Rehab Impulse™

MANUFACTURING GUIDELINES

Partial foot prosthesis

Promoting Independent Lifestyle

rehabimpulse.org

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Foreword

The polypropylene (PP) technology

This technology was created by the International Committee of the Red Cross (ICRC) in 1979. Its use is appropriate to specific contexts i.e., countries affected by war and low-income or developing countries.

The technology has been tailored to meet the needs of the physically disabled in the countries concerned.

The features of this technology are:
- Freedom from the transport and storage restrictions of other materials and no shelf-life constraints;
- Durable, comfortable, easy for service users to use and maintain;
- Its hard cosmetic shell helps the device maintain a good appearance throughout its life;
- Easy for P&O technicians to learn, use and repair;
- Standardized but compatible with the environment in different regions of the world;
- Low-cost but modern and consistent with internationally accepted standards (ISO certification and CE marked);
- Does not require expensive machines, tools, and a large setup;
- Easily available.

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

The Rehab'Impulse Brand – owned by ICRC made by Alfaset!

The ICRC registered the Rehab'Impulse trademark in 2019 with the aim of developing a brand identity for its technology. The Rehab'Impulse brand remains under the ownership of ICRC, while the components are manufactured in Switzerland by the Alfaset Foundation, a social enterprise employing persons with disabilities.

Objectives of the manuals

The “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 good practice.
- To provide support for training in the use of this technology.
- To promote and enhance Rehab'Impulse technology.

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

Rehab Impulse™

Introduction

The aim of this document is to describe a method for producing **partial foot prostheses** using polypropylene technology.

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

Remarks:

- The procedure described relates to one of the most common types of partial foot amputation, which is also known as Chopart or mid-foot amputation.
- If full end bearing is not possible, the Patellar-Tendon-Bearing (PTB) design should be used.

1. Footprint of sound side

- Copy the sound-side footprint on a sheet of paper and mark the foot rotation between 5° to 8° (Fig 1 and 2).

  Insert frontal line (Fig 1 and 2).

Fig 1

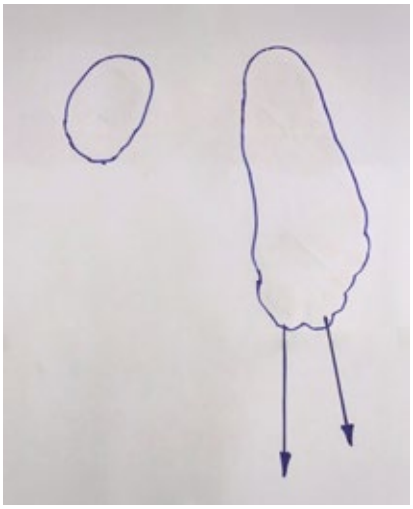

Fig 2

- Fix the paper against a window and copy the reverse side of the footprint (Fig 3).

  The print will help in the positioning the build-up of the foot on the prosthesis.

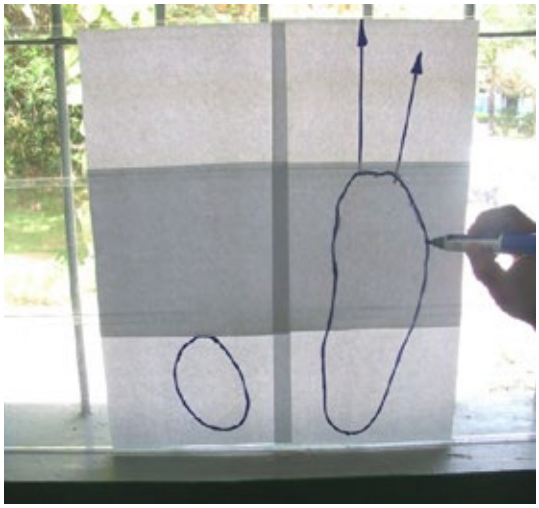

Fig 3

2. Casting and rectification

Service user assessment and casting are performed in accordance with P&O standards ensuring the cast is taken while the amputee is sitting down.

Service users who will have their full weight bearing on the prosthesis should stand before the plaster bandages have hardened (Fig 4 and 5). For more sensitive stumps the service user should stand on a layer of soft foam, and if necessary, a heel wedge may be added to compensate for an equinus position of the stump or the height of the shoe heel.

Care must be taken to ensure that the calcaneus is held in a neutral position in the frontal plane.

Fig 4

Fig 5

Rectification of the positive model impression is performed in accordance with P&O standards.

Reference lines can be added on the moulds (Fig 6, 7 and 8) and the footprint.

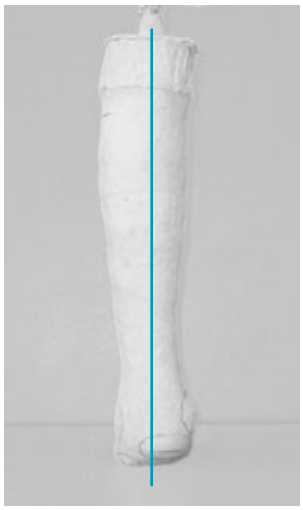

Fig 6

Fig 7

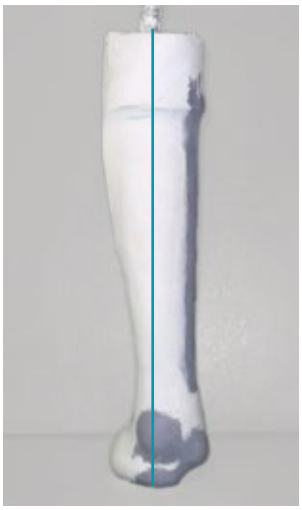

Fig 8

3. Soft socket fabrication

Fig 9

Fig 10

Fig 11

Measurement of EVA foam:

1. Circumference 2 cm above the head of the fibula (Fig 9)
2. Circumference middle of the calcaneus (Fig 10)
3. Length of plaster cast + 5 cm (Fig 11)

Cut a trapezoid from a sheet of 6 mm EVA foam according to the above measurements (Fig 12 and 13).

Fig 12

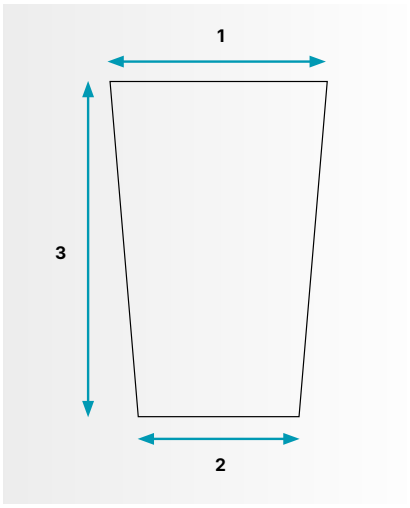

Fig 13

Note that in the case of more bulbous stumps, the width of the EVA foam in the narrowest part of the cast may need to be reduced to achieve a close fit. Sometimes it takes more than one attempt to produce a good fitting soft socket.

- Grind a 15 mm chamfer on opposing lateral sides of the EVA foam to zero millimetres (Fig 14).

Fig 14

- Apply Neoprene contact glue twice on both trimmed sides (Fig 15).

Fig 15

- Once the glue is dry (approximately 15 minutes), join the two surfaces to form a cone (Fig 16).

Fig 16

- Use a mallet along the seam to ensure a strong joint (Fig 17).

Fig 17

- Dust the plaster positive model and the inside of the EVA foam cone with talcum powder to facilitate sliding (Fig 18).

Fig 18

- Heat the EVA foam cone in an oven for about 3 minutes at 120°C and then pull it over the plaster positive model (Fig 19).

Fig 19

- To ensure the EVA foam forms the same shape as the plaster positive model, secure it with elastic bandages or place it under vacuum until it has cooled down (Fig 20).

Fig 20

- Trim the distal section of the EVA foam cone with a knife and smooth it by grinding (Fig 21).

Fig 21

- Apply two layers of Neoprene contact glue to the trimmed section and to the 12 mm thickness EVA foam socket cap (Fig 22).

Fig 22

- Heat the cap for 2 to 3 minutes at 120°C in an oven and glue it onto the soft socket (Fig 23).

  Cut off and grind to remove the excess EVA foam.

Fig 23

4. Forefoot build-up

- Glue layers of 12 mm heated EVA foam corresponding to the length of the sound foot measured before casting (Fig 24).

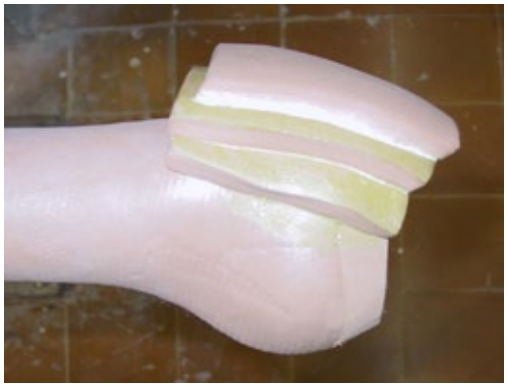

Fig 24

- Pre-shape the forefoot with a knife (Fig 25 and 26).

Fig 25

Fig 26

- Use the footprint taken before casting to determine the correct external foot rotation (approximately 5° to 8°) (Fig 27).

  Check the anterior/posterior and the lateral/ medial alignments against the measurement card maintaining the correct heel height.

Fig 27

- Finish shaping the forefoot on the grinding machine (Fig 28 and 29).

  Make sure that the plantar sole between heel and toes is parallel and, if necessary, that the heel height is correct. Where possible, shape the longitudinal arch support.

Fig 28

Fig 29

- For finishing, a sheet of 3 mm EVA foam is draped over the foot (Fig 30).

Fig 30

- Fit the sheet of EVA foam on the foot by cutting it round around the ankle (Fig 31).

  Apply two layers of Neoprene contact glue, then heat the 3 mm EVA in the oven for 1-2 minutes at 120°C before draping it. Cut and smooth the edges. A further sheet of 3 mm EVA foam sheet may be added (glued) to the sole.

  This operation can also be carried out after the first fitting of the soft socket on the amputee, described below.

Fig 31

5. First fitting of soft socket

- Before the polypropylene is draped, the soft socket must be checked on the service user.

  The soft socket must be removed from the plaster positive model without breaking it.

  On the posterior side, punch a 4 mm hole just above the calcaneus. This helps avoid tearing of the EVA foam when the soft socket is being removed from the plaster model (Fig 32 and 33).

  Draw a line or use a ruler to make a straight cutting line up to the proximal end of the socket (Fig 33).

  Remove the soft socket carefully and keep the plaster positive model.

Fig 32

Fig 33

- To check the fit, alignment and length of the soft socket, fix it with tape (Fig 34 and 35).

Fig 34

Fig 35

- Check the height of the prosthesis and its static alignment. Make the necessary modifications/ corrections by grinding off or adding EVA foam (Fig 36 and 37).

Fig 36

Fig 37

- Check also the length and rotation of the foot, and adjust it as described above (Fig 38 and 39).

  At this point it is not recommended that the service user be allowed to walk, as the socket and forefoot are too flexible. However, the amputee may take some steps inside parallel bars so that the dynamic alignment can be checked.

Fig 38

Fig 39

6. Draping of polypropylene

- Put the soft socket back on the plaster positive model and staple or tape the sides of the posterior seam together (Fig 40).

Fig 40

- Measurement of polypropylene sheet:

  Length from proximal part of plaster positive model to toes + 15 cm (Fig 41).

  Circumference of proximal part of soft socket + 5 cm (Fig 42).

  Circumference of mid-tibial section + 5 cm

  Circumference of foot-ankle (below medial malleoli, including calcaneus) + 5 cm

Fig 41

Fig 42

- Before draping the polypropylene, pull a lady's nylon stocking over the soft socket and dust it with talcum powder (Fig 43).

Fig 43

- Cut a 5 mm sheet of PP corresponding to the measurements taken above (Fig 44).

  Heat the PP in an oven between 8 to 20 minutes at 180° depending on the type of oven used (see the "Polypropylene thermoforming for Prosthetics-Orthotics" manufacturing guideline for a detailed explanation).

Fig 44

- Lay the PP over the mould without stretching it.

  Drape it first over the ankle towards the middle anterior part of the prosthesis. Then pull it around the forefoot (Fig 45).

Fig 45

- Finish draping the PP and stick it together along the middle anterior side of the prosthesis (Fig 46).

  Tighten the PP around the suction cone with a bicycle inner tube, a rope or a stocking and open the vacuum valve.

Fig 46

- With scissors or a knife, cut off the excess PP along the welding seam while it is still hot (Fig 47).

Fig 47

- Keep the vacuum on for about 5 minutes, but wait until the PP has completely cooled down before removing the mould from the vacuum cone for a minimum of 6 hours. See the guideline on "Polypropylene thermoforming for Prosthetics-Orthotics" for a detailed explanation (Fig 48).

Fig 48

7. Trim lines

Proximal trim line:
1 to 2 cm below the fibula head.

Lateral/medial trim lines:
On 1/3 of the proximal tibial section, 2 to 3 cm wider than the 2/3 distal tibial trim lines, which are drawn straight up just behind the lateral and medial malleoli (Fig 49).

Distal/posterior trim line:
Along the calcaneus tuberosity (Fig 50).

Fig 49

Fig 50

- **Forefoot trim line:**
  5 mm posterior to the head of the 1st metatarsal to the distal end of the phalanges, but keeping the distal tip of PP for protection of the EVA foam (Fig 51 and 52).

Fig 51

Fig 52

- Cut the posterior opening with an oscillating saw (Fig 53).

Fig 53

- To avoid damaging the EVA foam, do not cut the forefoot opening with an oscillating saw or knife. Instead, carefully grind it off (Fig 54).

  Or, alternatively, a small strip of EVA foam (6 mm) can be temporarily glued on the soft socket at the level of the metatarsals just before the draping operation. This temporary EVA foam strip will allow for easier cutting of the PP at the forefoot opening without causing damage.

Fig 54

- Remove the soft socket from the hard socket. Bear in mind that it might be difficult to extract the soft socket (Fig 55).

Fig 55

- Grind the anterior PP welding seam down to 5 mm and shape the trim lines of the hard and soft sockets (Fig 56 and 57).

Fig 56

Fig 57

- Shape also the trim lines of the forefoot opening (Fig 58 and 59).

Fig 58

Fig 59

8. Fitting

- During fitting and gait training, secure the proximal part of the prosthesis with tape (Fig 60 and 61).

  Modifications can still be made to the alignment, especially to correct the eversion or inversion of the foot, and to the heel height by adding EVA foam on the sole.

  If the prosthesis is too long, compensate for the difference in length either inside or on the sole of the shoe of the sound side.

Fig 60

Fig 61

9. Straps

- Position a Velcro strap (width: 25 or 40 mm) at the level of the largest diameter of the calf (Fig 62).

Fig 62

- Fix the loop on the medial wall and the Velcro strap on the lateral wall of the socket with tubular rivets (Fig 63).

Fig 63

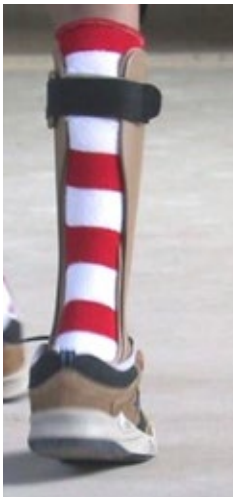

Fig 64

10. Finished partial foot prosthesis

Fig 65

Fig 66

Fig 67

List of manufacturing materials

Raw materials

Rehab'Impulse Code	Item Description	Used for
74-01085	Homopolymer, 5mm x 1m x 2m, 9.2kg, beige	Hard socket
74-01088	Homopolymer, 5mm x 1m x 2m, 9.2kg, olive	Hard socket
74-01090	Homopolymer, 5mm x 1m x 2m, 9.2kg, terra brown	Hard socket
74-00826	EVA Foam, 6mm x 0.95m x 0.95m, 0.90m2, beige	Soft socket
74-00829	EVA Foam, 6mm x 0.95m x 0.95m, 0,90m2, olive	Soft socket
74-00832	EVA Foam, 6mm x 0.95m x 0.95m, 0.90m2, terra brown	Soft socket
74-00827	EVA Foam, 12mm x 1.10m x 1.10m, 1.21m2, beige	Soft socket / Forefoot
74-00830	EVA Foam, 12mm x 1.10m x 1.10m, 1.21m2, olive	Soft socket / Forefoot
74-00833	EVA Foam, 12mm x 1.10m x 1.10m, 1.21m2, terra brown	Soft socket / Forefoot
74-00825	EVA Foam, 3mm x 0.95m x 0.95m, 0.90m2, beige	Forefoot finishing
74-00828	EVA Foam, 3mm x 0.95m x 0.95m, 0.90m2, olive	Forefoot finishing
74-00831	EVA Foam, 3mm x 0.95m x 0.95m, 0.90m2, terra brown	Forefoot finishing

Consumables

Rehab'Impulse Code	Item Description	Used for
74-00793	Bandage, Plaster of Paris, 15 cm x 3 m	Cast taking
74-01949	Examination glove, latex, non-steril, XL (10 - 11) - Pack of 90 pcs	Cast taking
74-01950	Examination glove, latex, non-steril, M (7 - 8) - Pack of 100pcs	Cast taking
74-00846	Pencil, blue indelible, for marking on moist surface	Cast taking
74-00788	Lady stocking, nylon, for cast taking & thermoforming, pair	Cast taking/Thermoforming
74-01754	Plaster of Paris, Powder	Positive model
74-01431	Glue, neoprene contact, drum of 4kg	Soft socket
74-01432	Solvent thinner, drum of 5L for glue neoprene contact	Soft socket
74-01430	Talc powder, conform to pharmacopoeia (asbestos fibres free)	Thermoforming
74-00699	Tubular stockinette, cotton, 100 mm, roll of 25 m	Stump protection
74-00700	Tubular stockinette, cotton, 120 mm, roll of 25 m	Stump protection
74-01331	Strap, Velcro, PVC, with loop, brown, 300 × 25 mm	Finishing
74-01332	Strap, Velcro, PVC, with loop, brown, 400 × 40 mm	Finishing
74-00913	Rivet, tubular, brass nickel plated, 13 × 12 mm	Strap fixation
74-00914	Rivet, tubular, iron nickel plated, 8 × 9 mm	Strap fixation

Accessories

Rehab'Impulse Code	Item Description	Used for
74-00805	Spare blade, for "Stanley Surform" round file 250 mm	Positive model rectification
74-00790	Spare blade, for "Stanley Surform" half round, 250 mm	Positive model rectification
74- 00901	Spare blade, for "Stanley Surform" std flat file, 250 mm	Positive model rectification

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