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Title
Sinridhorn National Medical Rehabilitation Centre (SNMRC) Guideline for Prosthetic Knee Test in Thailand

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Summary
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This report describes SNMRC guideline for prosthetic knee tests in Thailand, aims to assess mechanical properties required in ISO 10328:2006 and function of new designed prosthetic knee by observation, optoelectronic motion analysis system and questionnaires to promote development of prosth

Introduction
Nowadays prosthetic service in Thailand is constantly growing as the government and society become more aware of amputees’ potential capabilities. The appropriate prostheses are provided for individuals to maximize their functional capabilities, hence improve their quality of life. The prosthetic provision is currently inadequate due to the limited budget and expensive imported components. This urges the development of the prosthetic devices in Thailand. Sirindhorn National Medical Rehabilitation Centre (SNMRC), a leader in provision of prostheses, has high potential to facilitate the development of prosthetic devices, in particular a prosthetic knee joint. SNMRC intentionally serves as a prosthetic testing centre for mechanical and clinical evaluation of developing prosthetic knee joints
This report describes development process of the guideline to test the prosthetic knee utilized in SNMRC for safe in use and the development of the prosthetic knees.

Methods
There are 5 main steps1 as following:
2.1 Proposal step The proposal is submitted for vote by SNMRC prosthetic research committee to carry out the framework and form the working team.
2.2 Preparatory step This involves literature review and discussion among the working team members, and external specialists. The visit to Blatchford & Sons -design and mechanical testing centre- is arranged.

2.3 Enquiring step The submitted draft is discussed by the SNMRC prosthetic research committee. The consensus should be reached on the appropriate tests described.

2.4 Approval step The final draft is circulated among the SNMRC prosthetic committee for the final vote on the publication as the SNMRC guideline. If two third majority of the committee are in favor without any objections, this draft will be approved as SNMRC guideline for prosthetic knee test. Otherwise, this draft will be revised.

2.5. Publication step The approved draft will be published as the SNMRC guideline for prosthetic knee test

Results

The SNMRC guideline for prosthetic knee test consists of 5 main stages:

3.1 Design of the new prosthetic knee. The designers must state the user’s indications clearly.

3.2 Manufacture of prosthetic knee prototypes. The minimum of 4 prosthetic knee prototypes should be submitted for next stage.

3.3 Initial mechanical tests. The specimens are subjected to static proof test and cyclic test stated in ISO 10328:2006 before functional evaluation ensuring safe in use2,3. The specimens are required to complete 600,000 cycles without significant deformation. Otherwise the specimens must be modified i.e. return to the design stage.

3.4 Clinical test. The function of the prosthetic knee is assessed by 3 methods: clinical observation4, questionnaires5 and optoelectronic motion analysis system6.

3.5 Claim for compliance with ISO 10328:2006 .The centre are capable of running principal structural tests and separate test on knee lock. If the designed prosthetic knees pass these tests, they are sent to the testing centre abroad for compliance with the international standard before this prosthetic knee model could be prescribed for SNMRC customers.

The equipment utilised in SNMRC is the servo-pneumatic benchtop testing machine for the principal structural tests and separate test on knee lock and the optoelectronic motion analysis
for functional evaluation. These are supported by Structural Adjustment Loan (SAL) to promote human resources in Thailand.

**Conclusion**

The principals of guideline development process are literature review and consensus from internal and external prosthetic specialists and users i.e. trans-femoral amputees. This guideline is utilized to facilitate development of prosthetic knee in Thailand by establish safety of use through the assessment of the conformity of prosthetic knee with the strength requirements and obtain information on functionality leading to prescription and promote further research.

Currently there is co-research on the development of a polycentric four-bar linkage knee joint prosthesis and endoskeleton prosthetic component without foot component between SNMRC and the other organizations. This guideline will be reviewed and revised after the completion of this project. Afterward it will be revised every 3 years for updated information and advance technology available.

**References**
