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PERSPECTIVE

Whole-Body Electromyostimulation: More Effectiveness and Safety Due to More Regulation? Current Developments, Challenges and Perspectives

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Whole-body EMS is a training technology that originated in Germany. Commercially launched in about 2006-2007, the more than 2,700 commercial facilities to date indicate the rising popularity for this time-efficient and joint-friendly exercise technology. Thus, Germany might serve as a blueprint and indicator for upcoming developments, problems and challenges in WB-EMS application. Starting with occasional adverse effects in Germany/Austria [1,2] and Israel [3], predominately induced by inadequate initial WB-EMS applications [4], the first calls for its official regulation by the responsible authorities were published in 2016 (it's time to regulate whole-body electromyostimulation) Israel [3]).

Since then, high emphasis has been placed on safety, standardization and monitoring aspects through evidence-based recommendations, position papers and standards [5-7] that specify the application of WB-EMS in commercial, non-medical settings in depth. Of note, these specifications were only voluntary, however, which might have motivated the German authorities to produce a mandatory approach for the regulation of WB-EMS.

In 2019, the German "Federal Ministry for the Environment, Nature Conservation and Nuclear Safety" (BMU) published the revised German Radiation Protection Statutes, a mandatory standard that also covers WB-EMS (Applications of Non-Ionizing Radiation to Humans; NISV) [8]. Of interest, this directive did not refer only to EMS (including TENS) or WB-EMS, but to all relevant types of electric, magnetic and Electromagnetic Fields (EMF) used in non-medical applications. Coming into force in January 2021, the NISV regulated several aspects of commercial WB-EMS application. The first NISV aspect focused on mandatory registration with the local supervisory authority and included references for proper setup of the device and instructions by the manufacturer, the references for proper setup of the device and instructions by the manufacturer, the necessary knowledge for inspection and maintenance and functional testing before each use. The second aspect of the NISV placed an emphasize on client disclosure and included aspects of WB-EMS application and effects, risks and potential adverse effects. However in contrast to the non-mandatory DIN 33961-5 [6], the NISV falls short in specifying important

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aspects of WB-EMS application (e.g. supervision ratio [9]. The third aspect of the NISV refers to "documentation", not only with respect to installation, maintenance, malfunctions and damage of the device, instruction and qualification of the staff, but also to the individual WB-EMS application. The latter includes the documentation of WB-EMS specifications (e.g., impulse frequency, -intensity, duty cycle) as well as documentation of the long-term application (WB-EMS frequency, progression of intensity, adverse effects, their cause and consequences). Considering that the latest generation of WB-EMS devices save and forward the corresponding data, the workload for the facilities remains reasonable. Finally, the most significant innovation of the NISV is the mandatory education and certification (Fachkunde) of the persons that lead and supervise the WB-EMS application. In the area of WB-EMS, the prerequisite to be eligible for the WB-EMS education and certification is a 120 h exercise trainer license. Contents and specifications of the additional 24 h WB-EMS "Fachkunde" education were prescribed in detail by the NISV, but with some exceptions it did not differ from the present curriculum of recognized educational facilities. Due to the enormous amount of non- or inadequately licensed WB-EMS trainers, the NISV aspect of mandatory trainer education will come into force not before January 2022. Still, apart from the very high amount of certifications needed, another formal aspect collides with the availability of the cautiously estimated 5000 WB-EMS instructors needed in 2022. Although the formal accreditation of an educational facility according to EN-ISO/IEC 17024 [6,10], by the officially appointed authority (Deutsche Akkreditierungsstelle, DAkkS) is not mandatory (yet!), it ensures the assumption of conformity with EN-ISO/IEC 17024 by the supervising authorities, who might otherwise doubt conformity of the education and certificate. Nevertheless, accreditation according to EN-ISO/IEC 17024 [6,10] is a costly, rather complex, and very stringent process – reviewing the German market, only a handful of education facilities will be able to fulfill the criteria as yet.

Apart from this structural problem, another issue confronts the present WB-EMS market in Germany. Related to the upcoming enhanced regulation and their costs, the COVID-19 induced lockdown of WB-EMS facilities in Germany, and the "Peleton" phenomena, new business models focus on non-supervised WB-EMS application at home. Apart from the growing private client market, there is an increasing trend to commercial rental of low priced devices to former WB-EMS studio customers. The DIN 33961-5 [6], the recommendations on safe and effective WB-EMS application and in particular the radiation protection committee (SSK; [11] excluded the private, non-supervised application of WB-EMS; however, there is no official ban of this setting yet. It might be a waste time to once stress the importance of close supervision by an experienced and attentive instructor for effective and particularly safe WB-EMS application [9]. Common sense alone suggests that excessive private non-supervised WB-EMS application will significantly increase the prevalence of adverse effects with the consequences of further regulation by the BMU. Considering that due to its classification as high EMF exposure, commercial WB-EMS is only a hair's breadth from exclusive medical use [11], the desirable ban of private WB-EMS application might not be the only consequence induced by the well-known German penchant for regulating everything. We are aware that profit-oriented companies are not amenable to these arguments in general, but bearing in mind that there is considerable evidence to suggest that the next step in federal regulation will address the non-medical setting of commercial WB-EMS, the consequences for all stakeholders will be very far reaching [12].

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