MANUFACTURING GUIDELINES

KNEE-ANKLE-FOOT ORTHOSIS

Physical Rehabilitation Programme
MISSION

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Pierre Gauthier
Frank Joumier
Jacques Lepetit
Bernard Matagne
Joel Nininger
Guy Nury
Peter Poestma
Hmayak Tarakhchyan

and all prosthetists-orthotists who have worked in ICRC-assisted physical rehabilitation centres.
# Table of contents

Foreword .......................................................... 2
Introduction ......................................................... 4
1. Casting, measurement and rectification .................. 4
2. Preparation of reinforcements ............................ 6
3. Polypropylene draping and vacuum moulding ....... 7
4. Position of the side bars .................................... 9
5. Trim lines ....................................................... 11
6. Assembly and parallelism .................................. 12
7. Initial fittings ................................................. 13
8. Finishing ....................................................... 14
9. KAFO options ............................................... 15
List of components and materials .......................... 16
Foreword

The ICRC polypropylene technology

Since its inception in 1979, the ICRC’s Physical Rehabilitation Programme has promoted the use of technology that is appropriate to the specific contexts in which the organization operates, i.e., countries affected by war and low-income or developing countries.

The technology must also be tailored to meet the needs of the physically disabled in the countries concerned.

The technology adopted must therefore be:

- durable, comfortable, easy for patients to use and maintain;
- easy for technicians to learn, use and repair;
- standardized but compatible with the climate in different regions of the world;
- low-cost but modern and consistent with internationally accepted standards;
- easily available.

The choice of technology is of great importance for promoting sustainable physical rehabilitation services.

For all these reasons, the ICRC preferred to develop its own technique instead of buying ready-made orthopaedic components, which are generally too expensive and unsuited to the contexts in which the organization works. The cost of the materials used in ICRC prosthetic and orthotic devices is lower than that of the materials used in appliances assembled from commercial ready-made components.

When the ICRC launched its physical rehabilitation programmes back in 1979, locally available materials such as wood, leather and metal were used, and orthopaedic components were manufactured locally. In the early 1990s the ICRC started the process of standardizing the techniques used in its various projects around the world, for the sake of harmonization between the projects, but more importantly to improve the quality of services to patients.

Polypropylene (PP) was introduced into ICRC projects in 1988 for the manufacture of prosthetic sockets. The first polypropylene knee-joint was produced in Cambodia in 1991; other components such as various alignment systems were first developed in Colombia and gradually improved. In parallel, a durable foot, made initially of polypropylene and EthylVinylAcetate (EVA), and now of polypropylene and polyurethane, replaced the traditional wooden/rubber foot.

In 1998, after careful consideration, it was decided to scale down local component production in order to focus on patient care and training of personnel at country level.
Objective of the manuals

The ICRC’s “Manufacturing Guidelines” are designed to provide the information necessary for production of high-quality assistive devices.

The main aims of these informative manuals are as follows:

• To promote and enhance standardization of ICRC polypropylene technology;
• To provide support for training in the use of this technology;
• To promote good practice.

This is another step forward in the effort to ensure that patients have access to high-quality services.

ICRC
Assistance Division/Health Unit
Physical Rehabilitation Programme
Introduction

The aim of this document is to describe a method for producing \textit{knee-ankle-foot orthoses} (KAFO), working with polypropylene technology and commercial upright sidebars with drop locks as used at the ICRC’s physical rehabilitation centres.

1 \textbf{CASTING, MEASUREMENT AND RECTIFICATION}

The casting and rectification methods used correspond to international prosthetic and orthotic (P&O) standards of practice and are therefore not described in these ICRC manufacturing guidelines.

Some important points should nevertheless be taken into account:

1.1 \textbf{Anatomy and landmarks}

- Great trochanter
- Medial tibial plateau
- Head of fibula
- Malleoli
- The 1\textsuperscript{st} and 5\textsuperscript{th} metatarsal heads
- Navicular bone
- Base of 5\textsuperscript{th} metatarsal, if prominent
1.2 Cast rectification method

Once rectification is completed, check the following:

- The posterior line passes through
  1. the middle of the thigh
  2. the middle of the knee
  3. the middle of the ankle

- Heel and forefoot are flat on the ground

- The lateral line passes from the great trochanter to the middle of the lateral malleolus
1.3 Mechanical knee joint location

- Mechanical axes are defined in accordance with P&O practice, as shown here.

2 PREPARATION OF REINFORCEMENTS

The positive plaster remains in a vertical position:

- Drive two nails into the mould at the mechanical knee axis (they should protrude about 5 mm)
- Pull a nylon or cotton stocking over the mould
- Fix the EVA reinforcement according to the measurement card and requirements
- Dust the stocking with talcum powder
Cut a 5 mm sheet of polypropylene (PP) as follows:

- Upper circumference +10 cm
- Total length +20 cm
- Lower circumference +15 cm

Clean the PP sheet.

- Heat the polypropylene at 180° for 20 to 25 minutes, depending on the thickness of the polypropylene and the performance of the oven.

Drape the polypropylene over the plaster model. Lay the polypropylene over the mould without stretching it.

Drape it first over the ankle towards the middle anterior part of the orthosis mould. Then pull it around the forefoot.
Stick it together along the anterior side.

Tighten the polypropylene around the suction cone with a rope or something similar.

Open the vacuum valve.

With scissors or a knife, cut off the excess polypropylene along the welding seam while it is still hot.
Remarks

If the polypropylene sheet cut according to the measurements of the plaster is too big to fit into the oven, prepare two PP sheets instead of one.

Drape the PP around the plaster mould.

Pay attention to the overlap area, pulling the PP gradually and carefully; otherwise it will be stretched too thinly and be too weak.

Open the vacuum valve and remove the excess PP along the seam.

POSITION OF THE SIDE BARS

- On the bench, the positive mould is installed as follows:

- The position of the knee axis should be marked in relation to the vertical line indicating the location of the mechanical knee joint.
The uprights are cut to the required length, bent and adjusted following the curves of the PP shells.
During adjustment of the side bars, the position and parallelism of the knee axis must be respected.

Axis location and trim lines

5 TRIM LINES

Trim lines depend on the type of correction required and the function of the KAFO.

In most cases, trim lines should be drawn according to international P&O standards, as shown here:
The polypropylene is cut off and the trim line contours are ground and polished before temporary assembly of the KAFO for trial.

6 ASSEMBLY AND PARALLELISM

The side bars are temporarily fixed on the polypropylene shells with M3 screws and nuts.

Precise parallelism of the knee joint is of the utmost importance and must be ensured before the first fitting as follows:

Method 1: Using a Vernier calliper
Method 2: Using the centring pin

7 INITIAL FITTINGS

- Strap the KAFO on the patient's lower limb.

- Check the trim lines before the patient stands up.

Once the shoes are on, the patient stands up and gait training can begin.
FINISHING

- The trim lines are carefully polished
- The uprights are fixed with copper rivets
- The straps are fixed with tubular rivets
- The parallelism of the knee joint is checked again
- The uprights can be covered with fine leather
Some patients need an ischial seat support. In this case the brim has an anterior opening. The shape is similar to that of quadrilateral socket prosthesis.

The KAFO can be fitted with different orthotic joints (Swiss lock, drop lock, free offset, etc.).
**List of components and materials**

<table>
<thead>
<tr>
<th>ICRC Code</th>
<th>Description</th>
<th>Unit of measure</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For negative and positive cast:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ODROSTOCT60</td>
<td>Tubular stockinet, 60 cm</td>
<td>Cm</td>
<td>135</td>
</tr>
<tr>
<td>MDREBANDP10-12-15</td>
<td>Plaster of Paris bandages 10, 12 or 15 cm x 3 m</td>
<td>Piece</td>
<td>6 to 7</td>
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<tr>
<td>OTOOPLASPW40</td>
<td>Plaster of Paris powder</td>
<td>Each</td>
<td>As required</td>
</tr>
<tr>
<td><strong>For EVA and plastic moulding:</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>OPLAEVAFKIN06</td>
<td>EVA FOAM 6 mm x 0.95 m x 0.95 m, 0.90 m², skin colour</td>
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<tr>
<td>OPLAPOLYSKIN04</td>
<td>HOMOPOLYMER 4 mm or 5 mm x 1 m x 2 m 7.5 kg, beige colour</td>
<td>Sheet</td>
<td>0.5</td>
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<td><strong>For components/sidebars:</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>OCPKNEEBO20DL/16DL</td>
<td>ORTHOSIS, ADULT, 20 mm or 16 mm side bar knee joint w.drop lock (pairs)</td>
<td>Pair</td>
<td>1</td>
</tr>
<tr>
<td>OCPKNEEBO20SL/16SL</td>
<td>ORTHOSIS, ADULT, 20 mm or 16 mm side bar knee joint, Swiss lock (pairs)</td>
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<tr>
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<tr>
<td><strong>For straps and rivets:</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>OSB0VSB026</td>
<td>ELASTIC STRAP 25 mm x 25 m</td>
<td>Roll</td>
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<tr>
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<td>GLUE, SYNTHETIC</td>
<td>Litre</td>
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<tr>
<td>OSB0VSB036</td>
<td>LOOP 35 mm x 100 pcs</td>
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<tr>
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<td>PLASTER POWDER</td>
<td>Kg</td>
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<tr>
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<tr>
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<tr>
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<td>STRAP (PROSTHESIS) 35 mm x 50 m</td>
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<tr>
<td>OSB0VSB025</td>
<td>STRAP (VELCRO) 30 mm</td>
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<td>OOMAALIGORTH</td>
<td>CENTRING PIN FOR ORTHOSIS</td>
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<td>30</td>
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<tr>
<td>ETOOMEASC15</td>
<td>VERNIER CALLIPER</td>
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<td>35</td>
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<tr>
<td><strong>Special hand tools:</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>OTOOMEASCIR4 _ 7</td>
<td>COUNTOURING INSTRUMENT, ROUND BEAK</td>
<td>Each</td>
<td>2</td>
</tr>
<tr>
<td>OTOOMEASCFL</td>
<td>COUNTOURING INSTRUMENT, FLAT</td>
<td>Each</td>
<td>2</td>
</tr>
<tr>
<td>OOMAALIGORTHX</td>
<td>CENTRING PIN FOR ORTHOSIS</td>
<td>Each</td>
<td>1</td>
</tr>
<tr>
<td>ETOOMEASC15</td>
<td>VERNIER CALLIPER</td>
<td>Each</td>
<td>1</td>
</tr>
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