Blatchford

KATO 819018

Custom-made Medical Device

EN Instructions For Use

Blatchford Limited:Atlas Way:S4 7QQ : orthoticsales@blatchford.co.uk : +44 (0) 114 263 7900

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About Us

Blatchford is a multi-award-winning manufacturer of some of the world's most advanced prosthetic technology, bespoke seating solutions and orthotic devices.

Blatchford maintains a QMS system which is ISO 9001 and ISO 13485 accredited. Blatchford seating products and systems meet the essential requirements of EU Medical Devices Regulation 2017.

Product Description

Blatchford KATO is a lightweight and crash tested, custom made seating solution, available as a part or full system providing optimum support and correction combined with excellent accommodation and comfort for the user. Blatchford KATO is designed to offer high levels of pressure relief and weight distribution and can be interfaced onto most wheelchairs in the market place whilst being easily removable for cleaning and maintenance.

KATO has been crash tested to ISO 16840-4 and has an extensive range of accessories available to compliment the seating solution. The system is adaptable and partially adjustable by way of alternative interfacing options, including Blatchford Adaptable interfacing System (BAIS) and V-Trak.

Blatchford KATOs are custom made devices. They are defined by the Medical Devices Regulation as devices manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification. This provides under their responsibility, specific characteristics as to its design and is intended for the sole use of a named patient. This does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

Pre-Use Checks

Important Safety Information

Before using your KATO please check the following:

- The retaining strap on the base cushion (where fitted) must be securely fastened.
- Ensure the Blatchford Adapted Interface System is correctly seated and secure. For specific guidelines follow BAIS Interface IFU.
- If 3rd party equipment is combined with the KATO please follow the manufacturers IFU'S for correct usage.
- If using V-Trak or equivilent mounting systems, the backrest must be fitted to the wheelchair correctly ensuring the mounting pins are located into the mounting blocks on the framework properly and are secured with the locking levers.
- All additional postural support items such as postural straps and harnesses should be secured, free from obstructions and fitted correctly to the KATO and/or wheelbase. For more information please follow the IFU supplied with each device.

Safety Information

If after use, you see any red marks on your skin that are in contact with the device, which don't disappear after 30 minutes, stop using the Blatchford KATO and contact your healthcare professional for advice as it may need adjusting. Should you develop any sores or blisters you should stop use of the device at once.

Blatchford KATO are designed and prescribed for an individual's needs and should only be used by that sole user.

• Should your functional requirements or condition change during the life cycle of the device please contact your healthcare professional as it could affect the performance of the device.

• Blatchford KATOs must be regularly maintained to the mainenance schedule in this IFU.

Repairs and adjustments to the Blatchford KATO must be carried out by qualifed, trained healthcare professionals. Please consult a qualified medical professional should you have any problems with this custom product.

• May contain animal tissues such as leather. Conformity certificate is available for further details should this be required.

• Avoid strong magnetic fields, sources of electrical interference, atmospheres containing liquids and/or powders.

• Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.

•The device is not intended for use when immersed in water or as a showering orthosis unless specifically specified for this purpose by your healthcare professional.

Do not remove any serial or warning labels from the Blatchford KATO.

Blatchford KATOs may include flammable materials. Always be aware of fire hazards.

Blatchford Postural Belts could cause strangulation or restricted breating if not fitted correctly. Ensure the belts are fitted inline with the belts and harness IFU and are positioned away from the neck.

Blatchford KATO must only be used with the wheelchair it was prescribed for. If a different wheelchair is going to be used contact the Approved Healthcare Professional for help or advice.

• No alterations should be made to the seat nor should other company's components be fitted without the prior agreement of your healthcare professional.

• Blatchford KATO is NOT designed for use as a car safety seat.

Due care and attention must be taken at all times when using the Blatchford KATO. Take particular care when negotiating slopes, difficult surfaces or other obstacles.

Blatchford KATO forms part of a system of assemblies and custom products. Each KATO is different so it is very important that all IFUs are followed prior to use.

Never leave an occupant unattended. Ensure the headrest is fitted correctly and ensure the headrest is fitted during transportation. If the user shows any continued signs of distress or discomfort, stop using the product and immediately contact the wheelchair service provider

Ensure your seating system is fully attached to the wheelbase prior to transportation. Check before and after fitting the tiedowns. The back supports must be in an upright position during travelling and check that all secondary support devices are secure and function correctly. Always remove trays and knee blocks prior to transportation.

Beware of finger trap hazards when adjusting or moving any part of the Blatchford KATO.

Always refer to the Blatchford or 3rd Party manufacturers IFU, in particular when fitting high risk items such as belts and harnesses.

Any 3rd party products which have not been agreed or fitted by Blatchford healthcare staff or approved repairers may compromise the warranty of the product and may have the potential to cause damage to the user or device.

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Intended Use

KATOs are intended for occupants of a mass less than 100kg with moderate to high postural needs. The seating system is designed to be fitted onto an approved, crash tested wheelbase using an interface. Kato's are custom made to the prescription of the healthcare professional and they will provide advice on custom products and add-on 3rd party products such as headrests and postural belts.

The most common conditions include:

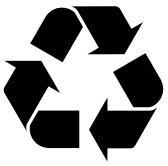
* Cerebral Palsy
* Muscular Dystrophy
* Scoliosis
* Spinal muscular Atrophy
* Aquired Brain Injuries

Blatchford products are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. Blatchford products are suitable for use on one or more wheelbases and can be used by most ages. Blatchford KATOs are always and only intended to be used where specified.

Blatchford KATOs are intended for users of 100kg or less are designed for low impact levels. Your healthcare professional will advise on the optimum Blatchford KATO for your needs.

Blatchford KATOs are intended for the sole use of the patient named on the conformity documentation. If the Blatchford KATOs is no longer required it must be safety disposed of. Please follow the guidelines below.

*** Removal of the label**
*** Remove any parts which can be dismantled to reduce the risk of re-use. Follow recycling guidelines where possible.**
*** Ensure the healthcare professional is aware that the device is no longer required.**
*** Be careful of sharp edges. Always wear gloves when dismantling and ensure the KATO is secured on a table to perform the task.**
*** Do not re-use any components unless a healthcare professional has provided a local risk assessment.**



Everyday Use

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The interface components have been designed to avoid unacceptable pressure on and stress levels in body tissues.

When seating an occupant the following steps should be taken,

1. Check the seat surface, belts and harnesses are free from debris and move/function correctly
2. Check the seat is firmly secured to the wheelbase and tilt the seat if possible.
3. Seat the occupant, ensuring the occupant is correctly orientated. Ensure creases are removed and Belts and harnesses engaged (if applicable).

- **It is normal to see red marks where pressure has been applied. These should disappear within 30mins. IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL.**

The forces of the Blatchford KATO may take some time to get used to. The Blatchford KATO should not be painful; however, it is not unusual to feel some initial discomfort. If you experience rubbing or blistering, please book an appointment with your Healthcare professional for immediate attention. If you are experiencing pain after two weeks please book a follow up appointment with your healthcare professional.

Safe Transportation

The Blatchford KATO must not be used as a car safety seat.
• The Blatchford KATO is designed to allow the seat and its user to be transported in a forward facing position in a vehicle designed for the purpose (for example, in a suitably equipped minibus).
• Blatchford Special Seating products are interfaced using BAIS, which conforms with ISO16840-4 .

This information should be made available for services making transport arrangements (e.g. schools and other organisations).

Securing the user, the Blatchford KATO and the host wheelchair in a vehicle:

1. During travel the Blatchford KATO must be securely fastened into its wheelchair as described earlier in this manual.
2. Posture belts and postural harnesses supplied as part of the seating system are designed to give postural support only. Where these items are fitted they should be used during travel but they must not be used as the only safety restraints.
3. The wheelchair itself must be fastened down in the vehicle – this must be in accordance with the wheelchair manufacturer's instructions. (The wheelchair manufacturer will issue these instructions separately. In case of query contact your healthcare professional).
4. A suitable, separate, passenger seat belt (fastened in to the vehicle) must be used by the occupant during travel. In order to achieve occupant restraint and optimum protection in a crash situation the seatbelt should have both pelvic and upper body sections (for example a 3 point type with the upper section fastened into the vehicle at the upper level) as a minimum standard.
5. The Blatchford KATO headrest should always be used during travel.
6. Always follow guidance from the wheelbase manufacture, 3rd party devices and accesory IFUs in combination with this manual.

Never leave an occupant unattended. Ensure the headrest is fitted correctly and used during transportation. Check that all secondary support devices are secure and function correctly. Always remove trays and knee blocks prior to transportation. Always secure your wheelchair with WTORS four-point, strap-type tiedowns. Where posture belts and posture harnesses are installed, they should be used during travel, but they must not be used as the only safety restraints. Ensure your seating system is fully attached to the wheelbase prior to transportation. Check before and after fitting the tiedowns.

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Intended Performance of Device

Environment: Avoid exposing the seating 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. Sytems are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: Our systems are not designed for high activity sports such as wheelchair basketball, or skate ramps Any such activities undertaken are done so completely at the users' own risk.

Lifetime : It is recommended that Blatchford KATOs are evaluated by healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Cleaning any Blatchford KATO is very important for both user safety and ensuring the longevity of the medical device. The device should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the device use a soapy soft cotton cloth and gently rub with circular movements to remove stubborn dirt utilising domestically available anti-bacterial cleaning products. Do not pressure wash your system. For more stubborn marks a dilute bleach solution can be used: 5% bleach to 95% water. Use a clean cotton cloth to wipe the area and dry the surface of the system after cleaning.

Note: These are recommended or suggested methods of cleaning. Blatchford is not responsible for damage incurred while cleaning. If you are not sure how best to clean your system please contact your prescribing medical professional.

Maintenance Schedule

Weekly

* User visual inspection.
* Inspect all over generally for any obvious signs of wear & tear.
* Check there is no damage to the retaining straps (if used) and that the buckles are working properly.
- Check that the user's shape is still accommodated by the shape of the Blatchford KATO.
- Check that the Blatchford KATO.is not too tight for the user as a result of growth or weight gain.
- Check there is no structural damage to the plastic shells or any of the brackets and that all securing bolts are still in place.
- Check the quality of the foam, particularly load areas.
- Check that all locking knobs on the brackets are in place and functioning correctly.

Six months

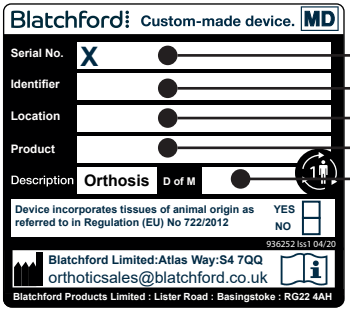
We recommend each device is fully serviced by the manufacture and any worn parts should be repaired and replaced as appropriate. Ensure all labels on the product are intact and never remove any warning or serial numbers from the device. Failure to comply may invalidate the warranty

Warranty

For all warranty enquiries please refer the website under the warranty section.

Label Indentifier

A label is located on each custom-made medical device. Due the custom nature of the product it may will be positioned where practicable.



Serial No. Quote this number with any enquiry

Identifier. Customer name or Initials (if applicable)

Location. Hospital/Clinic

Product. Product descrption

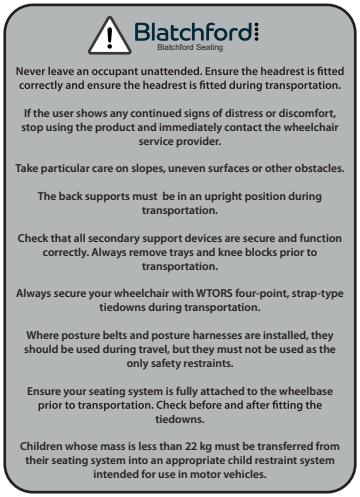
D of M . Date of Manufacture

Single user Use Only

Manufacturer of Medical Device

Must consult information for user

MD **Medical Device**



Warning Label

Please report any serious incident that has occurred in relation to the device to the manufacturer and the MHRA