

CEN-CENELEC Sector Forum on PPE N 405

Exoskeletons : legal status ?



Definition (1)

- a hard outer layer that covers, supports, and protects the body of an invertebrate animal such as an insect or crustacean (Cambridge dictionary)
- **1**: an external supportive covering of an animal (such as an arthropod) / **2**: bony or horny parts of a vertebrate produced from epidermal tissues / **3**: an artificial external supporting structure (Merriam-Webster)

Definition (2)

The field of exoskeleton systems is continuously evolving and re-inventing itself, so it is still difficult to create a singular definition. In general:

- Exoskeletons are wearable devices that **work in tandem *with* the user**. The opposite of an exoskeleton device would be an autonomous robot that works *instead* of the operator.
- Exoskeletons are placed **on the user's body** and act as amplifiers that augment, reinforce or restore human performance. The opposite would be a mechanical prosthetic, such as a robotic arm or leg that replaces the original body part.
- Exoskeletons can be made out of rigid materials such as metal or carbon fiber, or they can be made entirely out of soft and elastic parts.
- Exoskeletons can be **powered and equipped with sensors and actuators, or they can be entirely passive**.
- Exoskeletons can be mobile or fixed/suspended (usually for rehabilitation or teleoperation).
- Exoskeletons can cover the **entire body, just the upper or lower extremities, or even a specific body segment** such as the ankle or the hip.

Exoskeletons can also be referred to as: robotic suit, powered armor, exo-frame or exosuit, wearable machine, power jacket, etc...

Functionality ?

- Supportive : redistributing forces on body / correcting posture to avoid injuries or stress
- Reinforcing : adding strength (+ redistribution of forces)
- Medical/curative : replacing or reinforcing bodily functions that are weakened or lost

Remark : other functions (e.g. warning incorrect posture) also called 'exoskeleton'

Active - passive

- Active : include actuators
 - Electrical motor
 - Hydraulic
 - Pneumatic
- Passive : energy stored is only generated by movement of user
 - Springs
 - Dampers
 - ...

supportive



Working in a forward bended posture leads to high stresses in the back.



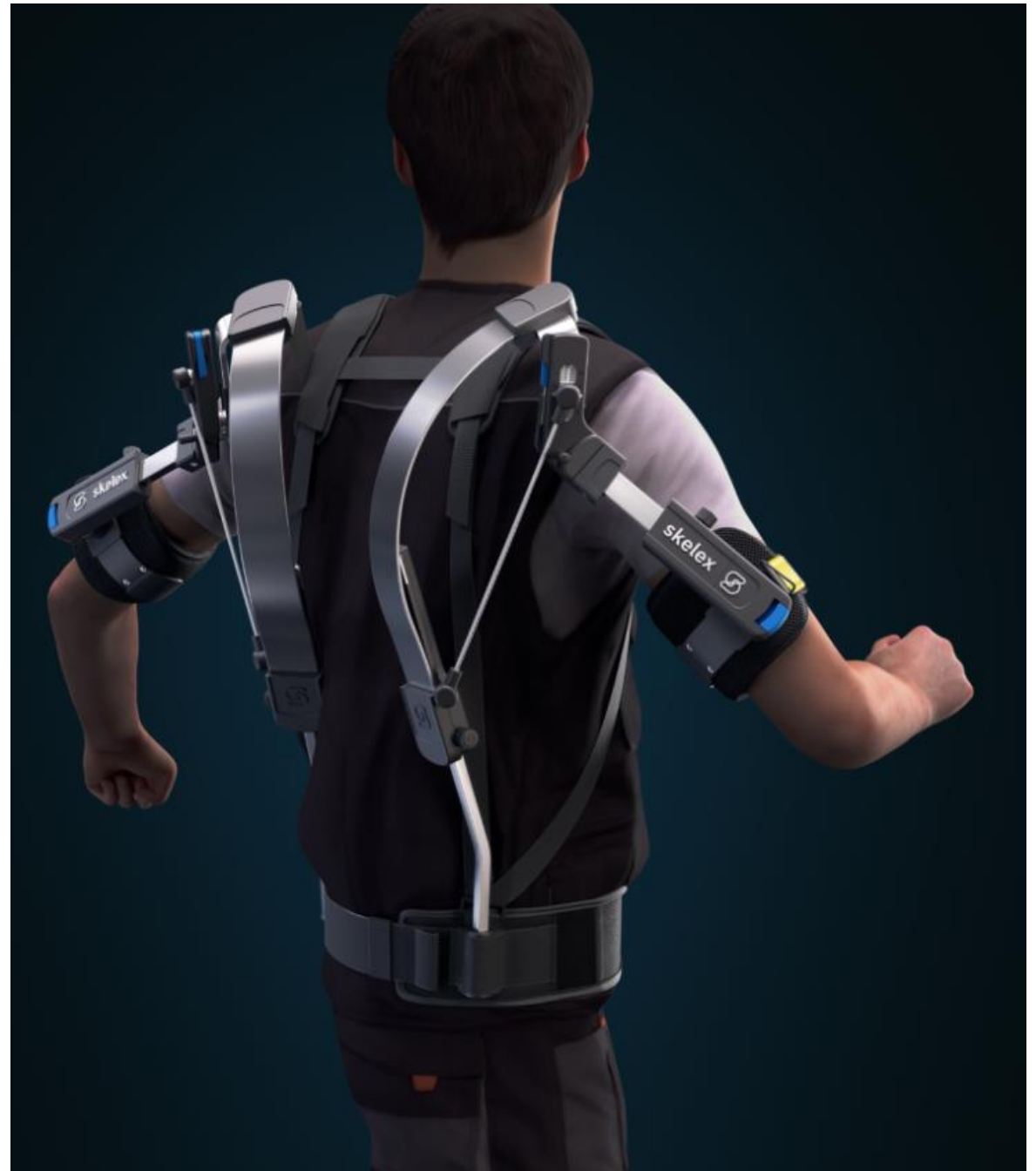
By leaning on your own knees, forces are transferred directly to your thighs.



The Laevo does the same. It supports your body weight, while you keep your hands free. The stresses in your back reduce with up to 40%.

Example Laevo – www.laevo.nl

supportive



Example Skelex – www.skelex.com

supportive



Example chairless chair – www.noonee.com

supportive



Example EksoVest – www.eksobionics.com

reinforcing

Often military or rescue applications



medical/curative



Examples : project March TU Delft – www.projectmarch.nl/en/project-march
Dublin City University - www.dcu.ie/exoskeleton/index.shtml
Rewalk – www.rewalk.com

Legal framework (1)

- Machinery : key words in definition : “fitted with a drive system other than directly applied human or animal effort”
- Medical Device : key words in definition : “to be used specifically for diagnostic and/or therapeutic purposes” and “diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap”
- PPE (Regulation 2016/425) : key words in definition : “to be worn or held by a person for protection against one or more risks to that person's health or safety”

Legal framework (2)

- Other legislation ?
 - General product safety
 - Electronics : Low voltage – electromagnetic compatibility - ...
 - REACH
 - ...
- Professional use : framework Directive 89/391 + e.g. PPE Use 89/656

Legal framework (3)

- Combination of several product legislative acts
- Notified Bodies
- (harmonised) standards

EU OSHA

- Discussion paper “The impact of using exoskeletons on occupational safety and health” published 08/2019 (<https://osha.europa.eu/en/publications/impact-using-exoskeletons-occupational-safety-and-health/view>)
- The 2020-22 Healthy Workplaces campaign focuses on the prevention of work-related musculoskeletal disorders (MSDs).

Concerns

- Safety of the systems
- How to measure effect ?
- Long term effects ?
- Priority is increasing productivity or preventing injury ?
- OSH hierarchy needs to be respected
- Multidisciplinary topic

Way forward ?

Bibliography

- EU OSHA discussion paper : the impact of using exoskeletons on OSH (<https://osha.europa.eu/en/publications/impact-using-exoskeletons-occupational-safety-and-health/view>)
- KAN Brief (3/19) - <https://www.kan.de/en/publications/kanbrief/>
- Tijdschrift voor Human Factors (April 2019 – several articles in English) – see FEES
- IFA practical info + risk analysis for exoskeletons - <https://www.dguv.de/ifa/praxishilfen/praxishilfen-ergonomie/exoskelette/index.jsp>
- INRS : e.g. video Exoskeletons at work, how to prepare for them ? <http://www.inrs.fr/media.html?refINRS=Anim-210> + other information and studies <http://www.inrs.fr/risques/exosquelettes/ce-qu-il-faut-retenir.html>

More examples of exoskeletons

- www.ironhand.eu/project_aim
- www.marsibionics.com/?lang=en
- www.wearable-robotics.com/kinetek/
- www.rb3d.com/en/exoskeletons/
- www.hocoma.com/
- www.axosuits.com/
- www.20knots-plus.com/marine-mojo/
- www.skimojo.com
- www.ottobock.com/en/company/ottobock-industrials/
- www.exoatlet.com/en
- againer-ski.com/
- www.phasexab.com
- www.bioservo.com/
- www.myseismic.com/
- And many more

Thank you for your attention



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