

Scientific/Clinical Workshop

Workshop Title

Assessing Internal Joint Forces due to Misalignment of Rehabilitation Robots Using Instrumented Dummy Limbs in Context of Safety Testing

Workshop Responsible

Gerdienke Prange (Roessingh Research and Development, Enschede, the Netherlands)

Speakers

Jan Veneman, Andrais Tath, Diego Torricelli, Jule Bessler, Gerdienke Prange

Attendee Engagement

The main topics of attendee interaction will be about:

- 1) Exchange of experiences between audience and speakers related to assessment of misalignment or other human-robot interaction forces, kick-started by presentations of specific examples by the speakers, and fostering exchange of ideas between clinicians/clinical researchers (e.g., about safe limit values) and developers/engineers (e.g., about ways to measure and minimize misalignment)
- 2) Identification of best practices from the wider rehab robotics community, as represented by the attendees. This will be done in various ways: a) by posing questions to the audience during/after each of the presentations and discussing them in the interactive section (using online voting app/online forms), addressing experience with hazardous events during rehab robotic use relating to human-robot interaction (forces), proposed causes of those hazardous events, applied testing procedures of misalignment or other human-robot interaction forces, current gaps and challenges encountered, etc.; b) by providing practical, hands-on how to information through demonstration (online or physically if possible).

Abstract

The assessment of rehabilitation robot safety is a vital aspect of its development process, but often experienced as difficult, partly due to limited availability of best practices and safety standards. Musculoskeletal injuries are one of the two most frequent adverse events reported in clinical trials with robotic gait trainers, attributed largely to misalignment between the human and the exoskeleton [1]. Obviously, it is technically impossible to measure the stress on bones and joints in vivo, besides ethical considerations about safety testing with humans. Instrumented dummy limbs therefore appear to be one of a few reasonable options for assessing this safety-relevant behaviour.

Three consortia, cascade-funded via the COVR project (H2020), contributed to solving this challenge for the upper limb (DOROTHY project) and lower limb (EXOSAFE and SALOEXO projects). In this workshop, we want to share their experience with developing instrumented dummy limbs and deriving relevant data from testing it with existing rehabilitation robots. To frame the context of these topics, we will shortly address the regulatory framework regarding medical devices. Next, we want to address the audience's thoughts and experiences on these topics to expand the body of knowledge emerging on this topic, by contributing to identification of best practices for assessing the influence of misalignment and discussing knowledge gaps, such as safe limit values. Furthermore, we will provide a practical example of testing the effect of exoskeleton misalignment on knee joint forces using a dummy limb and finish this workshop with practical information on how

to identify relevant standards and laws for your device and how to test safety-relevant behaviour with your device.

The objective of the workshop is to raise awareness about safety-relevant aspects of misalignment and foster inspiration between researchers, developers and clinicians for how to deal with this challenge.

