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A low-invasive wearable monitoring platform in sexual medicine

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Abstract

Objectives: In order to enable quantitative and continuous measurement of sexual performance with minimal invasiveness and inconvenience for the user, an accelerometer-based wearable system, named HU-MOVE platform, was investigated.

Methods: Design, implementation and development of HU-MOVE, a wearable platform equipped with an accelerometer sensor for monitoring inertial parameters for sexual performance assessment and diagnosis. The system enables quantitative measurement of movement parameters during sexual intercourse, meeting the requirements of wearability, data storage, sampling rate and interfacing methods, which are fundamental for human sexual intercourse performance analysis. HU-MOVE was validated through characterization on a controlled experimental test bench and tested in human model in simulated sexual intercourse conditions.

Results: HU-MOVE demonstrated to be a robust and quantitative monitoring platform and a reliable candidate for sexual performance evaluation and diagnosis. Characterization analysis on the controlled experimental test bench demonstrated an accurate correlation between the HU-MOVE system and a reference displacement sensor data. Experimental test in human model in simulated intercourse condition confirmed the accuracy of the sexual performance evaluation platform and the effectiveness of the selected and derived parameters. The obtained outcomes also established the project expectations in terms of usability and comfort, highlighted by the questionnaires that pointed out the low-invasiveness and acceptance of the device.

Conclusions: To the best of our knowledge, HU-MOVE platform is the first device for human sexual performance analysis compatible with the sexual intercourse; the system has

the potentiality to represent a helpful tool for physicians to accurately classify sexual disorders, *e.g.* premature or delayed ejaculation.

1. Introduction

Over the past few decades the increased level of awareness within health and physical fitness communities has created an emerging need for smart applications and comfortable/wearable devices that sense, classify, and provide feedback to users' activities of daily living in a pervasive fashion [1-6]. In particular, physical motion, which is a fundamental aspect for categorizing person's current health and activity, can be detected and recorded by using wearable accelerometer-based systems [7, 8]. Their recent "disruptive impact" is mainly due to their small size, low-invasiveness and intuitiveness, relatively low cost, and easy integration with existing platforms for sensor networks. They are also able to effectively provide indicative features of human movement corresponding to frequency and intensity of motion, which is important to assess, for instance, static posture characteristics [9].

An important field that may benefit from the use of a wearable monitoring inertial device is the sexual medicine, due to its consistent impact and influence on human life quality and the lack of quantitative and low-invasive monitoring systems for objective parameter analysis. Nowadays, basic and/or even invasive methodologies, often not compatible with sexual intercourse (SI), are used for diagnosing sexual disorders (*e.g.* premature ejaculation), such as simple stopwatches (mainly used for assessing the intravaginal ejaculation latency time parameter - IELT), invasive button-counter for calculating SI penetrations, and personal evaluation forms about the satisfaction level of the partner [10-14].

Basing on the above premises, an inertial monitoring wearable platform, suggested and named HU-MOVE by the author CBF, was developed by the authors with the aim to sense, record and analyse inertial parameters for evaluating human sexual performance for diagnostic purposes. Although a large number of devices already exists and widely represents the state of the art of the inertial monitoring systems [15-18], a custom-made platform was developed for this specific application due to the need to have an open-platform for accurately designing and tuning the hardware, firmware and software in collaboration with physicians and with the final aim to develop a novel diagnostic tool in sexual medicine; it focuses on precise sexual performance medical specifications in terms of derived indexes, intuitiveness, comfort and confidentiality issues.

HU-MOVE is intended for SI use by a male human operator and ensures compatibility and minimum interference with the sexual activity to be monitored. The platform measures and derives significant motion parameters for precise quantization of the physical sexual activity based on the sensed acceleration data. HU-MOVE can be exploited for diagnosing pathologies, such as premature or delayed ejaculation, which are the most common male sexual disorders [13, 19-23], potentially representing a fundamental tool for accurate diagnosis in supporting physicians in the monitoring and long term follow-up and along pharmaceutical or educational treatment activities.

2. Materials and methods

2.1 System overview

An inertial monitoring platform, named HU-MOVE, was designed and developed for figuring out human inertial parameters in sexual performance assessment; it consists of a low-invasive miniaturized wearable monitoring inertial device (WMID), a magnetic-based

trigger (MBT) (Fig. 1a) and a high-level data analysis remote station. In the clinical practise of SIs, the WMID will be attached to the human back with a patch and the activation and deactivation phases will be comfortably managed by the MBT card as a magnetic-based remote control.

The WMID is composed of a rectangular-shaped rigid protective package, a custom-made electronic board, and a rechargeable battery; it is 60 mm in length and 36 mm in width and has an overall thickness of 8 mm.

The electronic system comprises a miniaturized flexible rectangular-shaped electronic board, which includes a microcontroller, a triaxial digital inertial sensor, a non-volatile memory card for data storing, a magnetic Hall-effect sensor and a reed electrical switch for the control stages and light-emitting diodes (LEDs) as the control feedback for the user.

Regarding the software implementation, a specific low-level C-language code was developed and implemented in the microcontroller to record the data from the inertial sensor in a memory card, to manage the power and activation stages of the device, and to provide correct feedback to the user.

The MBT comprises a permanent magnet (N42 NdFeB axially magnetized magnet - K&J Magnetics, PA, USA) integrated in a credit card-shaped case and used for triggering status changes of the device approaching the card closed to the WMID.

A high-level software data analysis remote control station was developed and implemented on a personal computer for sensor data analysis, parameter extraction and data organization.

An overview of the HU-MOVE platform architecture is presented in Fig. 1b, whereas a detailed description of the single modules of the system is provided in the next sections regarding electronic system design and software implementation, respectively.

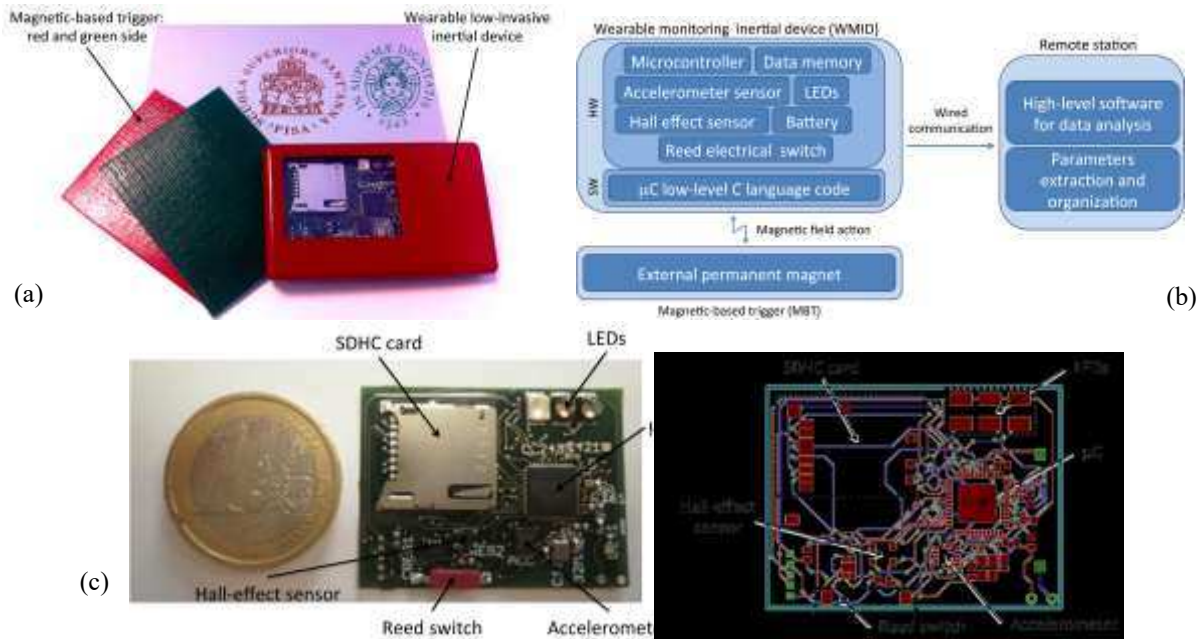


Fig. 1. (a) HU-MOVE: an accelerometer-based analysis solution for human sexual performance evaluation. (b) System architecture of the overall system composed of a WMID, a MBT and a high-level data analysis remote station. (c) Custom-made miniaturized electronic board and (d) electronic scheme of the board.

2.1.1 Electronic system design

A custom-made miniaturized electronic board was design and developed by integrating state of the art off-the-shelf components, in order to record and store data from an embedded accelerometer sensor. The board design and specifications were critically investigated due to the dimension constraints: the electronic board prototype is 27 mm in length and 36 mm in width and has an overall thickness (with components assembled) of about 3.5 mm. The electronics board integrates a CC2430 (Texas Instruments, USA) system-on-chip core component, selected for its low power consumption capability and suitable dimension and comprising a wireless controllability module [24] (wireless capability was selected for future software improvement in terms of data download and real-time monitoring). A digital triaxial accelerometer (LIS331DL, STMicroelectronics Inc., Switzerland) was embedded in order to

record acceleration data from the wearable device with an output data rate of 100 Hz or 400 Hz (100 or 400 acquired samples per second) and a variable measurement range of $\pm 2g$ or $\pm 8g$ (for the specific task a frequency of 100 Hz, and a measurement range of $\pm 2g$ were selected for suitability with sexual performance analysis). A 4 GB micro Secure Digital High Capacity (SDHC – Lexar, USA) memory card was integrated in the electronic board for storing X, Y and Z accelerations with a high data rate, avoiding data or time constraint of a wireless communication. A magnetic Hall-effect sensor (CYSH12AF, Chen Yang Technologies GmbH & Co. KG, Germany) and a reed switch (magnetic mechanical switch - CT05-3050-G1, Coto Technology, USA) were integrated into the electronic board for managing system transition stages (power and recording management), both controlled by the MBT card, whereas a voltage regulator was installed for peripherals power control (TPS78230DDC, Texas Instrument, USA). Finally, three multi-coloured LEDs were installed to provide feedback to the user about the wearable system functioning. The overall system is supplied by an integrated 280 mAh battery (Li-Po GM302547 - Power Stream, Utah, USA). A picture of the developed custom-made electronic board with the installed components is represented in Fig. 1c and its electronic CAD in Fig. 1d.

2.1.2 Software implementation

Software implementation consists of a low-level C-language code, integrated in the embedded microcontroller, and a high-level software data analysis remote control station.

Regarding the low-level code, a C programming language firmware was developed; the code is partitioned into three main operating blocks with specific functionalities, respectively named *sleeping mode*, *waiting mode* and *recording mode* and triggered by the MBT card.

Once the system is powered, the installed peripherals (*i.e.* microcontroller, accelerometer, magnetic Hall-effect sensor and SDHC memory card) are initialized and the system is led in

sleeping mode; in this status, all the internal digital circuits powered by the voltage regulator are turned off. *Sleeping mode* was implemented for achieving overall low-power consumption, allowing the inertial system to be stored for a long time (*i.e.* at least 42 months storage in this stand-by condition).

Once the MBT is drawn up to the WMID (*i.e.* both sides indifferently), the reed switch component enables logic status change and the system switches to *waiting mode* status (flashing orange LED visual feedback). In this operating mode, the microcontroller and the magnetic Hall-effect sensor are activated and the system can switch to *recording* or *sleeping mode* depending on the MBT magnetic field polarity (green or red side on the magnetic-based trigger - Fig. 1a). Once the MBT is drawn near the WMID from the green side, the microcontroller and all the peripherals are activated, the system switches to *recording mode* (flashing green LED visual feedback) and acceleration data are recorded in the SDHC memory card (5 hours and 36 minutes total duration). Finally, once the MBT is drawn near the WMID from the red side the inertial system shifts into *sleeping mode* again (flashing red LED visual feedback) ready for following activations. Working principle and software architecture workflow is represented in Fig. 2.

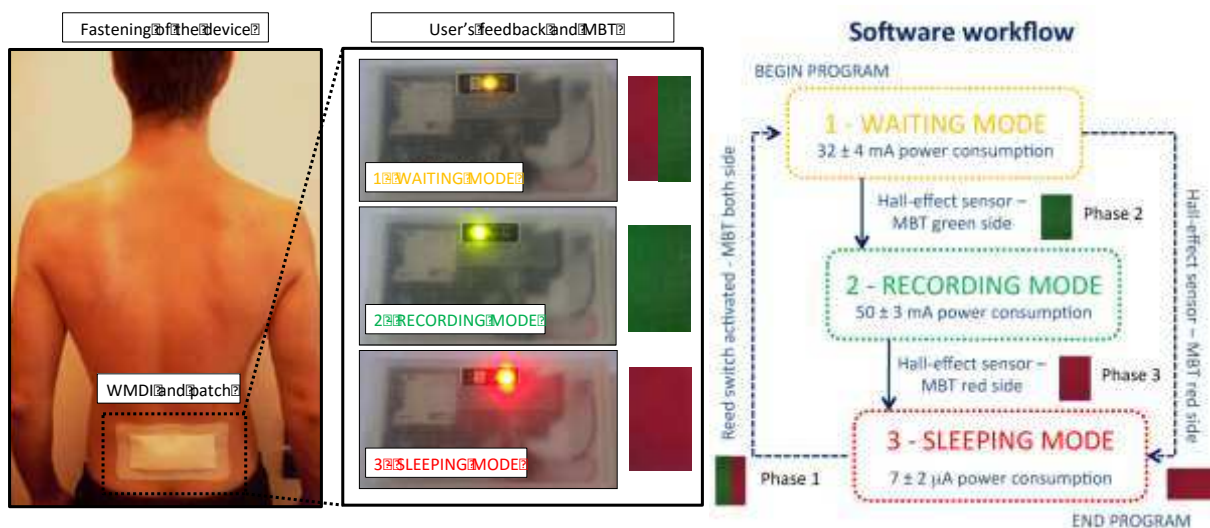


Fig. 2. Working principles and software architecture workflow. Once the system is activated and led in the *waiting mode* from the *sleeping mode (phase 1)*, the user has to approach the MBT card with the green (phase 2 for *recording mode*) and red side (phase 3 for *sleeping mode*) on the WMID to start and stop the data recording, respectively.

Regarding the high-level software, a dedicated routine with a proper user interface was developed in MATLAB (Mathworks, Inc., USA) for acceleration data analysis and parameter derivation. X, Y and Z acceleration data are acquired and data analysis was performed on the modulus of the signal (for recording combined movements independently by the user's position) after cancellation of the continuous interference by subtracting the mean value of the signal. Data analysis is aimed to extract significant parameters from the raw data. Parameters were properly indicated by the medical expert as the potentially most representative sexual performance indexes: i) SI time or intravaginal ejaculation latency time (IELT - until now estimated with a simple stopwatch), ii) an estimation of SI penetrations, as the number of times the signal exceeds a pre-defined threshold and iii) the signal significant frequency (*i.e.* significant number of penetrations per second of the signal). IELT and penetrations estimation are already assessed in the state of the art of sexual diagnosis [10-13], but hereby evaluable in a less invasive manner during SI. IELT is extracted by the accelerometer signal but for a more accurate estimation the user will be asked to switch the worn system on just before the beginning of the SI and off after the ejaculation event by the MBT card.

2.2. System validation

The HU-MOVE platform was validated in terms of effectiveness and reliability through characterization on a controlled model and in a simulated intercourse condition on a human

model with the aim to evaluate and tune the system for a forthcoming and realistic translation in the clinical practise.

2.2.1 System validation on a controlled model

The aim of the test is to evaluate the accuracy and reliability of acceleration and frequency calculation by the HU-MOVE platform with respect to an external high-precision laser displacement sensor benchmark (optoNCDT1401-10, Micro-Epsilon, Germany).

The WMID was properly fixed on an anthropomorphic robotic arm end-effector (RV-6SL, Mitsubishi Electric, Japan) and the controlled manipulator was programmed for performing 50 iterative movements along an 8 mm straight section (controlled model test 1: A-delay-B-delay oscillations along a straight path). Oscillations were recorded simultaneously by the accelerometer (integrated into the WMID - 100 Hz frequency, and measurement range of ± 2 g) and by the displacement sensor, varying the delay time (from 0.2 to 1 seconds with 9 incremental steps of 0.1 seconds) in each trial and setting the maximum robotic arm velocity and acceleration, corresponding to 9.5 m/s and 0.95 m/s^2 . Mean frequency and acceleration were obtained after appropriately processing the acquired data. The frequency data were computed with a Fast Fourier transform analysis for both the displacement and acceleration sensor data; acceleration was measured directly by the accelerometer sensor, while double derivation was used for the corresponding displacement data. A similar test was performed with the same test bench by setting the robotic arm linear velocity and the delay time at 9.5 m/s and 0.5 seconds respectively, and varying acceleration from 0 to 100% of maximum acceleration with an incremental step of 10% for each trial (controlled model test 2).

Comparative errors between sensors were figured out and reported in the result section as the mean errors \pm standard deviations (SDs) and ranges of error values.

2.2.2 *System validation on a human model*

An experimental validation on a human model was performed for evaluating and assessing the accuracy and reliability of the platform and software processing for parameters calculation in a controlled real, even if simulated, intercourse operating condition. The device was tested in a simulated SI condition in which 10 different non-pathological asserted male users (average age of 29 years, ranging from 26 to 32 years) were asked to perform 25 supervised movements along a straight path on the sagittal plane in an upright position (200 mm long A-B-A path). Each trial was repeated 3 times by each candidate with a 0.5 Hz, 0.75 Hz and 1 Hz movement frequency, respectively (human model test 1, 2, and 3 respectively - the frequencies, beaten by a time meter, were selected in accordance with the medical team to be representative values). Informed consent according to the Declaration of Helsinki (BMJ 1991; 302:1194) and to the Ethical Committee of the Scuola Superiore Sant'Anna was obtained before conducting the experiments. The WMID was fastened with a patch on the lumbar area, approximately between the L2 and L5 vertebral bodies; the device was activated and controlled by the user using the MBT card (Fig. 2 on the left). The specific area was selected for the low amount of fat (the position of the device is not related to the body mass index parameter) and to its sensitivity to the oscillatory movement. Due to the imposed experimental conditions, a IELT of 50 s, 33s and 25 s, SI penetrations of 25, 25 and 25 and a signal significant frequency of 0.5 Hz, 0.75 Hz and 0.5 Hz are expected for the human model test 1, 2, and 3 respectively.

The raw data were analysed by the software routine presented in the materials and methods section, assessing the error \pm SDs , mean values \pm SDs, median and ranges of values for the IELT, estimation of SI penetrations, and signal significant frequency and calculating the error in comparison with the aforementioned expected outcomes. Finally, a questionnaire was

submitted to the candidates for understanding the acceptance and invasiveness of the overall platform in the simulated SI.

3. Results

3.1 System validation on a controlled model

A consistent correlation between the accelerometer and displacement sensor data was observed during the controlled model test 1 (as represented in Fig. 3a and Fig. 3b), demonstrating that the entire developed monitoring platform can provide reliable estimation for the frequency and acceleration of WMID actual oscillations needed for the parameters assessment (mean errors of 0.0102 ± 0.0082 Hz and 0.0389 ± 0.0182 m/s² and error range values of 0.0008-0.0183 Hz and 0.0002-0.0389 m/s², respectively). Similar results were also obtaining during the controlled model test 2 and an accurate and reliable correlation between the accelerometer and displacement sensor was once more confirmed showing a mean error of 0.0078 ± 0.0051 Hz and 0.0107 ± 0.0066 m/s² and error range values of 0.0002-0.0175 Hz and 0.0383-0.0647 m/s² for frequency and acceleration, respectively.

3.2 System validation on a human model

Results on a human model assessed the effectiveness of the sexual performance evaluation platform and extracted parameters. The software routine figured out accurate parameters with a low error for IELT parameter, SI penetrations and signal significant frequency for the human model test 1, 2 and 3 respectively, in comparison with the expected outcomes imposed to the experiment conditions. Details about the mean values \pm SDs, median, ranges of values, and error \pm SDs for the derived parameters are reported in Table 1, while a typical acceleration signal representation and SI penetration analysis is reported in Fig. 3c and Fig.

3d. Obtained outcomes also confirmed the project expectations in terms of usability and comfort, highlighted by the questionnaires that pointed out the low-invasiveness and acceptance of the device by the users.

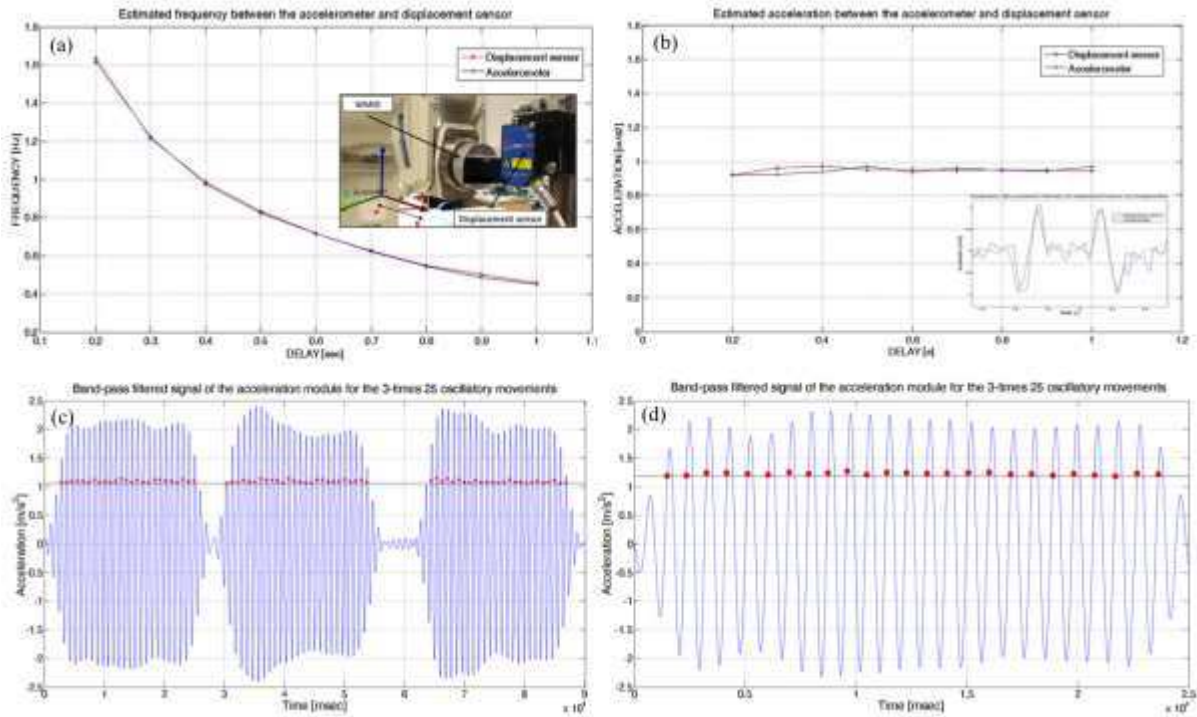


Fig. 3. (a) Vibration frequency [Hz] and (b) acceleration [m/s²] estimated by the external distance sensor and the embedded accelerometer simultaneously. Inset in figure 6a represent the controlled model test bench, whereas the inset in figure 6b represents the correlation between the acceleration signal measured directly by the accelerometer sensor (blue line) and by the displacement sensor (red line) after double derivation of data. (c) Band-pass filtered module of the acceleration signal for the oscillatory movements at a frequency of 1Hz and (d) relative enlargement of the single session (first in session in figure 3c). SI penetration numbers are represented with red dots in (c) and (d).

	IELT [s]				SI PENETRATION [A.U.]				FREQUENCY [Hz]			
	<i>Mean ± SD</i>	<i>Median</i>	<i>Range</i>	<i>Error ± SD</i>	<i>Mean ± SD</i>	<i>Median</i>	<i>Range</i>	<i>Error± SD</i>	<i>Mean ± SD</i>	<i>Median</i>	<i>Range</i>	<i>Error± SD</i>
Human model 1	49.73±0.43 (50)	49.77	51.89- 48.08	0.95±0.15	25.10±0.33 (25)	25	26-24	0.36±0.27	0.536±0.005 (0.5)	0.541	0.545-0.516	0.036±0.005
Human model 2	33.36±0.36 (33)	33.43	34.75- 31.63	0.67±0.25	24.96±0.43 (25)	25	27-24	0.43±0.36	0.804±0.006 (0.75)	0.800	0.841-0.793	0.054±0.006
Human model 3	24.89±0.20 (25)	24.94	25.60- 24.36	0.35±0.05	24.70±0.33 (25)	25	26-24	0.43±0.28	1.072±0.007 (1)	1.083	1.094-1.050	0.072±0.007

Table. 1. Results of the human model test 1, 2 and 3 as means ± standard deviations (SDs), median, ranges of values and errors ± SDs with respect to the expected outcomes (within the brackets).

4. Comment and conclusions

Diagnosis of sexual disorders in terms of premature or delayed ejaculation suggests and requires the use of a benchmark for measurement. Today, basic and/or even invasive methodologies, often not compatible with SI, are used for diagnosing sexual disorders (*e.g.* premature ejaculation), such as simple stopwatches (mainly used for assessing IELT parameters), invasive button-counter for calculating sexual SI penetrations, and personal evaluation forms about the satisfaction level of the partner [10-14].

The major considered issues for the diagnosis of sexual dysfunctions are their quantitative definition and assessment by non-invasive measurement during sexual activity. Along this line, an accelerometer-based custom-made monitoring wearable platform, the HU-MOVE platform was developed with the aim to sense, record and figure out inertial-based human movement parameters for objectively and accurately assessing human sexual performances with the potentiality to evaluate sexual dysfunctions, such as premature or delayed ejaculation, in a low-invasive and comfortable fashion during SIs.

An open-platform, adaptable and tuneable in terms of hardware, firmware and data processing software was developed for allowing flexibility in the implementation of solutions in the sexual medical research field. In this regards, the development of a custom-made platform guaranteed and will further guarantee tuning and customization through the interaction between the engineering and medical teams, with the final aim to develop a novel suitable biomedical tool for sexual disorders diagnosis.

The accelerometer characterization analysis in the controlled model demonstrated the reliability and accuracy of the development platform in the estimation of the movement frequency and acceleration. The system validation on human model in the sexual simulated condition confirmed the effectiveness in the movement assessment and the prospective

appropriateness of the system in the sexual medicine scenario as a potential aiding tool to the physicians for sexual performance evaluation and disorders diagnosis and treatment (*i.e.* for premature or delayed ejaculation dysfunctions). The HU-MOVE platform also demonstrated to be a comfortable, low-invasive and easy-to-use measurement system with the potentiality to be adopted as a standard tool for the sexual medical assessment; it has the benefit to be used during the sexual activity with the partner.

Future work will consist in the performance of an experimental investigation in a real operating environment on a large pool of non-pathological and pathological patients (also undergoing a pharmaceutical or educational treatment activity) for confirming the efficacy, suitability, low-invasiveness and acceptance of the system for human sexual performance assessment and dysfunctions diagnosis and also for improving the measurement system finely tuning and/or fixing the most representative parameters for effective analysis. Furthermore, the activity will allow deriving new diagnostic and therapeutic significant rules. For example, thanks to the insights on sexual disorders acquired by the HU-MOVE platform, it would be possible to develop a therapy system based on a controlled and sensed squeeze action of the urethra duct triggered by acceleration and/or pressure feedback.

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Legends to illustration

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	<i>Mean ± SD</i>	<i>Median</i>	<i>Range</i>	<i>Error ± SD</i>	<i>Mean ± SD</i>	<i>Median</i>	<i>Range</i>	<i>Error± SD</i>	<i>Mean ± SD</i>	<i>Median</i>	<i>Range</i>	<i>Error± SD</i>
Human model 1	49.73±0.43 (50)	49.77	51.89- 48.08	0.95±0.15	25.10±0.33 (25)	25	26-24	0.36±0.27	0.536±0.005 (0.5)	0.541	0.545-0.516	0.036±0.005
Human model 2	33.36±0.36 (33)	33.43	34.75- 31.63	0.67±0.25	24.96±0.43 (25)	25	27-24	0.43±0.36	0.804±0.006 (0.75)	0.800	0.841-0.793	0.054±0.006
Human model 3	24.89±0.20 (25)	24.94	25.60- 24.36	0.35±0.05	24.70±0.33 (25)	25	26-24	0.43±0.28	1.072±0.007 (1)	1.083	1.094-1.050	0.072±0.007

Table. 1. Results of the human model test 1, 2 and 3 as means ± standard deviations (SDs), median, ranges of values and errors ± SDs with respect to the expected outcomes (within the brackets).