Recommendations to ensure the safe maintenance and use of Knee Ankle Foot Orthoses

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Consultation process

This document has been through a consultation process with industry stakeholders and has been endorsed by:

- Becker UK Ltd
- Otto Bock UK
- AM Healthcare Group
- The National Orthotics Managers' Association Group (NOMAG)

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This guidance is intended to aid governance within a clinical setting and should be read in conjunction with **BAPO's Standards for Best Practice**

Key principles relating to safe use

Knee Ankle Foot Orthoses (KAFOs) – Professional Guidance on Safe Use and Compliance

Knee Ankle Foot Orthoses (KAFOs) play a vital role in supporting the mobility and well-being of many orthotic service users. However, due to their complexity and functional demands, KAFOs represent a significant safety risk if not properly maintained.

Safety and Structural Integrity

The failure of a KAFO can result in serious injury, most notably from falls. Therefore, regular and thorough safety checks are imperative. These checks must evaluate the structural integrity of the device and ensure that all joint mechanisms are free from excessive wear. Adherence to the knee joint manufacturer's guidelines—including recommended maintenance intervals—is essential.

Policy and Compliance Recommendations

The British Association of Prosthetists and Orthotists (BAPO) advises all orthotic service providers to implement a clear, robust policy that outlines the frequency and scope of safety checks in alignment with manufacturer recommendations.

Additionally, all stakeholders—including service providers, in-house manufacturers, and external clinical or manufacturing partners—must be fully aware of the specified working life limits of all orthotic components as defined by the component manufacturers.

Regulatory Considerations

These working life limits are mandated under the Medical Device Regulations: MDR(UK) for UK-certified components and MDR(EU) for those certified in the European Union. These requirements are intended to ensure that the materials do not exceed stress thresholds that could compromise safety. This information should be detailed in the Instructions for Use (IFU) provided with each orthosis.

Component longevity may vary across different manufacturers and even among different parts within the same device—for instance, ankle joints may have a different lifespan compared to knee joints. It is the responsibility of the service provider to track and manage these life limits appropriately.

Documentation and Record-Keeping

Service providers must maintain comprehensive records for each KAFO issued, including documentation of all completed safety checks and any communication with the user.

If a user fails to return their KAFO for scheduled inspection, or if the device approaches or exceeds its designated lifespan, they must be clearly advised that continued use is unsafe and strictly prohibited due to the elevated risk of harm.

Clinical Implementation and Responsibility

Certain inspection tasks may be conducted in clinical settings, provided that appropriately trained personnel and basic workshop facilities are available. However, regardless of the setting, all actions taken must be thoroughly recorded to ensure traceability and accountability.

Services must also ensure adherence to the applicable version of the Medical Device Regulations—MDR(UK)3 or MDR(EU)4—depending on the registration of the components used. Differences between these regulatory frameworks should be clearly understood and implemented as required.

Conclusion

KAFO safety and compliance depend on systematic monitoring, accurate documentation, and clear communication between clinicians and service users. A proactive, policy-driven approach will ensure these critical devices remain safe and effective throughout their intended lifespan

Description

A Knee Ankle Foot Orthosis (KAFO) has been defined as an orthosis that encompasses the knee, ankle joints and the foot by the International Organization for Standardization[1].

1 Function

The function of a KAFO may include[2]:

1.1 To manage a deformity including a) the prevention of a deformity, b) the reduction of a deformity, and c) maintaining a deformity.

1.2 To alter the range of motion of the joint(s) including a) to limit the range of motion of a joint, and b) to increase the range of motion of a joint.

1.3 To change the dimensions of a limb segment including a) to improve the shape of a segment.

1.4 To manage abnormal muscular function including a) compensating for weak muscle activity, and b) controlling the effect of muscle hyperactivity.

2 Fabrication

2.1 The KAFO may be either custom-made or prefabricated[2].

3 Construction

3.1 A KAFO will comprise the following components[2]:

3.1.1 Interface components (in direct contact with the user and includes shells, pads, and straps).

3.1.2 Articulating components (permits or restricts motions of anatomical joints).

3.1.3 Structural components (connects the articulating and interface components and maintains the alignment of the orthosis and includes uprights and shells).

3.1.4 Cosmetic components (the means of providing shape, colour, and texture to an orthosis).

3.1.5 The orthosis may be made from a variety of materials such as plastic, steel, leather and composites or a hybrid of these materials.

4 Maintenance

4.1 All KAFOs must be appropriately maintained to ensure they remain safe for the service user. Clinicians must adhere to the manufacturer's guidelines on how and when to check components for safety. At a minimum, all KAFOs should be serviced in line with the requirements published by the system manufacturer. Unless otherwise directed, due to longer service intervals being dictated by the system manufacturers, servicing should be carried out at a minimum of six-monthly intervals and on request, should a service user report a safety issue.

4.2 The manufacturer, with whom the clinician places an order for the fabrication of a KAFO, must supply the prescribing clinician with all maintenance documentation pertaining to the KAFO's construction.

5 Maintenance and safety of a KAFO

The regular maintenance of a KAFO is essential to the safety of the device and the protection of the service user.

To ensure the safety and efficacy of KAFOs, clinicians and orthotic service providers must adhere to the following best practices:

- **Manufacturer Guidance Compliance**
  All clinicians and associated personnel must be fully informed of the manufacturer's maintenance and safety recommendations for every component used in the construction of a KAFO.
- **Awareness of Component Lifespan**
  Staff must understand both the validated service life of each component and the risks associated with continued use beyond this period, including any "reasonably foreseeable use" scenarios.
- **Local Policy Implementation**
  The issuing department must establish and maintain a written local policy or standard operating procedure (SOP) that outlines processes for the safe management and routine maintenance of KAFOs.
- **Service User Notification Protocol**
  A robust method for notifying service users when their KAFO is due for a safety inspection must be in place. For example, departments should issue reminder letters at six-month intervals, clearly outlining the steps the user must follow to arrange a safety check. All communication must be documented in the service user's clinical record.
- **KAFO Identification System**
  Each KAFO must be uniquely identifiable. Where manufacturers have not provided permanent labelling, the issuing department should apply a non-removable identifier—such as a permanent or UV marker—and record the identification number in the clinical notes during each service user interaction.
  Note: BAPO advises against engraving identifiers into the KAFO structure, as this may compromise the device's integrity. Etching by manufacturers is acceptable only when performed under appropriate expert supervision in a controlled environment.
- **Documentation of User Education**
  Clinicians must document in the service user's notes that the individual has been informed of the requirement for six-monthly safety checks and that KAFO lifespan is actively monitored. The risks associated with missed inspections—and the service user's responsibility to present the device for routine checks—must be communicated in a clear and accessible manner.
- **Provision of Service User Information Leaflet**
  A comprehensive information leaflet must be provided to each service user. This should include guidance on proper care (e.g., cleaning instructions), how to perform basic checks for wear and tear, and contact details for the department. If the service user declines the leaflet, this must be recorded in their file.
- **Restriction of Use for Overdue Inspections**
  If a KAFO has not been inspected within the time frame recommended by the manufacturer—or in absence of such guidance, within six months—the user must be formally advised not to continue using the device until it has been properly assessed.

References

1 Standardization IO for. Standardization IO for ISO 8549- 1:1989 Prosthetics and Orthotics - Vocabulary. General Terms for External Limb Prostheses and Orthoses. Geneva: International Organization for Standardization; 1989.; 1989.

2 Standardization IO for ISO 13404 2007 (E). Categorization and description of external orthoses and orthotic components. Geneva: International Organization for Standardization; 2007.

3 The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024: guidance on implementation - GOV.UK UK MDR

4 Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex

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