

Instructions for Use

VGK-Go!



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Use the *Final Checklist* on page 16 to check the essential installation points

1 Introduction

1.1 Intended purpose

The VGK-Go! is intended to be solely used in lower extremity prosthetic limbs as a prosthetic knee joint to assist ambulation and activities of daily living. The product can be used for uni- or bilateral amputation. The VGK-Go! is compatible with osseointegration, however, permission MUST be obtained from the manufacturer prior to use with osseointegration. Permission for use with osseointegration is considered on a case-by-case basis.

The VGK-Go! is best used for medium and long femur length in the residual limb. For short transfemoral the VGK-S is recommended, and the VGK-X is a good alternative for people with body weight under 80 kg. Please see our website www.orthomobility.com

1.2 Technology

The VGK-Go! is a **Fluidic Processor Knee (FPK)**, which uses fluidic sensors to respond to changes in gait in real-time, by adjusting motion resistance within a single step.

1.3 Recommended user profile

The VGK-Go! is recommended for independent prosthetic users typically of mobility classes 1-4**. The user's body weight can be up to 125 kg.

** Users with significant comorbidity must be carefully monitored in the rehabilitation period to ascertain the suitability of the device for their needs.

1.4 Installation and adjustments

The VGK-Go! must be installed by a Certified Prosthetic/Orthotist (CP or CPO) to make sure the alignment and control settings are adjusted safely.

The user may adjust the controls under the guidance of their CPO. The CPO must assess whether the user is able to adjust the knee joint safely. There are special instructions with regards to use in a wet environment that must be passed to the user by the CPO.

1.5 Compatibility

The VGK-Go! is compatible with the full complement of prosthetic components, energy-storing feet,

hydraulic ankles, hip components, shock absorbers, etc.

1.6 Lifetime of the device

In compliance with the EU Medical Device Regulations, Orthomobility has defined a maximum usage period of **5 Years + 3 months for VGK-Go!**. The rate at which the device is used will vary between patients, but this limit puts a practical, manageable, and measurable limit on its use. The additional “3 months” have been added to allow time for shipping and replacement limb fitting.

VGK-Go! must not be used after the maximum usage period. The **usage period starts on the date of shipment by the distributor** and this date appears on the product label. If the shipping date is not known, the date of invoice will be used. Please contact the distributor if the start date is not available.

1.7 Identification of the device

A VGK-Go! unit may be identified with the serial number that is engraved on the product, as shown in **Fig 1.1**.

1.8 Normal use (note stairs)

The VGK-Go! has been developed for ambulation and ordinary mobility use: walking, sitting, kneeling, cycling, and occasional wetting by rain or tap water. The use of handrails or bannisters is recommended when descending downstairs. Note: to set up the knee for cycling requires a special procedure to be followed.

1.9 Contact with water

The VGK-Go! is suitable for occasional use in water up to a depth of 1.5 m. However, the knee joint has no buoyancy in water. There is also a risk of snagging on plants or objects.

If the knee joint is to be used in wet environments more frequently than once a month, this requires the manufacturer’s prior agreement such that a care and maintenance program can be discussed. The manufacturer may limit the use of the knee joint in wet environments if a care and maintenance program is not followed. Also note the instructions in **Section 6**.

1.10 Expectation management

Please advise the user that this device is designed to offer functionality that is compatible with a high level of safety. The high level of safety is likely to elevate their expectations of their ability, and consequently your patient may find limits in the performance of the device. When such an event happens, they are asked to record the circumstances and report the event back to their CPO.

1.11 Irregular and extreme use

Irregular and extreme use may occasionally be required and this should be agreed with the manufacturer beforehand. Such use may involve water and dirt, mechanical shock and forceful use. Whereas these may be considered as part of intended use, it will be required that written permission is sought from the manufacturer so that such irregular use can be risk assessed, supported, or denied on grounds of risk. A considered permission/denial/support programme will be discussed on request. Use of the product in a sauna is excluded. Avoid sand entering the knee.

1.11.1 Extreme temperature

The VGK-Go! has been designed for a stable performance over a range of temperatures. The use in very low temperatures (sub-zero) may cause some stiffening in the swing and yield action of the joint, which in hands-free slope and stairs descent could cause an imbalance. In this instance, it is advised to first try using it close to a handrail. In elevated temperatures (40 degrees plus), the VGK-Go! maintains its performance fairly well.

1.11.2 Extreme device settings

The VGK-Go! permits a high level of resistance in yield. The device has been designed to contain hydraulic pressures that arise during normal use, including leg-over-leg stair descent. However, when significant weight is placed on the leg, the device is *not intended to be loaded in flexion in a 'locked' mode*.

1.12 Body weight and additional load

The VGK-Go! has been designed to allow for a patient body weight of 125 kg and these persons, at this maximum body weight, to carry not more than 15 kg of additional load on a daily basis.

1.13 Prevention of overheating

Do not use VGK-Go! in the sauna because the heat may damage the metal surfaces. When used intensively, allow heat to escape via the frame by avoiding use of cosmetic foam covers.

1.14 Wear and tear

As with any device with mechanical elements, mechanical wear and tear will eventually occur, and the user and CPO are required to see that regular inspections and maintenance are carried out. Fair wear and tear includes the possible formation of corrosion due to regular wet use, especially in salt and chlorinated water, and urine. Cleaning with fresh water may reduce the impact of salt and chlorinated water. Fair wear and tear falls outside the standard scope of warranty.

1.15 Storage

The VGK-Go! must be stored in an extended position.



Fig 1.1: Location of serial number

2 Alignment

2.1 General alignment

The alignment of the knee joint must follow the straight hip-knee-ankle line. The 'Ankle' refers to where the natural ankle would be, that is between $\frac{1}{4}$ and $\frac{1}{3}$ of the foot length. Ideally the knee axis should be 10 mm behind the hip-ankle line (see [Fig 2.1](#)).

2.2 Leg length

To help the user easily initiate the swing release, the prosthesis length must be assessed as a LEVEL pelvis, or no more than 10 mm shorter. **DO CHECK THE LEG LENGTH.**

2.3 Socket flexion

A vertical hip-knee-ankle line must be maintained as well as possible, even if initial hip flexion is required in the socket. This may be achieved by moving the socket and foot forward relative to the knee joint, and letting the user exercise a small amount of hip extension to maintain extension of the knee (see [Fig 2.2](#)).

2.4 Foot alignment

The VGK-Go! requires a toe load in late stance to release into swing. Too much dorsiflexion of the foot may make it difficult to release the knee into swing if there is insufficient forefoot loading. Equally, an unusually high heel on the shoe will reduce the effective length of the foot and therefore may cause difficulty for swing release.

2.5 Kneeling

Extreme or maximum knee flexion will cause the socket to touch the hydraulic unit. This unit can take the forces of kneeling and squatting provided the contact is made in the region as indicated in [Fig 2.3](#). It is important to measure the indicated contact point to be 100 +/- 5 mm from the knee axle. If required, the socket may need a local build up, so that the internal structure of the hydraulic takes the load at the correct point. **DO** adhere to this rule. Alternatively, the socket may rest on the frame of the knee.



Fig 2.1: Alignment of VGK-Go!.

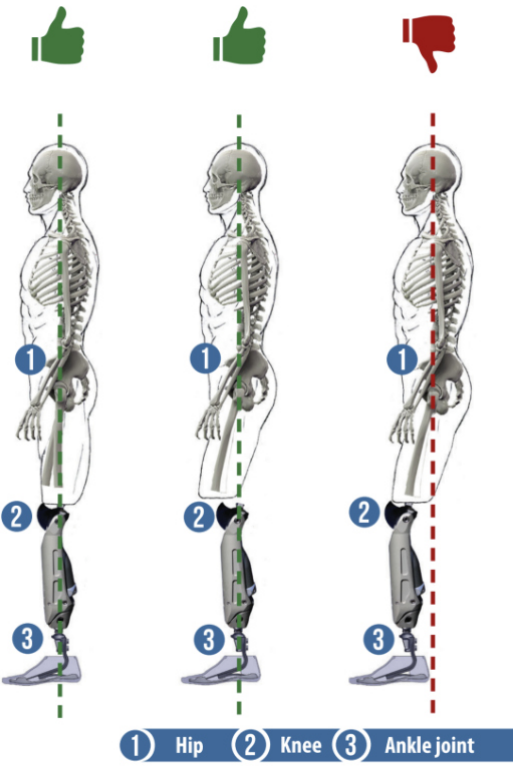


Fig 2.2: A vertical hip-knee-ankle line is the preferred alignment. A posteriorly placed hip/greater trochanter is liable to make swing release more difficult.



Fig 2.3: Kneeling onto the cylinder is permissible when the contact point is in the green regions

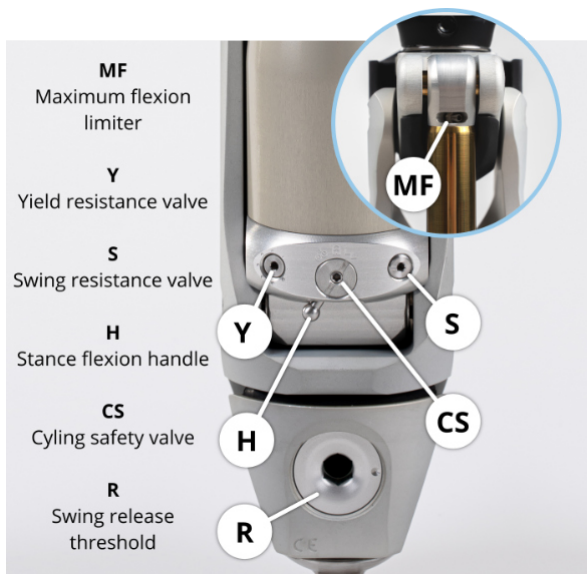


Fig 3.1: Locations of controls for clinical adjustments

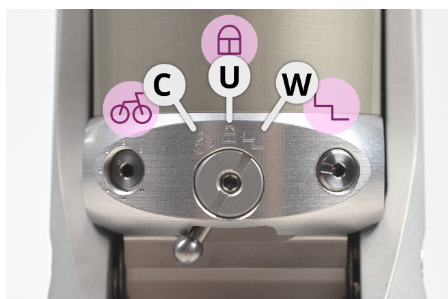


Fig 3.2: Positions of the Stance Flexion Handle



Fig 3.3: Avoiding unintentional swing release

3 Controls

3.1 Swing release

3.1.1 Setting swing release threshold

The VGK-Go! relies on the presence of knee extension and toe-load for swing-phase release. This condition is natural in terminal stance. For most users this switching behaviour is set to be as light as possible. For bilateral amputees, the transition may need to be more deliberate to secure standing balance. If the threshold for switching to swing-phase must be increased, the Swing Release Threshold, **R** in **Fig 3.1**, is turned clockwise using a 8 mm Hex key.

The VGK-Go! senses toe load by a slight swivelling action of the distal knee section. There is a spring system (a green spring) in the distal knee, which for safety allows the distal knee to be biased to the stance-phase position. When weight is placed on the forefoot, the distal knee can overcome the spring tension and swivel into the swing-initiation position. Therefore the more the spring is preloaded (by clockwise turning **R** in **Fig 3.1**), the higher the toe-load must be to cross the threshold for swing initiation. There is only a limited range of adding pre-load! A stiffer (red) spring can be ordered in case the tension needs to be higher. When used outside the parallel bars, no slack rocking action may be present between the frame and the distal knee.

3.1.2 Conditions for swing release

The knee joint will release into the swing phase when there is a hyperextension moment, immediately followed by a high knee flexion moment. Using the knee joint in a forceful way can, in exceptional circumstances, lead to an unintended release into the swing phase. An example of such non-recommended use is attempting to land hard on the mid-foot onto a curb or step (see **Fig 3.3**). This user-induced failmode is unlikely to happen in ordinary walking. User confidence in the VGK-Go! should not be lost, provided the usual behaviour continues after such an incident or event of exceptional use.

3.2 Stance Flexion Handle

The use of yield resistance (stance resistance) is set using the stance flexion handle, H in Fig 3.1. See Fig 3.2 for possible positions of handle H.

Position	Description
W	Stairs mode. Stance resistance compatible with ordinary walking, including stairs and slopes (adjustable)
U	Ultra high stance resistance
C	Cycle mode, which is a free mode with safety catch for when the piston exceeds a threshold speed (threshold is adjustable)

4 Adjustments

4.1 Adjusting the stairs mode

See [Fig 3.1](#) and [Fig 3.2](#). The stairs mode is selected by positioning the stance flexion handle (H) in position W. The rate of knee flexion in stance can be adjusted with the Yield Resistance Valve, Y. Use a 2 mm Hex key to turn the valve anticlockwise for faster knee flexion, or clockwise for slower knee flexion.

To get the right setting for the user, allow them to descend from the last step of a stairs and adjust the valve until it is comfortable. Then adjust the valve further as required to accommodate more steps being taken in sequence.

DO take note that the resistance in stumble recovery = the resistance in stance mode. Therefore it is recommended to keep the stance mode resistance as high as is comfortable.

4.2 Ultra high resistance mode

See [Fig 3.1](#) and [Fig 3.2](#). The ultra high resistance mode is selected by positioning the stance flexion handle (H) in position U. This mode effectively blocks the yielding, but allows free swing (as long as the walking speed is not too high). For this reason, this mode is NOT A FULL LOCK. The user can still release the knee into the swing phase.

4.3 Adjusting the cycle mode

See [Fig 3.1](#) and [Fig 3.2](#). The cycle mode is selected by positioning the stance flexion handle (H) in position C. In this mode, there is a safety catch that kicks in when the knee flexion speed crosses a threshold.

The factory setting of the cycling function is ultra-safe! In this factory setting, the cycling function may not work for the user. Use the Cycling Safety Valve (CS in [Fig 3.1](#)) to lower the safety threshold, therefore permitting higher cycling speeds.

4.3.1 Bench testing cycle mode

Bench test the prosthesis to become familiar with the cycling settings. Turn the stance flexion handle to cycling mode and observe that in the factory setting, the knee does not bend easily. This is because the safety valve activates almost

immediately. To turn the safety valve off, dial in the Cycling Safety Valve (CS in Fig 3.1) fully. Now the safety valve is effectively off and the knee should bend very easily irrespective of the flexion speed. By incrementally winding the Cycling Safety Valve screw anticlockwise again, a setting can be found where slow flexion movement is easy but fast movement incurs resistance. This is the basis for the VGK-Go! to differentiate between the slow cycling movement that is to be permitted, and fast movement that may occur if the patient tries to walk on the knee and it has accidentally been left in the “cycling mode”.

4.3.2 Clinical set up of cycle mode

For clinical set-up, first select the cycling mode and turn off the safety valve (by dialling in the Cycling Safety Valve, CS in Fig 3.1, fully). Now, let the user cycle and incrementally dial out the safety valve until the safety feature applies itself during cycling. Agree with the user how much to reduce the sensitivity of the safety feature, where if they simulated a collapse, they would still feel confident afterwards walking on it. Naturally, if faster cycling is required, there is less safety available in walking!

4.4 Swing phase adjustments

4.4.1 Maximum knee flexion limitation in swing

Reducing the maximum permissible knee flexion creates more forward drive of the knee. This is the MAIN control for swing phase adjustments.

The Knee Flexion Limiter (MF in Fig 3.1) is operated with a 1.5 mm Hex key. The valve is factory set with maximum knee flexion. To reduce the maximum permitted knee flexion, slot in the Hex key and slide the Knee Flexion Limiter over to the left (do not turn the key, only swivel across as in Fig 4.1).

4.4.2 Nominal swing phase resistance

If there is insufficient forward drive of the shin, even after adjusting the maximum knee flexion, the swing resistance can be increased. The Swing Resistance Valve (S in Fig 3.1) is operable using a 2 mm Hex key.

4.4.3 Terminal impact damping

The terminal impact dampening is auto-corrective and dynamically adjusts itself to the walking speed, and is not otherwise adjustable.

NOTE: there is no external adjustment to alter the extension resistance.

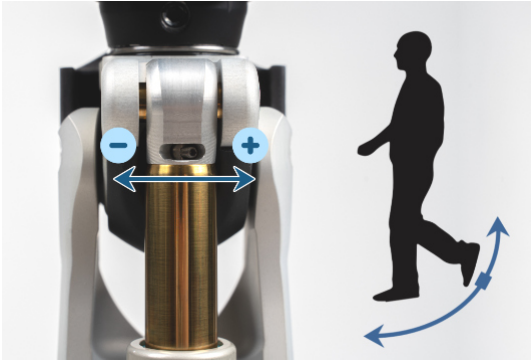


Fig 4.1: Adjustment of the maximum knee flexion

5 Finishing check points

5.1 Essential movement in mechanism

An essential part of the VGK-Go! mechanism is the slight swivelling motion in the distal knee section. The small gap between the distal knee section and the main frame must remain free of cosmeses, glue, dust particles, wedges, or anything else that could inhibit the movement. Warn the user against ingress of objects between moving parts and recommend a quarterly visual inspection. In case of doubt, a planned inspection by the clinician is recommended.

5.2 Cosmetic cover

When using a cover, regularly inspect the knee in case anything has fallen into the knee, to prevent damage between moving parts. Also ensure that the cover does not inhibit the essential movement described in [Section 5.1](#).

5.3 Final checklist

Use this checklist to finalise the set-up of the VGK-Go!:

- Socket contact in safe position? (see [Fig 2.3](#))
- Knee aligned **10 mm** behind Hip-Knee-Ankle?
- Is the pelvic level with contralateral side, or less than 10 mm shorter?

6 Care and maintenance

Regular inspection of the knee is recommended to prevent damage from accidental ingress of dirt and other foreign objects. Cleaning is mandatory if the device is exposed to a corrosive wet environment, such as salt or chlorine water, sand or urine. In this case, thoroughly hose down the knee joint with tap water and leave to dry. Any corrosion and subsequent damage is fair wear and tear.

If surface corrosion becomes visible, the user must inform their CPO so that an assessment can be made as to whether this could affect structural strength. This is particularly important when corrosion becomes noticeable in the form of lines that could indicate the onset of cracks. If in doubt, do not use the device and contact the manufacturer for advice.

The CPO must advise the user not to use the knee joint if it starts to malfunction. The user must inform their CPO of suspected device malfunction.

There is a risk of finger trapping between moving parts. Keep hands away from moving parts when bending the knee.

Please refer to www.orthomobility.com for more specific maintenance instructions

7 Product Disposal

Product disposal is covered on the website: www.orthomobility.com/disposal/

8 Warranty

Orthomobility Ltd. provides a time-based warranty against defects in materials and workmanship in accordance with terms and conditions of sale, and only when bought from approved suppliers. Defects arising from irregular and extreme use, and fair wear and tear are subject to the manufacturer's discretion. REGULAR/PLANNED WET ENVIRONMENT USE requires the manufacturer's AGREEMENT. As the use of a prosthetic device includes inherent risks, the manufacturer limits the liability arising from the use of the VGK-Go! to that liability directly arising from a malfunction of the device, due to faulty materials and/or workmanship and

excludes any other special, incidental or consequential damages. There is no implied warranty for corrosion-related breakdown following regular use in a wet and corrosive environment, where this has not been mitigated by thorough cleaning. For full details see Terms and Conditions on invoice.

9 Liability

The manufacturer liability for the use of the VGK-Go! is limited to faults that occur from a malfunction of the device, caused by faulty materials and/or workmanship and exclude incidental damage due to misuse. The manufacturer cannot take liability for continued use of a known malfunctioning device. For full details please refer to the Terms and Conditions provided on the invoice.

10 Reporting of a serious incident

VGK-Go! is a low-risk, Class I medical device. In the unlikely event of a serious incident in relation to the device, the incident should be reported to the manufacturer (Orthomobility Ltd.) and the competent authority of the Member State in which the user and/or patient is established.

11 Declaration of conformity



The VGK-Go! and its variations made by Orthomobility Ltd, Reg 5143375 conform to the Medical Device Regulation 2017/745. See www.orthomobility.com for the full declaration of conformity.



The VGK-Go! and its variations made by Orthomobility Ltd, Reg 5143375 conform to the UK Medical Devices Regulations 2002. See www.orthomobility.com for the full declarations of conformity.

12 Manufacturer details

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