Part 1: Upper limb Prostheses
TECHNICAL COMMITTEE REPRESENTATION

The following organizations 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 reviewed regularly. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.
Foreword

This 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 Upper limb prostheses either manufactured locally or imported into the country. The Standard also contains an annex for special prostheses. This is only a guide to the manufacturers, fabricators, service providers and users of upper limb prostheses.

Upper limb prostheses are devices designed to replace a missing part of the arm that can be either functional or cosmetic. Functionally we have two types: passives and active prostheses. Passive are assisted to do different tasks and cosmetic in nature. Functional prosthesis enables an amputee to perform tasks. These can either be electrically or body powered.

The arm uses a combination of mechanisms, including switches, movement sensors and force sensors that make the prosthesis move. The arm can be configured for patients with limb loss at the shoulder joint, mid-upper arm, or mid-lower arm, and for limb loss below the elbow or wrist joint.
KENYA STANDARD Prostheses – Specification Part:1 Upper limb Prostheses

1 Scope
This part of the standard specifies requirements for Upper limb Prostheses including medical and Biomechanical principles, materials, shape, workmanship, finishing, packaging, marking, cosmesis, components parts, accessories and performance of the Prostheses. In addition we have also included standard for special prosthesis in the Annex A.

Application

Upper limb Prostheses are used frequently on patients who have had Amputation of the hands at various levels due to various conditions 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 Terminology

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

2.1 Upper limb Prosthesis

Upper limb Prosthesis is an orthopaedic device designed to replace and aid movement to a missing body part.

**NOTE** Different professional disciplines are crucial in prosthetic management such as materials engineering, gait and activity of daily living analysis, body structure and functions, abnormal functions, application of forces and body’s reaction to the forces and behavior.

2.2 Upper limb Prostheses

Upper limb are devices applied externally to replace the hand or missing segment of the arm.

2.3 Levels of amputations

There are seven levels of upper limb amputations with the following corresponding prostheses:

1) Partial hand
2) Through wrist
3) Transradial
4) Through elbow
5) Transhumeral
6) Shoulder disarticulation
7) Inter scapula-thoracic
2.3.1. Partial hand

Partial hand amputation can be replaced by fitting a client with prosthetic fingers that are functional and well accepted. Most of the partial hand prosthetics are fabricated using silicon polymers.

2.3.2. Through wrist

Wrist prosthesis in extension and flexion at the level of the distal carpal row reduce the forces acting on the implant anchorage. The ellipsoid articular surface configuration restricts the degree of rotational freedom to a necessary extent so that low levels of muscular dysbalance can be absorbed. Additional soft tissue stabilizing measures are possible.
Below-elbow prosthetic devices are created for clients who have been amputated through their forearm. These prostheses can be operated by electronic parts or by a simple harness system (also termed “body-power”). The harness is intimately fitted to allow the user control of the prosthetic hand through other motions: moving the elbow forward, for example.

- There are many types of below elbow prostheses. The type that an amputee is fitted with depends on the shape, the length of the residual limb, cosmesis, financial capability, activity level, prognosis and individual preference. Prosthesis is custom made to the person that it is being fitted to.
- A Below Elbow (BE) prosthesis can be made for different purposes depending on the wearer. A cosmetic, or passive, prosthesis is used primarily to replace the body part that is missing. This promotes a healthy body image, but is also functional in that it can assist the sound side arm in activities such as holding or placing objects.
- A body powered, or conventional, prosthesis uses body movements to operate the terminal device (hand or hook). The prosthesis is connected to the body through the use of cables and a harness. By movements of the shoulders and the arms, the person can open and close the terminal device.
- A myoelectric prosthesis uses muscles of the affected arm to control the opening and closing of the terminal device. Electrodes are fitted within the prosthesis. By contracting the muscles of the arm which formerly controlled the opening and closing of an anatomical hand (amputated hand), electrical outputs are sent to a motor that open and close an artificial hand.

2.3.4. Through Elbow
Elbow prosthesis system provides an alloplastic replacement of the humeroradial joint through a modular radius head, which articulates with a humeral gliding surface at the elbow prosthesis.

2.3.5 Transhumeral
2.3.6 Shoulder Disarticulation Amputation
Amputations through the shoulder (glenohumeral and scapulothoracic articulations) are uncommon. Causes include serious injury, cancers, traumatic amputations and Congenital limb deficiencies.
The prosthesis should meet the following qualities: functional, comfort and cosmetically accepted. Every Prosthesis custom made for each patient / client.

3. Terminal devices for the upper limb prosthesis
3.1 Body Powered / Conventional
A Body Powered or Conventional upper extremity prosthetic device is operated by a harness system. The harness system is controlled by specific body movements. The advantages of a conventional prosthesis is that the heavy duty construction of the device gives it a long life; it offers sense of feeling and feedback (proprioception); it’s less expensive and lighter than myoelectric devices; and there is a reduced cost and maintenance. The disadvantage is on its Mechanical appearance and difficulty in using it by some Patients / clients due to their physical ability.

3.2 Myoelectric / External Power.
A Myoelectric upper extremity prosthetic device is powered by a battery system and is controlled by Electromyogram (EMG) signals generated during muscle contractions. The advantage of a myoelectric prosthesis is that there is an unlimited functional envelope; it offers functional cosmetic restoration; it offers comfort and increased range of motion.

3.3 Passive Functional / Cosmetic.
A Passive Functional or Cosmetic upper extremity prosthetic device is similar in appearance to the non-affected arm or hand and replaces what was lost. It provides simple aid in balancing and carrying. The advantages of this type of prosthesis is that they can be cosmetically appealing; lightweight; simple to use; there is little maintenance; they are great for partial hands and provides opposition.
3.4 Hybrid

A Hybrid upper extremity prosthetic device combines the use of body power and external power. The advantages of this system is that there is a greater functional envelope from the basic body powered device; it offers reduced weight from the myoelectric device; it offers the greater grip force like the myoelectric; the harness system is reduced.

3.5 Adaptive / Recreational.

A Recreational or Adaptive upper extremity prosthetic device is customized for a specific function or recreational activity. There are various adaptive devices available for activities such as sports, leisure, occupation and Activities of daily living (ADL).

4. Switch types.

A variety of motions are possible through different kinds of switching devices. Many switches are activated by pulling a cable or pressing a lever or button. Switches are designed to perform multiple functions and come in many presentations. These switches are Harness type, Push switch, Depressing switch and Multi position switch. Switches can be momentary (providing brief actuation while the switch is activated) or latching (maintaining function until the person activates the switch again).
5. 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.

5.1. Thermoplastics

Sheet thermoplastics are widely used in prosthetics 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. Polypropylene (PP) is a very rigid plastic that has found several uses in prosthetics. PP can be reshaped or remolded.

5.1.2 Thermosetting

These are plastics and settings that become rigid when setting. These are synthetic materials that strengthen during being heated but cannot be successfully remolded or reheated after their initial heat forming. These is in contrast to thermoplastics which soften when heated.

5. 2 Silicone and similar materials

Silicone has 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 hand restorations, to name a few. This material comes in many forms, colours and provides excellent padding that protects the skin from friction and abrasion.
5.3 Metals

Metals are used in making knee joints, pylons, ankle joints, elbow joints and wrist joints where movement and weight bearings are concerned. The commonly used metals include: Aluminum, Stainless steel, Titanium due to their different physical and chemical properties.

(These to be included in the glossary) 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. As with all of the trade-offs that must be considered in choosing prosthetic components, one must carefully weigh the advantages and disadvantages and choose wisely. The most expensive, strong and lightweight materials may not provide any discernible advantage over less exotic options if chosen inappropriately.

5.4. Liners and Sleeves

Liners

Liners are the materials that are either made during the fabrication process to fit inside the socket or those materials added after the arm is in use in order to accommodate for shrinkage of the residuum. The commonly used liners are: pilites, silicon, stump socks

Sleeves

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 upper arm and below elbow prosthesis.

5.7. 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.
6. Finishing

The finished prosthesis hand should be as near normal as possible both in function, safety and appearance. It should be:
   a) Custom made
   b) Cosmetically accepted
   c) Functionally appropriate
   d) Safe to use

7. Marking

Each pre-fabricated prosthesis shall be permanently and indelibly marked with the manufacturer's name, initials or recognized trade-mark and the size.

8. Packaging

8.1 Each pre-fabricated prosthesis shall be supplied with a user manual and packed using environmental friendly materials as per recommendations of kebs.

8.2 Custom made prosthesis shall have clear instructions to the user / client regarding the use and maintenance.
9. REFERENCES.

1. (by Jack E. Uellendahl, CPO) Prosthetic Primer: Materials Used in Prosthetics Volume 8 · Issue5 · September/October 1998 IN MOTION


9. "With a new prosthetic, researchers have managed to restore the sense of touch for a Denmark man who lost his left hand nine years ago.". USA Today, 4:54 p.m. EST February 5, 2014.

10 "Artificial hand offering immediate touch response a success", Channelnewsasia, Feb 07, 2014


30. ^ World Premiere of Muscle and Nerve Controlled Arm Prosthesis

31. ^ Permanently attached robotic arm, operated on mind-control


SPECIAL TYPES OF PROSTHESES.
Even though this standard was to address the upper and lower limb prostheses it has been found necessary to include the following types;

- Breast prosthesis
- Nose prosthesis
- Ear prosthesis

1. Breast prosthesis

External breast prosthesis is an artificial breast form that can be worn after a mastectomy (removal of the breast). It helps balance the body and keeps the bra on the side of the mastectomy from riding up, which helps prevent back and neck pain and a sagging shoulder. Breast prostheses are custom-designed for most women. They are made from several different types of material (such as silicone gel, foam, and fiberfill) that are of similar weight and feel to natural breast tissue. Some prostheses adhere directly to the chest area, while others fit into pockets of mastectomy bras to hold the prosthesis in place. Prostheses can also be made with an artificial nipple or a special shape depending on preferences.

Types of breast prosthetic devices

External silicone breast prosthesis. This type of prosthesis is made of silicone and designed to model natural breast tissue. The prosthesis is designed to weigh the same as the natural breast to help prevent shoulder drop and poor balance.

No silicone breast prosthesis. This prosthesis is a lightweight breast form made of foam or fiberfill and can be worn right after a mastectomy. It can also be worn during exercise, swimming, and in hot weather.

Attachable breast. An attachable breast is fastened to the chest wall using adhesive strips.

Post surgical soft-form camisole. A postsurgical (after surgery) camisole is made of a soft, stretchy material with lace elastic straps and is often worn immediately after a mastectomy.

Partial breast prosthesis. Also called an equalizer or enhancer, this prosthesis is made of foam, fiberfill, or silicone. It's designed to be worn over a client's own breast tissue to create a fuller appearance after a part of client's breast is removed.

Being fitted for a prosthesis
After you have completely healed from surgery, which typically takes between four and eight weeks, you can be fitted for prosthesis. At the first fitting appointment, it's recommended that the clients wear a form-fitting garment, such as a knit top, so you can see how the shape and size of the breast form matches the other natural breast. With proper fitting, the prosthesis will not be noticeable.

**Choosing breast prosthesis**

Choosing to wear breast prosthesis is a personal decision. Many clients select this option because they want to look the same when wearing clothing as they did before their surgery. Prosthesis offers these advantages as well:

- Protects your chest and surgical scars
- Helps balance your posture
- Keeps your bra from shifting side to side or riding up
- Helps prevent problems with curvature of the spine, shoulder drop and muscular pain in your neck and back.

.Size and weight: S:560g/pair,16*11*5.5cm,M:600g/pair,18*12*6.8cm, L:700g/pair,18*12*6.8cm,XL:800g/pair,20*13*6.8cm

Packing: 1pr/ploybag, 12prs/ctn
. Outer carton: 2-ply corrugated, 40*30*15cm

Care instruction: Hand wash in cold water, Air dry.
2. Prosthetic Nose

This nose is for cosmetic purposes and the protection of underlying tissue from exposure to possible damage. It has no capacity to breathe or smell. A person would use such a device if his or her natural nose were injured in an accident, destroyed or due to other health condition.

The anaplastologist (prosthesis maker) will tint and detail the piece with veins, pores, and a skin colour to make it more realistic.

Silicone noses such as this one below are light enough to be attached with adhesive and the outline masked with makeup.

3. Ear Prosthesis

Silicone Ear

If you choose to enhance your appearance with a silicone ear, it will be fabricated using a mold of the unaffected ear. This customized precision means that the prosthetic will match the new ear in shape, skin color, and size of actual ear.

There are two types of prosthetic ears. The first adheres to the skin using safe, biocompatible glue, and the second type is called osteointegrated prosthesis. If the clients choose to receive an osteointegrated prosthetic ear, the surgeon will place several titanium implant posts into the bone around the ear. The silicone ear snaps securely onto these implants. Both types of prostheses are removable. Ear prosthetics should be removed before you sleep or participate in athletic activities. The ear should be thoroughly cleaned including the underlying tissue. Normally these prostheses last between one and three years, depending on maintenance, environment, activity level, and other factors.

Silicone ears offer excellent non-surgical option for the treatment of microtia (deformity of the external ear) or traumatic deformity.