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**Digital Ergonomics in  
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**Exoskeletons certification: why and  
how?**

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# Topics

- Disclosures
- Why exoskeletons?
- Why exoskeletons certification?
- How to certify exoskeletons?



# Disclosures



# Disclosures (financial)

- Professor of Occupational Medicine and Director of the Occupational Medicine Unit of the Sant'Orsola Malpighi Hospital and of a University Department: my income is made up of my wage paid by the university and the hospital, plus a variable part produced by consultation work and financial revenues.
- No component of my income may be modified by the opinion expressed in this presentation.
- I have fully disclosed my patrimonial condition to my employers, according to current Italian regulation:
  - Law 441/1982,
  - Law 127/1997,
  - Presidential Decree 62/2013,
  - Regional Law (Emilia-Romagna) 9/2017.



# Disclosures (affiliations)

- Italian Society of Occupational Medicine (President 2015-2018, Past-President 2019-2024).
- International Commission on Occupational Health (Board of Directors, 2022-2024).
- The Bertrand Russell Society, member.
- The British Wittgenstein Society, member.
- **No other affiliation which may influence my way of thinking.**



# Disclosures (strong beliefs)

- "The good life is one inspired by love and guided by knowledge." - Bertrand Russell, What I Believe, 1927.
- "2. From its *seeming* to me - or to everyone - *to be so*, it doesn't follow that *it is so*. What we can ask, is whether it can make sense to doubt it." - Ludwig Wittgenstein, On Certainty, 1969 (Über Gewissheit, 1984).
- "...non-reproducible single occurrences are of no significance to science." - Karl Popper, The Logic of Scientific Discovery, 1959, page 66 (Logik der Forschung, 1934).



# Why exoskeletons?



# Why exoskeletons?

- Musculoskeletal disorders are the most frequently reported occupational health problem, almost in every country.
- Whereas significant uncertainties exist about their precise relation with occupation, it is generally accepted that part of some disorders (low back pain, shoulder pain) may be co-caused by biomechanical load associated with occupational tasks (heavy lifting, working with hands over the head).
- Anyway, it is necessary that at least the “heavier” tasks must be adapted to human requirements, as much as possible, in order to reduce workers’ discomfort (and possibly pain and disease).
- In the last years, this has been achieved using automation, but this is not always possible.



# Why exoskeletons?

- Automation may be used in some manufacturing activities, but not in all.
- Demanding tasks exist in some service activities, which are only partially (or not at all) amenable to automation (logistics, healthcare, cleaning, agriculture, etc.).
- Exoskeletons are promising devices which may supplement human capabilities, making the body more able to tolerate some efforts.
- In addition, passive exoskeletons seems to be the more usable of these devices in that they do not require an external power source, are lighter and can be put on and off (for example, to use a toilet) easily and quickly.
- Briefly, they can be considered like a Personal Protective Equipment against some types of biomechanical overload.



# Why exoskeletons certification?



# Why exoskeletons' certification?

- Exoskeletons are complex devices and if their use is to be diffused, buyers must be able to buy these devices with confidence (and possibly use them with satisfaction).
- Moreover, as exoskeletons are still “new” devices, a buyer must have some form of confidence that the device is safe to use and work as intended.
- National and international voluntary technical standard (ISO, EN, UNI etc.) for Personal Protective Equipments essentially fulfill this task and a buyer assume, buying a certified PPE, that the device is both safe and effective (the bottom line: worth the money).
- Currently, a few technical standards are being developed for the certification of exoskeletons for occupational use (e.g., ASTM F48, UNI Project 1611109), but none is close to adoption.



# How to certify exoskeletons?



# How to certify exoskeletons?

- Conceptually, certification of an exoskeleton is a process by which an organization (not affiliated with the producer) states that the device has passed some sort of tests of safety and efficacy.
- Safety tests should be directed toward demonstrating that the intended use of a device does not harm the user (including unintended, but foreseeable, circumstances).
- Efficacy tests should be directed toward demonstrating that the intended use of a device protect the user against harm, as compared to the same task performed without the protecting device.
- Safety and efficacy are easier to address in the short term, but more difficult to prove in the long term.



# How to certify exoskeletons?

- Addressing safety of exoskeletons in the short term is possible and relatively easy: test should be directed toward demonstrating that the use of the device does not expose the user to the injuries of different nature (mechanical, electrical, etc.).
- Safety certification should include usability evaluation.
- Addressing safety in the long term is more complex, as the question could be related to the use of the device, for example, for the whole working life (conventionally, 8 hours a day, 40 hours a week, for 40 years).
- However, to my knowledge, no existing PPE (e.g., shoes, gloves, helmets) has ever been tested for safety in the long term before being introduced to the market.
- To this end, the same could be done with exoskeletons, possibly introducing some for of post-marketing monitoring, after certification of safety in the short term.



# How to certify exoskeletons?

- Addressing efficacy of exoskeletons in the short term is possible but more complex: test should be directed toward demonstrating that the use of the device at least significantly reduce muscular effort during the intended use, as compared to the same task without exoskeleton (surface EMG is both effective and acceptable, to this end).
- However, some musculoskeletal disorders possibly co-caused by occupational biomechanical overload are thought to affect tendons or intervertebral discs and measuring the effect of exoskeletons in reducing the load transferred to these bodily structures requires, so far, invasive methods which may even be considered ethically not justified.
- Moreover, if a device is proven able to reduce at least workers' fatigue, it is not justified to postpone its adoption for concerns about its long-term safety which do not appear to be supported by plausible clues.





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