

QUESTIONS FOR THE ORTHOTIST , PROSTHETIST RELATING TO STANDARDS

There are two types of standard in the lower limb modular prosthetic components
TechGUIDE.

Structural testing of components In order of preference	
1	ISO 10328, ISO/DIS 15032, CE
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.

Table 1

Manufacturer or Supplier Standards
ISO 9000 series, AS 3900 series, EN46000

Table 2

1/ WHY IS A COMPONENT NOT INCLUDED IN THE **TechGUIDE** ?

The major reasons a component will not be included are:-

- It has never been submitted for inclusion to **REHAB Tech.**
- It has failed in one or more of the five categories used as a baseline for inclusion in the **TechGUIDE.** Usually it is lack of information on structural testing.

2/ HOW DO I COMPARE PRODUCTS IN THE **TechGUIDE** ?

Products can be compared on any of the listed data. When comparing the testing criteria. the level of testing as outlined in Table 1, a product which has been tested to standard 1 has achieved a more internationally recognised benchmark than one tested to the other standards.

A second consideration is the manufactures and or suppliers quality management program as outlined in Table 2. Manufacturers or suppliers with one of these programs should have a high level of consistency in the products they supply. Obviously products in the **TechGUIDE** have a higher standard than those that are not.

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3/ SHOULD I PURCHASE A PRODUCT TESTED TO ISO 10328 AND FROM A MANUFACTURER WITH AN ISO 9000 PROGRAM ?

In an ideal situation this would be the best option. However there are problems associated with this.

- There is not a comprehensive range of components that achieve both of these criteria.
- Components tested to standards previously to ISO 10328 being available will not necessarily be re tested.
- Components may be tested recently to a standard other than ISO 10328 due to local requirements or laws and will not necessarily be re tested.
- A company may have an in house testing facility, however has not achieved ISO 9000 as yet. (therefore it is difficult to ignore these test's).
- ISO 10328 and ISO 9000 may not be a requirement in the country where the product is made and therefore testing has been done elsewhere to other acceptable requirements.

Several criteria govern the selection of components however from the testing point of view, the general aim of the prosthetist should be to choose the highest standard of component and manufacture to achieve the desired outcome.

4/ WHO SHOULD CONDUCT THE TESTING?

Ideally all 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.

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 centres to confirm the testing procedures.

5/ IF THE HIGHEST TEST STANDARD AND A QUALITY MANUFACTURER HAS BEEN USED , DOES THIS MEAN THE COMPONENT WILL NOT FAIL?

No.

There are several reasons for failure not exclusively limited to the design and manufacture of the component and not always predicted by the testing.

REHABTech has a failure report service which can be used to report failures and assists with ongoing industry information and assessment.

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