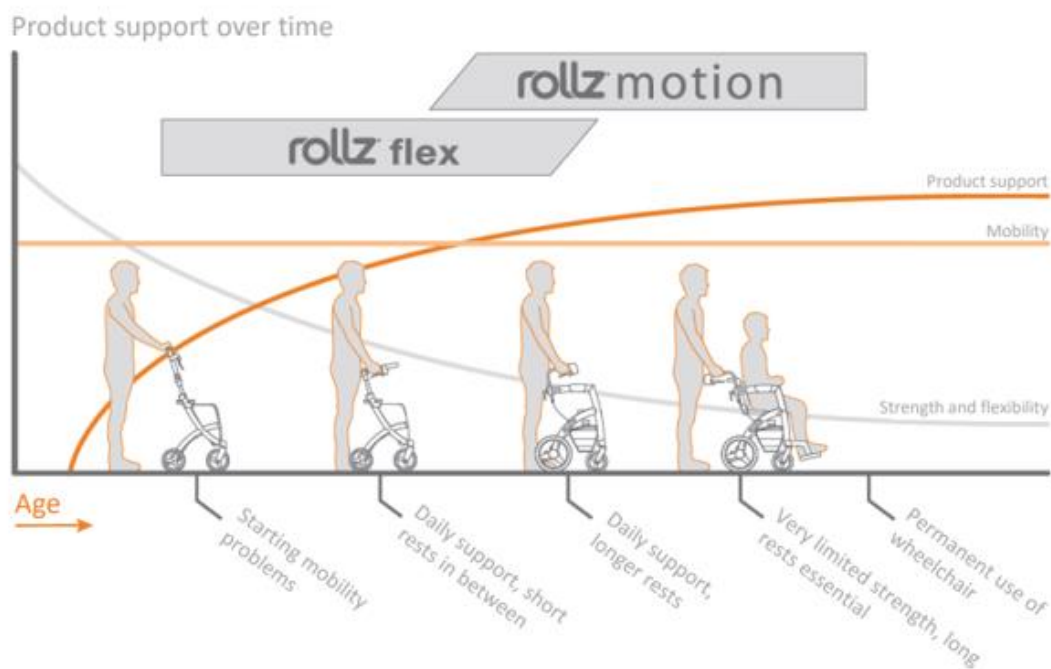
Summary of the Parkinson Rollator

rollz motion rhythm



About Rollz

We believe that a human has no shortcomings, only the technology is lacking to support one properly. By adapting the technology to the abilities of someone, the abilities and possibilities of the user enlarge. Rollz develops products that support the user in the mobility he or she needs to participate in society again and to live life to the fullest.



How we got to the first certified Parkinson Rollator

In 2017 we found out that a majority of our Rollz Motion users were people with Parkinson's disease. After market research we found that current Parkinson rollators do not meet the needs of the Parkinson patient.

We at Rollz International, discussed our findings with several medical specialist and we realised it was necessary to build the first rollator that meets the European Standards, in the attachment you will find all mandatory guidelines regarding safety and health risks as a certified laser (that will not cause blindness or eye-damage), radiation standards and TUV norms.

Rollz Motion Rhythm

The Rollz Motion Rhythm is a highly manoeuvrable rollator with unmatched stability and premium quality brakes. The large wheels cross obstacles easily and a folding mechanism allows compact transportation.

Multiple cues are included to help one regain or keep up the walking pace. Especially Parkinson's patients benefit from these product features and the adjustable rhythmic cues.

Multiple cues in one rollator

No Parkinson's patient is alike, so how could one rollator fulfil all their needs?

The Rollz Motion Rhythm packs multiple cues together that can be (de)activated on the go. This unique combination allows Parkinson's patients to always have the right cue at the right moment. Furthermore, each cue can be adjusted to perfectly fit the user's needs in terms of speed, intensity, and duration. This way, every person living with Parkinson's can use it in their own rhythm.

Regain your rhythm at the push of a button



A green laser line is projected onto the ground. This visual cue not only stimulates to break a freeze, but also improves the stride length and walking speed.



Handles vibrate at the rhythm of the pace. A big advantage of this tactile cue is that it is not noticeable by the surrounding people.



A metronome can also signal the preferred step frequency. The acoustic rhythm contributes to regulating the walking speed.

See the effect of the Rollz Motion Rhythm cues on a user on our Youtube channel: [RollzInternational](#). The effect can be seen in the following videos: 'Walking with and without Rollz's Parkinson's rollator' and 'Rollz Motion Rhythm tested by a Parkinson's patient'.

Synchronise your Rhythm to your phone

The app can be used to give the cues in sync with the rollator. While wirelessly connected to the Rollz Motion Rhythm, the smartphone can vibrate and/or play the metronome along with the rollator to increase the intensity of the cue.

The cues can be played solely on the smartphone as well. This enables to plug in earphones and to hear the metronome more privately. This enables the user to use the cues without others being aware they are doing so.

Literature review

Walking improves through clever use of newly discovered compensation strategies with a walking aid

The walking pattern in people with Parkinson's disease is characterized by slow, small, and shuffling steps with a reduced step height, a bent posture, an asymmetrically reduced arm swing and episodes of 'freezing' the feet while walking.

During freezing of walking, people with Parkinson's feel like they suddenly get stuck to the ground. This freezing usually occurs when starting to walk, while making a turn, when walking through a door frame, and also stress can provoke freezing. Because the feet suddenly stick, but the upper body moves forward, freezing while walking often leads to a fall and fall-related injuries.

Freezing therefore has a huge impact on the quality of life of people with Parkinson's disease. Special rollators have been developed that benefit many Parkinson's patients. These rollators provide extra stability because they have a U-shaped frame within which the patient walks. This stimulates the user to walk upright as much as possible. Sturdy manoeuvrable wheels make the rollator suitable for both indoor and outdoor use. In addition, these rollators come with a green laser light that projects a line onto the ground that the patient can step over. This acts as a visual cue and therefore helps with freezing problems. In addition to the visual cue, the Rollz Motion Rhythm also has an audio cue built in where different tone heights (and lengths of the cue) can prevent the user from ending up in a Freeze again.

During the development we found that users are also helped with vibrations in the handles, these are less conspicuous and therefore easier to use so as not to stand out. The combination of the three cues is also possible, so they can be used independently of each other. This allows us to support mobility from the diagnosis and can always adjust the cues with Physiotherapy and Occupational Therapy to trigger the end users to keep moving. The braking system can also be operated with one hand if desired. Even if the patient sits on it (and wants to use the device as a kind of triple chair), with the handbrake it does not roll away when standing up or sitting down.

The Parkinson's rollator has a small turning circle (< 85 cm), making it easy to use in small spaces such as toilet, bathroom, and kitchen. In addition, an additional drag braking function (with desired resistance and if necessary asymmetric) can be set for additional control. For the application of such a complex walking aid, it is desirable - and often necessary for reimbursement - for the patient to first try out the walker with the physiotherapist. This makes it clear whether it does indeed have added value and arguments for the application can be collected.

Below is a description of categories used in compensating for walking disorders in Parkinson's disease. In fact, with the Rollz Motion Rhythm we can contribute all six programs of walking to improved mobility as a training tool or in general daily use. If necessary, the Rollz Motion Rhythm can still be used as a wheelchair (with a conversion kit) so that it can still be used well after the diagnosis of Parkinson's disease. In addition, the Rollz Motion Rhythm can also be used when returning a product. After an inspection, the system can be used again by another user.

European Physiotherapy Guideline for Parkinson's disease

Aids, such as a walking stick, a wheeled walking frame, poles (Nordic Walking) or a bicycle with an electric aid engine can support exercising and increase a pwp's (Person with Parkinson's) independence and safety. However, at the same time they can make walking more complex, as using an aid while walking may be considered a dual task. Moreover, inadequate use of aids can worsen posture. For safety reasons, pwp with freezing episodes are advised against using a standard walking frame. They benefit more from a wheeled walking frame with compression-type brakes activated when the pwp leans on the frame. Pwp who benefit from visual cueing may benefit from a wheeled walker projecting a laser line on the floor to step over.

In case of severe difficulty in maintaining balance, a wheelchair should be advised because of co-morbidity related to a high risk of falling. Whether it falls inside the scope of the occupational therapist or rehabilitation physician to provide information on aids and support pwp in the application for the aids, it is often the physiotherapist who trains pwp in correct use of the aids (Keus et al., 2014, p. 71).

Movement strategy training

The rationale of movement strategy training is to compensate for the deficits with the internal (automatic) generation of behaviour. It includes cueing, attention, and strategies for complex motor sequences. When the strategies are applied to activities, they induce motor learning, possibly by gaining efficiency in compensatory pathways. To improve transfers or manual activities, often a combination of cueing, attention and sequencing strategies is used. To improve gait, often a combination of cueing and strategies for complex motor sequences are used (Keus et al., 2014, p. 81).

Cueing and attentional strategies

GRADE-based recommendations for cueing and attentional strategies

Strong recommendation for using cueing for gait to improve:

- Walking speed

Weak recommendation for using cueing for gait to improve:

- Step length
- Gait related balance capacity (DGI)
- Movement functions (UPDRS III; UPDRS posture & gait score)
- Freezing of gait (FOG-Q)

Weak recommendation for using cueing during transfers to improve:

- Functional mobility (timed sit-to-stand)

Weak recommendation against using cueing for gait to improve:

- Stride length
- Cadence
- Functional mobility (TUG)
- Standing related balance capacity (Functional Reach)
- Balance performance (FES, ABC)
- Quality of life (PDQ-39) (Keus et al., 2014, p. 81).

GDG advice: cueing and attentional strategies

- Set and agree upon individual, SMART goals in collaboration with the PWP (Person with Parkinson's) (also in case of group treatment)
- Provide physiotherapist supervised training, supported by self-supervised exercising on other weekdays: facilitate a home exercise program, using an Exercise Diary
- Train cueing for a minimum of three weeks, three times a week for 30 minutes – longer for attentional strategies and when people are in advanced stages
- Start with exploring the PWP's own tricks and tips
- Examples of cueing strategies:
 - Visual: stepping over strips(s) of tape on a floor, someone's foot or a laser line projected on the floor
 - Auditory: walking on the beat of a metronome or PWP preferred music such as by using a smartphone
 - Tactile: walking on the vibration rhythm of a vibrating wrist band
- Frequency of cueing:
 - Use the 6MWD or 10MW to determine baseline step frequency
 - To improve walking distances (specifically outside the pwp's home) in non-freezers; explore cueing frequencies up to 10% above baseline frequency.
 - To improve gait stability during functional and complex activities, mostly inside the pwp's home; explore cueing frequencies up to 15% below baseline frequency.
 - To improve gait in Freezers: explore cueing frequencies up to 10% below baseline frequency
- Examples of attentional strategies
 - Thinking about taking big steps
 - Choosing a point of reference to walk towards
 - Making wide turns (arc versus pivot)
 - Lifting knees high-up
- Examples of attentional strategies to initiate movement:
 - Rocking from left to right before starting to walk
 - Combine rocking with the instruction (of thinking) of taking a big step
 - Taking a step backwards before starting to walk
 - Suddenly swinging the arms in front (pointing the direction)
 - For bed transfers: Rocking bend knees from left to right before rolling over.
 - For Chairs transfers: Rocking truck forwards and backwards before rising from a chair.
- If feasible and safe, support pwp towards non-physiotherapist supervised cueing with intermittent follow-up: discuss this early in a treatment period to set realistic expectations (Keus et al., 2014, p. 82).

User research Rollz Motion Rhythm

Which parameters of the gait pattern can predict a freezing of gait and to what extent do these gait parameters change in the phase prior to a freezing or gait?

A literature search has established that a freezing of gait can be predicted on the basis of the gait speed, stride length, step frequency and duration of the uni- and bipedal phase (Ferster, Mazilu & Tröster, 2015; Nieuwboer et al., 2001). The extent to which these predictive parameters change prior to a freezing of gait are mainly based on a study population that does not use medication to suppress Parkinson's disease symptoms (Nieuwboer et al., 2001). However, in everyday life, Parkinson's patients who rely on a walking aid, such as the Rollz Motion Rhythm, are unlikely to take any medication. It is therefore important that the rate of change in gait speed, stride length, step frequency and duration of the uni- and bipedal phase in the phase prior to a freezing of gait is determined for a study population using Parkinson's medication.

The second pilot measurement shows that a number of freeze-provoking factors actually induce a freezing of gait and that it is quite possible for the Parkinson's patient to go through the entire measurement setup. It can be concluded that the established measurement protocol is suitable for generating a freezing of gait, so that the parameters can be measured in the phase prior to a freezing of gait. If the measures regarding COVID-19 permit this, it is recommended to perform the established measurement protocol with a larger study population using Parkinson's medication. Based on the degree of changes in the predictive parameters that follow from this, it can be determined when the Rollz Motion Rhythm's cues should turn on.

Archi, paleo and neo levels

The basal nuclei, including the substantia nigra pars compacta, are part of the paleo level of the brain. According to Cranenburgh (2016), there are three hierarchical levels in the nervous system: the archi-, paleo and neo levels, see figure 1.

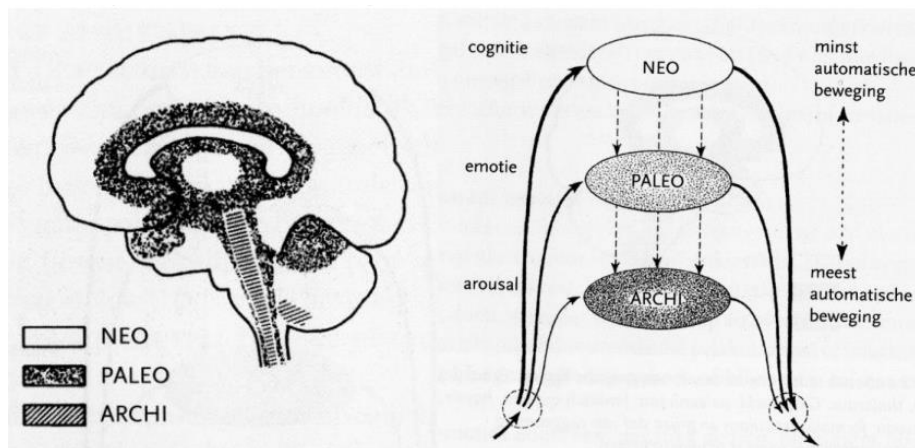


Figure 1: Hierarchical Levels in the Nervous System. Left: anatomical position, right: the phylogenetic model of the archi-, paleo and neo levels (van Cranenburgh, 2016).

The components of the archi level serve the most automatic functions such as the consciousness and reflexes. The paleo level is responsible for emotions and automatic movements, such as walking or writing. The neon level makes it possible to acquire new skills and relates to functions such as cognition and language.

When the function of the basal nuclei is compromised by Parkinson's disease, there is one lesion at the paleo level. This creates problems with automatic movements such as walking or writing (van Cranenburgh, 2016). In addition, there are motor symptoms that cause movement hindering, such as bradykinesia, freezing or gait, festinations, hypokinesia, rigidity, resting tremors, and posture and balance problems during movement (Michel et al., 2016; Beitz, 2014).

However, with conscious effort it is possible for the patient to perform the movements and suppress the symptoms, when the patient consciously thinks about the movements, he or she is doing it carries out, the movement takes place at the neo level. This level has not been affected and can therefore take over the function of the paleo level. In practice, however, it turns out that it is not possible to perform movements consciously for a long time, because over time the concentration on the movement sinks and switches the paleo level back on (van Cranenburgh, 2016).

External stimuli, such as visual, auditory, or tactile cues can help to return the information exchange via the neo level progress and thereby stimulate exercise (Ashoori et al., 2015; Nombela et al., 2013; Jiang & Norman, 2006; Fernandez del Olmo & Cudeiro, 2003).

As written in the literature review by M. Schmitz (2020).

Do the functions of the Rollz Motion Rhythm contribute to an improved user experience of the user with Parkinson's and an improved walking pattern?

The purpose of this research was to find out whether the functions of the Rollz Motion Rhythm contribute to an improved user experience and to an improved walking pattern of the user with Parkinson's.

This research shows that the curve laser, the vibration and the at random metronome contribute to an improved user experience. From the questions asked and the grades given to the cues, score the vibration and the at random metronome higher than the cue where there is one pitch being played. The laser projected on the ground would make for better user experience when its placement changes.

The subjects were from thought that the laser should be projected a bit more forward. Subject 1 wanted they would rather have projected the laser in front of the rollator, to walk towards the line each time. Test subject 2 wanted the laser to be projected 20 cm forward from the current spot, because then the test subject would have to look down less. To further optimize the walker, the height of the tones can be adjusted, so that people with poor hearing can also hear it well.

The bend laser was experienced as pleasant and helped to make a bend. The at random metronome contributes the most to an improved gait pattern. The subject walks during this cue with the smallest step frequency and the longest stride length (van Dijk, L., 2021).

Comments of Prof. PT Abe and 2 others PT at Rehabilitation Amakusa Hospital Japan

Triggers

GOOD:

- 1) Because condition of FOG (Freezing of the gate) differs between the patients, the variations of triggers are good. The rollator for FOG can adapt for a lot of patients.
- 2) Laser is effective for some patients.

ISSUES:

- 1) The therapists want triggers which do not stop.
- 2) They had not used a trigger of sound or vibration to their patients, so they were not sure about the effect of the trigger.

Buttons on the grips

GOOD:

- 1) Easy to use for patients and caregivers.
- 2) Simple for caregivers who are not good at the electric appliance.
- 3) The rollator let patients go out, e.g., shopping with caregivers.

ISSUES:

- 1) Can patients press the button immediately to restart the triggers?
- 2) It might be better if users can select the trigger with the grip button.

App

GOOD:

- 1) Easy to use.
- 2) There are a lot of combinations of triggers, so the rollator can be tried for patients with various symptoms.

ISSUES:

- 1) Can old caregiver use the App? (Frontier (agency of Rollz International for Japan)) needs to set up all.)
- 2) If the rollator can be set up several patterns for one patient according to the situation, it would be better.

Requests or wishes

- 1) Because Parkinson symptom is a progressive disease, the therapist wants an option of an elbow holder, not grips.
- 2) Because patients tend to stand away from the rollator, it will be better to light the laser nearer the feet.
- 3) Parkinson's patients are not good at making turns. For example, it is difficult for them to step back and turn to sit on the toilet, so the therapist wanted a wider angle of the laser.

Suitable users

- 1) Patients who need the service of visiting nursing
- 2) Patients who are always attended by their family or caregiver and the patients can follow the usage correctly
- 3) Patients who can walk again after a break or who can be taken home in the wheelchair (a separate accessory for the Rollz Motion Rhythm which makes the rollator into a pushing wheelchair) by their caregiver when they get tired.

4) Patients with Neurological intractable diseases. Parkinson's patient is less common in those with cerebrovascular disorders.

Other comments

1) Suitable for rental at hospitals.

2) Good for evaluations at hospitals. The therapists really wanted to try it with patients.

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Appendix



Security measures during development Rollz Motion Rhythm

- NEN-EN 111999 Loophulpmiddelen die met beide armen worden bediend – Eisen en beproevingsmethoden – Deel 2: Rollators.
- NEN-EN 12182:1999 Technische hulpmiddelen voor gehandicapten – Algemene eisen en beproevingsmethoden.
- NEN-EN 12183 Manual wheelchairs – requirements and test methods.
- NEN-EN 14971:2001 Medische hulpmiddelen – Toepassing van risicomangement voor medische hulpmiddelen.
- NEN-EN 1985:1998 Loophulpmiddelen – Algemene eisen en beproevingsmethoden.
- ISO 7176-1:2000 Wheelchairs – Determination of static stability
- ISO 7176-3:2000 Wheelchairs – Determination of effectiveness of brakes
- ISO 7176-5:2000 Wheelchairs –Determination of overall dimensions, mass and turning space
- ISO 7176-7:2000 Wheelchairs – Measurement of seating and wheel dimensions
- ISO 7176-8:2000 Wheelchairs – Requirements and test methods for static impact and fatigue strengths
- ISO 7176-16:2000 Wheelchairs – Resistance to ignition of upholstered parts – Requirements and test methods
- ISO 7176-22:2000 Wheelchairs – Set-up procedures
- NEN-EN-ISO 16840-3:2006 Wheelchair seating – part 3: Determination of static impact and repetitive load strengths for postural support devices
- NEN-EN-IEC 60825-1 (en) Safety of laser products - Part 1: Equipment classification and requirements (IEC 60825- 1:2014)