Erasmus+

Development of innovative training solutions in the field of functional evaluation aimed at updating of the curricula of health sciences schools

MODULE BIOMECHANICS FOUNDATIONS

Didactic Unit F: REQUIREMENTS OF A BIOMECHANICAL ASSESSMENT SYSTEM. CONCEPTS OF VALIDITY, RELIABILITY AND ACCURACY

F2. What do validity, reliability and accuracy mean and why are they important?.

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AMSE THE ASSOCIATION OF MEDICAL SCHOOLS IN EUROPE

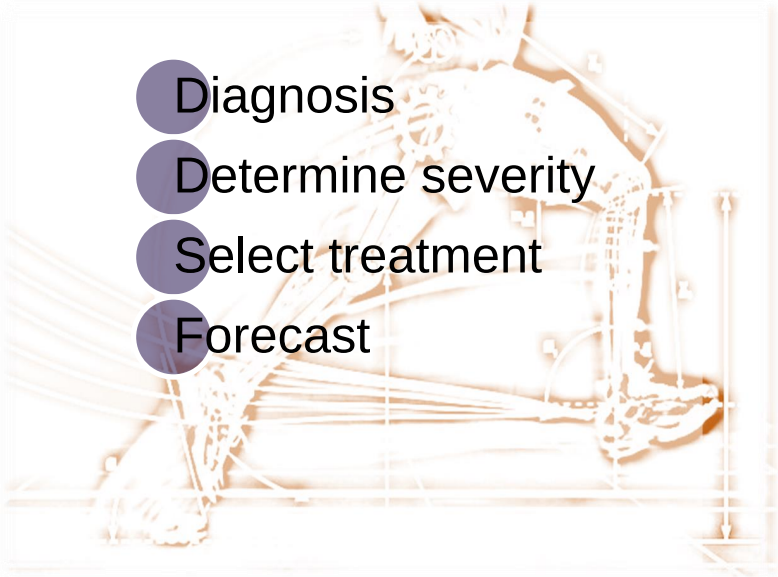
OBJECTIVES

1. Better understand the concepts of validity, reliability and usability in the context of biomechanical evaluation.
2. Develop critical ability to select valid, reliable and usable biomechanical assessment methodologies.
3. Introduce the European regulation on medical devices and its importance to guarantee compliance with the requirements of biomechanical assessment in its medical use.

INTRODUCTION

Do biomechanical tests serve as a complementary medical test?

Brand, R. Can biomechanics contribute to clinical orthopaedic assesments? The Iowa Orthopaedic Journal; 1989: 9, 61-64

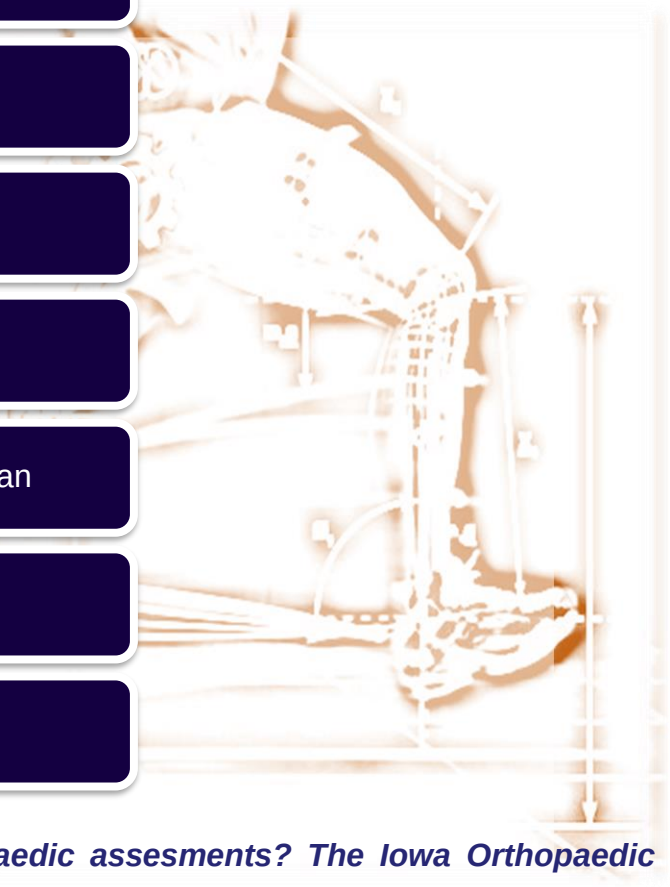


- Diagnosis
- Determine severity
- Select treatment
- Forecast

- *Technological sophistication does not ensure that biomechanical measures are useful.*
- *Some require interpretation by highly experienced clinicians.*
- *Some are highly variable.*
- *Some have not been validated.*

BIOMECHANICAL TESTING REQUIREMENTS

- Reproducible
- Does not alter assessed function
- Distinguish between normality and non-normality
- Valid
- Evaluates aspects that are not detected by an expert clinician
- Reports results understandable to the clinician
- Cost-effective



Brand, R. Can biomechanics contribute to clinical orthopaedic assesments? The Iowa Orthopaedic Journal; 1989: 9, 61-64

BIOMECHANICAL TESTING REQUIREMENTS

- Reproducible → **Reliability**
- Does not alter assessed function
- Distinguish between normality and non-normality
- Valid
- Evaluates aspects that are not detected by an expert clinician → **Validity**
- Reports results understandable to the clinician
- Cost-effective → **Usability**

Brand, R. Can biomechanics contribute to clinical orthopaedic assesments? The Iowa Orthopaedic Journal; 1989: 9, 61-64

RELIABILITY

Reliability: Provides similar records under similar conditions.

Accuracy: Refers to how close to the actual value the measured value is.

Reliable

Accute

Reliable and accute

RELIABILITY

Basic elements	Minimum requirements	Statistics
Instrumental technique	Equipment calibrated within the maximum allowable uncertainty	ICC
Technical maintenance and equipment calibrations	Intraobserver reproducibility 	Intraclass correlation coefficient Excellent> 0.9 Good 0.71-0.9 Mediocre 0.51-0.7
Standardized protocols and pre-established algorithms for calculating results	Interobserved reproducibility. 	SEM
Technical training of evaluators		Standard error of measurement
Standardized interpretation criteria		

Spine

SPINE Volume 36, Number 16, pp 1279–1288
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BIOMECHANICS

Reliability and Validity
Low

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Maria

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REHABILITACIÓN

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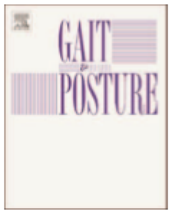
Gait & Posture 73 (2019) 545–546

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost



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Short communi

The reliabil
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Study of reliability of a software associated to a digital dynamometer for the measurement of hand grip isometric strength

C. Herrera-Ligero, S. Pitarch-Corresa*, H. De-Rosario, F. Peydro-DeMoya, J. Sellés-Vizcaya, M.J. Vivas-Broseta

Instituto de Biomecánica de Valencia- Universitat Politècnica de València, Biomechanical Assessment, Valencia, Spain

Juan López-Pascual [a,*], Magda Liliana Cáceres [a], Helios De Rosario [a,b], Álvaro Page [a,b]

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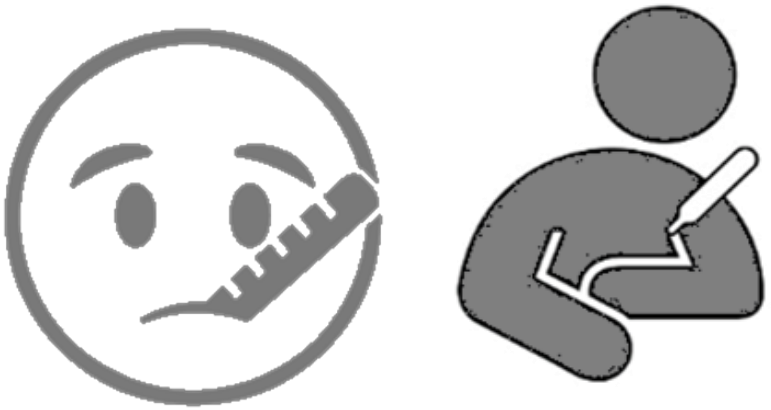
VALIDITY

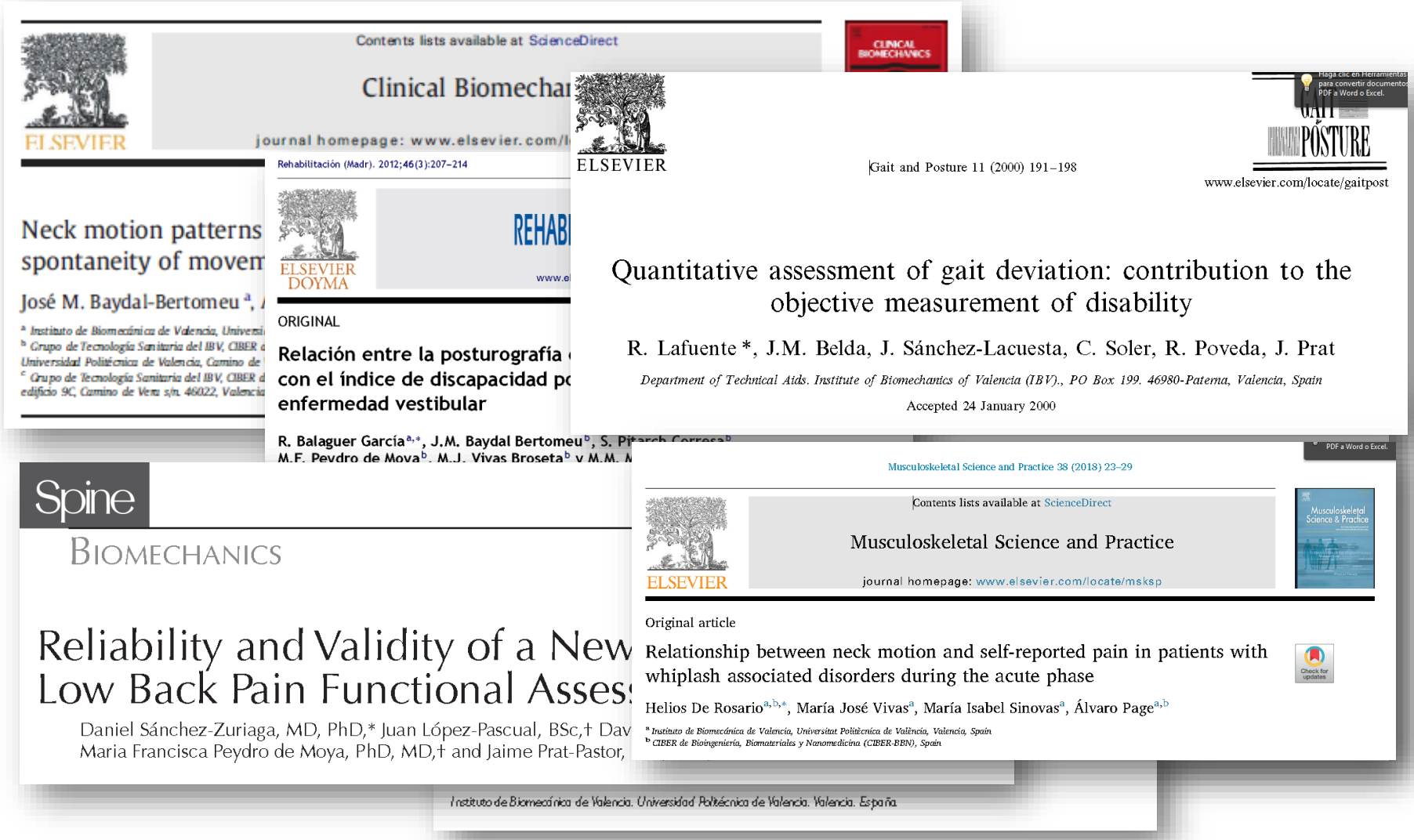
Validity: correspondence between what is measured by the tests and the characteristics of the reality that is to be represented.

"It is valid if you measure what it says to measure"



VALIDITY

Basic elements	Minimum requirements	Study designs and statistics
Solid theoretical foundations. Approach and validation of hypotheses through research studies.	Based on existing scientific knowledge. Adequate research methodology: • Properly stated objectives. • Representativeness of samples • Adequate study design. • Control of disturbing variables. • Statistical analysis appropriate to the objectives. • Etc.	**Relationship between gold standard and biomechanical tests.** Correlation Coefficients ... **Studies on classification in diagnostic tests** Regression studies ... Sensitivity, specificity **Comparison of samples.** T test, ANOVA ...



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Clinical Biomechar

journal homepage: www.elsevier.com/l

Neck motion patterns
spontaneity of movem

José M. Baydal-Bertomeu [a], A

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Rehabilitación (Madr). 2012;46(3):207–214

REHABI

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ORIGINAL

Relación entre la posturografía
con el índice de discapacidad po
enfermedad vestibular

R. Balaguer García[a,*], J.M. Baydal Bertomeu[b], S. Pitarch Correosa[b]
M.F. Peydro de Moya[b], M.J. Vivas Broseta[b] y M.M. M

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Gait and Posture 11 (2000) 191–198

www.elsevier.com/locate/gaitpost

Quantitative assessment of gait deviation: contribution to the objective measurement of disability

R. Lafuente *, J.M. Belda, J. Sánchez-Lacuesta, C. Soler, R. Poveda, J. Prat

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Accepted 24 January 2000

Spine

BIOMECHANICS

Reliability and Validity of a New
Low Back Pain Functional Assess

Daniel Sánchez-Zuriaga, MD, PhD,* Juan López-Pascual, BSc,† Dav
Maria Francisca Peydro de Moya, PhD, MD,† and Jaime Prat-Pastor,

Musculoskeletal Science and Practice 38 (2018) 23–29

Contents lists available at ScienceDirect

Musculoskeletal Science and Practice

journal homepage: www.elsevier.com/locate/msksp

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Original article

Relationship between neck motion and self-reported pain in patients with whiplash associated disorders during the acute phase

Helios De Rosario[a,b,*], María José Vivas[a], María Isabel Sinovas[a], Álvaro Page[a,b]

[a] *Instituto de Biomecánica de Valencia, Universitat Politècnica de València, Valencia, Spain*
[b] *CIBER de Bioingeniería, Biomateriales y Nanomedicina (CIBER-BBN), Spain*

EXERCISE 1 : Work with an example to identify and critically analyze its properties. Low back function.

Sánchez Zuriaga, D.; López Pascual, J; Garrido Jaén, D.; Peydro de Moya, M.F.; Prat Pastor, J.M. *Reliability and validity of a new objective tool for low back pain functional assessment.* Spine, 2011; 36(16): 1279 – 1288		**Aspects related to:**	
		Reliability	Validity
Function	Sit-to stand task, and lifted three different weights from a standing position	Reliability of the parameters was good (see results, and specifically tables 2 and 3).	The selected regression model correctly classified 97.3% of the patients. High correlations were found between the results of this regression equation and the Oswestry Disability Index scale (see results)
Instrumental technique	Force platforms and photogrammetry		
Results	Dynamical and kinematical parameters		

EXERCISE 2 : Work with an example to identify and critically analyze its properties. Hand grip strength.

Herrera Ligero, C., Pitarch-Corresa, S., De-Rosario, H., Peydro-DeMoya, F., Sellés-Vizcaya, J., Vivas-Broseta, M.J. *Study of reliability of a software associated to a digital dynamometer for the measurement of hand grip isometric strength.* Gait and Posture, 2019; 73: 545 – 546		**Aspects related to:**	
		Reliability	Validity
Function	Hand grip isometrc strenght	Reliability of the parameters was excellent (see results).	Not found in the article.
Instrumental technique	Hand dynamometer		
Results	Dynamic parameters		

EXERCISE 3 : Work with an example to identify and critically analyze its properties. Cervical function.

Baydal Bertomeu, J.M., Page, A.; Belda Lois, J.M., Garrido Jaén, D.J., Prat, J. *Neck motion patterns in wiplash-associated disorders: Quantifying variability and spontaneity of movement.* Clinical Biomechanics, 2011, Clinical Biomechanics 26: 29–34.		**Aspects related to:**	
		Reliability	Validity
Function	Cervical movement in three axis.	Not found in the article.	The selected regression model correctly classified 70 or 93% of the patients depending of the model (see table 3)
Instrumental technique	Photogrammetry		
Results	Kinematical parameters		

USABILITY

Set of properties that refer to efficiency for the evaluator, for the specifier / receiver of the test and security for the evaluated.

USABILITY

Basic elements

Simplicidad

Consumir el mínimo tiempo posible (coste/beneficio)

Robustez y nivel tecnológico adecuado.

Seguridad para el paciente.

Adaptadas al colectivo al que van dirigidos.

To consider…

Clinical application studies

Recognition of users and external entities

Documented protocols

Technical training of evaluators

Standardized reporting

ISO 13485 Quality Management System Certificate

bsi. ISO 13485 Medical Devices Quality Management

MD 703955

REGULATION OF MEDICAL DEVICES

What is a Medical Device? It is any instrument, device, equipment, computer program, implant ... intended by the manufacturer to be used in people with any of the following medical purposes:

[…]

Diagnosis, monitoring, treatment, relief or compensation of an injury or disability.

[…]

Every product for clinical use that falls within the definition of a Medical Device must comply with the applicable European regulations.

Biomechanical assessment computer applications used for diagnosis, monitoring, treatment, relief or compensation of an injury or disability are Medical Devices and must be developed and maintained in accordance with the regulations.

ISO 13485 Quality Management System Certificate

All stages of the life cycle of the Medical Device (MD) are developed under a Quality Management System according to the UNE-EN ISO 13485 “Medical Devices. Quality management systems. Requirements for regulatory purposes ”.

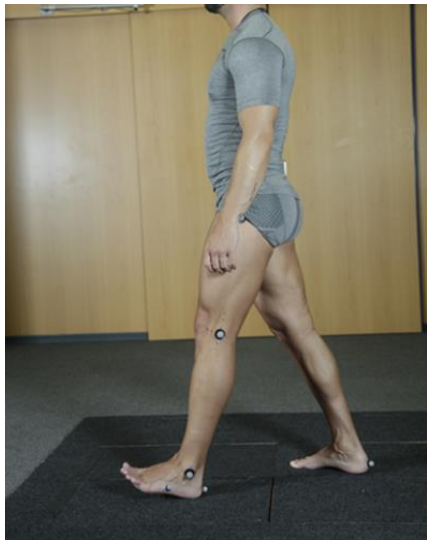
If you see a seal like this in an application for biomechanical assessment, you must understand that it has been developed based on that standard and, therefore, the RELIABILITY, VALIDITY AND USABILITY of the biomechanical test is guaranteed.

A good clinician…

…knows these requirements and demands them from the medical devices it uses.

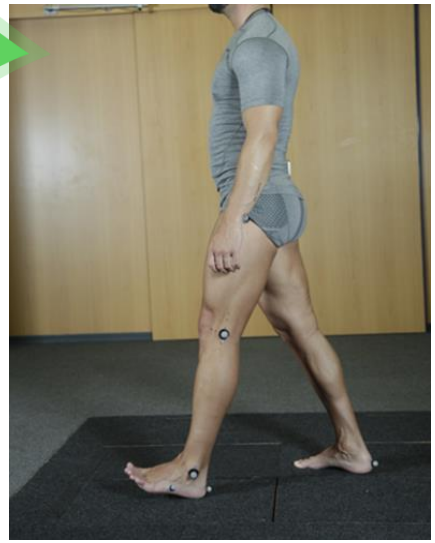
Functional assessment of balance by posturography for control after vestibular injury

ISO 13485 Quality Management System Certificate is required



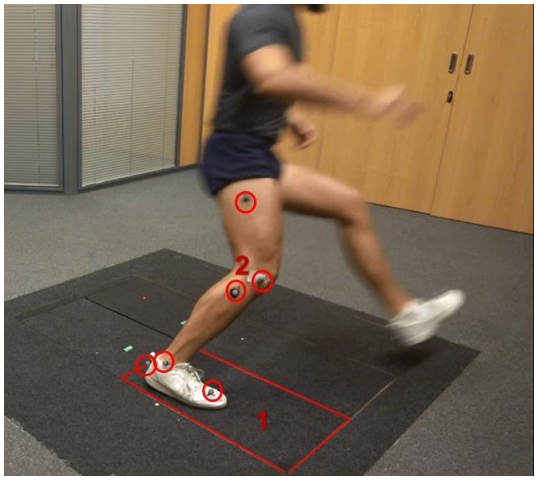
Functional assessment of gait with force platforms and photogrammetry for investigation

ISO 13485 Quality Management System Certificate is convenient but NOT required



Functional assessment of gait with force platforms and photogrammetry for control after stroke

ISO 13485 Quality Management System Certificate is required



Side-step cutting movement testing for improve sports performance

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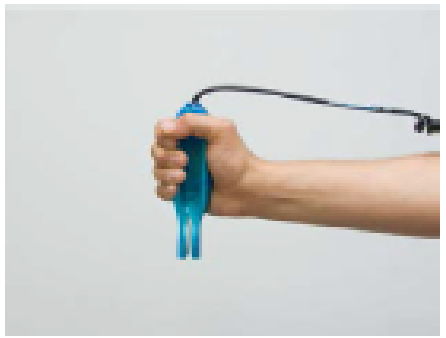

Grip strength assessment with a hand dynamometer to determine permanent injuries after a traffic accident

ISO 13485 Quality Management System Certificate is required

KEY IDEAS

- Biomechanical tests, to be used as complementary medical tests, must meet requirements related to reliability, validity and usability.
- In relation to reliability, it is essential that the test offer equivalent results when it is carried out under the same conditions on the same subject and by different evaluators.
- In relation to validity, it is essential that the evidence is based on solid scientific bases and methodologically correct research studies.
- In relation to usability, it is necessary that the test be safe for the patient, cost-beneficial and adapted to the scope to which it is directed.
- Medical devices, such as biomechanical applications for patient control, must comply with European regulations in this regard.

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