

## **STANDARDS ENCOUNTERED IN THE PROSTHETICS AND ORTHOTICS**

There has been some confusion in regards to standards mentioned in the **TechGUIDE** and what they actually cover. There are effectively two type of standards mentioned, these are structural standards and quality standards. Structural standards are one of the baseline requirements for component inclusion in the **TechGUIDE**. At present there are a myriad of standards used, mainly as the ISO standards for structural testing have only been available for a few years. Initially the ISPO 77 standard was the minimum benchmark for structural testing, but now ISO 13028 or equivalent is the minimum. **Eventually only the ISO standards will be considered for component inclusion.**

The other set of standards used are quality standards. Manufacturers with quality ratings have meet requirements on the constancy and service of their product.

When comparing components the structural test standard and where this testing was conducted should be considered along with the quality control program of the manufacturer.

### **STRUCTURAL STANDARDS**

These are the preferred Structural Standards For Prosthetic components and do not refer to any quality program the company may have.

In order of preference for inclusion in the **TechGUIDE** are:

- 1. ISO 10328, ISO/DIS 15032**
- 2. DIS ISO 10328**
- 3. Bundesministerium, DHSS, Tips "Tarif Interministeriel Des Prestations Sanitaires"**
- 4. ISO TC 168**
- 5. ISPO 77**
- 6. Criteria approved by REHABTech.**

### **ISO 10328**

The International Standards Organisation (ISO) standard covering the structural testing of lower-limb prosthesis. Allows components to be tested in three weight categories 100 Kg, 80 Kg and 60 Kg. It has no provisions for children's components, hips and components designed for use over 100 Kg. It makes no recommendations on who conducts the testing and test machines must sufficiently accurate be calibrated on at least an annual basis . Test samples are taken from normal production and four or more samples of each component is tested. The main aim of this standard is to ensure the component is structurally safe.

### **ISO/DIS 15032**

Draft ISO standard on the structural testing of prosthetic hips. This is a very new draft standard and once completed will be the requirement for hips being included in the **TechGUIDE**.

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### **CE, Bundesministeri, DHSS, Tips "Tarif Interministeriel Des Prestations Sanitaires"**

These tests are specific criteria for a country. These usually start with a structural standard, but also include additional requirements such as availability, quality programs or bio compatibility. Generally they are being replaced by the CE mark, which indicates the component has passed the requirements of the CEN standards in Europe. This standard uses ISO 10328 and ISO/DIS 15032 for the structural testing requirements for components. The CEN standard has further requirements including quality and bio compatibility requirements.

### **DIS ISO 10328**

The draft version of ISO 10328.

### **ISO TC 168 (WG3 N14)**

Recommendations for testing made by ISO Technical Committee 168 in the process of developing ISO 10328. Components tested to this standard should be re tested to the full ISO 10328 standard as many changes have taken place.

### **ISPO 77**

The set of recommendations agreed upon at the Philadelphia conference in 1977 on testing structural standards. This led to the work groups proceeding on an ISO standard. For many years the only standard available it is now obsolete and components should be moving towards ISO 10328 or ISO/ DIS 15032.

### **Criteria approved by REHABTech.**

This is for components or testing arrangements outside the general ISO standards. Generally this looks at testing of components either outside of the ISO standard or where standards are not available. The modified children's standards are an example where REHAB Tech has agreed on the test criteria, which is outside that of the ISO standards.

Often this involves testing to ISO 10328 with suitable modifications for the specified component. These modifications are included in the Test standard section of the TechGUIDE example in the **TechGUIDE** include:

- USMC Hip , Hips are not currently covered by ISO 10328,
- ISO 10328 for static tests. Cyclic tested for 1000,000 cycles at loads higher than ISO 10328. ISO 10328 requires 3,000,000 cycles.

**REHABTech main criteria for approval is that the tests conducted ensure the component is structurally safe.**

Some **REHABTech** approved criteria:

#### **Manufacturing dependant, Mainly Dependant on adjacent components**

Where the structural integrity of the component is dependant on the strength of an adjacent component. Laminated socket adaptors are a prime example where the strength of the adaptor in the final prosthesis dependant on the lamination of the socket. These component may still be required to undergo other structural testing.

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### **Modified for Children (ISO 10328 ISPO 77)**

As there is no standard covering children's components, modifications to ISO 10328 or ISPO 77 with reductions in weight have been used by different organisations to test children's components. Unfortunately the loads and weights used are not uniform between testing laboratories so check the test weight for these components.

### **REHABTech Conditional Accreditation:**

Where preliminary cyclic testing is conducted, and static and torsion tests are done to ISO 10328 by **REHABTech**. These tests give a good indication if the component will pass ISO 10328, but are not conclusive or as in depth. It is expected full testing of the component to ISO 10328 ( or ISO/DIS 15032 for hips) will be conducted within an agreed time frame.

### **WHO SHOULD CONDUCT THE TESTING**

Ideally or testing should be completed by an independent facility. An accredited in house facility or in house testing with an independent observer would be also be satisfactory.

ISO 10328 and ISO/DIS 15032 do not make any recommendations on who does the testing. The only requirements are for the calibration and accuracy of the testing apparatus. The testing facility must keep documentation of the tests and what was done.

In Europe testing of components is moving towards in house testing, with the move to the CE mark. The only check is the manufacturer can be audited. For CE inclusion the manufacturer has to fulfil other requirements.

With this happening in house testing has been allowed for some components at **REHABTech** discretion. This includes copies of the test report being submitted and information of quality control schemes the manufacturer has. **REHABTech** may also visit these centre to confirm testing procedures.

### **QUALITY STANDARDS**

#### **ISO 9000 series**

This is essentially a manufacturing and supply quality standard. Compliance with this standard is recognition that a manufacture has in place sound quality methods which ensure that the product is made the same way each time and that the product can be traced even after it is sold and distributed. This ensures like components are identical, while supply and replacement of components should also be consistent.

ISO 9000 requirements.

ISO 9001, 9002, 9003

*This standard makes no judgment on the functional or structural relevance of the design.*

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**THERAPEUTIC GOODS ADMINISTRATION  
PROSTHETIC AND ORTHOTIC POLICY**

Orthoses are excluded from the requirements of the Therapeutic Goods Act under Parts 9, 10 and 17 of Section 3 of the Excluded Goods Order. Other related excluded goods include walking sticks and crutches.

Generally artificial limb (prosthetic) joint assemblies and components are required to be listed on the Australian Register of Therapeutic Goods (ARTG) before they can be legally supplied. The ruling does not include the custom-made components associated with fitting artificial limbs (prostheses, e.g. sockets).

Artificial limb joint assemblies and components may be grouped under a single listing number by the sponsor if the devices are made by the same manufacturer and belong to the same Australian Device Group. This usually means only one listing is required per manufacturer. (Australian Therapeutic Device Bulletin 1/93, April 1993).

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## **ISO STANDARDS RELEVANT TO PROSTHETICS AND ORTHOTICS**

- **ISO 8548-1:**1993 Prosthetics and orthotics -- Limb deficiencies -- Part 1: Method of describing limb deficiencies present at birth
- **ISO 8548-2:**1993 Prosthetics and orthotics -- Limb deficiencies -- Part 2: Method of describing lower limb amputation stumps
- **ISO 8548-3:**1993 Prosthetics and orthotics -- Limb deficiencies -- Part 3: Method of describing upper limb amputation stumps
- **ISO/DIS 8548-4** Prosthetics and orthotics -- Limb deficiencies -- Part 4: Description of causal conditions leading to amputation
- **ISO 8549-1:**1989 Prosthetics and orthotics -- Vocabulary -- Part 1: General terms for external limb prostheses and external orthoses
- **ISO 8549-2:**1989 Prosthetics and orthotics -- Vocabulary -- Part 2: Terms relating to external limb prostheses and wearers of these prostheses
- **ISO 8549-3:**1989 Prosthetics and orthotics -- Vocabulary -- Part 3: Terms relating to external orthoses
- **ISO 10328-1:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 1: Test configurations
- **ISO 10328-2:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 2: Test samples
- **ISO 10328-3:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 3: Principal structural tests
- **ISO 10328-4:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 4: Loading parameters of principal structural tests
- **ISO 10328-5:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 5: Supplementary structural tests
- **ISO 10328-6:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 6: Loading parameters of supplementary structural tests
- **ISO 10328-7:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 7: Test submission document
- **ISO 10328-8:**1996 Prosthetics -- Structural testing of lower-limb prostheses -- Part 8: Test report
- **ISO 13405-1:**1996 Prosthetics and orthotics -- Classification and description of prosthetic components -- Part 1: Classification of prosthetic components
- **ISO 13405-2:**1996 Prosthetics and orthotics -- Classification and description of prosthetic components -- Part 2: Description of lower-limb prosthetic components
- **ISO 13405-3:**1996 Prosthetics and orthotics -- Classification and description of prosthetic components -- Part 3: Description of upper-limb prosthetic components
- **ISO/DIS 15032** Prosthetics -- Structural testing of hip units
- **ISO 9001:** 1994 Quality systems- Model for quality assurance in design, development, production, installation and servicing.
- **ISO 9002:** 1994 Quality systems- Model for quality assurance in production, installation and servicing.
- **ISO 9003:** 1994 Quality systems- Model for quality assurance in final inspection and test.

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