

Test regulations (Swiss Council for Accident Prevention bfu) for the acquisition of a bfu safety symbol for

Hip protectors

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1. Introduction

Hip fractures are a serious health problem among the elderly. Forecasts point to a sharp and disproportionate increase in cases when compared with age since life expectancy is on the increase. One way of preventing these injuries is the use of hip protectors.

Hip protectors absorb or distribute the forces that affect the hips in a sideways fall and reduce the risk of bone fractures.

In cooperation with the Swiss Federal Laboratories for Materials Testing and Research (Empa), St. Gallen, and the advisory group of the bfu programme "Preventing falls in old age", the bfu has compiled this test procedure as well as a list of requirements that hip protectors must fulfil.

Hip protectors that fulfil the requirements mentioned in these test regulations can be awarded a bfu safety symbol. There is no right to the awarding of the bfu safety symbol

2. Definitions

2.1 Protector

A *protector* is a shock-absorbing element that can be made of different materials.

2.2 Hip protector

A *hip protector* is understood to mean the entire product, consisting of protectors as well as elements for attaching the protector over the trochanter, e.g. textile trousers with the corresponding protector pockets or similar.

3. Test procedure

3.1 Pretreating hip protectors

3.1.1 Conditioning hip protectors

Before being tested, protectors must be stored for at least 6 hours in an atmosphere of $(20 \pm 2)^\circ\text{C}$ and $(65 \pm 5)\%$ relative humidity.

3.1.2 Washing hip protectors with removable protectors according to ISO/EN 6330 [1]

Protectors undergo a simulated handwash 10 times (normal washing process) at 40°C with a standard laundry detergent and are then dried flat.

The textile trousers undergo a standard triple washing procedure at 60°C using a standard laundry detergent without any intermediate drying and are dried flat.

3.1.3 Washing hip protectors with integral, non-removable protectors acc. to EN ISO 6330 [1]

Hip protectors with integral, non-removable protectors undergo a standard washing procedure 50 times at 60°C according to ISO/EN 6330 using a standard laundry detergent without any intermediate drying. The hip protectors are dried flat.

3.2 Measuring principle

The efficacy of a hip protector is investigated with the help of a mechanical hip model on which impact stresses can be practised by means of the impact of a falling object. Fig. 1 shows the artificial hip joint and the proximal femur. Fig. 2 shows how measurements are made. The most important components of the measuring equipment consist of:

- Steel femur with a triaxial force transducer in the neck of the femur, geometry to suit people's average physical dimensions
- Baseplate with an aluminium socket and joint to accept the steel femur
- 20-mm thick silicone tissue replacement in the area of the trochanter to permit a realistic distribution of the force exerted by the protector
- Falling object made of steel with a uniaxial acceleration transducer and suspended from a holder with a release mechanism
- Measuring system for the recording and evaluation of the forces in the neck of the femur that result when the falling object impacts the hip model (with hip protector) as well as the deceleration of the falling object that occurs on impact

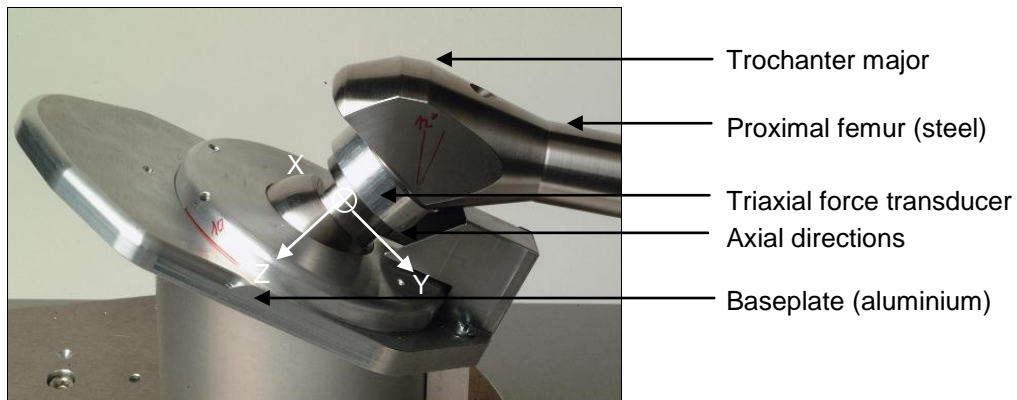


Fig. 1: Artificial hip joint and proximal femur

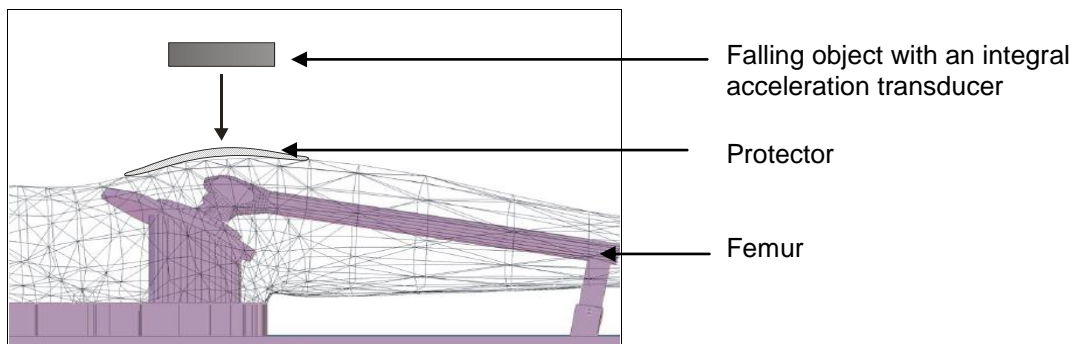


Fig. 2: How measurements are taken

3.3 Test parameters

The following parameters are used to test the hip protectors or protectors respectively:

Falling mass:	(9.9 ± 0.1) kg (flat, circular impact surface with a diameter of 0.20 m)
Fall height:	This is set so that there is an impact force of (6.8 ± 0.2) kN when the falling mass impacts the empty hip model.
Fall line:	The centre of the falling object is vertically aligned above the steel femur (trochanter).
Measuring method:	All measuring signals (one deceleration and 3 force signals) are filtered with a low-pass filter with a cut-off frequency of 1 kHz and recorded on computer with a sampling rate of 100 kHz over an interval of around 40 ms.
Environmental laboratory conditions:	(23 ± 5)°C, (20 – 70)% relative humidity

3.4 Implementation

For the tests in 3.4.1 to 3.4.3, three samples of protectors in each case are used that have been conditioned according to 3.1.1. Each individual sample is successively subjected to impact stresses 3 times according to 3.3.

The first impact occurs within 5 minutes following conditioning according to 3.1.1, the two subsequent measurements at intervals of (120 ± 10) s.

3.4.1 Testing centrally positioned hip protectors

The protector is fitted to the artificial hip in accordance with the manufacturer's instructions.

3.4.2 Central positioning of hip protectors, washed

Following pre-treatment according to 3.1.2 and 3.1.3 respectively, the protector is fitted to the artificial hip in accordance with the manufacturer's instructions.

3.4.3 Positioning with a hip protector out of position

The protector is fitted to the artificial hip in such a way that it is displaced by (5 ± 0.5) cm from the positioning as set forth in 3.4.1 or 3.4.2 towards the abdominal side.

3.4.4 Measurement figures

The following figures are measured when the falling body impacts the artificial hip fitted with a with hip protector:

a_{impact}	Deceleration [m/s ²] of the falling body over time
F _x , F _y and F _z	Forces [N] in the neck of the femur in 3 axial directions over time

3.5 Implementation when an extension of the bfu safety symbol is applied for

If an application is made for the extension of the bfu safety symbol (§7.4.3), the testing procedure is normally limited to the testing of 3 samples. Each sample is subjected to an impact force 3 times in accordance with §3.3. Initial impact occurs within 5 minutes after conditioning according to §3.1.1 and the two subsequent measurements at intervals of (120 ± 10) s. The samples will be tested in accordance with §3.4.1

3.5.1 Additional test in the event of deviation from the standard case

If, during the initial testing of the hip protectors, a moderate change in the safety factor of 0.05 is noted after the first wash, an additional 3 samples must be tested in washed condition in accordance with §3.4.2.

4. Requirements

4.1 Requirements of the Empa test

Based on research report no. 262 issued by Empa St. Gallen [2] and the publication "Assessment of hip protectors and corresponding hip fracture risk using stress calculation in the femoral neck" [3], the maximum tensile stresses, compressive stresses and safety factors are calculated using the forces measured in the neck of the femur.

4.1.1 Safety factor

Three protectors in each case must, when averaged, achieve a safety factor of at least 1.7 under the same impact load and under the same test parameters.

- The safety factor is the relationship between the average breakage stresses in the neck of a 75-year-old femur (breakage strength in tension: +129 MPa and breakage strength under compression: -175 MPa) and the tensile and compressive strengths respectively calculated from the forces measured on the hip model.
- Definition of a safety factor of 1.7:
This value means that, under the impact conditions given and under the assumptions made (parameter values, geometry of the artificial hip, position of the femur), approximately 75-80% of all 75-year-old people can be protected from a femoral neck fracture.

4.1.2 Washing the hip protectors

After washing the protectors, the following requirements are assessed. Their fulfilment is mandatory:

- No missing parts or damage caused by the washing procedure, which might, for example, lead to the absorption of water.
- Shrinkage/Elasticity:
 - Hip protectors must be able to be easily fitted to the hip model without causing any excessive stretching of textiles or similar materials.
 - Removable protectors must be able to be used without causing any excessive stretching of textiles or similar materials.

4.2 bfu requirements

4.2.1 Instructions for use

Each sales unit must contain instructions for use in French, German and Italian. It must contain a description of its use and how it must be cared for.

4.2.2 Cleaning instructions

The articles must be able to be cleaned in a manner commonly used in households. The method of cleaning recommended by the manufacturer must be listed in the instructions for use.

4.2.3 General requirements

- Using a check list as the basis, the applicant must confirm that the product satisfies both the requirements of European Directive 89/686/EEC for personal protective equipment (PPE)¹ and European Medical Directive 93/42/EEC for medical devices (MDD)².
- If a declaration of conformity based on European guideline 93/42/EEC for medical products (MedprRL) exists, this must be submitted instead of the check list.

¹ Council Directive 89/686/EEC of 21 December 1989, Journal no. L399 of 30.12.1989 pp. 18 - 38

² Council Directive 93/42/EEC of 14 June 1993 on medical devices, Journal no. L 169 of 12.07.1993 pp. 0001 - 0043

4.2.4 Marking

Manufacturers must mark the protectors with the date of manufacture and the recommended use-by date.

5. Empa test report

5.1 Results

The following results are summarised in the test report as the mean values for three protectors in each case, which were tested under the same impact and under identical test conditions:

F_{impact} Maximum impact of the falling object on the hip protector

F_{neck} Maximum resultant force in the femoral neck

σ_t and σ_c Maximum tensile and minimum compressive stresses in the femoral neck

Sf_t and Sf_c Safety factor calculated for tensile and compressive stresses in the femoral neck

5.2 Layout

- In accordance with Empa directives
- Reference to bfu test regulations
- Listing of the average values according to 5.1 and a complete list of all the results in the annex
- Assessment of the test results
- Photo of the protector tested
- Date, signature of the person responsible

6. bfu report

6.1 Fulfilment of bfu requirements

Fulfilment of the requirements according to 4.2.1 to 4.2.3 is assessed with yes/no.

6.2 Assessment of the hip protector

The fulfilment of all requirements according to these test regulations must be finally assessed with yes/no.

7. Legal and administrative conditions

7.1 General remarks

According to the regulations, a test is valid in each case for a precisely circumscribed quality of a hip protector with a designation of the article.

The following are integral components of these regulations:

- Information on the bfu safety symbol
- Test regulations for the bfu safety symbol

These documents as well as additional documentations can be downloaded from www.bfu.ch.

7.2 Conditions for the issue of a bfu safety symbol

- To ensure that the product can be issued with a bfu safety symbol, the requirements set out in section 4 of these regulations, in particular, must be met and approval received from the bfu Safety Symbol working group. This working group tests the product on the basis of the test regulations mentioned in 7.1 for the bfu safety symbol; in particular, this group scrutinizes the instructions for use and the assessment of the test results of the mechanical tests.
- The bfu reserves the right to evaluate the suitability and the practicality of hip protectors and to publish the test results.

7.3 Amendments to the product tested

The bfu must be informed of any amendments to the product or to the material(s) used. The bfu will decide whether additional tests are necessary.

7.4 Mandate and application for tests and the issue of a bfu safety symbol

7.4.1 Tests

The mandate to carry out the technical tests according to these regulations must be placed with Empa, Lerchenfeldstrasse 5, CH-9014 St. Gallen.

7.4.2 bfu safety symbol

The application for the bfu safety symbol must be sent to the bfu. The Empa test report must be enclosed. The application form can be obtained from the bfu, P.O. Box 8236, CH-3001 Berne or from info@bfu.ch.

7.4.3 Extension of the bfu safety symbol

The contracting partner will be informed in writing by the bfu prior to the expiry of the contract relating to the bfu safety symbol. If there is interest in extending the bfu safety symbol, testing must be conducted at Empa in accordance with §3.5. The contracting partner must submit 3 or 6 samples respectively to Empa for checking and send the bfu a copy of the test report.

7.5 Test objects

The following are required for **mechanical testing**:

5 hip protectors with removable protectors (size M)
or 10 pairs of trousers (size M) with integral, non-removable protectors

The following are required for **checking** in accordance with §3.5:

3 or 6 protectors respectively and one pair of trousers (size M) for removable protectors
or 3 or 6 pairs of trousers respectively (size M) with integral, non-removable protectors

7.6 Fees

The cost of carrying out the mechanical test is in accordance with Empa's fee schedule and applicants are invoiced directly by Empa.

The cost of the bfu safety symbol is listed in the fee schedule (www.bfu.ch) for the bfu safety symbol.

7.7 Rights and liabilities of holders of bfu safety symbols

When a bfu safety symbol is issued, the bfu concludes a separate contract with the holder on the rights and liabilities associated with the use of the safety symbol.

7.8 Amendments to regulations

These regulations are amended, if necessary, to meet the current state of the art or international standardisation.

7.9 Validity

These regulations will apply with retroactive effect from 1 January 2007 and replace those of 5 January 2004.

8. Bibliography

- [1] ISO 6330:2000, *Textilie – Nichtgewerbliche Wasch- und Trocknungsverfahren zur Prüfung von Textilien*. European norm, 2000: p. 18. ⇨ Page 3
- [2] Derler, S. and A.B. Spierings (2004). *Wirksamkeit von Hüftprotektoren: Entwicklung eines mechanischen Hüftmodells und eines Bewertungskriteriums.*, Empa: St. Gallen. p. 82.
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- [3] Spierings, A.B. and S. Derler (2006). *Assessment of hip protectors and corresponding hip fracture risk using stress calculation in the femoral neck*. Medical Engineering & Physics, 2006. 28(6): p. 550. ⇨ Page 6