Design and manufacture routine custom made devices to fitting stage to meet the prescription



#### **Overview**

This standard covers the design and manufacture of routine custom made devices. The devices are to be manufactured to fitting stage; this is to allow a certain amount of adjustment to be made to the fit of the device for the service user. To manufacture a device that meets the prescription you will have to take into account the materials being used in the construction of the device and the methods used to join and fix the materials to the various components being used in the device. Users of this standard will need to ensure that practice reflects up to date information and policies.

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## Performance criteria

#### You must be able to:

- P1 accurately position the components of the device in the specified location on the model and confirm:
  - P1.1 their fit
  - P1.2 their security
  - P1.3 their compliance with the functional and aesthetic requirements of the prescription
- P2 mount the model and articulate it correctly and consistently with any available anatomical information and record the necessary information correctly
- P3 modify, position and attach the prescribed components in a manner that:
  - P3.1 produces the required aesthetic appearance
  - P3.2 achieves the function as detailed in the prescription
  - P3.3 meets the manufacturers specification
- P4 shape and contour the appropriate components to the model
- P5 check the manufactured device to confirm that it:
  - P5.1 complies with the prescription and design
  - P5.2 is clean
  - P5.3 is free of defects and make any adjustments which are required
- P6 use working methods and systems throughout the process which:
  - P6.1 promote health and safety
  - P6.2 reduce the risk of infection and contamination
  - P6.3 are consistent with the assessed risks
- P7 clearly and accurately identify devices with the service user's unique reference and date of production
- P8 make complete, accurate and up-to-date records relating to identification, components and manufacture of the device and store records in the correct location consistent with relevant legislation
- P9 effectively clean the device, prepare and package it safely for despatch and return it to the relevant person at the agreed time

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## Knowledge and understanding

You need to know and understand:

- K1 the reasons for maintaining records throughout the process and of clearly identifying the products during the manufacturing process
- K2 the organisational procedures and requirements for the recording of information about incoming work, work in progress and work delivered, and the purpose of this
- K3 quality audit systems, their purpose, nature and procedures, impact of the relevant regulatory body, currently the Medicine and Healthcare Regulatory Authority, on the recording of incoming work, the detailed design and manufacturing specification and the recording of materials and processes
- K4 the principles of quality assurance, processes and procedures for quality assurance in your workplace
- K5 the methods used for setting and calibrating equipment and of testing that this is correct
- K6 the effects of modifying manufacturers' components and products to meet production/usage requirements on the physical properties of the components/products and the legal implications
- K7 the relevant regulatory body, currently the Medicine and Healthcare Regulatory Authority, in monitoring the progress of devices through the production process
- K8 health and safety at work legislation and related procedures and liability, principles of, and how to apply legislation and regulations
- K9 the characteristics, properties and the processing of the following commonly used materials:
  - K9.1 metals
  - K9.2 plastics: thermoforming, thermosetting, composites
  - K9.3 wood
  - K9.4 leather
  - K9.5 plaster of Paris
  - K9.6 adhesives
  - K9.7 fabrics
  - K9.8 foams
  - K9.9 polystyrene
  - K9.10 other materials
- K10 the following:
  - K10.1 hand tools: their selection, use and maintenance
  - K10.2 measuring instruments: use and methods of application
  - K10.3 machine tools: selection, installation, use and maintenance
  - K10.4 welding processes and equipment for metals and plastics
  - K10.5 sewing machines: selection, use and maintenance
  - K10.6 general equipment: ovens, compressors, vacuum formers, fume

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and dust extraction apparatus

- K10.7 workshop layout
- K10.8 health and safety regulations and practice
- K10.9 computers, including CAD/CAM
- K11 the roles and responsibilities of the interdisciplinary team
- K12 ethical considerations in rehabilitation technical services
- K13 prosthetics/orthotics/special seating care systems in the UK
- K14 prosthetic/orthotic/special seating measurement techniques
- K15 prosthetic/orthotic/special seating components and their application
- K16 prostheses/orthoses/special seating for a range of conditions
- K17 wheelchair systems and seating alignment
- K18 basic awareness of the musculo-skeletal system
- K19 anatomical terminology in relation to prosthetics/orthotics/special seating
- K20 basic awareness of the anatomical planes and reference points of the body
- K21 the pathological conditions giving rise to prosthetic/orthotic/special seating provision and the relevant terminology
- K22 the following in order to fabricate prosthetic/orthotic devices:
  - K22.1 the interaction of anatomical joints and prosthetic/orthotic joints in relation to centre of joint rotation, ground reaction forces, alignment and forces applied to tissue
- K23 or
  - K23.1 the relationship of the pelvis, spine and knee, including basic tissue mechanics, in order to fabricate special seating systems
- K24 elementary arithmetic and its application and the use of calculators

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#### **Additional Information**

#### **External links**

This National Occupational Standard was developed by Skills for Health.

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: HWB9 Equipment and devices to meet health and wellbeing needs

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Developed by	Skills for Health
Version number	1
Date approved	June 2010
Indicative review date	June 2012
Validity	Current
Status	Original
Originating organisation	Skills for Health
Original URN	RT6
Relevant occupations	Health and Social Care; Healthcare and Related Personal Services
Suite	Rehabilitation Technical Services
Key words	prosthesis, orthoses, seating, manufacture, prescription