



## Higher National Unit specification

### General information

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
(SCQF level 7)

**Unit code:** HE2Y 34

**Superclass:** PE

**Publication date:** May 2016

**Source:** Scottish Qualifications Authority

**Version:** 02

### Unit purpose

This Unit is designed to equip learners with practical skills and knowledge to enable them to understand the manufacture of a Trans-femoral prosthesis. It will give them an understanding of what clinicians need to consider prior to prescribing a Trans-femoral prosthesis. This Unit will enable learners to develop the practical skills required to manufacture Trans-femoral prostheses in line with health and safety regulations and quality assurance procedures.

This Unit is suitable for trainee technicians or technicians working in a prosthetics technical environment.

### Outcomes

On successful completion of the Unit the learner will be able to:

- 1 Prepare models for the manufacture of Trans-femoral prostheses.
- 2 Manufacture Trans-femoral prostheses to patient fitting stage.
- 3 Finalise the manufacture of a Trans-femoral prosthesis for patient delivery stage.
- 4 Maintenance and service of Trans-femoral prostheses.

### Credit points and level

1 Higher National Unit credit at SCQF level 7: (8 SCQF credit points at SCQF level 7)

### Recommended entry to the Unit

Access to this Unit is at the discretion of the centre. However it would be beneficial if the learner had a basic understanding of manufacturing and workshop technologies. It would also be helpful if the learner has a basic awareness of the line management system within their department is able to raise any design issues with the relevant person.

## Higher National Unit Specification: General information (cont)

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### Core Skills

Achievement of this Unit gives automatic certification of the following Core Skills component:

Complete Core Skill	None
Core Skill component	Critical Thinking at SCQF level 6 Planning and Organising at SCQF level 6

There are also opportunities to develop aspects of Core Skills which are highlighted in the Support Notes of this Unit specification.

### Context for delivery

If this Unit is delivered as part of a Group Award, it is recommended that it should be taught and assessed within the subject area of the Group Award to which it contributes.

### Equality and inclusion

This Unit specification has been designed to ensure that there are no unnecessary barriers to learning or assessment. The individual needs of learners should be taken into account when planning learning experiences, selecting assessment methods or considering alternative evidence.

Further advice can be found on our website [www.sqa.org.uk/assessmentarrangements](http://www.sqa.org.uk/assessmentarrangements).

## Higher National Unit specification: Statement of standards

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
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The sections of the Unit stating the Outcomes, Knowledge and/or Skills, and Evidence Requirements are mandatory.

Where evidence for Outcomes is assessed on a sample basis, the whole of the content listed in the Knowledge and/or Skills section must be taught and available for assessment. Learners should not know in advance the items on which they will be assessed and different items should be sampled on each assessment occasion.

### Outcome 1

Prepare models for the manufacture of Trans-femoral prostheses.

#### Knowledge and/or Skills

- ◆ Prescriptions
- ◆ Manufacturers' specifications/recommendations
- ◆ Trans-femoral devices, components, functions and assembly techniques
- ◆ Materials and tools
- ◆ Prosthetic terminology Model preparation
- ◆ Medicine and Healthcare Regulatory Authority (MHRA)
- ◆ Health and safety legislation
- ◆ Quality assurance

### Outcome 2

Manufacture Trans-femoral prostheses to patient fitting stage.

#### Knowledge and/or Skills

- ◆ Material types and properties
- ◆ Manufacturing techniques
- ◆ Bench alignment techniques
- ◆ Machine use
- ◆ Quality assurance
- ◆ Medical and Healthcare Regulatory Authority (MHRA)
- ◆ Health and safety legislation

## Higher National Unit specification: Statement of standards (cont)

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
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### Outcome 3

Finalise the manufacture of Trans-femoral prosthesis for patient delivery stage.

#### Knowledge and/or Skills

- ◆ Fitting instructions
- ◆ Material types and properties
- ◆ Manufacturing techniques
- ◆ Finishing techniques
- ◆ Machine use
- ◆ Quality assurance
- ◆ Medical and Healthcare Regulatory Authority
- ◆ Health and Safety legislation

### Outcome 4

Maintenance and service of Trans-femoral prostheses.

#### Knowledge and/or Skills

- ◆ Review procedures
- ◆ Repair and replacement of Trans-femoral prosthesis components and fastenings
- ◆ MHRA regulations
- ◆ Quality Assurance

#### Evidence Requirements

Learners will need to provide evidence to demonstrate their Knowledge and/or Skills across all Outcomes by showing that they can:

#### Outcome 1

- ◆ interpret three prescriptions for the manufacture of three Trans-femoral prostheses identifying models, materials and components required. These should be agreed by senior technician/prescribing clinician and meet manufacturers' specifications/recommendations.
- ◆ select and source tools, materials and components following quality assurance procedures.
- ◆ prepare four models conforming to the prescriptions or manufacturers' recommendations in terms of: correct valve position, trim lines, alignment, suspension devices, patient details match, and quality of finish within acceptable timeframes.
- ◆ adhere to relevant health and safety procedures, MHRA regulations, quality assurance and line management processes.
- ◆ complete documentation to comply with quality assurance procedures.

## Higher National Unit specification: Statement of standards (cont)

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The models should achieve the function as detailed in the prescriptions and meet the manufacturer's specification in relation to the assembly technique. Evidence should be generated in a prosthetics technical environment.

#### Outcome 2

- ◆ manufacture, in accordance with the manufacturer's specification, two Trans-femoral prostheses to fitting stage using the following manufacturing and bench alignment techniques: lamination, draping, forming, shaping, trimming, grinding, measuring, bonding and joining, finishing and assembly.
- ◆ adhere to relevant health and safety procedures, MHRA regulations, quality assurance and line management processes.
- ◆ complete documentation to comply with quality assurance procedures.

The two prostheses should comply with the prescriptions, be finished to a high standard, be fit for purpose without obvious flaw and presented with detailed technical notes.

Evidence should be generated in a prosthetics technical environment.

#### Outcome 3

- ◆ finalise a Trans-femoral prosthesis using two different finishing techniques and in accordance with prescribed finishing instruction and manufacturer's specification.
- ◆ adhere to relevant health and safety procedures, MHRA regulations, quality assurance and line management processes.
- ◆ complete documentation to comply with quality assurance procedures.

The prosthesis should comply with the prescription, be finished to industry standard, fit for purpose and cosmetically pleasing with no obvious flaws.

Evidence should be generated in a prosthetics technical environment.

#### Outcome 4

- ◆ carry out review procedures to determine whether two Trans-femoral prostheses are suitable for repair or are beyond repair and require replacement and this should be carried out in line with quality management guidelines and MHRA regulations.
- ◆ evaluate two Trans-femoral prostheses for service or repair in line with quality assurance and MHRA regulations.
- ◆ carry out routine repairs and replacements of two Trans-femoral prosthesis components and fastenings.
- ◆ complete documentation to comply with quality assurance procedures.

Evidence should be generated in a prosthetics technical environment.



## Higher National Unit Support Notes

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
(SCQF level 7)

Unit Support Notes are offered as guidance and are not mandatory.

While the exact time allocated to this Unit is at the discretion of the centre, the notional design length is 40 hours.

### Guidance on the content and context for this Unit

This Unit is suitable for either trainee technicians studying lower limb prosthetics or technicians working in a prosthetics technical environment within the public (NHS) or private (commercial) sectors.

This Unit is designed to enable learners to produce a body of work that will demonstrate their ability to examine different techniques in the production of Trans-femoral prostheses, their construction methods, components and materials, using them to influence the design and production of both fitting and delivery samples.

It will enable learners to produce finished fit for purpose device(s), which clearly show the production process and development of the device(s).

Learners will investigate various process and production techniques to product a minimum of two finished devices.

**(Note:** Finished devices should also be assessed at fitting stage prior to final cover application.)

#### **Outcome 1 — Prepare for manufacture of Trans-femoral prostheses.**

The learner could be given a brief which requires them to produce a thorough investigation on the preparation of various prescriptions for manufacture. These could include model selection and production, identification and preparation, component selection and identification, materials, and tooling required in production processes.

A minimum of three different prescriptions should be prepared by the learner as part of their evaluation.

Notes, sketches, photographs and prescription printouts could be presented in a log/work book for assessment at the end of the Unit.

#### **Outcome 2 — Manufacture of Trans-femoral prostheses to patient fitting stage.**

The learners are required to manufacture a minimum of two samples of prescribed devices from those prepared in Outcome 1. This will allow learners to demonstrate greater flexibility when developing their own skills.

## Higher National Unit Support Notes (cont)

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
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The samples produced must show an understanding of process, demonstrate skills and technique. Samples could be fairly complex in their construction and component selection which would reflect areas considered in Outcome 1, and could take several hours to complete.

Learners should be encouraged to reflect on work in progress and make judgments on possible technical solutions to socket design and component selection. Device(s) should be finished to a high standard and fit for purpose without obvious flaws, and presented for assessment with detailed technical notes.

### **Outcome 3 — Finalise the manufacture of Trans-femoral prostheses for patient delivery stage.**

Learners are required to manufacture a final device, which should incorporate at least two of the Techniques explored and for which samples have been produced in Outcome 2.

Device produced could be model/demonstration pieces or prescribed devices finished to a good industry standard, cosmetically pleasing with no obvious flaws. The finished device should use appropriate construction methods and materials and be produced to a fit for purpose standard of finish with no obvious faults or flaws.

Learners should show a clear understanding of the chosen materials and techniques and use these appropriately within their finished device. Technical notes, prescriptions, profiles and sketches to accompany the final device could be presented in a logbook.

The logbook could be in the form of text and photographs, prescriptions and/or worksheets.

### **Outcome 4 — Maintenance and service of Trans-femoral prosthesis.**

Learners are required to provide evidence to demonstrate their knowledge and skills by showing they can carry out review procedures to determine whether a Trans-femoral prosthesis is suitable for repair or is beyond repair and requires replacement, and this should be carried out in line with quality management guidelines and MHRA regulations.

Learners are required to review for routine service or repair at least two devices containing the techniques and components explored, and for which samples have been produced in Outcome 2.

Learners should show a clear understanding of problem solving techniques and use these appropriately within their reviewed devices. Technical notes, prescriptions, and sketches to accompany the final reviewed devices could be presented in a logbook.

The logbook could be in the form of text and photographs, prescriptions and/or worksheets.

## Higher National Unit Support Notes (cont)

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
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### Guidance on approaches to delivery of this Unit

This Unit is likely to form part of a Group Award designed to provide learners with the technical knowledge and skills for employment within a rehabilitation technologies environment.

If this Unit is delivered as part of the Rehabilitation Technologies PDA it is recommended that it should be delivered and assessed within the lower limb prosthetics section. Opportunities may be taken to link or integrate with other aspects of the Group Award and a thematic approach adopted for both delivery and assessment.

As an introduction to the Unit the tutor may provide examples of different styles and designs of Trans-femoral prostheses with alternative component selection and techniques in preparation.

Evaluation could be carried out by learners following either set prescription(s) or investigating and researching different materials, processes and production techniques to design and produce the prostheses that are fit for purpose.

It is recommended that learners should have access to a wide variety of appropriate tooling and materials, and be encouraged to (in conjunction with clinical and senior technical colleagues) source and explore alternative processes and manufacturing techniques.

Throughout this Unit learners should follow appropriate quality assurance procedures, safe and considerate working practices in line with COSHH, MHRA regulations, risk assessment, appropriate use of Personal Protective Equipment (PPE), and all necessary health and safety issues.

### Guidance on approaches to assessment of this Unit

Evidence can be generated by using different types of assessment. The following are suggestions only. There may be other methods that would be more suitable to learners.

Centres are reminded that prior verification of centre-devised assessments would help to ensure that national standard is being met. Where learners experience a range of assessment methods, this helps them to develop different skills that should be transferable to work or further and higher education.

### Assessment Guidelines

#### Outcome 1

The assessment of this Outcome could inform the assessments for Outcomes 2 and 3. Evidence could be generated through observation of practical performance and manufacture of final device. A log book containing technical notes, prescriptions, sketches, and photographs could be used to support the practical assessment evidence.



## Higher National Unit Support Notes (cont)

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The health and safety procedures may include reference to Control of Substances Hazardous to Health (COSHH), risk assessment and use of Personal Protective Equipment (PPE).

### Outcome 2

The assessment of this Outcome could inform the assessment for Outcomes 3. Evidence could be generated through observation of practical performance and manufacture of final device. Detailed technical notes could be used to support the practical assessment evidence.

The health and safety procedures may include reference to Control of Substances Hazardous to Health (COSHH), risk assessment and use of Personal Protective Equipment (PPE).

### Outcome 3

Evidence could be generated through observation of practical performance and manufacture of final device. A log book containing technical notes, prescriptions, profiles, sketches and photographs could be used to support the practical assessment evidence.

The health and safety procedures may include reference to Control of Substances Hazardous to Health (COSHH), risk assessment and use of Personal Protective Equipment (PPE).

### Outcome 4

Evidence could be generated through observation of practical performance of repair and replacement of Trans-femoral prosthesis components and fastenings. A logbook containing technical notes, prescriptions, sketches, and photographs could be used to support the practical assessment evidence.

## Opportunities for e-assessment

E-assessment may be appropriate for some assessments in this Unit. By e-assessment we mean assessment which is supported by Information and Communication Technology (ICT), such as e-testing or the use of e-portfolios or social software. Centres which wish to use e-assessment must ensure that the national standard is applied to all learner evidence and that conditions of assessment as specified in the Evidence Requirements are met, regardless of the mode of gathering evidence. The most up-to-date guidance on the use of e-assessment to support SQA's qualifications is available at [www.sqa.org.uk/e-assessment](http://www.sqa.org.uk/e-assessment).

## Higher National Unit Support Notes (cont)

**Unit title:** Prosthetics Lower Limb: Trans-femoral Prosthesis  
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### Opportunities for developing Core and other essential skills

There are opportunities in this Unit to develop the Core Skills of *Communication*, *Problem Solving* and *Working with Others* at SCQF level 5, although there is no automatic certification of Core Skills or Core Skills components.

The Core Skill of *Communication* may be developed through the production of technical notes, which may bring together both visual and written notes.

The Core Skill of *Problem Solving* may be developed through the practical stages in Outcome 2 where learners are encouraged to explore techniques, identify problems and devise solutions. In Outcome 3 the skill may also be developed as learners work to produce finished devices, and reflect on what they have achieved.

The practical nature of the workshops and equipment access, together with design and component use may mean that learners will have to negotiate access with other learners and work with clinicians in the design/selection phase of the final device. This may provide the opportunity to develop the Core Skill of *Working with Others* at SCQF level 5.

This Unit has the Critical Thinking and Planning and Organising components of Problem Solving embedded in it. This means that when learners achieve the Unit, their Core Skills profile will also be updated to show they have achieved Critical Thinking at SCQF level 6 and Planning and Organising at SCQF level 6.

## History of changes to Unit

Version	Description of change	Date
02	Core Skills Components Critical Thinking and Planning and Organising at SCQF level 6 embedded.	19/08/16

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## General information for learners

### **Unit title:**     **Prosthetics Lower Limb: Trans-femoral Prosthesis** **(SCQF level 7)**

This Unit is designed to enable you to develop knowledge and skills in lower limb prosthetics. It will allow you to evaluate and explore a variety of manufacturing techniques, production processes, produce sample devices to fitting using various techniques and complete sample devices to final delivery. Techniques explored could include forming, draping, laminating, component use, tooling, and machining.

The assessment for this Unit could be presented in the form of a brief or set prescription from which you will be expected to:

- ◆ evaluate various preparation routes enabling you to produce a thorough investigation on the preparation of various prescriptions for manufacture. These could include model selection and production, identification and preparation, component selection and identification, materials and tooling required in production processes.
- ◆ manufacture a minimum of two samples of prescribed devices to fitting stage from those prepared in the preparation process above. Devices produced could be model/demonstration pieces or prescribed devices produced to a good industry standard, cosmetically pleasing with no obvious flaws. The produced devices should use appropriate construction methods and materials and be produced to a fit for purpose standard of finish with no obvious faults or flaws.
- ◆ manufacture a final device, which will incorporate at least two of the techniques explored and for which samples have been produced to fitting stage(s) above. Device produced could be model/demonstration pieces or prescribed devices finished to a good industry standard, cosmetically pleasing with no obvious flaws. The finished device should use appropriate construction methods and materials, and be produced to a fit for purpose standard of finish and delivery with no obvious faults or flaws.
- ◆ evaluate various problem solving routes enabling you to produce a thorough investigation on the inspection, service and repair of various manufactured devices. You will be required to provide evidence to demonstrate your knowledge and skills by showing you can carry out review procedures to determine whether a Trans-femoral prosthesis is suitable for repair or is beyond repair and requires replacement.

Throughout the delivery of the Unit you will be required to follow appropriate quality assurance procedures, safe and considerate working practices in line with COSHH, MHRA regulations, risk assessment, appropriate use of Personal Protective Equipment (PPE) and all necessary health and safety issues.

This Unit has the Critical Thinking and Planning and Organising components of Problem Solving embedded in it. This means that when you achieve the Unit, your Core Skills profile will also be updated to show you have achieved Critical Thinking at SCQF level 6 and Planning and Organising at SCQF level 6.