

MDFD—a Portable Medical Device for Measuring the Electromechanical Properties of Skeletal Muscles through Electrical Stimulation

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Developed together with the Slovenian company TMG-BMC in the framework of a Eurostars project, MDFD allows assessing the health state of skeletal muscles by measuring their mechanical and electrical responses to an electrical stimulus. While CSEM designed and manufactured the electrical and mechanical hardware, as well as the embedded software of the device, the industrial partner developed algorithms for extracting relevant indicators from the measured data and performs trials on volunteers.

Musculoskeletal disorders affect more than 1.7 billion people worldwide. Existing diagnostic methods lack accessibility and are expensive and time-consuming. The MDFD project (medical device for measuring electro-mechanical properties of skeletal muscles) aims at developing a cost-effective, fast, portable, non-invasive, and selective tool for diagnosing pathologies. The device developed at CSEM has three modules: a stimulating module which injects precisely controlled electrical impulses into a selected muscle; a stylus probe which measures the mechanical displacement of the muscle (tensiomyography, TMG); and an electromyography (EMG) module which records the electrical response of the muscle after the electrical stimulation. The simultaneous recording of TMG and EMG allows quantifying training- and illness-induced changes of muscle fibers and their ability to contract.

The MDFD device shown in Figure 1 consists of a hand-held device and a table-top device. The hand-held device contains a trigger for starting the stimulation and a stylus probe for measuring the displacement of the muscle. The main parts of the electronics are located in the table-top device. They include the EMG module, batteries which make the device portable, and a Bluetooth module for communication with a smartphone and/or tablet. The inset in Figure 1 shows the setup of a recording with the MDFD device.

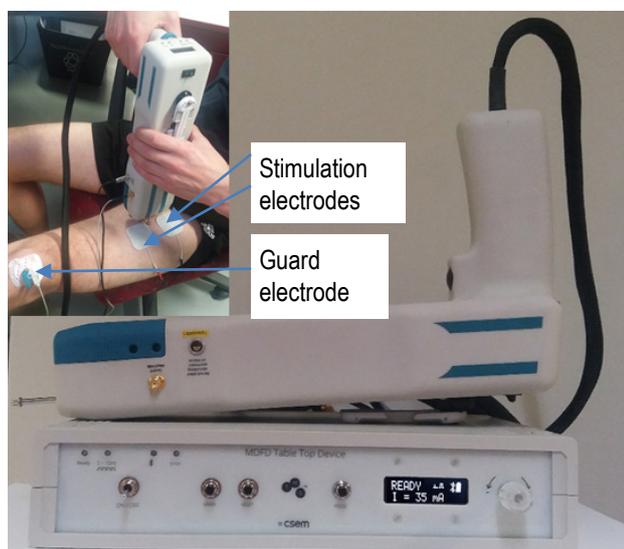


Figure 1: MDFD demonstrator, comprising (1) a hand-held device and (2) a table-top device. Inset: Use of the MDFD device on the vastus medialis muscle. The EMG recording electrodes are integrated in the hand-held device.

An important aspect of the development was the electrical safety of the device, since it is meant to inject electrical stimuli into the body. Therefore, the development was guided by the quality management system of our Medical Device Technology research activity (ISO 13485-certified), in particular the parts related to risk analysis and control, and by applicable standards^[1,2].

Figure 2 shows EMG and TMG curves from a surface transcutaneous femoral nerve stimulation in the inguinal region with a 90 mA x 1 ms impulse. The MDFD allows assessing simultaneously the mechanical and electrical activity of a muscle. In this regard, one of the most unique and important parameters is the ratio between the EMG and TMG amplitudes. This parameter is called the muscle performance index and is considered an objective parameter of the status of a muscle. The following additional figures—indicative for the health status of a muscle—are also derived from the EMG and TMG curves: contraction velocity, level of sustained contraction, relaxation velocity, muscle fibers composition, and maximum muscle force and endurance parameter. The industrial partner now studies if these data allow quantifying the recruited motor units and their ability to contract. Detailed results are expected at the end of 2019. In a future integration, the electronics will be further miniaturized and completely integrated in the hand-held device.

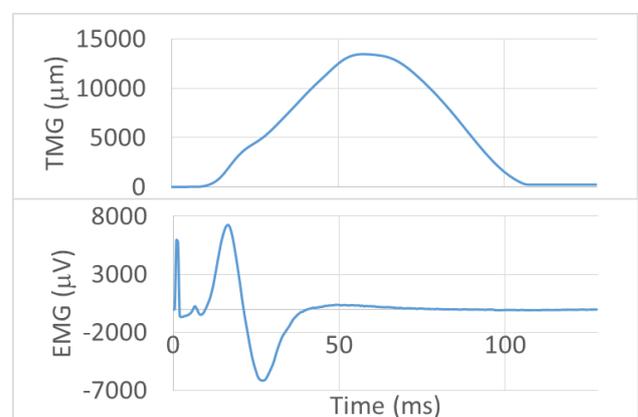


Figure 2: TMG and EMG signals recorded from transcutaneous nerve stimulations of the inguinal region with a 90 mA x 1 ms impulse.

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[1] "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance", International Standard IEC 60601-1.

[2] "Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment", International Standard IEC 60601-2-40.