Being safe around collaborative and versatile robots in shared spaces

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Case story:
How to apply the new rehabilitation robot standard IEC 80601-2-78 to a robotic gait trainer (an example)

Domain: Rehabilitation

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Project beneficiaries: Hocoma

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Author: Jule Bessler

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1 Overview

Rehabilitation robotics is a new and evolving field which is why the availability of safety standards and best practices is very limited. At the same time, rehabilitation robots are frequently physically attached to a patient's limb to allow for the support of movement which introduces risks. The standard IEC 60601-1 for medical electrical equipment deals with requirements for basic safety and performance. This standard is a harmonized standard, which means that all requirements as specified in the standard match with the relevant EU legislation. In other words, it can be used to indicate that a device complies with relevant EU legislation. It is however rather general and lacks details on application specific requirements. Therefore, application specific standards have been developed complementary to the IEC 60601-1. In 2019 a specific standard for rehabilitation robotics has been published. This standard IEC 80601-2-78 applies to 'medical robots for rehabilitation, assessment, compensation or alleviation', also referred to as RACA robots, which includes all rehabilitation robots. Therefore, also the gait trainer Lokomat (Hocoma AG, Switzerland, see Figure 1) falls under the scope of the IEC 80601-2-78 standard. This standard has not yet been harmonized, however this is expected to happen in the near future. It is therefore helpful for developers to start adopting this standard already to ensure compliance in the future.

This case story explains how definitions and terminologies used in the RACA standard can be adopted for a robotic gait trainer. The current example of translating and applying the standard to the Lokomat gait trainer will provide concrete guidance and inspiration for developers of other gait trainer robots, or systems with a similar or related set-up. With increased understanding of how to apply the RACA standard, its use is promoted, in order to facilitate the process to demonstrating safety of a rehabilitation robot for manufacturers.

Figure 1: Lokomat gait trainer

2 Challenges

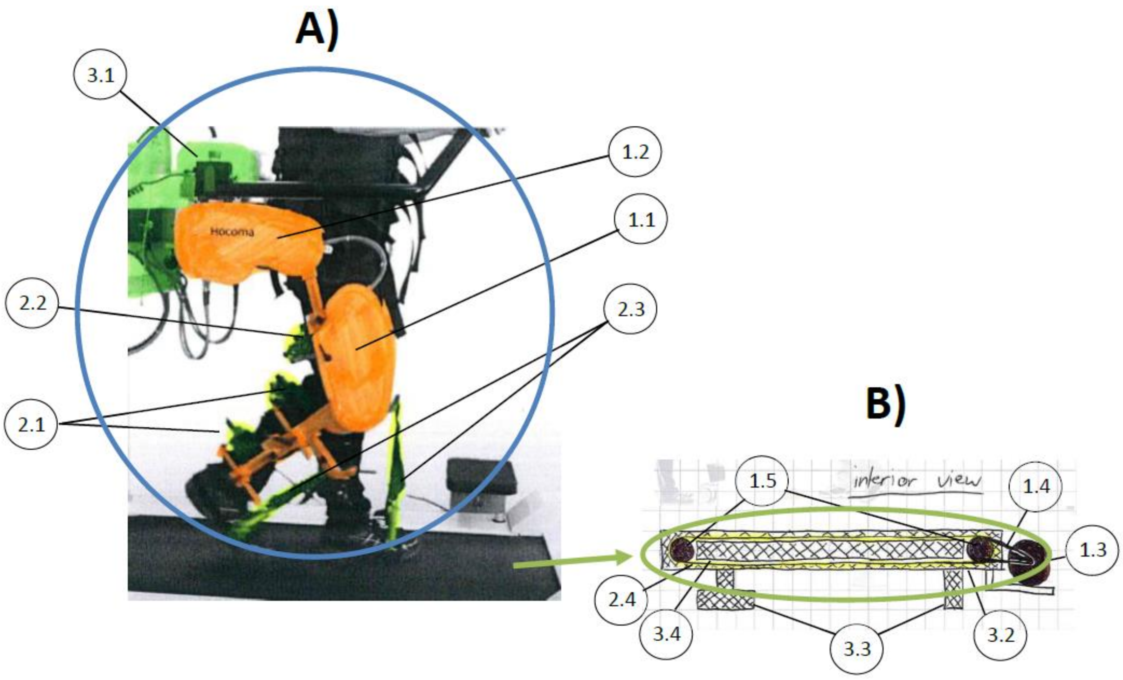
To use the information that can be found in the new 80601-2-78 standard for a Risk Management File, the definitions and terminology need to be applied to the rehab robot in question. An important aspect of the new standard is that it considers a RACA robot as consisting of different support systems, based on their function in moving or supporting the patient or patient limbs. To comply with this standard, the total load acting on each part of the robot needs to be calculated separately to account for the risk related to failure of a part. In addition to static forces and added loads (i.e. the weight of the patient's limbs), the dynamic forces play a role, which are influenced by the actuators. Therefore, the sub-systems of the robot can all have different total loads depending on their function and the architecture of the system. The total load of each of those sub-systems, including the influence they may have on the total load of the other sub-systems, should be evaluated in the risk analysis. For this purpose the standard identifies certain sub-systems of a RACA robot that are relevant in this case, being:

- Actuation system
- Actuated applied parts
- Support system
- Support system for patient

Examples showing this terminology of sub-systems for different types of devices can be found in the Annex of IEC 80601-2-78: 2019, figures AA 13 – AA 20. However, these examples do not include a gait trainer similar to the Lokomat, which is a common type of robot for gait training. To facilitate the application of IEC 80601-2-78 to the Lokomat gait trainer, the system architecture of the Lokomat was therefore matched with these specific subsystems.

3 Solution

The new standard based system description was applied to (A) the orthosis moving the leg as well as (B) the treadmill moving the feet (Figure 2). For the orthosis part, the actuated orthosis itself was identified as actuation system, the cuffs and foot lifters as actuated applied parts and the support structure on the column as support system. For the treadmill part, the treadmill motor, transmission belt and support cylinder were identified as actuation system, the walking belt as actuated applied part and the frame, base and weight supporting plate as support system.



A) or B) Actuation system

Number	Description
1.1	lower leg orthoses
1.2	upper leg orthoses
1.3	treadmill motor
1.4	transmission belt
1.5	support cylinder

Actuated applied parts

Number	Description
2.1	lower cuffs
2.2	upper cuffs
2.3	foot lifters
2.4	walking band

A) or B) Support system

Number	Description
3.1	support structure
3.2	frame
3.3	base
3.4	weight supporting plate

Figure 2: Lokomat system description based on IEC 80601-2-78 subsystems.

4 Considerations

Based on the identification of the two key actuation systems in this example (the orthosis and the treadmill), separate architectures could be drawn. These detailed architectures consist of all mechatronic elements (control layers, electronics, electromechanics, mechanical transmission, actuated applied parts) in the chain that constitute the whole actuation system. In each of these mechatronic elements, specific failure modes could occur that can lead to a functional failure of the subsystem, leading to hazardous situations related to its function. Therefore, the identification of the actuation systems and its elements helps in the identification of risks.

This case story adds an example of how to apply the system description in IEC 80601-2-78, which can help other rehab robot developers to identify the relevant subsystems in their own device, and use that as a starting point to identify risks associated with their particular device, and select appropriate mitigation measures where needed.