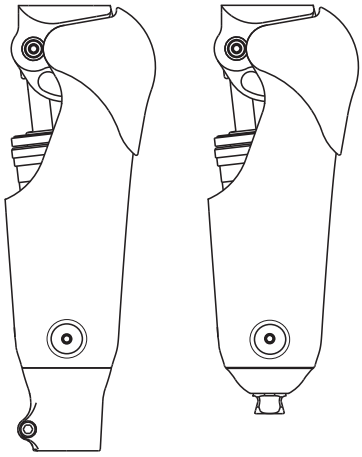

Mercury Hi-Activity Hydraulic Knee (Swing)

Instructions for Use

MH30 SWING (239552)
MHPYR SWING (239652)

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Blatchford

Contents

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1 Description and Intended Purpose

These Instructions for Use are intended for the practitioner and user unless otherwise stated.

The term *device* is used throughout to refer to the Mercury Hi-Activity Hydraulic Knee (Swing).

Please read and ensure you understand all instructions for use, in particular all safety information and maintenance instructions.

Application

This device is to be used exclusively as part of a lower limb prosthesis, intended for a single user.

This device is a compact prosthetic knee chassis with a proximal 4-bolt and T-slot transfemoral interface, providing secure connection and shift alignment, and a either a distal male pyramid or 30 mm diameter tube clamp, providing rotational alignment. The shin is fitted with an hydraulic cylinder to provide swing control (932287).

Features

- Tough carbon fiber frame
- 125 ° knee flexion
- Long life needle roller bearings
- Reinforced hydraulic unit
- Variable cadence
- Durable urethane kneeler pad
- Compact design

Activity Level

This device is suitable for Activity Levels 3 and 4 (weight limits apply, see *Technical Data*). The device is not suitable for Activity Levels 1 and 2 or for use in competitive sports events. These types of users might be better served by a specially designed prosthesis that is optimized for their needs. Of course there are exceptions and in our recommendation we want to allow for unique, individual circumstances and any such decision should be made with sound and thorough justification.

Activity Level 1

Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited ambulator.

Activity Level 2

Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

Activity Level 3

Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Activity Level 4

Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

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Contraindications

This device is not suitable for users with:

- Extreme muscular weakness, contractures that cannot be correctly accommodated, or proprioceptive dysfunction including poor balance.
- Contralateral joint instabilities or pathology.
- Complicated conditions involving multiple disabilities.
- Users, including bilateral transfemoral amputees who require a yielding function from the knee to descend stairs or to sit. This can result in damage of the brake mechanism that can adversely affect stability and durability.

Clinical Benefits

- Hard wearing components withstand high impact forces that occur with more active lifestyles.
- Hydraulic swing control allow for smoother gait.

2 Safety Information

This warning symbol highlights important safety information which must be followed carefully.

Users must be given gait training before using this device.

Beware of finger trap hazard at all times.

Any changes in the performance or function of the limb, e.g. instability, double-action, restricted movement, non-smooth motion, excessive play or unusual noises, should be immediately reported to your service provider.

Always use a hand rail when descending stairs and at any other time if available.

Any excessive changes in the heel height after finalization of alignment may adversely affect limb function.

Ensure only suitable retrofitted vehicles are used when driving. All persons are required to observe their respective driving laws when operating motor vehicles.

Assembly, maintenance and repair of the device must only be carried out by a suitably qualified practitioner.

The user must not adjust or tamper with the setup of the device.

The user is advised to contact their practitioner if their condition changes.

To reduce the risk of injury due to failure or loosening of the bolt connections, ensure the bolt threads are cleaned thoroughly before each installation.

Always use Loctite and apply the specified torque value to the bolts. Never use an alternative bolt.

Care should be taken when carrying heavy loads as this may adversely affect the stability of the device.

Avoid exposure to extreme heat and/ or cold.

The device is not designed for prolonged submersion or shower immersion but is suitable for outdoor use. Ensure any use of the device in water complies with the conditions given in ***Limitations on Use*****.**

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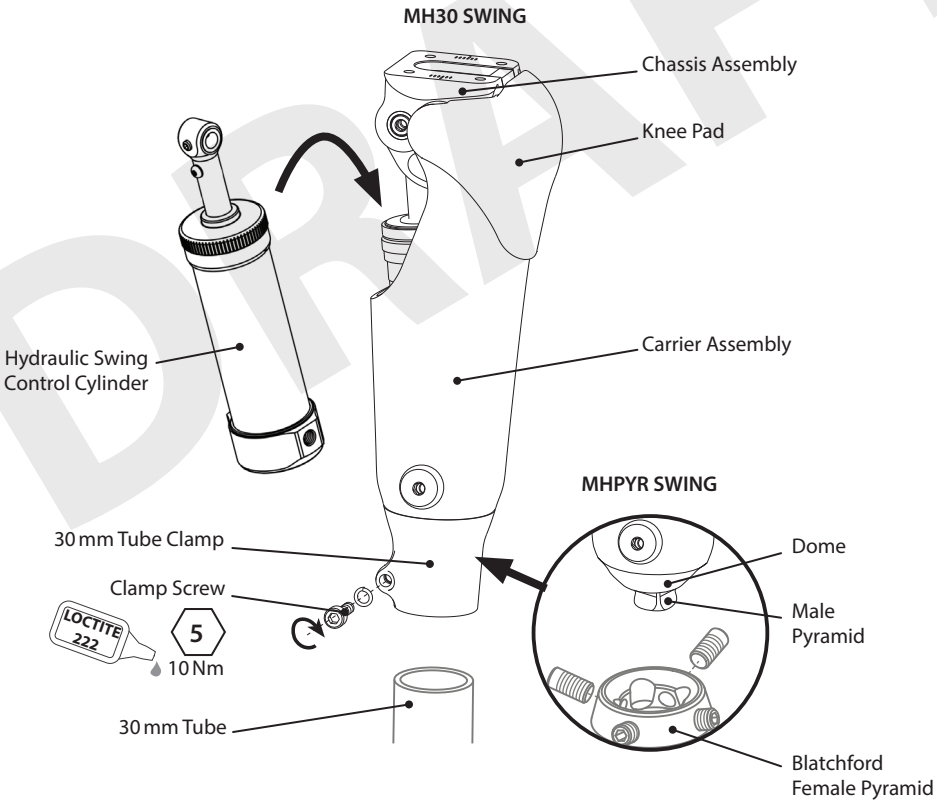
3 Construction

Principal Parts

• Carrier Assembly	Carbon fiber, stainless steel, steel bearings
• Chassis Assembly	Aluminum alloy, steel bearings
• Knee Pad	Urethane
• Hydraulic Swing Control Cylinder	Aluminum alloy, stainless steel, engineering thermoplastic, hydraulic oil
• Tube Clamp	Aluminum alloy
• Clamp Screw	Plated steel
• Male Pyramid	Titanium with stainless steel bolt
• Dome	Aluminum alloy

Component Identification



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4 Function

This compact and tough device is a single axis prosthetic knee, comprising a proximal chassis assembly for connection to a transfemoral prosthesis, and a distal carrier assembly providing one of two optional interfaces.

The MH30 SWING option provides a tube clamp for connection to a 30 mm shin tube.

The MHPYR SWING option provides a male pyramid and dome for connection to pyramid based components.

An hydraulic swing control cylinder housed within the frame assembly, between the chassis assembly proximal pivot and the carrier distal pivot, provides adjustable swing control of flexion and extension resistance.

5 Maintenance

Visually check the device regularly.

Report any changes in performance of this device to the practitioner/service provider e.g. unusual noises, movement, significant wear or corrosion that may affect proper function.

Inform the practitioner/service provider of any changes in body weight and/or activity level.

Cleaning

Use a damp cloth and mild soap to clean outside surfaces. DO NOT use aggressive cleansers.

The remaining instructions in this section are for practitioner use only.

This maintenance must be carried out only by competent personnel (practitioner or suitably trained technician).

To maintain optimum performance, a periodic inspection for unacceptable noise, play and stability of alignment is recommended. The period between inspections is determined by factors such as the activity of the user and frequency of usage. An annual check is recommended as a minimum.

The following routine maintenance is to be carried out:

- Check alignment. If loose, remove, clean, and realign limb; then apply Loctite 222 and tighten to the correct torque setting, see *Construction* section.
- Check the security of all attachments, stub axles, etc.
- Check for defects that could affect proper function.
- Check for excessive corrosion.

Ensure the user has read and understood all safety and user-level maintenance information.

Advise the user that a regular visual check of the device is recommended and signs of wear that may affect function should be reported to their service provider.

Advise the user to inform the practitioner/service provider of any changes in body weight and/or activity level.

If this device is used for extreme activity, the maintenance level and interval should be reviewed and if required advice and technical support sought to plan an appropriate maintenance schedule based on the nature and frequency of the activity. This should be determined by a local risk assessment carried out by a suitably qualified individual.

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6 Limitations on Use

Intended Life

A local risk assessment should be carried out based upon activity and usage.

Lifting Loads

User weight and activity is governed by the stated limits.

Load carrying by the user should be based on a local risk assessment.

Environment

Avoid exposing the device to corrosive elements such as water, acids and other liquids. Also avoid abrasive environments such as those containing sand for example as these may promote premature wear.

Exclusively for use between -15 °C and 50 °C (5 °F to 122 °F).

Suitable for outdoor use

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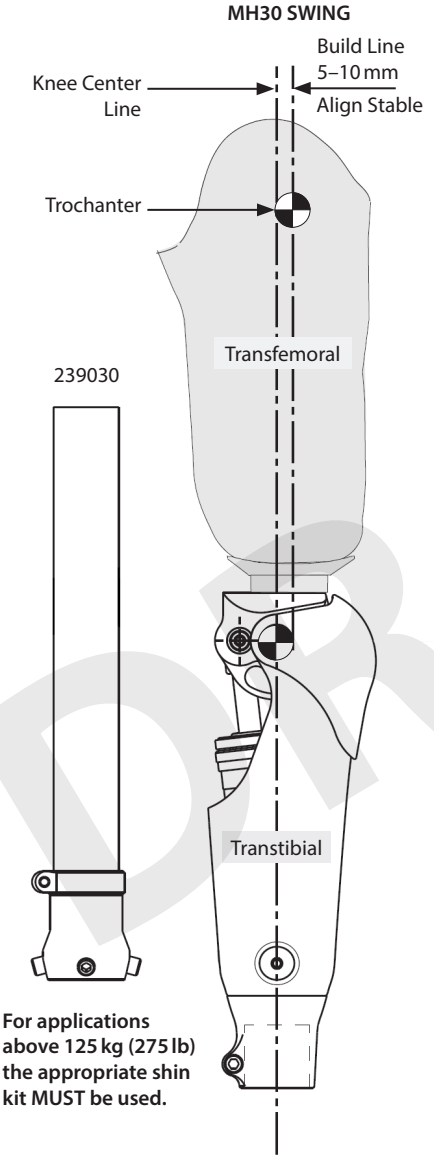
7 Bench Alignment

The instructions in this section are for practitioner use only.



For applications above 125 kg (275 lb) the appropriate shin kit MUST be used.

7.1 Static Alignment

To achieve optimal function from the hydraulic cylinder the knee must be aligned geometrically stable. Check flexion is fully accommodated when worn by patient.

Set-up Length

Typically include 5 mm to allow for axial compression of heel and toe (dynamic/energy storing feet).

Build Line

This should typically fall 1/3 of the foot length from the heel (see manufacturer's recommendations).

7.2 Dynamic Alignment

Coronal Plane

Ensure that M-L thrust is minimal by adjusting relative positions of socket and foot.

Sagittal Plane

Check for smooth transition from heel strike to toe-off. Ensure also that when standing the heel and toe are evenly loaded and that both are touching the floor.

7.3 Transfemoral Alignment

Align transfemoral components according to fitting instructions supplied with the knee, keeping the load line relative to this device, as shown.

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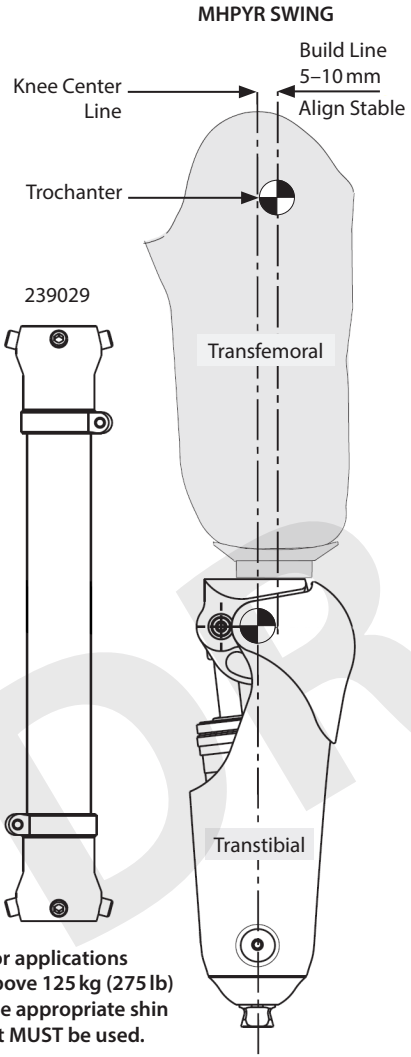

For applications above 125 kg (275 lb) the appropriate shin kit MUST be used.

7.4 Pyramid Alignment

To maximize the function of the knee, distal pyramid based components should be fixed in neutral alignment with the shin components vertical. When using dynamic feet requiring more anterior placement of the load line in relation to the foot, the shin may be inclined at the distal pyramid.

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8 Swing Control Adjustment

The instructions in this section are for practitioner use only.

Adjusting Flexion Resistance

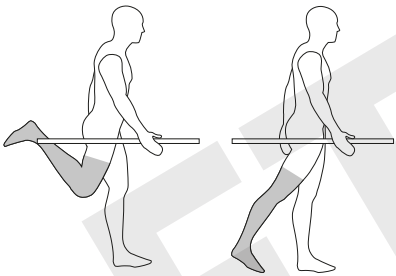
1

a) Initial adjustments are factory set (Extension 2, Flexion 4)

b) Observe the amputee walking

c) If there is excessive heel rise, increase resistance

d) If there is insufficient heel rise, decrease resistance

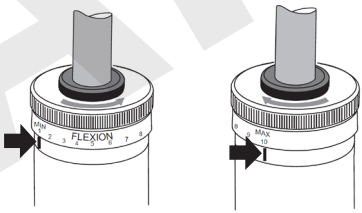


The Flexion Cap is numbered from left (MIN/1) to right (MAX/10).

Directly below the Flexion Cap is a fixed Indicator Mark.

When the cap is turned counter-clockwise, when MIN/1 is over the mark, flexion resistance is at minimum.

When the cap is turned clockwise, when MAX/10 is over the mark, flexion resistance is at maximum.



Minimum Flexion Resistance

Maximum Flexion Resistance

Note… Take care not to over adjust when using adjuster tool.

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8 Swing Control Adjustment *(cont.)*

Adjusting Extension Resistance

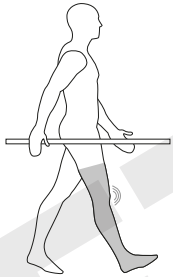
2

a) Observe the amputee walking

b) If there is excessive terminal impact on knee extension: increase resistance

c) If the knee does not extend satisfactorily: decrease resistance

Note… As a 'rule of thumb' flexion resistance should be higher than extension



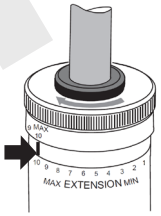
To adjust extension resistance use the same Flexion Cap (make a note of the flexion resistance before you start). By turning the cap in the clockwise direction until it reaches maximum and then continuing, the indicator mark will begin moving from right to left.

The indicator mark will move clockwise from 1 to 10 on the extension marker which is located directly below the indicator mark.

The flexion adjuster cap should then be readjusted to the desired flexion resistance.

Note… To reduce extension resistance turn the adjuster cap to minimum and continue turning until the desired extension resistance is reached. Readjust the flexion adjustment cap accordingly.

Minimum Extension Resistance



Maximum Extension Resistance

Note… If there is any doubt over the position of the indicator ring in relation to the settings, its position can be reset by turning the adjustment cap to maximum flexion, then maximum extension prior to making any adjustments.

Note… The flexion adjustment ring should always move with the extension ring when adjustments are being made.

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9 Fitting Advice

The instructions in this section are for practitioner use only.

Symptom	Solution
A recurring noise occurs at the knee interface	Confirm security/tightness of all screws, loctite and torque to the correct setting.
The adapter moves out of position	User must not use the device until adjusted, repaired or replaced.
Knee does not stabilize	Confirm limb is aligned according to the recommendations.
Heel rises too high during swing	Increase flexion resistance, see Swing Control Adjustment.
Heel rises too low during swing	Reduce flexion resistance, see Swing Control Adjustment.
User experiences terminal impact	Increase extension resistance, see Swing Control Adjustment.
Device does not fully extend during swing	Reduce extension resistance, see Swing Control Adjustment.

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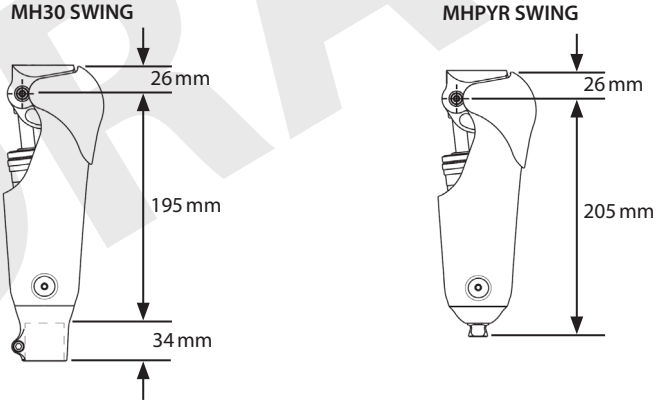
10 Technical Data

Operating and Storage Temperature Range:	-15 °C to 50 °C (5 °F to 122 °F)
Component Weight:	1.23 kg (2 lb 11 oz)
Activity Level:	3–4
Maximum User Weight:	Level 3: 150 kg (330 lb) Level 4: 145 kg (320 lb)
Attachment Type:	Proximal—4 bolt/T slot (Blatchford) Distal—Blatchford male pyramid (MHPYR SWING) Distal—30 mm tube (MH30 SWING)
Range of Adjustment:	5–10 mm shift A–P ±7 ° tilt from vertical (MHPYR SWING) 360 ° axial rotation (MH30 SWING)
Build Height:	See diagram below

Build Height



Storage and Handling

When storing for prolonged periods, ensure the product is stored upright (vertically), free from moisture and stored at room temperature.

11 Ordering Information

Device	Part Number
Mercury Hi-Activity Hydraulic Knee (Swing) - 30 mm diameter tube	MH30 SWING
Mercury Hi-Activity Hydraulic Knee (Swing) - male pyramid	MHPYR SWING

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Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for any adverse outcome caused by any component combinations that were not authorized by them.

CE Conformity

This product meets the requirements of the European Regulation EU 2017/745 for medical devices. This product has been classified as a class I device according to the classification rules outlined in Annex VIII of the regulation. The EU declaration of conformity certificate is available at the following internet address: **www.blatchford.co.uk**

Medical Device

Single Patient – multiple use

Compatibility

Combination with Blatchford branded products is approved based on testing in accordance with relevant standards and the MDR including structural test, dimensional compatibility and monitored field performance.

Combination with alternative CE marked products must be carried out in view of a documented local risk assessment carried out by a Practitioner.

Warranty

This device is warranted for 36 months.

The user should be aware that changes or modifications not expressly approved could void the warranty, operating licenses and exemptions.

See the Blatchford website for the current full warranty statement.

Reporting of Serious Incidents

In the unlikely event of a serious incident occurring in relation to this device it should be reported to the manufacturer and your national competent authority.

Environmental Aspects

This product is made from a recyclable material. Where possible, the components should be recycled in accordance with local waste handling regulations.

Retaining the Packaging Label

The practitioner is advised to keep the packaging label as a record of the device supplied.

Trademark Acknowledgements

Blatchford is a registered trademark of Blatchford Products Limited.

Manufacturer's Registered Address

Blatchford Products Limited, Lister Road, Basingstoke RG22 4AH, UK.

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Note the Chinese section will require special para styles and therefore will require its own table of contents (as does Arabic). This is currently beyonf the scope of the template- **but the ZH marker is required for the Chinese section to be listed in the Cover TOC.**

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