Kenya Standard — Prosthesis — Specification

Part 2: Lower Limb Prostheses

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TECHNICAL COMMITTEE REPRESENTATION
The following organizations were represented on the Technical Committee:

1. Association for the Physically Disabled of Kenya
2. Dokimos Construction Company.
3. Ministry of Health
4. National Council for Persons with Disabilities
5. Kenya Medical Training College
6. Kenya Society of Physiotherapists
7. Kenyatta National Hospital
8. National Association for Orthopaedic Technologist in Kenya
9. Isole Engineering Works
10. Ministry of Lands Housing and Urban Development
11. Association For Accessibility and Equality (AAFE)
12. Action Network for the Disabled
13. Skillpark Company

REVISION OF KENYA STANDARDS
In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.
Foreword

This part 2 of the Kenya Standard has been prepared by the KEBS/TC 132 Assistive Products for persons with Disabilities Technical Committee and it is in accordance with the procedures of the Bureau.

The Standard was found necessary in ensuring the quality of Lower limb prostheses either manufactured locally or imported into the country. This is only a guide to the manufacturers, fabricators, service providers and users of Lower limb prostheses. Lower limb prostheses are devices designed to fit missing part of the leg. They must permit comfortable ambulation during gait minimizing the shift of the center of gravity of the body enhanced by a well-fitted socket and proper alignment.
Prostheses - Lower limb Specifications

1. Scope

This part of Kenya Standard establishes a classification of assistive products, especially produced for persons who are either amputated or with congenital absence of the leg. This part of Kenya standard specifies requirements for Lower limb Prostheses including medical and Biomechanical principles, materials, shape, workmanship, finishing, packaging, marking, cosmosis, components parts, accessories and performance of the Prostheses.

2. Application

Lower limb Prostheses are used frequently on patients who have had Amputation of the legs at various levels due to various causes, especially due to accidents and diseases. The Prostheses are made and fitted according to levels of amputations. The considerations when choosing Prosthesis include the following:

- Amputation levels
- Contour of the residual limb
- Expected function of the prosthesis
- Cognitive function of the patient
- Occupation of the client
- Hobbies interests of the client
- Cosmetic importance of the prosthesis (Aesthetics)
- Financial capacity of the client

2. References

The following documents were referred to during the preparation of this standard, from which source we acknowledge with thanks:-


2. Physics: A First Course. "Connections, designing a better prosthetic leg"


4. © KEBS 2017 LOWER LIMB PROSTHESIS.


3 Terminology
For the purpose of this standard, the following terms and definitions given in ISO 9999 shall apply:

4. Different levels of lower limb prostheses

4.1 Lower limb Prosthesis

Device shall replace a missing leg and is made up of components fabricated by a manufacturer.
The two main subcategories of lower extremity prosthetic devices are;
1. Trans-tibial (any amputation transecting the tibia bone or a congenital anomaly resulting in a tibial deficiency).
2. Trans-femoral (any amputation transecting the femur bone or a congenital anomaly resulting in a femoral deficiency). In the prosthetic industry a trans-tibial
prosthetic leg is often referred to as a "BK" or below the knee prosthesis while the transfemoral prosthetic leg is often referred to as an "AK" or above the knee prosthesis.

4.2 Level of Amputation.

1. Partial foot Amputation.
2. Syme’s Amputation.
3. Transtibial Amputation.
4. Transfemoral Amputation.
5. Knee Amputation.
6. Hip disarticulation
7. Hemipelvectomy
3.3.1 Partial foot prosthesis.
The purpose is to restore foot function particularly in walking to simulate the shape of the missing foot segment.

Indication
1. Loss of one or more toes.
2. Transmetatarsal amputation.
3. Amputation or disarticulation through tarsals.

3.3.2 Syme’s Amputation.
Closed expandable syme’s prosthesis more patella tendon bearing (PTB) and less end bearing.

3.3.3 Trans-tibial prosthesis.
Amputation of the lower limb between knee joint and ankle joint.
Various types and models of transtibial prostheses exist, and the final product will be determined through consultation with the prosthetist and upon consideration of many factors including the patient's functional ability, stump size and shape, and funding source.

3.3.4 Trans-femoral
Trans-femoral (above knee) prosthetics refers to an artificial limb replacement where the knee joint has been removed and the individual still has part of the femur or thighbone intact.

Our goal in prosthetics is to fit the client comfortably with the greatest return of function, and to make it look as natural as possible. To achieve this goal, we must create an appropriate style socket (the part the residual limb fits into), and provide the best design knee, ankle, and foot to fit the client’s life style requirements.
3.3.5 Knee Disarticulation (Through knee amputation).
Knee disarticulation is when the knee joint is cut, severing the lower leg. The thigh is retained entirely.
A prosthetic foot, knee joint, adapters and connecting elements to the prosthetic socket form the artificial limb for this level. The socket is the component that connects the artificial limb to the residual limb.
What is known as a cosmetic cover can be applied over the prosthesis to make it cosmetically appealing.
3.3.6 Hip Disarticulation (Through Hip) amputation

In hip disarticulation, the amputation is performed in the area of the hip joint. With this type of amputation, the pelvis subsequently has to control the prosthesis. A prosthetic foot, knee joint, hip joint, adapters and connecting elements to the prosthetic socket are needed for the fitting of the artificial limb. The socket is the component that connects the artificial limb to the residual limb. What is known as a cosmetic cover can be applied over the prosthesis to make it cosmetically appealing.
3.3.7 Hemipelvectomy
Hemipelvectomy, the entire leg and parts of the pelvis up to the sacrum are amputated. With this type of amputation, the pelvis subsequently has to control the artificial limb. A prosthetic foot, knee joint, hip joint, adapters and connecting elements to the prosthetic socket are needed for the fitting of the artificial limb. The socket is the component that connects the artificial limb to the residual limb. What is known as a cosmetic cover can be applied over the prosthesis to make it visually inconspicuous.
4. **Devices / accessories used after amputation of both lower limbs and the pelvis**

4.1 **Socket**
This important part serves as an interface between the residuum (stump) and the prosthesis, allowing comfortable weight-bearing, movement control and proprioception. Its fitting is one of the most challenging aspects of the entire prosthesis. The difficulties accompanied with the socket are that it needs to have a perfect fit, with total surface bearing to prevent painful pressure spots. It needs to be flexible, but sturdy, to allow normal gait movement but not bend under pressure.

4.2 **Shank & Connectors**
This part creates distance and support between the knee-joint and the foot (in case of upper-leg prosthesis) or between the socket and the foot. The type of connectors that are used between the shank and the knee/foot determines whether the prosthesis is modular or not. Modular means that the angle and the displacement of the foot in respect to the socket can be changed after fitting.

4.3 **Foot**
Providing contact to the ground, the foot provides shock absorption and stability during stance. Additionally it influences gait biomechanics by its shape and stiffness. There are different types of feet, with greatly varying results concerning durability and biomechanics. These results are for adults and will probably be worse for children due to higher activity levels and scale effects. The heel is compressed during initial ground contact, storing energy which is then returned during the latter phase of ground contact to help propel the body forward.
4.4 Knee-joint
In case of a trans-femoral amputation there also is a need for a complex connector providing articulation, allowing flexion during swing-phase but not during stance.

6. Design consideration
There are multiple factors to consider when designing a transtibial prosthesis. Manufacturers must make choices about their priorities regarding these factors.

Other
The buyer is also concerned with numerous other factors:
   - Cosmetics
   - Cost
   - Ease of use
   - Size availability

7. Cost
High-cost
The cost of an artificial limb does recur because artificial limbs are usually replaced every 3–4 years due to wear and tear. In addition, if the socket has fit issues, the socket must be replaced within several months. If height is an issue components can be changed, such as the pylons.

Low-cost]
Low cost above knee prostheses often provide only basic structural support with limited function. This function is often achieved with crude, non-articulating, unstable, or manually locking knee joints.

8. MATERIALS
An important consideration in the design and fabrication of a limb prosthesis is the type of material used for its construction. Interface materials will influence the comfort of the socket. Structural materials will affect the strength and weight of the overall prosthesis. The prosthetist has a vast array of materials to choose from in designing the optimal prosthesis for a particular individual.
   . Each individual needs to be evaluated with careful consideration given to their lifestyle, expectations and physical characteristics.

Plastic Polymer Laminates (Thermosets)
Plastic polymer laminates are widely used for the fabrication of prosthetic sockets. This process is performed under vacuum pressure in order to create a product that is lightweight and strong.

Common types of plastic polymer laminates used in prosthetics are acrylic, epoxy and polyester. The advantage of plastic laminates is that the prosthetist has a great deal of control over the strength, stiffness and thickness of the finished product. These variables can be controlled such that the finished product may be strong and thick in certain areas and thin and relatively light in others.

One significant disadvantage of these thermoset resins compared with sheet thermoplastics is that the laminate is difficult and limited in its ability to be remolded after original fabrication. This means that if a specific area of the socket is uncomfortable due to tightness after the prosthesis is in use, it will be more difficult for the prosthetist to heat and remold that area.

**Reinforcement textiles**
Reinforcement textiles are the fabrics used in a laminate to provide strength. These include fiberglass, nylon, Dacron, carbon, and Kevlar.

These materials all have their advantages and disadvantages. For example, carbon fiber is used to create thin, lightweight and strong prosthetic sockets. This is one reason why a prosthetist might use several reinforcement materials in combination, a composite, to design a prosthetic socket. Carbon fiber is also used in several of the dynamic response (energy storing) feet and to create strong lightweight pylons.

**Thermoplastics**
Sheet thermoplastics are widely used for prosthetic interfaces as well as structural components. These materials are available in sheet form in various thickness and colors. The most basic types of sheet thermoplastics are polypropylene and polyethylene.

In addition to PP and PE, there are a multitude of "blended" plastics available to the prosthetist. Characteristics of these materials vary from very stiff to very flexible. A good example of this is Co-Polymer, which is a blend of polypropylene and ethylene creating a material that is fairly rigid yet more flexible and crack resistant than straight polypropylene. Stiff materials are often used for support so that the forces associated with walking can be transmitted from the amputee to the floor. The most common test socket material today is Clear Co-Polyester thermoplastic.

**Silicone and similar materials**
Silicone is used as a padding material in sockets, as a means of suspension in the silicone suction socket (3S Iceross type) and is the material of choice when making high quality cosmetic leg restorations, to name a few. This material comes in many forms.
and can be made in a firm durometer or a very soft durometer. When made in a very soft durometer, silicone not only provides excellent padding but also protects the skin from friction (shear). This can be very important because friction often is the cause of skin breakdowns. The silicone suction socket uses what could be called a silicone "sock" worn directly against the skin that incorporates an attachment pin at the bottom, locking the sock, and the amputee, into the prosthesis.

Metals
Th metal in a prosthetic components include knees, pylons, ankles and rotators. These components can be made of aluminum, stainless steel and titanium. Aluminum, in general, is considered as a lightweight alternative to steel. It's not as strong but depending on the particular application it is often strong enough to meet the design criteria and pass the necessary testing procedures. Certain knees are fabricated of aluminum, taking advantage of its light weight. Some of these knees are very strong and durable owing much of their strength to the geometry of the knee as well as the material used. Steel is certainly strong but it is relatively heavy. Because steel is strong, it can be used to create small components that may rely more on the strength of the material than the geometry of the design. Small knee units used for endoskeletal prostheses were originally made of steel. The material is fairly heavy however very little material is needed to construct these knees. Titanium is a strong, lightweight alternative. The penalty for using titanium is higher cost. Many of the endoskeletal components originally designed of steel are now available in titanium.

Liners and Sleeves
Liners are the materials that are either made during the fabrication process to fit inside the socket or those materials added after the leg is in use in order to accommodate for shrinkage of the residuum. Pelite is probably the most commonly used "soft socket" liner material. It is a closed-cell polyethylene foam material that is available in various durometers. This material is thermoformable, meaning that it can be heated and formed over the plaster cast. Pelite and materials like it have the advantage that they are easily adjusted by adding additional material when the residual limb shrinks. It is also convenient to use these materials if suspension of a below-knee prosthesis sleeves are worn over the outside of the prosthesis and are used to provide suspension. Some common materials used for sleeves are: neoprene, silicone, latex, and urethane. Sleeves are worn over the prosthesis and extend onto the thigh of the below-knee amputee. The most common materials used in prosthetics today are various plastics, but the more traditional materials such as wood, leather, metal, and cloth still have a role to play.
Wood
Wood is often used in lower-limb prostheses to provide shape and interior structural strength. The inherent properties of wood make it a very difficult material to replace: it is lightweight, strong, inexpensive, easy to work, and consistent in texture. Basswood (linden), willow, and poplar wood are most commonly used for prosthetic knees and shins because they are lightweight, strong, and free from knots and can be shaped easily by using standard woodworking tools. When a prosthesis is finished, it is hollowed out until the wood is only 6 mm (1/4 in.) thick to reduce weight.

Hardwoods are also used in lower-limb prosthetics. Solid-ankle, cushion-heel (SACH) feet have an interior hardwood keel that provides structural strength to the foot.

Leather
Leather is another material still commonly used in prosthetics for suspension straps, waist belts, and socket linings. Leather is easy to work with, has a soft natural feel, and is biocompatible.

Cloth
Cloth is used for prosthetic socks, waist belts, straps, and harnesses for upper-limb prostheses. Probably the greatest use of cloth is for prosthetic socks, which can be considered analogous to athletic socks since they keep the skin dry, cushion the limb, absorb shear forces, and take up volume to improve the fit. Prosthetic socks are commonly made of wool, cotton, or blends of these natural fibers often combined with nylon, Orion, acrylics, or other man-made materials.

Wool is the most common material used for prosthetic socks because of its characteristic elasticity, cushioning, and ability to absorb moisture without feeling damp. Wool also has good resistance to acids from perspiration. The blend of domestic and foreign wool fleece used in prosthetic socks provides greater resistance to shrinkage. Pure wool, however, must be washed carefully in a mild soap that will dissolve in lukewarm water. The sock should be rinsed in lukewarm water as well since a change in temperature will affect it adversely. Wool prosthetic socks should be dried carefully by first removing the excess water, wrapping them in a towel, and then drying them away from sunlight or any other direct heat. The recent development of machine-washable wool should reduce the need for hand washing in the future.

Cotton is also used for prosthetic socks but is more common in the form of a stockinette used to protect the limb during casting procedures. Cotton is also blended with wool in prosthetic socks, and some 100% cotton prosthetic socks are available.

Plastics
Nylon is used for prosthetic sheaths, plastic laminations, bushings, suction valves, and nylon stockings to cover prostheses. The major advantages of this man-made fiber are
its strength, elasticity, and low coefficient of friction. Nylon prosthetic sheaths are in common use for transtibial amputees. A thin sheath worn directly over the skin significantly reduces shear stresses and helps to pull moisture away from the skin into the outside prosthetic socks. A nylon stockinette provides inherent strength to nearly all prosthetic laminations.

*Acrylics* are thermoplastics that have greater durability and strength than polyester resins do. Acrylic fibers are frequently used in the newer synthetic blends for prosthetic socks since this material is soft, durable, and machine washable. Acrylic resin is increasingly popular for laminations in prosthetics because its high strength permits a thinner, lighter-weight lamination and its thermoplastic properties allow easier adjustments of the prosthesis by reheating the plastic and remolding it locally. Acrylic resins tend to have a softer feel than polyester resins but are more difficult to use during fabrication. Clear acrylics have been used for years in the sign and building industry for skylights and enclosures for shopping centers; they do not yellow and have good weather resistance.

*Polyester resin* is a thermosetting plastic that is most commonly used for laminations in prosthetics. Thermosetting plastics cannot be heated and reformed after molding without destroying their physical properties. Polyester resins come in a liquid form that can be pigmented to match the patient's natural skin tone.

### 9. Cosmesis

Cosmetic prosthesis has long been used to disguise injuries and disfigurements. With advances in modern technology, *cosmesis*, the creation of lifelike limbs made from *silicone* or *PVC* has been made possible. Such prosthetics, such as artificial limbs, can now be made to mimic the appearance actual ones. Custom-made cosmeses are generally more expensive, while standard cosmeses come ready-made in various sizes, although they are often not as realistic as their custom-made counterparts. Another option is the custom-made silicone cover, which can be made to match a person’s skin tone but not details such as freckles or wrinkles.