VGK
very good knee

Instructions Manual

Orthomobility
naturally adaptive

Contents

1. α-logic Control

The technology means to adjust the valve settings in accordance to user demand, i.e. to regulate the power that produces the desired motion and functionality, continuously manages flow and force levels inside the joint using intuitive, α-logic control. This Motion Feedback System (MFS) includes the Vortex Metering System (VMS), the patented flow control technology that counteracts possible variations in body weight and operating temperature.

1.1. Intended Purpose

The VGK is intended to be used solely in lower extremity prosthetic limbs as a prosthetic knee joint.

1.2. Recommended User Profile

The VGK joint is recommended for independent prosthetic users, typically of mobility classes K2, K3, K4. The patient 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.

1.3. Normal Use

The VGK has been developed for ordinary mobility use: walking, sitting, kneeling, cycling and occasional wetting by rain or tap water.

1.4. Non-ordinary And Extreme Use

Non-ordinary and extreme use may from time to time be required and known prior to the occasion. Such use may involve water and dirt, or 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 non-ordinary use can be risk assessed, supported, or on grounds of risk be denied. A considered permission/denial/ support program will be discussed on request.

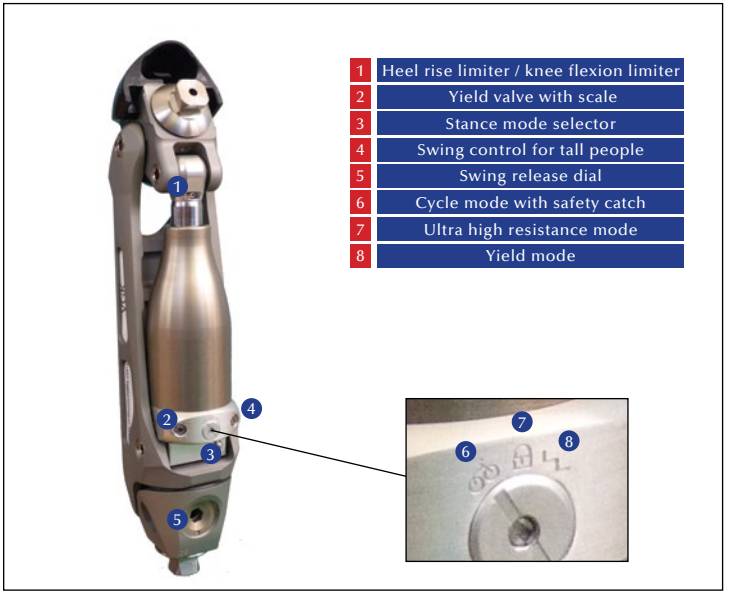


Fig 1: Adaptive α-logic Control Hydraulic Knee.

1.5. Expectation Management

Advise your patient that this device, whereas designed to offer a service compatible with a high level of safety, the same high level of safety is liable to increase their expectations of their ability, and consequently your patient may ultimately find limits of performance of the device. When such an event happens, they are asked to remember the circumstances and report any event back to their CPO.

1.6. Extreme Device Settings

Whereas the VGK permits a high level of resistance in yield, this function is not intended to effectively lock the joint at certain knee angles over 30 degrees when significant weight is placed upon the leg: the hydraulic pressures could damage the device. This warning does not apply to ordinary 'leg over leg' use.

1.7. Extreme Temperatures

The VGK 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 yield action of the joint, which in hands-free slope and stairs descent could cause an imbalance. In such a case it is advised to first try to walk down close to a handrail. In elevated temperatures (40 degrees plus) the VGK maintains its performance fairly well.

1.8. Prevention Of Overheating

Prolonged walking down slope and downstairs will heat up the joint due to energy dissipation. The frame acts as a cooling fin, and using an open structure cosmesis will optimise the temperature of the VGK.

1.9. Compatibility

The VGK has been designed to be compatible with the full complement of prosthetic components such as energy-storing feet, hydraulic ankles, hip components, shock absorbers, etc.

1.10. Body Weight And Additional Load

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

1.11. Wear And Tear

As with any mechanical device, mechanical wear and tear will eventually occur, and the user and CPO are required to see that regular inspections and maintenance are carried out.

1.12. Dirt And Water

In the event of ingress of water and dirt, the VGK can be washed with water and if so required, with soap. Contact with salt water requires cleaning with tap water. It is important to make sure that no sand or stones are trapped between moving parts, as this may lead to system damage. In case of use in environments with loose particles, the use of a protective (fabric) cover is recommended.

1.13. Stairs

The use of handrails or banisters is recommended when descending downstairs.

1.14. Storage

The VGK must be stored in an extended position.

2. Alignment

The alignment of the VGK follows the ideal of a straight hip-knee-ankle line. If the residual limb requires socket flexion, the hip-knee-ankle line should be maintained as well as possible. The distal pyramid must be used for neutral axial alignment only if body weight exceeds 100kg.

2.1. Socket Flexion

Socket flexion produced from tilting the socket at the distal socket only results in the knee centre to be anterior to the hip-ankle line. This may result in a diminished or absent knee extension moment in late stance, and may make swing initiation difficult. Fig 2 illustrates the preferred set up, irrespective of any hip flexion accommodation.

2.2. Foot Alignment

The VGK requires a toe load in late stance to release into swing. Too much dorsiflexion may cause insufficient forefoot loading and difficulty in releasing the knee into swing. Equally, an unusual high heel on the shoe would cause difficulty in swing initiation.

2.3. Swing Deviations

It must be borne in mind that the mass of the knee device helps the bilateral balance of body mass, but requires a correct mediolateral placement for optimum performance. As a possible guide for bench alignment, the VGK should be located in the plane of action as defined by the biological ball and socket hip joint and the push-point of the distal end of femur. In shorter residual limbs more lateral placement of the VGK is expected.

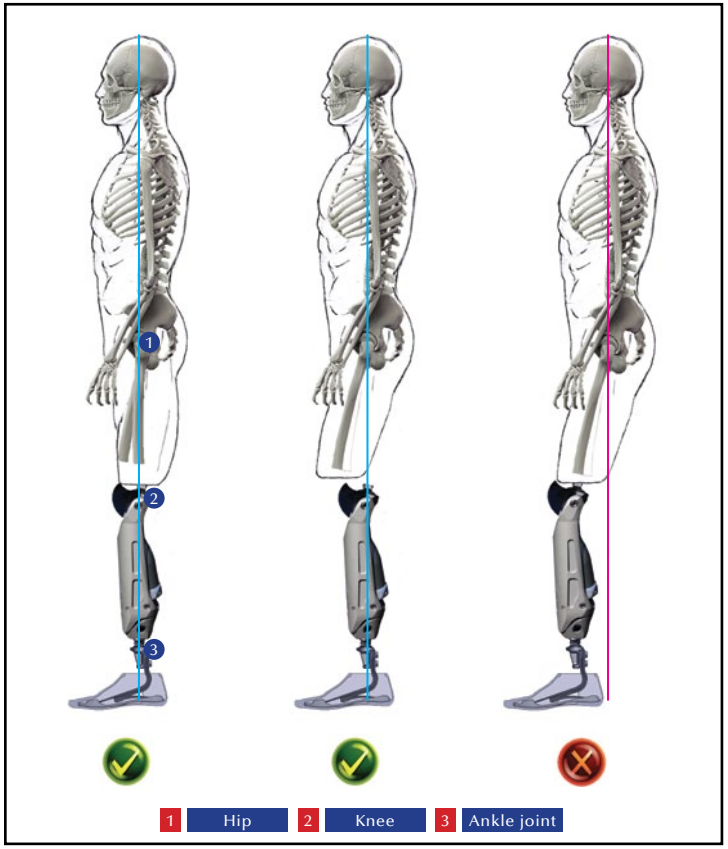


Fig 2: A vertical Hip-Knee-Ankle line is the preferred alignment. A posteriorly placed hip/greater trochanter is liable to make swing release more difficult.

2.4. 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 3. It is important to measure the indicated contact point to be 100 +/- 5 mm from the knee axis. 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 hydraulic valve housing.

3. The Controls

3.1. Swing Release Dial

The VGK 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 also to secure standing balance. If the threshold for switching to swing mode must be increased, the swing release dial as in fig 4 must be turned clockwise. This increases the pre-load on the PolyUrethane spring, requiring more weight on the forefoot before the PolyUrethane Spring gets further compressed due to the swiveling action of the distal knee (or spring housing), which supports swing release. When used outside the parallel bars, no slack rocking action may be present between the frame and the distal knee.

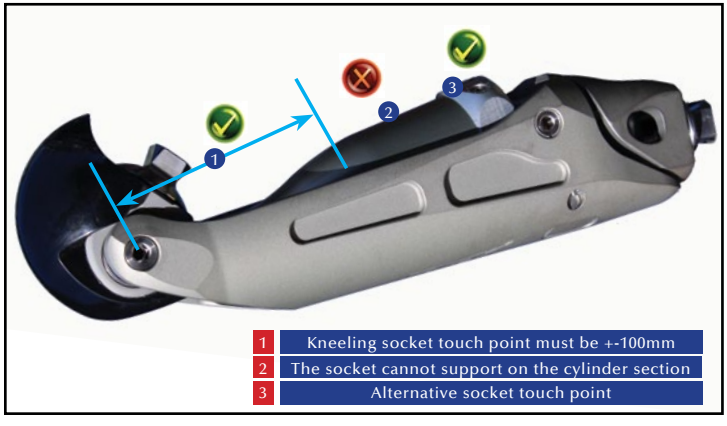


Fig 3: Kneeling onto the cylinder is permissible when the contact point is +-100mm from the axis.

Fig 4: Swing release dial.

It is important for the patient to understand WHAT NOT TO DO & AVOID

Forceful hyperextension as in hitting the ground hard with forceful extension immediately followed by a knee flexion moment may bring the knee into swing mode with consequential loss of weight bearing capacity. An example of such non-recommended use is attempting to land hard on the mid-foot onto a curb or step and rock over the foot up onto the curb or step. Remember that the joint will release into swing mode when the knee centre is in a state of hyper extension and simultaneously the mid and forefoot is loaded, followed by a knee flexion moment.

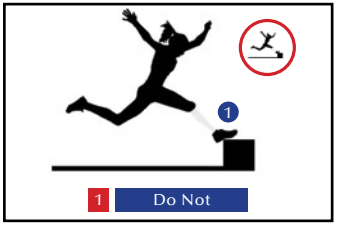
This user induced fail-mode is unlikely to happen in ordinary walking and fast walking style, but can happen in exceptional circumstances. Confidence in the VGK should not be lost if the usual safe behaviour continues after any such incident of exceptional use.

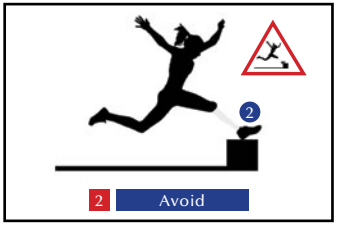
3.2. The Stance Mode Selector

The stance mode selector allows the choice of stance mode: the normal stairs mode with yielding, the ultra high resistance mode, and the free cycling mode with Safety Catch.

3.3. Stairs Mode

The 'yield' function refers to the joint flexion behaviour under load of body weight such as occurs in downstairs walking. The factory default setting provides too much resistance to the experienced user, yet provides a safe resistance for the first time user. The yield is adjusted as per fig 5. A clockwise turn of one dot provides a stepped increase in yield resistance, and vice versa. To get the right setting for the user, allow them to descend down from the last step of a stair and adjust until comfortable. Adjust as required when more steps are taken in sequence.





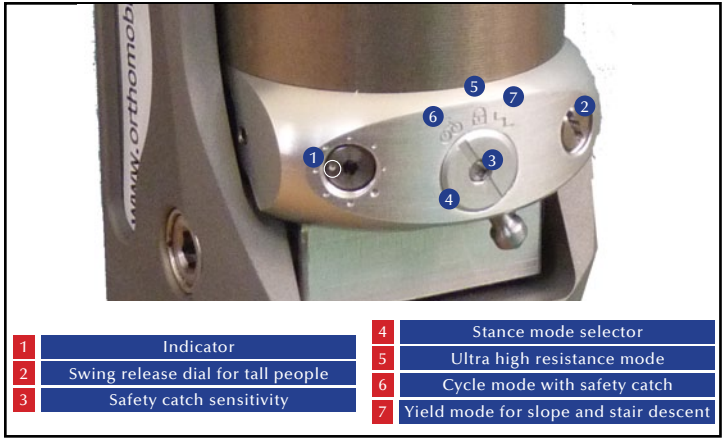


Fig 5: Dynamic Adjustments.

3.4. Ultra High Resistance Mode

Ultra high resistance mode, for ease of reference indicated by a 'padlock' is an ultra high resistance mode effectively blocking the yielding, but allowing free swing as long as the walking speed is not too high. For this reason this mode is NOT A FULL LOCK. The ultra high resistance mode is activated by placing the lever in the mid position.

3.5. Cycling Mode

For longer cycle rides the Stance mode selector may be toggled to Cycle. See fig 5. This renders the VGK free as long as the knee angle speed does not exceed the pre-set safety value. When the manual Stance mode selector is not set back to Stair or Lock mode, a safety valve will aid in reducing risk of collapse after use of the bicycle. A feeling of uncomfortable slackness in the joint in this use mode is normal, and the user is reminded to switch the stance mode selector to the normal stair mode. The cycling mode allows free movement of the knee within the limits of a pre-set flexion rate.

Setting Cycling speed: The factory setting of the cycling function is on ultra-safe! In this factory setting the cycling function may not work for the user. To get started, put the Cycle stance mode selector switch to Stair mode. In the centre of the The stance mode selector switch there is a small safety screw, the Safety Catch sensitivity (see fig 5) that sets the permissible rate of knee flexion before the safety valve is activated.

3.5.1. Setting Cycling Speed

To explore this mode, first test-bend the prosthesis in the stair mode: it does not bend easy. Put the The stance mode selector switch to Cycle mode, test the knee, it does not bend easy at a fast rate. Put the cycle switch to Stair mode, turn the Safety Catch in fully. Put the cycle switch to Cycle, test the knee, it bends very easy. Bend the knee fast, it still bends easy. Wind the Safety Catch anticlockwise for two full turns, test the knee in bending slowly and fast. If no difference, repeat procedure. A setting will be found where slow movement is easy, and fast movement is prevented after a little slack movement. This is the basis for the VGK to differentiate between the slow cycling movement that is to be permitted, and the fast movement that may occur in an otherwise uncontrolled collapse of the joint if it were left in the Cycle mode.

3.5.2. Adjustment with user

For clinical set-up, put the Stance mode selector to Stair mode, turn the Safety Catch sensitivity fully in. The user cycles, and incrementally the Safety Catch sensitivity is turned anti-clockwise until the safety feature applies itself during cycling. Agree with the user how much less sensitive they need the safety feature to remain safe in walking if they attempt a simulated collapse. Naturally, the faster cycling is required, the less safety is available in walking!

NOTE: If the cycling function is not required, make sure the Safety Catch sensitivity *is turned fully anticlockwise, the factory setting. This minimises any free knee movement if the patient touches the selector switch.*

3.6. Swing Phase

The swing phase is controlled by the Heel Rise slider (see also figs 1 and 6), and the Swing button (see also fig 5). The swing phase resistance is divided in two parts. From 0 to 40 degrees (approx.), the Swing dial gives more resistance to this initial swing phase, and is used with only TALL People as per fig 5. (When shank length causes long pendulum effect). Clockwise turning increases the resistance, and vice versa. Normally the swing button is set to light resistance to minimise the work necessary by the user (i.e as fully open as possible). The MAIN control is the Heel Rise Slider. Heel rise control, (or Maximum Knee flexion), is achieved by setting the lever as indicated in figs 6 & 7. A leftward swivelling movement lowers the maximum heel rise / maximum knee flexion and increases the 'power' of the knee joint to push the foot forward. A rightward move increases the maximum heel rise and lowers the 'power' delivered to the foot.

3.7. Terminal Impact Dampening

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.

4. Warranty

Orthomobility Ltd. offers a limited two year warranty against defects in materials and workmanship in accordance with terms and conditions of sale. Defects arising from non-ordinary and extreme use, and fair wear and tear are subject to the manufacturer's discretion. REGULAR / PLANNED WET ENVIRONMENT USE requires manufacturer's AGREEMENT.

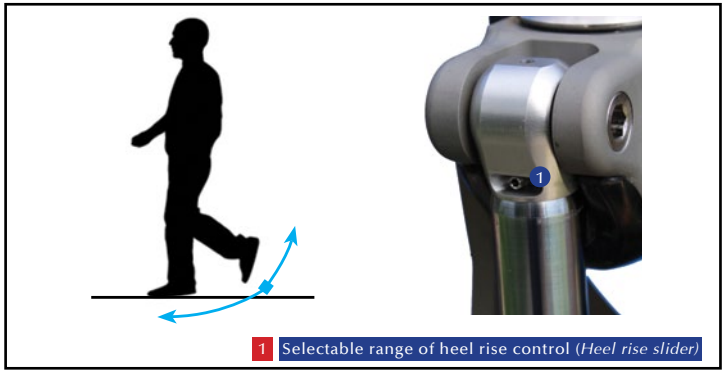


Fig 6: Adjustment for dynamic swing phase.

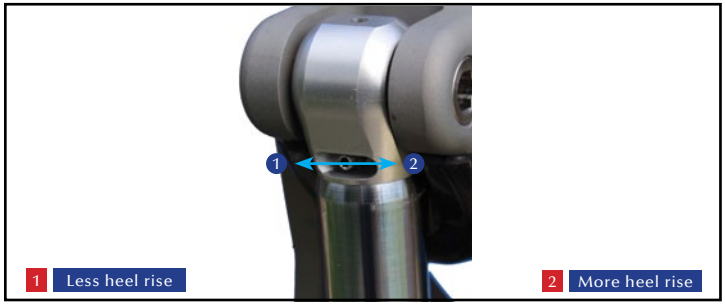


Fig 7: Heel Rise Slider.

5. Care And Maintenance

Due to fair wear and tear, the solid bearings may show wear and may need replacing from time to time. Please refer to www.orthomobility.com for more specific maintenance instructions.

6. Liability

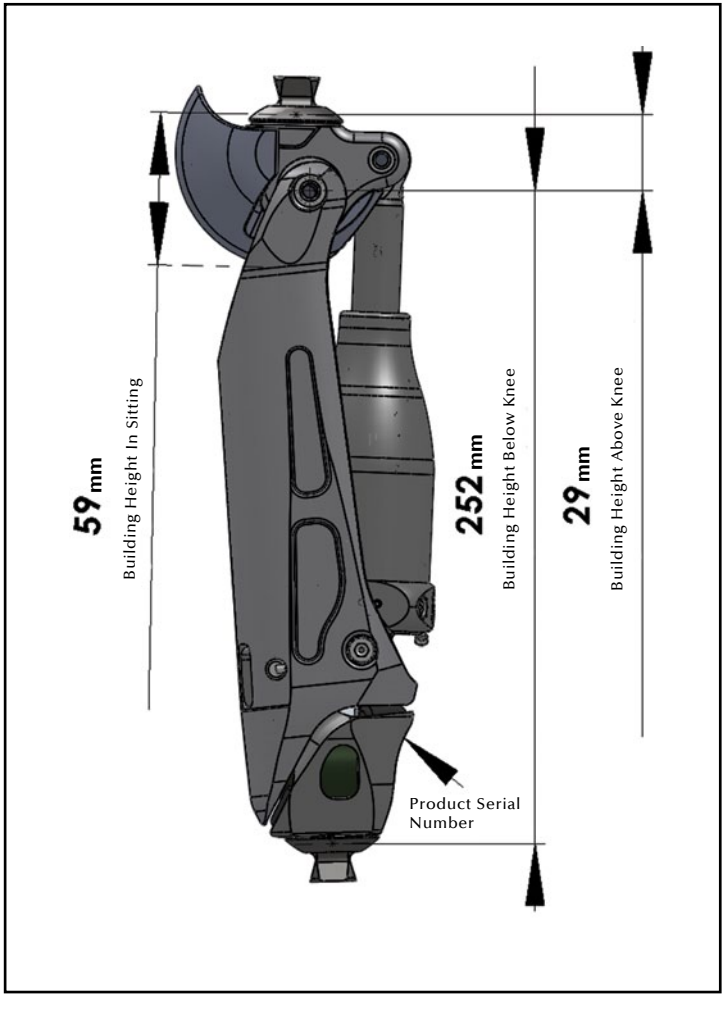
As the use of a prosthetic device includes a necessary risk, the manufacturer limits the liability arising from the use of the VGK to that liability directly arising from a malfunction of the device due to faulty materials and/or workmanship and exclude any other special, incidental or consequential damages. For full details see Terms and Conditions on invoice.

7. Training and Education

Orthomobility Ltd. continuously add new material of shared experience on their website, and clinicians are expected to check for new information to ensure continuous best practice with VGK.

TOPICS OF EDUCATIONAL INTEREST ARE:

- The Luetkemeyer-technique of walking downstairs.
- Dealing with very soft ground when walking down slope (like thick mulch).
- Training primary amputees.
- Case studies with double and triple amputees.
- Use in the great outdoors: successes and challenges.



8. Declaration of Conformity

The VGK and its variations made by Orthomobility Ltd, Reg 5143375 conform to the MDD Directive 2007/47/EC and 93/42/EEC and ISO 10328:2006

9. Ordering Numbers

VGK125P VGK Knee joint 125kg, with standard pyramid
VGK125A VGK Knee joint 125kg, with TK Anchor adapter
VGK125M VGK Knee joint 125kg, with M36 threaded head
Add Suffix 'H' to partnumber if used for Hip Disarticulation.
e.g; VGK125MH, VGK125PH
Add Suffix 'O' to partnumber if used for Osseo Integration.
e.g; VGK125MO, VGK125PO

For extended information visit: www.orthomobility.com

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